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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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OPEN SESSION

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

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TUESDAY,

MAY 20, 2003

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ROCKVILLE, MARYLAND

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The Advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, Room T2B3,11545 Rockville Pike, at 1:00 p.m., Dr. Manuel Cerqueira, Chairman, presiding.

COMMITTEE MEMBERS:

MANUEL D. CERQUEIRA, M.D., Chairman

JEFFREY A. BRINKER, M.D., Member

DAVID A. DIAMOND, M.D., Member

DOUGLAS F. EGGLI, M.D., Member

NEKITA HOBSON, Member

RALPH P. LIETO, Member

LEON S. MALMUD, M.D., Member

RUTH McBURNEY, Member

COMMITTEE MEMBERS: (CONT.)

SUBIR NAG, M.D., Member

SALLY WAGNER SHWARZ, Member

RICHARD J. VETTER, Ph.D., Member

ALSO PRESENT:

THOMAS ESSIG, Designated Federal Official, NRC/NMSS

ROGER BROSEUS, Ph.D. NRC/NMSS

RYAN T. COLES, U.S. GENERAL ACCOUNTING OFFICE

WILLIAM HENDEE, M.D., American Board of Radiology

DONNA-BETH HOWE, Ph.D. NRC/NMSS

MICHAEL T. MARKLEY, NRC/NMSS

CHARLES I. MILLER, Ph.D. NRC/IMNS

LINDA PSYK, NRC/NMSS

JEFFRY SIEGEL, Ph.D., Society of Nuclear Medicine

ANTHONY TSE, Ph.D. NRC/NMSS

ANGELA WILLIAMSON, NRC/NMSS

RONALD ZELAC, Ph.D. NRC/NMSS

A-G-E-N-D-A

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

(1:04 p.m.)

MR. ESSIG: As designated federal official for this meeting I'm pleased to welcome you to Rockville for the public meeting of the ACMUI.

My name is Thomas Essig, I'm Branch Chief of the Materials Safety and Inspection Branch, and have been designated as the federal official for this Advisory Committee, in accordance with 10CFR part 7.11.

This is an announced meeting of the Committee, it is being held with the rules and regulations of the Federal Advisory Committee Act, and the Nuclear Regulatory Commission.

The meeting was announced in the March 24th, 2003 edition of the Federal Register. The function of the Committee is to advise the Staff on issues and questions that arise during 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 views of the committee, and values them very much.

I request that, whenever possible, we try to reach a consensus on the various issues that we will discuss today, but I also value minority or dissenting

opinions. If you have such opinions please allow them to be read into the record.

As part of the preparation for this meeting I have reviewed the agenda for the members and employment interest based on the very general nature of the discussion that we are going to have today.

I have not identified any items that would 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.

At this point I would like to introduce the members that are here today. Dr. Manuel Cerqueira, nuclear cardiologist, who is Chair of the Committee; Dr. Douglas Eggli, nuclear medicine, member of the Committee.

Dr. Leon Malmud, health care administrator, member of the Committee; Nekita Hobson, patient advocate; Ms. Ruth McBurney, state representative, member of the Committee; David A. Diamond, M.D., radiation oncologist, member of the Committee.

Dr. Subir Nag, radiation oncologist, member of the Committee; Sally Schwarz, nuclear pharmacist,

member of the Committee; Dr. Richard Vetter, radiation safety officer, member of the Committee; and Dr. Jeffrey Williamson, therapy physicist, member of the Committee.

That concludes my opening remarks, Mr. Chairman.

CHAIRMAN CERQUEIRA: Thank you very much. We also have the next item, which is the Society of Nuclear Medicine Licensing Guide.

MR. ESSIG: Yes. One thing I would like to mention, initially, that the agenda item perhaps mischaracterizes the guide, itself. It is not titled a licensing guide, per se, it is simply a guide for the medical use of byproduct material in diagnostic settings.

We had, during the course of the, I just want to say a few remarks about the genesis of this guide. During the course of revising NUREG 1556, volume 9, we were, we received some comments from the Society of Nuclear Medicine that basically they felt that the NUREG that we had drafted at that time was much too detailed.

And we had completed the earlier draft prior to the Part 35 rulemaking, but then it kind of lost ownership and was put on the shelf for a while. So then we were challenged, as October of 2002 approached, when the Rule Part 35 would become final, and so we pulled the old Volume 9 of NUREG 1556 off the shelf and put it out

for comment.

And we held two meetings on that in the NRC auditorium, one on therapeutic, and one on diagnostic aspects. And what emerged from that was that the SNM came to us and felt that they could produce something than we had in the Volume 9 for diagnostic applications.

And so we invited them to proceed, and we met several times over the course of the production of the guidance document, and polished the language in it. And then the ultimate question became, well how will we promulgate the document and put it in general use?

And so what we ended up doing is entering into a licensing agreement with the Society of Nuclear Medicine, and basically bought the rights to distribute the document on our website, at no charge to the user community.

We announced this in a regulatory issue summary 2002-23, dated November 27th, 2002, and we specifically stated, in the regulatory information summary, and I would quote from that, the SNM's Guide for Diagnostic Nuclear Medicine provides information that may be useful to nuclear medicine professionals in understanding the applicability of NRC requirements to the use of byproduct material in diagnostic settings, and provides measures that practitioners may use to

facilitate the implementation of the revised rule.

The information provided in the document is not a substitute for NRC regulations. Licensees are required to comply with all applicable parts of Title 10 of the Code of Federal Regulations, unquote.

So that was just a, like all of the guidance documents that we have, they do not contain regulatory requirements, they are a method, or an accepted way of implementing that portion of the regulations that they address.

And so the diagnostic guidance document would be an adjunct to the NUREG 1556 Volume 9. And, really, that is all I wanted to say about that guide. I think we just may be clarifying a couple of points.

CHAIRMAN CERQUEIRA: Just for clarification, so this is different than your traditional guidance documents that are released?

MR. ESSIG: It is not, in a sense it is not precedent setting, in that we have other, on other parts of our regulative community, we do have, where we've engaged with stakeholder organizations, where they have felt that they could write some more user-friendly guidance, if you will.

In fact, we are encouraged to do that. There is an Act called the National Technology Transfer

and Advancement Act of 1995, that requires federal agencies to use consensus standards, whenever possible.

And so that we would -- we are encouraged to engage on issues like this. And if we could find that as an acceptable method of implementing that part of the regulations, and then we would just --

CHAIRMAN CERQUEIRA: No, I'm very supportive of it. The only question is that if the regulated community follows all the guidelines, and then they are not in compliance with the NRC, you know, if they follow official NRC guidelines they probably would have something to quote, or stand on, at the time of defending their actions.

Do these SNM guidelines have the same weight, recognition?

MR. ESSIG: Well, we -- I believe we recognize that in the regulatory issue summary, that we said they were an acceptable method of implementing that part of the NRC regulation.

So, yes, it doesn't -- I mean, they don't look like a regulation guide or a NUREG, and they have a different cover on them, and that sort of thing. But we, nonetheless, reviewed them and found them acceptable for implementing that part of the Rule that relates to diagnostic practices.

CHAIRMAN CERQUEIRA: Any questions?

MEMBER LIETO: Tom, then would it be accurate to say that this was a joint effort of the NRC and the SNM, in promulgating guidance?

MR. ESSIG: I wasn't intimately involved with it. But it was my understanding, we had several meetings. And whether that really, I guess you could call it a joint effort. I mean, if you have one meeting then it's probably not joint.

But as you get up to several meetings, and fine tuning the language of the document, yes, I would say it is a joint -- you could call it a joint document.

CHAIRMAN CERQUEIRA: Any other questions? Great.

So the next item, then, is the Update GAO's Review of Domestic Regulation of Nuclear Material. And Ryan T. Coles, and the GAO's office.

MR. ESSIG: You may recall, Mr. Coles was here at our last meeting, and he is here to update us regarding the GAO audit.

MR. COLES: Good afternoon, Mr. Chairman, Members of the Committee, NRC Staff. I appreciate the opportunity to come and speak to you today. My name is Ryan T. Coles, I'm a senior nuclear analyst with the United States General Accounting Office.

And today I just want to give you a brief update on some of our work. Unfortunately the timing of this meeting is somewhat inopportune, because we are in the process of wrapping up our work on regulation of nuclear materials in the United States.

So there isn't a whole lot that I can tell you in terms of our findings, but I can talk to you about three things today. First of all, I can give you a status report on our three separate efforts looking at materials regulation and security.

Second, I can describe some about our objectives, scope and methodology, of looking at the domestic regulation of nuclear material. And, third, to the extent that we have time, I can update you on the findings of the one report that we have released, thus far, on the Department of Energy's outside source recovery program.

As you may recall from our previous meeting, we have three ongoing efforts looking at nuclear materials regulation in the United States. The first report, which was issued in April, and it was just issued to the public a couple of weeks ago, was looking, specifically, at the Department of Energy's outside source recovery program.

For those of you who are not aware, this

program is DOE's effort to collect unwanted, and unused, greater than Class C sealed sources that are present in the United States, primarily from academic licensees, although there are some medical licensees, as well, that have these sources.

Materials we are dealing with are primarily transuranics and high concentration strontium, cessium, cobalt sources. We, weeks ago, got some press coverage, got some coverage from the Department of Energy, and I can discuss that in a few moments, if we have time.

The second report that we have been conducting has been looking at international efforts to control sealed sources. And this has been primarily looking at the Department of Energy's and NRC's international efforts with the International Atomic Agency, with the Russian Federation.

Some of the conferences, meetings, and efforts that have been ongoing to control potential sources of radiological dispersion device materials. That report has just been issued to our requester, which is Senator Akaka, and should be released, publicly, within the next three weeks.

Finally, the sort of the capstone report of our efforts has been looking at the domestic regulation of nuclear materials. That report is scheduled to be

issued to our requester on July 3rd.

It, likely, will be released to the public shortly afterwards, three, four weeks afterwards, I would say, so I think we are looking at the end of July, early August, before we issue that report.

We have just finished a first draft, we are about to give NRC their first opportunity to take a look at some of our findings, to provide us with any technical comments, and as we proceed through the next couple of three weeks, I think more and more information will be coming out, and we should be just about finished with our report.

Unfortunately I can't really share our conclusions and recommendations with you, at this point, because we haven't given NRC the opportunity to look at, and that is one of our standards, is that affected agencies have the opportunity to comment before the report is released publicly, or to our requester.

But I can talk to you a little bit about the work that we have conducted. This has been a very extensive review, and from the beginning we knew that we were biting off a lot, and decided, and over the course of our review we have proceeded to sort of change the scope of the review, to narrow down the focus to what our clients on the Hill were particularly interested in.

We've tried to take it from an educational review point, that is to try to teach our clients, teach the lawmakers, how radioactive materials are regulated in the United States. And also to narrow in and focus on specific security concerns.

We have been asking what is the scope of the use of radioactive materials in the United States, specifically what is the known number of licensees, how many sources are being used, what are the typical uses of radioactive materials in the United States.

We have also been wanting to know incidents related to the use of those materials, lost, stolen, or abandoned sources, misadministrations, malfunctioning devices, those types of things that are required, on the part of the licensee community, to report to their agreement state, or NRC regulators.

We have also been looking at the effectiveness of federal and state controls over sealed source material. And, finally, what efforts have been initiated, or considered, since September 11th, to safeguard radiological material.

And to answer these questions we distributed surveys to all 32 agreement states, the 18 non-agreement states, Puerto Rico, the District of Columbia, and officials in NRC's four regional offices.

We focused the survey to obtain information about each state's radiation control program, specific and general licensing activities, enforcement actions, the effectiveness of the controls over sealed sources, their program evaluation processes, and transportation of sealed sources, and also the impact of September 11th on their regulatory programs.

We distributed the survey in February of 2003. We received responses from 29 of 32 agreement states, and 11 of 18 non-agreement states. We also received a survey from Puerto Rico, and from all four NRC regional offices.

We did not receive responses from three agreement states, Arizona, New Hampshire, and Maine. We also did not receive responses from the non-agreement states of Alaska, Connecticut, Minnesota, Missouri, Pennsylvania, South Dakota, and Wyoming. We also did not receive a survey from the District of Columbia.

In addition to our survey efforts we visited and interviewed a number of officials at the state and local level, and also licensees. We visited the following states during our review, and these states were chosen based upon the size of their programs, the numbers of licensees, and the uses of materials within those states.

We visited Illinois, Maryland, New Jersey, North Carolina, Pennsylvania, Rhode Island, South Carolina, and Utah. We also interviewed officials from Massachusetts, Nevada, New York, and Ohio.

In each of these states we visited a selection of radioactive materials licensees representing a variety of uses. We tried to get a sample of uses in the academic, research, medical, and industrial communities, and visited a total of -- we visited three decommissioning and decontamination sites, two low level radioactive waste facilities, two moisture density gauge manufacturers, a selection of industrial radiographers, medical licensees, specifically several hospitals.

We visited several large irradiator facilities, well logging licensees, nuclear pharmacies, and several academic licensees.

The purpose of our visits was to discuss with them the effectiveness of the current regulatory framework and, also, to observe first-hand physical security measures that are being undertaken at these facilities.

We also had extensive discussions with a variety of NRC staff offices, including nuclear materials safety and safeguards, nuclear security and incident response, and the office of state and tribal programs.

We also involved the organization of agreement states, and the conference of radiation control program directors.

As I said, in addition to NRC we also interviewed officials from other federal agencies, including the Department of Transportation, the Environmental Protection Agency, the Federal Emergency Management Agency, and the Department of Justice, and the Department of Energy.

As I said, we are in the process of completing our work, and we are completing a draft report for NRC's review, and expect our work to be completed within the next month.

We are probably running a little short on time, but I do want to say that our first report on DOE's outside source recovery program has received some attention in the media, and with the Department of Energy.

Basically we found that the Department of Energy is not giving the problem of collecting greater than class C sources sufficient attention. The program within the Department of Energy is not at a high enough priority.

The Department of Energy does not believe that the environmental management, the office of

environmental management, that this is their appropriate mission to be conducting, to be going out and collecting greater than Class C material, and in the nearly 20 years since DOE was required to provide for permanent disposal of greater than Class C material, the agency has made no progress towards coming up with eventual disposition.

The Department of Energy responded to our report and stated that we had made several errors. First they stated that we had not given enough credit to the Department of Energy, and the Nuclear Regulatory Commission, in the work that they have been doing to categorize the sealed sources of greatest concern.

We disagree with DOE. We do mention the working group report. However, at the time our report was published, this working group report was, A, still draft; and B, classified as for official use only, so we could not discuss it in a public forum.

It is interesting that DOE released the report in response to our report. So we will address that report in much more detail in the domestic job that is coming up in the next month or so.

DOE also criticized us for not giving them enough credit for sources they have already picked up. On the contrary, we did note that they picked up over 5,000 sources since the program's initiation, and they have

been doing a good job.

It is simply that their future commitment is questionable. And, finally, they criticized us for not interviewing any policy executives during the course of our review.

We don't understand this criticism. We met, on several occasions, with numerous policy executives at the Department of Energy, including three meetings with the Deputy Assistant Secretary, three attempted meetings with the Assistant Secretary, two of which she canceled, and one that we finally attended, but we didn't get any substantive information at.

And it is also an interesting remark that they make, that we didn't meet with any policy executives. Is DOE saying that the policy executives are going to give us a different story than program management officials?

Because, to me, that indicates a larger problem than simply -- it indicates a disconnect in communications. If program management isn't giving us the same information as policy executives, then it sounds like there are communications problems within the Department of Energy.

I would be happy to answer any questions that I can, and I apologize for not being able to be more

specific on our findings, but I will try to answer whatever I can.

CHAIRMAN CERQUEIRA: Questions for Mr. Coles?

MEMBER DIAMOND: Mr. Coles, thanks for coming back, it is nice to see you again.

Earlier today Mr. Cox, in a closed door session, spoke to us about some of the compensatory measures that NRC is working on, and the Committee as a whole was very pleased to see that a lot of logic and common sense was being applied as far as the selection of sources and threshold limits in developing these measures.

It is very hard for us to comment on what you are doing with regard to the regulation of domestic sources, because we haven't seen your report, you haven't sent it to your client, yet.

But the concern that I have is that this report will, obviously, be the framework for possible legislation. And my caution would be that it is very, very important, that our legislators get information that not only is accurate, but also has a lot of common sense.

Because we have the real potential for developing legislation which could, really, adversely impact the practice of medicine, if we are not smart, on

threshold limits, some care in the regulation, if it is desired, into the field of norm.

So that is my only comment, or concern, to you to pass on.

MR. COLES: I appreciate that comment, and I think I'm not giving away anything in terms of our conclusions and recommendations, by saying that it is vitally important, in any discussion of additional security be placed on this material, that that additional security be balanced with the beneficial applications of this material.

NRC and the appropriate agencies need to take great effort in determining exactly what the greatest risk materials are, and those security efforts that are already being placed upon them, so that we do not place additional burdensome regulations on materials that have beneficial uses.

We are doing our best to tell our clients on the Hill that we can't take a broad brush approach to security, that we have to be very specific in regulating to the best sense possible those materials of the greatest concern, without discouraging their beneficial use in medical, industrial, and research practices.

CHAIRMAN CERQUEIRA: Any other questions for Mr. Coles? Thank you very much for your presentation, we

look forward to your next report with some real data.

MR. COLES: Thank you, Mr. Chairman, I appreciate it.

CHAIRMAN CERQUEIRA: The next item is training, education, board certification, and the new Part 35. Dr. William Hendee, President of the American Board of Radiology will be presenting.

Welcome, Dr. Hendee.

DR. HENDEE: Thank you very much, thank you, Mr. Chairman. And thank you to each of the members here of ACMUI for allowing the American Board of Radiology to make comments regarding the training and experience requirements, as denoted at the present time, in the revisions of Part 35.

We appreciate, very much, the opportunity to be here. I am the President of the American Board of Radiology, my name is William Hendee, or Bill Hendee.

I'm also Senior Associate Dean and Vice President of the Medical College of Wisconsin, and Dean of the Graduate School of Biomedical Sciences, there.

I'm a Board certified health physicist by the American Board of Health Physics, and also a board certified medical physicist by the American Board of Radiology. I have been a member of the Board, now, of radiology for about ten years. I'm the current

president, I'm a former member of the American Board of Health Physics, as well, and a former examiner for ABHP.

The comments that I'm going to make today relate to the training and experience requirements as laid out at the present time, in the proposed rulemaking for revisions of Part 35, and there are basically four issues that I want to bring up for discussion.

But I want to tell you, first, that members of different boards, certification boards, met this morning with members of the NRC staff, and we had an excellent, open, and frank discussion on several issues, including those which I will bring up this afternoon.

And I want to bring special attention to the three people that were sitting around the table with us, from the NRC, because of their openness and willingness to listen to our concerns and questions, and to work with us towards solutions.

And those are Roger Broseus, Patricia Holohan, and Sandra Wastler. So thank you all very much for allowing us. And I think, in fact, we came to some resolution of many of the issues that we hope the Council here will also agree with.

So there are four issues. I would like to raise each of these issues and see if there are any questions for me on each issue, before we go forward to

the next.

And the first issue is the issue of default pathways to NRC recognition and board certification. Board certification, by a recognized specialty board, is proposed as a pathway to demonstration of adequate knowledge, to be recognized by the Nuclear Regulatory Commission.

As an authorized medical physicist, authorized user, authorized nuclear pharmacist, or as a radiation safety officer, you have that in the proposed rulemaking.

And then you have, in the proposed rulemaking, an alternate pathway to NRC recognition through the process of individuals attaining specific numbers of hours of didactic instruction and supervised practical training.

The proposed rulemaking, however, is vague on whether the specific number of hours of didactic instruction, and supervised practical training, must be explicitly required by a specialty board before the NRC will acknowledge board certification as a pathway to recognition, as one of the four categories, authorized medical physicist, etcetera.

Now, it has been the presumption of the American Board of Radiology that the NRC wishes to

consider board certification by a recognized specialty board as a true default pathway to service, as an authorized medical physicist, radiation safety officer, authorized user, or authorized nuclear pharmacist.

We presume, but it is difficult to tell, from the proposed rulemaking, that the default pathway of board certification is not viewed by the NRC as simply an assurance that candidates meet the very specific hours of didactic instruction and supervised practical training considered essential by the NRC.

Because if you were to take that approach, then, essentially the default pathway of board certification is no more than perfunctory and is a redundant process in the proposed rulemaking.

So here is what we recommend. The ABR recommends that the NRC not be prescriptive in its recognition of specialty boards. The ABR recommends, instead, that well established specialty boards, such as the American Board of Radiology, be recognized as a default pathway to service in any of the categories that recognition will be appropriate.

While at the same time allowing the board to define the education and training experience most appropriate to the safe and effective delivery of quality care to patients.

Now, we had an excellent discussion on this point this morning. And in that discussion we described the board certification process, which is composed of three different elements.

One is there are education, training, and experience requirements to sit for board certification. Once you've attained those qualifications, and you are admitted into the board process, you go through a rigorous examination process, which is composed of written examinations by the American Board of Radiology, followed by an oral examination in your particular specialty.

Those examinations cover, they are certainly not limited to, but the cover radiation safety, the aspects of radiation safety pertinent to the particular specialties.

And we examine in those areas. And, in fact, one can make the case that examination in radiation safety, and radiation protection, is a much more effective way of determining the mastery of a body of knowledge, than is simply hours of training and experience.

I think we have reached consensus on this, this morning. And that is that a certification board could apply for dean status, as a default pathway, could

describe the areas it examines in, those areas would be consistent with the areas that are required by the NRC for recognition.

And if, in fact, the examination covers those areas, and if the board requires mastery of that body of knowledge, then that board will be recognized as a default pathway, without having to state, explicitly, an explicit number of hours of training and experience.

We are very comfortable with that, and we hope that you all will be comfortable with it as well. Now, let me stop there, and see if there is any question in that particular area.

CHAIRMAN CERQUEIRA: Jeffrey?

MEMBER WILLIAMSON: I was just looking at our proposal that came back from the Commissioners, you know, with some minor modifications. And our intent was, and my understanding of what came back, does not require a specific number of hours for any of the boards.

DR. HENDEE: And I'm very happy with that response. It is part -- part of my reason for being here is to clarify issues of uncertainty that I think need to be clarified, and need to be clarified in the final report of this Commission, and in the final rulemakings, not confusion or ambiguity in what is and is not required.

So I'm very pleased with that response.

CHAIRMAN CERQUEIRA: I guess one question that came up during the discussions is that you take a board like the ABR, which covers an extensive body of clinical, technical, basic science information. And, theoretically, somebody could pass the board, but could have failed all the questions related to radiation safety.

So what assurance is there that a candidate who passes the board has met knowledge criteria in the areas of radiation safety?

DR. HENDEE: Well, in several cases the written examination focuses on different areas. Let me give you an example.

CHAIRMAN CERQUEIRA: Sure.

DR. HENDEE: In examining candidates in various certification areas of radiological physics, for example, the candidates take an oral examination. That oral examination consists of questions in five different areas.

One of those areas is in radiation protection and safety. You must pass that oral examination. You can't -- you cannot do poorly on that exam, and have doing well on other parts of the exam compensate.

CHAIRMAN CERQUEIRA: And that consists of 30, 40 questions, that are documented, or --

DR. HENDEE: Well, this is the oral examination. So in the oral examination you typically have about five minutes, in each of five different areas, per examiner. And there are five examiners examining in that area.

And so you ask five questions per examiner, you ask one question by each of five examiners. But that question is an open-ended question which then leads to a lot of discussion. So you cover the ground pretty well by the time you are through.

And then in the written examination there are multiple questions on radiation protection safety.

MR. NAG: I would like to ask --

CHAIRMAN CERQUEIRA: Yes, Richard? Go ahead.

MEMBER VETTER: I just wanted to underscore, for you, and the Committee and the general audience, that when the subcommittee began to draft its recommendations, one of its positions was that, in fact, that it felt that passing an exam was, much better demonstrated that an individual had the competency, than sitting for a certain number of hours.

So it was never the intent that a board

would be qualified on a prescriptive number of hours. It was passing that exam. I'm sorry, not just passing that exam, it is a whole certification process.

DR. HENDEE: But, thank you again. I mean, you are confirming what our belief was, but it needs to be explicitly stated, so that everyone understands this.

MR. NAG: The American Board of Radiology has a very extensive curriculum on radiation safety. What would you say to another board who wishes to apply for the exemption, but may have a lot more limited radiation safety curriculum, if we don't say there must be X number of hours in the curriculum?

The American Board of Ophthalmology says, well we have done one, but we have radiation safety in our curriculum that for anyone who has passed the American Board of Ophthalmology will be an authorized user, or can be an authorized user.

How would you deal with that situation? It may be hypothetical, or it may not.

DR. HENDEE: I think it is clear, in reading through the alternate pathways to the default pathway to board certification, if I read the other ways that you can become certified, I think it is clear what is expected, in terms of a body of knowledge.

I think you can surmise what is expected in

terms of a body of knowledge, from reading those alternate criteria, not so much the number of hours, but the areas to be covered, and what you would expect.

And I think that a board that was applying for dean status, as a default pathway, would be expected to have a method to examine and test, and evaluate, a candidate's mastery of knowledge in those areas.

So I think, in fact, the basic information is there in the proposed rulemaking that would allow you to decide whether a particular board was providing adequate, had an adequate expectation of mastery of radiation safety or not. I think you could do that.

CHAIRMAN CERQUEIRA: Jeffrey, you had a question?

MEMBER WILLIAMSON: No.

CHAIRMAN CERQUEIRA: That is unusual.

MEMBER WILLIAMSON: Well, anyway, there was an effort -- I'm going to ask one.

In each of the categories authorized nuclear pharmacist, medical physicist, and so forth, we made an effort to define broad criteria for what constituted an acceptable, you know, in the case of the medical physicist it told an appropriate masters and doctor's degree, have two years full time practical training and/or supervised experience in radiation oncology

physics, some requirements that it has to be in a clinical radiation oncology facility, pass an examination which assesses knowledge and competence in clinical radiation oncology, safety, calibration, etcetera, etcetera, listing --

Is that an acceptably broad specification of the body of knowledge that, you know, any eligible board would have to asses? And in particular the American Board of Radiology?

DR. HENDEE: I think so. When we looked through that list we said, well we test, we evaluate candidate's mastery of this body of knowledge in this areas, we could meet this requirement, so long as we are not held to some specific number of hours of training and experience.

I hear you saying that wasn't your intent. I just have to tell you that when reading the proposed rulemaking it is a little bit hard to know exactly what is intended in order to determine whether a board will meet those, will be accepted or not. And you are clarifying that now.

CHAIRMAN CERQUEIRA: David?

MEMBER DIAMOND: Dr. Hendee, what we were trying to -- since Dick, and Jeff, and I, were the ones who wrote most of this fun stuff, again, what we are

trying to do is give the specialty boards this latitude and, really, reinforce you, support you as the default pathway, and only in the circumstances where an individual would need, for some reason, to follow an alternate pathway, in that particular instance be very, very prescriptive.

So when I listen to you, and when I review the proposal, I really don't think there is any true friction going on. I understand that you are -- that there may be a little confusion, but we really tried to insert that operator OR in there, to be very, very clear, that only in that alternate pathway would we have those very prespictive guidelines come into effect.

DR. HENDEE: Mr. Chairman, I'm perfectly satisfied with this response. I think it is very helpful to get this clarification. And I think I can go back and assure the Board of Radiology, and I think other specialty boards as well, that we understand, now, how to go about this process, and we appreciate the latitude that you have given us.

CHAIRMAN CERQUEIRA: Good.

DR. HENDEE: And I do want to move to another issue.

CHAIRMAN CERQUEIRA: I suggest we go on to the next issue, because we have about 15 minutes left.

DR. HENDEE: This is a fairly, I think a fairly simple issue. And that is that oftentimes individuals, now looking at individuals and their qualifications, oftentimes an individual acquires the training and experience to serve as an authorized user.

This is particularly true with physicians, while the physician is in a residency, or a fellowship program, that is accredited through the accreditation council, the graduate medical education review by the residents review committee, and all those kinds of things.

In those situations the person in the institution that is most responsible for assuring the training of residents or fellows, is the program director. And we would recommend that for individuals who receive their radiation experience, and radiation training, while in an accredited residency, or fellowship program, that the person best suited to attest to that training is the program director.

For individuals who did not receive their training and experience in an accredited program, certainly the authorized user would be the person you would go to. But in the case of accredited programs, the individual most responsible for assuring that the training actually occurred the way that it was stated to,

supposed to have occurred, is the program director.

And we would recommend that that be the person that provide the attestation statement in those situations.

CHAIRMAN CERQUEIRA: Do you have any questions on that point, or --

MR. NAG: Should it be the training, that the principal and the authorized user, or should it be an -- for example, there may be a friction between the authorized user and the program director.

You know, the program director may not like, for whatever reason, a resident. And I will not certify you, while the authorized user, how do you deal with conflicts like that?

DR. HENDEE: It is our impression that the attestation statement is provided by one individual, and in those situations the person that is responsible for assuring the educational experience meets the standards of the residency review committee, and the AGCME, is the program director.

And so I would feel much more comfortable that the program director would attest to the training, rather than an authorized user, especially when there is a conflict like that.

CHAIRMAN CERQUEIRA: Jeff?

MEMBER WILLIAMSON: Your statement, or your description basically replacing the program director with preceptor, was exactly the intent of the subcommittee when we drafted the regulation.

DR. HENDEE: Replacing the authorized user with the program director?

MEMBER WILLIAMSON: Precisely, or a preceptor. But, you know, what has happened is the Commissioners had their go at this and they, basically, have ruled that we have to put the preceptor now, who I presume is somebody mentioned on an NRC or agreement state license, back in as the signatory.

So I think we are going to learn, later today, the consequences of that. But, you know, that was -- I'm not sure, at this point, what we can do about that.

DR. HENDEE: Our advice to you, from the profession and from the Board of Radiology is, the program director would be a more appropriate individual to sign off. But I do understand that we all respond to people who have authority. So that is just our advice.

MEMBER DIAMOND: I would just like to echo Jeff's comments. Again, if you look through all the drafts, every single draft that we wrote included the language for the residency program director and as the

powers that be, when you get to the proposed rule, it was replaced.

So we did our best, we agree with you.

DR. HENDEE: Okay, thank you. I will move on to the third point.

This is also, maybe, a somewhat complex point. But I think we certainly reached consensus on this, this morning. And that is the issue of certification examinations as a measure of competency.

Because in various aspects of the rulemaking, even though I think you took out the issue of verifying competency by the preceptor, I'm not sure about that, you can comment on that.

Here is what the American Board of Radiology recommends. The American Board of Radiology recommends that references to examination as an evaluation of competence, in reference to specialty board certification, be removed from any and all sections of the proposed revisions to Part 35.

Specialty boards evaluate education, training, experience, and mastery of a body of knowledge, and its potential applications in a clinical setting. That is what we evaluate, that is what we test.

Specialty Boards, including the American Board of Radiology, do not evaluate the competence, or

diligence, of individuals conducting technical or medical procedures in a clinical setting, we don't do that.

We have had long discussions about this, at the board level, and we have concluded that we do not evaluate, or test, for competence. We test for mastery of a body of knowledge, and its applications.

In fact, here is the mission statement of the American Board of Radiology, and the mission of the American Board of Radiology is to serve the public, and the medical profession, by certifying that its diplomates have acquired, demonstrated, and maintained a requisite standard of knowledge, skill and understanding essential to the practice of radiology, radiation, oncology medical physics.

Nowhere in there is the word competence. And we would only recommend that in this rulemaking, as you revise it once again, you take out the evaluation of competence anywhere that the boards are referred to.

And you might think about whether or not that is something that you can really, also, evaluate or not. Mastery of a body of knowledge is one thing, attesting to competence takes a one on one oversight of the individual in a clinical study, over time. The boards don't do that. I suspect the NRC would have a hard time doing it as well.

MEMBER DIAMOND: Bill, this is another subject that we spent a lot of time thinking about. In today's hyper-litigious world, no one really wants to be the one stating whether an individual is competent in the subject, or not.

We had a tremendous number of individuals telling us that they, as program directors, did not feel comfortable being the ones signing a statement attesting to competence, they did not want that liability.

And they all said to us, it is the boards, the boards are the ones that are supposed to go and help prove to us that these individuals were competent, so take us out of the loop for an attestation of competence, we will be happy to go and sign off that they fulfilled the requirements of the program, but put that in there for the boards, which is exactly what we did.

And now, of course, you are making the point that you are testing on a body of knowledge, but are not capable of attesting to an individual's body of knowledge and competency in the subject as a whole.

So we are left in a very difficult predicament here, members of the Committee, we have been through this quite a bit. I welcome any other thoughts.

CHAIRMAN CERQUEIRA: Any comments?

MEMBER DIAMOND: Where does the buck stop?

DR. HENDEE: You define competence in terms of what it is that you are evaluating.

MEMBER VETTER: Well, just briefly, the issue we struggled over was whether or not a preceptor needed to certify that the individual was competent. And we chose not to put that in our recommendation, but that has been added in.

What you are raising is an additional point relative to the certification process, where these -- these are just draft rules, where it says, assesses knowledge and competence, that is where David -- somehow we were encouraged to build competency into this process.

So that is how those words ended up there, that is what we recommended, because we were not recommending that the preceptors sign for competence. So now we end up with both of them.

DR. HENDEE: If you define competence as mastery of a body of knowledge, and its potential applications in a clinical setting, that is what the board evaluates.

But if you define competence in some other way which requires some kind of, you know, on-site over time evaluation of the practice of the individual, we don't evaluate that.

MEMBER WILLIAMSON: You require letters of

recommendation for candidates to sit for the board. Those letters of recommendation request the evaluators to give the opinion of the individual's competence in the training environment.

You presume, you know, that these people have had --

DR. HENDEE: We do ask whether or not -- I don't remember exactly how it is worded, but we do ask whether or not the person who is signing off are attesting to the individual's eligibility to sit for the exam.

Whether or not that person feels as though the person is qualified to sit for the exam. But we don't ask if the person is competent to practice. I mean, we have avoided this after long, long discussions, we have decided that we can't evaluate competence.

And it sounds like you all are starting down the same road of having the same discussion.

MEMBER VETTER: I was just going to mention, I'm fairly certain that the American Board of Health Physics is the same way, it asks someone to asses whether or not the individual is qualified to sit for the exam.

CHAIRMAN CERQUEIRA: Dr. Nag?

MR. NAG: I mean, if the American Board of Radiology and the other boards are not capable of

certifying competence, I mean, how are we going to be, you know, how can we even think about certifying competence?

I would say we go back to the Commissioners and say that we can talk about having the knowledge, or having a body of knowledge, but not certifying competence.

CHAIRMAN CERQUEIRA: Again, I think the point that the committee had made to the Commissioners was to, you know, certification of competency was difficult, but that was put back into the draft rule to Part 35. Dick?

MEMBER VETTER: In your position as President of the ABR, in your opinion who should determine competence of the authorized user, or any of these other positions?

DR. HENDEE: Well, certainly in the work environment that individual reports to somebody else. And there is a medical board in the institution, and there are supervisors over the work of the individual, and those people are on-site, and over time if the person is incompetent, that information will come forward.

But I can't see doing it in some sort of way that a board could apply.

MEMBER VETTER: So whether a board assesses

knowledge, etcetera, or whether the NRC has prescriptive hours, do either of those determine whether a person is competent?

DR. HENDEE: No, not at all.

MEMBER VETTER: Ruth?

MEMBER McBURNEY: I agree. I would tend to not want the word competence in there if it meant something other than have the knowledge and training, and so forth, to do the job.

Or to redefine competence in terms of just what you had read earlier, as to what the board certifies, or attests to.

CHAIRMAN CERQUEIRA: Sally?

MEMBER WAGNER SCHWARZ: I was just thinking that it is possible that the words need to be changed to essentially state that certifying -- then certify that a body of knowledge has been achieved, I mean, accomplished.

DR. HENDEE: Mastery of a body of knowledge and its applications?

MEMBER WAGNER SCHWARZ: Correct. Just change the words to essentially say -- we are all saying the same thing.

DR. HENDEE: We are.

MR. NAG: And have qualification, or has the

requisite qualification, rather than saying competency, that is one word we could use. The other thing is that I would not want to add to be evaluated by the hospital or by the supervisor, because that could lead to a catch-22 situation.

If you have a new employee to do the work that must mean having an NRC authorized user, he cannot get that unless he is working, and has been supervised by somebody else. So I would not want to have, you know, someone in the department supervising people, and get the license.

CHAIRMAN CERQUEIRA: Jeff?

MEMBER WILLIAMSON: So I guess the question is, maybe to Tom, can we delete the word competence, and put in some more general specifier, as has been discussed within the guidelines presented to us by the Commissioners decision?

MR. ESSIG: Well, certainly the Rule is up for comment, and if that is a comment that comes -- I mean, --

MEMBER WILLIAMSON: And I will comment, just for information purposes, it may help explain some of the confusion about this, is there are errors in the way this draft rule, that was just distributed today, are written. It really is not written, at all, with the same logic as

the original proposal.

I assume this is an error that was not intentional.

MS. HOLOHAN: I'm Trish Holohan from IMNS. The Commission SRM is specific saying we can't change the preceptor statement, but we can certainly clarify that the word competency means sufficient attestation to demonstrate that the candidate has knowledge to fulfill the duties of the position for which certification is sought.

So we can do it in the statements of consideration.

CHAIRMAN CERQUEIRA: Dr. Hendee, was that something that the ABR would find acceptable?

DR. HENDEE: Yes, very much so.

CHAIRMAN CERQUEIRA: So clarification of the word competency?

DR. HENDEE: Sure, define it in a way that we can actually evaluate it.

CHAIRMAN CERQUEIRA: Yes. Ralph?

MEMBER LIETO: I was going to ask Trish, would that be in the definitions of Part 35, that you define competency in the Part?

MS. HOLOHAN: No, it would be in the statements of consideration for implementing the Rule.

MEMBER LIETO: Ruth just kind of whispered to me the same comments that are going through my mind, because statements of consideration, they are out there that one time.

And I think if you had what, exactly, it was right in the Rule, I don't think you would have this history going on with what does it really mean? And basically we are talking mastery of a body of knowledge, and the ability to function independently.

MS. HOLOHAN: I think in addition to clarifying the statements of consideration, we can also clarify the forms to indicate what competence means. The form 313 and we are looking to create another form that boards submit.

CHAIRMAN CERQUEIRA: Dr. Nag?

MR. NAG: Yes, I think an important enough point that even though what has been written, we should still be able to insert, in the main Part 35, rather than supplement the thing.

One point I think we can talk to the Commissioners, we have a meeting next week, if the ACMUI feels that this is an important enough, even that one word, it may be worthwhile talking directly with the Commissioners.

CHAIRMAN CERQUEIRA: Right, so this is the

revision of Part -- the revision of the revision of Part 35. So it is still, you know, being considered, and I think could appropriate, with the recommendations of the Committee, and the approval of Staff, be advanced in that format.

So I gather, from the ACMUI, and the presentation, that people agree with the ABR's recommendations. Thank you. Your last point?

DR. HENDEE: Well, my last point is composed of a comment, a statement. And my comment is that the American Board of Radiology supports the website listing of specialty boards that serve as default pathway to service, as AMP, AMU, ANP, and whatever.

We like the idea of web listing. However -- - so that is a comment. Now, the statement is that in spite of that the ACMUI is on record, in a previous report, of making certain recommendations that the American Board of Radiology strongly objects to.

So I would like to make those objections, even though I realize that, in fact, there is going to be no inclusion of any boards in the rulemaking itself.

The objection goes as follows: Recommendations of ACMUI dated August 1st, 2002, recognized board certification by three specialty boards, American Board of Health Physics and Comprehensive Health

Physics; American Board of Medical Physics and Medical Health Physics, and the American Board of Science and Nuclear Medicine and Radiation Protection, as a default pathway to recognition by the NRC as a radiation safety officer.

The ABR strongly objects to this listing because it omits board certification radiological physics, and in medical nuclear physics, by the American Board of Radiology, as pathways to recognition as a radiation safety officer.

Individuals presently serving as radiation safety officers for many nuclear medicine programs across the country are board certified in radiological physics for medical nuclear physics by the American Board of Radiology.

Further educational experiences for ABR certification of these specialties meet, or exceed, those for each of the three certification boards that were originally proposed as default pathways by ACMUI.

So we went on to say that we want those two specialty certifications included, if there is going to be boards mentioned in the rulemaking itself. Now, we realize that no, it is not going to be the way it happens, it is going to be on the website.

But I just wanted to be on record, here,

that the Board of Radiology strongly objects to being excluded from the listing of boards that originally ACMUI put forward. That is our statement. I don't know that it needs any discussion.

But it does raise, now, the issue that I do want to bring up. And it has to do with the fact that one explanation for why the Board or Radiology was excluded goes as follows:

Omission of ABR certification of medical nuclear physics, and radiological physics as default pathways to NRC recognition as a radiation safety officer, has been defended by some. I got this explanation from a couple of people.

Who point out that persons recognized as an authorized medical physicist, that is, through board certification by the American Board of Radiology and Therapeutic Radiological Physics, roentgen ray and gamma ray physics, X-ray and radium physics, or radiological physics, those are all historical certifications, can serve as a radiation safety officer.

So there was an alternate mechanism coming through these therapeutic radiological certifications that would allow someone to serve as radiation safety officer.

However, this pathway to service as a

radiation safety officer is restricted to responsibilities over "similar types of use of byproduct material for which the individual has experience".

The board certification pathway, as I mentioned above, with the exception of one of them, radiological physics, are designed for individuals working in radiation oncology, where the uses of byproduct material are for therapeutic applications.

It is not clear, it is not clear, whether an authorized medical physicist would be considered qualified, by the NRC, to provide radiation safety oversight of the use of unsealed radioactive materials for diagnostic procedures, or in research.

These diagnostic applications constitute by far the most widespread use of byproduct material. The ABR presumes that it is the NRC's intent to extend the radiation safety responsibilities of authorized medical physicists to diagnostic applications of byproduct material.

If that presumption is correct, then the NRC should state its intent, explicitly, in the proposed regulations. Can an authorized medical physicist, working in radiation therapy, be designated as a radiation safety officer, for unsealed radionuclides used in diagnostic procedures, and in research?

If the answer to that is yes, provided they have some training in that area, which they all would have, then the answer is settled. If not, because the specific applications that the person is responsible for are basically sealed sources in therapy, then I think we've created a problem of who is going to be the radiation safety officer for these diagnostic nuclear medicine programs around the country.

And I can't tell, from reading the regulations, what the intent is.

CHAIRMAN CERQUEIRA: Richard?

MEMBER VETTER: I don't remember the specific points of discussion. Some of this gets a little convoluted. Tend to exclude anyone, but relative to the point you make about, okay, what is the -- relative to a scope of that person's certification, how would that relate to the scope of the program if they are named RSO?

I can't answer that, off-hand, without reviewing this in more detail. And, you know, it is not ultimately our decision, anyway. But as we are -- I was hoping to be able to explain to you what we did, and I can't remember the specifics of the discussion relative to that particular point, comparing the scope of AMP, for example, versus the scope of the program.

DR. HENDEE: Let me just respond to that before Jeff. It all hangs on the definition, or the interpretation of this statement, responsibilities over similar types of use of byproduct material. It all hangs on that, and you have to explain what that means, and then I will understand what you intend, what you are trying to get at.

MEMBER VETTER: Right.

CHAIRMAN CERQUEIRA: Jeff?

MEMBER WILLIAMSON: Well, I think similar types of use means 300, 400, 600, I mean, that is the way NRC categorizes them, and I'm sure that is how it was intended. So I think the intent was, whether it was advisable or not, that RSO of a broad scope licensee needs a broader certification credential, like medical health physics, or American Board of Health Physics.

I think that was the intent, and the thought was that the smaller licensees that fall short of being broad scopes, would be caught by the condition at the end, which allows authorized users, authorized medical physicists, and ANPs, to be radiation safety officers for programs involving byproduct uses similar to those of their experience.

But I think you've brought up a case where radiation oncology in a small hospital, maybe, is the

main source of technical expertise for doing health physics, and there really isn't a viable choice, other than the ANP, to be the RSO for the whole operation.

And that, you know, if we don't repair this, and I support your proposal that we do do something to repair this, it may be that we will actually be worsening radiation safety by forcing these programs to have off-site RSOs, and consultants, and so on, as opposed to having somebody on-site, full time being the RSO.

So I could see that maybe the proposal could do some harm.

DR. HENDEE: Could I just respond? I think you really want to think this through very carefully. In my institution, which has a broad license, and has a wide spectrum of programs, as do most of your institutions, I can see where we could have a person certified by the American Board of Radiology and Medical Nuclear Physics, serving as radiation safety officer over all the diagnostic applications.

And we could have a radiation therapy physicist serving as radiation safety officer over all the therapeutic applications, and now we have two radiation safety officers, instead of one.

So I think this is a complicated -- I think it is not just small programs, it also creates problems

in large programs, as well. So I think you really need to think this through.

And our recommendation, by the way, is that a person certified as an authorized medical physicist, should be given authority to serve in the radiation safety officer over research and diagnostic applications, provided that he has had some basic education in the sue of unsealed sources, and what constitutes radiation safety and protection practices for those sources. Then the problem would be solved.

CHAIRMAN CERQUEIRA: We are about out of time, here. Any other questions, or any other comments? Yes?

MEMBER LIETO: I had two comments. One, I think maybe you shed some light on where that areas of expertise came into play. I think there was concern that if you had, say, a physicist who is board certified in just diagnostic radiology becoming an RSO over a program with radioactive materials, that there wouldn't be the expertise there, even though he was the physicist of the facility.

And it would be that situation, and also maybe a physician, whose expertise may be just in diagnostic uses, and then in a program with radiation oncology, Brachy therapy, might be asked to become e RSO

for the license.

That being said I definitely support your points about the authorized medical physicist, actually from reverse end, that someone could be board certified in medical nuclear, and yet there might be questions about their ability to be RSO over either a brachy therapy program or a broad scope program.

And definitely would create, I think, significant shortages of competent RSOs over those types of programs.

DR. HENDEE: Thank you very much for hearing us out, thank you all.

CHAIRMAN CERQUEIRA: Thank you. All right, the next presentation is a discussion of NRC licensing timeliness proposal for monthly, bimonthly, ACMUI teleconference.

MR. ESSIG: Okay. This caption for this topic was only meant to serve as a point of discussion to increased engagement between the Staff and the Committee. And I don't believe that anybody should seriously, should interpret that we were seriously considering monthly and bimonthly conference calls.

That was not, that was just a suggestion for more frequent engagement. I think on the benefit side of more frequent engagement we see more timely exchange of

information between the Committee and the Staff, more timely resolution of issues, and more opportunity for the Committee to provide input.

Now, some of the concerns that we would have with the additional engagement, what I'm talking about here is more engagement than the two times during the year, semi-annual meeting.

That, first of all, additional is more time consuming on everybody's part, especially us preparing for the additional engagements, in whatever form they are.

We have to decide, in advance, when these will occur, so that we must publish these meetings in the -- or these conference calls, in the Federal Register.

And then once we do that we will kind of be locked into the schedule, unless there is a very serious reason to change it. Sometimes we may have trouble getting a quorum together to reach resolution on an issue.

The -- so those are just some of the concerns. And, of course, then the increase in cost, because we would pay the members for preparation for the conference call, engaging in the call, and then the follow-up activities.

And so as an example, if we wanted to try

that yet this fiscal year, it is probably going to be difficult to do, because of our budget is pretty well all spoken for.

So this might be something that we would have to defer until fiscal '04. And even though that is relatively fixed, there may be opportunity to do a little trading within the budget. That is to reduce some effort in some other area to create the resources to address this area.

What I would suggest is that on a trial basis, starting -- let's see, our next meeting of the Committee is going to be in the fall, so probably the October, November time frame.

I would suggest that we institute a series of noticed conference calls, publicly noticed conference calls, to fill in the three month -- during the, roughly, at the midpoint of the six month interval in between meetings.

So that we would have, the first one would probably be in the January '04 time frame, and we would put out a Federal Register Notice, we would have an agenda in that notice, and we would have to set up a conference call bridge that interested members or the public could call in to a toll free number, and listen in, and we would give them an opportunity to make comment

if they so desire.

And so -- yes, I'm sorry?

MEMBER DIAMOND: It may be, that from the discussion earlier today, we may have addressed this issue. As you recall, we made a recommendation earlier today, that approximately two weeks after the disbursement of the Staff response, we would have an open telephone conference call, ACMUI, Dr. Miller's office, and the public, the purpose being primarily to go and resolve issues of discord, try to move priority items forward.

And perhaps at that same call we could also go and conduct this business. And that would fall perfectly in the middle between our spring and fall meetings.

And I think that one conference call between scheduled meetings here would probably suit our needs quite well.

CHAIRMAN CERQUEIRA: I think we had a discussion this morning, and just a statement, I'm against these preset monthly or bimonthly scheduled meetings which, you know, if we don't have enough agenda items, it is a waste of everyone's time.

And as we discussed this morning, in a closed session, we follow-up on the minutes, and then the

Staff review of the previous meeting would be adequate. That would be, you know, at least two additional contact points a year, for a conference call.

And we could see how that works out, and then see if we need additional ones, if there are burning issues.

MR. ESSIG: I'd like to suggest that just on a trial basis, and then revisit the question. So we might, possibly, go ahead and schedule two of them in 2004.

CHAIRMAN CERQUEIRA: Yes, that would be reasonable, because that would put some, you know, focus time commitments from the Staff to get the minutes out, and to find out whether the issues were addressed.

MR. ESSIG: Yes, and we could cover the issues that Dr. Diamond is reminding me of, and also any new agenda items, any -- this would be a good time to discuss any emerging issues that have come up, questions and so forth.

Yes, Ruth?

MEMBER McBURNEY: Would there be a funding problem to have one between this meeting and the fall meeting? You said that --

MR. ESSIG: I would have to look into it, to be sure. It is hard to say, off the top of my head, but

I would be willing to look into it.

MEMBER McBURNEY: Good.

CHAIRMAN CERQUEIRA: All right. Well, thank you very much, and maybe we can move on to the next time, which is the T&E Rulemaking Status and Discussion, and Roger Broseus will be leading the discussion.

DR. BROSEUS: I want to thank you all for having me here today.

CHAIRMAN CERQUEIRA: Roger, if you could maybe move to the side, because you are directly in front of the screen, there. Yes, just use that other microphone there, get a little closer to the microphone. That is good.

DR. BROSEUS: By the way, there are a few extra slide sets here, I'm afraid we don't have enough for everybody in the audience. Angie, want to put these in the back?

This is essentially a slide set I put together to cover both of our meetings today. I was lucky enough to be coordinating a public meeting this morning, with the Board present, and members of the public, as well as briefing, so a dual purpose set.

Before I launch into the discussion, I just want to point out that there are a couple of members of our working group here in the audience today. Ron Zelac

is with MSIB, material inspection safety inspection branch. I think that I saw John Zabco. John is back here, he is with the Office of State and Tribal Programs.

Other members of the working group, which I'm the coordinator for, are David Walter, he is representing agreement states on the working group. He is from Alabama.

Susan Chidakel is from our office of General Counsel. Susan, I'm sorry, you are short, I didn't see you. It is an inside joke. Sally Merchant from the office of enforcement, and we also have representatives from our administration and office of information.

Some of the slides I'm going to present to you today, I'm going to run through very quickly, because we are short on time, and I want to be able to emphasize certain areas where we are looking for some input from ACMUI.

And this is one that I'm going to go through very quickly. You guys are familiar, already, I'm sorry ladies and gentlemen, with how we are to where we are today, with you all briefing the Commission, and so on.

This led to subpart J being incorporated into the Rule, etcetera, Staff working with ACMUI, Tony Tse is over here in the corner, he and Linda --

CHAIRMAN CERQUEIRA: Roger, for the sake of

time and discussion I -- we should acknowledge all the people that have been involved, but if we list everyone it is going to eat up the whole time. And I don't mean to disrespect anyone.

DR. BROSEUS: In the end there was a Staff paper that went forward to the Commission, with three recommendations, which was to use ACMUI's recommendations as the basis for the Rule, it was adopted by the Commission in SRM-02-0194. With the proviso that we list recognized boards on our website, rather than in the Rule.

We discussed, already, to a certain extent, and others have mentioned that we have to keep a preceptor statement as written in the Rule, and there was some discussion of that by Dr. Hendee, with the clarification that it is not clinical competency, but attestation of knowledge that we are after.

And we have heard the comments on that, and we will be working to that end. The SRM required a clear radiology determination to meet criteria, and they also talked about implementing procedures, which I want to come back to later in my discussion.

Now, ACMUI members have draft rule text that is pre-decisional, which the working group has put together in your materials that were presented to you

this morning.

I want to mention how we got to where we are at in that today. First of all, the first part of your recommendation, to list the boards in the Rule is not there, because that was direction from the Commission, to be on the website, and all boards must be evaluated, okay?

We adopted most all of the changes, or intended to adopt most all the changes in the word of the Rule or the new Rule text that ACMUI presented, but we found some need for wording changes, which are reviewed in some slides that come up later.

There are also some changes you introduced into what have been commonly termed alternate pathway, which go a little bit beyond, in some cases, just writing rule text for recognition of boards, and the working group looked at that, too.

Now, one of the things that I want to mention, specifically, is ACMUI recommended that individuals, that T&E of an individual be evaluated to make sure that they have training or experience with new modalities, or new applications, or the ones they are going to be working with.

And an example of where that came in was in 35390, and your recommendation was the final little D in

parenthesis. Now, you won't find it written that way in the draft that the Staff has prepared. We changed the numbering around to try to avoid redundancies.

So, in general, there may be some cases where our numbering is a bit different from what you had in your draft. There are references in this presentation to numbering, they are the numbering in the revised draft proposed rule text, that is in the left-hand column of that table.

Another example of changes that we came across that feel are needed, and where the numbering needs to be addressed is in 392 and 394, there are back references to the experience requirements that ACMUI recommended, were oral administrations, for example.

And so the Staff has found a need that we are going to have to address, making sure that cross reference within the Rule is taking care of, when there are cross references back to 390. And we didn't see those changes in the ACMUI text.

The next point I want to get to, where we need some advice, is ACMUI recommended including the Royal College of Physicians and Surgeons of Canada in the list of approved entities for recognition of residency programs, and excuse my use of the term, and also as one of the boards that would be in the pathway for

recognition of board certifications.

The Staff feels that we don't have a clear basis for including the Royal College of Physicians and Surgeons of Canada in the Rule. And so we would like to solicit some input from ACMUI on the basis for that.

CHAIRMAN CERQUEIRA: Jeff?

MEMBER WILLIAMSON: Well, I'm confused, because I thought we were taking all references to specific boards out of the rule. That I thought your revised rule text was going to have them all on a web page, so why does it matter whether we answer the question now?

DR. BROSEUS: There is a, and you will have to look at the Rule text later on. I wish I had time to go into these in detail, I just can't. There is a paragraph, or a section in here, where the Canadian Board is referenced in the Residency area, but not in the Board certification pathway.

DR. DIAMOND: Yes. I think you're correct on that point. Just from a writing standpoint, the reason that language was probably included was simply that of precedent. When we were making a team to rewrite these for clarification and updating we did not go and substantively change that type of information, so I cannot go and tell you why it is that way except that we

did not add nor delete in our early draft versions. For example, the same thing would hold with the American Board of Osteopathic Radiology. When we made an attempt to delete that as an authorized user enumerated board, we ran into all that trouble with that.

DR. BROSEUS: The key issue here is it's a foreign board, no intent to separate out Canada from the rest of the world or whatever.

MS. McBURNEY: It's an accreditation.

DR. BROSEUS: Pardon me?

MS. McBURNEY: It's an accreditation rather than --

DR. DIAMOND: Yes. I don't think that's a board.

MS. McBURNEY: It's a residency program.

DR. BROSEUS: A residency program. So we need a basis for including that. Given the amount of time I have, I'd like to move on, and then we have some time for more questions and discussion at the end, we'll go with that.

Going up to Slide Number 8, staff decided to recommend inclusion of -- I'm trying to present this efficiently. In the current rule, specialty awards may be recognized if they meet the requirements in the so-called alternate pathway. And there was some discussion

in fact during your meeting last summer that that option be continued as a way for a board to satisfy NRC requirements. But it didn't come through in the final version of the document that you presented in the options paper.

Staff feels that keeping that option as one mechanism by which a board may satisfy NRC requirements is something we should have. It also satisfies the potential need of there is one board that has been recognized using that pathway, and we want to make sure that they don't lose their certification by some change to the rule.

I'd like to just hold the questions, if I can, to go through a couple more points.

CHAIRMAN CERQUEIRA: But it's an issue that does need to be brought up, I think. Jeff?

DR. WILLIAMSON: The intent of our group was to come up with general criteria that would not exclude the Board of Nuclear Cardiology and that would replace the more prescriptive requirements. As you know, we accepted that there was significant value added by the examination process and therefore felt somewhat more justified in making the alternate pathways more prescriptive, but I think the intent was all along that the alternate pathway requirements would at least be

necessary conditions for fulfilling the more general requirements so that any board that satisfied the alternate pathway requirements would satisfy the general ones. That was the intent, so I'm not sure why it's necessary. Because I'm reading the text of your revised rule. I was very confused, and I thought that there was an error in transcribing it. And as I read it more carefully there may not be, but it's very convoluted.

DR. BROSEUS: Let me see if I understand what you said. Right now the rule allows a board to be recognized if they meet the alternate pathway. And you see that as something that's just to continue.

DR. WILLIAMSON: No. We thought that we were covering that case by adopting a more general set of criteria, that any board which met the alternate pathway requirements would also meet the general requirements minus the examination.

CHAIRMAN CERQUEIRA: This went back to long discussion about hourly requirements and eligibility requirements for the board, and I think several years back the feeling was that if a board could demonstrate that they had certain requirements in terms of content and hours, that that was one of the prerequisites for them being considered for the boards, and that was one of the criteria that was used. And I think it was the

feeling that that should be continued to a large extent because it showed that at least the candidates for the board had had the minimum requirements for the alternative pathway. So I think the feeling of the Committee was to continue that.

DR. WILLIAMSON: To continue there might be some concern to recognizing and promoting a board that didn't require a peer review examination. That's also another concern, because you know what boards NRC recognizes has sort of impact on educational and training policy that goes beyond the specific application here.

DR. BROSEUS: When I finish up I'm going to -- I'll say it now -- I'm going to ask for feedback from you on some of the points I've made. But I will take right now absent additional feedback on this topic that it's the consensus not to put an "or" in there which would permit the boards to be recognized using the current system, basically.

CHAIRMAN CERQUEIRA: I didn't understand.

DR. BROSEUS: It's not clear?

CHAIRMAN CERQUEIRA: No.

DR. BROSEUS: Let me take an example.

DR. EGGLI: Why don't you take 390 and just walk us through 390 and what you mean. Take Page 11, I mean just to grab one that I'm looking at right now.

DR. VETTER: What about 290 since that's the Board of Nuclear Cardiology. It's under 290, isn't it?

MR. WILLIAMS: I don't know if that's a good case.

DR. BROSEUS: Can we go with a simple case for the sake of example, okay? It's at the beginning on the first page.

PARTICIPANT: Which page are we talking about?

DR. BROSEUS: Of the draft. At the bottom we have a certified -- or Number 2 -- "Certified by specialty board for the certification process includes all the requirements in Paragraph B of this section in the certifications we have recognized by the Commission on Agreements States." So this is basically retaining that, and it's my understanding that ACMUI doesn't want to do that. In other words, the could do what you wrote as the criteria for recognition of a board, which I'll loosely term academic intestine, or meet the alternate pathway, which is allowed now.

CHAIRMAN CERQUEIRA: It wasn't that the alternate pathway alone would be sufficient, because the examination and all those things needed to be looked at, but I'm just a little confused.

DR. WILLIAMSON: Two ninety isn't a good

example because this is one in which we did say, I think, that the qualifying features of a board for imaging and localization actually would be the $700, all that business. So this actually -- we lied to Dr. Hendee.

DR. BROSEUS: For RSO, ANP and AMP -- I think AMP, I'm not sure, I'd have to look at it.

DR. WILLIAMSON: But the AMP is --

DR. BROSEUS: In some cases it wasn't required.

DR. WILLIAMSON: Yes, that's right. So the AMP and I suspect maybe the Radiation Oncology authorized user for sealed source for radiotherapy may have been different.

CHAIRMAN CERQUEIRA: Ruth?

MS. McBURNEY: I would think that for Radiation Safety Officer we would not want it just to be the alternate pathway inclusion, the 200 hours, for a board to be recognized, that the board certification should be the bachelor's degree and graduate degree and minimum of 20 college credits and so forth.

DR. VETTER: The intent of the Subcommittee was, I didn't have this in front of me before, but it was not to -- the intent was to not exclude any boards who had already been recognized.

MS. McBURNEY: Right.

DR. VETTER: So the Nuclear Cardiology Board. And therefore when we wrote this we accommodated that within our proposal. The intent also at that time was not to provide that pathway for any other boards but rather to write general criteria for which the boards would qualify.

DR. BROSEUS: Well, I've thrown in a red herring which I'll pull out of the water unless by the end of our -- unless later on you have additional thoughts. So I'll pull that out, okay? Okay. Now with that, I might move on. To me it was an important issue to make sure we're doing the right thing with this rule.

MR. LIETO: Are you pulling out the "or" or whatever comes after --

DR. BROSEUS: Well, for example, on Page 1 at the bottom of this draft, where there are -- where there's a retention of a board meeting the current rule as an alternative to what ACMUI wrote, I'll pull that off. I think I've confused things too much, and unless ACMUI feels that we should be doing something more than -- Dick just said it, I think, and I think it's a settled issue here.

Let me move on. There are some slides that I want to go over very quickly because we are very short on time. And what I'm going to ask is that the

information I'm presenting in these slides that you consider this and if we have time for me to come to them, but I doubt that we're going to, but that ACMUI provide some feedback to me later on. And it's where I've talked about terminology, using quantities for where a written directive is required rather than therapeutic quantities and so on.

So I'm going to skip over slides up through Number 12 and go on to implementation with one exception. And during the discussion by Dr. Hendee in our meeting this morning -- let me look at my notes here -- I heard in the meeting earlier on that it wasn't ACMUI's intent to prescribe numbers of hours of training. However, in certain cases, the way you wrote the proposed rule, by referencing what's already in the rule that actually happened. And so I take it that you did not mean to overwrite that, and do we need an example?

DR. WILLIAMSON: I think that you're absolutely right. In reviewing what we originally wrote for 190, 290 and 390, we kept the hours of training and experience and the detailed breakdown in tact I think under the belief that that requirement was considered uncontroversial in terms of board eligibility compliance. Now, that may not be true, and if that's -- we explicitly decoupled those in the case of 400, 600, the AMP and the

Radiation Safety Officer, but we did not decouple them for 100 to 200 and 300.

DR. BROSEUS: Okay. Mr. Malmud?

DR. MALMUD: I apologize for my ignorance, but I am totally confused by what you are trying to get me to understand.

DR. BROSEUS: That's my fault.

DR. MALMUD: May I ask what's the first point that you would like me to understand under the proposed rule to amend 10 CFR Part 35 requirements D and E, these slides, as it applies to this text? What's the first item that you would like me to understand.

DR. BROSEUS: To understand or to get feedback on?

DR. MALMUD: I didn't hear you, I'm sorry.

DR. BROSEUS: To understand or to get feedback, I'm sorry.

DR. MALMUD: To understand. I can't give you feedback until I understand it.

DR. BROSEUS: Okay. The very first one is that we used ACMUI's recommendations, the basis for draft and proposed for the text that you have in the left column of that handout.

DR. MALMUD: You are proposing that on Page 1, Item 35.50 be accepted as it is.

DR. BROSEUS: No. No. It's for you to look at and review. This is our draft. This is first column in this handout that you have --

DR. MALMUD: Yes.

DR. BROSEUS: -- is our Working Group's first draft, our best attempt to get what ACMUI wanted to --

CHAIRMAN CERQUEIRA: Roger, could you get closer to the microphone? I think some of the audience in the back probably -- yes. All right. So current rules means that revised Part 35 --

DR. BROSEUS: Yes. Yes.

CHAIRMAN CERQUEIRA: -- which was published in May of 2002 and became the rule --

DR. BROSEUS: Yes. Yes.

CHAIRMAN CERQUEIRA: -- in October 24, 2003, that there was a draft proposal that was put together by Dick Vetter and his Committee addressing some of the problems that we had not dealt with adequately in terms of board certification and other things. And so that was submitted to the Committee. Now, the draft proposed, which is on the left hand side of Page 1, that is your modification of what was sent to you? Is that --

DR. BROSEUS: This is what we have come up with as draft proposed rule text based on ACMUI's

recommendations and then qualified with the points that I'm making where we saw a need for changes of wording and so forth.

DR. DIAMOND: See, Roger, the problem is this: I have my redline copy of all the work that Dick's Committee went through, and this is the first time I've seen your draft modifications. As I'm going through, there are differences in numbering, there's differences in wording, there's differences in syntax and structure, and I'm getting one hell of a whopper headache over here trying to figure out if the response I'm giving to you and Dr. Hendee is still what I tried to write or what Jeff tried to write.

CHAIRMAN CERQUEIRA: Well, it was the old -- the revision or the revision of the revision, and I'm not sure we can adequately deal with this seeing it for the first time.

DR. DIAMOND: It's really difficult because I'm probably the only one here that has all this redline, what we were trying to do, how we proceeded with it, and I've been here for 20 minutes --

CHAIRMAN CERQUEIRA: I'm doing basically three and a half years worth of the Committee's work, to a large extent, because the revision of the revised rule was dealing with -- you know, making some modifications

to address specific issues that had arisen. And this really kind of takes it in a whole other direction that I'm not sure we want to go in. Ralph?

MR. LIETO: Can I make a recommendation that you take what the Subcommittee submitted to the Working Group and do an editing with the strike-throughs and redlining and so forth? That way we will be able to compare. That way we can give you feedback as to what you're doing that meets the intent of the Committee as well as do we really have some points of contention. Because --

DR. BROSEUS: Yes. I hear you.

MR. LIETO: And I think that might be the easiest place to go from here.

CHAIRMAN CERQUEIRA: Trisha, do you want to make a comment?

MS. HOLOHAN: I agree with that comment. If we could do what Dr. Lieto suggested and do a redline strike-out of the ACMUI Subcommittee's recommendations and give them the revised rule language that the Working Group has come up and make corrections, yes.

CHAIRMAN CERQUEIRA: But I'm a little disappointed that this far into the process this is basically being presented to the Committee without having had some discussion with Dr. Vetter and his group. I

think there should have been discussions with them, and certainly any kind of presentation to get meaningful advice from the ACMUI should have been given to us earlier.

DR. NAG: Manny, I'd like to make a suggestion. Whenever we are having a Subcommittee meeting reform and making a major discussion and changes, we have the appropriate member of the NRC be placed in there so that they are aware of the discussion, because otherwise we write up a recommendation and give it to them. They may not be fully aware of all the discussions that have gone on, and it goes round and round and round. If they are there at the beginning, they know why we make certain recommendations and why that was done, and that miscommunication would be less.

MS. HOLOHAN: But if I can make one comment. Really what we need from you today is the basis for the Royal College of Physicians in Canada. And you indicated that there wasn't a real basis, and --

CHAIRMAN CERQUEIRA: I'm not sure we understood it, to be honest, and I don't think we can just take one specific thing out of the whole package.

DR. WILLIAMSON: Could I make a recommendation?

CHAIRMAN CERQUEIRA: Sure.

DR. WILLIAMSON: I think that these are a whole panoply of very complicated issues has been raised. I don't think we can do justice to any of them, including the Canadian College issue, so I recommend that we schedule a Subcommittee meeting with Roger and others who are involved, publicly noticed if necessary in the near future, to work through these nitty gritty details and then report back to the parent Committee. I really think that we need to do much more work, have a lot of advance time to read through this document. I think we've been apprised of some of the issues. We did have a large briefing book put together for us on all the different specialty board, which may well have included the Canadian organization, so we'll have to do a little research on that issue.

CHAIRMAN CERQUEIRA: I think definitely -- I mean the Subcommittee did a lot of work, the main Committee and those of us who've been on this thing for four years have spent a lot of time, and you're sort of relatively new into the process. There's a lot of stuff that's going on, and to just get this now without being able to review it in detail I don't think is going to be meaningful to you.

DR. BROSEUS: I appreciate that. Part of this is an artifice of the time constraints we're under

to get something out and have it in place before Subpart J disappears.

CHAIRMAN CERQUEIRA: Well, but that's why this Subcommittee did its work in a very timely fashion. I think Dr. Vetter should be commended --

DR. BROSEUS: Well, I wasn't saying --

CHAIRMAN CERQUEIRA: Well, but to get it out -- just to get it out without making it accurate we're going to run into the same problem we had the first time.

DR. DIAMOND: It's very important. This document under Dick's leadership we met a timeline for July of 2002 and we worked our tails off to make it happen. And it would have been much better had we had our submitted language and then perhaps your revisions or a redline of the same, because there's -- this is no basis for comparison today.

CHAIRMAN CERQUEIRA: And some discussion with the group. The group would have been willing to discuss this with you, and any kind of redlining without understanding some of the reasoning that went into it is just going to be more work, and I think some discussion with Dick or with the Committee would really identify some of these issues, giving people the chance to go back and review why certain decisions were made. That's critical.

DR. BROSEUS: I'm going to have to ask Trish and Sandy about what we can do timewise to accommodate that suggestion and how we can move forward. One suggestion is to distribute a redline strike-out to have reaction back. Another one is for the Subcommittee to reconvene and talk and so on. And I can't say yes or no.

CHAIRMAN CERQUEIRA: Well, just a comment on my part. Getting back to some of the discussions we had this morning and where the communication between the Committee and the staff has fallen apart, this is a clear example of it, and I think the Committee feels frustrated that we spent a lot of time, a lot of work, we set timelines that we're going to be able to get the revision out in a timely fashion to meet the 2005 implementation deadline, and all of that work was not dealt with appropriately by the staff. You were not involved in the process from the beginning, so I don't want to fault you, but I think we need to communicate with the Committee so that we've spent the time giving you the recommendations and you're recreating a lot of work that with some input from the Committee could have been verified and you wouldn't have had all these issues.

DR. VETTER: Let me just say that Roger did call me on one occasion a couple of weeks ago to try to clarify a few things. This is the first opportunity I've

had to see anything in writing. But I don't want us to go away thinking that Roger and his Subcommittee weren't attempting to communicate with the Committee.

DR. BROSEUS: I do want to say that we were diligent about being careful to take ACMUI's recommendations to heart and where we had differences to identify them. And my purpose in coming here today was to identify those defenses. I think all the difficulties are arising from there's so much to deal with in such a short period of time.

PARTICIPANT: Roger, we can't hear you back here.

DR. BROSEUS: I'm very sorry. I said I just wanted to point out that we were very diligent in working to make sure that we used ACMUI's recommendation, as modified by the SRM and so on. And my purpose in coming here today was to identify where those differences came up. I think that the difficulty arises we have such a short period of time to review it that that's the hurdle. I've asked for some advice on what I can do from our Deputy Division Director, and can you help me out on this a little bit, Trish?

MS. HOLOHAN: And I just wanted to point out that there's very few changes -- there's about half a dozen changes from what the ACMUI recommended, except for

the preceptor statement that was directed by the Commission to be identical to the current rule. Otherwise, there's about half a dozen changes, and I wanted to say that we can certainly work with the Subcommittee or the full Committee in resolving this, but our timing is such that we have to get a final rule up to the Commission by the end of July. So whether we do it by Subcommittee, and we're certainly happy to work with them, or the full Committee --

CHAIRMAN CERQUEIRA: Well, I'd recommend that you work with the Subcommittee at this point, because they've been involved in the issues.

DR. BROSEUS: I'd like to remark about the recommendation of preparing a redline strike-out. The way the rule language is structured and so on, a redline strike-out in making a direct comparison between ACMUI's draft and what we have would be somewhat difficult, and there may even be a need to identify differences as I have today, because it's not just a matter of feeding it into the computer and out comes the redline strike-out, because there are so many different --

CHAIRMAN CERQUEIRA: Roger, can you bring the microphone closer?

DR. BROSEUS: Yes. There are so many differences that we're not going to be able to just feed

this into the computer and get a redline strike-out. I'll leave that as it is.

So what I'm hearing is that we need to get back together with the Subcommittee maybe chaired by Dr. Vetter and look at what we've done?

CHAIRMAN CERQUEIRA: Richard, are you and the Subcommittee willing to do it?

DR. VETTER: Can this be done by conference call?

CHAIRMAN CERQUEIRA: I think that would be the most efficient, and it's a subcommittee so we don't need all the public notices, correct?

PARTICIPANT: No.

PARTICIPANT: Maybe two weeks notice.

CHAIRMAN CERQUEIRA: Two weeks? Okay. All right.

MR. LIETO: I'm confused. Now, the Subcommittee is going to work with Roger. What about the rest of the Committee?

CHAIRMAN CERQUEIRA: Once they've had a chance to go through, I think, make some of the clarification points, then it needs to come back to the Committee for the review of it. To get the whole Committee involved I don't think is going to be an efficient use of the time. It would be better don with

a small number of people who are intimately involved with developing it and then bring it back to the main Committee.

MR. NAG: There's a problem with the timing because they have to do this by the end of July. If the Subcommittee works with Roger, when does the whole Committee get together? And then by July they have to send it to the Commission.

MS. HOLOHAN: And we have to send it out to the Agreement States as well for a 30-day comment period.

DR. BROSEUS: Is it possible to work with the Subcommittee and have them bring substantive issues back to ACMUI?

CHAIRMAN CERQUEIRA: No. I think they can issue it to the whole report. We don't have to physically, publicly meet on it. I think it can be sent out to them as a draft, solicit comments and then the comments can be sent to me and I can -- if there are substantive disagreements, then I can make the decision whether we need to convene a conference call of some sort, but I think that's the most expedient way to get it done.

MS. HOLOHAN: Can I make another proposal?

CHAIRMAN CERQUEIRA: Yes.

MS. HOLOHAN: If we send it out to the

Agreement States as well as the full Committee at the same time and get your comments and we can get the Agreement State comments too.

CHAIRMAN CERQUEIRA: Okay. Jeff Brinker?

DR. BRINKER: If you can't supply us, and I hear that you may not be able to in appropriate fashion, a redline comparison, it might be helpful for you to reproduce your new wording with highlighted or annotated explanations of what you think are substantive changes that you had to introduce, felt you had to introduce and perhaps why there was a change so that as we go over this ourselves, we could rapidly identify where a change was made and get some idea of why you changed it.

CHAIRMAN CERQUEIRA: I think that would be an appropriate thing. We've gone over our break period. I think we should break and try to reconvene at two o'clock. Now, Roger, I don't mean to cut you off but we're starting to fall behind.

DR. BROSEUS: I understand.

CHAIRMAN CERQUEIRA: And so the plan is to basically have you work with the Subcommittee to get the intent of some of these issues and then try to come up with a version that will go to the main Committee and the Agreement States at the same time to try to meet a July 1 timeline.

MS. SCHWARZ: I'm just thinking that in terms of a redline copy at least it would be good to see what we had written originally as the Subcommittee on the one side and then what you're writing on the other side, just so that they sort of line up and we can see where you've changed things as you go, even if it's not really truly redlined.

DR. BROSEUS: Would that be more useful than having a side-by-side comparison of revised proposed rule versus the existing rule?

DR. NAG: It would be more helpful to have what the issue and what the Subcommittee proposed and what you propose side by side.

MS. SCHWARZ: Right.

DR. NAG: That would be more helpful.

CHAIRMAN CERQUEIRA: That would be helpful. Jeff, one last comment.

DR. WILLIAMSON: Okay. I think it's unfortunate we didn't get to the one substantive point that I'm really concerned about that could make quite a mess of this. We are required to put the preceptor back in in exchange for program director, and I think if it's left in such a position as to be a qualification for a board, we could be precisely back where we were, so I think some thought how to incorporate the preceptor

requirement the Commission has imposed on us without making it impossible for the boards that exist to qualify is a challenge that I wish we would have had some time to talk about.

CHAIRMAN CERQUEIRA: Yes. Okay. Let's try to reconvene at 3:05. Thank you.

(Whereupon, the foregoing matter went off the record at 2:57 p.m. and went back on the record at 3:09 p.m.)

CHAIRMAN CERQUEIRA: All right. "Sealed Source Model Numbers as License Conditions." Donna-Beth Howe, Ph.D., will now do the less controversial presentation, I hope.

(Laughter.)

DR. HOWE: Well, I think based on this morning, I'm not sure I'd go there. Essentially this is one of the issues that the ACMUI brought up as a recommendation at the last advisory committee meeting, and Angela later on will be going through the other recommendations and the results of those recommendations.

So if you look in your tabs, update recommendation for fall 2002 meeting, you'll see on page 2 of 3 a little bit more text that goes with, that explains the resolution.

I only have essentially four slides. Two of

them are to remind you of what the current regulation is, and the other one is to give you the recommendation and then the results.

Okay. At the last advisory committee, the ACMUI recommended that NRC initiate a rulemaking process to modify 10 CFR Part 35 to overrule 10 CFR Part 30.32(g)(1), to allow more generic listing of interstitial seeds and sources on NRC licenses.

Well, the staff took your recommendation, and they evaluated it. They put it in the context of what else is happening at the NRC, and they came to a determination that they were unable to support the stated rulemaking initiative.

And I've summarized the staff's reasoning on the next slide, and you'll see, I think -- as you were settling in, I was trying to indicate that you'll see on one of your later tabs a little more lengthy discussion of this.

But essentially the staff decision was based on protecting public health and safety. They felt that the rulemaking would ultimately reduce the radioactive source accountability, and in today's environment after 9/11, the NRC and the Commission are very concerned about source and material accountability and security.

They felt that the regulation in Part 30 as

it stands insures licensee maintain a full accountability, and it assist them in making an accurate inventory and in preventing losses of their sources and devices.

And by identifying the requirements for all sources and devices, they thought they were reasonable in assuring accountability and that was a result of 9/11, it's not prudent at this time to reduce accountability requirements.

And they looked at this issue in relationship to the Commission actions with other sources and devices, specifically looking at what we're thinking of doing with the general license devices, which would be in a similar category.

And then the next slide was just to remind you of what 30.32(g)(1) says. You have two alternatives. One is to identify the sources or device by manufacturer and model number as it's registered with the Commission in the sealed source and device registry.

The other would be to provide additional information which is much more lengthy in 32.210, and the last slide shows you that.

We will point out that you only have to identify the source or device by manufacturer and model number. So if you have a device with sources in it, you

can identify the device by manufacturer and model number, and then the sources that go with it will automatically be understood.

So you asked if I brought a noncontroversial issue, and based on this morning, I know it's not a resolution that the ACMUI wanted to hear, but this is where the staff came out.

CHAIRMAN CERQUEIRA: Okay. Jeff, your hand was up first.

DR. WILLIAMSON: Well, I guess I don't understand how this jeopardizes source accountability or health and safety. I think one of the applications we had in mind where there would be a serious problem is prostate brachytherapy, where the number of seed models available on the market are from two in 1999 to now nearly 20, and essentially prostate brachytherapy seeds have become commoditized, and you know, this would be a serious restriction in the ability of hospitals to negotiate for the best price for seeds that many regard as generically equivalent.

So I'm wondering if some other solution that wouldn't have the implications for other devices couldn't be developed whereby, for example, in the source accountability process within Part 35 you required recording of the model number to be done with the other

information, but yet would free the user or licensee from having to write a license amendment every time they wanted to change source vendor.

So this was the issue. So I'm wondering if with a little more thought put into the matter, if a solution couldn't be developed that would eliminate this essentially nitpicking requirement that doesn't serve public health at least within the context of interstitial brachytherapy, but yet respond to the concerns, the general, I'll admit, very vaguely stated concerns about public health and safety and accountability that you mentioned.

DR. HOWE: I think right now the recommendations that are being made to the licensees is that they up front list as many manufacturers and model numbers as are on the market in order to maintain that flexibility.

CHAIRMAN CERQUEIRA: Jeffrey, what's wrong with them doing that? Is there a negative to that?

DR. WILLIAMSON: Well, yes. New sources seem to be appearing and disappearing, you know, still at quite a clip.

CHAIRMAN CERQUEIRA: Okay. So, again, it's just that new things come out all the time, and it sounds like the rate of new systems is very rapid.

DR. NAG: I think there be confusion in the part that when you see they are new in the sense of a model number, but essentially they're the same. They have the same or very similar number of millicurie or the same material, whether iodine or paladium. It looks the same. The size are the same.

So there is no essential difference between these 15 or 20 new sources. So there should be no difference in terms of basic safety, in terms of public safety whether they are using Model A, B, C, D, E, or F.

So I think you can very easily write a generic statement "encapsulated radioactive iodine" or "encapsulated paladium," and that's it, rather than saying Model XYZ from Theregenics (phonetic) or Model ABC from this company.

CHAIRMAN CERQUEIRA: So, Dr. Howe, that's not a possibility based on your interpretation of the rule; is that correct? I mean, that would be an easy fix.

DR. HOWE: I think our guidance right now from our general counsel is that the requirement in 30.32 stands, and to meet that requirement a licensee needs to provide the manufacturer and model number of sources, or if you're lucky enough to have a device that has a number of sources, then you can do that for the device.

MR. LIETO: That doesn't happen with IDBT. You have to list -- you get approved for the device. Okay? They come out with a new source that goes into the source registry, just a different activity source. You have to amend your license, and so that doesn't really occur.

If the issue is about accountability and inventorying, okay, I'll be honest with you. Thirty doesn't have anything to do with it. Okay? You have to keep inventories already as a part of Part 20 and Part 35 and doing inventories on your sources. In fact, you do it on more sources than are listed actually on your license because you're doing it for your dose calibrator sources, all of these other things that are not listed specifically in your license by model number.

You're doing accountabilities, leak testing to meet that requirement. So Part 30 really I don't believe -- if the issue is that you need to have it registered because Part 30 says that for accountability, really licensees are doing it to meet the other regulations for sources that aren't even covered by this.

And so like I said, also every time you get a new source or let's say you have a device that's approved and a different vendor comes out with a source that's compatible with that and the source has been

registered in the source registry. You still have to go back and amend your license for that source in that device.

DR. HOWE: And Part 20 has your security and accountability requirements. The group that evaluated your request believes that Part 30 also aids in, and the General Counsel has made a decision that when the licensee provides this information, that it goes onto the license, and then NRC can also search. There are licensing databases to determine who has specific sources.

CHAIRMAN CERQUEIRA: But, Dr. Howe, you said counsel made recommendations, but the staff itself that reviewed it, did you have any concerns, you know, relative to the safety of the public, patients, and users?

DR. HOWE: I am the messenger.

(Laughter.)

DR. HOWE: And I was not part of the group that made the decision. So I cannot --

CHAIRMAN CERQUEIRA: Is General Counsel Here who reviewed it?

MS. CHIDAKEL: I am here from the Office of General Counsel.

CHAIRMAN CERQUEIRA: Can you use the mic?

MS. CHIDAKEL: What do you want to know?

(Laughter.)

PARTICIPANT: What is the basis of the decision?

MS. CHIDAKEL: I'll tell you the truth. I will have to take your concerns and questions back.

I'm sorry. Hi. I'm aware of this opinion by the Rulemaking Division of the Office of General Counsel. However, I am just really here more to listen to Donna-Beth today rather than to address the issues. I really came here because of my working group affiliation with Part 35 on that rulemaking on the T&E.

If you have specific questions or concerns, I think the best thing to do would be to just let me know them and let me take them back to the office and consider them rather than giving you answers off the top of my head.

MS. WILLIAMSON: State your name, please, for the record.

MS. CHIDAKEL: I beg your pardon?

MS. WILLIAMSON: State your name for the record.

MS. CHIDAKEL: Oh, Susan Chidakel, C-h-i-d-a-k-e-l.

CHAIRMAN CERQUEIRA: Great. Well, thank

you, Susan.

MS. CHIDAKEL: And I'll be happy, you know, to consider your questions, but I just don't feel prepared right now just to give you answers on this.

CHAIRMAN CERQUEIRA: Jeff?

DR. WILLIAMSON: Could you identify the safety and health hazards that you think this change would -- well, two questions. What are the health and safety hazards you think would result from this change?

And, two, if the issue is that this is a very general restriction where you think it has value, for example, making people list the model of Cobalt 60 teletherapy sources in their license, you don't want to get rid of that.

Is it not the case that in Part 35, which is more specific, you can have rules that contradict for a very limited class of sources the Part 30 and Part 20, and then those rules would, in fact, prevail but only over that limited domain?

DR. HOWE: The concept that you could have more restrictive language in Part 35 that would be more appropriate for 35, that's true, and your recommendation was taken to the Rulemaking and Guidance Branch, also the branch that I'm in, and the division, and they looked at your issue in the scope of what the Commission is doing

right now in all areas and decided that this was not the time to go forward with this rulemaking initiative.

As the messenger, I cannot give you the discussion and rationale that went through as they came to this discussion. I can only reiterate the --

DR. WILLIAMSON: Couldn't a more surgical and restrictive exemption to 30.32 be made within the language of Part 35 that wouldn't extend to all of these other sources, sealed sources, that may be of concern to that group?

Because it's hard for us to believe that iodine and Iridium 192 interstitial sources are the cause of their concern.

DR. HOWE: I wasn't there, but my understanding is there was a concern that at the time when the Commission is going forward to identify sources and may be moving in a direction from generally licensed to considering whether some of the generally licensed devices need to be regulated more tightly and may even go into specifically licensed, into specific licenses, that the staff didn't feel comfortable moving in the opposite direction to these.

DR. WILLIAMSON: But we are not under a general license. This has nothing to do with that issue.

CHAIRMAN CERQUEIRA: Donna-Beth, as a health

physicist --

DR. HOWE: Yes.

CHAIRMAN CERQUEIRA: -- I mean, the question was asked in terms of risks to patients, physicians, you know, users, and the public. Do you see any risk how not listing an individual, you know, manufacturer, serial number, and everything on the license would somehow impose a greater risk to those groups as a physicist?

DR. HOWE: Let me pass that to Ron Zelac.

DR. ZELAC: This is Ron Zelac, for the transcriber.

I was not involved in the decision on this.

(Laughter.)

DR. ZELAC: Nor was I involved in the follow-up to it. However, I have heard peripherally that one of the reasons that was stated for not moving in the direction of having, if you will, a general entry on the license was that if the licensee was contemplating the use of a particular manufacturer's sealed sources and had to supply to the agency the model of that source and the manufacturer, this gave the licensing agency, us in this case, the opportunity to be sure that that particular source was, in fact, registered through the sealed source and device registry and had been deemed satisfactory for the intended medical use.

If it was a general authorization that the licensee had, a particular licensee could be approached by some organization claiming that, in fact, the source was registered, and if the licensee didn't demand proof of that, they could be, in fact, moving in the direction of starting use of a source which had not been deemed yet as satisfactory for such applications.

CHAIRMAN CERQUEIRA: Well, I guess I'm a little confused in the sense that, you know, if it's a political or if it's sort of an NRC administrative issue that, you know, for safety concerns and everything they're not going to do it relative to national security, that's one thing. And I guess you've pretty much heard the opinion of the committee that it really doesn't compromise safety in any way.

You know, Jeff, this may be an appropriate time to basically make a motion to the committee that it be reconsidered, that it's the feeling of the committee that there is no additional risk to patients, users, or public.

DR. NAG: Well, I think what may help, just like there used to be misunderstanding or lack of communication between staff and ACMUI, maybe a member of ACMUI would talk with the General Counsel who may or may not have the full knowledge about the differences between

different models and different types of sources. That might clear up that issue in some way so that, you know, we have more communication not only with the staff, but more communication with the General Counsel.

CHAIRMAN CERQUEIRA: Yeah, I think that would be appropriate because, I mean, you know, obviously as you said, you're the messenger. Counsel wasn't involved, and so the committee has made a recommendation, you know, feeling that this was the best thing to do, and now we're told we can't do it, but are not able to really discuss with anyone who was involved in the decision process.

DR. WILLIAMSON: Yeah, with no good reasons being provided other than rumors.

CHAIRMAN CERQUEIRA: And that's frustrating. So I guess, Jeff, did you say you had a motion?

DR. WILLIAMSON: Yeah, I guess. Whereas, the ACMUI sees no patient, no conceivable patient or public health hazard from listing interstitial brachytherapy sources generically on license applications, the ACMUI asks that NRC reconsider and develop a strategy for eliminating this burdensome licensing requirement for this narrow class of sources.

CHAIRMAN CERQUEIRA: Excellent. Do we have a second on that?

Okay. Further discussion?

DR. BRINKER: Can I ask one question of Mr. Zelac?

CHAIRMAN CERQUEIRA: Yes.

DR. BRINKER: Because his point did ring a little bit in my mind.

Do people who make these sources not have to have some sort of regulatory certification to sell them for medical use?

DR. NAG: FDA.

DR. BRINKER: So if they have that, doesn't that preclude that some unauthorized product might be introduced surreptitiously, or whatever that word is?

DR. HOWE: I can clarify a little bit of that, and then I can pass it back to Ron, and that is that we have a good example with the Novoste, intervascular cardiology. Novoste went to FDA for approval, but they had an IDE exemption in order to use the Novoste product before they got FDA approval.

So they were able to use the sources. They elected not to get into the sealed source and device registry until they had finalized the product. So in that case we had research basically going on in the broad scope licenses because the broad scope licenses have a little bit more leeway on the sources that they hold in

which the source wasn't part of the registration process until later in the game.

Most of the other sources and manufacturers we had have come in for the sealed source and device registration early on, and they've been in the registration as soon as they've gone out for use.

CHAIRMAN CERQUEIRA: But this is an exemption, right? I mean --

DR. HOWE: That's just an example.

DR. DIAMOND: That's not a fair comparison, however, because you know, as we made our recommendation and as Jeff recapitulated it, this is a specific example dealing with permanent interstitial seeds with isotopes and designs that have been in existence for many years.

Your example cites a different modality.

DR. HOWE: But I'm citing an example in which there are cases in which there are sources out there being used in medical that may not have gone totally through the FDA process, nor gone through our sealed source and device registry process.

DR. WILLIAMSON: But you see, you don't need to do this because already it says in Part 35 that the sources that are allowed for specific scope licensees in 35.400 already are in the SSDR. I think it's very clear in part 35.

So now you're saying, well, you don't believe that users are capable of following the rules and that they're going to go off and use non-SSDR approved sources if you don't check specifically which ones you order.

Now, what is is the basis of performance based regulation and this nitpicking and prescriptiveness? You know, the basic philosophy of Part 35 and the revised licensing applications is to minimize this and put responsibility on the users and, you know, audit their performance and see if they're doing it right and punish them if they're not.

CHAIRMAN CERQUEIRA: Exactly. That was the whole basis for the --

DR. WILLIAMSON: So what you should do is keep the requirement in Part 35 that the maybe model number be logged as part of the inventory, and then you have the legal basis for checking their performance on this.

So, you know, why do you have to have duplicative requirements for the same thing? It's already spelled out in Part 35?

CHAIRMAN CERQUEIRA: One last comment and we should really vote and move on.

MR. LIETO: There were just two points I

wanted to make, if you can take back, and one is that the motivation for this is to reduce the burden on licensees in regions to going through a paper shuffle process because that's all this is, and what happens is that you will be delayed. It can take up to three months, you know, to get approvals. Okay?

So during that time period you can't use that source even though it's in a registry and the fellow across the street is using it in the same type of a hospital distinctly because the paper work isn't there. Okay?

The other thing is that when you're inspected during inspection, they don't look at your model numbers. I've never had an inspection where they ask you, "What model number is that source?"

What they're concerned about is what your inventory is and what that inventory -- does it coincide with what your possession limits are and is it, you know, in accordance with those isotopes?

I've never had an inspector come through and look at, you know, what's the model number on this. Okay. Show me that the model number in this device is the one that you're approved for.

Because, you know, there's no way to prove you wrong. You think you could go in the HDR machine and

look at the model? No.

(Laughter.)

DR. WILLIAMSON: Okay? You just have to take that the manufacturer sent you the right thing. Now, could he send you the wrong thing? Very likely. Okay. I mean, I shouldn't say very likely. Very possibly.

But who's going to know?

DR. NAG: That is an example where I think NRC is making a laughingstock of itself, and we would like to give you advice that is very relevant, that is simple, and yet not impeding on any recent safety or any health hazard, and you know, because of your prescriptiveness you are using and hear our suggestion.

And this is the type of interaction where I think the ACMUI feels very frustrated. You have given an example, one example.

CHAIRMAN CERQUEIRA: Right. I think we've shot the messenger enough now. So let's -- we have a motion. We've had discussion. I call for a vote.

All those in favor of Jeff's motion to go to the NRC.

(Show of hands.)

CHAIRMAN CERQUEIRA: Opposed?

(No response.)

CHAIRMAN CERQUEIRA: Dr. Howe, thank you very much.

MR. ESSIG: Is it clear what you're going to come to the NRC and ask us to do?

CHAIRMAN CERQUEIRA: To reconsider -- Jeff, do you want to?

Well, you should be able to pull the --

MR. ESSIG: To undertake a rulemaking to change this?

DR. WILLIAMSON: Yeah, to develop an alternative rulemaking that addresses this narrow class of sources and, you know, does not compromise safety with the other sources that evidently this group, who's unwilling to share their rationale with us, is concerned about.

MR. LIETO: Well, he didn't say rulemaking. He said alternative pathway.

CHAIRMAN CERQUEIRA: Pathway.

MR. LIETO: Rulemaking could be one, but it also could be just a change in how headquarters tells the regions to handle licensing.

CHAIRMAN CERQUEIRA: Interpretation or guidance.

DR. HOWE: Well, I think in this particular case you need rulemaking because --

DR. WILLIAMSON: But I said alternative approach.

DR. HOWE: -- because a number of years ago, and Susan is right, a number of years ago OGC interpreted Part 30 to mean that licensees needed to provide this information in order to get a license, and it needed to be updated on amendment process.

And so the only way to not provide this information is to go to rulemaking, and that's a pretty serious step for the NRC. You might be better if you can articulate why. This is the rational the staff gave, if you look at your --

DR. WILLIAMSON: But it's too vague to make any sense. I mean, the specifics --

CHAIRMAN CERQUEIRA: And there's no discussion.

DR. WILLIAMSON: The only specific that's been brought up is your fear that somehow users are going to use non-SSDR approved sources who are specific licensees.

MS. CHIDAKEL: I'm sorry. I want to apologize. I want to make it clear that I have not been involved in this effort from OGC. So you know, it's certainly not any reluctance on my part to share our rationale as far as the Office of Legal Counsel, you know

Office of General Counsel goes.

Again, you know, I have not been involved in this. So I need to go back to my office, and if you want answers I'm sure that I can help you get answers as to what the rationale was. It's not an unwillingness to share a rationale. It's, frankly, on my part, like I said, a lack of knowledge because I have not been involved in --

DR. WILLIAMSON: Well, I didn't mean to suggest you personally were --

MS. CHIDAKEL: No, I know that.

DR. WILLIAMSON: -- but whoever is responsible has failed to share the rationale with us.

MS. CHIDAKEL: You know, I want to speak on behalf of the staff, too. I don't think there's any unwillingness to share any information.

CHAIRMAN CERQUEIRA: But I think we need to move on. I think that the motion was basically to consider alternative ways. If rulemaking is the only way to do it, then I would expect during the next conference call we have with the staff, they would tell us that it has been brought to the Commissioners' staffs and it has been discussed and, you know, rulemaking is the only way to make a change.

And then we can basically give you some

feedback. Thank you very much, Dr. Howe.

The next item is National Materials Program Pilot Project on operating experience evaluation, and Michael Markley.

Again, both for the presenters and the people asking questions, we kind of need to keep focused and moving. So I don't want to cut off discussion or presentations, but if we're making the same point over and over again, I will try to cut you off more than I have.

MR. MARKLEY: One thing I'd like to do, I do have some members of the pilot project here. So I would like to also have the ones who are remotely located on the bridge so they can have the benefit of your wisdom.

CHAIRMAN CERQUEIRA: Sure.

MR. MARKLEY: If that's okay.

(Pause in proceedings.)

MR. MARKLEY: Marsha, are you there? Debbie?

MS. GILLEY: This is Debbie.

MR. MARKLEY: Hi, Debbie. We're here now and we're getting ready to start.

MS. GILLEY: Great.

MR. MARKLEY: We'll get it extended a little bit of time also.

I apologize for the delay.

CHAIRMAN CERQUEIRA: No problem.

MR. MARKLEY: Just to mention real quickly, the members of the pilot team are Cynthia Taylor from Region II, and she's in the audience here in the back; Marshal Howard with the State of Ohio; and Debbie Gilley with the State of Florida. And I know that we have Debbie on line. I've been unable to reach Marshal today. So I'm not sure whether she's here or not.

CHAIRMAN CERQUEIRA: Okay, great.

MR. MARKLEY: Okay. Now, the reason I'm here today -- let me see if I can get rid of that.

CHAIRMAN CERQUEIRA: Just click somewhere on the screen.

MR. MARKLEY: Okay.

CHAIRMAN CERQUEIRA: It should -- click the other side. Yeah, there you go.

MR. MARKLEY: Okay. Thank you very much.

The reason I'm here today is really to seek your wisdom. I'm coming early in the process. We've developed the charter.

CHAIRMAN CERQUEIRA: Right move.

(Laughter.)

MR. MARKLEY: Well, I've had a little bit of experience with advisory committees. So I know the

benefits that we can derive from it or hope to, and so today I want to get your thoughts early as we develop the work product plan.

We hope to come back again in the fall and tell you where we are in the process, and as we approach completion next year, tell you some of the things we found and some of the recommendations and solicit your agreement, disagreement, and support.

CHAIRMAN CERQUEIRA: Just click on the other button. I think it will advance it.

MR. MARKLEY: Okay. It doesn't like it, Mr. Brown. There we go.

Okay. The purpose of the pilot is it originally started out as an event evaluation, and because of things that have changed, operating experiences that have occurred, we've expanded it to cover really a broader issue other than just event evaluation and how you would evaluate individual events.

So what we're hoping to do is to, you know, use common operating experience information from licensees in trending and in an integrated way. It's not an evaluation of agreement state performance, but we're trying to use information and data to make better decisions in terms of how we allocate resources and what we use for our decisions in the regulatory process.

We want to develop a structured process for evaluating that data such that whether the agreement states or the NRC were using it, if you had the same inputs, the process being similar, you should come up with reasonably similar outcomes.

So in the process, we're going to take a test case area, use some criteria that we will have developed collectively between the team members and evaluate it and see how we can examine the process and reengineer the methods and tools of evaluation, and then from that we would hope to derive other applications and to use more broadly in the oversight process.

We want to focus on cumulative data. Our processes may differ right now in some ways, you know, from state to state and from the NRC in how we treat some of these, but the attributes and the objectives of what we're trying to accomplish are pretty much the same.

DR. WILLIAMSON: Can I ask you to define cumulative data and performance so that we understand what you're talking about?

MR. MARKLEY: Well, that's what this slide is about. So what do we mean by operating experience?

Domestic and foreign event reports, inspections; special studies that may have been done whether by the NRC or by industry; generic reviews,

whether it's an individual event generic review or a review of a population of events. Industry-wide analyses, there are lots of different organizations out there looking at their little cut set of the industry, and it's not just medical It's the industrial applications and the whole breadth of the materials area.

And we want to use risk insights and metrics. There has been some studies done, but we really I don't think have been very successful so far in integrating risk insights in how we make decisions. Let's just say we have an event. How are we using risk metrics?

We developed NUREG 6642, but in terms of how we get that into the process of making decisions, whether for inspection follow-up, enforcement and things like that, those are the kind of things that we want to look at and see how we can better use risk information.

And to look at possibly developing performance indicators or thresholds for regulatory action. There's, you know, certainly no benefit in spending a lot of time looking at lower tier criteria even if it is something that may not be a full compliance. If we need to change a regulation, then we need to change a regulation.

If there's a reason why there are things

happening out there that cause there to be a lot of amendments or emergency actions on a licensing basis, those are the kind of things that we would like to be able to pick up along the way.

And so the process that we're really driving toward is how do we modify our oversight programs, inspection, licensing, and enforcement.

CHAIRMAN CERQUEIRA: Yes, Tom.

MR. MARKLEY: Okay. That's where we are.

So the scope of activities within the context of the pilot is evaluating events for generic implication, possible regulatory action.

Consider the processes that we've looked at in terms of the materials, the issues, and then adverse licensee performance.

As you probably know, one of the things that has been developed and approved since the original materials program was the AARM process, the agency action review meeting.

So we want to make sure that what we're doing dovetails and comports with those types of pieces of information we're interested in as well, and so, you know, with our special events and you were talking about what do you mean by operating experience or data; special studies provide us with a lot of insights across a

variety of levels, like the St. Joseph's event or Schlumberger or for the reactors, Davis-Besse.

And so there are crosscutting issues that affect all of our programs that we want to learn from and fold into the process.

DR. WILLIAMSON: Just a comment. I mean, you mentioned maybe some nuclear reactor events that perhaps most of us aren't familiar with.

MR. MARKLEY: Right.

DR. WILLIAMSON: I personally have very little grasp of how what you're talking about relates to our field.

MR. MARKLEY: Well, some of the problems with Davis-Besse, and I'll use that as an example, there were operating experiences. They had indications from other licensees where they had defects that were not taken into consideration fully. The NRC didn't act fully, whether it was training issues or inspection issues or materials issues, root cause analysis.

There are things that cross-cut these types of programs that are really generic to all of the regulatory processes, not just reactors. And so if there are things that are out there -- and there is an entire population of work going on on the reactor's area in response to Davis-Besse.

And along those lines, NMSS has created an operating experience committee to look at how that affects each of the NMSS divisions. And I'm chairing that committee as well as this pilot. So we do have some continuity in that process. I did the initial Davis-Besse evaluation as well.

So it's not trying to drag reactor issues here, but there are common threads. Management expectations of what we would have our inspectors looking at that were not fully implemented.

So the proposed framework, hopefully what we derive out of all of this is some recommendations on improving the procedures, how we review things, evaluation methods, the sources of information that we would consider, the methods to better communicate.

One of the main things that I think is the near term payback, the agreement states, as well as the NRC do a lot of things, but we don't necessarily do a great job at communicating the results of those studies or evaluations with each other.

So in my thinking one of the near term paybacks is better communicating, and part of that is with you and key stakeholders, such as yourselves, but with agreement states.

If we have a piece of information or a study

that we've done, it should be fully available, and the state should be fully aware of all of those things that we're doing. And, likewise, if they have issues that we should maybe disseminate more fully among the non-agreement states, those are the kind of things we want to do.

We want to make the process work. I mean, that is really in my view -- and, of course, I can't predict how things will go, but that's the easy win-win, is improving the communications.

The data analysis and the metrics that we might use are the harder things that will take more time and will be debated certainly a lot more fully.

So at the end point I don't see either the agreement states or us having a windfall in resources, and if we don't find ways to do things smarter and better and reduce burden on ourselves and theoretically down the road for licensees, as well, then we will have failed. We have to find ways to work smarter and use our resources better.

Okay. Where we are today. The pilot charter has been approved. We have the participants. We may add more over time. It depends on how things go. But we have a good core to get started, and we're doing the best we can, you know, in partnering with the states,

trying to keep them involved.

Really we can't do this without the states. It's absolutely essential. One of the key points that was originally laid out in the materials program were things that they could pick up and adopt. It seems to me that it's really more of the things that we can all do together better.

I met with CRCPD in the earlier part of this month, gave them a similar presentation to what I'm talking to you about here today: about feedback, about the extra member, Debbie from Florida, and so it was beneficial for me in many ways to get the feedback in the sense of the things that are important to them. It was absolutely essential with this kind of a pilot.

I see down the road as we get some results and see, you know, the fruit of our labors, if you want to call it, we will need to have public meetings and get other stakeholder input, but right now we're still at that early developmental stage.

Okay. As I mentioned before, there's an operating experience group. Between NRR and Research, they have a steering committee, a task force, a working group. They have about 20 people working on this.

At this point in time it's really just myself and our friends in Region II and in the two states

that we have. So we can't spend the resources that they're throwing at it, but what we are doing is because of this working group, we're going to tie in the state representatives on the meetings that we have every two weeks. We're going to have, you know, the reviews of the things that NRR and Research are doing so that the pilot will be fully up to date with everything that's going on there, and we want this thing to be a national materials program, not just an NRC materials program or an agreement state program.

But we do need to be consistent and to make things comport with what the agency is doing on a broader basis, and so this particular committee is not -- we don't have a charter. We do have a mission statement, but the intent of it is to be decision driven, not to develop a lot of paper other than the things we need to support the decisions and recommendations that would affect the NMSS and materials type programs.

We will still maintain the continuity. We'll still have single points of contact, which at this point in time is me, but you know, that's the intent.

We don't need to create a lot of paper with boundary conditions. We can pull more things in as we realize things along the way and make changes.

The research is evaluating options for how

they can support a more robust materials program, which is good. Right now they're focusing a little bit more on the generic safety issue aspects, but for the most part they're looking for opportunities. So we're going to see how it will fit. Right now I can't predict what that will be.

And one of the things that we passed out at the CRCPD meeting -- and these are the same kind of questions we would hope to get feedback from you on -- are how can we use this information; how can we better community it between us and the agreement states; how can the information and tending optimize our programs and better help us utilize our resources?

We don't have a lot of resources to apply to these kind of things, and so we really do need to work smarter.

And how can we use risk insights? And from my view that's really one of the major tools and opportunities we have to reduce burden, look at the risks, and see how those lead us to making sounder decisions, things that are more risk significant and should have more attention.

If something is not very risk significant, we shouldn't be spending a lot of time on it. There's no advantage to the NRC or the licensees wasting resources

on things that are not risk significant.

CHAIRMAN CERQUEIRA: Excellent. Well, thank you very much.

Have we got some questions? Dick.

DR. VETTER: Thanks for coming to us real early in the process. That's very nice to see what you're thinking.

MR. MARKLEY: Thank you.

DR. VETTER: I think this process supports a learning organization, and I would view the entire regulatory community working together as an organization in this endeavor.

It also has the opportunity or provides the opportunity to promote consistency among regulators, agreement statements, NRC, et cetera, and I hope there's a possibility of extending that to non-agreement states.

MR. MARKLEY: Certainly.

DR. VETTER: I think it also supports a performance based system. You could use it to help make the checklist longer, but I think with the NRC's philosophy in recent years becoming more performance oriented, I think this actually does that.

One thought for you to consider is whether or not the data that you're collecting to help the regulators couldn't also be useful for the regulatees.

MR. MARKLEY: Absolutely.

DR. VETTER: And there might be some mechanism to share that. So if you see a trend in something occurring around the country --

MR. MARKLEY: Right.

DR. VETTER: -- in addition to sending out -- I mean, you'll do that now occasionally on I forgot what you call it; a letter that goes to regulators saying -- regulatees, licensees.

MR. MARKLEY: Information notice?

DR. VETTER: Information notice.

MR. MARKLEY: Right.

DR. VETTER: It might be something that's more regular.

CHAIRMAN CERQUEIRA: Ruth.

MS. McBURNEY: I don't know if it was brought up at the CRCPD meeting, but I know that some states -- well, one of the universities in Texas has taken a lot of our inspection data and done some trending analyses on how many violations of different types and the severity levels, and so forth in the different types of licensees, has taken data from some other states, too, along those lines.

And I think that would probably be beneficial if you could have them analyze, you know,

NRC's data along those lines and --

MR. MARKLEY: Right. We would love to see what they're doing.

MS. McBURNEY: Yeah.

CHAIRMAN CERQUEIRA: I think one other area, you know, trying to get cooperation between NRC and the agreement states is with the Part 35 revision. The training and experience guidelines, I think, potentially can create a lot of paper work for the users, as well as for the NRC in the agreement states, and a compliance was supposed to be, you know, complete agreement between the two.

But we've been hearing rumblings that some of the agreement states are a little unhappy with this, and I think trying to look at the process, the simplification, that would be very, very useful.

For the sake of time, unless anybody has any burning questions, I think maybe people could talk to Michael afterwards, but thank you very much for --

MR. MARKLEY: Thank you.

CHAIRMAN CERQUEIRA: -- including us in the process, and we'd really like to take part in whatever way possible that we can.

Thank you.

The next presentation is the "Content and

Status of the Direct Final Rule to Clarify Definitions, Notification Requirements, and Record Keeping Requirements and to Eliminate a Certain Restrictions." Dr. Tse, welcome.

DR. TSE: Thank you, Mr. Chairman and members of ACMUI and ladies and gentlemen.

Mine will be relatively simple compared to the others you heard prior to me. So I'll be going relatively quick, and if anybody have any comments, please just stop me.

I'm going to discuss very briefly about Part 35 direct final rule, which is a clarifying and one minor amendment.

Why do we -- first of all, the status. Next slide, please. The status. The rule was published in April 2003, and one month public comment period, which the direct final, as you know, is we publish a proposal and a final rule.

So the proposed rule public comments would be -- ends tomorrow. As of today, I have not received any comments. I checked with the Web site on the rulemaking Web site. I did not see any comments either. So I think probably by tomorrow we will not receive any adverse, significant -- significant, adverse comments.

Therefore, if that's true, the rule would be

effective on July 7th, 2003.

Next please.

Why do we need a direct final rule? Because after the publication of Part 35 rule, the staff has identified certain areas might need clarification or change, and there are some necessary, apparently necessary inconsistencies and also unnecessarily restrictions.

Next.

What are the changes? The first one is the apparent inconsistencies. I say "apparent" because if you read the rule as a whole, it's not inconsistent because Subpart J was put in, and to include the Subpart J, you need to look at implementation section to understand that.

But if somebody just looked at the rule by itself, then they may say in, for example, 290, 390, only the new items, new T&E are listed without listing 920, 930, et cetera.

So to avoid these apparently inconsistencies, it's better to insert these sections into various training, T&E, and also 100, 200, 300 because that's the preparation of unsealed sources.

So we add those Sections 920, 900, et cetera, into the appropriate regulations and then said

prior to October 24, 2004, these sections also applicable.

Next one.

In some sections, an emergency situation. The one requirement you say that the licensee should notify the RSO, and also the AU. The AU may not be there if a patient may be in an emergency situation or dies. So we change that to an AU. Therefore, any AU would do.

Next, please.

This is truly for clarification. In this section, Section A says that licensee may perform the calibration by himself, and then Section B says the licensee may use somebody else's number like a manufacturer and so on, but doesn't have a connection between A and B.

So somebody raised the question. So to make sure, we just add those phrases in there to make the connection.

Next.

This one is to eliminate unnecessary burden or restriction. In the regulation, current regulation, the training of ophthalmic use of Strontium 90 can be only done at the medical institution, and staff believes there is no reason why the training cannot be done by an authorized user in a medical private clinic or eye

ophthalmic office, and that's what this change is.

The next one is a correction.

Anyone have questions? Oh, sorry. Next.

The next one is the correction which for some reason the National Institute of Standards and Technology become National Institute of Science and Technology, which in the United States we do not have such an institution.

(Laughter.)

DR. TSE: And I checked with this. Korea has one.

(Laughter.)

DR. TSE: But I checked the other place. Everything is right, except in this section is incorrect. So we just make a correction.

The last one, next, please; the last one is also for consistency. In the section requiring calibration, it says that calibration can be done by the licensee or by manufacturer or by calibration laboratories.

But in the corresponding record keeping section, it doesn't say that. It just says requires signature of AMP, and we believe should be consistent if the action section requires the last individual or also accepting the manufacturer or other calibration

laboratory's calibration.

Then the record keeping shall say those people, and that's what to make it consistent.

Okay. I think I finished. Any questions, please?

CHAIRMAN CERQUEIRA: Rick.

DR. VETTER: That was so good. Could you add a little sentence somewhere that says any source could be used for interstitial purposes?

(Laughter.)

DR. TSE: I think some other staff member will take care of that.

DR. DIAMOND: I myself developed a designate competency will make you the arbiter of competency for all AUs.

DR. TSE: I'm not sure I qualify for that.

CHAIRMAN CERQUEIRA: Well, thank you very much.

DR. TSE: Oh, by the way, I take this opportunity to also thank the members of the subcommittee and committee when I was working on this paper. I really appreciate your help.

Thank you.

CHAIRMAN CERQUEIRA: Excellent. Thank you very much.

The next presentation is "HHS Database of Regulatory Actions: Status and Discussion." Linda Psyk.

MS. PSYK: Okay. Are we on? It's hard for me to hear up here. Can you hear me back there?

Thank you. I like the nods of the head. Thanks.

Okay. Good afternoon. Are we all still awake?

Okay. My name is Linda Psyk. I'm from the Division of Industrial and Medical Nuclear Safety.

We're going to switch topics a little bit. I'm going to briefly cover the health care integrity and protection database.

What I'm going to discuss shortly today is the purpose of the health care integrity and protection database. From here on in I'm going to refer to it as "database" so that we all know what I'm talking about.

I'm going to describe a little bit about what the NRC will report and how we will report this information.

I'm going to give the status of our management directive. The management directive is actually our procedure that NRC will use in order to identify what needs to be reported and how we will report it.

I'm also going to provide some examples of some past actions that we will be reporting to the database.

And finally, I'm going to discuss the responsibility of the agreement states in reporting.

I didn't realize it was set up to do this individually. Excuse me.

Okay. What is the HIPDB or database? The Health Insurance Portability and Accountability Act of 1996, this is referred to as HIPAA. I'm sure we all know what HIPAA is at this point.

Basically HIPAA was promulgated due to the burden of health care fraud in the United States. HIPAA required the Department of Health and Human Services to create a national fraud and abuse control program.

In response to this, the HIPDB, or database, was established to compile certain final adverse actions, which were taken against health care practitioners, providers, and suppliers.

It's important to know that the contents of the database are going to be confidential. Access will not be allowed to the general public.

Entities reported to the database will be notified. So if an individual or an entity is reported, they will be notified by the HHS that they were reported

to the database, and they will be able to access that information.

Information will also be available to the state and federal agencies, health plans, health care practitioners, providers, and suppliers, as I said, requesting information concerning themselves.

The database requirement is codified in 45 CFR Part 61. It requires reporting from state and federal government agencies who license or certify health care practitioners, providers, or suppliers.

Also, it requires that health plans, such as insurance or programs that provide health benefits, that these organizations also report to the database.

What is the NRC going to report? Basically there are three criteria that determine whether or not that action will be reported.

The first one is it must be a final negative action or finding.

The second criteria is that the actions are made publicly available.

The third one and the most important one is that the adverse action must directly affect health care. That's very important, either medical practice or health care. That's the big criteria that we have to -- I'm sorry. I'll just read the next.

An example, let me give you two examples, brief examples of what NRC would report. The first one would be the revocation or suspension of a license. That type of adverse action will be reported to the database.

The second example, and I'm going to give some very specific examples at the end of my talk. Second example would be actions that limit the scope of practice. This would include individuals that are banned from NRC licensed activities.

The type of licensees and employees who may be reported to the database include the following who work under NRC license. And they can include lots of different people: the physicians, the AMPs, the health physicists, or as you can see the list, clinics, hospitals, radiopharmacies. Any one of these individuals or entities that we feel meet the criteria for adverse action would actually be reported.

How are we going to report this information? Management Directive 8.6 has been drafted. Basically, the management directive gives the policy and direction to our staff on how we will identify who's reported, how it will be reported, and so on. And this will be done by different individuals in the agency.

For example, the regional staff will identify whether or not something needs to be reported.

They will follow up with the licensee to receive the information that they need to report to the database.

That information is forwarded to the Office of Enforcement. The Office of Enforcement actually inputs the data into the database.

What's the status of this management directive? At the last ACMUI meeting, this topic was brought up for the first time. And members of this committee were concerned that we were doing something that we hadn't actually informed you about.

So a memo went out in January of this year describing the actions that we were going to take, why we were going to take it. We gave you the rule involved, and a draft of the management directive. And also some examples of past adverse actions that we will be reporting to the database.

Currently, the NRC offices and regions are reviewing for final comment. Those final comments are due back to me by the end of this month. Hopefully I am going to be finished with this by August of this year. So the management directive should be complete, and the regional staff will start identifying actions that need to be reported.

Okay, I'm going to briefly review some examples of past actions that require reporting. The

first one is -- actually these two are individuals. The first one is Perry Beale.

Perry Beale was a health physics consultant who was consulting to hospitals in Virginia and West Virginia. He falsified documents for the licensees that he was working for. We prohibit him from working under any NRC license, or being involved with any NRC licensed activities because of his actions.

The second individual is Dr. Jose Fernandez. He was a physician who had over 100 medical events due to an incorrectly calibrated Strontium-90 device. He also failed to have a QMP and an authorized user on site. His license was modified to exclude the use of that Strontium-90 for ophthalmic treatments.

Okay, I have two more examples. These are examples of different facilities that will be reported. The first one is the Advanced Medical Imaging and Nuclear Services.

Their license -- they were operating their license without an authorized user or radiation safety officer. Their license was suspended for a certain period of time. This type of action would be reported to the database.

Second example is the Fairbanks Memorial Hospital. They were issued a notice of violation with an

accompanied civil penalty. The licensee failed to obtain the signature of the authorized user on a written directive prior to administration of a dosage of I-131 greater than 30 microcuries.

You may question why is this reportable. The reason this is reportable is because this could directly affect health care. If this was not signed by an authorized user, how do we know that the individual administering that iodine is doing it according to the written directive over that authorized user. This could potentially directly affect health care.

And I'll answer your question after I'm finished. Thank you.

DR. DIAMOND: I'd actually like to ask for it now.

(Laughter.)

DR. DIAMOND: I just want to be very clear -- So I'm getting ready to go and give 100 millicurie to my thyroid cancer patient up on the floor.

MS. PSYK: No, no, wait a minute. First of all, we have to go through the first criteria. The first criteria, one of the criteria, they received an NOV with a civil penalty. They actually received a notice of violation accompanied by a civil penalty.

Start from there. Now we look on. Why did

they receive that notice of violation? They received it because they didn't have an AU sign that written directive.

In your instance, if something happened like that in your case, you may not receive a notice of violation accompanied with a civil penalty. That criteria comes first.

Do you see what I mean?

DR. DIAMOND: I'm just asking a very simple question.

MS. PSYK: Okay.

DR. DIAMOND: The typical patient I'll do a couple times a week. I admit to the hospital. We have them up there with the physicist. We went through everything with the patient. Room's done.

What would happen if that patient of mine, let's say a young lady, took that oral capsule of 100 millicurie of sodium I-131 three seconds before I went and signed the written directive?

MS. PSYK: Well, first of all, you wouldn't get a notice of violation for that. Remember, that's what I said, the first criteria. The first criteria -- this facility got a notice of violation with a civil penalty.

In fact, if they received a notice of

violation without a civil penalty, they wouldn't even be included in our database. They wouldn't even be something we looked at.

DR. DIAMOND: So this is something where there was a systematic issue?

MS. PSYK: That's right. I'm sure there was more of an issue that what I'm just describing here. And that's why --

DR. DIAMOND: The reason I'm getting your attention is because --

MS. PSYK: -- they got a civil penalty on top of their notice of violation.

DR. DIAMOND: The reason I bring it to your attention is because if you learn about HPOMER **, generally you'll recognize that physicians nationwide are furious with some of its provisions.

And I think we're becoming justifiably paranoid in some circumstances as to some of the penalties that we may be facing for inconsequential activities.

MS. PSYK: Well, in reality, this is not a penalty. What I'm talking about here is we're talking about what we'd be reporting to the database. That's not an actual penalty.

DR. DIAMOND: Aha. But you see, the way the

world works --

MS. PSYK: No one sees that information, except for --

DR. DIAMOND: -- this world. You live in a different world, because the fact remains that this information can get out. This information can be used against you in a court of law. I'm just trying to -- we're getting a little off tangent, but I'm just saying this can be very, very deleterious to a person's career.

MS. PSYK: Okay. Well, that's duly noted, although we will be going forth with this, because it is the law.

DR. WILLIAMSON: To follow up with this, if for example the AU's intent was to deliver this, and that one prescription maybe out of 100 the individual forgot to sign it, or perhaps it was done on an emergent basis and the person failed to sign it 24 hours later.

I mean, I would expect that this is not unusual, that there may be a one percent rate of essentially paperwork failures that do not represent a -- do not indicate a substantial problem with the program. May be even self-correcting.

So you're going to put somebody in this database for that? That's what it sounds like you're saying. This does not seem reasonable.

MS. PSYK: No, actually -- and actually Sally Merchant's here from the Office of Enforcement. She may have a few more words she wants to say about that.

MS. MERCHANT: Well, I would like to make one comment, and that's that this was not something we wanted to do. This was something that was brought to our attention from outside the agency, asking us how are you complying with this requirement.

We've had to put a lot of resources in it. We were -- It was not something we wanted to do. It's something that we're being required to do. We kind of have many of the same feelings as you do, but we don't have an option.

DR. NAG: I think you do have an option. One of the things you said was if it impaired or affected any patient's safety. Now, there's two things that can happen, giving an example.

One thing is that a level or what you sign, but the level that was given was 100 millicurie or whatever, 100 millicurie of I-131, and it was given. And the pressure of time and so on, it wasn't signed.

Now, that does not affect the safety of the patient, although legally because it wasn't signed on the paper. And when you do an audit of 1,000 injections, you

are going to have one or two of those. And that does not affect patient safety.

Now, you said that you are only going to report important things that have penalty and that affected patient safety. So something like that doesn't affect patient safety.

On the other hand, if that injection was given, no one gave the orders, and obviously no one signed those orders, then it affected patient safety, and that should be reported.

So I think you have to make that distinction between those two, although both on paper looks the same.

MS. PSYK: But you have to realize that in the first example you gave, they would not receive a notice of violation. They wouldn't even be on our radar. That type of situation we wouldn't have even considered to look at.

MS. MERCHANT: Additionally, look at the data on that. The EA-96, which means that's 1996. That was in a period of time before we went with the new rule-making; before we went with the more performance-based philosophy.

Hopefully if a case came to the Office of Enforcement where there was no deliberate attempt to do anything wrong we would certainly consider that. As I

said, look at it in the context.

The one above I'd like to comment on. And in this particular case, this particular service set up business, negotiated with an authorized user. Never quote, "hired him or contracted him," and proceeded to do more than 500 patients, with no authorized user at all. They had lied about the one they were putting on the license.

Same thing with the authorized user. And I think any of you would find a problem with that.

DR. NAG: I don't think any of us have a problem with that. The problem we have is where there's some paperwork missing, and that was a penalty.

MS. PSYK: That will not even come up on our radar. That won't even --

CHAIRMAN CERQUEIRA: To rephrase -- Gentlemen, we need to go on.

MS. PSYK: Yes, thank you. Okay.

CHAIRMAN CERQUEIRA: I'm not sure what additional discussion on this will do, okay?

MS. PSYK: Okay. Agreement state reporting. Agreement states were also required to report adverse actions to the database. I was going to actually ask Ruth, do you know if the State of Texas has begun reporting?

MS. McBURNEY: I was going to ask you is that through State and Tribal Programs, or through -- directly through Enforcement?

MS. PSYK: Actually, it's the -- You mean who's going to be initiating it?

MS. McBURNEY: Who will report to?

MS. PSYK: It actually has to be every government agency. So in other words, the NRC is a government agency. Texas is a separate entity. They will have to do their own reporting to the database.

MS. McBURNEY: Directly to --

MS. PSYK: Directly to the database. And what the NRC will do is once the management directive is finalized, we will send an all agreement state letter just to remind agreement states that they are required to do this.

This came up as something several years ago that we didn't even realize was out there. I mean, this was published in 1996, and we didn't even realize that this was a requirement.

MR. LIETO: Maybe I'm missing some dates here or something like that, but by what I've understood here, you're going to report any actions that you have taken since 1996?

MS. PSYK: Yes, that is correct. And I'm

sorry I didn't cover that. The rule became effective in 1996, and I forget the exact date, which means that we must go back and look at all of our enforcement actions, and all of our adverse actions that occurred, back to that date, and report back from that date.

So in other words, if something happened, like I gave an example that happened in 1997, we will have to report that.

MR. LIETO: Because I thought it didn't become effective initially until like 1999 or thereafter.

MS. PSYK: No, 1996.

DR. DIAMOND: It's a different provision. It's come into place at different points. So for example, some of the provisions relative to physicians and hospitals have come into effect only within the last several months.

There are other provisions I would gather that were antecedent to that.

MS. PSYK: Right. Okay. In summary, I talked a little bit about the adverse actions that we will report. I talked a little bit about the status of our management directive and how we're going to use that. And also that agreement states are required to report on their own, because they are considered a government agency that issues their own licenses.

Are there any other comments?

DR. NAG: Now, most of these violations, if not all, would have been reported on your NRC newsletter or whatever anyway, right?

MS. PSYK: That's right. In fact, that's a very good point.

DR. NAG: It is something that you wouldn't get otherwise?

MS. PSYK: That's a very good point, because in fact, all the examples that I provided, all of those are available because they were enforcement actions and are available on our NRC website.

So it's not like other individuals in the public couldn't see that information.

CHAIRMAN CERQUEIRA: Thank you very much.

MS. PSYK: Thank you.

CHAIRMAN CERQUEIRA: Excellent job. The next discussion is going to be, "Written Directives for Brachytherapy not Associated with Permanent Implants." And Dr. Zelac.

DR. ZELAC: Mr. Chairman, committee members.

DR. NAG: Dr. Zelac, can you move to the side?

CHAIRMAN CERQUEIRA: Use the next place. Push Tom out of the way there.

(Laughter.)

DR. ZELAC: You'll see me several times today and tomorrow. Initially I was asked to make a presentation on that aspect of involvement with the medical rule implementation that i've really been working on.

However, I was then asked to give a couple of presentations, and this is one of them, on other aspects relating to, I believe, issues or questions that have been raised by the advisory committee in the past.

In this particular case, apparently there was concern ont the part of someone that the particular written directive requirements that appear in the rule relating to brachytherapy, other than high dose rate brachytherapy, were not appropriate, and that they only applied, and were really applicable only for permanent implants, and not for temporary implants or other types of brachytherapy.

So the question is are these written directive requirements appropriate. The specific rule section involved, and this again is the revised rule that we're working with, the current rule, 10 CFR 35.40(b)(6), which covers the written directive requirements for all brachytherapy except HTR which has its own section, (b)(5).

The specific requirements that appear in that section of the rule are that the authorized user has to stay in the written directive before implantation, what the treatment site is, what radionuclide's going to be used as part of the treatment, and what the intended dose is as part of that treatment.

After implantation, but before completion of the procedure, the authorized user on the written directive needs to verify the treatment site, verify the radionuclide, and now provide in the written directive the number of sources that were utilized, the total source strength and exposure time, or alternatively the total dose.

Now what are the changes in this particular revised rule section that make it different from what appeared previously? Now the number of sources is entered after implantation rather than before implantation.

Secondly, individual source strengths are no longer required. And finally, the treatment site and the dose need to be entered into the written directive prior to implantation besides being verified afterwards.

The basis for these changes: discussion with the advisory committee on comments received on the proposed rule. This specifically had to do with the

entry of the number of sources post-implantation, and no need for individual source strengths.

And secondly, the consistency with requirements for other sealed source therapies, where the treatment site and the intended dose are identified prior to the procedure.

Now, I think it's important to note that so far, the requirements have not introduced anything which I personally, nor in consultation with others, have found to be inappropriate.

For example, for temporary implants, afterloaders, manual afterloaders, iridium seeds, in ribbons removed, temporary implants, you still need to identify the number of sources, you still need to identify what nuclide it was, and you still need to identify the total dose that was intended for delivery.

DR. NAG: I have a question about that.

DR. ZELAC: Yes.

DR. NAG: I think that on your slide on -- before implantation, the treatment site, radionuclide and dose. Why when that was there before was treatment site, radionuclide and I think it was activity. And that was more appropriate for a removable implant, but inappropriate for the permanent implant.

So to rectify that, they put in dose which

is now more appropriate for the permanent implant, but may not always be appropriate for the removable implant.

And the reason for that is once in a removable implant, in a temporary removable implant, you may want to put in the sources, and then do your calculation and see how much of the isodose you start with.

And you may want to change your dose depending on the volume. In the removable implant, many times what you can do is put the number of sources you want and then calculate, find out what volume you're getting.

And the volume and dose are inter-related. So depending on the volume you have, you may want to either take down or increase the dose. So in a way, if you are having only the word "dose" there, it may tie the hands down for the removable implant.

DR. ZELAC: Well, the comment that I would make is that the written directive is the intended treatment plan, if you will.

DR. NAG: Right, but --

DR. ZELAC: That certainly doesn't preclude modification later of the written directive based on the findings associated with the treatment itself.

DR. NAG: But say you tried to correct one with dose that the previous directive was not really suitable for the permanent implant, and you made it now not totally suitable for the removable implant.

You can very easily correct that by saying dose or activity. Or, you can have a separate way of writing the directive for a removable implant, and a separate directive for a permanent implant. Because the two, although they are both brachytherapy, have a different method of how you do it, and how you plan it.

DR. ZELAC: You've indicated that there would be a better way of stating the requirement. Do you find that the way that is existing in the rule now would, in fact, represent a problem?

DR. NAG: Are you saying the old 35 or the 35 now?

DR. ZELAC: No, I'm talking about the rule that we're living with right now.

DR. NAG: The new one.

DR. ZELAC: Right. That's really what we're commenting on.

DR. NAG: Yes, it would. If in the removable implant, if you are having total dose, and you are saying that, well, I want to give 3500, but the way the sources are placed, if you give 3500 you're going to

overdose that area. Then if it's a different volume, you say no, my intended dose is now going to be 2500.

DR. DIAMOND: But Subir, you could modify your written directive based on plan.

DR. WILLIAMSON: Yes, you can modify your written directive. I mean, I think I agree with both of you. I do believe that the way the current revised Part 35 that we're now living with is written, I don't think it precludes the radiation oncologist from changing the prescription.

It's necessary to have a two-part prescription, because treatment planning is not always completed by the time the sources are loaded. So that's important that that be there.

On the other hand, I tend to agree with Subir that in the old Part 35, the way the two-part prescription was written it was actually more useful for temporary implantation because it essentially was more consistent with a set of instructions or guidelines. How the patient was to be loaded, what sources, what activity.

That's what you know at the time. You don't know what the total dose is going to be or the total time. So from a safety perspective, there probably was a little more added value to the old regulation compared

to this.

But I don't think this is a major problem. It doesn't hinder us from doing anything.

DR. ZELAC: Well, obviously the problem it was intended to correct was having to specify in advance of implantation the number of seeds that were going to be utilized. And you know, that makes --

DR. WILLIAMSON: Right. You're trying to make it work for both permanent seed implantation and temporary implantation.

CHAIRMAN CERQUEIRA: So it sounds like it's accomplished the purpose.

DR. ZELAC: Mr. Chairman, we have someone from the audience.

MR. FORREST: Rob Forrest. I'm the radiation safety officer at the University of Pennsylvania.

Two comments on that. If some of the new modalities in 35-1000 fall into this category, it does present some problems, because SIRSpheres, for example, is considered brachytherapy. And it would be very difficult with up to 80 million spheres to determine the number that was administered. So that presents a problem with this regulation as written.

In addition to that, I heard several times

that an authorized user can revise the written directive. But part C of that says a written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before administration.

So the way the rule is written right now, you can't change it right in the middle.

DR. NAG: After completion, not before completion.

DR. ZELAC: The other thing is, the comment is that the sections in the part of the rule that I'm discussing now apply to specific modalities which are covered in the base portions of the regulations, and do not apply to any requirements relating to 35-1000 utilizations, which will be covered by microspheres.

And it has its own specific requirements for just about everything. When they can fit and match with existing requirements in other sections, that's done. When they don't, then they certainly don't apply, and that would be the case here in terms of specifying the number of sources.

CHAIRMAN CERQUEIRA: So that clarifies it. One last comment from Jeff.

DR. WILLIAMSON: Yes, I think I just read the part C here that the member of the general public. I think, depending upon how you interpret this, it's

okay.

It says before the administration of the dosage of unsealed by-product material, the brachytherapy dose. So that phrase to me implies you can revise it up to and including the point where the original dose is delivered. But if it goes beyond, then you can't.

DR. NAG: Therefore, if it's in a permanent implant, the implant is never finished, so you can do it up to 100 years.

DR. WILLIAMSON: That has never been clear, and I think that's where --

DR. ZELAC: Well, that is currently under consideration by our Office of General Counsel: when does the procedure end. I will not specify, because it's still pre-decisional, what their determination of that was. They haven't completed it yet, but there will be a stated endpoint for such procedures.

DR. NAG: The other question that brings up is, you know, if you're taking a removable implant, I am prescribing just 3,000, okay? But, because of the way the sources are kept, it can go up to 4,000 or 5,000.

So now I am doing my calibration after the original prescription of 3,000 is done, but before my new intended, which is 5,000. So what does that mean?

DR. ZELAC: Well, there are two -- First of

all, keep in mind that the information that's asked for prior to the implantation is quite general. What organ are you treating? I'm treating the prostate. You don't have to say the extent of it, whatever. I'm treating the prostate.

What is your approximate intended dose to be delivered? If you give a number, there's nothing to preclude you from giving a range as opposed to a specific number. And as long as you are within that range, you should be satisfactory.

Yes. The answer to the question is excellent. Yes, Part 35 written directive requirements appear to be appropriate for brachytherapy that involves temporary implants, and are not specifically written to only apply to permanent implants.

CHAIRMAN CERQUEIRA: Thank you very much Ron, excellent. All right, the next presentation is on "Downloading Part 35 from the NRC Webpage."

MR. ESSIG: This will be very, very quick.

CHAIRMAN CERQUEIRA: Excellent.

MR. ESSIG: Shorter than the others by a long shot. You have a hand-out, and I think members of the public have it as well. It's titled "Saving Part 35 to Disk from NRC's Website."

You can read that at your leisure. Any

credit can go to Roger Broseus for articulating this. He's one of our resident computer gurus. And we tried it, and it works. It's referenced to Netscape, because that's the browser we use. But it should work on other browsers as well.

So this answers the question, hopefully. There were concerns a member brought up the last time about the way the website instructions, you can only download a piece at a time. This allows you to download the entire. Not only Part 35, but any part of the regulations you want to.

CHAIRMAN CERQUEIRA: Fabulous. So our last presentation is going to be "Society of Nuclear Medicine's Suggested Guidance for Therapy Applications." And Dr. Jeffrey Siegel, Society of Nuclear Medicine, will be making his way to the podium.

DR. SIEGEL: I'd like to thank the chairman, members of the ACMUI, the NRC staff, for allowing me to take up your very valuable time today. I know it's been a full schedule. We're all a little bit tired, so I'm going to be really brief.

As Tom Essig said, when we developed the diagnostic, as you know, Part 35, divides by-product material, or BM, as I like to say, into seven types of medical use.

So therefore, out of necessity, Part 35 contains requirements for a diagnostic as well as therapeutic medicine. So in meeting with Chairman MEserve on December 19, 2001, it was agreed upon that there was a need to publish a separate, stand-alone guidance document for diagnostic nuclear medicine applications to simplify all the paperwork involved.

SNM/ACNP subsequently proposed to publish a stand-alone guide for therapeutic nuclear medicine. The term, of course, "diagnostic nuclear medicine" does not appear anywhere in the regulations, but it's understood to pertain to 35-100 and -200 material.

And therapeutic nuclear medicine is understood to pertain to 35-300 material. And as you know, the NRC does classify material as to written directive or non, and physical form sealed or unsealed source.

We know that the applicable parts of the regulations you've been debating over T&E can't be viewed in isolation because there are license conditions and, of course, regulatory guides. NUREG-1556, Volume 9, is the licensing guidance for the revised 35.

We know that licensees must have written procedures. And that's stipulated in Part 20. But these policies in implementing procedures are not published in

the regulations. They exist only in guidance base, which means from a regulatory point of view, they don't exist, unless the licensee commits them to use, and therefore it becomes a license condition. Otherwise, they are non-existent. Guidance is guidance. It's not mandatory.

Generally, nuclear medicine licensees have used NRC guidance. And this is the reason that we decided to publish a guide as an alternative. We worked collaboratively, as Tom said, with the NRC, and we're very happy that the statement was made. I'm not going to read it again.

It includes all the applicable NRC regulations. Not just Part 35, but Parts 19, Parts 20, 30, all other applicable parts to diagnostic nuclear medicine.

As we'll see tomorrow, the number of misadministrations and medical events that have occurred over the last four years as a result of diagnostic nuclear medicine was two in 2000, zero in 2001, zero in 2002, and one in 2003. So not many medical events or misadministrations.

It was designed to make it much easier for all involved in diagnostic nuclear medicine to be familiar with the regs. It's only 73 pages. It contains step-by-step instructions. And again, this includes

everything distilled from Part 35, Part 19, Part 20, Part 30.

Additional guidance is necessary of therapeutic nuclear medicine, and that's why we sent to each member of ACMUI a copy of the companion guide for therapeutic nuclear medicine. And you each should have a copy of that. It's divided into six parts which I'm not going to go into. Let's all turn to page 36. I'm only kidding.

We thoroughly appreciate the review of the ACMUI, and any comments you may have. And ultimately we would look for ACMUI endorsement of this document to the commission. And I thank you very much for your attention.

CHAIRMAN CERQUEIRA: Thanks, Jeff. One question that I have, which I sort of asked related to the diagnostic, is people use this to make decisions about how they set up their practices.

And I'm worried about liability in the sense there's -- you know, when the NRC puts out a guidance document, the government is behind it. Now when the SNM puts out a document, who's liable.

And what if a physician acts in accordance with these guidelines that you've put out, and then is found to have significant violations, loses his license

or something.

Do they have any -- you know. Is the SNM liable in any way?

DR. SIEGEL: Well, we have the SNM's attorney here, sitting in the background. But again, these guides were written as minimal guides. They were not meant to be the things you could do to the nth degree.

CHAIRMAN CERQUEIRA: I mean, the regs ultimately are what determines what's appropriate.

DR. SIEGEL: That's absolutely right. And there's more than one way to skin a cat, as you know.

CHAIRMAN CERQUEIRA: Right.

DR. SIEGEL: And one could take the guidance in 1556, Volume 9. Or one of the guides that we've proposed, the diagnostic or the therapeutic guide. And the question that you ask is an important one, and I'm glad we do have the SNM attorney here.

But I think that the important thing here is that in a risk-informed performance-based situation that we're in. And when inspectors come in, I don't know what they're going to be comfortable with.

So if they're not comfortable with the SNM guide, but they're familiar with NUREG-1556, and they see violations that don't amount to safety problems, that's

one issue.

But let's say they see violations that amount to medical events or misadministrations, which is the question, and the only important question, in my opinion, that you're asking. Is it because of their policies and implementing procedures?

And I can't see that as a problem, except that they're not following any policy or procedure whatsoever. Like they were talking about before, a facility operating without an authorized user and a radiation safety officer.

I would suggest that knowledge is almost irrelevant and unimportant, because who would consider doing that? Obviously, there are people out there that are doing that. But if you have no policies and implementing procedures at all, you're likely to experience misadministrations and medical events.

But if you have minimal standards in place which you're following, and not even to the letter. Given from the NRC's presentation tomorrow, there are essentially no medical events or misadministrations to speak of in this century.

CHAIRMAN CERQUEIRA: Okay, well that will be an interesting presentation.

DR. SIEGEL: But I'd like for you to speak

on this, Bill.

MR. UFFELMAN: As I recall in the beginning of the guidance there's a paragraph that specifically --

MR. ESSIG: Name please?

MR. UFFELMAN: Bill Uffelman, Society of Nuclear Medicine. I'm general counsel and director of public affairs. U-F-F-E-L-M-A-N and I'll give you my card when I'm done.

But basically recall, your whole -- the way you behave is directed by the regulations, Part 35, Part 20, et al. The guidance, both the NRC's guidance and the SNM guidance, are just that. Guidance.

Ultimately, the regulation is what controls your activities. And your license, which you said, I'm going to do these things. And so in effect, the guidance that SNM prepared, that the NRC reviewed and said yep, this meets it too. Both of those, the NUREG and that, both of them are just that. Guidance on how to comply.

If your attorney, or your RSO, or somebody else said, hey, here's something we can do that conforms, you can do that too. It becomes, though, when you're inspected, is there some something that you can point to and say I did that because it made sense.

And again, it goes back to it's a performance-based standard, and if you're performing,

then you have met the criteria, the fundamental criteria of the regulation.

Are you, in fact, having misadventures out there, or is everything hunky-dory in accordance with --

CHAIRMAN CERQUEIRA: Right, but some of those are subject to interpretation. As you've heard today, what we've put down and the way it's being interpreted is not always the same.

And I think once you've created guidance documents, then our constituents could basically be following recommended policies, but may end up giving them a violation.

I see that the NRC guidance documents are basically from them, and probably are, you know, they're probably a little bit more protective in terms of what people do.

Does the NRC give the same weight to the SNM guidance for diagnostic and therapeutics?

MR. UFFELMAN: On the diagnostic, the NRC put its name on the cover of the publication. As an alternative to NUREG Volume 9.

CHAIRMAN CERQUEIRA: But does that mean they fully endorse it, the way they do their own guidance documents?

MR. ESSIG: For the diagnostic, I think we

-- that's --

MR. UFFELMAN: That's --

CHAIRMAN CERQUEIRA: Is that what counsel? I guess she's gone. Okay.

MR. UFFELMAN: That's why they licensed it. They licensed it from us to publish it as an alternative to NUREG Volume 9.

MR. ESSIG: An acceptable way of implementing --

CHAIRMAN CERQUEIRA: I guess having this in the minutes of the meeting, or at least in the transcript, I think makes me feel a little more confident.

DR. SIEGEL: That's a very important point, because when we were speaking with staff and the commissioners --

CHAIRMAN CERQUEIRA: Right.

DR. SIEGEL: Guidance being guidance. They didn't give it the same weight as the regulation. And I'm glad Bill brought up that point, because given that this is guidance, and that there are alternative methods, and this is sort of "use at your own risk".

One certainly can't escape, I guess, liability in the sense that somebody's going to say, well, I saw this here, and because I did this, look what

happened.

MR. UFFELMAN: That's a challenge I would willingly face in court.

DR. SIEGEL: But that's also something that could happen as a result of somebody following to the letter NRC guidance.

DR. BROSEUS: Mr. Chairman, I have a comment.

CHAIRMAN CERQUEIRA: Yes.

DR. BROSEUS: I'm not going to speak to the liability issues, but it might be useful, and I will make sure that a copy arrives for ACMUI tomorrow. There was a regulatory -- a RIS. What does RIS stand for? Regulatory Issues Summary.

And that stated clearly what the NRC's intent was with regard to making the Society's guide for diagnostic uses available to the public. And we'll make that available tomorrow.

MR. ESSIG: I had mentioned that earlier.

CHAIRMAN CERQUEIRA: Okay, that will be good. Now, the other question is, I mean this is coming from the SNM on therapeutics. And are there any other stakeholders who should have input into this?

DR. NAG: I do not have input into this document. But what I'm wondering is is such a similar

guidance required, or would it be helpful for the NRC if, for example, the ASTRO would develop something similar for therapeutic radiology?

DR. SIEGEL: See, I hoped that when we had these workshops that Tom was talking about several months back, that more of the professional societies would have come forward.

And I'm quite surprised that in the 50 or 60 or so years, nobody has come forward. And that we were as a professional organization the first to come forward to have some professional standards.

I mean, purportedly professional health physicists have the training and experience that they shouldn't be following guidance blindly. Not that guidance necessarily is bad, but they ought to have their own organization, or professional standards with which to operate.

DR. WILLIAMSON: We do, I just want to interject. The AAPM, the ACR, ACMP, have many standards of practice in radiation oncology dealing with --

DR. SIEGEL: No, no, I know that you do.

DR. WILLIAMSON: Okay.

MR. UFFELMAN: The other -- The reason we wanted to bring this to you today was if you recall when we did the diagnostic, we had distributed for peer review

to a couple hundred people.

And you all said, well gee, we didn't see it. The notion was it's here. And as Jeff said, there's a comment sheet there that we invite your comments.

We hadn't intended that it would get into the publicly released pieces that went out, but that's okay if they want to comment too. But obviously, the copyright remains in the SNM, and what we were looking for was input from you all on the document because we will be publishing it as an SNM document.

And if, you know, somehow, some way, the NRC also recognized it, that's a nice thing too.

CHAIRMAN CERQUEIRA: Any other questions for Dr. Siegel? Thank you very much, Jeff.

DR. SIEGEL: Thank you very much.

CHAIRMAN CERQUEIRA: So that ends today's session. Jeff?

MR. LIETO: Just quick. I notice that the timeline for review is May 10.

DR. SIEGEL: Oh, that's fine. Obviously that can't happen.

(Laughter.)

MR. LIETO: Thank you for recognizing that. But what -- I mean, are you looking at something, since most of us have just gotten this within the past week,

what are you looking at? Something like within 30 to 60 days, or what?

DR. SIEGEL: I think if you could do that, that would be great.

MR. LIETO: Okay.

DR. VETTER: And where do we send the comments?

MR. UFFELMAN: I think the address is inside.

DR. SIEGEL: Should be a comment sheet.

MR. UFFELMAN: Does it say somewhere 1850 Samuel Morris Drive?

DR. VETTER: No. There's a comment sheet, but no address on it.

MR. UFFELMAN: The letterhead on the front. Send it to the Publications Department, Society of Nuclear Medicine, 1850 --

DR. SIEGEL: Or give them your home number so they can call at night.

MR. UFFELMAN: No, I don't want to talk to them. And Jeff gave you way too much time. If, in fact, you could comment in the next two to three weeks, that would be appreciated, because we're going to the annual meeting.

My anniversary is the 21st. So somewhere

around the 21st of June we'll be at the annual meeting. And the notion was we would be able to say the review had been completed by the time we got there.

CHAIRMAN CERQUEIRA: Excellent. Tom?

MR. ESSIG: Just one point. I realize we're about to adjourn the meeting for the day.

CHAIRMAN CERQUEIRA: The open session.

MR. ESSIG: Just wanted to mention that we will reassemble. And I think those of you that need security badges need to pick them up over at the other building. I believe that's the arrangement.

CHAIRMAN CERQUEIRA: Should we do that and then come back?

MR. ESSIG: And you can do that, and then come back. And why don't we take about 10 minutes, then resume our closed session from this morning.

MS. WILLIAMSON: Before everybody leaves, can I make some quick announcements concerning your badges. Just real quick, just a minute. To get your new badges, all you have to do is walk over to the other building and surrender your current badges. That's it.

Ms. McBurney, I need to talk to you.

(Laughter.)

(Whereupon, the above-entitled matter went off the record at 4:55 p.m. and went back on

the record at 5:08 p.m.)

DR. WILLIAMSON: I think on the remaining concerns of Part 35, we clearly have the issue of licensing conditions for sealed, interstitial brachytherapy sources, that remains an issue that we're quite concerned about and should probably be mentioned to them.

Another one that is a concern for me was alluded to in the last session, which, you know, basically the Office of General Counsel is going to decide almost, you know, what fraction of properly done prostate implants today are going to be medical events tomorrow.

You know, and this is the issue of how to interpret the language of what's permitted in permanent brachytherapy in terms of prescription revision. And just so you know what the issue is, is that implants are preplanned based on minimum dose to the prostate capsule, usually.

But when implants are executed, you know, because of the inability to place the seeds precisely where you want to and seed migration and prostate edema and so forth, the minimum dose on average that you get at the end of the procedure when you do a post-implant CT and look at it, comes out to be sometimes only 60 percent

of what that was prescribed.

So practically speaking, what is used is the dose to 90 percent of the target volume as a parameter for determining how good the prostate implant is. And somehow, you know, we have to have some influence on this process to make sure that a realistic, a clinically realistic interpretation of how to write written directive for prostate implant is developed, or the NRC could be swamped with thousands of meaningless medical events.

DR. NAG: Now let me add a couple of things. It also depends, when you're saying the dose is often implied, you are saying that the dose is 13,000 or 15,000, is purely obviously because it depends on how you do the volume of the prostate.

And we have done this at the study between our members. We had asked them excellent work known like a Therapist to circle the prostate, and all the ten circles were different. And I can give you that study.

So if you take the dosimetry from those ten people, from the same implant, same prostate, that those were different in the prostate by ten different people.

And in all, all the human control, the dose in the, I wouldn't say meaningless, but it depends on how you are interpreting the dose. So just because we like

13,000 or 15,000, that doesn't necessarily mean, you know, that you're under those in the prostate, all were those in the prostate.

And the important thing is that the therapy of the basin not undermine the, because they are basically cured.

DR. WILLIAMSON: So I have great concern when I hear about an attorney who has like no conception or understanding of the clinical process and what constitutes, you know, essentially an avoidable technical error, and what constitutes a properly done prostate implant.

CHAIRMAN CERQUEIRA: So this is a concern that we need to bring up with them.

DR. WILLIAMSON: Absolutely.

CHAIRMAN CERQUEIRA: And maybe the two of you, since, you know, this is not an area where I have a lot, maybe you could just draft a few slides for me, and we can get those in.

So issues related to therapy with, you know, issues for brachytherapy for, that's one area of concern.

DR. NAG: Especially permanent implants.

CHAIRMAN CERQUEIRA: Permanent, okay.

DR. WILLIAMSON: Yeah.

CHAIRMAN CERQUEIRA: And then we have the issue of the training and experience which, again, I just got a list from Lloyd. So far three states have bought into the NRC proposal, the agreement states.

But the others we haven't heard from. We have no idea how they are going to deal with this.

DR. WILLIAMSON: Lloyd just entered the room.

CHAIRMAN CERQUEIRA: Did he? Okay, yeah, Lloyd and I were talking. And so, you know, and I'm not sure there's anyway of knowing at this point what they remaining agreements states will do with this. And certainly for the physician authorized users it's going to be a major problem.

MS. MCBURNEY: Dr. Cerqueira?

CHAIRMAN CERQUEIRA: Yes.

MS. MCBURNEY: Just speaking for one agreement state, we have adopted everything except the, just about, except the training experience. And we were waiting until we get all this, the other issues worked out on that.

CHAIRMAN CERQUEIRA: Right. And Wisconsin is doing the same thing.

MS. MCBURNEY: So that we wouldn't have to do two rule makings dealing with training experience,

that we would just do one. And I think a lot of the states are waiting for this additional rule making before they --

DR. WILLIAMSON: Are you going to represent the state of this in your general summary about the ACMUI?

CHAIRMAN CERQUEIRA: No. One of the items is just sort of a --

MS. MCBURNEY: Implement.

CHAIRMAN CERQUEIRA: Yeah. ACMUI feedback on the status of implementation of the revised 10 CFR Part 35. And, you know, we don't have all that much feedback at this point. I haven't, you know --

DR. WILLIAMSON: Well, is the training and experience a separate agenda item or covered under the --

CHAIRMAN CERQUEIRA: No, it's not a separate agenda item. It's going to be covered under here.

DR. WILLIAMSON: I think that it might be good to maybe, I don't know if Dick will be attending this or not.

CHAIRMAN CERQUEIRA: The commission briefing?

DR. WILLIAMSON: Yeah, to make some comments about residual issues and some responses to --

MS. MCBURNEY: Yes, he is going to be --

CHAIRMAN CERQUEIRA: He is going to be there, right.

DR. WILLIAMSON: So you don't need to cover that, then.

CHAIRMAN CERQUEIRA: Right.

MS. MCBURNEY: Right.

CHAIRMAN CERQUEIRA: Okay. Well, what other, you know, again I don't have to go on very long. I think that some of these issues about the prostate -- yes, what else?

DR. WILLIAMSON: Well, I think that since you're covering, generally, the status of the ACMUI, as our Chairman, I think you should allude the issues of communication and our concern, you know, about, you know, what we talked about this morning.

So I think you should summarize that and summarize our proposal.

CHAIRMAN CERQUEIRA: Right. For the follow up conference.

DR. WILLIAMSON: Yeah, that we've sort of settled on the third way, which is, you know, we want to have some kind of a codification of how, I don't know, not disputes exactly, but you know --

CHAIRMAN CERQUEIRA: Sort of follow up on important issues.

DR. WILLIAMSON: -- how are advice needs to be handled when we get a negative reception over some issue we feel strongly.

DR. MILLER: I think what you're looking for is in instances where you have a passion about a certain recommendation that you've made and the staff doesn't take you up on your recommendation, you'd like to make sure that the Commission is aware of, of your concerns and your position.

DR. WILLIAMSON: So I think a little bit about some of the past history and our recent concern. I'm sure this has probably reached them if any of the Commissioners have ever looked at the transcript or the summary of our minutes.

It would be worth summarizing this when --

MR. ESSIG: And I think it would be worth contrasting the difference between this Advisory Committee and the other two. Namely, that they report directly to the Commission and they issue a letter from the Chairman of the Committee to the Chairman of the Commission with recommendations.

Whereas, this Committee reports within NMNS and because of its narrower focus, in large measure, and so that the recommendations come up and in a way that could be a lead in to what you're going to share with

them then.

CHAIRMAN CERQUEIRA: Okay, all right. So, okay, now that's a good point. The structure, the reporting structure for this Committee is different from the other two that -- okay.

DR. NAG: Manny, I have one thing. Whether it would be worthwhile to bring up the example we had this afternoon where you had 15 or 20 different types of sources with them all essentially similar, but because of the way they were interpreted you have to get a license every time you change from one to the other with no base and consequences.

DR. WILLIAMSON: I think that's on your list, right?

CHAIRMAN CERQUEIRA: Yeah, the first two items.

DR. WILLIAMSON: Yeah, the licensing --

CHAIRMAN CERQUEIRA: Licensing conditions for interstitial and implanted brachytherapy devices, yeah. And you guys are going to give me some, well some, just some of the talking points, because, you know, it's really important.

MR. ESSIG: Could I suggest that since Paul Lohaus and his staff are here --

CHAIRMAN CERQUEIRA: Yes.

MR. ESSIG: -- they came this morning. We had to turn them away and they've come back now. And we can talk about Ralph's slides.

CHAIRMAN CERQUEIRA: Excellent, yes.

MR. ESSIG: And, Paul, if you want to come up to the table here and this is, Ralph Lieto has the lead for this, on the 28th, this presentation is on the, on the agenda.

He is going to be summarizing on behalf of the Committee and we stumbled on a couple of things this morning. So, that we're, so, Ralph, do you want to kind of pick up and maybe Paul can help answer the issues.

MR. LOHAUS: Hello.

MR. LIETO: Where do I start? Here. I think in basically some of the comments I got back from the Committee members this morning, I think the stumbling block had to do with the issues regarding areas of concern.

And that there was support for the alliance concept or methodology of program, National Material Program, which was the working group recommendation.

And that there were four main components of that alliance program. And the one, or one of the four that was of concern, potential concern, had to do with NARM, regulation of NARM.

And its potential increased regulatory burden, impact and so forth. Where we really got into stumbling I think was on understanding, I think, from the working group report that was reviewed and presented at the last meeting.

It had to do with state program issues and funding. Okay. And the alliance program, that is really in essence not much, I'm sort of asking a question, is not much of a change than what is going to be existing now, except you're going to have NARM. Is that accurate?

MR. LOHAUS: Let me, in response, let me provide a little background information because on one hand the alliance structure that the working group recommended, is really a further evolution and advancement of where the National Materials Program is today.

And I always like to start out and indicate that there is a National Materials Program today. It's basically, what the program is, in terms of the states and the NRC.

And over the past several years, and it's really more than several years now, we've been very effective in terms of using a combination of state and NRC resources through a working group process to address

areas of new guidance, rule making activities, common regulatory issues.

And working groups will develop a product that can then be utilized, whether it be by NRC or the state. And that is really at the heart of the alliance concept. What the alliance concept or structure does though, as envisioned by the working group, is it expands that out and has additional factors that you don't necessarily see in today's program.

The concept of using centers of expertise. For example, you can see that in places today. For example, Texas took a lead earlier and developed a well walking rule that was sort of a center expertise and they took the lead to develop that.

But you don't see that in a, in a heart sense as a structure or practice that's carried out. The alliance also includes a concept of what's called the administrative core. And I have a hard time getting my hands around exactly what the administrative core is.

Because if you look at this and you look at the alliance process, there needs to be an organization, and right now I think NRC is probably that organization, that helps take on accountability, make sure products, when they are needed, are completed.

Completed on schedule. That they meet their

intended purpose. That they are the right standards of quality, etcetera. And the alliance concept, as you see that in the working group report, it talks about this administrative core, but it's not really clear exactly who that administrative core is or how it functions.

And it could be a consortium of CRCPD, OAS, and NRC. It could be CRCPD. It could be NRC. And that's something that I think will have to be sorted out in the future. And I think today, if I were to answer the question, it's really NRC sort of has the lead and carries out that responsibility.

But it's done through some of the kinds of mechanisms and processes that you would see in an alliance program. And that's one of the reasons that when we went back to the commission on the pilot projects, the staff recommendation, and this was really not only a staff recommendation, but a recommendation that CRCPD and OAS agreed with, was to use what we called a blending of the current program.

The current program as it exists today, and the alliance option, which is to try and push further the state of the art in the evolution in terms of how the alliance process could work in the future. But there are some unanswered questions.

MR. LIETO: So it continues to be a hybrid

of agreement and non-agreement states?

MR. LOHAUS: In this case, it's principally NRC, agreement states and CRCPD and, on occasion, a non-agreement state if there is an issue that, where we want non-agreement state input. But the primary, central focus of this, is really agreement states.

Not non-agreement states. Although, when you bring CRCPD into this, you bring in both agreement and non-agreement states. And I realize that's hard to make that differentiation, but I think in terms of looking at the National Materials Program, it would be best characterized as NRC and the agreement states.

I would not bring the non-agreement states in. But, what you're seeing on certain issues, such as regulation of NARM and questions like that, which have an impact on agreement state programs, what we're doing is we're involving CRCPD and bringing in, through that organization, a non-agreement state perspective to have the benefit of those views on questions that have an effect on the non-agreement state programs. Ruth?

MS. MCBURNEY: Yeah, I would add that normally if, on matters of byproduct material and so forth, even the CRCPD puts someone in from an agreement state on working groups and steering committees, to the mix.

MR. LOHAUS: And that's, that's a very good point. Because if you look at the process of developing the suggested state regulations, one of the things that we've tried to do more recently is to try and work NRC's rulemaking process and work the suggested state regulation process in parallel.

Which means that the, the individual within that conference committee that has responsibility for that particular suggested state regulation part, would work, if we had a working group set up to deal with that, would work on that working group.

So you'd have both the benefit of the conference committee and the working group and the cross over that would occur, so the two could proceed in parallel. And we tried to do that on Part 35, as well as I think you're aware, and that was one of the, it wasn't really a pilot, but it was, the process, the idea was to try and work that process in parallel.

And some of it worked well, and some of it didn't work quite so well. There's, we're going to, as we continue to do this, gain experience and reflect that back. But I think that to say that the non-agreement states are part of the National Materials --

MR. LIETO: I guess that's still a fundamental issue that I think was not clear in the

report or maybe misunderstood from the report is that when you say NRC, okay, does that include individual states?

For example, Michigan is an NRC-regulated state. So when you're talking NRC, do you mean Michigan? Do you mean Minnesota?

MR. LOHAUS: No. NRC, solely NRC.

MR. LIETO: Okay. That's, that's, I think, part of the issue here. Okay. You're saying it doesn't involve non-agreement states. Okay. So where do they fall in the alliance? They're not part of a National Materials Program?

How do you call it a National Materials Program, if the states that are regulated by the NRC are not part of the process. See, my, well, I understand the alliance about, with the agreement states, okay.

And that's what I think is part of the misunderstanding. Maybe it's a misunderstanding or confusion. Is that, it seemed like an alliance, the alliance is that the states, all states sort of achieve an agreement state status.

And you have the NRC as this, or whatever Agency, CRCPD, OAS, whatever, or a hybrid of the three, as this, in alliance with the states.

MR. LOHAUS: If the atomic energy --

MR. LIETO: Because you keep talking states and NRC, and that's where I'm trying to understand. I understand where non-agreement states fit in, or agreement states fit in. Where do the non-agreement states fit ?

MS. MCBURNEY: They are regulated by NRC.

MR. LIETO: But he just said they are not part of NRC.

MR. LOHAUS: No, they are regulated by NRC, but I guess I was looking at this through the standpoint of if you were to look at the National Material Program and in terms of where that program is today, it addresses Atomic Energy Act materials, and it consists of the agreement state programs and NRC's regulatory program, which covers the suite of agreement material licensees, Atomic Energy Act materials licensees nationally.

It does not include a non-agreement state, such as Michigan.

DR. WILLIAMSON: But if you expand the legislative mandate, if you amend the Atomic Energy Act to include NARM, then you are going to force the non-agreement states either to become agreement states or shut down their non-regulatory programs and make way for you.

MR. LOHAUS: I mean that's certainly an

issue that would need to be addressed as a part of consideration of any legislation to amend the Atomic Energy Act to consider NARM. It's how you would handle states, non-agreement states, that have NARM Programs.

And some register, some license, there's differing degrees. But I think in general most of the non-agreement states do have programs of regulatory oversight over NARM. And that's a question, as a part of the legislation, if that were to be considered, that would have to be addressed.

DR. WILLIAMSON: I think we should stick, I'm just making a suggestion to you, Ralph. Because I think to get caught up in all of this bureaucratic -- I don't understand hardly a word you've said, to be honest with you.

This whole program sounds so vague and ephemeral and I think this is an administrative issue that impacts the regulatory agencies and the state, and you know our mandate is to speak for medical licensees, in both agreement and non-agreement states.

So I think we should maybe put the emphasis of your presentation on the potential negative impacts of regulating NARM by NRC or some combination of NRC and the agreement, plus or minus non-agreement states.

Which, you know, that's a big mess. I

think, you know, we're concerned about increasing the cost or availability of PET imaging for our patients. We are concerned that, you know, we're taking a problem where we don't see, basically taking a set of radiation medicine procedures where there's no perceived problem or public health hazard, and all of a sudden imposing a regulatory burden on it.

You know, and we don't see the rationale very clearly. We are concerned that by NRC taking on the mandate to have to develop the expertise to handle a whole new set of medical applications that they don't have familiarity with, with an ever shrinking population of licensees, that this is going to increase the cost burden to all licensees that continue to be regulated by NRC.

So I think these are some issues we're concerned with and are reflected in our transcript of the October meeting.

MR. LIETO: And I think, my feeling is just pulling that whole slide out. I think this slide about state programs is a, it's quicksand. And so, there is other ways I'd rather drown.

DR. WILLIAMSON: I just think it's too far from our community to worry about.

MR. LIETO: Maybe just not try to profess or

maybe create more confusion than already exists, and some misrepresentations to the Commission. Definitely we don't want to do that. So I think it might be because this is so much in the early phases.

And I think, as Mike pointed out earlier, there's, which was before this, that there are pilot programs going on in some aspects that, you know, maybe the thing to do is just make sure that we just address the PET issue and the issues about cost.

MR. LOHAUS: What I was going to offer is in the pilot programs specifically, is that recognize that the report that we provided to you, is a working group report. That report was provided to the Commission. The Commission has not endorsed or accepted or approved any particular option.

They have not endorsed the alliance option in particular or approved the alliance option in particular. But what they have done is provided direction to the staff, and in a sense, to the states, to work together on five pilot projects using a blended approach.

Which is really using the existing program, but sort of pushing that a little bit further in the direction of the alliance. And based on the results of that and the report is due to the Commission in November

of '04. Then there will be further consideration of whether there should be any additional direction or guidance provided to the staff.

And I think, in this case, the states relative to how that, how the program should be managed and going forward. So I think you're very correct in terms of the, it's maybe premature at this time given the fact that the pilots are underway.

We're trying to develop a better base of information so all of us can better understand and the Commission can get a better base of information to make some of these decisions. And it maybe premature to try and force some --

CHAIRMAN CERQUEIRA: Premature to have answers, but at the same time, these are issues that need to be addressed. And I would be rather in favor of bringing it up now, while it's in a draft form, rather than waiting until it becomes more solidified. Charlie?

DR. MILLER: Let me see if I can help you. Maybe I'll make it worse, but I'll try not to. On Jeff's concern, I mean if the committee has got concerns about, specific to NARM regulation, and the NRC regulating NARM, on the one hand you can say, well, since it's just the legislative proposal at this point in time, the Commission has no authority yet, so what can you gain by

addressing the Commission.

But on the other hand, if you feel strong enough about that, as a Committee, about concerns about the NRC doing that, you have two choices, as I see it, to go forward.

You can let the Commission know what your concerns are, so as the Commission addresses with Congress comments on proposed legislation, they can factor that in. Or, each of you, by other means, can lobby the Congress with regard to your concerns.

But as a committee, I would think the best you could do now is to say to the Commission, here are our concerns about the NRC doing this. And as the legislative proposal goes forward, the NRC does periodically get the opportunity to comment on those.

And the Commission, in its wisdom, could decide if they wanted to do that or not.

CHAIRMAN CERQUEIRA: I think it would be important to bring it up. Is that, is that the --

MS. MCBURNEY: Yes, I do.

CHAIRMAN CERQUEIRA: -- anybody opposed to keeping it on the agenda?

MR. ESSIG: Let me just add one point, though.

CHAIRMAN CERQUEIRA: Sure.

MR. ESSIG: That we'll do a little role reversal. I'm going to give you some advice.

CHAIRMAN CERQUEIRA: Okay.

MR. ESSIG: Okay. The advice that I would give you is that recognize that the Commission has already endorsed the need to regulate NARM, specific sources now, not, probably not even those that are used in most routine, run-of-the-mill diagnostic programs.

And I'm sure PET isn't even on the radar screen of concern. What the concern was that, as I think I hopefully mentioned earlier today, when I was describing it as the whole source security issue that we're dealing with now for Atomic Energy Act material.

The impetus for the NRC proposing to the White House that we jump on this bandwagon was the idea that there may be some sources, either discreet naturally occurring materials, like Radium 226, that were used a number of years ago in medical applications.

Or some discreet sources of accelerator-produced materials, although maybe not used in medical applications, might be used in other applications like industrial radiography and so on.

My advice would be that you just simply recognize that the Commission has some concerns over the security of all sources, including accelerator-produced,

and that was the basis for mentioning, for endorsing that proposal to Congress.

And then you can say, however, the baggage that goes with that, as far as we're concerned, is that NRC would be regulating, as Jeff was saying, in the states that opt not to become agreement states, that we would then be the regulatory authority.

And the baggage that goes with it, is that we, the NRC then, would be regulating things like PET. But we didn't start off to do that. We started off to level the playing field in terms of security sources.

DR. WILLIAMSON: So I think to --

MR. ESSIG: So that's an important point to recognize so you don't --

CHAIRMAN CERQUEIRA: Right. I think Ralph --

MR. ESSIG: -- because you're weighing in on something the Commission has already decided more or less to do for a different reason and just recognize that.

DR. WILLIAMSON: To maybe argue that for these medical sources, there isn't really this security risk. And bring that point that we're going to have to suffer and maybe our patients will suffer and, you know, it's going to cause, certainly a lot of confusion and chaos with no really incremental improvement in safety,

public safety in this sphere of unauthorized usage of sources. Okay.

CHAIRMAN CERQUEIRA: Excellent. Ralph, you've got all this down. We're behind you, don't worry.

MR. LIETO: Verbatim.

(Laughter.)

CHAIRMAN CERQUEIRA: Yeah, I think they are good points, yeah.

DR. VETTER: Have the agreement states all been notified of the existence of the program?

MS. MCBURNEY: Oh, yes.

MR. LOHAUS: Yes.

DR. VETTER: Have the non-agreement states who are applying to become agreement states, been notified of the program?

MR. LOHAUS: Yes. And when you refer to the program, you're talking about --

DR. VETTER: The National Materials Program.

MR. LOHAUS: Yes. As a matter of fact, one of the things that we've tried to do is to have a very open process. And at the CRCPD meeting we had a special topic session, where each of the Chairs for each of the five pilots presented information on what we're doing.

And we answered questions and talked about some of the issues that we're going to have to be dealing

with. We were trying to get everybody thinking about this and feeding back into the process.

And I agree, Dr. Cerqueira, that earlier is better than later. And we do seek and desire, and the Commission does desire and seek feedback. And that was identified in their SRM. So, and I know and appreciate the earlier comments that you all provided to us.

And those, we have those and they are being factored into our process as well. So, that's --

CHAIRMAN CERQUEIRA: So, I think there's agreement. Now, Ralph, what other issues do you have for Paul? Is that it?

MR. LIETO: Well, I think the issues about the costs, that was going to be one of the other points, was that, again, it came from the state versus, the state issues in that the current structure is that the cost of the program from NRC is a fee-based program that, you know, basically you have to assign fees to cover your annual operating budget, okay.

And that, with this shift in the program, okay, there is a concern that how is that program going to be able to be maintained without significantly increasing the cost to NRC-regulated licensees, okay, with that type of structure.

In that there really needs to be a part of

the, or the funding mechanism needs to be a part of the Congressional. A suggestion would be that if you're going to go this way, you need to look at, relook, re-evaluate in the way that you could do the funding.

MR. LOHAUS: That's a, yes, a very good point. And the key for the consideration by Commission in looking at the National Materials Program, because the thought is if you look at this, about 75 percent of the licensees are in agreement states, yet the bulk of the infrastructure work is basically done by NRC.

And part of the concept in the National Materials Program. And it's reflected in the alliance process is that there be a shifting, if you will, a more equitable shifting and shearing of the infrastructure work load by the states in state licensees. And that part of the concept.

But, again, there is a long way to go before that comes out and the question of funding and how you handle that in fees and things like that is a very key issue here because of the --

DR. WILLIAMSON: You still face the issue that you're going to take over a whole bunch of non-agreement states' programs, probably, in this area. And, you know, you have to develop in-house expertise to handle TARs and accelerator expertise and so on, and this

is a concern of ours.

MS. MCBURNEY: You're just trying to make a NARM issue.

CHAIRMAN CERQUEIRA: The NARM issue. We need to keep going, otherwise -- any other questions for Paul?

DR. WILLIAMSON: I mean I think the idea of apple pie and motherhood and so on applying to the existing domain, you know, is one thing, and maybe it will help save some costs. Maybe there is a chance.

But I think, you know, the concern of the committee, as expressed in our last meeting, is you are now introducing a new source of disequilibrium and funds are going to flow in and out.

The states are all strapped for budgets, maybe even more than the federal government, since they can't deficit spend and to sort of expect the states to take on part of this infrastructure load may not be very realistic.

CHAIRMAN CERQUEIRA: Excellent point. Okay, Ralph, anything else for Paul?

MR. LIETO: Thank you, Paul.

MR. LOHAUS: Okay, thank you very much.

CHAIRMAN CERQUEIRA: Thank you. We appreciate you spending your time. All right, so, Ralph,

do you have any other points?

MR. LIETO: No.

CHAIRMAN CERQUEIRA: Ruth, do you want to go next?

MS. MCBURNEY: Mine is on the emerging technologies and issues subcommittee. And basically I'm going to be just talking about the process. And then if we can reach consensus tomorrow on some, and identify some of the issues involved with the three initial licensing guidance input that we have asked to do, then I will bring that up at the briefing.

But, in order to do slides, I could only do what we have done so far, and that's identify the --

DR. WILLIAMSON: We haven't done anything so far. I mean, I'm supposed to be on the subcommittee, I've never gotten a call about a meeting.

MS. MCBURNEY: I sent out an e-mail asking for input early on. I didn't get any, and so we are meeting at this meeting and that's part of tomorrow's agenda.

DR. WILLIAMSON: Okay.

CHAIRMAN CERQUEIRA: Right, right. And there's going to be quite a few items on the agenda from the various interest groups tomorrow, that I think will -- but unfortunately I think it's just going to be, you

know, another turf issue that's going to come up, and I'm not sure how much --

MS. MCBURNEY: On the training experience issue.

CHAIRMAN CERQUEIRA: Right. Right.

DR. NAG: One question on that. Is there, I mean I've heard rumors, a move to get interstitial brachytherapy out of 1,000 and into the regular brachytherapy? And if so, what mechanism? That's one. Number two, what is the mechanism when it's something new coming up, it comes under 1,000, but once it becomes an accepted practice, after two or three or four years, it will have to go under one of the other therapies, what mechanism for that?

CHAIRMAN CERQUEIRA: That's sort of an NRC staff question. I don't, do we have a precedent that something was approved under the 1,000 --

DR. NAG: Well, the 1,000 just came out. So there will be no precedent. But, I mean, you can never, if something is emerging, I mean, you know, something emerges then it becomes a routine.

MR. ESSIG: Well, I suppose you would contemplate a rule making initiative at some point. Either from outside --

DR. HOWE: I think you could look at the

gamma knife and the HDR and you'd see. I think you could look at the gamma knife and the HDR and see that those were new technologies back in the '90s.

They developed to the point where there was enough use and enough licensees needing it, that it became a part of the new Part 35. You're wrong in that there maybe some emerging technologies that never are large enough to require rule making.

There may be some very small things that are emerging technology that may stay in 1,000 forever. Now there may be other technologies that really take off, and it becomes a point where they justify their own particular rules.

And then you would want to go through the rule making process like you did with the gamma knife and the HDR, to bring that guidance into a legitimate --

DR. NAG: I mean in that, I mean, for example, interstitial brachytherapy in 1,000, but if you're using iridium afterloading, that's the same as brachytherapy.

And if you are using a high dose rate for intravascular HDR brachytherapy. So at some point things will have to be moved. Then this is something that I heard over the grapevine that once the intravascular brachytherapy has been moved into brachytherapy, this

just a little more, there is something about that. Does anyone know?

DR. HOWE: At this point, for NRC it's a rumor. We, it was indicated in the Statements of Consideration as a 35.1000 use. And so that's where it is right now with its guidance up on the web site.

CHAIRMAN CERQUEIRA: So, do we want to bring that up before the Commissioners? I'm not sure we have anything --

DR. NAG: If we don't have anything, I wouldn't --

CHAIRMAN CERQUEIRA: Okay, so we agree not to do that. What else, so basically, and what potential could emerge tomorrow from the discussions?

MS. MCBURNEY: If we get some consensus on training experience, for example, for each of those three items. I've got an outline of what I'd like to go over.

DR. WILLIAMSON: Could I ask a question of clarification?

CHAIRMAN CERQUEIRA: Yes.

DR. WILLIAMSON: I think it would be, many of the proposed recommendations make reference to the vendors' product insert and instructions for dosimetry and so on. Could that be made available to us tomorrow so we can have that to refer to you?

Could we get copies of them? Because I think it is going to be very difficult to conduct a technical conversation about these things without that material. We once had it, I think about two years ago, two or three years ago.

I remember seeing the TheraSphere product insert duplicated. But since the, you know, your proposal makes reference to that, we're going to have a tough time if we don't have a copy.

DR. NAG: We've never seen a Sirtex insert. We had seen, there was a small presentation from TheraSphere from, from MDS Norton, but we've never had a presentation from Sirtex.

Which is similar in some ways, but dissimilar in many other ways.

DR. WILLIAMSON: So, we need those materials.

MR. ESSIG: I'd have to ask my staff here. Do we know if we have those?

DR. HOWE: We have some of those materials. Are you talking about everything in 1000 or --

DR. WILLIAMSON: No, no, just the products that are going to be discussed tomorrow.

DR. NAG: The iodine for leocite. The Sirtex.

DR. HOWE: Because tomorrow, at one point or another, we're talking about all the things in 1000.

DR. WILLIAMSON: Well, I think the use, I guess, if you're involved in orchestrating the discussion and you know the proposals make reference to, you know, those vendor supplied materials, I'd say use some judgment in, you know, duplicating what you think would be necessary for us to be able to have an -- because otherwise we're going to be asking, well, you say you recommend what the vendor says to do, and then you'll have to be telling us all about what the vendor said.

MR. ESSIG: I mean, if we have some vendor supplied material, we'd be happy to share it with you. It's just --

DR. WILLIAMSON: Well, you must, because you based your proposed -- I read through the slides and they make references to it that you would endorse certain --

DR. HOWE: In most cases we talk about vendor training because we believe the vendor is the best person to train people on the new device. They know the ins and outs, they want the product to roll out while they have the knowledge base.

But I don't think we talk about following other package inserts, because we're not tied to package inserts. Although we do for, the question came up on how

do you determine if you've got the material into the, you know, you have source material left over, you have material left over at the end and the vendors have come up with some radiation detection devices that they measure certain distance around the four sides of the delivery system, and we allow that to be used.

DR. WILLIAMSON: Here's where your proposed guidance, on Page 2 of 7, for Y-90 microspheres prescribed dose means the total dose documented in the written directive.

And somewhere in here you made reference to how it was specified by the --

DR. NAG: I think the first thing that we are asking is that some of us may have some idea what Sirtex is, what TheraSphere is. And others may have absolutely no idea.

Now we cannot give you any knowledgeable guidance if we have no idea what it is. So if you have any information on what that product is, and I mean, I know all of these, something, they do have a brochure that they have sent out. I have it at home. Just, I mean, give us those handouts.

MS. SCHWARZ: These are the ones that I mentioned here in your slides.

DR. HOWE: A lot of the information we have

is from direct communications with the manufacturers on how their product works, etcetera. And so we don't --

DR. NAG: They didn't give you those handouts? Normally, I think, I get, we are consumers so they send it to us. We have it.

DR. HOWE: We don't necessarily have all the labeling that goes with it. In some cases we have the labeling that was submitted with the premarket approval applications, that have since been updated.

I mean we try to stay current with what they're doing by talking to the manufacturers, but I don't believe we've tied anybody to the package insert. We tie it to the written directive, but that's, that's not the same as a package insert. That's the NRC written directive.

DR. WILLIAMSON: Oh, I understand the difference.

DR. HOWE: Yeah.

DR. NAG: They didn't give you a three or four page thing about what, you know, and what the, and how it is --

DR. HOWE: We have some documentation on that, but we don't necessarily have the most recent stuff that the manufacturer has.

DR. NAG: It doesn't have to be most recent.

It has to be something that says what it is and how, what are the safety problems and how the manufacturer addressed the safety problem. I know they do have that in their handout.

CHAIRMAN CERQUEIRA: So you would like that material tomorrow?

DR. NAG: If you have it.

CHAIRMAN CERQUEIRA: If you can find it.

DR. HOWE: We'll try.

CHAIRMAN CERQUEIRA: If you can get copies, that would be fine. If you can't, I think we can go on. If the manufacturers were here, they probably would have it.

MS. MCBURNEY: For our initial charge for the subcommittee is just limited to the IBB, they Y-90 microspheres and the GliaSite. And part of what I would like to get input from the subcommittee on is the training experience.

What sort of physician training? How much vendor training? If there's to be a team approach, what's the team to be comprised of? Presence and duties of the team members, and the written directive content.

DR. NAG: And what time, what time do we have for the subcommittee to meet? Are we going to meet separately or --

MS. MCBURNEY: It's at the end of tomorrow. It's like from 3:00 --

DR. WILLIAMSON: I think another issue we'll have to take on with all these specialized devices is to what extent is NRC going to step in and, you know, basically, impose upon users the requirement to follow exactly the product insert or the, you know, and so forth.

For example, in intervascular brachytherapy they limited the indications that are allowed under NRC licensing guidance to in-stent restenosis.

DR. HOWE: That was originally. We're now a much broader authorization. It's for intravascular brachytherapy use.

DR. DIAMOND: But we had a guidance document issued, oh, it's been over a year now, that clarified the issue that no longer would it be construed that an off-label use of one of these devices would be considered a misadministration.

So, for example, at our institution, we routinely will go and use vascular brachytherapy for in-stent restenosis in the peripheral arterial system. We've done saphenous vein grafts.

We've done brachycephalic arteries, arterial venous fistulas, the whole works, following that guidance

released over a year ago.

CHAIRMAN CERQUEIRA: Yeah, that's good. But this is going to be on tomorrow's agenda. And you know, it's ten to six, we really kind of need to wrap up the Commissioner's Briefing and not go over all of these points tomorrow.

So that would take, right. And then, you know, we can see what, some of your things, and then it sounds like the SNM is going to be here and so there's going to be quite a bit of a --

MS. MCBURNEY: And ASTRO and some of the others.

DR. WILLIAMSON: Perhaps, it will not be possible for you to make a good outline of slides until after tomorrow. You know, it's very speculative what the major issues would be.

CHAIRMAN CERQUEIRA: And I think you have to be aware that, you know, we want to get them to the Commissioners, but at the same time some of these issues are only going to be discussed today and tomorrow and, okay.

And, Dick, do you want to go over the T and E recommendation.

DR. VETTER: Sure. T and E. The purpose of this was simply to bring the Commission up-to-date on the

ACMUI T and E recommendations. The first thing I want to do is express to them our appreciation for the opportunity to address T and E issues through an ACMUI subcommittee mechanism.

The, Slide 2, Page 2, shows that we still do, we have the old method for becoming an authorized RSO, AMP, nuclear pharmacist or authorized user. It's through the old Subpart J, but this is very temporary.

You know, this was not very prescriptive. Certification by Boards on a list or meeting some specific training requirements. The revised 10 CFR 35.50, was very prescriptive requiring Boards to incorporate into their qualifications very prescriptive training requirements.

ACMUI had a problem with this because it created some unintended consequences. There was only one Board, out of the many Boards in the country, that met these requirements.

None of the others met the requirements which resulted in an increased burden on NRC staff to look at the alternate pathway qualifications for everyone who wanted to become any one of these authorized individuals.

We felt it marginalized Board certification and it undermined and affected industry standard.

Consequently, the ACMUI called this to the Commission's attention in February of '02, appointed a subcommittee that same month who's charge was to develop a proposal establishing Board certification as the default pathway.

DR. WILLIAMSON: But they know all this. So, do we want to spend all this time going over the history? Because they're the ones who have thrown the ball back in our courts now.

DR. VETTER: Well, that's what the, you, let me finish and you can tell me. So far, how much time have I used? Okay, ACMUI subcommittee then held a public meeting, they held two public meetings.

Made recommendations to NRC in August of last year. Options made for October 30th. The Commission made their decision on February 12th. The Commission decided to accept the recommendation of the ACMUI to allow Boards to certify these authorized individuals rather broadly, rather than requiring Boards to incorporate various prescriptive requirements for recognized individuals.

However, the Commission did re-institute, against the ACMUI's recommendation, the preceptor certification. The impact of that decision is that default pathway through professional Boards has been re-established as was currently present in the temporary

Subpart J.

And this will now allow many Boards to certify individuals who will meet the requirements for the various responsibilities in Part 35. However, it does not, it does create the problem relative to preceptor requirements.

What I'd like to say about that is, ACMUI is very happy to work with the NRC staff to resolve satisfactory implementation of it. And that's the end of the story. What did I leave out, that you think I should be --

DR. WILLIAMSON: Well, I think, you know, the residual issues that are of importance is if the preceptor requirement is left in as a Board qualification criteria --

DR. VETTER: I'm not going to say that.

DR. WILLIAMSON: Yeah, but that's a problem. None of the Boards will probably comply with that because they don't require the people who sign off on the diplomates to be authorized users or authorized medical physicists on licenses and so on.

That's a little different kind of world. And so I think to comment that that's one problem we have to resolve. You know, a second problem that was raised is the C-3, the 190, no, the 100, 200 and 300 categories

still mention hours of combined didactic and practical experience with, you know, sort of an outline of what that's supposed to consist of.

And then we have to determine, you know, whether the ABR diagnostic radiology and the various nuclear medicine Boards satisfy that requirement.

So it might be necessary to fine tune these. Maybe we don't want to say that to them. I don't know what's wise and prudent to say to them. But that's the issue. That's what really has to be done. Is we have to really --

CHAIRMAN CERQUEIRA: Let's go back and try to deal with each one of those. Because, you know, the thing with the preceptor statement, we had put in pretty strong recommendations to take that out, but it came back as in there.

And the reason we had put this in, in the beginning, Jeff, was, you know, this whole, we wanted to put some bite into that preceptor statement so that the NRC didn't have to assume the responsibility.

And that's why we put it in originally. And I think the NRC, at this point, is quite willing to let the Board, you know, it's not a competency, it's mastery of the body of knowledge for clinical, which is what we tried to make.

You know, the ABR tried to make and I think Roger's committee, to some extent, was going in that direction. But it seems like what Roger presented today was, you know, a shifting of what this consists of.

DR. WILLIAMSON: He's now in the room.

CHAIRMAN CERQUEIRA: Well, I'm not going to say anything nasty.

DR. WILLIAMSON: The CRM says preceptor requirement has to be there, okay. And the only way to eliminate that as a requirement is to make a pitch to the Commission to change their SRM.

Now, I don't know if that's wise or prudent to go after that because it was a three to two vote. I think maybe to point out that it's a problem and that, you know, we'll accommodate it, you know, probably by rewriting the logic of the rule.

One, you know, there are some other solutions that I think would keep Board certification as an important component.

CHAIRMAN CERQUEIRA: And it wasn't clear to me by how we were going to do that as a result of today's discussion. There was this mention made that we could define it as, you know, this competency was mastery of a body of knowledge that can be --

DR. WILLIAMSON: That's a different issue,

actually. That's a different issue, yes.

DR. NAG: That's a different issue. The word competency versus having mastery --

CHAIRMAN CERQUEIRA: But isn't that in the preceptor statement?

DR. WILLIAMSON: No. That's not in, that's in the purpose of the exam. We specified that one of the required components of a recognized Board certification process is that it has an exam that tests the competency of the x, y, z to, you know, do a, b, c.

So, you know, it was recommended that we have to change that, and it sounds like that can be done without running afoul of the Commission's SRM. But this issue of the preceptor is sort of a hard constraint as far as the staff is concerned.

You know, they can't change that and make that go away. The only people that can make that go away are the Commissioners. So, you know, I think that a --

CHAIRMAN CERQUEIRA: So what do we tell them? We already told them the first time.

DR. WILLIAMSON: Well, I think we tell them that, you know, this could potentially pose a problem, but that we'll look at taking it out of the requirements for Board certification process and sticking it in as an additional requirement at the end, along with the

modality-specific training.

That would be a logic solution. So then --

DR. DIAMOND: So, Jeff, when they ask why, how do you respond?

DR. VETTER: I would recommend we not propose any specific mechanism for taking care of that at the Commissioner level. That we simply say we are happy to work with the staff to accommodate that. And leave it wide open.

CHAIRMAN CERQUEIRA: Given their short time line of July 1st, of getting it back to the Commissioners and, you know, that puts a certain amount of motivation to get it done.

DR. WILLIAMSON: Well, you see, I think it's an issue of strategy. If we felt that this would destroy the proposal. Okay, to have the preceptor requirement would mean that no Boards could qualify as being recognized by NRC.

We'd be back where we started, wouldn't we? But, I think maybe there are some possibilities.

MS. MCBURNEY: Are most, are most Program Directors not authorized users?

DR. EGGLI: Most Program Directors are not authorized users.

CHAIRMAN CERQUEIRA: Right. Certainly

that's true in cardiology.

DR. EGGLI: For diagnostic radiology residence use, most Program Directors are not authorized users. For diagnostic radiology residency it would be rare for the Program Director to be an authorized user.

For a nuclear medicine residency, it would be very likely that the Program Director was an authorized user.

DR. NAG: In therapy they could be or --

DR. EGGLI: Or could not be, yeah.

CHAIRMAN CERQUEIRA: Right. So what do we want Richard to say to them?

DR. WILLIAMSON: Well, that's why I'm bringing the issue because what we say to them really depends on our perception of how we can accommodate this requirement without destroying the integrity of Board certification.'

That's why I'm bringing it to your attention.

CHAIRMAN CERQUEIRA: So how do we do that, Tom?

DR. NAG: I think we can --

CHAIRMAN CERQUEIRA: No, let's get from Tom. Tom, how do we do that? Based on your, you know, intimate contact with the --

DR. WILLIAMSON: Okay, I think that Rich, that Dick should have a phone conference, a telephone conversation with Roger or whoever and determine whether it's feasible to, you know --

CHAIRMAN CERQUEIRA: Roger is right here.

DR. WILLIAMSON: -- yeah, to stick this outside of the Board qualification section.

CHAIRMAN CERQUEIRA: Roger, why don't you come forward while we have you here.

DR. BROSEUS: Well, be nice to me.

DR. WILLIAMSON: You know, anything that's really, really, yeah.

DR. BROSEUS: -- a couple of weeks ago, she said be prepared to duck. And I didn't understand what he meant.

DR. VETTER: At least he didn't say "die".

CHAIRMAN CERQUEIRA: So what strategy do we take? I mean, with the issue of, you know, the preceptor?

DR. BROSEUS: Let me tell you where the working group is right now. First of all, to interpret in the supplementary information, the meaning of competency as being training and not being clinical competency.

Okay, that's number one. Now number two, the way we read things, in the SRM and so on, is the

Commission said don't change the preceptor statement and certification by an authorized user is basically a requirement as we read this.

So, what are the alternatives? That's what I hear being discussed. One alternative might be, you know, once this rule goes out, it isn't decided. It's at the proposed rule stage, and so there are other alternatives during the proposed rule stage, for comments to come in, you know.

And if the staff sees good arguments. I'm speaking now for myself as the working team member, not having had this good before management, but I think that this is a fairly valid statement.

If we see good reasoning coming in, maybe even as a result of our discussions with Dick and so on and you, you know, we may put that into the supplementary information or the discussions of where we are with getting to the proposed rule. So I think there are several ways to skin the cat.

DR. DIAMOND: Like what?

DR. BROSEUS: Like what I just said, and I guess I wasn't clear. And that being that --

DR. WILLIAMSON: What's supplementary information?

DR. BROSEUS: Well, we'll have, there will

be, there will be, I'll call preamble, front matter before the proposed rule language, which is the discussion of how, the rationale for the what the proposed is.

And if we get additional information at this point, I think it might be possible to say at the proposed rule stage that ACMUI or others have said, you know, a Program Director might be the more appropriate person to do this certification.

And so offer that as an alternative. Offer it for public comment, and possibly go to the Commission with that. That's my understanding of the rule making process.

DR. NAG: Why can't we do that now? Why can't we go to the Commission now and say, you know, the discussion here has led to the suggestion that the Program Director is the most appropriate person? I mean we have already made those comments.

DR. BROSEUS: I would expect that there is certainly an alternative, but things move slowly. You also have new Commissioners, so the makeup of the Commission isn't the same.

MR. LIETO: Can I make just a couple of points. And this also refers to one of Dick's slides also. Preceptors don't certify, okay. And I thought we

kind of had that, made that point. So, I mean, again, I don't know if it's an old terminology that kind of has come back or whatever, because this was like in the proposed comments where, that this issue, this specific issue came up.

Preceptors don't certify, okay. I mean they never can and they never will. So, again, it may be semantics, but it gets to this whole issue also about the competency issue too, okay.

That, I think that, and I would like to again make the recommendation, that competency go into like a definition to Part 35, okay. I know that they're talking about putting it in the preceptor statement, okay.

The preceptor statements can change from one administration to the next. And I think that it really needs to go in the definition of the rule, as to what they are testing the competency of.

Okay, which is the issue that you've already covered.

CHAIRMAN CERQUEIRA: I'm totally confused on this now. I thought I understood it, you know.

DR. BROSEUS: I've heard two different issues. One is what does competency mean, and the other one is, does it have to be signed by an authorized user

or can it be a Program Director?

DR. WILLIAMSON: Those are the two issues, but is there enough wiggle room in what the Commission said in their SRM that competency can be redefined as mastery of knowledge and body of skill?

DR. BROSEUS: Not anymore.

CHAIRMAN CERQUEIRA: See, it was my understanding that the competency thing was strictly in the preceptor statement. Now Jeff is telling me that that's been put back into the Board. And I, you know, and again, this thing is hard to read.

You know, first off, the pages are flipped and everything else, but, you know, if I'm confused, and I'm the Chairman, and I, you know.

DR. BROSEUS: I don't blame you for being confused, there's a lot --

CHAIRMAN CERQUEIRA: Well, no, no, no, no, no. But thing is, I thought we were on track. I mean those of us who have been involved in the process, there was a certain logic and flow to things. And I thought that was included in Dick's proposal. But now it's just kind of come out all --

DR. BROSEUS: We have identified really a third issue. And that is that -- sorry, I'm not close enough to the mic, thank you. As I understand it, that

ACMUI's intent was not to have a preceptor statement as part of the qualifications, the criteria for recognizing a Board certification process.

CHAIRMAN CERQUEIRA: I thought that was in the revision of Part 35, and did we take it out completely from your, the original?

DR. WILLIAMSON: No, no. We put it back in as a Program Director's testament.

CHAIRMAN CERQUEIRA: Right, and then it was sent back to us as, you know, as you need it to certify competency.

DR. WILLIAMSON: That's correct.

CHAIRMAN CERQUEIRA: But that was in the preceptor statement.

DR. WILLIAMSON: Yeah, well, I think that there were, you know, multiple issues here. If you look at, for example, the physicist one here. I'm trying to find it, on what page it is.

DR. EGGLI: Well, should I read Commissioner Meserve's comment in that regard?

DR. WILLIAMSON: Well, let me just find the section here under authorized medical physicist. Okay, it says --

CHAIRMAN CERQUEIRA: See, but this applies to the health, you know, to the medical physicist, to the

authorized user.

DR. WILLIAMSON: Here. Passes an examination administered by diplomates of the specialty Board which assess knowledge and competency in clinical radiation oncology.

And so this was the concern that this is not what the ABR and other organizations bill their exams as about. So, you know, I think a third issue, if you want to call it that, is to strike the competency word out of the section describing the Board examination, because otherwise it's making the Board squeamish about --

DR. BROSEUS: Is that in the, I don't have the stuff --

DR. WILLIAMSON: This is in your draft rule text, and it was in our draft rule text as well. So this is a correction. I would have thought maybe this is relatively minor since, you know, perhaps the Commission didn't pick on this particular point.

DR. BROSEUS: Well, in my reading, if it's in what the exam does, that's certainly within the purview of ACMUI to change its mind.

DR. WILLIAMSON: Okay, so we can fix that.

CHAIRMAN CERQUEIRA: So we can recommend that instead of competency, as documented by being a diplomate or passing the Board, that that be changed to

represent mastery of a body of knowledge sufficient to, you know, in a clinical setting, which is what I think Dr. Hendee had said.

So is everybody in agreement with that?

DR. WILLIAMSON: I think so.

CHAIRMAN CERQUEIRA: And that's, again, that's passing the Board. Now, just in terms of the Boards alone, what are we doing about hours? Did the Commissioners, were they willing to take that out?

Because I thought, I thought your proposal that went through, certainly for the user, had hours. It does.

DR. VETTER: That is not our proposal. That's --

DR. EGGLI: No, but is the final revision.

CHAIRMAN CERQUEIRA: You know, I mean, so --

MS. SCHWARZ: In the book there is a section where the actual original that you compiled. In the book that we received there is the listing as Dick wrote it. But this is different.

DR. BROSEUS: Well, first of all, my reading of that recommendation were for a certain pathways to reference what was in the oral --

DR. WILLIAMSON: And we did that, that's correct.

DR. BROSEUS: And that included hours.

DR. WILLIAMSON: That's right. It did.

CHAIRMAN CERQUEIRA: But the hours were included as part of the alternative pathway.

DR. WILLIAMSON: No, that's not correct, Manny. No, no, no, no. For 100, 200 and 300 we left in, I think, 700 hours or whatever. Some number of hours. And we said, we didn't specify the breakdown between didactic and practical, but we said it had to be didactic plus practical and enumerated the various things it must include and this was just lifted out of Subpart J.

DR. BROSEUS: Now let me add something to that. My understanding of what training programs somebody has to go through, being at 700 hours is duck soup.

DR. WILLIAMSON: Yeah.

DR. BROSEUS: And so to me, since it doesn't specify it has to 40 hours, 60 hours there, and so on, it's not a big deal.

DR. WILLIAMSON: So, anyway, I think that this requires some discussion with the ABR to find out, you know, if this is reasonable. But I would have thought --

CHAIRMAN CERQUEIRA: Well, but the ABR is not the only Board. We have, you know, for the

physicists we have Boards, for the physicians and for the health physicists.

DR. WILLIAMSON: Well, this only applies to 100, 200, 300, for the physics Boards, for the Radiation Safety Officer and for the authorized user of sealed sources, we eliminated the hours all together. That is true.

MEMBER BROSEUS: I would recommend that this particular issue be kind of tabled a little bit and be discussed again when we're looking at fine-tuning the words when we have our discussion later on.

CHAIRMAN CERQUEIRA: But if this is due July 1st, we don't have that much time. And if we have to meet with the commissioners next week, we have to make some decision on what we feel the important points are going to be so that Dick can make his slides.

Mike has been waiting.

MR. MARKLEY: I think I have an approach that you might want to consider. There at the draft rule stage, if you have continuing concerns, it would be very easy to itemize what those are.

And I think a good point that you could deliver to the Commission would be, "We would like the staff to explicitly solicit public comments on these issues during the comment period." You could provide

them in the Federal Register notice and ask for that kind of feedback.

CHAIRMAN CERQUEIRA: But, see, part of the reason to move this forward was that we implemented a rule which becomes in all the agreement states in October 2005. We then put in this ability for people to meet the criteria by both the new rule as well as the old part 35.

And so in order to avoid in October of 2005 potential problems, we wanted to get this revision of training and experience rulemaking done in time to be implemented.

In order to do that, we had to keep it on track. And if we wait for public comments and everything else, we're not going to be able to do that. That may be the only option we have, but if that's the case, we have to agree on that.

What I would like to try to do is salvage it in some way possible if we can work with Roger and his group to wordsmith the language so that everybody is in agreement, but then we also need to make a presentation to the commissioners to try to get their buy in as much as possible. And that's on the 28th.

So those are the issues as I see it. Now, if we can address those, then I think we can be done.

MEMBER BROSEUS: Just let me add that during

the board presentations this morning, our discussions, I don't think this issue coming up was a concern.

MEMBER WILLIAMSON: It was point number one of Dr. Hendee's.

CHAIRMAN CERQUEIRA: To take out the hours. He was confused about it.

MEMBER WILLIAMSON: No. We were confused in our answer. There are hours in some of our --

CHAIRMAN CERQUEIRA: There are.

MEMBER WILLIAMSON: Yes. And we said there weren't.

CHAIRMAN CERQUEIRA: Yes, there are.

MEMBER VETTER: As the alternative pathway and for --

MEMBER WILLIAMSON: No, no. That's not true.

CHAIRMAN CERQUEIRA: But doesn't it say that the board has as its requirements the hourly requirements --

MEMBER WILLIAMSON: It does. So read what we --

CHAIRMAN CERQUEIRA: So it's still tied into it.

MEMBER BROSEUS: I think that Dr. Hendee, though, expressed agreement with the approach that we

were taking in the end.

CHAIRMAN CERQUEIRA: But he was the only one who made a presentation. He's one board. All right? And I represent the physicians. We have the physicists. Well, we don't have the physicists. We have the radiation safety officer.

MEMBER BROSEUS: Well, we had all of them --

CHAIRMAN CERQUEIRA: Right.

MEMBER NAG: Dr. Hendee made that on the basis that no hours --

MEMBER WILLIAMSON: We were mistaken.

MEMBER BROSEUS: We clarified in our meeting this morning, the meeting of the boards, that there were some sections in part 35 --

CHAIRMAN CERQUEIRA: You've told him correctly. We mislead him. Okay? But that's not an issue. The issue was, what does this Committee want to do. You know, I think we had kept the hours in. Do we want to just take them out and say that the --

MEMBER WILLIAMSON: Manny, could I just rephrase your question a little bit?

CHAIRMAN CERQUEIRA: Okay.

MEMBER WILLIAMSON: We don't need to decide what to take out or keep in at this point. I think the key decision we have to make is what questions require

commissioner input.

So if this is a small change that we could make in fine-tuning the rule language that doesn't run afoul of the main points of their SRM, we can just do it and we don't have to make a big deal next week. But I think the --

CHAIRMAN CERQUEIRA: But the problem is we are not sure if that is the case.

MEMBER WILLIAMSON: No, we're not.

MEMBER BROSEUS: And I'm not either.

MEMBER WILLIAMSON: Yes. So I think we'd better just mention it as an issue and not make a big deal about it.

MEMBER BROSEUS: At the same time, this gives us an opportunity to put the right spin on it before the commissioners that eventually have to buy it off. So it is an opportunity for us. And that's why --

MR. ESSIG: I wanted to come back to what you got from the Office of the Secretary emphasized in two places where it says ACMUI should provide some positive recommendations how the Committee feels it can assist the NRC staff.

In another place, it says, "How can the ACMUI help the NRC?" I think if you raised this particular issue, saying, you know, you respect the

Commission's decision, and so it's caused us to have to do some things. And here's how we're going to help the staff make those things happen.

And so just present it in a way so the Commission clearly sees that you intend to make a contribution to help the staff; in other words, to provide the advice that the Committee is supposed to provide.

CHAIRMAN CERQUEIRA: But we should give them some indication of the direction we want it to go. I mean, that's putting a spin on it.

MEMBER WILLIAMSON: I think one issue is fairly clear that we can put a spin on it, and that's I think that we have to say, I think, that it's still our view that the issue of whether the person in the board certification process attesting to the candidate's readiness to sit for the exam has to be decoupled from this concept of preceptor as an authorized user or authorized medical physicist because that is not practical given the way these programs are structured.

It will be back at square one if we can't fix this. So we will work with -- the subcommittee will continue working with the staff to figure out how to preserve the integrity of the board certification structure in this process and try to take this into

account. That's the best we can say.

MEMBER BROSEUS: Is that coupling necessary for anything other than authorized users, like AMPs or ANPs?

CHAIRMAN CERQUEIRA: That's how we got into this problem in the first place, was because most of the medical physicist programs, people didn't have to take all the requirements. I mean, they could dabble in one area or another. And we wanted to try to make it more specific.

MEMBER WILLIAMSON: The problem is that the boards do not require that the individuals attesting to the candidates' knowledge base or whatever, completion of the training program, whatever word is appropriate, need not comply with this additional requirement.

CHAIRMAN CERQUEIRA: So this side of the table has been fairly quiet. I mean, Ralph, how do we get out of this? What are we going to --

MEMBER WILLIAMSON: I don't think we know yet. I think we just --

MEMBER LIETO: I have already done my swimming with a lead preserver here. Really, I think that the way that Dick was going with stating that we need to work with staff to address the preceptor stage and now maybe we also need to simply add that we need to

work with staff to address about the competency issue and just --

CHAIRMAN CERQUEIRA: So that's easy. Working with staff is just one of these general things. But we've got to give them so spin. Okay? Go ahead.

MEMBER LIETO: But I was going to say I am not too sure that you can totally get rid of the hours issue because for authorized users in the diagnostic modalities, especially, I believe, in cardiology, that's how a lot of them become authorized users. So we've got to be a little careful there.

With just that sort of in the back of our minds, I am still kind of sitting on the fence as to whether we really need to give them a spin. I don't know. There's still an issue. We need to come back to it. It may be coming back to you again. And we are all in agreement that we need to work on it, both staff --

CHAIRMAN CERQUEIRA: Authorized users.

MR. ESSIG: Well, Bob Ayres --

CHAIRMAN CERQUEIRA: Leon?

MEMBER MALMUD: I must say you lost me a long time ago. Now, what issue are we talking about? Are we talking about the certification for medical physicist or are we talking about physicist plus radiologist plus physician?

MEMBER NAG: Authorized users.

MEMBER MALMUD: Now, why are we grouping them all together? Why is a physicist the same as a physician the same as a radiotherapist the same as a nuclear physician? They are different. So why are we making one set of rules for everybody?

MEMBER NAG: There are different sets of rules.

MEMBER MALMUD: I beg your pardon?

MEMBER NAG: Each of them has different --

MEMBER MALMUD: I agree. I agree. All right. I'm just asking a question.

Now, Dr. Hendee said he had four issues, and he presented to us four issues. Those were his issues, meaning the American Board of Radiology's issues.

Is there anyone here at this table who thinks that the Nuclear Regulatory Commission is going to decommission the American boards of medical specialties? Does anyone think they're going to be that crazy and have every congressman in the United States going down the throat of the NRC? Do you think that your board is going to be decertified or my board or your board? Of course not. That's not the intent of the NRC to do that. They're not suicidal.

MEMBER WILLIAMSON: I wouldn't be so sure

about that.

MEMBER MALMUD: Oh, I think, listen, we are all rational beings. And these gentlemen who are a part of the NRC are as smart as we are, if not smarter. They're not going to do something like that. No one wants to do anything like that.

So Dr. Hendee's question really touched on something that we should be addressing. He said, is the board certification adequate or must there be an alternatively specified number of hours of training?

Now, as far as I know, no one has challenged the board certification. Is the NRC challenging existing board certifications --

MEMBER WILLIAMSON: Yes.

MEMBER MALMUD: -- or the ability of the boards to certify?

MEMBER WILLIAMSON: Yes.

MEMBER MALMUD: You say yes. I'm asking the NRC subcommittee.

MEMBER BROSEUS: The NRC has set criteria by which the adequacy of certifications can be judged.

CHAIRMAN CERQUEIRA: On radiation safety --

MEMBER BROSEUS: Yes, radiation safety.

CHAIRMAN CERQUEIRA: -- alone, not clinical competency or all the other things, --

MEMBER BROSEUS: Yes, radiation safety.

CHAIRMAN CERQUEIRA: -- that's the NRC's only concern, to make certain that if you're a radiologist, nuclear medicine physician, cardiologist, or medical physicist, you have picked up enough knowledge to be able to practice in a safe manner. Whether it's competent or not is not the issue.

MEMBER MALMUD: But the number of hours that they have required was 200 to 700. What was the number of hours? Does anybody remember the number?

CHAIRMAN CERQUEIRA: Training and experience was either 700 or 1,200 hours depending on whether you took it as a concurrent or whether it was simultaneous for the 500 hours lots.

MEMBER MALMUD: But that's training and experience. It doesn't say training and experience in medical physics, does it?

CHAIRMAN CERQUEIRA: That was really up to the authorized user, alternative pathway. I don't know for the physicists.

MEMBER MALMUD: We haven't gotten --

MEMBER VETTER: Seven hundred hours. Seven hundred hours total in categories of radiation physics and instrumentation, radiation protection, mathematics for training, use, and measurement of radioactivity,

chemistry, radiation biology.

MEMBER MALMUD: The minimum length of any board is 3 years, which is 6,000 hours. Two thousand hours a year times three is 6,000. So 700 hours in the 6,000 revolved --

MEMBER NAG: No, no, no. They are saying in medical physics and this. The board has a problem in certifying that we have given you 500 or 700 hours of this basic thing. It includes a lot of other things.

MEMBER MALMUD: I think you said math in there as well, did you not?

MEMBER WILLIAMSON: Leon, the case is that the currently published training and experience requirements, basically all the boards were judged. The only one that passed muster was the American Board of Nuclear Cardiology. All the other boards, every single one fell short and was rejected.

MEMBER MALMUD: That's because the American Board of Nuclear Cardiology was designed specifically to meet the criteria that they anticipated might be imposed.

MEMBER WILLIAMSON: Correct.

MEMBER MALMUD: That did not decertify all of the other boards. If it did, then tomorrow there will be no one practicing any kind of radiology or radiation physics.

MEMBER WILLIAMSON: What do you mean by "decertify"?

MEMBER NAG: No, no. There are two different issues. One is your ability to practice medicine in the subspecialty of radiation oncology. The other is your ability to be an authorized user by the board certification pathway.

MEMBER WILLIAMSON: Okay.

MEMBER NAG: Those are two different things.

MEMBER MALMUD: No one is challenging one's ability to practice, only to be the authorized user?

MEMBER WILLIAMSON: That's correct.

MEMBER NAG: Authorized user using the board certification pathway.

MEMBER MALMUD: As a means or an alternative --

CHAIRMAN CERQUEIRA: Or a radiation safety officer or medical physicist.

MEMBER WILLIAMSON: That's correct.

MEMBER MALMUD: Or an alternate number of hours in lieu of board certification.

MEMBER NAG: No. It might require all that number of hours. That is why the board gave certified --

MEMBER BROSEUS: While we're talking about hours, ACMUI didn't write their draft for some areas as

requiring hours. It's only certain ones.

MEMBER WILLIAMSON: Yes, that's right.

MEMBER BROSEUS: So it's irrelevant when we're talking about RSOs. And I can't remember everything.

MEMBER MALMUD: What's irrelevant? I'm sorry. I didn't hear you.

MEMBER BROSEUS: The hours issue is irrelevant for RSOs and other categories. It's only relevant, really, as I recall, for authorized users, user categories. Okay? So it's not an issue except in that area.

MEMBER MALMUD: So it only relates to the ability to be an authorized user?

MEMBER BROSEUS: As I recall.

MEMBER MALMUD: It does not relate to training --

MEMBER BROSEUS: Well, I came in here to sit --

CHAIRMAN CERQUEIRA: But it does because I know the radiochemists are a group that we haven't talked about. And they had like a 700-hour requirement.

MEMBER McBURNEY: Sally knows.

MEMBER MALMUD: You mean they have a training requirement in their own program?

CHAIRMAN CERQUEIRA: Right.

MEMBER MALMUD: Well, that's okay. No one has imposed it upon them. They have decided to do it themselves. So do I understand, therefore, that the question is just the number of hours required to be an authorized user? It has nothing to do with board certification except that board certification is the means to become an authorized user if you have the requisite number of hours?

CHAIRMAN CERQUEIRA: Again, the certification group of cardiology applied, met the criteria, and they had hours that were put in there.

MEMBER MALMUD: How many hours are put into nuclear cardiology requirements?

CHAIRMAN CERQUEIRA: Seven hundred.

MEMBER MALMUD: Seven hundred? Over how many years?

CHAIRMAN CERQUEIRA: A three-year training program.

MEMBER MALMUD: Three.

MEMBER VETTER: I think we are diverging. I would like to suggest -- and you can all send me hate mail if you don't like this. I would like to suggest that what I will tell the Commission, I will try to keep this in broad terms, but what I will report to the

Commission is that we are happy with their response reestablishing professional boards as the default pathway. We will accept the fact that boards will be listed on the Web site.

The preceptor attestation -- I'll change that word -- attestation is something that we originally that we did not recommend be included in the process for board certification, but we will on that issue work with NRC staff to resolve that issue.

And relative to -- let's see. Relative to the issue of preceptor, well, that's all I'll say about it because that involves a couple of issues. One is the board side, and the other is whether it's authorized user or program director. I think we can work with the staff on that as well.

MEMBER NAG: The other question, do you want to say anything about having a body of knowledge?

MEMBER VETTER: No.

CHAIRMAN CERQUEIRA: What was the word you used?

MEMBER VETTER: Attestation, preceptor attestation.

CHAIRMAN CERQUEIRA: Yes. I think, look, we're not going to come to any conclusions. To go forward with the right recommendations and the right

spin, we will have to work with the staff. And I think that is a very good political compromise.

I'm sure the commissioners may have some questions that they want to bring up.

MEMBER McBURNEY: I think that we'll have questions.

MR. ESSIG: One of the purposes of submitting the slides in advance is because they review them, they have their staffs review them, and it helps prepare the commissioner for when they sit down at the table, then they have some questions in advance on their presentation. So that's why we have talked about getting --

MEMBER WILLIAMSON: So I think a really, really --

CHAIRMAN CERQUEIRA: No, no, no. Dick, go ahead.

MEMBER VETTER: One more question. A comment was made about all of this history. Should I pare that down?

CHAIRMAN CERQUEIRA: Yes, yes. You know, again, you've got like ten minutes. So if you do like a three or four-minute presentation at most, which that will give enough time for questions for issues that they feel are important.

And, again, I think as a result of tomorrow's discussions, we will know a little bit better what to do with some of these things, I guess, although that is only going to deal with the one --

MEMBER MALMUD: I'd give history as a document but not actually present it because I thought it was very lucid.

MEMBER VETTER: We could do that as backup slides.

MEMBER MALMUD: Yes.

MEMBER VETTER: Right. Okay.

CHAIRMAN CERQUEIRA: Excellent.

MEMBER WILLIAMSON: Although they poked fun of my extensive backup slides once when I did that.

CHAIRMAN CERQUEIRA: We've come around to your way of thinking on this.

MEMBER WILLIAMSON: I think in general, a very careful review of that SRM and the residual issues, just identifying them, that we think are important and pointing out the issues and, as Dick said, we'll work with the staff to try to resolve them. And I think mainly that is what they would like to hear, probably our response to their SRM. They have thrown the ball in our court now.

MEMBER VETTER: I think so.

CHAIRMAN CERQUEIRA: And we talked about it during the open meeting, but what I would like to do is maybe Dick -- were you involved in the therapy writing or was that David Diamond?

MEMBER WILLIAMSON: I wrote most of the therapy ones.

CHAIRMAN CERQUEIRA: All right. So maybe the two of you and I could talk to Roger and sort of try to -- because we're still all a little confused. We need to go back, look at the material, talk to Roger and his group to sort of give them some advice.

And then we're going to have this meeting or conference call of the subcommittee. Hopefully by that time, a lot of these things will be worked out because that has to be an announced public meeting, which means it is going to be in two weeks, the soonest.

And then hopefully from that, we will be able to get a recommendation or an agreement with staff and the subcommittee which we can then send out to the full ACMUI Committee with the hope and intention of trying to meet the July 1st deadline. Right?

MEMBER BROSEUS: The idea was to reconcile what we could and distribute to the agreement states and to the ACMUI Committee.

CHAIRMAN CERQUEIRA: And to the Committee.

That's fine. That's great. Excellent. I would like to thank everybody --

MR. ESSIG: Could I mention one quick item while we are still in the closed session, which is the comment earlier or, actually, the presentation from SNM on the therapy guide.

We have no plans. The NRC staff has no plans to review that. We have been asked to review it. We do not plan to review it. Meaning no disrespect to anyone in the room, but the SNM part of the therapy scene is a pretty kind of minority player.

CHAIRMAN CERQUEIRA: Yes. That's why I brought it up.

MR. ESSIG: So we have just finished NUREG-1556, Volume 9. The ink is sort of dry on it. Why would we undertake a review of some other guidance that is more or less contained in -- people may not like the way it is worded and all, but I just wanted to make that point clear.

Neither are we going to ask you as a group to undertake a review. If you are doing a review, it's --

MEMBER LIETO: I would definitely support that, that stance, Tom. I just kind of opened a couple of pages. There were some things that said, "Well, you

should do this." I think for actual regulations, it said, "You must."

So if that is the kind of guidance that we may be running into, it may be more extensive than what we have time to do, especially if they're only giving us three weeks to give them a response, which I think is a little --

MR. ESSIG: And we also made reference today to the regulatory issues summary, where we stated that the SNM diagnostic was -- I don't want to say we endorsed, but we said it was an acceptable way. So you can read what we said about it.

CHAIRMAN CERQUEIRA: But you have to be careful whether your name is going to be linked to it. That's why I kept bringing up all these issues of, you know, your support. And you're going to assume some liability.

It is something that's out there, but unless it's really been reviewed extensively by the NRC --

MR. ESSIG: All we say is one key sentence, "The SNM's guide for diagnostic nuclear medicine provides information that may be useful to nuclear medicine professionals in understanding the applicability of NRC requirements for medical use of -- in diagnostic settings." That's part --

CHAIRMAN CERQUEIRA: And is the NRC still going to be on all of this?

MR. ESSIG: I'll pass it out so you can see --

MEMBER LIETO: Will the NRC seal be on the document?

MR. ESSIG: No, no, no.

MEMBER WILLIAMSON: I am sure your lawyers have looked at it.

MEMBER LIETO: The fact that you basically made it readily available through your Web site, whether you like it or not, you are endorsing it.

MEMBER NAG: Implied perception.

MR. ESSIG: But the RIS is also on the Web site, right next to the --

MEMBER BROSEUS: Let me just add one thing. We've gone through a crazy process to get the paper by and available. There's going to be a disclaimer on the inside cover of the document that's distributed in paper form. Okay?

CHAIRMAN CERQUEIRA: It may not be an endorsement, but if your name is on there, whether you intend it to or not, it's implied that you support this.

MEMBER WILLIAMSON: You must feel fairly comfortable with the procedures suggested within and --

MEMBER BROSEUS: Let me tell you just very quickly what we did do. The staff did review the document. And we looked closely to make sure that it was congruent with the rule and true to the rule. Okay? We didn't want somebody passing out bad guidance that the SNM says, you know, we weren't cooperative at all.

CHAIRMAN CERQUEIRA: Jeff does a good job, and he knows what he's doing. But Ralph said he went over through some of the therapeutic things and he had some questions and reservations. But Jeff wrote both of them, essentially.

MEMBER WILLIAMSON: So if you did it for diagnostic, why wouldn't you want to do it for therapeutic? Why wouldn't it be --

CHAIRMAN CERQUEIRA: Because of the risk involved.

MR. ESSIG: First of all, I think we considered the diagnostic procedures to be pretty low-risk. And so even if --

CHAIRMAN CERQUEIRA: Can we get that on record, low-risk?

MR. ESSIG: It's on the record because I -- no. I think it's primarily a resource issue that -- for us to review something where we have just promulgated guidance, NUREG 1556, Volume 9. And now to undertake --

we just don't have the resources to do a review of some additional guidance.

CHAIRMAN CERQUEIRA: But why not let it go out under SNM's --

MR. ESSIG: I can't control. I mean, they're going to issue it, a list of questions.

CHAIRMAN CERQUEIRA: Well, the diagnostics are already too late. It's on your Web site.

MR. ESSIG: Yes, yes.

CHAIRMAN CERQUEIRA: That would have been a more prudent way to go about it.

DR. HOWE: Before you leave, I have an issue that we had hoped to get in if we had time in the closed session. And that is we have a medical physicist that we were looking to bring before you at the board, here at the Advisory Committee.

It's clear you don't have time for it, but I just wanted to make you aware that we may have three or four more. And we may be sending them out to you for a decision on whether their training and experience is equivalent to what is in the requirements.

CHAIRMAN CERQUEIRA: Now, is that something that just goes to individuals on the Committee? Does it go to the whole Committee for a vote?

DR. HOWE: We've done it both ways before.

We've done it to the whole Committee or in some cases, the chairman has set up a subcommittee of people that have experience in that particular area and gotten their input and then written us back a memo that says that it was reviewed by a subcommittee.

MEMBER NAG: My suggestion is that the therapy -- you know, Diamond and I --

CHAIRMAN CERQUEIRA: Maybe include one or two --

MEMBER NAG: But here it was the physicists. So I think the physicist in the group should be the one deciding. I would have no idea.

DR. HOWE: And we've got I think maybe three or four physicists that are going to be in this category.

MEMBER WILLIAMSON: That come from the Canadian?

DR. HOWE: We've got two from the Canadian certification. We've got some others in other categories. So if we can't make a clear determination, we think it's wise to bring it.

MEMBER WILLIAMSON: By the time I read it, I was gone. And I didn't have access to the Web site. So I couldn't download information about the Canadian College of Medical Physics so we would know. That was not included in the package, and I would --

DR. HOWE: Right. I have a printout. I went out on the Web this morning, and I printed some of that out. And so I'll try to get you a copy of that.

CHAIRMAN CERQUEIRA: So, Jeff, Ralph, and Vic, do you guys want to review it?

MEMBER WILLIAMSON: We can do that.

CHAIRMAN CERQUEIRA: That will be good.

MEMBER WILLIAMSON: We can just send you a memo on this or --

CHAIRMAN CERQUEIRA: Yes. Just send me a recommendation. And I will pretty much go with your recommendation.

MEMBER LIETO: Because I think they are looking at meeting someone for our transit because they're losing their --

DR. HOWE: It ends up that they're covered now. They've got an interim physicist that is leaving tomorrow for something. And then they have another physicist that is qualified that they can use as an authorized medical physicist.

They're covered right now. They still want to use this person eventually as their authorized --

MEMBER WILLIAMSON: Maybe we can deal with it in --

CHAIRMAN CERQUEIRA: Yes. Why don't you

deal with the details?

MEMBER WILLIAMSON: I guess I will schedule a conference call on this issue.

CHAIRMAN CERQUEIRA: Yes, yes.

MEMBER WILLIAMSON: Do we need a staff attending this conference call?

DR. HOWE: I could probably answer questions that you might have.

CHAIRMAN CERQUEIRA: That might be good.

I would like to end this session, but I would personally like to thank Charles Miller for having sat through the entire session. This is the first time.

(Applause.)

CHAIRMAN CERQUEIRA: Usually his predecessors made a token appearance and then were gone.

MEMBER WILLIAMSON: Thirty minutes. So this is great.

CHAIRMAN CERQUEIRA: Thank you.

DR. MILLER: One of the things I am trying to do is to assess what the Committee is about, what the Committee does, how they service, the concerns that you have.

I heard a lot of things today that I think the staff needs to work on with regard to its relationship with the Committee. And that is something

that I need to undertake as a director of this division with my staff to try to improve that.

I can't promise that we'll make a step change and get it all perfect, but I think hopefully we can progress in the right direction and improve the communications because lots of what I heard today had to do with communications between the Committee and the staff or lack thereof, yes. And if we can work on that, then I think we can help you to do your job in helping us.

CHAIRMAN CERQUEIRA: We want to work with you. Thank you. We are adjourned.

(Whereupon, at 6:45 p.m., the foregoing matter was adjourned.)

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