Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Tuesday, June 12, 2007

Work Order No.: NRC-1614 Pages 1-325

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

MEETING

+ + + + +

Tuesday, June 12, 2007

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The meeting came to order at 8:00 a.m. in room T2B3 of Two White Flint North, Rockville, Maryland, Leon S. Malmud, MD, Chair, Presiding.

MEMBERS PRESENT:

Leon S. Malmud, MD - Chairman

William Van Decker, MD

Douglas F. Eggli, MD

Ralph P. Lieto

Subir Nag, MD

Sally W. Schwarz

Orhan H. Suleiman, PhD

Jeffrey Williamson, PhD

James Welsh, MD

Darrell Fisher, PhD

Debbie Gilley

NRC STAFF PRESENT:

Scott Moore

Sandra Wastler, Designated Federal Officer

Andrew Mauer

Duane White

Angela McIntosh

Cindy Flannery. Alternate Federal Officer

Ashley Tull

Theron Brown

Lydia Chang

Donna-Beth Howe

Patricia Rathbun

Ron Zelac

Ed Lohr

ALSO PRESENT:

Lynne Fairobent
Richard Morin
Phil Alderson
Terence Beven
Melissa Martin
Herb Mower
Kent Lambert
Henry Royal
Ram Bhat (phone)
Ian Hamilton (phone)
Darlene Metter (phone)
Richard Ratliff (phone)
Bruce Haffty
Gerald White
Paul Schmidt (phone)
Mike Stevens (phone)
Dean Broga
Margaret Roybal (phone)
Daniela Bowman (phone)

A-G-E-N-D-A

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Adjourn

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

8:09 a.m.

MS. WASTLER: Welcome everyone.

As the Designated Federal Officer for this meeting, I'm pleased to welcome you to Rockville for the public meeting of the Advisory Committee on the Medical Use of Isotopes.

My name is Sandra Wastler. I'm the Chief of the Medical and Events Assessment Branch. And I've been designed as the Federal Officer for this Advisory Committee in accordance with 10 CFR Part 7.11

Present today as an alternate Designated Federal Officer is Cindy Flannery, Team Leader for Medical Radiation Safety.

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

The meeting was announced in a May 8, 2007 edition of the *Federal Register*.

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

Commission. The NRC solicits the views of the Committee and values their opinions greatly.

I request that whenever possible we try to reach a consensus on various issues that we will discuss today, but I also recognize that there will be minority and dissenting opinions. If you have such an opinion, please them to be read into the record.

As part of the preparation for this meeting I've reviewed the agenda for the members and employment interests based on their very general nature of the discussion that we're 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 Committee's decision making activities. However if during the course of our business you determine that you have a conflict, please state it for the record and recuse yourself from the particular aspects of the discussion.

At this point I would like to introduce the individuals seated at the table today. Dr. Leon Malmud, Chairman; Dr. Jeffrey Williamson, therapy physicist; Ms. Sally Schwarz, nuclear pharmacist; Mr. Ralph Lieto, nuclear medicine physicist; Dr. Subir Nag, radiation oncologist. Dr. Van Decker is supposed

to be joining us. He's apparently not here right here. He's the nuclear cardiologist. Dr. Douglas Eggli, nuclear medicine physician; Dr. Orhan Suleiman, FDA representative; Dr. James Welsh, radiation oncologist; Dr. Darrell Fisher, patient advocate; and Ms. Debbie Gilley, State Government Representative.

I would like to welcome Dr. James Welsh to the ACMUI. Dr. Welsh is a radiation oncologist at the University of Wisconsin Cancer Center Riverview. He has completed the NRC security clearance process and is joining us a full member for this meeting.

I would also like to recognize the newest member of ACMUI, Dr. Darrell Fisher. Dr. Fisher is a medical physicist at Pacific Northwest National Laboratory, and he is serving at the patient's right advocate on ACMUI. Dr. Fisher has completed the NRC security clearance process and is also joining us as a full time member.

Dr. Vetter, the RSO representative, was unable to be here today. He had a conflict with the schedule.

And I would also like to mention that Ms. Debbie Gilley from the State of Florida is representing the agreement state since the state government position is currently vacant.

I'd like to thank Ms. Gilley for acting in this capacity.

And lastly, I wanted to note that Dr. Thomadsen will be joining us tomorrow. He has been selected as the therapy medical physicist to replace Dr. Williamson later this year. Dr. Thomadsen is a medical physicist at the University of Wisconsin, Madison. And his full ACMUI membership is pending completion of the security clearance.

Dr. Malmud, ACMUI Chairman, will conduct today's meeting. Following a discussion of each agenda item the Chair and his option may entertain comments or questions from members of the public who are participating with us today.

And I'd also like to mention that we are also having an open discussion this afternoon where we will have a facilitator. And that facilitator will be Dr. Patricia Rathburn.

Thank you.

Dr. Malmud?

CHAIRMAN MALMUD: Thank you, Ms. Wastler.

We'll move right ahead with the agenda, if we may. And I'd like to introduce first Scott Moore, who is filling in for Ms. Schlueter, who is unable to be here today.

MR. MOORE: Thank you, Dr. Malmud.

I'll just have a few remarks.

I'm Scott Moore. I'm the Deputy Director of the Division of Material Safety and State Agreements. As Dr. Malmud mentioned, I'm filling in for Janet Schlueter, the Division Director, who is recovering from a medical test that she had at the end of last week.

We have a full agenda this week. You're discussing today the NARM rule implementation and guidance regarding the NARM rule units specialty boards. And finally, you're going to have a facilitated discussion this afternoon on training and experience.

Tomorrow you have a similarly packed day with a number of topics presented by both NRC staff and members of the Board.

I would like to bring your attention to a medical list server that NRC Staff has prepared to keep the Advisory Committee licensees and other interested stakeholders informed about NRC's publications. It's on NRC website that's operated by ORNL. Ashley Tull, our coordinator for the ACMUI will provide you with that ORNL website, and we'll get it posted for you by the end of your time period here.

But we want you to know that the ORNL website is one that the agreement states use frequently. Debbie Gilley knows it fairly well. And we get literally hundreds of thousands of hits in a given year. So it's one that will make the information that's available to the medical community more available to everybody. And so we will provide that website information to you today or tomorrow.

I'd like to introduce a new ACMUI coordinator to the Committee, Ashley Tull. Ashley is sitting back there. And she's serving as the coordinator for this meeting.

And finally, I'd like to note that this is Dr. Williamson's last meeting. He served as a member of the Board since 2000. And the Staff has prepared a certificate of appreciation for him.

Thank you very much, Dr. Williamson.

(Applause).

MR. MOORE: That concludes my remarks.

Dr. Malmud.

CHAIRMAN MALMUD: Thank you very much.

We will then move on to the next item on the agenda, if we may. May we move ahead of our agenda? Are we allowed to do that.

MS. WASTLER: That's fine. Oh, yes,

please.

CHAIRMAN MALMUD: Thank you very much.

The next item will be presented by --

MR. BROWN: Regions, the PowerPoint is down on our system. So what I'm going to do is try to project from the camera to the screen so you all can follow the slides as you can. So you got to bear with today, okay?

MS. WASTLER: Thank you. Technical difficulties we had to let the regions know about.

CHAIRMAN MALMUD: Thank you.

So the next item on the agenda is the NARM rule discussion by Lydia Chang. Ms. Chang?

MS. CHANG: My name is Lydia Chang. Last time I briefed the Committee was back in October 24th of last year. And back then we were still in the middle of evaluating all the comments. So today I'm just going to provide you an update since last time I briefed you.

Again, just summarize a couple of items. Back in July 28, 2006 we did publish a proposed rule in the *Federal Register*. I've provided a citation here.

On August 22nd we had a public meeting in Las Vegas to solicit comments. Quite a few societies

did show up to give us written comments as well as verbal comments.

The public comment ended back in September 11.

Most recently on April the 3rd we have issued a Commission paper to the Commission for the draft final rule. And it's issued as a SECY-07-0062. Last month on May the 14th the Commission has approved the draft final rule and has issued an SRM.

You probably saw this slide from last time when I updated you. We received a total of 39 comment letters. Fourteen comment letters were from the states, 14 from other federal agencies. And the remaining comments were from citizen groups, professional organizations, universities, medical communities and industry.

Today I just want to highlight a few items that we have changed since the proposed rule that was published.

One is the definition of discrete source. We did indeed add the nitrogen and oxygen to Part 20, Appendix B table per ACMUI comments and a whole bunch of other medical communities' comments.

We did revise a little bit of the regulatory approach for items containing radium-226

We did try to clarify the production of PET produced radioactive materials and also the noncommercial distribution of PET radionuclides and PET drugs.

And I also wanted to highlight some of the implementation items that you might want to be aware of.

The definition of discrete source I have listed here three definitions. The very first one is the one that we included in the proposed rule. It stated that a discrete source is a source with physical boundaries which is separate and distinct from the radiation present in nature and in which the radionuclide concentration has been increased by human processes with intent that the radionuclide concentrated radioactive material will be used for its radiological property.

We received a huge number of comments associated with this definition. A lot of the people indicated that the definition was way too complicated and so convoluted. A lot of comments was also focused on the need to include physical boundary. I think including the word "physical boundary" created a lot more confusion and ambiguity. People also made comments on why should it be limited to just for its

radiological property.

So after we considered all the comments that we received, the Staff did come up with a much more simplified and still captured the essence of what we want to include in the source and not changing the intent, specifically not to regulate the TNORMs, the technically enhanced radioactive materials such as fly ash from coal burning power plant or fertilizer or such. So we did not change the intent, per se, but we did try to simplify the definition by changing some of the words.

So within the SECY paper the draft final rule we revised it the discrete source to be a radionuclide that is distinct from sources of radiation present in nature and that has been processed so that its concentration within the material has been purposely increased for use for commercial, medical and research activity.

This revised definition is definitely consistent with Energy Policy Act. We also throw in the words for use for commercial, medical and research activity, which is in the exact words that is in the Energy Policy Act, which also narrow the NRC restriction on what we're supposed to be regulating in with the source.

We also removed a word human process because once it's increased, it's by definition -- it's by humans so it's no need to emphasizing the human factor. It's going to be purposely concentrated, then it is regulated.

We also have removed for radiological property because as long as it's concentrated, whether it's going to be used for its chemical or radiological, we will be regulating. This approach is similar to depleted uranium. We don't care what depleted uranium is used for, it's uranium, radiologic property or for its physical property, you know, for its density as a shielding. So this is real consistent with NRC's past regulatory process.

However, once we submitted the Commission paper to the Commission, the Commission did come back and wants to further simplify the definition. And, you know, after discussion with the technical assistants within the Commission and also the technical staff within the working group, we have further revised the definition by deleting the word "distinct from sources of radiation present in nature."

By having this phrase it actually creates a little bit more confusion because people thought --

the radium-226 it's actually from the nature, but then once it's processed, it's actually already removed from the nature.

Another thing that the technical study included as far as originally was for the purpose of decommissioning consideration in the future. And for the evaluation we thought this is not needed because once a discrete source is defined as a byproduct material, it will always be a byproduct material. If you spilled it or it leaked into the environment, then the decommissioning criteria would kick in. It really doesn't matter whether it's still distinct from the nature or not. The decommissioning criteria such as DC-GL, another criteria that uses distinct from background, that will kick in. So this is sort of like a phrase that's really not necessary. So we further simplified the definition to be a radionuclide that has been processed so that its concentration within the material has been purposely increased for use for commercial, medical and research activity.

And we also have discussed this new revised definition with all the agreement states. And they all concur that this is much simplified and easy to understand definition.

Again, as I indicated before, we did

include nitrogen and oxygen-15 in Part 20 Appendix B table, table 1 and table 2. Table 1 is for occupational value and the column three it's for derived air concentration for inhalation and listed here are the values for both nitrogen and oxygen.

We also included table 2 column one F1 concentration for air. And, again, the volumes are listed here.

Items containing radium-226, it's probably not an interest item for ACMUI, but for the completeness I have included here. Within the proposed rule we actually exemption for timepieces and also limited number of repairs within timepieces. And we have since modified that within the rule. Only include intact timepieces containing 1 microcurie or less of radium-226.

We also have further refined the general license approach. The general license approach would allow individuals to acquire, receive, possess, use and transfer the list of items here including antiquities. There are no limits on the number of antiquities or the type of antiquities. An individual can have them under the general license approach.

For intact timepieces containing greater than one microcurie of radium-226, that's not exempt,

it's also being included in here along with NARM intact timepieces and hands and dials. There is no limit under this item, so individuals can have as many as they like under the general license approach.

We're also including luminous items stored in air, marine and land vehicle. This is a modification from the proposed rule. In the proposed rule we only allow luminous items stored in air under the general license. But based on the comment letters we have included marine and land vehicles since a lot of museums and defense organizations do have those items installed in airplanes and ships and jeeps.

We also modified it, the fourth item to allow less than 100 items of other luminous products used or stored at the same location at any one time. This would allow, you know, individual collectors to have a number of items in hand and still -- and not present a significant risk to those individual collections.

And the last item, we did not make any changes under the general license.

The general license approach is really sort of like a risk-informed approach and try not to be too burdensome to the public. Under general license an individual does not need to come to NRC to

get a license. They do not need to pay a license fee. There's only limited requirements that they have to meet such as, you know, if an item leaked, they need to notify us. They are not supposed to dispose of the items unless it's disposed at a permitted facility. And that they also need to respond to NRC's informational requests if NRC does make such a request. From what I understand, we haven't made that kind of request for the past 10 years. So it's really minimal burden and try to provide as much flexibility to the individual collectors as possible and still ensure that the item does not pose a significant hazard to the public.

And, of course, anything that's not covered under exemption or under the general license will require a specific license.

The radionuclide production for Part 30. In the proposed rule even though in presentations we have indicated that it is regulated under Part 30, but a lot of the commenters were still confused on how does that work. In a sense a lot of the medical use licensees also have cyclotrons that produce radionuclides. So in here we tried to further clarify that radionuclide production facilities are indeed regulated under Part 30. And within that we have also

added the noncommercial distribution within 30.32 and 30.34 to make sure that everybody's clear what's allowed to do under Part 30.

Specifically section 30.32, it's allows noncommercial transfer, and then section 30.34 it's the labeling and measurement requirement, which is all very similar to 30.32 -- 32.72.

Of course, we did not make any changes to Part 32 the commercial distribution for byproduct material. If you a PET cyclotron that you are manufacturing radionuclide -- PET radionuclides or PET drugs under the commercial distribution, you can still do that under Part 32.

And under Part 35 for medical use licensees, we specifically allow the medical use licensees to receive radioactive drugs from commercial distributors, which it's already in Part 35, but we also added the noncommercial transfer from a PET radionuclide production facility within a consortium.

The definition of consortium is also new to the final rule. Within the proposed rule we did not have a definition for consortium. Several commenters indicated it's necessary to include a definition, so we did include that in the final rule. And it is defined as an association of medical use licensees in

a PET radionuclide production facility in the same geographical area that generally own or share in the operation and maintenance costs of the PET radionuclide production facility but produces PET radionuclides used in producing radioactive drugs within the consortium from noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a federal facility or a medical facility.

And I guess once during the agreement state review and also ACMUI revealed the draft final rule, comments did raise regarding the geographical area. They thought that that was a little bit limiting. However, based on the technical Staff's evaluation that PET radionuclides are fairly short lived, so most likely for consortium to use the radioactive drugs within their consortium, they normally are located in a very close proximity. And the interpretation of same geographical area could also be somewhat flexibility. For instance, Washington metropolitan area, it's considered geographical area. So you could go as far as Baltimore to NIH. I mean, that would still be considered geographical area. But if somebody from -- I don't

know, Florida, its operating something to try to ship to D.C., that would be a little far. And from what we understand, those are quite often operated under a commercial production type of scale that they know the operations and they have airplanes, you know, on the standby to ship the material. So those are, in our opinion, more on a commercial basis rather than on a noncommercial basis. So we did in fact still have those same geographical area within the definition.

Another comment that we received was from agreements regarding the second sentence. They were confused of whether -- you know, that the consortium has to be located at an educational institution or federal facilities or medical facilities. They thought, you know, geographical area kind of covers it, why doesn't it still have to be located in different kind of facilities. And in our mind, the purpose of the noncommercial distribution was purely for the medical facilities and educational institutions and federal facilities for them to maximize their radioactive material usage. It's not intended for commercial purposes at all. So we still have that limitation to try to narrowly allow what it's allowed under the noncommercial distribution.

Here I just want to kind of summarize the

specific provisions for Part 35, some of which have not changed since the proposed rule, but I kind of just want to summarize it for you since ACMUI's most interesting Part 35 medical use licensees.

The Part 35 does include effective date under 35.10, the effective date is 60 days from the day of the publication of the final rule. The authorization to continue to use until the individual have license. Under Section 35.11 it's for new license application, those individuals will still have up to one year from the effective date to submit a new license application.

Section 35.14 it's for amendments. We have made any changes to that, so the licensee still has up to six months from the effective date to submit a license amendment.

Section 35.13 its relocation. To relocate a PET radioactive drug production area or delivery line, we have not made any changes. 35.13 require amendment for such relocation.

Grandfathering certain individuals. Between the proposed rule and the final rule, we did delete the revision to the definition of authorized user and authorized medical physicist and authorized nuclear pharmacist. And the reason we deleted it is

because we believed that the grandfather clause included within 31.13, .14 and .15 and .57 are sufficient to provide a grandfathering clause. There's no reason to change the definition to further complicate things. And another reason is the agreement states also was objecting to the change of definition since definitions are compatibility category Bs that would have forced agreement states to have a definition that may not be consistent with their existing program.

Again, section 35.13 permits individuals who has worked to continue to work as the authorized user or authorized nuclear pharmacist and authorized medical physicist.

35.14 it's allowing use of notification to inform NRC that these individuals are indeed work as AU, AMPs and AMPs.

35.13 is a grandfathering clause grandfathering those individuals who used only NARM material from the training and experience requirements.

And the last item is the generators. We have added strontium and rubidium generators within Part 35.

35.204 is for the contamination

concentration limits for the generator which is .02 microcurie of strontium per millicurie of rubidium.

And 35.2204 is the record keeping of the results from those analysis.

For PET radionuclides in drugs 35.63 basically would allow medical use licensees to determine the activity level based on numerical calculations using volumetric measurements and measurements that they got from the manufacturer or they got from the noncommercial distribution from PET radioactive drug under Part 32.32(j).

And as far as NARM PET radionuclide and NARM PET drugs there are no changes needed within Part 35.

Some of the implementation considerations that you might need to be aware of is the waiver termination. The waiver will be terminated once the final rule becomes effective for the federal agencies and Indian tribes. And we also have included several states such as Delaware, Indiana, Wyoming, Montana, District of Columbia, Puerto Rico, U.S. Virgin Islands. So these states and territories their waiver will be terminated on the effective date once we publish a final rule.

As far as the agreement states, I'm sure

Andrew will go into all the details on how the waiver termination and how the transition plan will work. But in short, the agreements states waiver will be terminated once the final transition plan is published. By then all the governors would already be submitting -- will at least have submitted their certification for the adequacy of their programs. So it will be a seamless transition since they are regulating the NARM material already under the waiver, they will continue to be regulating the NARM material under NRC authority once the final rule is published and becomes effective.

As far as the non-agreement states, we are using a phased approach probably two to three stages to terminate the non-agreement states depending on whether those non-agreement states have expressed interest to become an agreement states and whether they have extensive NARM program and whatever it would take time for NRC to transition over.

And, of course, the waiver would expire I guess in August 7, 2009. So that would be the bottom line the we would terminate. There's no extension on that.

License for NARM, as I have included before, the license amendments individual have six

months from the effective date or waiver of termination to submit license amendment. New license applications they have one year from the effective date to submit that.

The start of the clock gets a little bit tricky. Because even though the effective date might become effective, but the waiver's still in effect. So you really need to take a look at two components, you know, whether the waiver has been terminated. So even if the effective date has arrived, you might still be operating under the waiver and you can continue to use the material until the waiver termination date or the waive expiration day.

We also have made a minor adjustment between the proposal and the final rule on the waiver expiration date. I guess in the proposed rule individuals doesn't have that six month and one year built in on top of the waiver expiration date. And we did make that minor adjustment so that upon waiver expiration day, the individual still has six months to submit amendments and one year for a new license application.

The next step, right now we're revising the draft final rule per the Commissioner's direction, such as revising the discrete source definition, make

some minor corrections. We are also working on clarifying military use of radium items within the final rule to make sure it's clear on the exemptions for military use.

And we will be forwarding the final rule to the Office of Management and Budget for review and approval. OMB has 60 days to review the final package, so therefore you know you're probably not going to see the final rule published until at least two or three months from now. Probably sometime in September or so.

That's what I have. Thank you, Chairman.

CHAIRMAN MALMUD: Thank you for a very complete review.

Are there any comments or questions for Ms. Chang? Sally

MEMBER SCHWARZ: Thank you, Lydia. That was a nice presentation. I did have a couple of questions. I was reading, you had sent out the copy of Commission paper and some enclosures were on the website.

MS. CHANG: Yes.

MEMBER SCHWARZ: So I had it on the website and I was comparing what was there to what we had received initially.

And in your presentation, I think in Part 35.100 and .200 originally, I mean you're stating that the facilities can still receive PET radionuclides because they've taken that out of what's on the list. They only have drugs listed, and I was real curious about why they had taken out PET radionuclides.

MS. CHANG: Oh, okay. The reason -- the PET radionuclides is a radionuclide you can always transfer from a Part 30 license to anybody, as long as it's not used for medical use on human beings. You can transfer without any other specific authorization. That was one of the reasons and would still include--

MEMBER SCHWARZ: Okay --

MS. CHANG: If you have the pharmacist that would transfer -- I guess that can bless the radionuclide to become a drug, then yes.

MEMBER SCHWARZ: Okay. I was just curious why --

MS. CHANG: That was the reason.

MEMBER SCHWARZ: And then the other question that I have is the transition plan. And I know that you probably can't give me an answer, but I'm going to ask the question anyway. I do realize that we've defined the first group of states that will have the waiver lifted. And I'm realizing that there

probably will be two additional groups. And since there are a limited number of nonagreement states, it would certainly be tremendously beneficial when they publish this rule that the other two groups would be designated in writing so that the states would know what the plan is. I mean, we're talking about a limited time period here anyway, and that certain if those states could have a true idea of when their waiver would be lifted, you know when the rule is published, that would be tremendous.

MS. CHANG: Right. I'm sure Andrew has all the details once he does his presentation. I do know that, you know, several states already expressed interest to become agreement states. So those would definitely be leaning towards the later part of the waiver period to be terminated, such as Pennsylvania, New Jersey and Virginia. I also know that Andrew has been communicating with many of the states both agreement and nonagreement states. So I'm sure that he will be able to give you a lot more information on that.

CHAIRMAN MALMUD: Are there other questions? Dr. Suleiman?

MEMBER SULEIMAN: I just wanted clarification for the PET consortiums. That they would

be for noncommercial use. So if the facility wanted to use it for commercial, they would have to have a commercial license?

MS. CHANG: That's correct. If they want to use commercial, they have to get 32.72 license.

Thank you.

CHAIRMAN MALMUD: Any other questions? Mr. Lieto?

MEMBER LIETO: I have a question to follow up to Dr. Suleiman's regarding the consortium definition. And you were talking about in geographical areas.

MS. CHANG: Yes.

MEMBER LIETO: There are some very large medical facilities that are located in the northern states that have facilities in southern states. And what this would seem to be is overly restrictive in that if they did have such a facility and wanted to ship to their sites, they would be precluded from doing this because of this definition?

MS. CHANG: Well, in our view the geographical locations really are very flexible. And it could be really during the licensing process. I mean --

MEMBER LIETO: I guess the point is why

not just delete it?

MS. CHANG: Well, because you don't --

MEMBER LIETO: You're saying it's for noncommercial uses anyhow. So whether you go across the street or you go across the country, what does it matter if it's for noncommercial use and it's from one of these three types of facilities that you've indicated?

MS. CHANG: Yes. Because the only reason we included noncommercial distribution for PET radionuclides it's because of the short half life. And it just does not make sense when you have to ship from cross country. That would take, you know, a long, long time. And then it also means that you're going to be producing a huge volume of radionuclides just for noncommercial --

MEMBER LIETO: But if the consortium wants to have -- if they want to ship it to their site and they want to have an increased amount of activity and pay for the added shipping of the increased shielding, why restrict them? It's for noncommercial use. To me the person that's going to be compromised here is the patient.

MEMBER NAG: This is Dr. Nag.

Let me support the last viewpoint. In the

modern day and age this may no longer matter. I mean, you can say one particular area means, you know, the whole earth is one geographical location, which is a different planet, but that's not what you're meaning. No.

Nowadays, shipping from one place to the other is not a problem. People even have their own -- so I would say remove would be a practical approach.

MS. CHANG: Well, for commercial distribution we have no -- you know, you have people ship things all the time. But the whole purpose of noncommercial distribution is to allow a nonprofit organization to not waste the radionuclide that they produced --

MEMBER NAG: Right.

MS. CHANG: -- to enabling for third use close by. If you had to manufacture such large quantities, then you should be a commercial distributor.

MEMBER NAG: For example, Mayo Clinic has -- Rochester, Minnesota is the main place. They ship it to other Mayo Clinics, they're all Mayo Clinics but one is in Florida and one is in Arizona. And it's much easier for them to ship it, you know, between each other than to buy a separate from some other place.

MS. CHANG: I don't know. I mean, you know the technical Staff really sees it differently. Because if you're going to produce so much and the decay is what? Less than an hour, right?

MEMBER EGGLI: A 110 minutes.

MS. CHANG: What?

MEMBER EGGLI: A 110 minutes for FDG. A half life. A 110 minutes for FDG.

MS. CHANG: Right. Basically in a day the material, it's already gone. I mean the whole purpose--

CHAIRMAN MALMUD: Some nuclides could be longer, but I think we're talking about fluorine 18, which has an approximate two hour half life.

MS. CHANG: Yes. More than 80 percent of the time we're talking about fluorine 18 and sometimes oxygen or nitrogen, which is even shorter half life. I mean, the whole purpose is not for you to make a huge amount of the material and pose health and safety concerns to the medical facility and then be able to ship, you know, by the time it gets there a fraction of that material. The whole purpose of noncommercial distribution is enough for you to not waste what you already produced.

CHAIRMAN MALMUD: Well, or stated

differently, what I hear Lydia saying is the reason the Staff included a provision for noncommercial distribution in the regulations was to allow for short half life material to be used rather than waste it, essentially.

MS. CHANG: Right. Right.

CHAIRMAN MALMUD: And the argument you're making is for, if there are large activities, very large activities, then that negates the argument --

MS. CHANG: Right.

CHAIRMAN MALMUD: -- that, you know, it would have to be wasted.

MS. CHANG: Right.

CHAIRMAN MALMUD: Dr. Schwarz?

MEMBER SCHWARZ: In terms of if you are not a consortium, I guess Mayo Clinic would be a consortium, but there would be other institutions shipping noncommercially not being consortiums. And that is provided for in the regulations, right?

MS. CHANG: If it is radionuclide, yes.

Okay. Thank you.

CHAIRMAN MALMUD: Are there other concerns? Ralph?

MEMBER LIETO: Just some clarifications. So your grandfather provisions there's not going to be

any wording change? You're saying that the wording in 13.12, .13, 14 and .57 are appropriate enough that we don't need to make any changes to those specific rules?

MS. CHANG: We did not make any changes to the definition, but within the 35.13, .14, .57 we actually made additional clarification to make sure that they are indeed authorized users and authorized nuclear pharmacists. So we actually add one sentence to further clarify that.

MEMBER LIETO: All right. And then regarding the dates. If a nonagreement state is pursuing agreement states status, you're saying that by August of '09 if they're not an agreement state by then they're going to fall into some type of a transition plan?

MR. MOORE: The transition plan questions will be addressed by Andrew in the next presentation and Duane.

MEMBER LIETO: Okay. So just hold off on that one?

MR. MOORE: Yes.

MEMBER LIETO: All right. And the dates regarding the waiver, you seemed to indicate that the waiver has precedent over the effective date?

MS. CHANG: Yes.

MEMBER LIETO: And that even when that last date occurs, you still have six months for an amendment, another year or less a license regardless of when those dates are, is that correct?

MS. CHANG: Repeat that. Let me make sure I understand.

MEMBER LIETO: If you have a waiver, there's a waiver date which will have precedent over an effective date?

MS. CHANG: Right. Right.

MEMBER LIETO: And then whichever one is last, you still have another six months --

MS. CHANG: Six months to a year.

MEMBER LIETO: -- for an amendment or a year before the license is up.

MS. CHANG: That's correct. That's correct.

MEMBER LIETO: Okay.

MS. CHANG: So the final drop dead day is August, 2009 if the waiver has not been terminated earlier than that.

CHAIRMAN MALMUD: Thank you, Lydia.

If we may, we'll move on to the next item on the agenda, which is the NARM transition plan. And

that will be presented by Mr. Mauer and Mr. White.

MR. MAUER: Good morning. I'm Andrew Mauer, and this is Duane White, and we're working together to implement the transition plan that we developed for NARM. And the purpose of our briefing this morning is to give you update on our efforts to publish the plan and to implement it.

And the transition plan, the formal name is the Transition Plan To Facilitate an Orderly Transition of Regulatory Authority for NARM. And we'll go through each of the different components and give you an update of where we are this morning.

I'm sure that Lydia's covered the first bullet here under the overview. But one thing we wanted to mention is this is actually a requirement of the Energy Policy Act that the agency publish a transition plan. And so that's what we're working to do.

Lydia also mentioned the waiver. We issued a waiver following the passage of the Energy Policy Act on August 31, 2005. And that will allow states and individuals to continue their activities involving NARM until we terminate the waiver or it expires. And as was mentioned, we plan to terminate the waiver in phases starting with the effective date

of the rule and ending on August 7, 2009.

And to clarify the question from before, just to reiterate really, once the waiver is terminated in the jurisdiction, that's when the effective date is for that jurisdiction. So, hopefully, that's clear.

As far as the transition plan, it was developed to address each of the different transition scenarios, and we'll walk through those.

Our plan is to publish the final transition plan in between the time that the final rule is published and when it becomes effective. So once the rule is published, it will be effective 60 days later and the transition plan will be published within that time window.

So given that the timing that Lydia mentioned as far as the schedule, the earliest possible effective date would be realistically three to four months from now, given the OMB review process that Lydia mentioned.

The transition plan addresses agreements states. When we put these slides together we had 31 certifications from agreement state governors documenting that their state has a program for licensing the new materials and that they intend to

continue to regulate those materials. Since then we've received certifications from the remaining agreement states, so we now have certificates from all of the agreement states indicating they intend to continue to implement their programs.

Our plan is for the NRC Chairman to sign responses back to the governors approving the certifications in conjunction with the effective date of the regulations. And this is 60 days after their published that effective date.

Overall, in this aspect of the transition plan we expect transparency. And what we mean by that is really transparency from an agreement state licensee standpoint they shouldn't see anything different.

For the nonagreement states, federal agencies and tribes that constitutes another few components of the transition plan. We kind of tried to consolidate for our presentation here today because these entities are similar as far as the transition goes. And we've been closely coordinating with the nonagreement states, licensees and industry groups through various communication methods. And we'll talk about those in a later slide. But one thing that Lydia mentioned concerning the waiver is once it's

terminated, that will be the effective date for folks who are effected and all persons that possess the new materials in NRC jurisdiction must be in compliance with the regulations immediately. And they'll be given a time period to apply for a license amendment or a new license if they don't already have an NRC license. And those time periods are six and 12 months respectively.

And the next slide just lays out for the nonagreement states which ones will have the waiver terminated on the effective date of the regulations and also just to reiterate federal government agencies and federally recognized Indian tribes will also have the waiver terminated coincidentally.

For the remainder of the nonagreement states we plan to terminate the waiver in phases. We're tentatively looking at summer to fall 2008 for the second phase. And the final phase being in the spring to summer 2009 with the latest possible date being when the waiver expires.

And I understand the need to have as much notice as possible. And I can assure you that once we make a decision, we will inform everyone. We have not made the decision yet. We're still waiting to see whether any nonagreement states express interest in

becoming agreement states. Currently we have Pennsylvania we're working with, New Jersey and Virginia. And if we have any other formal letters of intent that we receive, we'd like to factor that in and really when we communicate the information, we want to only do it once, and we want to have it right. But we would expect to have at least six months notice. I personally think it will be more notice than that. And I believe that once we do provide notification on which states will fall into the second phase, we may even be able to -- well, you'll at least be able to understand which states will likely fall into the final phase if we're not prepared to actually set a date for it by process of elimination.

And the last bullet here indicates that states that become agreement states by August 2009 will have their waiver terminated coincident with the effective date of their agreement. So they're not going to fall into a particular phase necessarily. For example, we're currently working with Pennsylvania. And if they become an agreement state in the near term, their waiver will be terminated coincidentally with the effective date of their agreement with us.

The transition plan also addresses what

I'm calling some miscellaneous scenarios. The NRC will assume regulatory authority for exempt distribution of NARM. And that will occur upon waiver termination. We're currently working with a limited number of licensees effected there to effect that transition.

And from the standpoint, we're also working to assume regulatory authority for all sealed source and device, evaluations and registration for NARM and jurisdictions that do not have that authority. In other words, for nonagreement states or agreement states who did not assume that authority within their agreement with the NRC. And that will occur the same time, upon waiver termination.

And as you can see the common theme is once your waiver is terminated, that's when the transition will begin for you.

The last slide is called communications. And this is really something that we've had to focus on and tried to focus on extensively throughout this process. And hopefully more so in the future. And because we're really going to be communicating with in a new area, and in some cases with folks who haven't been regulated by the NRC. So we're trying to get our message out with respect to -- for now we've been

focusing on the schedule and what our estimates are and when all the different pieces of the implementation will fall together as far as the guidance, which you'll hear from in the next presentations, and the regulations and the transition plan. How everything fits together. So in that regard actually issue a regulatory issue summary in March giving all licensees a status update, and we also put some frequently asked questions at the end there that we thought would be helpful. And you all should have received a copy of that being an addressee.

And we've tried to take the information, the pertinent information from that RIS, summarize it and communicate it through other avenues, through other industry groups and other forums to try and get that message out. So we're working beyond our addressees for a material licensee standpoint and we've asked our agreement state partners to communicate, disseminate the information to their licensees as appropriate.

And we're currently planning to do a follow-up regulatory issue summary once the regulations are published to let folks know this is your effective date, at least for what we're calling

the first phase with the effective date of the regulations. So once the regulations are published, we're actually planning to issue another regulatory issue summary.

And I would just close by noting a website that we've developed with all items NARM, hopefully, for general use. It includes information on the regulations, the guidance, the agreement state governor certifications, letters that we've sent to the states. You can find a copy of the draft transition plan there. And maybe some other things.

That concludes the presentation. With that, we would take any questions you have.

CHAIRMAN MALMUD: Thank you, Mr. Mauer.

Are there any questions or comments for Mr. Mauer? Sally?

MEMBER SCHWARZ: I just wanted to restate what I asked Lydia. And in terms of the last two groups, is it your thinking that those states that are becoming agreement states might have formed the later group and that possibly the remaining nonagreement states would be in the phase 2?

MR. MAUER: We would see -- if you look at the remaining nonagreement states including those that are intending to become agreement states, we would see

some states in phase 2 and some states in phase 3.

I guess the answer to your question there may be nonagreement states who do not become agreement states that are in phase 3. Does that --

MEMBER SCHWARZ: Any idea what would move them into phase 3?

MR. MAUER: Well, there's three factors that we're looking at from a selection standpoint. We're looking at intent, expressed intent to become an agreement state. We're looking at what their current regulatory program is for these materials. And we're looking at the size of the program.

MEMBER SCHWARZ: And size would make them go later or soon?

MR. MAUER: Let me just make sure. I named two of the things for sure, and I just want to-- let's see. The scope of the current state's regulatory program, the estimated number of total licensees impacted and the states level of interest in becoming agreement states as far as -- we're looking at all three areas together and kind of looking at our overall transition as an agency as far -- we're seeing a lot of increased workload with the transition that our regional offices in particular will be facing. So we're trying to spread it out and divide it up, if you

will. But in a manner that's risk-informed.

MEMBER SCHWARZ: All right. Thank you.

MR. MOORE: This is Scott Moore.

And learn from the transitions as the happen. Since it's a three phased transition, we should learn from the transition in phase 1 and make phase 2 and phase 3 that much more efficient.

In phase 1 we have some states that have less robust programs, you know, or very little regulatory oversight programs in some of the states. And other states that have, you know, full regulatory programs or territories that have full regulatory programs.

And so in phase 1 we're trying to pick up the programs that don't have much. In phase 3 we're trying to leave some of the programs that may become agreement states so we don't, you know, move work that we may not need to do. So the ones that are in between are in phase 2.

Does that answer your question, Ms. Schwarz?

MEMBER SCHWARZ: It helps.

MR. MOORE: Okay.

MEMBER SCHWARZ: Essentially, you know, kind of waiting where programs would lie based on the

amount of work that they have and the extent of the program that they're dealing with?

MR. MOORE: Right. As we get into phase 1, I think we should have a much better handle on which will be in phase 2. And then that will dictate which are in phase 3.

MEMBER SCHWARZ: And you think that that will be posted or essentially made known shortly after the rule is published?

MR. MOORE: I don't know about after the rule is published, but as we move into phase 1, I think, yes.

MEMBER SCHWARZ: Within six months maybe of publication do you anticipate?

MS. CHANG: Something like --

MR. MOORE: Yes. I think --

MEMBER SCHWARZ: Somewhere that information can be made available. I understand it's a difficult decision to make, but certainly for all the licensees involved, it's very important. The sooner that we know, the easier it is for us to begin to prepare.

MR. MOORE: Absolutely. And then I'd like to note, you know, as Lydia and I think Andrew noted, once the state, the nonagreement state transitions

over to NRC jurisdiction, the licensees within that state if they have an NRC license and they come and they have NARM accelerator-produced material and discrete sources of radium-226, they still will have six months to apply for an amendment if they already have an NRC license or a year to apply for a new license if they don't yet have an NRC license.

MEMBER SCHWARZ: Thank you.

CHAIRMAN MALMUD: Thank you.

We also have a question from a member of the public.

MS. FAIROBENT: Yes. Lynne Fairobent with the American Association of Physicists in Medicine.

Andrew, for the two states that have just recently announced their intent to go agreement, Virginia and New Jersey, given the time that it takes for a state to go agreement realistically other than Pennsylvania, do you anticipate they can make the August date for 2007? Is there going to be an expedited review process for transitioning Virginia and New Jersey to agreement status?

MR. MAUER: Well, at this point those states have expressed letters of intent to become agreement states. And they've indicated to us they expect to submit a draft request for an application.

Obviously they're -- you know, we'll need to look at that. We're not going to expedite anything as far as compromising our processes or anything like that, but we're going to continue our normal processes. But we'll need to receive quality applications, obviously given what you note as there's not the crunch time frame up until August 2009. But at this point we can't say one way or another how that's going to work.

We need too see where they are in process at that time, and at that time we can make a decision and look at how those states would transition, if you will.

MS. FAIROBENT: And the August 9 date is a hard date without congressional relief, correct?

MR. MAUER: That's the date --

MS. FAIROBENT: August, 2009?

MR. MAUER: August 7, 2009 is four years after the Energy Policy Act was passed, which is the longest that the waiver can be in effect for. So we put that date as the latest the waiver can be in effect.

MS. FAIROBENT: Okay. Thank you.

CHAIRMAN MALMUD: Any other questions? Yes.

MEMBER GILLEY: Debbie Gilley.

Andrew, you mentioned that the governors would be notified in the agreement states 60 days after the final rule, is that correct?

MR. MAUER: Correct.

MEMBER GILLEY: Will you also be notifying the director members that those letters are on the way to the governor?

MR. MAUER: We have a multi-stage notification process with all sorts of notifications planned out. Basically after the transition plan is published, I mentioned the transition plan will be published within the 60 day window. And then on the effective date -- well, when the transition plan is published, that's when the governors' certifications become effective. And so once they're effective, we can approve them once we have regulations that are effective.

So to answer your question, there will be several notifications, we'll issue a press release, more than likely the state programs will be notified, ACMUI will be notified. Everyone's going to be notified.

MEMBER GILLEY: Thank you.

CHAIRMAN MALMUD: Thank you.

If we may, we'll move on.

Thank you, Mr. Mauer.

We now move on to Mr. White -- oh, excuse me. Mr. Lieto?

MEMBER LIETO: Yes. I had one question for the gentleman for the nonagreement states, which obviously are the minority of the states involved in this process. But I think there's maybe some confusion with, obviously, the transition plan is just how the dates and when the rules become effective and so forth. From the standpoint of license applications, in the regulatory issue summary that you issued there were just only a couple of questions that addressed this. And as far as the individual licensee is concerned in the nonagreement states, it's not clear if they are under an NRC license right now using both old byproduct and new byproduct -- in other words, NARM plus the old byproduct definition, that they're going to have to amend their license. If they're not, you don't have radionuclide specific. For example, you have a 100 and 200 licensee, they're using thallium, gallium, indium, other NARM type materials. That's not specified by radionuclide, but it seems to indicate that they have to go and get a new license amendment when the new rule comes into place. And I don't think that's the intent, but that

point needs to be clarified.

So I think in your next RIS, I think you need to look at -- you know, kind of sit in the seat of the licensee and say do I really need a license amendment? Do I need -- because I don't think you want to burden the regions with a licensing amendments that are superfluous and just take up a lot of time, especially in the time crunches that are going to be going on here.

You know, very few medical licensees have radium sources. I imagine there might be a few out there. I could see those might need to be -- these might need to be specified by a license amendment. But I think it needs to be really specific do I need to apply or don't I need to apply. The same thing for Part 300. There's not really radionuclide specific, okay So if they get some NARM -- NARM generated radionuclide comes down the pike that's used for therapeutic purposes, do they need to apply for a license amendment? My way of thinking no. But, you know, I think that needs to really be laid out clear because most of the things in that RIS that came out in March are aimed more at dates or more addressing when things become effective and so forth. Not as what needs to be specifically amended in your license

in an agreement states -- excuse me. Nonagreement state.

MR. MAUER: That's a very good point, and something that we're definitely aware of and looking at. We can definitely take a look at whether we can include something in the next regulatory issue summary in that regard. But your understanding is consistent with the approach we're taking as far as if your license is written in a manner that the authorities that you'll need to operate under are already there and you don't need any changes. You won't need to have your license amended.

CHAIRMAN MALMUD: Thank you.

Lydia Chang has a comment.

MS. CHANG: Actually, I just wanted to respond to Mr. Lieto's question. And Andrew is absolutely correct. Within the final rule we also have addressed comment response. And there were quite a few comments asking a similar type of question that you have raised. And our response, it's really consistent with what Andrew said.

If your license is so broad to only byproduct material by having the final rule become effective, that byproduct material would in fact include all the NARM material. Therefore, no license

amendment is necessary. So we actually have clarified within all the responses on comments associated with that question.

CHAIRMAN MALMUD: Thank you.

Thank you again, Mr. Mauer.

And we'll move on to Mr. White.

MR. WHITE: Actually, I don't have anything to add. Actually, for the transition plan, I don't have anything to add.

CHAIRMAN MALMUD: Okay. We'll be going to the guidance.

MR. WHITE: Okay.

CHAIRMAN MALMUD: Which is your item.

MS. TULL: Dr. Malmud, we were actually at a break.

CHAIRMAN MALMUD: Ah, then why don't we take the break now. Is that okay with you, Mr. White?

MR. WHITE: That would be fine.

CHAIRMAN MALMUD: We'll take the break now and return here, let's see, 9:35.

(Whereupon, at 9:20 a.m. a recess until 9:43 a.m.)

CHAIRMAN MALMUD: Thank you all. We'll resume now, and the next item on the agenda is the presentation by Mr. White regarding NARM guidance.

MR. WHITE: Thank you.

Yes, I'm going to give you an update of the NARM guidance and what we've been doing. First I'd like to give you an overview.

The NARM guidance writing team was established in the summer of 2006, and our purpose was to evaluate and look at all of the NUREG 1556 volumes and determine what volumes would need to be revised based on the new NARM rule.

After our review, we determined that the most pressing volume that needed to be revised was Volume 9 and Volume 13. Volume 9 is program specific guidance about medical use licensees, and Volume 13 is the program specific guidance on commercial regular pharmacy licenses.

We also determined that we needed a new volume now that we're dealing with accelerator produced materials. So we came up with Volume 21, which is the program specific guidance about possession licenses for production of radioactive material using an accelerator.

We did recognize some other volumes that needed to have minor revisions, but those volumes would be done at a later time, but Volumes 9, 13, and 21 are the volumes that we wanted to get out pretty

much by the effective date of the NARM rule.

During our process of revising and developing the new guidance, we sent out comments, sent out the volumes to the ACMUI, and unfortunately Volumes 9 and 13 we were not able to receive comments because we already went through the Steering Committee, and we asked that the committee would provide comments during the public comment period.

But we were able to get comment for Volume 21, and Sally provided comments for that.

Due to the extension of the rule, we haven't had the public comment period yet. Well, Volume 21 is now in the public comment period, but we never did receive your comments because of the extension of the rule and we had to wait on any other changes until after the rule was, I guess, finalized as far as the second draft.

I want to give you the update on Volume 13. I'm the volume leader for Volume 13 and Volume 21. So I'd like to give you an update on volume 13 as far as what was contained in that volume.

We added guidance for facility and equipment specific to PET radiopharmacies giving them a better understanding of what they need to provide.

We also provided some additional

radiopharmaceutical safety recommendations because of the handling of higher energy photon emitting radionuclides, and an example of that would be to recommend using pocket dosimeters.

We also insured the applicants of where that if they do have discrete sources of Radon 226, that they now need to be identified and licensed by the NRC.

In addition to those revisions outside of the NARM, we also saw the need to add the new 313A AMP form to Volume 13, which will be found in Appendix G, and we also revised the appendix on transportation making it less descriptive and a little more general because Department of Transportation changes their regulations, and we were not able to make sure that your guidance was constantly updated to the regulations.

For Volume 21, which is the new volume, production of radioactive material using an accelerator, the first thing that was our decision for this guidance or for production rad. materials, that the license would be a separate license, a separate specific possession license, which would be associated with other licenses such as a broad scope or somebody would be something where you would need to provide all

of the information on this production of radioactive material using the accelerator.

Also, in our last meeting, we had the term "authorized user" in the guidance, and there was some confusion as that might cause confusion because the medical in Part 35 authorized user is defined specifically, and so what we did is we changed that section to say individuals that are authorized to handle materials, as you will have some person that will be experienced in this and on the production license. So we did make that change.

Also, Sally had a concern or mentioned the fact that for activation products, before we mentioned it, you should list all of your products and give an estimated maximum activity. We know that that could be somewhat hard to do for especially the bigger facilities. So we did put in a provision to authorize the one through 83.

However, when we go to the broad scope, we had to note that the financial assurance might be higher. So that's why we also wanted to give the option to smaller licensees who might -- you know, they can usually get their information from the manufacturer if they needed to.

And another thing that we added since the

last meeting when I spoke is we did add an appendix on the consortium. For those members who produce radioactive materials or to consortium members, we did add some guidance on that. So that can be found in Appendix P.

Currently Volume 21 is out for public comment. It was released on May 29th in the Federal Register. The official date on the Federal Register is comments are due back by June 28th. However, we did send out the Website a little bit later. So we will be accepting comments at least until July 5th. We ask that you still provide comments on that.

For Volume 13, we expect to release that at the end of this month, and again, we'll have 30 days to comment on that. And Volume 9, we're looking at mid-July for that one.

We will provide the ACMUI the guidance as soon as we can. It will probably be close to that date. It might be a week or so before, but in general you'll receive a copy when the public comment period starts.

And staff will review and adjust the comments, and we hope that the guidance will be finished by the fall of 2007.

And that's all for mine. Dr. Howe is

going to give an update on Volume 9. Were there any questions on Volume 13 or 21?

CHAIRMAN MALMUD: Are there any questions for Mr. White?

(No response.)

CHAIRMAN MALMUD: There are none.

Dr. Howe.

DR. HOWE: Okay. Duane essentially covered two of the volumes, and I have the third volume, and as you know, Volume 9 is quite thick, and what we did was we essentially did surgical revisions to Volume 9, and those revisions are focused very narrowly on the NARM rule, on the new NRC Form 313As, security related information, and minor updates.

And you see I have a lot of slides, but that just goes in to kind of fill out some of these topics. For the NARM rule we added the definition of byproduct material. We added sections about addressing the 10 CFR 30.32 authorization for the noncommercial transfer within a consortium, and Duane's Volume 21 addresses noncommercial distribution within the consortium for the educational facilities and the federal facilities, and Volume 9 includes the noncommercial distribution for the medical facilities to other medical facilities.

And since we have changes for noncommercial distribution, we now have conforming changes in the medical use license for this noncommercial distribution. And Lydia went over some of those changes, like you can now use the measurements that are provided by the noncommercial distributor the same way you could use the measurements provided by commercial pharmacy or the drug manufacturer.

Implementation, Lydia talked to you earlier, and Andrew talked to you about the act that there are several dates that are important. One is the implementation of the effective date of the rule for federal facilities. There's an implementation 60 days later for non-agreement states. It depends on when your waiver is terminated, and as Lydia indicated, those are parts of the regulation. Well, we've added that information into Volume 9 for the medical use licensees.

She also indicated that we have new experienced individuals that have used non NRC-regulated material, and we're recognizing them as authorized users, authorized nuclear pharmacists, and so we've added guidance for those individuals.

There is now an amendment request. If you

make a change to a 100 or 200 medical use area only if it has to do with moving a PET production unit around in that area or moving a PET transfer delivery line in that area. Otherwise you're still covered under notification and broad scope licenses do not have to either get an amendment or notify NRC of those changes.

We added the strontium and the rubidium generators.

One of the major things we did in Volume 9 is we added a lot of reminders. Volume 9 is a unique document. There are many, many kinds of licensees that are using this document, and they tend to pick it up and use parts that are relevant to them as opposed to the nuclear pharmacy license or the accelerator production where you may start at the beginning and work your way through.

So we've added a lot of reminders in various places in Volume 9 that essentially just tell people now non NRC-regulated material and discrete sources of Radium 226 are now regulated by NRC, and remember these are parts of your radiation safety program.

That means that in the past occupational dose was only looked at by NRC if there was NRC

material involved. Then you picked up the non NRC-regulated material because of the byproduct material. Well, now the byproduct material has expanded. So if you had an individual that was working primarily with thallium, they are now part of that occupational dose for NRC purposes.

We've put references in that there may be some legacy sources out there that were either reviewed or not reviewed by the non-agreement states with non NRC-regulated material in them, and what should licensees do if they have a device that doesn't have a sealed source and device registry.

We added a specific leak test for Radium 226. In this case we went to nationally recognized standards and exerted the leak test for individual Radium 226 sources where you put them in a vial and then check for radon.

If you have a larger device and the source is in the device, then you use the standard leak test that you use for any other device.

We also clarified that we don't think there's any medical use of Radium 226 out there now, but the new rule doesn't prohibit it. So we wanted to make it clear that in the past, they've been used for manual brachytherapy. We would consider manual

brachytherapy to be an accepted use because that was used in the past, but if you're using any unsealed Radium 226, that's definitely going to be a 35.1000 use, and if you were using Radium 226 for something other than manual brachytherapy, we consider that to be a 35.1000 use also.

Jeff.

MEMBER WILLIAMSON: What about Radon 222 seeds? I don't think there is a radon seed plant in existence, but there are actually more implants probably done with the 20s and 30s with radon than with radium.

DR. HOWE: We'll have to deal with that.

MEMBER NAG: Now, radium, you get unsealed Radium 226. Now, 226 half-life is so long. It's 1600-something years. How can you have unsealed?

DR. HOWE: We don't think it's out there. We just put it in to cover the bases to make sure that people didn't start doing something without contacting us, but we don't think anybody is going to use it and we don't think it's out there, Dr. Nag, but we --

MEMBER NAG: But I think the next question about radon is if you think about it radon long-range seeds, I think people will still be using it.

DR. HOWE: We'll find out.

Yes.

MEMBER FISHER: Is the NRC anticipating the use of unsealed Radium 226 or sealed in the form of targets for producing other short-lived alpha emitters?

DR. HOWE: That would not be subject to this particular NUREG because this NUREG is the medical use. If it was being used as a target to develop new isotopes, then that would come under Volume 21, which is Duane's. That would be making accelerator produced materials with an accelerator.

Okay. In the 30.32(j), which is the authorization for noncommercial transfer, we've added the guidance in Appendix AA. We have a lot of appendices in this volume. That gives you the guidance on how to submit an application for this authorization.

Because of the noncommercial transfer that can be done by medical use licensees, we've also added things like you may now be responsible for filling orders and shipping where in the past you were more responsible for ordering materials and receiving. So we've added shipping.

And we've also addressed more non-medical uses in users specifically in the guidance. We've

tried to cover the bases that we can think of. In many cases we've put a disclaimer in that says you may have to supplement this, the model procedures, which are always optional for the non-medical uses that you may be involved with.

Okay. Lydia told you that our non-users are grandfathered. We revised Appendix C to include these individuals in the T&E submissions for all pathways. We tried to make that a lot clearer how to capture everyone.

And also you need professional licensing information for physicians and pharmacists.

One of our big changes as far as pages goes would be the introduction of our new NRC Form 313As. We had one NRC Form 313A that was developed as a result of our changes in the 2002 rule, and at that point we were told to make minor changes to the form, and the form had to fit about 25 different types of professional individuals. And it was very, very complicated, and the comment we got from everyone was, "Can you do something with the form?"

So we made six of them, and we grouped them this way. There's a 313A RSO that covers individuals that are subject to 35.50. There's a 313A AMP that's for 35.51. There's a 313A ANP for 35.55.

We divided up the physicians into three groups, the AUD, D standing for diagnostic. That's the 190, the 290, and the 590 physicians. The AUT; T stands for unsealed therapy. Those are your 390, 392, 394, 396 physicians, and the AUS and the S stands for sealed source, and those are your 490, 491 and 690.

You had a chance earlier to look at those forms several meetings ago. We put the new forms in Appendix B. We've revised the guidance to go with these forms. That's in Appendix D. The new forms are up on the Website right now.

The guidance, we have a minor tweak to that once we get our no legal objection again on the minor tweak, we'll revise that on the Website, too.

We also use these sample forms in the sample 35.200 application.

Security related information, security is a big issue. We added a section that reminded applicants and licensees that if they are including security related information, they need to mark it appropriately and separate it out. We provided references to the Website that gives further clarification.

We marked a diagram, a facility diagram, that showed exactly where the material would be used

and who was located above and below.

We also in the sample application for the 200 user because it had a facility diagram to say exactly where the material would be used. We marked on the 313 form that it included security related information, and we marked that page in the sample application.

Do we also changed the format of all of our sample licenses to remove the NRC logo, to make them look less like official NRC licenses. They contain the same information, but they do not look as much like an NRC license as they did in the past.

And then we did some very minor updates. We changed the agreement state numbers in the map. We added federally recognized Indian tribes. We had a number of tables in Appendix U that had typo errors in it that we have corrected, and we've made some other very minor changes.

So that's kind of a quick overview for our changes to Volume 9. Are there any questions or comments?

CHAIRMAN MALMUD: Questions or comments for Dr. Howe?

MR. BHAT: This is Ram Bhat. Can you hear me?

CHAIRMAN MALMUD: Yes. Could you identify yourself, please?

MR. BHAT: Okay. Ram Bhat from U.S. Air Force, Bolling Air Force Base.

I have a question. U.S. Air Force has several sites which contain Radium 226 and in some buildings. So how do you interface the decommissioning aspects of this Radium 226 which are contaminated with the soil?

DR. HOWE: You're talking about decommissioning and this particular talk is not relevant to decommissioning, and I cannot answer that question. We are currently dealing with revisions to the rule and to the guidance and to the statements of consideration in the rule to address Radium 226 that's been used for military uses.

And Lydia Chang is the individual that would be able to respond to that, and Lydia is not here right now.

PARTICIPANT: Thank you.

CHAIRMAN MALMUD: Any other questions or comments?

(No response.)

CHAIRMAN MALMUD: There being none, thank you, Dr. Howe.

We will next hear from two people who are identified here at TBD, but they will be more specifically identified after they assume their seats. First I believe it's going to be Cindy Flannery.

MS. FLANNERY: Yes.

CHAIRMAN MALMUD: And there is a handout which you should all have in front of you.

MS. FLANNERY: Okay. Good morning. Cindy Flannery.

I just have some introductory information before I pass this over to Dr. Williamson, who by nature of his profession and involvement in AAPM task groups has a lot more to say on this topic.

Shortly after the last ACMUI meeting in October, NRC had received a couple of requests for NRC to require vendors as well as users to only use Air Kerma Strength in the calibration of brachytherapy sources instead of apparent activity in millicuries.

And around the same time that these requests came in, there were also several medical events that had been reported at that time having to do with the confusion of Air Kerma Strength and apparent activity in millicuries. And these errors had resulted in treatment delivery errors.

Now, the NRC's regulations for

manufacturing and distribution of sources and devices do not address the units of measurement.

Okay. So here's the first E-mail, and the emphasis is mine here with the bold and underline, but the person who had sent in this E-mail explains that the contained activity is necessary for the purpose of transportation; goes on to say that the treatment planning systems, the modern ones, do only use Air Kerma Strength, and that there is no real useful purpose for apparent activity in millicuries, and then ends up by just suggesting that the NRC consider abandoning apparent activity and requiring the vendors to do that also.

Here's a second E-mail that just came in a couple days later. Again, the italics and the underlining here, the emphasis is mine. But I just want to point out this first one here, that this individual had personal experience with ordering some brachytherapy sources and having the manufacturer fill that order in the wrong units.

And just like in the previous E-mail, the previous slide, this individual is asking NRC to enforce the units of Air Kerma Strength instead of millicuries and apparent activity.

So the next couple of slides that I have

here just have some of the more recent medical events that have been reported to the NRC as a result of confusing these two units. So I have them listed here in reverse chronological order and also I had it color coded by the error.

So I'm just going to start out with the data entry ones here in pink. So for this first event here that was a data entry error, and the total activity was determined for this patient in millicuries, but the treatment planning system has a default in Air Kerma Strength.

So when this individual entered in the activity, the operator didn't actively go and change it to millicuries, and as a result, the treatment planning system calculated a higher number of seeds, and it resulted in a 24 percent increase in dose.

And this right here, a more recent one, is another example of a data entry. Some of these events that are listed here were reported in agreement states, and so there's not quite as much information. If it's reported to NRC, it's followed up with a reactive inspection, and we go and gather a lot more information, but as far as the agreement states, that's all handled by the state inspector. So some of them don't have as much information as others.

So I have no more information than just the wrong units of measurement where entered in the treatment planning system.

So that's the data entry type of errors. The other one I want to point out here is in purple, and this is where the licensee made an error in ordering, and in this particular case, the licensee or the treatment planning system calculated in units of Air Kerma Strength .5, but when it was ordered, it was ordered in .5 millicuries. So it ended up being a 27 percent overdose.

The next slide here, exact same type of error. The treatment planning system calculated in Air Kerma Strength, but the licensee ordered it in millicuries. But in this particular case ten patients were affected, and what happened here is this licensee had a new medical physicist come in and saw the error right off the bat, and they found out that there were ten people who were affected by it when investigated it.

Okay. So a third type of cause here is where the manufacturer makes an error in filling the order, and the licensee did not realize that when the brachytherapy sources were received. In this one particular case, the licensee had ordered in units of

Air Kerma, but the manufacturer filled the order in units of millicuries. It resulted in an overdose, and then the opposite here, and it resulted in an under dose.

MEMBER WILLIAMSON: Do you know if the shipping vials and the certificates were correctly filled out or were they erroneously filled out?

MS. FLANNERY: That information was not in the NMED report.

MEMBER NAG: I mean, I have had many close misses or I have seen many close misses, and many times the problem is that the person who is giving the order is someone who may not realize that there's a difference between millicurie and Air Kerma Strength. So they make the call, you know. "I want 0.5 millicuries," and they have it or the other way around. "I want 0.5 Air Kerma Strength," and the only thing they have is millicuries. So they just put 0.5.

And similarly, some of the technologists may not know the difference between the two. No, the physicist would know.

So I think it's a very common error. The risk is very high. You know, once we have that knowledge department we said no one is going to use two different things at the same time. Whenever you

have two different units applicable at the same time, you know, the likelihood of mistake is extremely high, especially when the difference is only about 30 percent of most isotopes.

CHAIRMAN MALMUD: Ralph.

MEMBER LIETO: The units here are millicuries or apparent activity; isn't that correct?

MS. FLANNERY: That's correct.

MEMBER WILLIAMSON: I'll just comment I'm anticipating my own talk. When I was actively doing brachytherapy physics I order hundreds of probably 400 seed orders. I never had an erroneous delivery, but that's because of the way I did it. Okay? I insisted on verbal verification and verification in writing by a fax.

So before the seeds were delivered, I knew what their intent was to deliver.

MEMBER SULEIMAN: I have a question. but you were dealing with one vendor. So you had established a relationship which implied tighter controls. So I think --

MEMBER WILLIAMSON: That helps. In fact, we had two vendors, but you're right. There was a very limited number in that era.

CHAIRMAN MALMUD: Those two speakers were

Williamson and Suleiman.

Any other comment?

MS. FLANNERY: Another thing I wanted to point out here is a conversion error, and while some physicists think that the milligram radium equivalent is an obsolete unit, if you look at a very recent event, which just happened a couple of months ago, that same error was made, the exact same error. The conversion from milligram radium equivalent was not done before it was entered into the treatment planning system.

In this particular event there were a couple of things that went wrong. One of them was that conversion was not done, but also this is the first time that this licensee had ever used iridium, and the acceptance testing was not done, and so the treatment planning system did not have the correct dose rate factor in for Iridium 192.

I had listed several different kinds here, the conversion errors and so forth, but I really want to focus your attention really on the three types of errors here, namely, the data entry error, the error caused by licensees in ordering the seeds, and then also the errors in the manufacturer filling the order and the licensee not catching it once the shipment is

received.

So I just want to conclude by reminding everybody that there are no regulatory requirements for using AKS as opposed to apparent activity, but I just want to request of ACMUI is just to provide some input on NRC's role in this, and I guess now having laid out the radiation safety concerns cause by errors infused in the units resulting in unintended adverse consequences, I'll pass this over to Dr. Williamson.

CHAIRMAN MALMUD: Thank you, Cindy.

MS. FLANNERY: Thank you.

MEMBER WILLIAMSON: Thank you, Cindy.

What I thought I would do is present a little technical information, place this in some perspective because I think those of you outside of radiation oncology might not appreciate the technical differences and what the physicist does in day-to-day practice to mitigate the errors that can arise from these conversion processes.

So I'll discuss the concepts of apparent activity and Air Kerma Strength mainly for low energy seeds in relation both to primary standards and dose calculation; review some of the potential error pathways; talk about some practical techniques for mitigating errors; and discuss some recommendations

for future action.

Here are some individuals, some prominent brachytherapy physicists in the community I talked to to get some more current information than I have regarding what the vendor interfaces are like. So I'll talk a little bit about that as well.

Okay. So I think that you all know about Palladium 103 and Iodine 125 implants. We now have Cesium 131 as a new addition to this armamentarium. There are now of the order of 50 to 80,000 of these procedures being done annually for prostate cancer. So it is probably at the moment the most frequently practiced indication for brachytherapy. So it is quite important.

So how is strength of clinical brachytherapy course determined? And the answer is much in the same way we determine the quantity, the output of a low energy X-ray unit, by measuring the Air Kerma rate on the transverse axis of the seed via an ion chamber. You have a special quantity for representing this measured output, which is defined by the AAPM called Air Kerma Strength, represented by the symbol S_k, and it is equal to the Air Kerma rate in free space on the axis of the source times the square of the distance.

So it has units of microgray meter squared per hour or centigray, centimeter squared per hour, and frequently the special symbol mu is used to represent this mouthful of units. It's kind of a handy set of units because the Air Kerma Strength represents numerically the centigray per hour of that brachytherapy will deliver in tissue, approximately. So it's very closely related to a quantity of clinical interest.

This is the primary standard at the National Institute of Standards and Technology that is used for defining Air Kerma Strength for low energy seeds. So it's basically a cylindrically shaped, free air chamber where the seed is -- I don't have a pointer, but this little rotating seed holder is on the other side of this lead barrier, and there's an aperture that defines the beam. So it's a very handy system for defining a -- thank you -- primary standard for Air Kerma Strength individually for each of the now approximately 20 to 25 seed models that are available on the market.

So this is apparent activity. I think because of the dominance of nuclear physics in our field, activity-like units are in common use to describe radiation output quantities. So apparent

activity is the activity of a hypothetical, unfiltered point source of the same radionuclide that gives the same Air Kerma Strength as the given source. So it is a basically kind of odd way of stating the Air Kerma Strength or radiation output of a brachytherapy source in multiples of a hypothetical point source.

So this has no connection whatsoever to the nuclear medicine standards for activity. It would be inappropriate to measure this in a dose calibrater unless said calibrater were calibrated against the wide angle free air chamber.

So one can define it. You divide the Air Kerma Strength by the essentially exposure or Air Kerma rate constant, which is this animal right here. The AAPM has a guidance document which essentially fixes the two constants at standard values of Iodine 125 and Palladium 103. So they are very close to one another, 1.27 microgray meter squared per hour per millicurie for iodine, 1.29 for palladium.

Hence you can see the origin of the 30 percent errors that were described by Cindy.

So what does the AAPM say about this? Well, I defined here what "directly traceable calibration" means. This means essentially a source or an instrument calibrated directly, with no

intermediate steps against the wide angle, three-year chamber.

Secondarily traceable is mainly what vendors have available and what we as practicing clinical physicists have available in our clinics. It means we specify or measure the Air Kerma Strength of our seeds in an instrument that has been calculated, that doesn't itself have a directly traceable calibration.

So what is recommended and required? Well, all clinical sources shall have secondarily traceable Air Kerma Strength calibrations. This is what AAPM recommends. This is what I believe is the intent of 35.432, which is the section on calibration in 35.400. It basically says if the vendor has not provided a secondarily traceable AKS calibration, then you as the end user are responsible for doing so, one or the other.

The AAPM goes one step further. It basically says each user should verify the vendor calibrations with secondarily traceable SK measurements. In fact, it gives specific guidelines suggesting that at least ten percent of the sources should be assayed experimentally by the end-using physicist.

Many institutions are doing this. Most institutions that participate in multi-institutional clinical trials do this because they are required as a condition of being credentialed to participate. So most academic institutions and large private practices who put patients on clinical trials for prostate cancer are, in fact, doing this or have the capability of doing this.

Okay. So the status of these calibrations, all advisory and scientific groups that have considered the issue recommend unanimously that Air Kerma Strength be used for source ordering, planning, prescription, and recording treatments; that basically apparently millicuries and other obsolete quantities, such as milligram radium equivalence, should not be used.

All source vendors and planning software that you can currently purchase allow the use of Air Kerma Strength in a more or less straightforward and transparent way. Source certificates, all that I know of, report both units. The dominant planning system, which is Varian's VariSeed, the user can choose Air Kerma Strength and apparent activity.

And when you choose one or the other, the units are displayed clearly both on the interactive

screens and on the printed output of the plan, but this is user choice.

Most of the published dosimetry data is Task Group 43 and Air Kerma Strength compliant, as the quantities are normalized in terms of Air Kerma Strength. Virtually all sources that you can purchase have mixed traceable calibrations that meet the intent of 35.432 and the recommendations of the AAPM.

The AAPM maintains registry of sources that adhere to its recommendations, which may be of interest to NRC if you haven't looked at this, and as I mentioned, many clinics, most maybe, maintain in-house calibration capabilities for carrying out what is now from the NRC perspective a voluntary verification assay.

However, apparent activity in millicurie units is still widely used in clinical practice. I'm discussing only low energy seeds, but in high dose rate brachytherapy, it can be even more confusing because now, you know, there are at least three quantities floating around. There's Air Kerma Strength. There's milligram hours and milligram radium equivalent that are used in some institutions for intracavitary high dose rate brachy, and of course, there are curies and curie seconds that are

used by some institutions. So you do have to really be careful.

And here the potential for errors is much larger. They can be a factor of two because the conversion factor from curies and milligram radium equivalence to Air Kerma Strength is a factor of two different for these two quantities, four versus 8.25.

Okay. So for implementing the AAPM recommendation for verifying within the individual hospital or clinic the Air Kerma Strength of purchased seeds, most institutions use a dose calibrator or reentrant ionization chamber. This is a cross-section of a common dose calibrator. This is one of the specialized, but more difficult to use reentrant chambers that you can buy specifically for brachytherapy. These instruments need to be calibrated specifically against the Air Kerma standard for the individual source model. You cannot use the same method of transmitting calibrations to end users that's used in nuclear medicine.

I will point out this is the major reference, the revised Task Group 43 report that covers, I think, in one single reference all of this material. So for the benefit of the NRC staff who are interested in working on this issue, this is the

document, the most important document to go to.

I'll talk about the relationship now to dose calculation. The Task Group 43 report provides a table based dose calculation algorithm that I have managed to condense down into one slide basically what it is.

(Laughter.)

MEMBER WILLIAMSON: It's very simple. The dose rate from a brachytherapy seed is the Air Kerma Strength times the dose rate constant times inverse square law times a factor that describes the fall-off of dose along the transverse axis due to attenuation and scattering. This is like a depth dose from which inverse square law has been removed. This is an asymmetry constant that corrects for the fact on average that the dose distributions around these seeds is not spherically symmetric.

The dose rate constant is maybe the most important one to consider. This is the ratio of dose rate at one centimeter in tissue divided by Air Kerma Strength. This has a value of the order of unity, that is, 1.0 as I mentioned earlier, although the specific value can vary anywhere from about .85 up to about 1.05 for the brachytherapy seeds that have been used in clinical practice.

For a high dose rate brachytherapy source, this would be about 1.11.

So this is the only quantity that is affected by the choice of calibration units. So there you have it, the five-minute introduction to the Task Group 43 formalism.

So now if we were going to calculate within a treatment planning system dose using Air Kerma Strength, we would just use the equation directly. If we were going to select the menu option that allows you to use apparent activity, the same equation would be used internally, except they would slip in another conversion factor that basically not surprisingly is the ratio of Air Kerma Strength to apparent activity that I had mentioned previously.

These two equations would give absolutely identical numerical results if the same factor were used consistently through the process of ordering seeds and planning the implant and reconstructing the delivered dose distribution.So you can obviously see there is a possibility of error if different people involved in different stages of the process don't use a consistent value of this correction factor.

Okay. This is hard to see. This is a typical calibration certificate that you would get

from Oncura for the GE Healthcare Model 6711 seed. This is the most widely used iodine seed still today and historically. And so as you can see, it gives the Air Kerma Strength in microgray meters squared per hour, and it gives the apparent activity in millicurie. Two quantities. I think it's very clear. It gives the activity, and it decays it very conveniently to the specified date of the implant.

So when you imagine, if you telephone Oncura to order these seeds, you've got to specify three things clearly to them. You've got to specify the date of the implant. You've got to specify the quantity of source strength that you want, and you've got to specify the quantity that you're dealing with.

As I understand from talking to my expert consultants, if you do this in writing, you can use either apparent activity or Air Kerma Strength, and the form makes it fairly clear which choice you are making. If you do this on the telephone, Oncura will discuss this only in terms of apparent activity. They expect you to take the initiative as the user to convert it to their unit.

Now, when I was doing this some ten years ago, it was even more difficult. First of all, they would only decay it to the Monday closest to your

shipping date. They would not give you the average activity. They would give you the upper and lower bound on the activity group. So you had to sit there with a calculator and not only convert it from Air Kerma Strength to apparent activity, but you'd have to average their upper and lower bound, and you would have to do this decay correction. So there was a lot of possibility for error, and one has to be very careful.

Okay. This is the calibration certificate. Well, I'll mention one more thing since I think misinterpreting these certificates can be one of the possible pathways for error. They mention various other conversion factors here that contained activity. The apparent to contained activity conversion factor is buried here in the footnotes to this text. They also tell you what the conversion factor is if you want to express apparent activity in megabecquerels instead of the doubly obsolete millicuries.

This is the Theragenics/Bard calibration certificate, and I might mention this is made more complicated by the fact that for palladium especially, there are multiple pathways. You won't have to deal with just Theragenics or Bard, but I believe there are

several other companies that sell this particular seed. They each will have their own telephone interface. So there's a lot more complexity than there used to be.

So you can see there are many more quantities here you have to worry about. There's the Air Kerma Strength, the Air Kerma range, the seed activity and its range in megabecquerels, the apparent activity and its range in millicuries. So they have everything here in a nice table. So it is more complicated.

Usually the reference date is the implant date, but not necessarily, and you actually have to make steps to make it clear that's how you're specifying it or it could be a different date.

The order and quantity, you can use either, but the telephone, they will only accept Air Kerma Strength units. So there is a difference, and this is in general true. There are now 20 different models of seeds you can order, and as an individual user, you need to understand the weaknesses and pitfalls of the vendor's ordering interface that you are dealing with.

Okay. So what are some error pathways? I'll give you kind of a diagram here to show you. So,

you know, we go all the way from vendor calibration to institutional calibration to clinical prescription, which usually has to do with making it pre-planned and translating the desired dose that you want to give into some quantity, say, apparent activity; doing the implant; and then performing the dose calculation and seeing what the dose is.

So there is a chain of activities here, all of which involve consistently selecting the same quantity or if there is a change in quantity in any one of these steps, properly converting from one to the other.

So possible error pathways are we have the vendor for V, the client for C, which usually is the physicist but not necessarily, and the physician who is in our institution certainly not the person who does the ordering. So what are some possible errors?

Well, the client order can match the prescription quantity, that is, the P quantity, but not these quantities, and this might not be picked up by these. So there could be a V-C miscommunication.

The client order could match the vendor order in quantity, but not the physician's prescription quantity. So the physicist could misunderstand the physician's prescription and order

in Air Kerma Strength instead of apparent millicuries, or the other way around.

C, V, and P could all agree on the quantity, but V fills the order with the wrong units. So there would be an operational error on the part of V. Now, V could do this in two different ways. The shipping container and the certificate could clearly specify which quantity it's specified in. So it would be actually from their perspective correct, or it may be incorrect. I think there's two possibilities, and we're not clear which happened.

Occasionally the worse error where it's actually mislabeled has happened. There could also be, I think, a reference implant date disagreement. This could be either due to a misunderstanding between the client and the physician or the client and the vendor, and one could wind up with seeds that are erroneously labeled as to date, and this might not be picked up.

Okay. At the treatment planning level, the wrong quantity from the V certificate could be input into the computer where one could pick off Air Kerma Strength from the certificate into a computer where the option apparent activity has been selected.

One could select the correct activity from

the certification, but select a wrong planning system menu option.

Another error could be the wrong conversion factor could be programmed into the software for that particular seed model.

Another possibility is an incorrect decay correction to correct for differences between reference and treatment date could be in place. This could be either an error in introducing the half-life into the software or simply erroneous entry of the date into the planning computer.

So there's a lot of different error pathways. I'd also like to point out that we could worry a lot about this particular mechanism, but there are many, many other sources of error. One could have the wrong dose rate constant in which would have basically no dependents necessarily on the choice of quantity.

So what do we do in clinical practice to avoid this? Well, as I commented earlier, the client must anticipate the vendor ordering system flaws and use redundant communication. So what I always did is I insisted that the vendor repeat back the order to me so that I would hear what it is they had written down to reduce miscommunication.

I would also insist, and we do this today still in my institution even though I'm not the one involved, that they fax a copy of the order to us immediately so that before it's shipped, we can pick up on any error that has been made, and I think this is -- I agree with Dr. Nag -- it has happened more than a few times that it has been incorrect, and this is the place to catch it.

Another something else that can be done and is required by 35.457, I believe, which has basically a skeleton set of commissioning tests that have to be done of any brachytherapy dose calculation algorithm.

This should catch any systematic flaws in the algorithm or its programming the constant, such as wrong dose rate constant or wrong conversion factor.

Another test that one can do is what I call end-to-end testing. So what does this mean? Well, one is following the AAPM recommendations. One will have the capability of verifying via a dose calibrator or reentrant chamber the Air Kerma Strength of any batch of seeds that you order. So a very useful test to do is to basically simulate a treatment. Order an extra seed or take the first set of seeds that you order for a patient, calibrate them,

get the Air Kerma Strength, which is usually fairly clear from the calibration certificate supplied for the chamber that you use, manually calculate the dose rate, then go through the normal clinical process as if you were planning a patient, but do it only for one seed, and compare the calculated dose distribution to the manually calculated dose. And you will be able to pick up any errors due to mishandling these quantities or units throughout the chain of converting from one step to the other. So this is certainly a very good test that I think any physicist would do coming into an institution for the first time.

And it is, in fact, what the Radiological Physics Center does when they come and site visit an institution that's participating in multi-institutional clinical trials.

Okay. For protection against random errors, I think the best protection is written procedures and forms to capture key data: dates, units, and quantities. So if at the time one is doing the seed assay, for example, has the written prescription information in front of one and the date of the implant, it's very easy to check at the time of seed assay whether an error has been made or all the pieces of paper are together. One can check what's

written on the calibration certificate against the prescription.

On the other hand, if the forms are scattered all over the department, the prescription form is in the patient chart and not in the record book in the same physical location where the seeds are received, this may be missed if this is carried around in somebody's head.

So one has to have, I think, a rationally designed process. I had mentioned already what one can do to control and understand the vendor ordering interface. I think the third step one can take is to follow the Task Group 56.43 Air Kerma Strength assay recommendations. They're excellent protection against random errors in either labeling the seed product or misinterpreting the certificate or misreading the certificate that comes.

The fourth thing that can be done is an independent physics review of the plan per TG-56 guidelines. And once a plan has been done, a physics review of the plan would consist of basically checking the source strength printed on the treatment plan against the calibration certificate against the written prescription checking all of the dates and decay and checking via some independent dose

calculation algorithm that the dose distribution computed by the plan is at least approximately correct.

So what could I say in terms of conclusions? Well, multiple source strength quantity certainly is a source of potential error. I'll comment though we shouldn't single this one out. There are many, many other sources of error that can creep into the process and will creep into the process in any poorly organized system.

And I think one thing I would say is that the regulations do not have a fine enough mesh to basically force a clinic to have a bomb proof system for capturing all errors. This is basically the task of the qualified medical physicist to organize and document the process, design it so that it is very robust against all of these bad things that might happen.

So there's really no excuse for, no alternative to having a qualified and experienced individual to take charge of the process and make sure that this and other sorts of errors are mitigated.

Okay. So I would say that regulating apparent activity out of existence isn't warranted. You know, as I count up the number of patients

affected by this three to four-year experience reported by Cynthia's handout, there are approximately 50. If I doubled the risk, given the number of permanent implant procedures that are done, it's about five times ten to the minus four. So it's fairly small, and many of the errors were caught it sounds like at fairly intermediate points so that the dose delivery errors were only of the order of six percent instead of the full 29 percent or a factor of two.

Secondly, I think the community adaptation at least in the short term to outlawing apparent activity since it's so widely used could also cause more errors in the short term. It's maybe better that the community, that the readership within the regulated community keep pushing on the users to gradually abandon this.

Fourthly, it's well documented and straightforward, and minimum practice standards should be sufficient to address this problem. Many of them are in the address or alluded to within the regulation, but the regulation never will be a sufficient practice guide and will never be a substitute for following, I think, recommended practice standards.

So I think given that this has happened,

a reasonable recommendation or course of action is to draft an information notice highlighting the potential problems and what some of the solutions are.

Another action that could be undertaken by the NRC is to have your liaison to the AAPM basically take on the task of discussing this with the brachytherapy subcommittee chairman, who is Dr. Mark Rivard and, you know, ask the AAPM to put on its radar or on its agenda the task for trying to push the users and the users' vendors to promote the use of Air Kerma Strength, I think, on a more consistent and wholehearted basis.

I think the structure that exists now to insure that all of the clinical use seeds have adequate dosimetry data sets backing them is essentially a voluntary guideline that the AAPM has put in place through collaboration with NIST and the vendor. So that's worked very well, and I think that if this is thought to be an item of high concern, and we certainly agree we should continue pushing on this, I think they would be in a very good position to do this.

That concludes my presentation.

CHAIRMAN MALMUD: Thank you, Dr. Williamson, for an extraordinarily detailed and

understandable explanation of errors that have occurred and might occur. There must be some comments. We'll start with Dr. Nag.

MEMBER NAG: Yes. You have given a very thorough presentation. I would like to highlight some of the clinical portion. You know, you have done it from a physics standpoint and I'll do it from a clinician's standpoint.

A couple of things that have a major element of error I think. If you are going to involve an information notice, you highlight: (a) If there's a change of personnel. But a new physicist comes in. The physicist is used to doing it one way in the other institution. When you come to a new institution, you are going to do another, but maybe the wrong way.

Second is when you are changing a vendor, for example each vendor has their own way of doing things. So if you were ordering iodine C from vendor A in millicuries, for example, vendor B might doing it another way.

So those are two places where you have most -- where -- you know, error can occur may places, but these are two ways that you have the higher risk of making those errors. So I think those are two places you should try to consent.

And then the third thing that although it's possible to use many methods, each institution should use one method. For example, the ideal role everyone should use air kerma strength; that is the idea rule. If you can do it that way, that would be the best, but if that cannot be enforced, at least each institution should do it one way. You cannot have one institution ordering in air kerma one day and millicurie another day. So these are little things that I enforce at my institution.

MEMBER WILLIAMSON: That's right. I mean, this whole process within the institution the practitioners have control of, that they should document it and basically do all of the steps in one quantity or the other and minimize the amount of fiddling around with manual calculators. That's really good advice.

I agree with all your points.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I have a question. You said that one of the studies or whatever they sampled ten percent of the seeds for accuracy?

MEMBER WILLIAMSON: Basic no, I didn't say that. I said that the AAPM recommendation is that two verify the vendor's calibration, the minimum number of

seeds out of a, say, a batch of 100 that you buy that you should measure or assay individually is ten.

MEMBER SULEIMAN: Are there any results to share with those how well do those agree or what sort of deviation do people observe when they do such sampling?

MEMBER WILLIAMSON: Well, it depends on --

MEMBER SULEIMAN: Are they all within five percent, are they off by 25 percent, 50 percent? Just I want to get a --

MEMBER WILLIAMSON: No, I can give you -- I'd say there have been large errors occasionally reported, but with fairly low probability. The sorts of things that are usually are found are of the order of three to maybe seven percent changes. And to some extent this is due to random fluctuation because, you know, the seed-to-seed variation within a batch of seeds typically has a standard deviation of about two to three percent under the best of circumstances. So if you have a small number of seeds, like for an iodine implant where maybe you might use as few as eight seeds, this can be important and you would want to probably assay every single one of those seeds and maybe consider using your own measured value --

MEMBER SULEIMAN: What's the vendor's

stated accuracy? They don't state better than five percent, do they?

MEMBER WILLIAMSON: Well, I'm not sure they -- this is a topic of active discussion within the AAPM as to how to improve the uncertainty or reduce the uncertainty of vendor calibrations. I think it's thought to be around 3 to 5 percent under the very best of circumstances. It can be measured with a total uncertainty of about 2 percent within an institution if you're really careful. But, yes, the answer is especially for a small number of seeds, it's about 5 percent.

MEMBER NAG: One comment there. Basically I have told my physicists to report to me for any deviation of more than 5 percent, otherwise they don't even report to me. But the other comment that the ten percent assay, the recommendation from AAPM, however, did not like -- when they tell you you don't necessarily have to do it unless you are in a treating institution, you know, it's not mandatory.

MEMBER WILLIAMSON: That's correct. I will say that there have been occasionally reports which are much larger than 5 percent deviations. In 1997 it was discovered that the main palladium vendor, its calibration precipitously changed, systematically

by 10 percent. This was not noticed by the vendor. This was observed by the users. And this was a fairly serious incident. There have been other incidents which are much rarer and more random of very large deviations.

So the answer is that there are random fluctuations of the order of 3 to 5 percent and the AAPM basically says five percent is the limit that you should proceed to rectify the discrepancy before you proceed. But 5 to 10 percent systematic deviations have been noticed and occasionally much large random deviations have been noted due to mislabeling of a shipment.

CHAIRMAN MALMUD: I think there was another comment. Dr. Fisher?

MEMBER FISHER: Thank you. Darrell Fisher, the patient rights advocate.

I do have experience in this area. I do brachytherapy seed order checks for two institutions representing four vendors and one independent treatment planning center in the Seattle area. And so the reason I do seed order checks is for the exact reason that you've pointed out, that there are a number of places where errors can occur. And I would like to concur with all of your points, Dr.

Williamson, the answer to this dilemma is not eliminating the apparent activity unit. It's putting in place a good quality assurance system for checking orders and making sure that when orders are received, they match the order.

The independent check of a seed order by a second medical physicist has helped us reduce errors from about ten percent down to zero for the last year and a half. We also revised the order forms for each vendor because the order forms themselves created mistakes and had errors.

We do careful matching of dates, times, especially the dates, times, and units. The date the seed is calibrated, the date the seed is intended to be implanted making sure that all the dates are right with patient name, number and other identifiers. Make sure that a QA system is well documented and in place.

And now the errors that we notice are in filling the send order, which we try to check when the seed orders arrive. And so I think major problems now that we experience are with getting the order quantity and product at the hospital when it's needed.

CHAIRMAN MALMUD: I believe Dr. Welsh had a comment.

MEMBER WELSH: So I've heard that there

are so many potential weaknesses in the system and avenues through which errors can occur, such as vendor A might have a different policy from vendor B for iodine-125 and then a different policy may exist for palladium-103, as you mentioned, with the telephone ordering.

It seems that the fact that there are so few errors is a testament to the quality of the clients, the physicists and physicians who are involved in all this. The double checking system that I've heard, Dr. Nag's system, Dr. Williamson's approach all seem to be excellent solutions. But it would seem logical that if apparent activity is considered obsolete, why not consider abandoning it at this point?

It seems that the estimate of increased errors in the short run may be preventable if this were a very gradual transition. Because it's obvious that there are checks and balances that prevent errors when they are so likely to occur with the current system. Why not just take that extra step out?

CHAIRMAN MALMUD: That's a question. Does anyone on the Committee wish to respond? Dr. Fisher?

MEMBER FISHER: For compliance with other regulations, transportation of sources and possession

limit.

MEMBER NAG: Again, those I think that can be gained, too. Because if you are going to make a systematic approach, then, you know, you have to begin in all the areas.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Apparent activity has nothing to do with the transportation. It's the actual activity. So if you take apparent activity out of the equation, you still are going to have the activity that has to be shipped. And actual activity, like I guess maybe there might be some rare legacy type treatment planning systems that might use that value, really the only time you're going to use the shipped activity is simply on your transportation labeling. It doesn't get into the treatment planning system at all. Apparent activity is a different quantity altogether.

CHAIRMAN MALMUD: So your comment, Mr. Lieto, is meant to say that the system with the older terminology could be abandoned?

MEMBER LIETO: Yes. The apparent activity value, yes.

CHAIRMAN MALMUD: Debbie?

MEMBER GILLEY: Yes. As far as regulatory

requirements, we don't use apparent activity. We use activity as possession limits, so again we wouldn't have an issue with apparent activity anymore.

CHAIRMAN MALMUD: All right. Orhan?

MEMBER SULEIMAN: Would a requirement -- there's sometimes a role for government in terms of mandatory standards if it's safety related. Would a requirement that such sources have a NIST traceable standard, and therefore you automatically adopt the way NIST is recording that activity and since NIST is pretty much in sync with this AAPM protocol, would that solve the problem?

MEMBER WILLIAMSON: No. Because without-- you know, there already is the requirement within the 35.457 that basically there be essentially this tray. It doesn't say it so many words, but it says industry standards. But basically all of the sources are supplied with NIST traceable calibrations. They may not be the lowest of them, they may not all meet the uncertainty standards we'd all like, but they're there. But the problem is the vendors translate them into other units and quantities. The reason they do that is because the users want them translated into other quantities and units and that's what they use in their institutions.

CHAIRMAN MALMUD: Jeff, I'd like to ask a question. Not being a radiation therapist or physicist. The errors that have occurred, which are of an order of magnitude of concern, not the other errors -- after all seed placement has such an order of magnitude of potential error that these smaller errors may be insignificant. So just addressing the larger errors that have occurred historically, what has been their source of error? Is there --

MEMBER WILLIAMSON: Well, I'm not sure I understand the question.

CHAIRMAN MALMUD: All right. I'm not being clear.

There are clinical errors that are the magnitude of concern?

MEMBER WILLIAMSON: Yes.

CHAIRMAN MALMUD: But there were not many of them. Of those clinical errors that were of a magnitude of concern, was there a common thread among those?

MEMBER WILLIAMSON: I don't -- I think actually to try to answer the question, I think the dominant source of errors that exceeds this -- that is more serious than this kind of error frequency wise, and Sandra or Donna-Beth may correct me. I'm not sure

who is tracking all these errors now. It's geometry. You know, if you get the source in the wrong place, that's going to cause -- has the potential to cause percentage wise a much larger error or catastrophic error than I think these unit conversions. And I think this happens numerically more often than these kinds of errors.

The second ranking item of concern I would say is, indeed, treatment planning related errors where somewhere the dose is reckoned incorrectly and a clinical decision is made upon an incorrectly calculated dose rate, which is what I would classify-- this would be a subclass of those errors. But there's many more indications and pathways for this error than just this.

DR. HOWE: Dr. Malmud, if I could just give a little anecdotal --

MR. MOORE: One second. This is Dr. Donna-Beth Howe from the NRC Staff.

CHAIRMAN MALMUD: Do you have a mike there, Donna?

DR. HOWE: I think I do.

CHAIRMAN MALMUD: Go ahead.

DR. HOWE: I think I would agree with Jeff Williamson. If we look back at our medical events that

are reported, we have more often than not they're in the wrong place. And generally if you look to see why they're in the wrong place, it's because of improper interpretation of ultrasound. And so I think that's where we get our most severe medical events.

CHAIRMAN MALMUD: Thank you.

So that's what I suspected. And that being the case, is there really a need to alter any of the procedures in place today with regard to the units when it appears that the errors that have occurred as a result of the units are trivial compared to the errors that have occurred because of human error or physician practice, which is unrelated to these issues?

And I'll just make a statement, which is that we can spend enormous amounts of energy and funds on establishing standards which are applicable to maybe two standard deviations or three. Once we get beyond that, there's an extraordinary expense involved both in human effort and in dollars in correcting errors that might occur outside of three sigma.

Now in handling airplanes, one is concerned about every incident. But the question here is are we dealing with issues that are clinically significant? I realize that they are numerically of

concern, but do they really have any clinical significance considering the fact that the placement of these therapies is a human skill which has much greater errors associated with it than the errors which appear to have been presented here as being common errors.

MEMBER WILLIAMSON: Well, I would agree with your conclusion but not your reasoning. Okay.

I think that in an individual patient, a 30 percent error can have clinical significance. But what I would say is I think this is one category of errors out of many possible pathways. To be able to do modern brachytherapy with a high level of reliability, safety and accuracy, you need to have a very well organized process and system with double checks built in and qualified personnel to staff it. I don't think that it is the role of the regulation to look at every single detail and say you must do it this way, you must do it this way, you must do it this way. I do think that's not appropriate to regulate this small issue.

I think we should take the opportunity to call attention in an information notice to the kind of safety processes and practices that are necessary to mitigate this and other classes of error. And since

this has come up, I think we should do an information notice and draw attention to what is really needed to do this kind of therapy safely. And I think if you have a good process, it doesn't matter whether you use apparent activity or air kerma strength. We'd all prefer that apparent activity and milligram radium equivalence would fade away into the sunset, but you know my job is to design -- or used to be to design systems that are robust enough to work reliably no matter what quantity we use.

CHAIRMAN MALMUD: And my question is, "Do physicists currently believe that the system is flawed?" If you asked me as a clinician what I believed was the number one protective element for the patient in this system, it is the presence of a qualified compulsive, attentive physicist.

MEMBER WILLIAMSON: And physician.

CHAIRMAN MALMUD: Yes. But I mean before it gets to the physician.

MEMBER WILLIAMSON: That's true. I'd agree. I wouldn't call the system flawed. I think the flaw is in ourselves because, you know, some institutions have an allegiance to these old-fashioned units and quantities. But I think with a good system it doesn't matter.

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: I would like to just chime in here reiterating what Dr. Nag pointed out earlier about this system. It could work well if you have a consistent team with a conscientious physician and a compulsive physicist. But if you get a new physicist who may be just as compulsive but not use to that particular system, then the flaws within the system itself become apparent and it becomes far more challenging than it needs to be.

MEMBER WILLIAMSON: That's the task of, you know, clinical management to make sure that when you get a new person on board, they are well oriented and, you know, double checked. I think that would be part of the system you'd have to have. And the more the system is carried around in an individual's head instead of written out on paper in the form of a process that more than one person can share, the more likely that is to happen.

CHAIRMAN MALMUD: I think Dr. Nag?

MEMBER NAG: Yes. See, I have been investigating the medical events the last couple of years. Although not systematic, just from memory I think the largest magnitude of error has been called a misplacement because the physician, whoever this

order it is, an oncologist, did not know enough about ultrasound and thought anything that looks black was the -- that's the largest magnitude. However, in terms of the number of errors I think miscalibration links quite high -- not miscalibration, but misidentification that is oddly the millicurie or apparent millicurie and so forth.

For iodine being 30 percent it is not all that bad. It's bad, it's still a misadministration because it's more than 30 percent. But for iridium, it's 1.79, so it's 79 percent difference. So that is a pretty large magnitude and it's not a trivial amount.

Unquestionably, I would favor that that means some type of regulatory push to have everything in terms of --

CHAIRMAN MALMUD: Again, as a non-radiation therapist, non-radiation therapy physicist, looking at the details of what you've presented, Dr. Williamson, I mean I'm impressed with the detail and the thoughtfulness. What concerns me is how we recommend that a system be changed in some fashion which is not so complex that itself generates unintended consequences.

And of the suggestions that I've heard

here today, the one that seems most easily applicable and might reduce the number of errors from the outset is that each institution adhere to one system and one system only of its choice in the beginning. And that that would in theory reduce some of these errors that are occurring for institutions that are currently using two different systems.

MEMBER WILLIAMSON: I don't want to make it seem like I'm defending, you know, old-fashioned units. I think what I'm defending -- I'm trying to caution against is making a hard and fast regulation to deal with it. That's very costly. Okay. It's going to take a long time to do it. It may have unintended consequences. It's one sided. It tends to sort of warp one's perspective because, you know, regulation should be made only about very important things.

I think what we could do that I think is reasonable and would capture both what Dr. Walsh and Dr. Nag and I have been saying, is I think to strongly encourage or recommend institutions and vendors to get with, you know, get on board and use modern quantities and units, really pay attention to this. And I think there are ways to do that that fall short of an explicit regulations which I think is the strongest

possible response that NRC can make to something besides, you know, punishing you know an individual institution. So there would be recommendations in the regulatory guide covering 35.400 that this quantity be used. There can be an information notice pointing out these problems and recommending. There can be efforts to work more closely with the AAPM on a plan to get more compliance with these recommendations to use this quantity that have been on the books now for 20 years. And as the AAPM has a very good track record of bringing the different groups together and getting voluntarily compliance with even more difficult issues than this. Making the transition from older systems of dosimetry to TG-43 was a major achievement of the AAPM and the regulated community. And it was done without any regulatory push from FDA or NRC.

CHAIRMAN MALMUD: Dr. Williamson, is that your recommendation that we invite AAPM to send us an informational item regarding what their recommendation is for dealing with this issue?

MEMBER WILLIAMSON: Yes.

CHAIRMAN MALMUD: May we take that as a motion to this Committee?

MEMBER WILLIAMSON: So moved.

MEMBER LIETO: Seconded.

CHAIRMAN MALMUD: It has been seconded by Mr. Lieto.

Is there any further discussion about asking AAPM to send us a memo which would be a consensus document from AAPM regarding its recommendation for how this specific issue might begin to be addressed? We're not speaking of regulation, we're speaking of transition? Dr. Nag?

MEMBER NAG: Yes. AAPM already has a recommendation, though, we don't need a separate one. I mean, they already of their recommendation. I think what we should be doing is say the recommendation, it is recommended that the users follow the AAPM recommendation. The recommendation, though, you were one of the authors of that recommendation.

MEMBER WILLIAMSON: Well, I think that the suggestion goes a little further than that. It's basically asking the AAPM to collaborate with NRC in producing an information notice specifically for the regulated community to encourage some motion on this issue.

CHAIRMAN MALMUD: Well, but Mr. Williamson--

MEMBER NAG: Okay. I would agree with that. Yes.

CHAIRMAN MALMUD: Is that the motion you're seconding?

MEMBER LIETO: That was my understanding of the motion and its intent.

CHAIRMAN MALMUD: Mr. Moore?

MR. MOORE: The Staff, through information that it gets back, can do things such as discuss incidents or talk about what's happened out within the regulated community. It can talk about best practices that institutions may want to adopt. It can put out information that's available and that other organizations have available. But we are limited to some extent in what we can put out through regulatory information statements or information notices. To not put out something that has any appearance of being a requirement or a regulation in the sense that, you know, our general counsel will tell us it can't look like it's a requirement. So we would have to walk a fine line and not using the word "recommendation."

We could put out something that another organization may say is a recommendation and say attached is, you know, something that AAPM believes is useable.

CHAIRMAN MALMUD: I believe that's exactly what we've been seeking, which is an informational

item from the NRC which incorporates the recommendation from the AAPM, which would be nothing more than an informational item, but it would be distributed because currently I don't think that there is a uniform document that's been distributed to all of the users, is there?

MEMBER WILLIAMSON: That's why it's a collaboration because, yes, it has to be something that fits the format of this kind of a information dissemination pathway.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Scott, using your own terminology if we specify -- I mean if it's specified in the draft that comes back to the NRC as a result of this motion of using the terminology these are best practices or things of that nature, which essentially are standards, I mean as long as they don't say "recommendation," I mean is that the key not using the word recommendation?

MR. MOORE: The Staff can come up with something that would work. And certainly something that AAPM puts out itself, the Staff can forward other agencies' documents and make them available through the use of an information notice or a RIS to the regulated community to make the regulated community

know about good practices, basically.

MS. WASTLER: And part of what could be done in the IN is, was as recommended, is to describe some of the errors that we've seen and how they might result and recommend or suggest those best practices, some of which were discussed today that might help eliminate it, you know. Because our goal is to try to minimize if not eliminate events happening no matter what their significance might be.

MEMBER WILLIAMSON: Yes.

MS. WASTLER: You know, to totally protect health and safety.

CHAIRMAN MALMUD: And that's what I think that we're striving for is essentially an informational item --

MS. WASTLER: Right.

CHAIRMAN MALMUD: -- which incorporates the recommendation of the physicists so that at least the information is distributed and available for the users to incorporate into their practices, but it is not a regulation. It is a transmission of someone else's recommendation.

Orhan?

MEMBER SULEIMAN: I'm a little conflicted, not a lot conflicted. Because if the purpose was to

inform the vendors to switch over, you've communicated that. If the NRC comes out with an advisory or something that doesn't have the force of standards behind it, the vendors could still ignore you and continue -- why have they ignored you up to now?

So my question is maybe the vendors have an ear and they'll go back and they'll standardize the way you like and this problem is solved.

MEMBER WILLIAMSON: Because it's the community. It's actually the customers who want it this way, that's why they do it. Vendors typically do things because in response to customer demands and preferences. They don't do it because they're stubborn cusses, you know.

MEMBER SULEIMAN: Maybe the fact that you've appeared today and made this presentation may be sufficient initiative to solve the problem?

MEMBER WILLIAMSON: I think the fact that -- well, I suggested a two pronged approach. I think making it appear an item of regulatory concern, which an information notice does, will bring more attention to it.

I also suggested, I don't know if Dr. Zelac is still is the -- are you the liaison to the TPC, the Therapy Physics Committee of the AAPM?

DR. ZELAC: Yes, I am.

CHAIRMAN MALMUD: For the record, Dr. Zelac's indicating yes. Yes.

MEMBER WILLIAMSON: Okay. That's very good. Well, I would recommend a second recommendation. That is Dr. Zelac take this issue to the TPC Committee and basically see if the AAPM has interest in trying to promote uniformity on this issue. I think that if it's properly discussed in advance with the Chairman of the appropriate subcommittee that I indicated, I think you will find that the AAPM is interested and might have some ideas that fall short of an explicit regulation or trying to promote more unanimity.

CHAIRMAN MALMUD: Is that a corollary to your motion?

MEMBER WILLIAMSON: Yes.

CHAIRMAN MALMUD: Mr. Lieto, do you second that corollary, or would you like them to be two separate issues?

MEMBER LIETO: Can I answer it?

CHAIRMAN MALMUD: Please do.

MEMBER LIETO: I think that's unnecessary. I think it's pretty obvious because it's medical physicists that have been raising the issue regarding the difference in the units. And I think there's

already that interest in the AAPM community.

So I think the information notice of the motion is going to incorporate all the aspects that Dr. Williamson has stated. And I think rather than weigh it down with corollaries, that we just leave it as was so nicely put originally and move on.

CHAIRMAN MALMUD: Well, Mr. Lieto prefers to leave the motion as it stood without weighing it down with Dr. Zelac, who is not that heavy a weight. So is there further discussion? Ms. Gilley?

MEMBER GILLEY: I don't want to muddy the waters, but there are 34 agreement states that might like to participate in this information notice also. And since it's not going to be a regulatory requirement at the federal level, I would like consideration to be given that we also include them as another partner in this activity.

CHAIRMAN MALMUD: Thank you for reminding us of that. Thank you.

MR. MOORE: We would coordinate the information notice with the agreement states.

CHAIRMAN MALMUD: All right. There is a recommendation on the table. Shall we call the vote for the recommendation?

All in favor? Any opposed? Any

abstentions?

You have receive unanimous approval of your recommendation, Mr. Williamson. And thank you again for a very clear well thought out presentation, as usual.

Is this your last presentation before --

MEMBER WILLIAMSON: This is my last presentation, yes.

(Applause).

MS. WASTLER: Perfect timing.

CHAIRMAN MALMUD: I hope that you will notice that the Chairman has brought the Committee to the conclusion of the morning session at precisely 11:29. Lunch is extended by one minute.

We'll see you back here at 12:30 for a discussion of specialty boards. Thank you.

(Whereupon, the Committee was adjourned, to reconvene this same day at 12:32 p.m.)

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

12:32 p.m.

CHAIRMAN MALMUD: We are going to begin this afternoon's session with Cindy Flannery, who is going to speak to us about an update regarding the approval status of specialty boards. However, we will wait for a few more people to join us at the table. Thank you. Cindy, you are on.

MS. FLANNERY: Good afternoon. This is just a brief informational presentation to provide the status of recognition of the specialty boards as well as provide updates to the boards that are already currently listed since this topic was last presented at the October ACMUI meeting.

This right here is a list of the boards that are recognized thus far. Each time I have given this update at the three previous ACMUI meetings, there have been nine specialty boards that have submitted applications. But since the October ACMUI meeting, we have now added a tenth to that list. That is the last one here, the Certification Board of Nuclear Endocrinology.

They just submitted an application a couple of months ago. The NRC staff went back to them, requested some additional information, which

they have submitted. And it is with NRC staff right now for review.

The only other board right now that is not yet recognized is the second to the bottom there, the American Board of Medical Physics. Their status has remained unchanged for a little over a year and a half now.

Early on in the process, they submitted an application. NRC went back to them, requested some additional information. And we are still awaiting that supplemental information from ABMP.

Having said that, they have expressed an interest very recently to us that they are interested in pursuing and continuing the recognition process.

So that covers the only two boards that are not yet recognized of the ten that have applied. Now, as far as changes to the currently recognized boards since the last ACMUI meeting, there have been changes to two of the specialties in the American Board of Radiology, namely the diagnostic radiology and the radiologic physics specialties. And at the request of ACMUI, NRC has gone to the ABR and asked them what they can do about recognizing their diplomates who have obtained their certification prior to the recognition date.

And those two specialties that I have mentioned have proposed some methods for reviewing the qualifications of those diplomates who have obtained their certification prior to the effective date.

And this right here is just the different sections of recognition.

Yes?

MEMBER LIETO: I am a little confused. Maybe it's just the table setup.

MS. FLANNERY: Okay.

MEMBER LIETO: Under your ABR, American Board of Radiology and Radiological Physics was comprehensive. And I hope somebody from the board will correct me if I'm wrong. It was no longer offered and hasn't been for a few years.

Those are the others. Now, granted they are the RSO applications, but those are the specific specialties of certification listed under it. The two you have listed up above it are the same as the two that are listed below the third one. Am I making sense? I don't have a pointer.

MS. FLANNERY: These three, these are subspecialties of the radiologic physics.

MEMBER LIETO: No. Your certificate will say American Board of Radiology Diagnostic

Radiological Physics, American Board of Radiology Medical Nuclear Physics. There's no radiologic physics in the certificate. It's not a specialty of certification.

There used to be analogous to maybe the American Board of Health Physics comprehensive. If you got radiological physics, it meant you were competent in all three specialties, which I don't believe is offered any longer. Is that correct?

CHAIRMAN MALMUD: Microphone and introduce yourself.

DR. MORIN: I am Richard Morin, the diagnostic radiologic physics trustee for the ABR. The way it is categorized like that, I think, Ralph, is because within the ABR, we have three areas in which we certify: radiation oncology, diagnostic radiology, and radiologic physics.

So radiologic physics just refers to the overall area of where the physicists are, but you're quite right. We don't have an exam any longer in radiological physics.

MEMBER LIETO: But the first two listed are the same as the two specialties listed underneath.

DR. MORIN: They are only physicists.

MEMBER LIETO: I'm sorry. Okay. Got you.

MS. FLANNERY: As far as the method that ABR has proposed for these specialties was to review the qualifications of the diplomates and amend their certificates to say either AMP-eligible or RSO-eligible above the seal of the certificate.

So right now the therapeutic radiological physics is recognized under 35.51, which is the training and experience for authorized medical physicists. So their certificates can only say AMP-eligible on them; whereas, the other two are listed under 35.50, which if you look on the next page, it's for RSO.

Their certificates if they meet the qualifications of the training and experience requirements, I should say, then their certificates will read RSO-eligible on them. So that's what they have proposed.

And they're going to review on a case-by-case basis the qualification of those diplomates at the request of the individual and amend their certificates accordingly.

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Could you review, Cindy, for a moment what were the major reasons for rejecting each of the ABR categories prior to June

2007 or 2006, as the case may be, what the ethical --

MS. FLANNERY: As relates to all three of the specialties --

MEMBER WILLIAMSON: Yes.

MS. FLANNERY: -- or just the physics?

MEMBER WILLIAMSON: All of them.

MS. FLANNERY: Well, there are various reasons. One of them is because some of the diplomates have received their training and experience or their work experience, I should say, in the Canadian program. And the way NRC's regulations are written, it needs to be their work experience as an AU, which for the most part means somebody practicing in the U.S. or listed on a U.S. license. So that is one of the reasons.

I think there may have been some reasons for what was on the exam itself because NRC regulations would specify what the exam content must include.

CHAIRMAN MALMUD: Does that answer your question, Dr. Williamson?

MS. FLANNERY: And I think that's all I can think of right now. There may have been other reasons.

MEMBER WILLIAMSON: I am trying to think.

So let me ask more specifically, then. For therapeutic radiological physics, for being an authorized medical physicist, what was the grounds for rejecting those certificates prior to June 2007?

MS. FLANNERY: I think one of the reasons is for the Canadian program. And I don't know. Maybe somebody from the ABR could answer that question. I don't know. What's been expressed to me is that there are some reasons why even some of the diplomates who will be certified after the recognition date of June 2007 will not meet, but it has not been really conveyed to me as to why they can't meet NRC's current criteria.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: What about radiation oncologists who are board-certified in radiation oncology prior to June 2007? Would they be able to handle the 390, the unsealed radioisotopes because previously although that was included in the curriculum, it did not really have those things specified?

MS. FLANNERY: That has been brought to the American Board of Radiology. And a request has been submitted. But what NRC has proposed is to break it down, instead of including 390, 490, and 690

altogether, to break it down.

So, say, for example, if they can demonstrate that their diplomates from a previous year prior to June 2007 can meet NRC's current criteria for, let's just say, 490, they could do that. So 390, 490, and 690 can have different dates.

Now, the message that has been conveyed to me is that they're going to do that and provide the dates, but it has not been submitted yet. So I think for the 390 what happened is that they had to make changes to the certification process to meet NRC's current criteria.

So I don't think this June 2007 date can be changed for 390. However, 490 and 690, it can.

MEMBER NAG: Now, for the 690, one question has been that if you did gamma knife in one use a long time ago and haven't done it for a while but you're still in therapy and now going back to a new institution and it's been more than seven years, how you're going to handle those. I think those are becoming the questions to handle. Do we have any solutions yet?

MS. FLANNERY: I guess I'll look to some of the other NRC staff here, but I think it has been longer than seven years they would need to demonstrate

some training and experience in that modality.

And then the ABR, I mean, depending on if they were recognized, for example, or listed to review the qualifications of the diplomates who got certified prior to the effective date, the ABR could do the review, see if their qualifications meet NRC's current criteria. But, you know, they could also apply to the region, and the review could be done that way.

Training and experience would need to be obtained within that modality the last seven years.

CHAIRMAN MALMUD: Other questions? Yes?

MEMBER EGGLI: Doug Eggli. I have, I guess, a question for representatives of the American Board of Radiology for Diagnostic Radiology. The current approval is for 290 and 292. Yet, the training and experience requirements for 394 with the exception of the case experience are virtually identical.

My residents now are going out grumpy about with their board certification not qualifying them under 394. Does the board intend to have 394 added since essentially all you have to do is get the case experience if you have met the other T&E requirements?

DR. ALDERSON: I am Phil Alderson. I am

the President of the American Board of Radiology. And I am in diagnostic radiology and nuclear medicine. So I will attempt to answer Dr. Eggli's question.

Our understanding, not the same as what you have just said, was that in order to be qualified under the higher level of radioiodine, it took quite a bit more training, not just a little more case experience.

MEMBER EGGLI: If the total training requirement under 394 -- under 390 is 200 hours, but under 394 is 80 hours and they're achieving those 80 hours as they qualify for 392, all they need is case experience as I read the regulation. Can the staff help me on this?

DR. ALDERSON: You will have to refer that back to the NRC for some interpretation of the regulations and what was required. It was our understanding that a lot more training would be required for the higher doses. Accordingly, we felt in radiology residencies, that would be hard to achieve and, therefore, we went with a smaller amount of training.

And we currently have no idea about trying to change that, but we would, of course, if we had misunderstood the regulations.

MEMBER EGGLI: But 390 is the category that requires the 200 hours of training for a broader spectrum of therapeutic nuclear medicine but 394 is radioiodine in ranges higher than 33 millicuries and the regulation says the didactic and laboratory requirement is.

MS. FLANNERY: Unless, Ron, you could answer that?

CHAIRMAN MALMUD: Dr. Zelac, are you able to address the question?

DR. ZELAC: Yes, sir.

CHAIRMAN MALMUD: Thank you.

DR. ZELAC: If the requirement, we're talking specifically 392 and 394, the requirement in each case is 80 hours. However the phrasing is, it's 80 hours.

MEMBER EGGLI: Didactic and laboratory.

DR. ZELAC: Thank you. And in each case, it requires patient experience --

MEMBER EGGLI: Right.

DR. ZELAC: -- for three cases.

MEMBER EGGLI: Right.

DR. ZELAC: So unless there was some significant difference in the information being presented for less than 33 millicuries versus more than 33 millicuries, the training should suffice for both.

MEMBER EGGLI: The training for handling greater than 33 millicuries qualitatively is identical. Quantitatively we put a little bit more emphasis on some of the spills, some of the exposure. But qualitatively the knowledge, the mathematics, the basic radiation biology, the health physics are identical between 392 and 394. It's sort of it's a function of quantity of emphasis, rather than quality of knowledge.

DR. ZELAC: So what you're basically saying is that if the classroom and laboratory training were directed towards --

MEMBER EGGLI: Three ninety-four.

DR. ZELAC: -- 394, it --

MEMBER EGGLI: It would satisfy all of the requirements --

DR. ZELAC: That's correct.

MEMBER EGGLI: -- of 392.

DR. ZELAC: That's correct.

MEMBER EGGLI: And then all you would need would be three cases.

In my practice, clinically we are a thyroid cancer practice, rather than a hyperthyroid practice. And my residents come out with 15 or 20 cases of experience with thyroid cancer and 5 or 6 with hyperthyroid disease. And then they want to know why they can't get a preceptor statement that qualifies them for Part 394 therapies.

I hope I am not misrepresenting this wrong, but I have read the regulations several times.

MS. FLANNERY: I think it's also a matter of whether -- the programs that they're in, say a four-month program, for example, are they going to get an opportunity to do three cases of iodine 131 administrations greater than --

MEMBER EGGLI: In my practice, in that four-month period, they will do twice as many thyroid cancers as hyperthyroids. They will do twice as many cases greater than 33 miillicuries. And under 33 millicuries, we log their experience, but at the end, it doesn't go anywhere because the current ABR/AU status doesn't apply to Part 394.

I think the answer is in many practices yes. Even if all of the practices don't do that, is

there any reason to constrain those who can get there by not having 394 for ABR diplomate?

MS. FLANNERY: The question would be, is the ABR requiring that of all of their programs?

MEMBER EGGLI: The training that ABR is requiring very effectively targets the T&E for 394. As I understand what ABR is asking you to train our residents to, I think it qualifies for 394 with the exception of the case experience.

DR. ALDERSON: Were the ABR to understand this in the way it has been expressed today, we might apply to include 394. But to answer Ms. Flannery's question directly, no, we are not now requiring all programs to do what would be required for 394. They are required only to have three thyroid therapies, not six. And they can be either lower or higher. But they are not required to have what is needed in 394 because of the way the regulation has been interpreted to us previously. But we would have to do further paperwork and reapply if there is a new understanding.

CHAIRMAN MALMUD: Dr. Zelac?

DR. ZELAC: One thing to be added -- and this is the reason I wanted to take a look at the regulation -- under 392, one qualification to be automatically authorized for 392 is to be authorized

for 394. So if you are authorized for 394, you are automatically good for 392, meaning less than 33 millicuries as well. So if the target were to prepare for 394, that would cover both.

DR. ALDERSON: So it is clear that --

MEMBER EGGLI: Can I ask a clarifying question? If they qualified under 394 with 3 cases of greater than 33 millicurie, would it automatically qualify them for 392 so they wouldn't have to have an additional three cases of less than 33?

DR. ZELAC: Yes, yes.

DR. ALDERSON: So the question in the field -- and this was the issue when the board originally determined how to approach this -- is not among the big programs. It's quite clear that that can be met. It's among all the small programs and whether they, in fact, can get their residents the experience required at the higher dose levels. That was the issue, and that is why we went the way we did.

MEMBER EGGLI: Could ABR apply in such away that they could offer 394 if the program can meet the threshold or do all ABR programs have to meet that threshold?

MS. FLANNERY: I think all programs would have to meet that. Is that correct?

MEMBER WILLIAMSON: I think that that is true for the board certification pathway. The resident could always apply under the alternate pathway. I think it would be somewhat difficult. To add parenthetically, at Washington University, where I was on the faculty for some years, for example, it's radiation oncology that does all of the radioiodine applications for a malignant indication. So unless a diagnostic radiology resident sought out the additional case experience, they would not normally get that.

CHAIRMAN MALMUD: Dr. Howe has a comment.

DR. HOWE: The ABR could put things on its certification that would recognize, let NRC recognize, the person was eligible for 394. And they could put something on that certification that NRC could look at and see they were only eligible for 392. It is their choice as to what they do because we have distinguishing things on other certifications for other boards.

MEMBER EGGLI: Thank you, Dr. Howe.

CHAIRMAN MALMUD: Does Dr. Howe's comment answer the concern?

MEMBER EGGLI: It answers my question.

CHAIRMAN MALMUD: It answers your

question. Okay. Dr. Eggli says it answers his question. So now we may move on to the next question. I saw a hand. Sally Schwarz?

MEMBER SCHWARZ: Okay. I have a question about the pharmaceutical specialties. I know originally we were approved for both 35.55 and 35.50. And I'm curious as to why the ability to become an RSO for a pharmacy practice --

MS. ROYBAL: Excuse me. I'm sorry to interrupt, but we cannot really hear some people. Some people talk so low we cannot hear the questions.

MEMBER NAG: Sally, I think you need to bring the microphone to your --

MS. ROYBAL: We are on the maximum here volume, and we can't hear the questions and sometimes the answers.

CHAIRMAN MALMUD: Thank you. We will ask Ms. Schwarz to move the microphone closer.

MEMBER SCHWARZ: Excuse me. I am asking a question in regard to the Board of Pharmaceutical Specialties. Our status allows authorized nuclear pharmacists 35.55. And before the review, the actual acceptance of boards, we were allowed 35.50 status as well if we were board-certified by the Board of Pharmaceutical Specialties. And I'm wondering why

that never came through as a status for the Board of Pharmaceutical Specialties.

MS. FLANNERY: It really hasn't for any of the boards just because under 35.50 there's a pathway for authorizing individuals. So that means authorized users, authorized medical physicists, and authorized nuclear pharmacists. That is a pathway.

So if you are AMP or ANP and AU, you can become an RSO. So they don't need to be specifically listed under 35.50.

MEMBER SCHWARZ: But are you saying by the alternate pathway or by virtue of our specialty?

MS. FLANNERY: Well, it would depend on what pathway you applied for that authorization in the first place. So if you're an AMP, for example, then you can become an RSO by virtue of being an AMP.

MEMBER SCHWARZ: ANP.

MS. FLANNERY: Then you wouldn't have to submit, you know, the training and experience --

MEMBER SCHWARZ: Right.

MS. FLANNERY: -- or submit the documentation that you would have to under the alternate pathway.

MEMBER SCHWARZ: So, in other words, if you are board-certified by the Board of Pharmaceutical

Specialties, you could then submit eligibility to become an RSO?

MS. FLANNERY: Right. You could submit your certificate to show that you are an ANP. Then you could get listed as an ANP on the license and an RSO.

MEMBER SCHWARZ: Thank you.

MS. FLANNERY: Does that make sense?

MEMBER SCHWARZ: Yes.

MS. FLANNERY: Okay.

CHAIRMAN MALMUD: Does that mean that a pharmacist ANP can automatically apply to be a pharmacist RSO once having been certified as an ANP?

MS. FLANNERY: A certified nuclear pharmacist, we want to get to be an ANP on the license, the authorized nuclear pharmacist. They could apply under the certification pathway. And then they could also pursue being an RSO, which one of the pathways for being an RSO is to be an ANP. So it would be a matter of submitting a copy of the board's certificate. Is that correct? Am I stating that right?

PARTICIPANT: And also they would require a preceptor.

DR. HOWE: For the ANP, the certification

pathway, like every other pathway, is a board certification that's listed by the NRC on its Web site and an attestation that the training has been complete and the person can function independently as an ANP.

And then if you're applying for an RSO, the pathway is 35.50(c)(2), which is you are already an ANP. And currently our regulations take you down to (d), which says you have an attestation that you are an ANP, essentially you are an ANP, and that you can function independently as an RSO, and that preceptor comes from an RSO.

MEMBER SCHWARZ: And we do need a second attestation statement from an RSO in order to be able to be an RSO.

DR. HOWE: That's the current interpretation of the regulations.

DR. ZELAC: But if I can -- this is Ron Zelac. If I can address that issue? We at NRC, as you on the Advisory Committee, are very well-aware that this is something that was not intended, not in the past, and ought not to be there. And our intent is to go the direction of removing the requirement for an attestation for an authorized individual, be it AU, AMP, or ANP, to get a second attestation when seeking authorization as an RSO.

What will remain, what is there now, is the need to have specific training relative to that for which you wish to have RSO responsibilities. But that can be documented in another way, and an attestation will not be required.

But Donna-Beth is correct. At the moment it is.

MEMBER SCHWARZ: And, Ron, how much longer will it take to make that change? Excuse me. How much additional time will be required to make that change?

DR. HOWE: This is Donna-Beth Howe. You will be hearing this tomorrow in my presentation. So it's one of the potential changes to Part 35. We have a rulemaking that should be starting this summer that will address issues that you heard before for changes to 35. The length of time it takes for it to become final we can't tell you, but there is rulemaking in the process.

MEMBER SCHWARZ: Thank you.

CHAIRMAN MALMUD: Other questions for Cindy Flannery? Dr. Williamson?

MEMBER WILLIAMSON: What is the status of the AAPM petition for rulemaking, which would generalize or liberalize the 35.57 grandfathering

clause to pick up most of the diplomates, I think, before October 2005 if I'm not mistaken.

MS. FLANNERY: I don't think I am in the best position now to answer that question. And I don't know if it was the intent to cover that now under this part or under the next item in the agenda. What would be the appropriate place to do that?

DR. RATHBUN: Excuse me for interrupting, Cindy. Yes. In the next session, we can discuss the status. But, unfortunately, we will not be able to discuss the petition itself.

MS. FLANNERY: Thank you.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Yes. This was specifically asked and addressed prior to this meeting, what the status of the three petitions affecting medical use was. I got generalized statements answers to the first two. And the issue regarding the AAPM petition it was specifically indicated to me was going to be addressed in this session.

And I think to tell this group now that they have got to wait, especially when we have got a large body out here of people that are here for this specific purpose, I think it kind of gets to a large portion of the problems that we're addressing here

because there's a large number of people. And contrary to staff's opinion, there are a number of people out there that are not applying because of these deadlines or these start dates that are put out there. And so you have a lot of medical physicists and some health physicists for RSOs that are being adversely affected by these dates.

So I think it would be nice to have an update as to what the status of that is. And to say it's in a working group and can't be addressed I think is not very helpful.

MS. WASTLER: Mr. Lieto, I apologize. I realize that it is not satisfactory. But the process that we have requires us to not disclose. It's all pre-decisional information. And so we cannot discuss the, say, suggestions, proposals that are going on in the working group in an open forum.

Ron can address when we feel that we would be able to. And I know that is not satisfactory. I mean, I think folks want answers. But we have a responsibility to complete our process, put the recommendation to management, and then it be, you know, the resolution of that be, made public.

But, Ron, could you address where we are on that, please?

DR. ZELAC: My name comes up because I am the representative from the medical radiation safety team to the working group that's considering the petition. It was anticipated that there would be great interest in knowing what the status of this petition was at the moment. And that has been conveyed to the chairman of the working group, who is in a position to make a statement as to where we are and what the timetable is and where we seem to be going.

The gentleman's name is Mr. Ed Lohr, and he's in the audience. And he can handle it from this point on.

MR. Lohr: Hi. I know I am new to you folks. I am a health physicist. And I work in rulemaking. I'm the team leader for this Ritenour petition that you all are referring to.

What I can tell you, as Sandy said, is very limited. However, we did receive the petition in September. It was published in the Federal Register November 1st for public comments, closed on the 16th of January.

There was 165 public comments received. A working group was formed. I am the team leader. We are diligently working on the petition. We anticipate

by the end of the summer to have resolution of it.

Other than that, I'm not sure what else I can share with this group.

MR. MOORE: This is Scott Moore. If I may provide some more information, our petition review process is a formalized regulatory process within the agency. When we receive petitions for rulemaking, they're docketed within the agency. And we put it out for formal comment to the public. And we get comments back that are docketed and that are on the record. So it has a legal standing within the agency.

If we discuss it in an open setting and we take additional comments on it then, then we would be obligated to consider those comments as well as part of the petition review process.

And so we take the comments. And then the petition review process is closed then, and the petition working group considers those comments, all of those comments and the incoming petition, as part of the petition review process.

The petition working group considers those and makes a recommendation to the petition review board. There's an actual board within the agency. The petition review board meets. And, as Mr. Lohr just told you, it ought to meet sometime I believe in

the August time frame and come to some conclusion. And then it will issue a decision back to the petitioner on the resolution of the petition itself.

So it's a formal regulatory process that happens within the agency.

CHAIRMAN MALMUD: Thank you.

Dr. Welsh?

MEMBER WELSH: I have a general question about what I see on your chart there. In radiation oncology, American Board of Radiology, recognition date is June 2007. My question is about the recertification process. If somebody is recertified in 2007, does that mean that they are recertified with their certificate when they had it in, say, 2000 or is it now 2007 board certification?

MS. FLANNERY: It would be anybody who obtained their certification after the June 2007 date. It's not applicable to the recertification. They would have to meet NRC's current criteria.

And right now, you know, you can see on some of these I have an asterisk. And what that indicates are the boards, the specialties, that are doing a review of the individuals' qualifications on a case-by-case basis.

Right now they are not doing that for

radiation oncology, but they are, of course, say, for example, diagnostic radiology. In that case they could go back, review the qualifications. And if that individual meets NRC's current training and experience criteria, then they could reissue a certificate and the person could apply for authorization under the certification pathway.

CHAIRMAN MALMUD: Does that address your question, Dr. Welsh?

MEMBER WELSH: Somewhat.

CHAIRMAN MALMUD: Other questions or comments for Cindy Flannery?

MS. FLANNERY: Thank you.

CHAIRMAN MALMUD: Hearing none, thank you.

A question is asked. And that is, can the subject be discussed in a closed executive session?

MR. MOORE: Is there a need for it?

CHAIRMAN MALMUD: Yes.

MR. MOORE: I don't know.

MS. WASTLER: We will have to ask that question. I'm not sure.

CHAIRMAN MALMUD: Thank you. Perhaps you can let me know when you get the answer to it.

MS. WASTLER: Yes, I will.

CHAIRMAN MALMUD: The next item on the

agenda is the T&E implementation issues. And this is going to be a discussion which you are going to monitor for us.

DR. RATHBUN: Yes, sir.

CHAIRMAN MALMUD: Thank you.

DR. RATHBUN: You're welcome.

All right. Let me introduce myself. My name is Patricia Rathbun. And I do work for the NRC. However, I do not work in this area or certainly haven't in the past ten years. So please think of me as a neutral person who is here.

I understand that this is a very tough issue. And I also understand, as Ralph pointed out, there are lots of people in this room who have lots of knowledge. And so we're trying to establish a methodology here whereby we can tap the expertise in the room.

And so essentially I am going to pass out now a very brief agenda, which will just kind of show because I realize this is a little bit different than we normally do things. So we'll have a little different type of meeting. I think there's enough for everyone.

Our purpose here is to collect data. It's not to resolve any issues. And I know that in a

professional group like this with many experts -- and I always want to do this -- we want to immediately jump and fix the issue. What is the question? What is the answer? Let's answer it, and let's get on with it.

I'm going to ask your indulgence to work with me. So if you've gotten your handout now, really, I'm just trying to take the administrative burden off here and put it on myself. And if I understand correctly, if you've gotten it, what we've received so far is we have some written statements. We will also have some other types of statements. And we also have people on the phone.

So if you could take just a minute and take a look at the agenda? Our goal again is to hear from as wide a variety of stakeholders as is possible. And we would like positive as well as negative experience if that is plausible on this part of Part 35.

The ground rules, which I would like to try and hold to, would be to start on time, stay on time, and stop on time. Having said that, we are starting at 1;15. So we'll adjust that accordingly. I had planned on having a break at 2:30. And I had planned on coming back from 2:45 to 5:00 and truly

ending at 5:00 o'clock out of respect for people's schedules.

The rest I think one thing that is going to be a problem is that once an issue has been addressed and hopefully captured, we'll try not to go back too often. It's especially difficult because we have people on the phone. So you have to try and get the -- and we will put the issues in writing up in front of you.

Okay. Having said that now, Ashley will be typing what she hears you say. Watch the board. If it's wrong, you tell me, and we'll fix it.

If you look now at part 3, the presentation of examples, I want to start with the written statements that have already been provided to the NRC, then go to the telephone, and then take the comments from the rest of you in here.

Before we do that, I would like to hear from the people on the telephone who is out there. Speak up, and we'll just handle it.

MR. RATLIFF: Richard Ratliff with the Texas Department of State Health Services.

DR. RATHBUN: Okay. Thank you.

MR. SCHMIDT: Paul Schmidt representing the Organization of Agreement States.

DR. RATHBUN: I didn't hear that. Oh, Paul. Hi, Paul.

MR. SCHMIDT: Hi.

DR. RATHBUN: Anybody else?

MR. STEVENS: Mike Stevens with the Florida Bureau of Radiation Control.

MS. ROYBAL: Margaret Roybal and Daniela Bowman with New Mexico Radiation Control Bureau.

DR. RATHBUN: Welcome. Okay. So, then, when you speak, we have to remember to identify ourselves because this meeting is being transcribed. So when you are speaking on the phone, please say your name first for the transcriber.

All right. Who would like to give the first written statement? Who were the statements from?

MS. TULL: SNM.

DR. RATHBUN: Okay. Thank you.

MR. BEVEN: Thank you. Terence Beven representing SNM. We appreciate the opportunity to comment on the training and experience requirements. I would like to just highlight some of the items which are of interest to us.

SNM supports the removal of the preceptor for those in the board certification pathway. The

American Association of Physicists and Medicine and other groups discuss this in greater detail in their various written statements.

SNM recommends that the NRC and ACMUI review the impact of the effective date concept. AAPM and other groups also discuss this in greater detail. SNM is concerned that it's unclear what is required of a physician who completed a residency program more than seven years ago and now decides to apply for authorized user status. Specifically, do they have to repeat all of their training? And if not, if they worked in a nuclear medicine lab after they completed their training, would this ongoing experience mean that they had met the seven-year requirement?

The 200 hours of classroom and lab training required in 10 CFR 35.390 cannot be justified since this is nearly a complete overlap of 80 hours of classroom and lab training required by this regulation; specifically as an example I-131 therapy, which has been mentioned, below 30 millicuries and greater than 30 millicuries.

A syllabus of materials to be covered by classroom and lab exercises could be developed conjointly by the NRC and professional educators. I'm sure the boards and the residency review committees

would appreciate the opportunity to participate in such a process.

SNM believes the certification boards should determine the acceptable training methods for the education of physicians regarding activities such as eluting the generation system, performing, measuring, and testing of the A08, processing the A08 reagent kits to prepare radioactive drugs, and administering radioactive agents. Recent clarifications have stated that the only acceptable method of training for these various tasks is physical, hands-on.

We are also concerned that our Canadian members may be problematic insofar as meeting the T&E requirements. Individual physicians trained in Canada if they did not receive their training under the supervision of an authorized user may not be qualified. Ideally, there should be a defined pathway by which a Canadian nuclear medicine physician could meet the new T&E criteria without necessarily being trained by a U.S. NRC-licensed user.

A potential good approach would be that a Canadian physician should have their training verified by an authorized user in the U.S. and that they should also be required to take a few hours of additional

training to confirm they are knowledgeable in these areas.

In closing, SNM appreciates the opportunity to share our perspective on the implementation of Part 35.10 of the requirements. And we hope that this discussion is the beginning of a long-term dialogue between the NRC, ACMUI, certification boards, professional societies, and other stakeholders. We fully support NRC's efforts to work closely with all stakeholders and particularly educators to enhance the clarification and implementation of the various T&E requirements.

Thank you.

DR. RATHBUN: Thank you so much for doing that. And if I could just get you to help me a little bit with sort of the key points? That was a lot of information for Ashley to hear. So could you help me with some categories that I want to put up here? The first one we got, remove the preceptor statements.

MR. BEVEN: Yes.

DR. RATHBUN: Review the impact of the effective date.

MR. BEVEN: Yes.

DR. RATHBUN: And clarify the requirements for a physician to complete the residency

program. I think you had a few more.

MR. BEVEN: The Canadian members.

DR. RATHBUN: The Canadian. And I know we have the letter, but I want to be sure that everybody in the room also knows what's in your talk.

MR. BEVEN: I think that encompasses all of our bullets.

DR. RATHBUN: Okay. Thank you so much. Okay. What is the next one?

CHAIRMAN MALMUD: There is another issue.

DR. RATHBUN: Oh, I'm sorry. Okay.

CHAIRMAN MALMUD: The 200-hour.

DR. RATHBUN: Okay. Thank you.

CHAIRMAN MALMUD: And included in that 200-hour in parentheses is the question of developing a syllabus.

DR. RATHBUN: Thank you. And the next -- I'm sorry?

PARTICIPANT: There's one other item.

MEMBER LIETO: This is Ralph Lieto. I think there was one other one, and that was having to use live generators to demonstrate acceptable training.

CHAIRMAN MALMUD: All right. That was part of --

MEMBER LIETO: It's supposed to be a part of the 200-hour?

CHAIRMAN MALMUD: It's separate, but okay. We'll make it a separate item. It really refers to the current prescriptive requirements of the NRC, which really tread on the traditional turf of the specialty boards, which determine that which is required for their trainees.

DR. RATHBUN: This is really what we're putting on, isn't it? This is the key point.

CHAIRMAN MALMUD: This is an example of what is perceived currently --

DR. RATHBUN: Right.

CHAIRMAN MALMUD: -- to be overly prescriptive --

DR. RATHBUN: Right.

CHAIRMAN MALMUD: -- since the average nuclear physician, nuclear radiologist, nuclear cardiologist has no need to and no day-to-day experience in eluting generators.

DR. RATHBUN: Okay.

PARTICIPANT: We're getting it together.

DR. RATHBUN: Okay. What's the next letter we got? AAPM? If I'm going too fast, you stop me.

CHAIRMAN MALMUD: Well, are we staying with the issues that relate to nuclear medicine training? Is that the first topic?

DR. RATHBUN: No. What I really --

CHAIRMAN MALMUD: Go through the letters?

DR. RATHBUN: I think so.

CHAIRMAN MALMUD: Okay.

DR. RATHBUN: And then after we hear from each one, let's see what our real topics are.

CHAIRMAN MALMUD: Okay.

DR. RATHBUN: Is that right? Okay.

CHAIRMAN MALMUD: Then we have another member of the public. Would you introduce yourself, please?

MR. WHITE: I am Gerald White. I'm the President-Elect of the American Association of Physicists in Medicine. And, for the record, we represent 6,500 medical physicists in the United States and Canada.

I would like to discuss a written document that we sent that is a summary of discussions held at a meeting of stakeholders that you have in front of you and also a document that was a letter written by the AAPM to Commissioner Klein.

I will do some bullet points here. I

think maybe one thing that we would like to make plain is that the original idea of listing the boards on the Web site was a good one. But earlier today someone talked about unintended consequences of regulation. And this is an incredible series of unintended consequences, as is demonstrated by the packed audience here today of educators, physicians, physicists, other professionals who have given several days of their time and hundreds of hours prior to this to sort out this mess that we're in.

We have a uniform professional agreement, although some disagreement perhaps on the details, that there are serious problems with this process. And we hope that both the NRC and the ACMUI will agree with that as well. There is increasing complexity and no benefit.

We have a number of work-arounds that have been proposed by the staff. And they are in many cases analogous to traveling from Philadelphia to New York by way of New Orleans, Los Angeles, and Seattle. It's possible, but it creates no benefit to the public and doesn't enhance radiation safety.

We have agreement with the preceptor statement problem, that essentially in the board certification pathway context, it is redundant.

During the application process for the boards, there are multiple sign-offs by physician proctors, although perhaps not in exactly the format that NRC would like. There is an examination process and proctored clinical experience that make the preceptor statement completely unnecessary in the board certification pathway.

And, for reasons that we have detailed in the letter, it is also problematic to obtain these statements because preceptors are reluctant to sign in the method that NRC requests.

The issue of marginalizing the certifying boards by virtue of both the preceptor statement and what we call the failure to grandfather those people who were previously board-certified is a significant issue.

The issue of effective date of board recognition was not discussed and not anticipated during the lengthy multi-year process that AAPM and other organizations participated in with this group in developing the regulations.

To give you an example of one of the places where the silliness, if I can use that word, has really manifest. Can you put that? Is that an allowed word on the --

DR. RATHBUN: It's a good word for me.

MR. WHITE: There is a statement that describes how one can use board certification to be a supervisor of an educational program for aspiring AMPs. And the requirements for that are that the person has been certified by a specialty board recognized by the NRC or agreement state.

However, to be an AMP, you have to be certified by a specialty board whose certification process has been recognized by the NRC. Simple one-word difference. And in the former case, all board certificates issued by the ABR qualify, but in the latter case, none prior to 2007 do. No one anticipated that sort of distinction, and it certainly makes no sense in the radiation protection context.

We have talked a lot about the potential difficulties in the letter here about people becoming authorized medical physicists due to the way authorized medical physicist has become a recent construct, the difficulty of physicists becoming RSOs because there's only one RSO on the license, compared to physician AUs, where there may be multiple folks in that category.

And I won't go through all of those particular objections but just to say again that there

were people who were qualified by their board certificate prior to October of 2005. And the next month, same person, same board certification suddenly are not qualified. It makes no sense from a public health standpoint.

I would like the Committee and the NRC to consider the Occam's Razor principle that --

DR. RATHBUN: Oh no, not that.

MR. WHITE: Yes. Well, but in this case I think it's not only applicable. I think it's the key to the solution.

And I'll note that the AAPM has a petition for rulemaking, which I know cannot, dare not be discussed in this context. But we feel that the petition for rulemaking provides an Occam's Razor-type solution. It doesn't take us from Philadelphia to New York by way of the West Coast.

And it's certainly something that we think that the Commission and this Committee should support. And we're hoping that the Committee will support the actions requested in this petition sometime today before we leave.

These issues need to be resolved. We need to have pathways for resolution, hopefully within the NRC or outside of the NRC. But these need to be

resolved. And I think there is uniform professional agreement on that.

DR. RATHBUN: Okay. Thank you very much.

I think we will go back after the next statement because I am starting to hear some overlap. We can put these issues out. Even if they are in the petition and they are brought up in this venue, we can discuss them.

What is the next one? We just had two. All right. Going out to the telephone, is there anybody out there who has a prepared statement to make?

(No response.)

DR. RATHBUN: Okay. All right. Then let's go back, then, to this.

CHAIRMAN MALMUD: Are you able to hear us on the phone? I think there are four external parties.

MR. RATLIFF: Yes. This is Richard Ratliff, Texas Department of State Health Services. I just have a short statement from our Texas Radiation Advisory Board, governor-appointed advisory board, requesting that the NRC and the Committee change the requirement 35.392, training for oral administration of sodium iodide 131 from a category B to a category

C compatibility.

DR. RATHBUN: Okay. I have written that down. The Texas Board of -- how do you say it?

PARTICIPANT: Texas Advisory Board.

DR. RATHBUN: Advisory Board recommends that the requirement in 35.392 be changed from a category B to a category C compatibility. Is that right?

MR. RATLIFF: Yes.

DR. RATHBUN: Okay.

MEMBER NAG: Can someone amplify on what that change means from a B to a C?

DR. RATHBUN: Okay.

CHAIRMAN MALMUD: Can you in Texas tell us what you are trying to achieve?

MR. RATLIFF: Yes, sir. This is Richard Ratliff again. Currently our Texas regulations for controlled radiation have been stricter than the NRC's training and experience. And this would allow us to continue having stricter requirements requiring ACGME training for all physicians who would use iodine in therapy.

CHAIRMAN MALMUD: Thank you for clarifying your position.

DR. RATHBUN: The concept of a category B

and a category C, is that something we should talk about here?

MEMBER NAG: I have no idea what that means.

DR. RATHBUN: Have you heard of that before? Okay. Who is here?

CHAIRMAN MALMUD: Please clarify.

DR. RATHBUN: Yes. Okay. I am looking for a victim.

(Laughter.)

DR. RATHBUN: Where are all of my victims when I need them?

MR. MOORE: Yes. I'll try to answer it.

DR. RATHBUN: Okay.

MR. MOORE: And, Debbie, help me if I don't get the exact words.

(Laughter.)

DR. RATHBUN: There's my victim.

MR. MOORE: The category B level of compatibility means that the agreement states for a regulation that's passed by NRC will have regulations within the agreement states that is essentially identical to NRC's regulations. It doesn't have to be verbatim, but it does have to be essentially identical to the regulation that NRC passes.

Category C has to have the essential objectives of the regulations that NRC has. And so the agreement state may pass something that's different, but it meets the same objectives of the same, which means the state could be more restrictive than NRC's regulations.

For instance, in the area of training and experience, it could require more hours of training or could require additional evidence that the training has been taken or that kind of stuff but still meets the same objectives, which is to show that the training and experience has been taken and obtained. Does that explain it?

DR. RATHBUN: Did you have anything to add to that, Debbie?

MEMBER GILLEY: I believe this particular -- Debbie Gilley -- incident has to do with iodine for thyroid carcinoma or for therapeutic applications. And under Subpart J, a limited number of hours were required for physicians that do that, though the potential risk for harms may be greater than the diagnostic nuclear medicine physicians doing diagnostic studies.

So some of the states have indicated that they would like to have more training and education

for those people doing therapeutic applications than what is currently required in the regulations.

DR. RATHBUN: Texas, is that okay with you? Does that characterize your issue?

MR. RATLIFF: Yes.

DR. RATHBUN: Good. Okay. Anything else?

CHAIRMAN MALMUD: Any other external stakeholders who are on this phone conversation who wish to make a comment?

(No response.)

CHAIRMAN MALMUD: If not, we will move on.

DR. RATHBUN: We have one more.

CHAIRMAN MALMUD: Here, but we are done with the phone entries.

DR. RATHBUN: It sounds like, yes.

CHAIRMAN MALMUD: Thank you.

DR. RATHBUN: Thank you.

CHAIRMAN MALMUD: Member of the public?

MS. MARTIN: Thank you very much.

CHAIRMAN MALMUD: Please introduce yourself.

MS. MARTIN: My name is Melissa Martin. I am here today representing the American College of Radiology. I have served for the last six years as Chairman of the Government Relations Committee of the

ACR's Medical Physics Commission.

For those who aren't aware -- but I am sure everyone in this room is -- the ACR represents 32,000 members. So when we're discussing our organization, we are a large part of what is affected by these rules and regulations.

The ACR has been a very active participant with the NRC throughout this development and implementation of the T&E requirements. It is our belief that the current NRC staff's implementation of this rule is inconsistent with the understandings and deliberations that were part of the rulemaking process.

We basically have three areas of concern. And these should be very consistent with what you have already heard. Number one, there are no health or safety concerns raised by permitting those persons who were deemed competent to practice on or before October 24th, 2005 to continue to practice. Imposing additional regulatory burdens upon these individuals is unwarranted.

Number two, the notion that recognized status for approved boards will have an effective date was not contemplated prior to the rule becoming finalized. This interpretation, along with the delays

in recognizing certifying boards, has been problematic for both authorized users and others, who were not eligible for grandfathering and, yet, sat for their board exams before the board's effective date.

Number three, the ACR recognizes the unique difficulties faced by medical physicists relative to grandfathering. It is a fact that the term "authorized medical physicist," this concept is relatively new in many states. And, therefore, the opportunity to be grandfathered is limited. And the licensees have only listed a single RSO on their license.

The next concern, we recommend that the NRC should develop a mechanism to ensure that all individuals seeking authorized status who are adversely affected by this effective date constrict be given the opportunity to come in under the board certification pathway.

One other area of our concern is the preceptor requirement. The preceptor requirement has proven to be extremely problematic in practice. There is significant concern about the potential among potential preceptors as to the liability they face in attesting to the qualifications of others.

We are faced with a difficult choice. The

preceptor must either sign a statement and risk the personal, professional, and potentially economic ramifications of signing or agreeing to sign a statement and accept the potential liability thereof.

We have been made aware that it is not consistent application in documenting the requirements for these preceptor statements. Some areas are requiring facilities to further substantiate the assertions made in preceptor statements.

Our recommendation is that preceptor statements are redundant given the thoroughness of the board certification process and should not be required for those members that are already certified by the American Board of Radiology in any of the categories.

The other item that we would like to bring up is the attention of the shortage of qualified personnel to function as radiation safety officers under the current construct. The RSO shortage is caused by an implementation of the rule and is severely stressing the system to the point that some facilities will have no one qualified to be RSO with the current requirements.

What this is forcing is that some RSOs are being asked to be listed on several facilities' licenses. The question is, how many facilities can an

RSO adequately serve?

So we would recommend that the ideas already given be adopted by the NRC. Thank you very much.

DR. RATHBUN: Thank you.

Could you help me on this one? It was your one just before the shortage of qualified RSOs. Could you say that one again for me?

MS. MARTIN: Is that relative to the preceptor statement or the RSO?

MEMBER EGGLI: It was actually captured in number 7.

DR. RATHBUN: Okay. All right. So we're doing better. We're on the same wavelength here. Okay.

Having done this, then, is there anybody else in the room who would like to pose an issue? We'll come back, and we'll go through possible solutions, but I would like to make sure we get all of the issues out. Yes, sir?

MEMBER NAG: Yes. This is Dr. Nag, radiation oncology. In radiation oncology, we have the manual that is the 400 and then the 600, which is the high-dose rate brachytherapy and gamma knife.

If someone is recently board-certified, it

is not a problem. However, the problem is that many people will graduate or have graduated some time ago. And then they have worked on something, not worked on something.

And then let's take an example of someone who graduated seven or eight years ago, had training in all of the modalities, worked on one of those modalities but in that institution did not work on the HDR.

Now he goes to another university or another place and now wants to do the HDR. Then he is told that "You haven't had this for seven years. And, therefore, you have to retrain on HDR," which is easy enough. You do a few cases of HDR. You show the recentness.

And then you are now told that because it's more than seven years, you have to do all of the other training, which is not fair because they have been taking care of other parts of radiation oncology.

So it is something that we have to show, but one possibility is that if you are board-certified and, again, no matter what, if you have to show your recent training, you don't have to show the recentness of all the 700 hours, but that component, for example, HDR or gamma knife, you just have to show that you

have had some recent training in that component.

That's one solution. You might think of other things.

DR. RATHBUN: So are you saying if you are, say, working on gamma knife and then you transferred and you wanted to work on an HDR, you wouldn't be able to do that? Is that what you are telling me?

MEMBER NAG: At least that is how it has been interpreted.

DR. RATHBUN: Okay.

MEMBER NAG: That is how, you know, some states and well as some NRC offices are interpreting it.

DR. RATHBUN: Is that something that would have happened in an agreement state situation? Have you heard of that, Debbie?

MEMBER GILLEY: I have not heard of that being an issue.

MEMBER NAG: I have given a written statement to the NRC last week of the actual happening and the order of events it went through.

DR. RATHBUN: Okay. Okay.

MEMBER NAG: So that is in your file.

DR. RATHBUN: Good. Excellent. Okay.

That's exactly what we want is a specific example.

MR. MOWER: I am Herb Mower. I am Chairman of the American College of Medical Physics, in addition to the things that Gerry White mentioned from the AAPM, which we cosigned the letter.

Relative to the preceptor, which there are various concerns about, if somebody has been working and board-certified prior to the cutoff date but in the period prior to that had done the right number of hours and whatnot but their preceptor is either in an institution which is addressed in here which does not allow you to say more than somebody attendant there or, worse yet, the preceptor is, in the words of the TV series, six feet under. What do we do in a situation like that?

And no one else has addressed the fact of a preceptor who is no longer with us. And what does that do to the person who went through the program? Do we expect them to start all over again in order to get a new preceptor who would be working with them?

DR. RATHBUN: So you said if his preceptor was gone six feet under, leave that alone. How does he or she become certified?

MR. MOWER: How do they get the preceptor statement, right.

DR. RATHBUN: How they get the preceptor statement. That's an interesting point.

DR. BROGA: Good afternoon. My name is Dean Broga. I'm the RSO at VCU. I will not speak on behalf of any societies but more in a problem of a physicist working in the field.

The problem of the RSO has become a big issue in community hospitals and smaller outpatient facilities, which would be counting a large number of licensees now, with physicians with limited experience.

And, as Melissa mentioned earlier, a lot of pressure has been put on existing RSOs to cover these facilities, even though they may go there infrequently. This has been an approach taken by the NRC to solve this problem. Otherwise we would be shutting a lot of facilities down.

I would like to see it change so that they identify some kind of RSO in training at that facility who is being covered by an RSO but not have another RSO named as responsible person.

I feel it really puts us in a very big bind to be covering a facility where we only may be able to get to every three months when there is a person on site who could be named as an RSO in

training or whatever who has much more authority on a day-to-day basis. Unfortunately, that is the model that is occurring right now in a lot of facilities.

DR. RATHBUN: And presumably as a result of the implementation --

DR. BROGA: It's a problem that I have had two or three cardiologists who want to leave a group to start their own outpatient office and they ask me about getting a license. I say, "Well, okay. The biggest, first problem you have is who is going to be the RSO."

Especially if you are a break-away cardiologist and the group you are leaving is not sympathetic to your move, they are not going to sign anything. So, you know, I have had a couple of people who did not break away because they couldn't get an RSO, which is unfortunate.

DR. RATHBUN: Okay. That's really interesting. Okay. All right.

MR. MOWER: If I could just do a point of clarification? If you go back to me, I'm not Rick Morin. I'm Herb Mower, M-o-w-e-r, same as power mower.

(Laughter.)

MR. MOWER: I said my name is Rick Morin.

(Laughter.)

DR. RATHBUN: Unfortunately, you caught Ashley over there stealthily doing that. That's one of our really big tricks.

Yes, sir?

MEMBER EGGLI: I think as you cycle back to something that appeared in several of the issues, one issue that needs to be dealt with is preceptor liability or at least perceived liability on the part of preceptor.

As a person who does about 15 of these a year, I understand what those comments were. And that touches in several of the areas. And the ability to get preceptor statements is that the preceptor is perceived as a significant liability issue.

And the preceptor wants to be -- which I think was NRC's intent -- very sure of the people that are preceptoring. But preceptor liability is a major contributor to a lot of the topics that we're seeing listed.

DR. RATHBUN: It's kind of like being a kindergarten teacher, I guess. The most serious thing you do is hurt somebody's kid. Okay.

DR. BROGA: Can I comment on that?

DR. RATHBUN: Sure.

CHAIRMAN MALMUD: Come to the microphone and introduce yourself.

DR. RATHBUN: Say your name.

DR. BROGA: Dean Broga again. I think that is a huge problem. We know the NRC has prosecuted people for signing preceptor statements erroneously. It is in the records. It's not a question that it hasn't happened. And that was when you were attesting training and experience, not competency. That statement says competency.

And the third statement in that thing about the regulations and emergency preparedness and so forth, it's poorly delineated. I have no idea what it means.

If someone were to ask me to sign a statement about their competency and I have some liability in it, there's a great hesitance on my part to do it.

And so we have gone from saying "training and experience" to "They are competent to do this job." And then we have ambiguous statements that don't delineate what we're really covering.

There is a number of major medical facilities that are having problems with this.

DR. RATHBUN: Okay. I think we've got

this one.

CHAIRMAN MALMUD: If I may, I would like to put a little historical perspective on this. The members of the Committee will all recall that, I believe, to a man and to a woman, we all protested the use of the word "competency."

We can attest to the fact that an individual has received certain levels of training and that he or she appears to have absorbed that training. We cannot attest to an individual's competency. An individual who is competent today may be totally incompetent tomorrow or may commit an act tomorrow which betrays his training.

Coming from Philadelphia, where there are more lawyers than there are educators, I can tell you that putting a statement down as to someone else's competency leaves the training program director or the attester potentially liable. And it is not a worthwhile gamble, not in Philadelphia.

DR. RATHBUN: Dr. Eggli?

MEMBER EGGLI: In the original discussion and consideration, I think that when we got to this, one of the concepts that we had sort of agreed to was that we could attest to mastery of a body of knowledge, as opposed to competency.

I actually thought that that is how the final reg would be written at the time, but competency sneaked back in there. We just looked at the various sections of the reg, and the word "competency" is in there.

I think it's easier to attest the mastery of a body of knowledge than it is to attest the competency because I can test for mastery of a body of knowledge. As already said, I have no idea how to test for competency.

DR. RATHBUN: Right, right.

CHAIRMAN MALMUD: And it should be in the minutes that the members of this Committee protested the use of the word "competency." And we were assured that it probably would not appear. And, yet, it did appear.

As the Chair of the ACMUI, I must tell you that I am distressed and disappointed that something that was unanimously opposed by the members of the ACMUI was ignored at the time of the final writing of the document.

It's as if we don't exist. If our purpose is to participate and to give you our opinions, for them to be ignored totally, then I believe we are a purposeless committee and should be dissolved.

MEMBER NAG: So be it.

DR. RATHBUN: I can sympathize with your feelings. To dismiss it is the worst feeling.

CHAIRMAN MALMUD: I believe I am speaking on behalf of the entire membership.

DR. RATHBUN: Am I getting everybody showing their hands on this?

CHAIRMAN MALMUD: Do you want a show of hands?

MEMBER NAG: Yes.

DR. RATHBUN: Yes.

(Whereupon, there was a show of hands.)

CHAIRMAN MALMUD: Everyone who was on the Committee at the time agrees.

DR. RATHBUN: Okay.

CHAIRMAN MALMUD: And we regard that as a betrayal.

DR. RATHBUN: Okay. I can understand that.

CHAIRMAN MALMUD: Strong words but strong feelings.

DR. RATHBUN: Well, it's clearly very important.

CHAIRMAN MALMUD: Because we're interfering with the practice of medicine and

certification of individuals. Some actions which are taken to protect the public actually have the opposite effect.

For example, if there is a shortage, different subject, if there is a shortage of RSOs and RSOs are, therefore, require, those who are certified, are required to cover more than one institution, we have diluted the competency.

We have not improved the competency because the individual who is the RSO for three or four or five or six or more institutions cannot be physically there all the time. That's not progress. That's regression.

So we have to look at the unintended consequences of some of these actions that are taken with all of the good intention in the world but are not responsive to the advice given by this Committee, which I recognize is an advisory committee.

But if our advice is worth nothing, tell us. And we have better ways of spending our time.

DR. RATHBUN: Well, did you want to respond to that?

MR. MOORE: The Advisory Committee's advice is certainly important to the agency. And we can go back and look at the record and see what

happened, but we certainly do value your advice.

One of the things that we haven't brought out much in this discussion is the agreement states' views on the training and experience requirements beyond what the Texas Radiation Advisory Board's position is on the one compatibility issue.

And I remember when we were promulgating Part 35. The states played an important role and had some fairly strong views. And so, you know, we do have Debbie Gilley, the Chair of the CRCPD, and Paul Schmidt, the Chair of the Organization of Agreement States, on the phone and other agreement state representatives on the phone.

Now, I wonder if any of you all would like to bring in a state perspective on the T&E requirements and talk about any of the state-specific issues.

DR. RATHBUN: Okay. Paul, could you go first on this one? Paul?

MR. SCHMIDT: Yes, I'm here.

DR. RATHBUN: Okay. Could you speak to this issue a little bit?

MR. SCHMIDT: I'm going to have to keep it somewhat general here.

DR. RATHBUN: Okay.

MR. SCHMIDT: There's another individual I was hoping was going to be on this phone who could speak to it much more specifically. I don't believe they are, though, from what I have heard.

DR. RATHBUN: Okay. Well, Debbie is here. And we thought that we would let you go first.

MEMBER GILLEY: Thank you so much.

MR. SCHMIDT: I would be happy to have Debbie go first.

(Laughter.)

DR. RATHBUN: You want Debbie to go first. Okay.

MEMBER GILLEY: Well, let me take it from a personal state perspective first. There are four states that have medical physicist licensure laws. They are very prescriptive licensure laws. And for that, those four states, there are going to be some compatibility issues that are going to come up because there is statutory language that requires certain qualifications for a therapeutic medical physicist. State of Florida will have difficulty meeting the attestation requirement and the preceptoring requirement as it's currently in Part 35.

So that very little world is the State of Florida. I believe Texas may have some issues, New

York and Hawaii also. Of course, it is not an agreement state, but they also have medical physics licensure law.

The agreement states did participate in this activity all along. And they did try to bring -- I'll choose my words carefully here -- a common sense approach to this. The way we have been working for many years appeared to be working fine with us with the board recognitions as they were identified prior to 2005 or prior to Part 35 implementation.

So the compatibility issue B was a surprise to us later on in the process. So with all of those comments, we were led down the path, much like the ACMUI was, with how things were going before we saw what was the final product and the final compatibility.

DR. RATHBUN: Okay. It looks like we will have no trouble setting the issues out. I know we aren't going to get the solutions, but we can set the issues out.

Okay. Dr. Malmud, did you want to add something right now?

CHAIRMAN MALMUD: No. I just wanted to recognize Dr. Van Decker.

DR. RATHBUN: Okay. Thank you.

MEMBER VAN DECKER: I just wanted to add a comment to the compatibility B issue from the provider perspective. Obviously providers sometimes go from state to state in their careers. And so from the provider issue, it would certainly be a more reasonable thing to have a uniform status for T&E across the nation that is reasonable and acceptable to everyone than to go state to state and find out you can do something in one state but if you cross the border, you can't do it in another state. It's problematic.

DR. RATHBUN: That's a good point. Thank you. So you run across the border and practice medicine.

CHAIRMAN MALMUD: Dr. Williamson wanted to be recognized.

MEMBER WILLIAMSON: And I think to comment that if one looks at the record of past ACMUI deliberations, we have strongly been in favor of a uniform regulatory apparatus and not allowing individual states to penalize providers more than other states, which it sounds like Texas would like to do, have more strict -- you know, we might be in this setting more empathetic to states who wish to have better work-arounds than the NRC does, but --

(Laughter.)

MEMBER WILLIAMSON: -- to make things worse than they are now seems like just incomprehensible.

MEMBER GILLEY: May I respond? Again, if we had the old Subpart J and it was not a compatibility theme, the new Part 35, many states would have remained the same as it was prior to the implementation of Part 35. And you would have had less restrictions, what is currently required of NRC.

DR. RATHBUN: Okay. When we come to the part where we talk about solutions to some of these things, I suspect that we will have some things to say about that, how that came about.

Yes, Dr. Eggli?

MEMBER EGGLI: I would like to give the other side of Dr. Van Decker's comment. Again, as I'm a purveyor of preceptor statements, I guess is the way I appear here, I preceptor about 15 people a year. And I get calls from people who several years later are moving to another state. And now the requirements are different. And the training program that they were in was not designed to meet the requirements of the most restrictive of the agreement states.

And we have to tell these people they

can't practice anymore because I cannot write them a preceptor statement for the state that they want to move for because our program wasn't designed to meet the most restrictive of preceptor requirements among the 34 agreement states. And it ends up being a serious problem for the individual practitioners as they try to move from state to state.

So Bill was talking about it from the side of the affected individual. I see it from the side of the purveyor, who has to essentially tell these people that I'm changing their career choices because I can't write in a preceptor statement.

DR. RATHBUN: So the categorization is also making this issue more complex. Do we have somebody on the phone who wants to talk?

(No response.)

DR. RATHBUN: Okay. Debbie?

MEMBER GILLEY: Just saying that there is reciprocity between states and the agreement states and NRC. So there are other mechanisms through reciprocities by being listed on a license and a non-agreement state or another agreement state and coming into the new state versus using reciprocity as the basis.

MEMBER EGGLI: Yes. Sadly sometimes these

are first-time licenses for these individuals.

MEMBER GILLEY: And they're working at broad-scope licenses that don't list them on a license, --

MEMBER EGGLI: Yes.

MEMBER GILLEY: -- as I understand it.

MEMBER EGGLI: Yes.

DR. RATHBUN: Okay.

MEMBER NAG: I'm again Subir Nag, radiation oncology. Radiation oncologists have two major roles. One is external therapy. The other is radiation implant of brachytherapy.

Not all radiation oncologists do both equally. Most people do more external and less brachytherapy. And if the regulations are overburdensome, more and more radiation oncologists will do less and less brachytherapy.

So that you are going to see brachytherapy disappearing. Although medically it's very useful, many radiation oncologists choose not to do these and let their license lapse.

So I think if the NRC is not really -- you may make some of the procedures not available because people just don't want to go through this. And this is a real possibility.

And I will be presenting even in brachytherapy an alternative tomorrow that may make some people choose not to use radioactive implants.

DR. RATHBUN: Okay. So that may result in changing the way somebody practices medicine. Is that what you are saying?

MEMBER NAG: Yes.

DR. RATHBUN: Okay. Is there anybody else in the back of the room who would like to speak? All right. We'll put you in line behind this gentleman.

MR. LAMBERT: My name is Kent Lambert. I'm here representing the American Board of Health Physics. Because I understand that these proceedings are transcribed verbatim and because I know my limitations as a public speaker and because, as Mark Twain once said and I quote, it takes more than three weeks to prepare a good impromptu speech, --

(Laughter.)

MR. LAMBERT: -- I have prepared remarks. The American Board of Health Physics was formed in 1958 and has granted over 2,000 certifications in health physics over the last 48 years. Over 1,300 certified individuals are still active. Under current regulations, only 53 certified individuals are eligible to be a radiation safety officer based on

their certification.

It's apparent that the certification board requirements of part 35 were modeled after the ABHP certification requirements. However, minor differences between the two sets of requirements prevent a blanket assertion by the American Board of Health Physics that all of us diplomates prior to 2005 meet these requirements.

As a result, the current regulations require that individuals certified prior to 2005 by the American Board of Health Physics use a so-called alternate pathway to become an RSO.

Consequently, it's more difficult for individuals who have more post-certification experience to become RSO than it is for recently certified individuals, who by definition have less work experience. As Lieutenant Commander Spock would say, that is not logical.

The current regulations imply that individuals certified prior to 2005 are less capable of performing as radiation safety officer than those certified subsequently.

However, there's no evidence to support that premise. Therefore, the additional steps of using the alternative pathway pose a burden upon

individuals and licensees without a corresponding increase in public or worker health and safety.

And I have to skip all that part about Dr. Ritenour's petition. So I've got --

DR. RATHBUN: Did Mr. Spock say anything else?

(Laughter.)

DR. RATHBUN: This is a joke because I have a dog named Mr. Spock.

MR. LAMBERT: In summary -- okay. Then I can go ahead. Dr. Ritenour's position offers a solution to these issues. And by amending the existing regulations to recognize individuals who are certified by a board that was listed in Subpart J of the old regulations for radiation safety officer, the NRC would allow safety professionals that were previously considered qualified to serve as radiation safety officer on a medical use license to do so without any additional hurdles.

The ABHP recognizes that Ritenour's petition specifically focuses on the American Board of Radiology and American Board of Medical Physics in this discussion. However, the actual language, which I just stated, is much more general. And, as such, it includes recognition of individuals certified by the

American Board of Health Physics.

In summary, the American Board of Health Physics believes that as its current certificate process effectively determines the competence of professional health physicists, so did its past processes.

Individuals certified by ABHP, both before and after 2005, have demonstrated that they possess a substantive foundation in health physics through study and professional experience. And they have demonstrated technical competence through successfully completing the ABHP certification exam.

These credentials should be recognized by the NRC as sufficient for the individual to serve as radiation safety officer without discriminating based on a date of certification.

DR. RATHBUN: Thank you.

DR. BROGA: Dean Broga. And as someone certified by the ABHP, the ABR, and the ABMP for over 30 years, I would like to ditto that remark.

DR. RATHBUN: It looks like you are the answer to the problem.

DR. BROGA: My other concern is that the staff has now broken out the RSO at test stations to categorical areas. And this can create a huge problem

for new categories being added at a licensee.

For instance, the RSO for a gamma knife is broken out. So if a community hospital that is using one of its oncologists as an RSO because they have no full-time physicist there now wants to add a gamma knife, that physician is going to have to go through some other gamma knife somewhere in the United States, convince the RSO there to take him under his wing for some period of time undefined, and then to attest to him. I think that's a huge problem. And it may limit the scope of what a lot of facilities can do.

A couple of people have asked me about this already, even just adding seeds. And I said, "You have an authorized physician user RSO. This is a huge problem to get them named and attested to to use these materials."

The more esoteric or the newer the practice or the procedure that is being implemented, the bigger the problem is going to be. The first facility is obviously going to have to have the Adam and Eve concept. Who is going to be the RSO for there is no RSO to attest to you? And then everybody else who wants to be an RSO added all over the country are going to have to go to that facility to get attested to, which seems to me traceably burdensome for the

medical facilities.

DR. RATHBUN: Dr. Malmud?

CHAIRMAN MALMUD: May I ask a question of our guest?

DR. BROGA: Yes.

CHAIRMAN MALMUD: And that is, how would you propose that physicists be certified as competent RSOs and in new technologies such as the gamma knife? I mean, it's an issue that we have always dealt with historically. And I'm not taking a position on it. As we add a new technology, we somehow learn it on the job, by sometimes visiting other institutions.

What would you propose to protect the public from the application of new technology, in which those who are applying it have no evidence of experience?

DR. BROGA: I believe that with almost any new -- first of all, the principles of radiation protection and safety haven't changed for any of these methodologies. They may be new treatment methodologies, but the basic concepts of shielding time, distance, interlocks do not change.

And most of the people who are board-certified and/or previously had historical experience can certainly work with the manufacturers

to learn the variance in concepts here, as would be the physicist requiring to get manufacturers' training as well as the physician to get manufacturers' training when the new modality is brought in.

I don't know why a similar concept can't be taken for the radiation safety officers. There are certainly other people, not necessarily RSOs, who could provide that training.

CHAIRMAN MALMUD: So you are suggesting that the system as it has stood in place for decades is actually functioning well and shouldn't be altered, namely that those of us who are practitioners, those of us who are physicists learn the new technology on the job with the database and the knowledge base that we have had over the years and that we now employ with the new technique?

DR. BROGA: I believe that is what I am saying. And I believe that is only proven by inspection.

CHAIRMAN MALMUD: That is what I wanted to hear you say. Thank you. So you believe that the system as it was was not proven to be defective.

DR. BROGA: I don't know where it was broken, but that was never pointed out to me before, sir.

CHAIRMAN MALMUD: Thank you.

DR. RATHBUN: Okay. Thank you.

MR. MOWER: Herb Mower. That's M-o-w-e-r.

(Laughter.)

MR. MOWER: American College of Medical Physics. Following up on what Dean Broga said, one of the things that we learned as we were being trained for our profession is not how to by rote apply two plus two equals four but how to think to adapt those things that we have learned to new situations, which can also be new modalities. That's part of the process of being a professional.

The regulations that had come out with strict programs. And I don't believe there's any strong documentation to show that they were previous programs that needed to be addressed or corrected.

I think the NRC's goals should be to provide access to the greatest number of people, to the highest quality diagnostic and therapeutic procedures while supporting good radiation safety practices. And with the rules as they have come out, I feel that it is going to very much limit this process for many of our people.

DR. RATHBUN: So you are telling me if it wasn't broken, it shouldn't have been fixed?

MR. MOWER: One can always improve, but one should not break that which is not broken.

DR. RATHBUN: Okay.

MEMBER WILLIAMSON: It is Jeff Williamson, member of the ACMUI. Yes, in fact, I think with any new regulation, there is supposed to be some process -- I think the OMB requires it -- that the burden on the regulated community be balanced against the benefit. And I think I am told now that in order for this regulation, this T&E regulation, to work, the ABR is going to have to review thousands of old applications for board certification that were previously filed over the years, including mine, as it turns out, since I do not satisfy the recency of training requirement.

DR. RATHBUN: You didn't make that yet?

MEMBER WILLIAMSON: No. That's right. They are going to bill the individual certificate holders for this process. This was a cost I'm sure that was not anticipated in the OMB analysis. So, you know, I think there is a strong I would presume regulatory basis or legal basis for going back and scrutinizing this concept of effective date of certification approval because this was not a concept that was considered in the original deliberations and

I'm sure was not part of that analysis. That's point one, I believe.

I also would like to point out that the ACMUI Subcommittee on Training and Experience was the group that, perhaps now to our discredit, drafted the original rule language for what is now the current training and experience requirement.

Unfortunately, there were some small changes made, a few words here and there that were inserted, both I'm sure through the machinations of the staff as well as the Commission. One has already been alluded, the use of the word "competency."

And I think the second point I would like to make is that historically the intent of the ACMUI in drafting this rule language was that the existing Subpart J boards, almost without exception, should be approved without question.

We made every effort to try to diligently parrot what we thought was a reasonably general gloss on the eligibility requirements for both the ABR, the ABMP, and other certifying organizations. We also made the initial recommendation that the Subpart J legacy boards be hard-wired into the regulation and that the case-by-case review commence only with new boards that might materialize or in reverse could be

exercised if an existing board appeared to be deviating from their past practices and constituting a new source of health and safety concern.

This was, unfortunately, ignored and removed, which defeated the whole purpose and I think has essentially caused all of this complexity because of interpretation of a few words.

could be exercised

DR. RATHBUN: Let me make sure. And I am new to this. What you're telling me is, in your working group, these were issues that you had kind of worked out. And when you saw the ensuing rule, you saw words come in or things that didn't go the way you thought they were going. Is that what you're telling me?

MEMBER WILLIAMSON: That's correct. I'm sure that as an Advisory Committee, what we thought has no official standing or legal standing --

DR. RATHBUN: That's right.

MEMBER WILLIAMSON: -- in this matter, but this was, for the record, the intent.

DR. RATHBUN: The group.

MEMBER WILLIAMSON: And this was the original language was crafted with these assumptions

made in mind basically.

DR. RATHBUN: Okay.

MEMBER WILLIAMSON: And the words were no longer adequate when the assumptions were changed.

DR. RATHBUN: Okay.

MEMBER WILLIAMSON: The language was no longer adequate to ensure the goals of the regulation once the various protections grandfathering protections were stripped out by the Commission.

DR. RATHBUN: Okay. You said put grandfathering down here, too.

CHAIRMAN MALMUD: Mr. Lieto wanted to make a comment.

DR. RATHBUN: Yes, sir.

MEMBER LIETO: Well, actually, it's just to follow up a point that Jeff's made in that another item that this Committee opposed, not on one occasion but on several, was the preceptor statement. We were opposed to it.

The only place we saw that was meant to be in the alternate pathway, where training and experience had to be submitted and that there was an added station by an individual, that they had documentation that that information is accurate and complete. It was never meant to be tied to the board

certification route.

And, like I said, it was not on one occasion but more than one where this went all the way up to the commissioners, where we were mandated that this had to be in there.

And so I guess it kinds of gets back to we're like a prophet in our own land. And what we say seems to not bear a lot of weight. And we need the input of the regulated community to come here and say that maybe there was some validity to what we said several years ago.

DR. RATHBUN: Dr. Eggli?

MEMBER EGGLI: If I may complete the circle that they have started here --

(Laughter.)

MEMBER EGGLI: -- by saying that the intent of the alternate pathway was to allow qualified people who were not board-certified to become authorized users.

Now what we have created is a whole bunch of board-certified people who can't become authorized users by the board certification pathway. We have created approximately a two-year gap of disenfranchised people between the effective date in October 2005 and when the boards qualified and then,

finally, because of the liability now associated with the prescriptive attestation, the alternate pathway, which could salvage all of these people, is functionally dead because preceptors will not write an alternate pathway statement because of liability.

Since the new regulation came into effect, I have not written a single alternate pathway preceptor statement and will not.

DR. RATHBUN: That's pretty clear. Okay. All right. What I think I would like to do next is to be --

CHAIRMAN MALMUD: May I --

DR. RATHBUN: Sure.

CHAIRMAN MALMUD: I think there is one other point that we discussed. I apologize --

DR. RATHBUN: That's okay.

CHAIRMAN MALMUD: -- for perhaps being redundant. The alternate pathway route is one that about 20 percent of radiology residents must take because they will not have passed their boards first go-around. So the alternate pathway requirements turn out to be requirements that the board itself must adhere to, recognizing that about 20 percent of its graduates will have a gap between completion of their residencies and board certification, assuming that

they will pass the boards on the second go-around.

Therefore, the boards must teach to the alternate pathway. Therefore, the NRC in a de facto means has established the academic criteria for the boards.

If the boards must teach to the alternate pathway, then the NRC has established the teaching requirements. Some of these teaching requirements are not logical and cannot be met by the board.

I think we have reached an accommodation with regard to the definition of the number of hours required of training for radiology residents -- I'm speaking of radiology residents now -- and that their experience can include clinical work as well as didactic lectures.

Otherwise the didactic lectures in a definition that was debated in this Committee some months ago would have taken up the entire time of their training period in nuclear medicine. And they would have had no clinical experience in nuclear medicine in order to satisfy the requirements for nuclear medicine, physics, and radiopharmacy.

I think we have reached an accommodation on that issue.

DR. RATHBUN: It sounds like you did on

that.

CHAIRMAN MALMUD: But my point is that the alternate pathway has converted from an assistance to a liability in terms of getting the radiology residents', who do constitute the largest group of residents finishing each year, eligibility for authorized user status.

And, interestingly, the states that would be most negatively affected by this are the states which demanded higher standards to begin with because they are the ones who will not have radiologists able to take positions in small departments -- I think one of the states referred to these as Mom and Pop operations -- because they cannot get authorized user status.

So there is this unintended consequence of good intentions driven by the state, not driven by the NRC but responded to by the NRC on behalf of the states. And that's the history of how this evolved.

DR. RATHBUN: Okay.

CHAIRMAN MALMUD: It was a classic case of the tail wagging the dog.

I'm sorry. I think you have --

MR. MOORE: Yes.

DR. RATHBUN: Scott. Okay. Good.

MR. MOORE: Dr. Malmud, that's an issue, you know, that you and the Committee have brought up consistently for a number of years, including when the Part 35 was being developed.

And we certainly recognize that it's an impact of the regulations that we're aware of, but it certainly was not an intent of the regulations.

CHAIRMAN MALMUD: Correct.

MR. MOORE: The regulations recognize three alternatives for practicing grandfathering, board certification, or the alternate pathway. And the programs that the boards come up with on their own are those that the boards choose to develop, whether they choose to go with that that's required by the alternate pathway because numbers of graduates don't pass or can't apply is a decision that the boards themselves make. We recognize that it does lead to an impact of the way the regulations are written.

CHAIRMAN MALMUD: I agree with you up to the point where you say it's a matter for the boards to choose. The boards' hands are tied into the standards of the alternate pathway. If the boards recognize the reality -- and they do -- that about 20 percent of their graduates will not pass the boards the first year.

If that's the case, then 20 percent of the residents coming out will not be qualified to be authorized users except through the alternate pathway.

If that's the case, then the boards must teach to the alternate pathway. Otherwise, 20 percent of our residency graduates in diagnostic radiology we know will not be authorized users to staff these small departments scattered in these Western states that seem to be most concerned about this issue.

So that it was an unintended consequence. And I said very clearly not the intent of the NRC but a response of the NRC to this requirement. In fact, the boards must teach to the NRC requirements or 20 percent of their trainees will not be able to take positions in small departments and be authorized users within and until they're board-certified unless the board itself has met the standards of the NRC.

And the standards of the NRC became extremely prescriptive. That prescriptive standard of the NRC basically told the boards "This is what you are going to teach or 20 percent of your graduates will not be authorized users, eligible to be authorized users."

MR. MOORE: Right.

CHAIRMAN MALMUD: This creates a status of

conflict between the mission of the NRC, which is, correctly, the protection of both users and the public from unnecessary radiation risk and intrusion into what should be taught by the boards, which I believe the boards have done a good job in for the last 60 or 70 years. Nothing is perfect, but they have done a good job.

MR. MOORE: Thank you.

CHAIRMAN MALMUD: And now we have lined up with the boards being told "This is what you will teach," not that we, the NRC, wish to do this to you, but a couple of states have concerns. Those concerns are addressed by us. And in addressing the concerns of a couple of states, we are now going to flip it and become the academic adviser to the boards, unintentionally, an unintended consequence; nevertheless, one that we have to live with.

I believe we worked out a solution to that in how we define the number of hours that are going to be taught to radiology residents in their rotations through nuclear medicine. They're less prescriptive now. They don't demand didactic classroom hours.

However, it is the way things evolve. And the same thing appears to be a problem for the physicists in a different way. And, of course, the

most disappointing thing has been the assertion of a word that we all agreed would not be there.

That is a betrayal of the confidence of the Committee in making a recommendation since the Committee was very specific, repetitively so in kind terms in more robust discussions, to use a term that's favored now in Washington, in our opposition to that word. And, yet, the word somehow appeared. That is a big disappointment for us.

Dr. Nag?

MEMBER NAG: Yes. And I listened to what you said. It's not only the alternative pathway. The NRC is basically telling the board that we will recognize you only if you have these in the curriculum.

So it's not only for the alternative pathway. It's for the board itself because if the board did not have all of those requirements, the board would not be recognized. And, therefore, to take that into recognition, the board has to incorporate all of that into their curriculum.

CHAIRMAN MALMUD: Are you speaking to the Radiology Board or the radiation oncologists?

MEMBER NAG: Radiation Oncology Board.

CHAIRMAN MALMUD: Because in radiology, I

think there was a collegiality on the part of the American Board of Radiology in saying, "Yes, we agree we should teach A, B, C, and D. But don't tell us how many hours specifically of each."

I think that was the spirit, not the specific words but that was the spirit. I thought that the boards were trying to be as collegial as possible.

MEMBER NAG: Yes.

CHAIRMAN MALMUD: But when it became prescriptive as to the number of hours in classroom versus definition of didactic, then it became truly intrusive and obstructive to the goals that we wanted to achieve.

But I think there was a collegiality demonstrated on that issue between the NRC itself and the board in trying to achieve an agreement that was workable, I hope.

MEMBER NAG: My point was that you're saying that it was only to meet those 50 percent who are not board-certified. But even those who are board-certified, the American Board of Radiology has to incorporate all the NRC requirements so that they would become recognized by the NRC. That's all the point I'm trying to make.

CHAIRMAN MALMUD: Yes. I agree with your point except I think that I'm speaking on behalf of the ABR. Perhaps I shouldn't. I was impressed with their collegiality in wanting to respond to the request of the NRC in teaching things but not in being prescriptive as to the numbers of hours and what the definition is of a didactic session. I think that's where the differences lay.

I think that that issue was resolved. The issue that was not resolved -- I think that issue was resolved, but the issue that was not resolved was the insertion of the word "competency" again. When we protested in every way humanly possible, it didn't belong there.

MEMBER NAG: We have an ABR representative behind you.

CHAIRMAN MALMUD: Please speak on behalf of the ABR.

DR. MORIN: I am Richard Morin for ABR trustee. I just want to amplify Dr. Malmud's comments in one area that the Advisory Board may not be familiar with. The board itself doesn't demand curriculum in everything else that it does. It's the Radiology Residency Review Committee that defines the curriculum. This is really an exception.

And the board did go out of their way. And any certification board in general doesn't define the curriculum. It's the practice or the professionals in that field that generate what the job is. A test content outline is developed from that. The curriculum flows from that. And then the board is responsive to what is the nature of the job.

Now, this was a big exception. And I think I will pass on your remarks to the president at the time that was quite collegial, I think.

And so this is a major, major effort. And it does have downstream ramifications for professionals as they leave their residencies.

DR. ALDERSON: Phil Alderson, President of the American Board of Radiology. I wanted to amplify that comment a bit further and provide one clarification. For first-time takers of the American Board of Radiology, only about ten percent fail, not 20.

But, in fact, the points made by Dr. Morin are quite correct. It was the programs that had to accommodate. The board through a broad communication matrix nationwide made it quite clear that it would accept only the types of training that you have been discussing, the more rigorous types of training. And

if those weren't provided, then we would not authorize as an authorized user eligible person any radiology diplomate. So the RRCs in the programs had to provide that level of activity.

And to say how it exacerbated the problem of availability that you have been discussing, in fact, some programs did not. Some programs acknowledged that they could not provide that particular level. And so they told the board that our own diplomates or our own candidates will not, in fact, be AU-eligible.

And so, in fact, it was even worse than the problem Dr. Malmud pointed out, but many, many more radiology residents around the country aren't able to do this in any regard.

DR. ROYAL: My name is Henry Royal. I'm the Executive Director of the American Board of Nuclear Medicine. And I just wanted to also confirm what Leon said, the effect of these regulations on the training requirements that boards impose.

If there is any rationale behind the -- for example, if we look at 35.390, if there is any rationale behind asking for 200 hours of classroom and laboratory training in 390, then the boards would want to provide that training, but one of the problems is,

as we have heard today, that there is a lot of overlap between the 80 hours for 390, the 80 hours for 394, the 80 hours for 396. And it is hard to understand where the 200 hours come from.

So, on the one hand, the boards would like to meet these requirements because we would like to believe that there was some rationale --

DR. RATHBUN: Person on the phone, could you identify yourself? Hello?

DR. METTER: I am from the Texas Radiation Advisory Board, a member on the Medical Committee from Texas. And we have also our Vice Chair of the Texas Radiation Advisory Board for Texas, Dr. Ian Hamilton. And I'm Dr. Darlene Metter.

DR. RATHBUN: Okay. Can we just hold your comments here because we have a gentleman from the American Board of Nuclear Medicine speaking. And then I'll come back to you.

DR. METTER: Yes. Thank you.

DR. HAMILTON: Sorry. We didn't realize we were making comments. We weren't sure we were hooked up.

DR. RATHBUN: Okay. We'll get back to you in just a minute.

DR. METTER: Thank you.

DR. ROYAL: So the bottom line is that the regulations for classroom and laboratory do affect the boards and the boards' requirements.

MEMBER NAG: Before you leave, could you clarify what you meant by you support Dr. Leon Malmud? He made a lot of comments. So which portion of that are you supporting?

(Laughter.)

MEMBER NAG: Could you be more specific? I think that would help the matter. I want to be specific.

DR. ROYAL: The specific thing that I was supporting him on is that the training and education requirements do affect what boards then include in their regulations. So, even though the NRC regulations say that the boards are not required to meet the classroom and laboratory standards for the alternative pathway, the actual reality is that they feel that they must meet those requirements.

MEMBER NAG: I said basically the same thing. You know, I am glad that you are pointing that out.

DR. RATHBUN: Should we hear from those people on the phone? All right. Texas, could you now give your talk or your comment?

DR. METTER: Okay. Dr. Hamilton, did you want to make a comment or did you want me to make my comments?

DR. HAMILTON: Go ahead and make your comments. Yes. Dr. Metter has been very succinct in stating our position and helping Mr. Ford, our chair, and myself put our position statements together along with Kim Howard, who is the chair of our Medical Subcommittee. Go ahead.

DR. METTER: Well, I had four specific concerns. And I agree with Dr. Royal regarding the maintaining the training and experience requirements as they need to be strict because we are dealing with therapy of a radionuclide, particularly I-131, that is really one of the most serious radiopharmaceutical we use routinely for therapy in nuclear medicine.

And my first comment would be that the current proposal has a major impact on the standard of patient care and public safety. The ACGME, which is our accrediting body for our training programs, sets and monitors the training requirements. And we maintain a tight relationship with our board certification requirements, as Dr. Royal has said. And it does ensure a quality standard for patient care.

If we allow certification to be a non-standard or generic training process, you really have an unknown quality of training you receive and, hence, the question of quality of patient care, particularly likely if you lowered the standards of training and experience.

And also with this unconfirmed standard, you are unable to confirm the fulfillment of the training requirements other than a certificate, which can be made by any organization.

Number two, the major inherent differences between therapeutic and diagnostic procedures are very important because diagnostic procedures use routinely a low energy short half-life tracer, namely technetium. And our therapy that is being in question is sodium iodide, which is a long half-life, high energy radionuclide that has gamma and beta emissions and actually can destroy tissues and if used in the wrong amount can actually kill the patients by destroying their bone marrow.

And if someone doesn't understand this, that training and experience is the most important part of therapy with radioactive sodium iodide, then they really should not be doing this procedure.

Number three is that the proposal for the

training and experience that is being proposed is really a passive learning experience. And currently in our ACGME-accredited institutions, we do both passive and active training. And we confirm our individual learning the information through exams, either at the end of the course, our annual in-service exam or through board certification, that has the individual physicians on this very important information.

And some of these courses that have been proposed are eight consecutive days of ten-hour days in physics. And unless you really, really like physics, I think after one hour, it's going to be very questionable how much you have learned after just one hour.

And there have been studies shown that people sitting and learning in a classroom only retain about 20 percent of that knowledge at the end of one hour. And this decreases exponentially over time.

DR. RATHBUN: This is why you're getting a break shortly. This is a great statement.

DR. METTER: And I have just a couple of more. The financial impact if you have nonstandardized programs, who will actually check them and monitor them? Right now the ACGME currently

monitors and trains in the training programs with regular site visits and reviews. And this is very costly.

I just was at an ACGME meeting yesterday. And I asked one of the chairs what it cost just for them to review 30 programs. And it's $45,000 for the ACGME just to mix 2 days' review of 30 programs. So it's going to be very costly for the taxpayers to monitor and review these processes to ensure a quality standard of training and experience.

And, lastly, access to basic science and training and experience needs to be through an accredited institution. And these institutions are available all throughout the country. And, like for our institution, I do not know of any time where we have refused to accept people from outside to come and participate on a preceptorship regarding our training and experience in radiology or in nuclear medicine.

And that's what I have to say.

DR. RATHBUN: Okay. Dr. Metter, Dr. Malmud has a comment for you.

CHAIRMAN MALMUD: Dr. Metter?

DR. METTER: Yes?

CHAIRMAN MALMUD: May I ask, what is your recommendation to the Committee? I understood each of

the points that you made, but I am not sure I understand what you wanted to achieve.

DR. METTER: What I want to achieve is to maintain a high quality of the standards for training and experience for an authorized user. And I believe depending what category -- are you for 35.390 or 35.292 or 35.294?

It's just that I would like to maintain a high standard of quality of training and experience for the authorized user being attained in ACGME institutions to assure the quality of training and experience of the authorized user because of the hazards of therapy for I-131.

DR. RATHBUN: And is the real issue we're talking about here the compatibility category?

DR. METTER: And the compatibility is not compatible, correct. These are people. This is not interstate industry. And lowering the standards would be wrong. It would majorly impact on patient care and the public safety.

CHAIRMAN MALMUD: Dr. Metter?

DR. METTER: Yes?

CHAIRMAN MALMUD: We thank you very much for your comments. We fully agree with you that standards should not be lowered and that we do feel a

strong sense of responsibility for the health and welfare of both the public and the providers. And we are very supportive of your maintaining those standards.

DR. METTER: Thank you.

DR. HAMILTON: Thank you very much. All we are worried about is the gate-keeping, like Dr. Metter has stated, and to maintain that safety that we are all talking about.

DR. RATHBUN: Okay. Let's take Dr. Eggli and then Dr. Nag and then Dr. Williamson.

MEMBER EGGLI: First of all, I want to address Society of Nuclear Medicine's comment on the 200-hour requirement for Part 390. I think the 200 hours is a bit over the top. I think I am on the record as having said that back at the original considerations.

It doesn't take 200 hours to learn the radiation safety part of high-dose iodine therapy. The part that, in fact, the 200 hours detracts from is the clinical decision-making, the patient evaluation, the therapy planning, which are the key parts of administering radioactive iodine to a patient with thyroid cancer or, in fact, any other therapeutic application of radiopharmaceuticals.

With some exceptions, safety experiences are broadly applicable. As our radiation therapy colleague said, there are some specific issues with each modality that one must master. But it doesn't take 200 hours to master that.

What that 200 hours does is detracts from the really important part, which is learning how to practice therapeutic nuclear medicine safely to treat disease appropriately and to garner enough clinical experience treating disease, not stoppering and counting vials but treating patients with disease to be competent and effective and practice good quality medicine.

It's the same issue that we had before in considering that all 700 hours had to be in radiation safety that takes away from the time allotted to learn the critical clinical skills that are a very critical part of treating patients.

If I can handle isotopes safely but I haven't learned when to use high-dose radioactive iodine, I am going to do far more harm than if I occasionally spill some iodine, which, honest to God, I have never done.

(Laughter.)

MEMBER EGGLI: But I would like to ask

either Dr. Alderson for the American Board of Radiology or Dr. Royal for the American Board of Nuclear Medicine to comment on what they consider the important parts of the learning experience here.

DR. RATHBUN: Hold on here. We're getting out of process. I need to --

MEMBER NAG: That's fine.

DR. RATHBUN: Okay. You're okay?

MEMBER NAG: I will back off.

DR. RATHBUN: Are you going to back off? Because I promised you next. And then I need to get Scott. And then I need to get --

MEMBER WILLIAMSON: Since we have spent this time discussing the State of Texas' objections to the current training and experience requirement, I wish somebody would make it clear what it is in the current regulation they object to.

DR. RATHBUN: Okay. I think State of Texas is talking, really, about the compatibility category. And I --

MEMBER WILLIAMSON: What is in their view incompatible with the existing requirement? What is it they want to do that the current requirement doesn't do? It just would be helpful if they would lay out briefly what is the material dispute here,

material basis of the dispute.

DR. RATHBUN: Here is my problem. I'm looking at a bunch of really tired people. And what I would really like you to do is to go away and take a break.

(Laughter.)

DR. RATHBUN: I think that would be better because let me tell you what Ashley and I would like to do during the break is to review our notes and put the issues out in order because I think we have come to a point where we have kind of run through all of our issues.

I realize we need clarification from Texas, but I think that might be we could shift, then, from listing the issues or the areas of problem to some potential solutions. And that might work.

Okay. You can be my last speaker before the break.

DR. ALDERSON: All right. This is Dr. Alderson at request from Dr. Eggli's comments. I'll make it very brief. I just want to say that I strongly support and I think the American Board of Radiology would strongly support what he had to say. It is hard to believe that in a clinical environment anything could be ALARA without a good sense of

clinical judgment about when radiation should be used and how it should be used.

DR. RATHBUN: Okay. With that, I'm going to declare a break. And I would like if you all could come back at 3:00 o'clock.

(Whereupon, the foregoing matter went off the record at 2:44 p.m. and went back on the record at 3:08 p.m.)

CHAIRMAN MALMUD: Ladies and gentlemen, we are ready to resume our session, and we look forward to another active, stimulating, and robust discussion.

DR. RATHBUN: Okay. Can you all hear me? Can you hear me now?

PARTICIPANT: Yes.

DR. RATHBUN: All right.

DR. HAMILTON: Before you start, can you hear us in Texas?

PARTICIPANT: Maybe.

(Laughter.)

DR. METTER: Yes, we can.

DR. HAMILTON: Good. Okay. We want to make sure that we're plugged in. Thank you. Now we can start.

DR. RATHBUN: Thank you.

Okay. What we tried to do quickly at the

break was to go through the issues and try to get them, you know, into one standard list. So let's just go through them. This is not by order of importance or anything else. It's just how it came out in the discussion.

Okay. Number one, the preceptor statement has associated with it liability, redundancy, inconsistent application, and we did hear you about the word "competency," and understand.

Okay. A lot of the -- yes.

MEMBER WILLIAMSON: Well, there was another point in that --

DR. RATHBUN: Okay.

MEMBER WILLIAMSON: -- it asks you from time to time to attest to the unattestable --

DR. RATHBUN: Okay.

MEMBER WILLIAMSON: -- because of, you know, changes in technology.

DR. RATHBUN: Attest to the unattestable.

MEMBER WILLIAMSON: It asks you to represent competency of individuals --

DR. RATHBUN: Okay.

MEMBER WILLIAMSON: -- in areas where you have no experience with it.

DR. RATHBUN: And that ties to that,

doesn't it?

MEMBER WILLIAMSON: Well, that's different.

DR. RATHBUN: Okay. Okay. I like that, too. Maybe it's not a word, actually.

(Laughter.)

DR. RATHBUN: Incomprehensible. We'll make it up. Okay. Very clearly -- yes, sir.

DR. BROGA: You didn't include the difficulty of obtaining it with more esoteric users.

DR. RATHBUN: Okay. Oh, wait. We're out of control. Can you -- we're out of control, because the translator/reporter doesn't know who's talking.

PARTICIPANT: We're getting a lot of echo.

PARTICIPANT: We are getting it here in Texas as well. Tremendous echo.

DR. BROGA: Dean Broga. I just wanted to add the --

PARTICIPANT: Here in Texas we can still understand.

DR. RATHBUN: One second. Person on the phone, could you guys hold again? Could you hold just a second and we'll come right back to you.

(Off the record discussion.)

DR. RATHBUN: We're going to send you,

Richard, the list.

MR. RATLIFF: Yes, that would be helpful.

DR. RATHBUN: Excuse me?

MR. RATLIFF: Yes, that would be good. Thank you.

(Off the record discussion.)

(Applause.)

DR. RATHBUN: Okay.

DR. BROGA: Do I have to say that live? I wanted to make sure we added the difficulty obtaining attestation for more esoteric uses.

DR. RATHBUN: Okay. More esoteric uses.

MS. WASTLER: Difficulty of obtaining.

DR. RATHBUN: Difficulty of obtaining same. Difficulty of obtaining same -- difficulty of obtaining certain -- that's all right.

MS. TULL: Is this what we want?

DR. RATHBUN: Okay. Is that looking good?

PARTICIPANT: Yes.

PARTICIPANT: That's fine.

DR. RATHBUN: Okay. The impact of the effective date, is that too neutral, or would you like to add some words to that?

(Off the record comments.)

DR. RATHBUN: Okay, 200 hours. All right,

it's interesting. Now Texas, we're getting into No. 5, the compatibility issue. And would you like to give us your position again?

MR. RATLIFF: Yes, this is Richard Ratler. Dr. Metter and Dr. Ian Hamilton have been on the line. But our Radiation Advisory Board's position was that our regulations as they currently exist were more stringent, especially on the therapy; and when the NRC changed the compatibility from compatibility C to compatibility B, it has impacted our ability to keep our regulations in the way that the Radiation Advisory Board felt they should be.

DR. HAMILTON: That's exactly the point we were trying make. Thank you, Richard.

DR. RATHBUN: All right. Hang on a second.

(Off the record comment.)

DR. RATHBUN: All right. I'm sorry. We were sending you another email. Could you just say that again and Andrew is here. So he can help with the compatibility categories. Would you say it again, Richard?

MR. RATLIFF: Yes. You know when we developed our rules, changed them on medical, we have stricter requirements on iodine therapy and when the

compatibility category was changed from a C which would let us continue to a category B, that has limited our ability to remain compatible by keeping our rules with the stricter requirements.

DR. RATHBUN: Okay. Scott, you're going to address that further, aren't you, the states' position, but it doesn't have to be right now.

MR. MOORE: Not now.

DR. RATHBUN: Okay. Dr. Malmud.

CHAIRMAN MALMUD: This is Leon Malmud. May I ask you a question in Texas?

MR. RATLIFF: Yes.

CHAIRMAN MALMUD: Can you give a concrete example of how something has been altered with respect to your imposing more strict requirements than the NRC has?

MR. RATLIFF: Yes. What our current roles require is the actual training. You can't go the 80 hours. You have to have your training at ACGME approved facilities.

CHAIRMAN MALMUD: They can't do the commercial courses for physics.

MR. RATLIFF: There is no alternative pathway like you've seen in the NRC rules for the therapy.

CHAIRMAN MALMUD: I'm still -- Can you give me a concrete example?

MR. RATLIFF: Well, basically what we have is physicians many times come in who have not had the training in all of the didactic and clinical but they want to come in to the alternative pathway and think they meet that requirement. So we take each of those cases individually to the medical committee of our Texas Radiation Advisory Board for them to look at the training to determine even though it may meet the NRC requirements, is it adequate for what our medical advisory board feels would be acceptable.

MR. MOORE: This is Scott. To answer Dr. Malmud's question, Richard, you're saying that Texas would require for the 80 hours ACGME training.

MR. RATLIFF: Correct.

MR. MOORE: And NRC's requirements would only require 80 hours. So you're saying in Texas those 80 hours would have to be received in an ACGME training program.

MR. RATLIFF: Training program.

CHAIRMAN MALMUD: Now under the --

PARTICIPANT: Hold it. If I had to move the category here --

MR. MOORE: But that's going an example of

where Texas has more restrictive standards than NRC standards.

CHAIRMAN MALMUD: How are we interfering with your ability to have stricter standards if you want?

MR. MOORE: That's compatibility.

MR. RATLIFF: When the Commission developed their compatibility levels, a compatibility C allows agreement states to be more stringent. But when you go to compatibility B you're looking at trans-boundary indications and you have to be almost identical. so you cannot be stricter than the NRC requirement.

CHAIRMAN MALMUD: I see. Thank you.

MEMBER NAG: This is Dr. Nag. Do you have examples of physicians who have done this in our states and are already doing it in other states, but they move to Texas and now they cannot practice in Texas? And if so, what do you do with them?

MR. RATLIFF: Typically, it's been endocrinologists who want to do hyperthyroidism treating who have not had the ACGME training and so we will bring the application forward to our medical committee of our Texas Radiation Advisory Board to have them review the qualifications of the individual

physician to determine should we add them to a license.

PARTICIPANT: I don't think that's the question.

MEMBER NAG: My question was they were doing hyperthyroid treatments the day before that in Ohio and California and they moved now to your wonderful state of Texas and now is he out of a job or can he practice?

MR. RATLIFF: Correct. That's why they would have to go through the process of having us take it to our Radiation Advisory Board to determine do they -- Since they don't meet our standards that in rule, are they acceptable and should we put them on the license?

DR. METTER: We would take it on -- This is Darlene Metter. We would take it on an individual case-by-case basis. If they are on a broad license and are on the license as an authorized user, there really shouldn't be a problem.

DR. HAMILTON: They just have to come before the Board.

DR. METTER: Correct. And it's on a case-by-case basis.

DR. RATHBUN: Would you like me to move

on, Dr. Malmud?

CHAIRMAN MALMUD: Please do.

DR. RATHBUN: Okay. Let's go down to grandfathering and the situation where preceptor might not be available. You might never get a new statement. RSO requirements, I don't know that we flushed this one out because there was a lot of discussion around that.

MEMBER NAG: I think, No. 6.

DR. RATHBUN: Yes.

MEMBER NAG: Those two are separate issues --

DR. RATHBUN: Okay. So that's seven.

MEMBER NAG: Yes. Separate things.

DR. RATHBUN: Fine. Okay, and -- Okay.

(Off the record comments.)

DR. RATHBUN: All right. Let's flush out eight a little bit more because we didn't get it all up there or now nine.

PARTICIPANT: Eight.

DR. RATHBUN: Eight. Yes, ma'am?

MS. FAIROBENT: Yes, Lynne Fairobent with AAPM. Can you just go back up to six? I just want to be sure that the grandfathering of diplomats is also tied to the effective date assignment of Board

recognition. It is an issue that was captured by the AAPM petition to recognize individuals who had been certified by boards that had been previously listed in Subpart J. So they are tied together, but they are separate items. But I really would like maybe a sub-item under the grandfathering of diplomats that also reflects the effective date assignment problems.

DR. RATHBUN: All right. Tell Ashley exactly what you want her to put there.

NS, FAIROBENT: Ashley, I would just list petition for Rule 35-20 and it's the issues that are specified in the Ritenour petition, PRM-3520. That's the PRM number for the Ritenour petition.

DR. RATHBUN: Okay. Thank you. Any other comments? Yes sir?

MR. WHITE: Gerald White, American Association of Physicists and Medicine. I'm sorry. You left the compatibility number just a bit quickly unexpectedly. There is an issue between the B and C compatibility having to do with licensure of medical physicists in states.

DR. RATHBUN: Right.

MR. WHITE: And if that could go on the list as well. We can talk about that.

DR. RATHBUN: As a result of the B. All

right. The RSO. I don't have my notes right now, but could you all expand that or do you like it the way it is? The seven year recency of training.

MEMBER NAG: I think that needs to be subcategorize as training in each modality -- recency of training in part 35.390 or 35.490.

DR. RATHBUN: Right. Modalities.

MEMBER NAG: With each individual type of procedure.

DR. RATHBUN: Okay. Procedure such as gamma knife, HDR.

MEMBER NAG: Yes.

DR. RATHBUN: All right. I know what I'm thinking about. Go back up on the RSO. We're now having a shortage of RSOs.

MEMBER EGGLI: That relates to the one per license.

DR. RATHBUN: Okay. Yes, ma'am?

MS. MARTIN: Do you want me to add?

DR. RATHBUN: Yes.

MS. MARTIN: This is Melissa Martin. Go back to your RSO question please. One item that we didn't really reiterate but I know it has come to my attention just as practicing as an RSO. One of the questions is if you look at new qualifications, in

other words, someone recently certified effective June `07 is now qualified to be RSO in medical physics for their particular specialty. So, in other words, a nuclear medicine physicist would be qualified to practice radiation safety in nuclear medicine physics only. I would go back to the problem of one per license and shortage because most community hospitals have one RSO. That person is supposed to cover therapy and nuclear medicine and I'm not giving you an answer. I'm just saying it is a problem when you say that that person to be RSO has to be broad certified in every category and that would be whether it's a nuclear medicine physician or radiation oncologist, how we're going to handle that. But I think that's a real problem.

DR. RATHBUN: Okay. How would you have us word that? Can you help us word that? Sometime --

MS. MARTIN: Cross categories training.

PARTICIPANT: Cross modality.

MS. MARTIN: Or cross modality training.

DR. RATHBUN: Okay.

(Off the record discussion.)

MEMBER WILLIAMSON: Jeff Williamson. Does the concept that's the statement preceptor statement --

DR. RATHBUN: Yes.

MEMBER WILLIAMSON: -- cover the issue of having to have two preceptor statements if you come in under the AMP/AU route?

DR. RATHBUN: Let's put the in there.

MEMBER WILLIAMSON: That they have not only a preceptor statement for your first primary --

DR. RATHBUN: We need to put that in.

MEMBER WILLIAMSON: Okay.

DR. BROGA: I would like to go back to two things perhaps to add onto what Melissa said. Dean Broga, by the way. We used to have a category on the license called Assistant RSO. I understand the concept to have one individual identified as RSO who is looking at the overall program especially when there's a complexity of modalities involved. But there is still a need to have someone who understands each of the modalities. I don't know why we can't have one RSO and a subgroup of assistant RSOs assigned responsibility in specific areas which also allows them documentation of time and training to be named RSO as was done in the old way the NRC handled it.

The other issue that I brought up earlier is the one that I think is a problem at a lot of small outpatient facilities, a lot of small community

hospitals, is when one RSO leaves and they have no one qualified. You're presently forcing consultants to take on the role of RSO when they're only there infrequency. I'd rather have an RSO in training or somebody or even assistant RSO named under that who was more onsite responsible because it's very hard when you're 300 miles away to deal with problems on a day-to-day basis.

DR. RATHBUN: Okay. So you want to talk about an assistant RSO.

DR. BROGA: And assistant RSO and/or some kind of RSO responsibility in training.

DR. RATHBUN: Okay.

DR. BROGA: I don't know the terminology where there's another RSO overviewing him, but that RSO is not totally responsible for a facility he is 300 miles away from.

DR. RATHBUN: After we get through this list, we're going to get a chance to put all the fixes up there that you want.

DR. BROGA: Okay. Great.

MS. TULL: Does this go in the fixes?

DR. RATHBUN: That's a fix, yes. The fix is in.

MEMBER WILLIAMSON: Where do we put the,

I think what was expressed earlier, sense that this is inherently unfair that a whole group of practitioners that once were considered to be eligible in a very straightforward way to be AMPs, etc., now have to go through a much more complex and costly and time-consuming --

DR. RATHBUN: Post-2005. So let's go back up to the 2006.

PARTICIPANT: That's the grandfathering. Wouldn't you say that a grandfathering issue?

MEMBER WILLIAMSON: Yes. Right. I'd say kind of unfairness.

DR. RATHBUN: Okay.

MEMBER WILLIAMSON: Lack of a balance between cost and benefit.

DR. RATHBUN: Okay.

(Off the record comments.)

MS. WASTLER: We have it at the very end, isn't it?

MEMBER WILLIAMSON: I don't know.

MS. WASTLER: Yes, the last one.

DR. RATHBUN: There we go.

MEMBER WILLIAMSON: Okay. There it is. Okay. Good.

DR. RATHBUN: Okay. Seven years, go down

to nine. We have that. Nine, is that now -- That's all right. How about 10?

MR. MOORE: I have a follow-on on 10.

DR. RATHBUN: Okay.

MR. MOORE: I think that 10 accurately describes some of what we talked about. But deriving from 10 when Part 35 T&E requirements were being developed, there was an intense dialogue for a long period of time between the agreement states and NRC about the prescriptiveness of the requirements that were needed in the regulations with the agreement states arguing for more prescriptiveness being needed and NRC trying to strike a balance between a call for a prescriptiveness and the ACMUI's views on what were needed in the T&E requirements.

It might be helpful with the ACMUI assembled here if we could get some of the thoughts out from the agreement states if anybody can articulate those about what the agreement states face and why they thought prescriptiveness was needed since there are certainly some unintended consequences that we're seeing now. at least since we have everybody assembled, it might help to bring those forward and get the whole discussion happening in one place. Does Paul or Debbie, do you all want to talk about that?

MEMBER GILLEY: One of the reasons the agreement states like that is that we don't all have medical advisory boards that can determine whether or not the people are qualified. So if there are prescriptive requirements as far as number of hours in each particular subject matter, it makes it a lot easier on us to deem that those people have met the minimum requirements. That was ease of availability, lack of having the technical expertise to make those judgment calls as much as Texas has.

DR. RATHBUN: Richard, are you out there? Richard?

MR. RATLIFF: Yes. They keep cutting out on us.

DR. RATHBUN: Okay. Can you help with Scott's question?

MR. RATLIFF: Well, yes. The main things we've seen because of the change in the rule on training and experience like I said is how we have many people who because we have not changed our rules yet don't qualify. We have to go through the process of going back and forth to the advisory board to double-check to see do they consider them acceptable.

We also in Texas have a -- We license medical physicists. So we have a problem because we

have state legislation that's put in effect a medical physics program and now we're faced with the NRC rule that doesn't recognize those and we have a conflict there.

DR. RATHBUN: I'm jumping ahead, but when we come back to this, let's talk about what would be the fix.

MR. RATLIFF: Sounds good.

DR. RATHBUN: Okay. So we have 11.

(Off the record comment.)

DR. RATHBUN: I'm sorry.

CHAIRMAN MALMUD: I would make a suggestion and that is that board certification should be sufficient.

DR. RATHBUN: Fine.

CHAIRMAN MALMUD: If the person is not board certified, all they need is a statement from the director of the training program that attests to the fact that the individual has completed the residency in preparation for the boards and is qualified to sit for the boards. That's it. Because that's really what a residency director does is to attest that the individual has had the requisite education and is now qualified to sit for the boards.

So all right. If only ten percent of the

residents are not going to pass the boards, this will encompass the ten percent who don't pass in the first go-around. I thought the number was 20 percent, but I'm corrected. It's ten percent for the first go-around, but it's probably larger than that to include those who are taking the boards for the second time.

AP: Yes, it's about five to seven percent larger.

CHAIRMAN MALMUD: All right. So it's about 15 percent. That's a fair compromise.

(Laughter.)

CHAIRMAN MALMUD: So it's 15 percent and I believe that most, if not all, residency training program directors would be willing to attest that the individual has completed the training and is able to sit for the boards. How is that?

MEMBER GILLEY: Clarification. We were never looking at minimum number of hours for those people who were board certified. The 200/500 hours were alternative pathways.

CHAIRMAN MALMUD: Yes, and I'm suggesting that the alternative pathway is defective in that it has unintentionally become the standard of training and therefore, we could get around that by accepting either board certification or a statement from the

training program director that the individual has completed the training program and is not able to sit for the boards. That's it. That means that we would have accepted, we being the NRC, the training program standards as being the standard. Now would the states accept that too?

MEMBER GILLEY: We would accept what was Subpart J which the alternative pathway doesn't have to be done in a medical educational program. There are other ways of becoming adding to a license other than going through your educational program as a physician in training. So there --

CHAIRMAN MALMUD: I'm sorry. I was speaking to the issue, the large issue, of radiology residencies.

MEMBER GILLEY: Okay. That was never in -- The only time that alternative pathway came into play prior to the implementation of the new Part 35 was if the radiologist wished to get put on the license prior to board certification. In your program, it wasn't always acceptable, but there is a subset of people that go to a private, 200-hour educational program and then they convince their medical institution that a radiologist can receptor them for their 500 hours of clinical experience that

are not associated with a residency program. That is a pathway that they can get put on a license.

A lot of cardiologists early on, this was their pathway for getting on a license. So there's a subset of people that that is why we wanted the prescriptive language. We were not interested in the prescriptive language for the board certification. We didn't think that problem was -- that that was a problem. But we did want some prescriptive language for those individuals that were not in a radiology, nuclear medicine, radiation therapy program. Well, I can't include radiation therapy. They are completely separate, but to be able to do those procedures.

CHAIRMAN MALMUD: I see. I didn't realize it was possible to practice radiology without being trained in radiology.

MEMBER GILLEY: The early on nuclear cardiologists were in a program like that. There is a couple of formalized training programs to get the 200 hours by going for four or five weeks for a 40 hour week course and then you can at your medical institution with the approval of your radiation safety committee set up a preceptor program and you can actually get your hours and be signed off on authorized users.

DR. METTER: I'm sorry. We're having problems with the audio where you're cutting in and out.

MEMBER GILLEY: I speak loud.

PARTICIPANT: Don't need a mike.

PARTICIPANT: We, too.

CHAIRMAN MALMUD: Can you hear me?

DR. METTER: Yes.

CHAIRMAN MALMUD: We'll try and ask each of our speakers to hold the microphone closer to their mouths.

DR. METTER: Thank you.

MEMBER GILLEY: Okay. Can you hear me now?

DR. METTER: Yes.

MEMBER GILLEY: Okay. Debbie Gilley with CRCPD/OAS/State of Florida. In the current regulation, not the current, the old regulations of Subpart J prior to the implementation of 2005 Part 35 T&E there was a mechanism available for any physician who wanted to go through the 200 hours of classroom experience and get 500 hours of work experience to be put on the license as an authorized user for diagnostic nuclear medicine and many of the earlier nuclear cardiologists, this is the pathway that they

took because there was not board certification available for them. They were cardiologists that attended a five or six week training program and they were also approved by their radiation safety committee and they had an authorized user that preceptored them and that is the area that the agreement states with the rewrite of Part 35 was interested in keeping very prescriptive. They wanted the minimum amount of education that was required in the 200 hours of didactic training and they also wanted the work experience to be there. So those are different issues than the residency program that you've been referring to where you have 10, 15, 20, however many people that need to be put on by alternative pathway.

CHAIRMAN MALMUD: Okay.

DR. RATHBUN: Okay. So I think we are down to 11. We did that. Okay. Are there any issues that you think we missed? Yes.

MS. MARTIN: And maybe I just didn't see it. Melissa Martin. Did you get the Canadian?

DR. RATHBUN: Yes, we did.

MS. MARTIN: Then I slept. Sorry.

DR. RATHBUN: Yes. Got it. Okay. Well, now we come to the good part. Let's figure out and I think in this discussion some of the NRC staff will

speak and speak to perhaps if they have a fix in mind or things that you haven't learned about yet. But let's now proceed to figure out how we're going to fix these issues. So let's go to one.

MS. TULL: I'm sorry. I was --

DR. RATHBUN: Let's go to one. One. There you go. Okay. Is there anything that the NRC wants to say about one? That would be you, Ron.

(Laughter.)

DR. ZELAC: Two things. Not to be pointing fingers or trying to place blame, but we have to keep in mind that what we as a agency do reflects what our Commissioners tell us will be. We can put forth suggestions, proposals, ideas, but the bottom line is the Commissioners want something and that's the way it goes. Now if it turns that it's not satisfactory for whatever reasons, there's always obviously the option of making changes. However, what we did in the case of the preceptor statement was what the Commission told us to do in terms of the staff.

This is, I will quote from the Staff Requirements Memorandum that came out from the Commission in February of 2003. "In addition, the preceptor statement should remain as written in the final Part 35 rule," meaning the 2002 rule which, of

course included the word "competency," which included, in fact, the word "certify" but that was changed to "a test."

"The staff should clarify that the preceptor language does not require an attestation of general clinical competency but does require sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which the certification is sought. This form of attestation should be preserved for both pathways of certification, i.e., through board certification or through training and experience."

So the Commission was very clear. The 2002 rule which was viewed by everyone as faulted was to be changed. The preceptor statement, however, would remain, would remain applicable to both the board's cert pathway and the alternative pathway and would speak of attestation as opposed to certification and was intended to not be dealing with or not be referring to or not be implied to apply to clinical competency but simply adequacy of knowledge to fill the duties of the position for which certification is sought.

DR. RATHBUN: Comments?

CHAIRMAN MALMUD: Ralph?

MEMBER LIETO: I don't know if we're at a position to just offer other solutions even in light of what Dr. Zelac has pointed out, but my recommendation would be that the attestation be removed from the board certification pathway and the intent, I think, all along was that it would be for the alternative pathway because originally, in the origin Part 35 for 2002, the only place an attestation had to be was for an authorized user coming in under the alternative pathway. Anybody else coming in under an alternative pathway did not have to have an attestation. Well, we didn't have ANP but the therapy physicists and so forth. So to me, it's sort of a compromise in the sense that any alternative pathway requires an attestation, but that the board certification route because of the redundancy that's been pointed out earlier really is not necessary.

DR. RATHBUN: Yes. Dr. Williamson.

MEMBER WILLIAMSON: Yes. I do recall the events that Dr. Zelac has related, but I would say that's a political problem and the solution would be to go back to the Commission and say it's not working.

DR. RATHBUN: Scott, what is our mechanism for that?

MR. MOORE: We can always go back into the

Commission with a proposed change to the rule based on experience. We would have to have a basis to do that obviously. I guess I have a question for Mr. Lieto. The question would be this. We've talked about the unintended consequences of the alternative pathway becoming the de facto requirements for the board certification. Could you go back actually for a second? If we remove the attestation from the board certification pathway, but if we kept attestation requirement in the alternative pathway, would it, in fact, then still become a de facto requirement for everybody going through a program where they all need one, in fact, to get through the program because they may, in fact, not pass the boards?

DR. RATHBUN: Dr. Eggli.

MEMBER EGGLI: Well, as a writer of preceptor statements, I don't write preceptor statements until I know whether or not they've passed the boards. So that helps me in that pathway. I think the idea that you have to deal with the whole issue of the reluctance of preceptors to preceptor the alternative pathway and I think if the word "competency" is changed to "mastering of a body of knowledge," that would make preceptors a little less reluctant to preceptor an individual.

And then again, we have to go back to the issue that the agreement state wanted prescriptiveness, but if you could make the alternative pathway a bit less prescriptive and say the attestation of the preceptor covers the ambiguity in the prescriptiveness of the alternative pathway, again that could solve some of the problem, I think.

MR. MOORE: That helps.

DR. RATHBUN: Ron and then Dr. Malmud.

DR. ZELAC: Several things. First, to get back to what Ralph was saying, the 2002 rule did require preceptor statement for the board cert pathway. It did require preceptor statement for the alternative pathway and that's from what I read previously is what the Commission wanted retained.

MR. MOORE: Right.

DR. ZELAC: Second --

MR. MOORE: But they've asked could we present it back to the Commission and --

DR. ZELAC: I understand that.

MR. MOORE: Right.

DR. ZELAC: Okay. Secondly, the current Part 35 specifically for the RSO has one attestation which does not include the word "competency" and that's for the radiation safety officer. So it could,

in fact, perhaps serve as a model for modifying the others similarly.

I'll let you read what the current rule is with respect to attestation for the radiation safety officer. This is in 35.50(d). "Has obtained written attestation signed by a preceptor RSO that the individual has satisfactorily completed the requirements in paragraph E" which, in fact, as a reminder, are the additional specific training requirements, and in paragraphs A(1) and A(2) and so forth which refers to the other pathways in which one can become an RSO and here's where we're getting to the good stuff, "and has achieved a level of radiation safety knowledge sufficient to function independently as an RSO for a medical use license." There is nothing about competency. It's about obtaining a sufficient -- a level of radiation safety knowledge sufficient to function independently.

DR. RATHBUN: Dr. Malmud.

CHAIRMAN MALMUD: Ron, when you read the other statement about competency, did I hear that it didn't mean -- it was competency, but it didn't mean competency?

DR. ZELAC: It did not mean clinical competency. That was understood by the Commission and

it was intended to be conveyed.

CHAIRMAN MALMUD: It states that in black and white.

DR. ZELAC: In black and white.

CHAIRMAN MALMUD: For purposes of that statement, competency does not mean clinical competency.

DR. ZELAC: Indeed, it does.

CHAIRMAN MALMUD: And therefore, one would assume that a training program director couldn't be sued -- Well, the basis of a suit is the desire to sue, but one would assume that it would be without much merit to sue someone when competency doesn't mean competency according to that statement. I mean, words mean what they're defined as and here it says that competency does not mean clinical competency.

DR. ZELAC: It does not. The intent was the person was competent in the radiation safety aspects of that work which they were being authorized for.

CHAIRMAN MALMUD: Thank you.

DR. RATHBUN: Dr. Williamson.

MEMBER WILLIAMSON: So would you be more comfortable certifying somebody's physics skills in competency to be safe in treating patients as opposed

to certifying their clinical competent?

MR. MOORE: No.

CHAIRMAN MALMUD: No, I don't think that I'm --

MEMBER WILLIAMSON: Competency does mean competency, but it means competency in a narrower range of activities than you imagine.

CHAIRMAN MALMUD: I know.

MEMBER WILLIAMSON: But competency is still competency.

DR. ZELAC: That's why I was referring to the RSO attestation as it exists today which does not include the word "competency" --

CHAIRMAN MALMUD: No.

DR. ZELAC: -- as a possible model.

DR. RATHBUN: Donna-Beth wants to speak.

DR. HOWE: One possible solution would be to add the competency definition that the Commission believed it was defining to the rule. In other words, the Commission --

CHAIRMAN MALMUD: Couldn't hear you. Sorry.

DR. HOWE: The Commission in its SRM wrote a definition of competency. That would be another solution.

CHAIRMAN MALMUD: Yes.

DR. RATHBUN: Thank you, Donna-Beth. Dr. Nag.

MEMBER NAG: I remember the conversation we've had when the ACMUI met directly with the Commissioners and we had brought this up and I don't know which of the commissioner, but one of the commissioners said it is fine. We don't have to have the word. They still wanted a preceptor statement, but the word "competency" could not be there. It would be to attest to having a body of knowledge. So I think what you are talking about in the RSO that would also be translated to the other so that the word "competency" would not be there would make people more -- or would make them more comfortable to sign the preceptor statement.

DR. RATHBUN: I think Cindy would like to add something.

MS. FLANNERY: Cindy Flannery. I just want to follow up on something that Donna-Beth said with the SRM and I just want to read you something from the Statements of Consideration. It states that "the preceptor statement should remain as written in the current regulations" as stated by the Commission. "However, the Commission emphasized that the preceptor

language does not require an attestation of general clinical competency but requires sufficient attestation to demonstrate that the candidate has the knowledge to fulfill the duties of the position for which certification is sought." And I think that's the definition that Donna-Beth was suggesting could be put in.

(Off the record comments.)

MR. MOORE: What it really comes down to is will that provide a level of comfort for people to sign preceptor statements and we don't know the answer to that.

CHAIRMAN MALMUD: I think it depends on the individual. It gives me comfort. It doesn't give Dr. Eggli sufficient comfort and it doesn't appear to give either Dr. Williamson or Mr. Lieto any comfort.

MR. MOORE: Then it doesn't solve the problem.

CHAIRMAN MALMUD: I thought it was a clever means of dealing with the issue that Donna-Beth raised.

DR. RATHBUN: Dr. Eggli.

MEMBER EGGLI: It's half of the key component.

DR. RATHBUN: Okay.

MEMBER EGGLI: The other half is the prescriptiveness of the alternative pathway and if that could be loosen up a bit and then say that the attestation of a body of knowledge.

DR. RATHBUN: Right.

MEMBER EGGLI: Historically, in regulation, you define what that body of knowledge is. The question is do you need to attach a specific number of hours because there are some people that are going to spend 80 hours on this and never master the body of knowledge. Some people are going to master the body of knowledge with ten hours effort.

What I'm comfortable with is an attestation that the individual has mastered a body of knowledge because we can document that objectively through testing that they have mastered a body of knowledge. What I prefer not to have is a prescription on how I impart and test that body of knowledge. Tell me what the topics are that you want me to teach, but allow me to design a curriculum which meets that need and then I will attest to mastery of that body of knowledge because I again for whoever comes back and looks at me, whether it's NRC or an individual candidate later, I will documentation that they have, in fact, achieved mastery of the body of

knowledge via a testing process.

DR. RATHBUN: Should we take the comment in the back and then take --

MR. WHITE: Gerald White, AAPM. A couple comments. One is I'd just like to use the Occam's Razor Rule again and say that what's under discussion here is how to fix something, at least, for the board certification pathway that is redundant and unnecessary and I believe the commissioners could come to that understanding as well.

Secondly, I'd like to say that this is not just an issue for, even if the grandfather issue is fixed for the physicians, it's not just for the first time you get on a license. It's every time a physician is placed on a license through their entire career by a mechanism other than already on a license and just to make it clear again, just because a physician in on a license doesn't mean they can use that license to get on the next license and there are issues of accessibility, record keeping. I could go through all the reasons.

DR. RATHBUN: How would we word that fix?

MR. WHITE: I think the fix would be to remove this requirement from the board certification pathway and that would solve the problem for the

majority of physicians.

DR. RATHBUN: Dr. Williamson.

MEMBER WILLIAMSON: Yes, I would like to expand on that a bit. I think this conversation has been confined to basically writing preceptor statements for young physicians that have just gone through the training experience. And so older practitioners who need to be basically have new preceptor statements to attest to their current level of knowledge mastery, who is to sign that? There is no formal testing process within the physics community to do that. When a person who was your student 20 years ago needs to show mastery of a body of material for a new modality, who is to sign that?

Certainly, the old preceptor from 20 years, that falls under the category of attesting to the unattestable. So I would have to agree with Mr. White. I think the simplest thing is to drop it barring some sort of demonstration that it's improving public safety. There is a lot of cost associated with going through this.

DR. RATHBUN: And I promised Dr. Nag he could be next, but then Ron would be after him.

MEMBER NAG: Just to point to one is similar to what Jeff said is that if the person is

board certified, then the board cert is the pathway. You don't need any other thing. But the second point is with Dr. Eggli for those who are not board certified if you need the alternative pathway, I think I disagree with that. It would be easier to attest to the fact that someone has undergone so many hours of this and so many hours of that. It may be more difficult to attest to the fact that the person has this wealth of knowledge because you can test some of it. You can't test everything. You only test, how many, 40 or 50 questions. So it may be easier for the person who are not board certified to say, "I attest to the fact that that person has undergone 200 hours of this and 80 hours of that." That might be right. So I disagree you there.

DR. RATHBUN: Ron.

DR. ZELAC: Three things. First, relating to the question that had come up about the alternative pathway, it's important to note that there's nothing new about having specific requirements in an alternative pathway. Those have existed in the NRC regulations since at least 1985. So everybody has been functioning with those things for well over a quarter of a century presumably satisfactorily.

Second, with respect to the comment from

Mr. White concerning preceptors not being, or maybe Dr. Williamson, with preceptors not being available or not being available for new modalities, there is not a requirement that the preceptor be the one who provided the training. There is a requirement that someone who is functioning in a particular role as an authorized individual can verify by whatever means they choose that you as the person they are signing for have had the appropriate training and experience and secondly, that you're a reasonable person to take on similar responsibilities and act independently.

And I'd like to very briefly in support of that position that I just stated quote from the Statements of Consideration for the 2005 rule, the one that we are now discussing. This is in response and this is essentially the NRC basis for requiring preceptor statements. This was in response to a comment. I will not read the comment, but I will read portions of the response and if you can bear with me, this is slightly long, but I think it will help with where we are in terms of what the agency's position has and at this point continues to be, speaking for the Commission which I shouldn't do.

"The NRC continues to rely on preceptor statements to determine if an individual has

satisfactorily completed requirements for T&E and has a level of knowledge sufficient to serve as an RSO, AMP, ANP or AU. The NRC believes that it is essential to have individuals who are familiar with the duties of RSOs, AMPs, ANPs and AUs through personal experience to serve as preceptors. Individuals who serve in these positions are best qualified to attest that an individual has achieved a level of competency sufficient to function independently as" the same list.

Further down in the answer, the response, "The NRC," and this hasn't come up yet, but it may well, "The NRC does not agree that removing the requirement to acquire a preceptor statement would minimize the delay in approvals of individuals to serve as" these authorized folk "because other means would have to be used to evaluate the competency of these individuals which would increase the amount of time needed for these approvals." And what's being referred to, although not explicitly stated, was possibly examinations, possibly course reviews and certifications, both of which were options that had been considered as alternatives to the preceptor statement.

And I'm getting close to the end, but if

you can bear with me, I think this might be helpful. "The NRC," and this has to deal with various preceptors attesting for one person, "The NRC accepts multiple preceptor statements from licensees in these circumstances. As indicated under the discussion of comments, the word "the" was removed from the phrase...to help clarify that more than one individual may serve as a preceptor."

And finally, this is specifically speaking of RSOs. "The adequacy of T&E for individuals to serve as RSOs is insured by requirements in the final rule for a preceptor statement and for training in radiation safety, regulatory issues and emergency procedures for the types of use for which a licensee seeks approval." Now this is getting at the specific requirements in Section 35.50(e), the training that's specific and you note also that similar specific requirements were inserted as part of this rule for both authorized medical physicists and for therapeutic radiation oncologists, again, at the direction and request of the advisory committees. I call that to your attention.

DR. RATHBUN: Now, so what is the real root of those disconnect? Let's go to the back.

DR. BROGA: I think part of the problem

and it's apparent that we're not going to change the way the regulations are written now.

DR. RATHBUN: Now you don't know that yet.

DR. BROGA: Well, we're not going to change it tomorrow and probably not for a year the way the process goes.

DR. RATHBUN: You know we can't do that.

DR. BROGA: But you asked what the real problem is and that's what I'm going to get to. We've had preceptor statements associated with this process for years. I think the change in the terminology has raised some paranoia as to what is going to be the applicable implication of this in the field. When you attest to somebody's competency or their training skills with this expanded definition, you wonder what's going to happen a year from now when you show you to do a inspection and one of your radiology residents who's asked about a linearity test said, "Well, I'm not sure I really understood that."

Now what is my liability for signing that statement? I think that's what a lot of us are concerned about. It's very difficult to assess the total competency in this broad scope of area when you have, in some cases, minimal contact with this person to the depth you're talking about. What's going to

happen to me when that happens is what we're worried about.

DR. RATHBUN: Ron, do you have an answer for that?

DR. ZELAC: No.

DR. RATHBUN: Okay.

(Laughter.)

DR. RATHBUN: Okay. I'm going to take Dr. -- At least, he's honest. Dr. Williamson. Dr. Welsh and then we'll go back to the back of the room.

MEMBER WILLIAMSON: Well, I think this is a reasonable concern because for RSOs especially for a physician if an RSO is supposed to sign this, the RSO may not have had any contact with the training of a particular resident in this regard. So if NRC wanted to insist on retaining this requirement, perhaps they should investigate some method of granting preceptors immunity from civil and criminal prosecution. Honestly. I think that's almost what is needed because if an incident happens, a serious incident happens, with a person who has been given authorized status based on someone's preceptor statement, my guess is if a serious incident like the HDR source loss in 1991 occurred, there would probably be a witch hunt and go after anybody that had anything

to do with this case.

DR. RATHBUN: It's usually us that they go after.

MEMBER WILLIAMSON: Well, that's your perception but I think that --

DR. RATHBUN: I think we have a paranoia, too.

MEMBER WILLIAMSON: Yes, we're paranoid, too.

DR. RATHBUN: Right.

MEMBER WILLIAMSON: Because we're laying our reputations on the line and if something bad happens, what happens? Then basically, Dr. Zelac read the phrase "by any means you feel necessary." Well, what are those means? What's considered adequate?

DR. RATHBUN: Okay.

MEMBER WILLIAMSON: This is a rather difficult area.

DR. RATHBUN: Okay. I have a comment here from Sandi that is saying to me, "How do you plan to handle this discussion given that it's 4:00 p.m. and we're only on issue one?"

(Laughter.)

MS. WASTLER: A practicality.

DR. RATHBUN: Which is usually what I say

to the people. I guess I got too interested in the subject. So I guess -- I don't know what to do. Let's take these two gentlemen and then let's -- Oh, I forgot you. Okay, and then let's kind of reconnoiter and decide what we want to do. Dr. Welsh, I'm sorry.

MEMBER WELSH: I have a suggestion regarding that second sentence there, the change "competency" to "master of a body of knowledge." To my mind, neither one of them is really satisfactory. Competency has obviously raised the sense of paranoia or at least an appropriate level of concern about the possibility of prosecution.

Mastery of a body of knowledge is also not adequate because if this is somebody that's just failed the board exam, I'd have a hard time saying that this person has mastered a body of knowledge and there's my attestation. Why not just keep things very bare minimum to what is factual and that is this individual has met the minimum training and experience requirements and that's it? Because that is something that you can say and it would probably not lead to any kind of legal ramifications down the road should that individual prove incompetent or not demonstrate a true mastery of the body of knowledge.

DR. RATHBUN: "Has met" seems to be a pretty deep thing to say.

MEMBER WELSH: "Has met the minimum training experience" is something I think we could feel comfortable signing.

DR. RATHBUN: Right. Let's take the two gentlemen out there and then we'll --

MR. HAFTY: Bruce Hafty from American Board of Radiology and I'll also speak with respect to my role as the Vice Chair of the ROC in Radiation Oncology. We've already heard that the program requirements have been modified to fulfill NRC regulations or guidelines, etc. So once a person -- And this is in support of eliminating the preceptor statement for board certified individuals. They've already gone through an approved program. At the end of that -- And all of those requirements in that program fulfill NRC requirements and in the end, the program director attests to a statement that they fulfilled those requirements. Actually, also attests to their competency because we have to do that as part of ACGME rules.

So in fact for the clinical folks anyway, we've attested to the fact that they've been through these requirements and they've fulfilled them and they

are competent to practice independently which is part of the standard language. So that is my statement that I would support elimination of the preceptor statement which is redundant for those who have been through this process.

DR. RATHBUN: Okay.

DR. ALDERSON: This is Dr. Alderson again and I also speak in favor of eliminating this requirement for those who have the board pathway and I'm going to make an analogy but I'm not going to burden the board with this analogy. So this is strictly my own thought about an analogy.

I tried to think of a simple program that we all deal with that's government regulated, that has risk, that's associated with frequent renewals and the obvious one is drivers' licenses. So think to yourself. What would happen if every time you had to renew your driver's license somebody had to sign that you were, they had to train you and then say you were competent to drive. Think how they would feel about that. Every seven years you go back in and if your record is clean and you all have records because when medical incidents occur you know about them, so if the record is clean and you have a license, you get a new license. So if you have a board certification and

your record is clean, you ought to be able to get back in there.

If you move to a new state, well, then the states have different regulations within a narrow corridor and people easily get their license and go back to driving if they're safe. You could do the same thing. So I think that other government programs that have major states' rights' issues in them have been able to be resolved in a simple way that satisfies the people. I think you all ought to be able to do the same thing.

DR. RATHBUN: Okay. Dr. Malmud, let's talk about what we might want to do next. We have -- How many do we have?

MS. TULL: Eleven.

DR. RATHBUN: Eleven I believe.

MEMBER NAG: One hour each.

DR. RATHBUN: Is there any --

MS. WASTLER: This topic just by the discussion we've had is very important to a lot of people for a lot of different reasons and we are faced with the situation where up to this point not all the agreement states have implemented this particular requirement.

DR. RATHBUN: Right.

MS. WASTLER: So in reality, we have a situation that under the NRC auspices we have about 20 percent of the licensees. The agreement states have 80 percent. So many of the agreement states haven't implemented this rule.

So this was an opportune time to find out exactly what these implementation issues are. We're very, very committed to finding out where the problems are, why there are problems, and discuss from all our different perspectives how we can move forward to try to resolve these issues in various different mechanisms. This is very important from our perspective and in all of yours.

So I don't want to shorten this discussion, but I want to be fair and make sure because some people came today for this very discussion. I don't know that moving it to tomorrow is an alternative. Those people that came -- You know, we have a full day agenda tomorrow. So there are people that are going to come tomorrow that want to do topics.

That's the rationale for raising this now. It's quite clear that we have a lot more to talk about. There's a lot of good ideas, a lot of good thoughts, out there that we want to capture, but I

think we need to figure out -- take a moment now and try to figure out how we're going to complete this task that we set forward.

Obviously, we didn't factor sufficient time into the process. So that's where I was coming from in raising the question.

MEMBER NAG: Are we allowed to stay in this room after 5:00 p.m.?

MS. WASTLER: Yes. We have the opportunity to stay later. But the fact that we're on one and there's eleven and you said an hour for each topic, I don't know that that would go over real well with a lot of folks in the audience. So I just wanted to say -- just wanted to raise it so that we could get some kind of agreement what might work best. I will leave that to Pat to raise.

DR. RATHBUN: Well, we have some options. Honestly in all the years I've done facilitation, I don't think it will do any good to go past 5:00 p.m. People will get tired. People will get bored and I think we need to end where we said we were going to end.

We can, the staff can, look at these issues and try to come up with what would have been our answers. You know what that is. It's just

another rule. Right? So we like that. Okay. Dr. Malmud.

MS. WASTLER: I purposefully want to hear what they have to say.

DR. RATHBUN: Yes.

CHAIRMAN MALMUD: May I suggest that we try and reach closure on this first item?

DR. RATHBUN: Yes.

CHAIRMAN MALMUD: Now we know now a couple of facts that have been reviewed for us very eloquently by members of the staff. Number one, the Commission itself wants the term "competence" in there. That's been made very clear to us. That's the Commission.

DR. ZELAC: No. They want the attestation.

MEMBER NAG: No. That's not it. They want the preceptor statement.

CHAIRMAN MALMUD: To include the word "competence." But their definition of the word "competence" is not clinical competence.

DR. ZELAC: What I had read from the statements of -- from the staff requirements memorandum was a directive from the Commission to staff to keep the preceptor statement unchanged which

meant that it was to remain the same as it was in the 2002 rule which did for all of the categories except RSO include the word "competency."

CHAIRMAN MALMUD: So the NRC Commission wants the preceptor statement to stay and wants the word "competency" in there but defines competency not as clinical competency. So that is something that they want and we recommend and they heard us and they decided that's what they wanted. Okay.

I feel unthreatened by statement in which the record indicates that the word "competence" doesn't mean clinical competence because I couldn't even assure you of my own clinical competence next week. I mean, who know what will happen to me? The point is that that satisfies me, but it may not satisfy everybody else.

And Donna-Beth had an idea which was also one which helped to accommodate a solution. It is true. It is not the straight line between two points. It may be a spiral. But, nevertheless, it does get to the other point for me.

And the other part of that was, that first issue, the prescriptiveness in the -- Well, maybe that's not a part of it. Is that part of the issue about the alternative pathway? Yes. Is that the

prescriptive issue simply be to the body of knowledge, not to the number of hours in a lab working with a well-type counter, etc. and eluting a generator. I mean, the specifics should be given to the individual training programs to deal with.

I sat in in an unrelated issue at a hearing at the Commonwealth of Pennsylvania in which some of the legislators wanted to dictate the curriculum for our universities and the presidents said no. A state-related university. The president said no. It's an intrusion into the academic world and the answer is no. And there was a threat that they cut the funds and he said, "Then cut them, but the answer is no."

I believe this is a similar issue, not of such great significance, not of equal significance, but a similar issue. The training of physicians has traditionally been in the hands of these residency training programs. They've done a good job. Let them continue to do it. Specify you need to have -- you want them to be able to train -- If you want us to train our residents so that they're competent or have a fund of knowledge so they can practice, fine, we'll do that. But just don't tell us it has to be six hours eluting a generator and X hours doing something

else and zero hours reading scans. That's not practical. It's just not practical. Will it work? It can't work. No one will sign on it.

Now I also know, and we haven't discussed here, but I also know that there was a rumor that someone some years ago said that they were signing attestation forms and didn't even adhere to them. It's just a matter of paperwork and that raised the hackles of everyone who was concerned about it, other program directors, the NRC. If someone is going to do something which is not truthful and honest, that individual will have to pay the consequences. But it doesn't seem to me that the whole world has to pay the consequences and if someone is discovered not adhering to the rules, no one will go after him or her more aggressively than the American boards or the NRC.

DR. RATHBUN: Right.

CHAIRMAN MALMUD: So I don't think that we can practice based upon a statement that one person might have said which might have been an accurate description of his behavior, but is unethical.

DR. RATHBUN: Would you like to address next, Dr. Williamson?

MEMBER WILLIAMSON: Yes. With all due respect, I think that the consensus point of view is

that we should go back to the Commission and ask them to drop the preceptor requirement, at least, from the board certification pathway, possibly from the alternative pathway or write a far more restricted and focused one and I think that we could debate all evening to try to reach consensus.

DR. RATHBUN: Right.

MEMBER WILLIAMSON: I think we should call the question and essentially vote on which of the two alternatives.

CHAIRMAN MALMUD: Sally.

MEMBER SCHWARZ: I just have a statement to make. I think that the --

DR. RATHBUN: Get closer to the microphone.

CHAIRMAN MALMUD: You have to reach Texas.

MEMBER SCHWARZ: I think that we should go ahead as Jeff just stated because I think what's happened today is not usual precedence. The public is here, I mean, in regard to a problem that exists in the community and I think with that the staff goes back to the Commission and asks essentially that this be repaired, that it is a problem in the community, that there is something that was not broken and it was repaired and now it is broken.

I think that we have different commissioners that will begin as well. Possibly they will have a different point of view as we approach them. But I think that as the staff can take back the communities' concerns as well as ACMUI's previous statements, I think we are certainly being backed up by the community and the next step the community has is the Congress and to me, it seems more effective that all of these people are interested and concerned to come here.

DR. RATHBUN: Okay.

CHAIRMAN MALMUD: Debbie.

MEMBER GILLEY: Could I please, Dr. Zelac, what the date is on those statements of consideration?

DR. ZELAC: Yes, March 30, 2005.

MEMBER GILLEY: Well, we have some new commissioners since that time. So I think the makeup of the commissioners are such that there may be interest at reviewing this.

CHAIRMAN MALMUD: Sally, can you make a motion?

MEMBER SCHWARZ: Sure. I would like to move that essentially we do remove the attestation from the board competency review completely. Excuse me. I'm not speaking well. I'd like to move that

remove the attestation from the board certification process and essentially that we then rewrite the attestation to remove "competency" and change it to "mastery of a body of knowledge" for the alternative pathway.

MEMBER NAG: Not mastery. I thought we already mentioned mastery of the body of knowledge, but minimum hours of --

MEMBER SCHWARZ: Yes, the minimum hours.

MEMBER NAG: "Met minimum training and experience requirement."

MEMBER SCHWARZ: Yes. "Met the minimum training and experience requirement."

CHAIRMAN MALMUD: That's a motion. Is there a second to the motion?

MEMBER NAG: Second.

CHAIRMAN MALMUD: Any further discussion?

(No response.)

CHAIRMAN MALMUD: All in favor?

(Show of hands.)

CHAIRMAN MALMUD: Is it unanimous or was there an abstention?

MEMBER GILLEY: I'm the guest. I don't know that I get a right to vote.

CHAIRMAN MALMUD: Okay.

MEMBER GILLEY: I'll vote if I can but I don't think I can.

DR. RATHBUN: Sorry. You can't vote.

CHAIRMAN MALMUD: All of us who are members?

(Show of hands.)

CHAIRMAN MALMUD: Okay. It's unanimous.

MS. TULL: Dr. Malmud, this is actually a clarification. Is that correct to strike through that? That is not to be included in the motion.

CHAIRMAN MALMUD: That is correct to strike through it.

MEMBER NAG: Let's see. Change "competency" too.

DR. RATHBUN: "Competency" too.

MEMBER NAG: Yes.

MS. TULL: Okay.

CHAIRMAN MALMUD: Change "competency" to "has met the minimum training requirements."

MS. TULL: Thank you.

CHAIRMAN MALMUD: Thank you. Okay. So we've closed on that first issue. Now let's move forward.

MS. WASTLER: That's very good.

CHAIRMAN MALMUD: What's the second issue?

Impact of the effective date, that apparently is a significant issue. We have to -- Is there a motion regarding that?

MEMBER LIETO: I think -- I don't know how to maybe state this as a motion, but the intent is, I think, that the NRC needs to get out of credentialing boards. The whole process that originally was the intent for the alternative pathway of describing boards when they decoupled -- I should back up. When they decoupled the boards from Part 35 and wanted to list them on web pages, the intent was to establish the criteria in order to get listed. The effective date was never part of that discussion and the very descriptions used to describe the boards that would get listed have now, in effect, actually precluded the board certifications before that listing. So it's almost been used against them.

I think as Kent Lambert pointed out earlier for the American Board of Health Physics. I mean, the model that we started with for describing these boards and now it's almost a minority of those individuals that can actually get -- whose boards are being recognized.

CHAIRMAN MALMUD: Are you recommending that all those who had board certification be

grandfathered?

MEMBER LIETO: Yes.

CHAIRMAN MALMUD: Is that a motion?

MEMBER LIETO: So moved.

CHAIRMAN MALMUD: Is there a second?

MEMBER WILLIAMSON: Second.

CHAIRMAN MALMUD: Discussion?

(No response.)

CHAIRMAN MALMUD: All in favor?

MEMBER GILLEY: I have a clarification. Are we going back to subpart J again?

CHAIRMAN MALMUD: Yes.

PARTICIPANT: It's effectively subpart J.

MEMBER GILLEY: Thank you. Okay.

CHAIRMAN MALMUD: All in favor?

(Show of hands.)

CHAIRMAN MALMUD: Any opposed?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: It's unanimous. Next, item number three.

(Laughter.)

MS. FAIROBENT: Lynne Fairobent with AAPM. Just a question to follow-up Debbie's question

regarding whether or not we're going back to subpart J. I think, that as again to get back to the AAPM petition, we were very careful in writing the text of that petition to not preclude any other board who may have been granted recognized status that was not originally part of subpart J to continue to be recognized under the board pathway and specifically I'm talking about the Nuclear Cardiology Board because they were not originally in subpart J. So I just throw that out for your consideration.

CHAIRMAN MALMUD: The motion did not refer to subpart J at all. The motion was that all of those who were certified be grandfathered regardless of their board.

MEMBER GILLEY: Then all I suggest is that there be a mechanism to add new boards as more boards become available so that we don't lock ourselves down.

MS. FAIROBENT: Yes.

MEMBER GILLEY: I don't know of any, but --

CHAIRMAN MALMUD: That would be a separate issue.

MEMBER GILLEY: Right.

MR. MOORE: May I ask a point of clarification?

CHAIRMAN MALMUD: Please.

MR. MOORE: Would that have the effect of essentially removing 35.59, the --

DR. RATHBUN: That's the old subpart --

CHAIRMAN MALMUD: If I may, I would leave it to the NRC staff which has excellent lawyers in it to figure out which regulations are going to apply. This body believes that those who have been board certified should not have their board certification interfered with. That is the spirit of this body and that is the intent of this motion unless I interpreted it incorrectly. And let the NRC which has a wealth of staff to deal with this figure out how they're going to put it into one pot or another. But clearly, this is interfering with the practice of medicine and the delivery of health care to patients which is what we're concerned about. Item number three.

DR. METTER: Can I make a comment from Texas?

CHAIRMAN MALMUD: Yes please

DR. METTER: I'd like to make a comment that the board -- There are 24 boards that are recognized by the American Board of Medical Specialties and the American Board of Nuclear Cardiology is a self-appointed board and it's not, I

believe, part of the American Board of Medical Specialties and I just wanted to make that comment.

(Off the record comments.)

CHAIRMAN MALMUD: Thank you for your information.

MEMBER EGGLI: I would like to make one additional comment about that if I might, item number two.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: I think the intent of the motion was not to disenfranchise any board currently recognized but to cover the gap between October 24, 2005 and when the boards are currently recognized.

MR. MOORE: We understand.

MS. WASTLER: We understand that.

MEMBER EGGLI: Okay.

CHAIRMAN MALMUD: Item number three was 200 hours. Does someone want to pursue that?

MEMBER NAG: Before that, I think Part 35.59 should be taken off under number two because that has the recency of training over the last seven years and I think it should be a recommendation that that need not apply.

(Off the record comments.)

MEMBER LIETO: Yes. I think, isn't

grandfathering one of the points farther down?

(Chorus of yes.)

MEMBER LIETO: All right. Maybe could we address it then?

MEMBER WILLIAMSON: I think there's a recency of training bullet as well that will come.

(Chorus of yes.)

MEMBER WILLIAMSON: I think that does need to be discussed.

CHAIRMAN MALMUD: We'll get to that one.

DR. RATHBUN: That's No. 9.

MEMBER NAG: Those can be similar. They have some similarity.

CHAIRMAN MALMUD: That's item number nine. Can we move down the list and move down to that one?

MEMBER NAG: Okay.

CHAIRMAN MALMUD: Okay. Number three, 200 hours. Who wants to describe that and make a motion? Dr. Eggli.

MEMBER EGGLI: The description of the issue is that for Subpart 390 200 hours is excessive radiation safety training, the basic concepts of radiation safety. Although there are some small areas of domain knowledge that are required for each of the modalities, 200 hours is an excessive safety training

program in that for Part 390 again, when we originally discussed this in ACMUI we recommended somewhere between 50 and 80 hours for a Part 390 and that 200 hours is kind of over the top and basically, I can't design a training program that will productively consume 200 hours of safe handling and basic knowledge.

The basic core knowledge is the same across all of the radiation safety. I need a little bit of domain knowledge for each of the modalities, but I can do that in far less than 200 hours of training. If we have to do it to comply, it will be Mickey-Mouse time spent not doing anything really productive and useful. It will just be marking the clock.

And again, I think that what needs to happen is that we should specify the content to be mastered, not the number of hours spent on it. This is the same as you would down the board certified pathway. You have to design training programs that teach the basic concepts that you need to learn to safely and effectively administer therapeutic treatment with open sources.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: This gets to maybe a

broader philosophical difference between the 200/300 versus 400/600 domains. As I recall 400 and 600 explicitly allowed for a more rigorous and prescriptive alterative pathway; whereas, in 200 and 300 and 100, I think that you tried to make the criteria for recognition of a board in the alternative pathway requirements, you said, is one and the same. Is that not correct? And are you --

DR. ZELAC: That's not correct.

MEMBER WILLIAMSON: That's not correct. Okay.

DR. ZELAC: No. For 490 and for 690, the requirement for the board certification pathway does not get into subjects, does not get into lengths of time. It simply says you've gone through a residency program.

MEMBER WILLIAMSON: That's what I said, but I believe that 200 and 300 don't do that.

DR. ZELAC: That's correct.

MEMBER WILLIAMSON: I think 200 and 300 are the opposite. They link the alternative pathway with the content of the ACGME, the residency training and experience. So are you proposing more fundamentally that those be decoupled?

MEMBER EGGLI: Well, what I guess what I

would be proposing is that the material to be mastered can be prescribed. But again, the amount of time it takes to master that material should not be prescribed and that, in fact, I don't think I can design 200 hours of useful education to cover this and not waste a lot of time. And again, I would ask any -- I don't know if I can, but I would ask Dr. Royal if he could address that issue from the American Board of Nuclear Medicine.

MEMBER WILLIAMSON: So to clarify my -- to answer my question, you basically -- This is a change you propose for both the alternative pathway and the board certification pathway.

MEMBER EGGLI: No, 200 hours is not imposed in the board certification pathway.

MEMBER WILLIAMSON: I see.

MEMBER EGGLI: It's only right now imposed in the alternative pathway. But if the boards have to train to the alternative pathway level of training, then it becomes a de factor requirements for the board.

(Off the record comments.)

MR. ROYAL: So I would just make the comment that when Deb was talking about these number of hours, she referred to them in the alternative

pathway as being the minimum number of hours that were required.

MEMBER GILLEY: For a non-residential program. This is not a residency program.

MR. ROYAL: But it's hard to -- From a board's point of view, if this is perceived as the minimum amount of training for the alternative pathway, it's hard to understand why someone who is in the board certification pathway would not also require this minimum amount of training. So when you say 200 hours for 390 for the alternative pathway, it's hard for the boards to ignore that.

One of my fundamental problems with it is it's irrational. We had this discussion early in the afternoon about the 80 hours for 392 and the 80 hours for 394 and I thought I heard everyone say "Well, those are the same 80 hours." And yet, if you do 390, you're supposed to do 200 hours. But if the 80 hours for 392 and 394 are the same 80 hours, then somehow you're supposed to do 80 more hours for 396. It's hard to understand with all of that overlap how you could possibly get to 200 hours. So I think the regulations just don't add up mathematically.

CHAIRMAN MALMUD: Yes?

MR. MOORE: I would just like to say on

this issue that the staff will certainly look at and value any guidance that we receive from the ACMUI. But when we were developing Part 35, the issue of how many hours and especially the 200 hour mark was a serious sticking point with the agreement states.

We had extensive evaluation of what should be the appropriate number of hours. We went back. The staff had a working group that went back and looked at the amount of training that was offered in general training programs and found that 200 was a general amount that was available outside.

I think that we would certainly value any input from the ACMUI and look at it. But we will have an extremely tough time with agreement states if there is a change in this to remove a number of hours entirely and not specify a number of hours.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: When this came up in the final review, Ed Bailey who was the state representative at the time said, in fact, it wasn't all 34 agreement states, that it was driven by two agreement states who were particularly insistent and the rest kind of went along. That was what he reported back to this committee.

So I'm not convinced that this burns in

the heart of all agreement states, but we know from Ed Bailey that it did in two particular agreement states. And maybe Debbie could address that issue or Paul.

MEMBER GILLEY: We do suggest to state regulations. We have a subpart G that is the equivalent or parallel to NRC's Part 35 and that has been adopted and approved by the Conference of Radiation Control Program directors with that 200 hours in place there. The 200 hours is nothing new. That again has been since 1988. We required that for alternative pathways. This is not a new requirement because of Part 35. It is an existing requirement and it is not driven for those residency programs for nuclear medicine or radiology. It's that other subset of programs that are out there and there are private companies that provide this training and that is where that oversight comes from, is required. It's for those organizations.

DR. RATHBUN: Lynne.

MS. FAIROBENT: Lynne Fairobent, AAPM. As with some of the ACMUI members, I think I've been at every public meeting where these points have been discussed since probably 1991 or so, 1995. A couple of things that maybe will get us out of this dilemma for the 200 hours in the Part 200 and 300 series of

regulations. Perhaps what we should look at now is, and I hate to say this, but a three-fold-type criteria where you have the board pathway and we develop language similar to what was done in 400 and 600 to recognize those individuals that come out of approved residency programs for nuclear medicine and then have an alternative pathway for individuals who are not coming through approved residency programs to get to Debbie's point of where the original basis for the 200 hours came from.

That was not looked at or discussed during the development of the rule. Because if you remember, the number of hours that OAS proposed was at the 11th hour between the draft and the final rule and was truly not put out for public comment officially to comment on the number of hours that came out in the final regulation other than the minimum 30 day period of when a final rule appears.

So perhaps we should really go back and investigate if there is a way in which to develop language to recognize the bona fide residency programs in this area and then an alternative pathway if someone is not coming through residency programs.

DR. RATHBUN: Scott.

MR. MOORE: Lynne, to the fairness of the

Organization of the Agreement States and to the ACMUI, it's NRC's practice to provide the draft final rule and the draft proposed rule to both the Organization of Agreement States and to the ACMUI in pre-decisional form to both the ACMUI and the OAS and that's why they see it in pre-decisional form and comment back to us on it, the ACMUI and OAS.

MS. FAIROBENT: Right, but, Scott, my point was the number of hours was never put out in a public forum for the public to have an opportunity to comment on the 200 hours. If you go back and look at the record, it appeared between the publication of the draft rule for comment and the final rule that was pre-decisional and provided to ACMUI and the agreement states to comment on it. It was only at the ACMUI meeting discussing this that there was any public discussion on the origin or the basis of the number of hours being input into the final rule.

DR. RATHBUN: Let's --

MEMBER LIETO: This is Ralph Lieto. I just wanted to support what Lynne just said because we actually had a teleconference on this very issue because it was such a substantive change from what had been proposed from the get-go. When it had gone through advanced notice through proposed, there was

never those specific hours and then they come in. It really took everybody quite off-guard. So in all fairness, the regulated community, the stakeholders, did not have the opportunity to see those changes and comment on them before they became final rule.

DR. RATHBUN: Dr. Welsh.

MEMBER WELSH: I might be reiterating what's already been said here, but I would like to advocate --

DR. RATHBUN: Dr. Welsh, could you bring the microphone closer? Thank you.

MEMBER WELSH: I'd like to advocate a bit of caution here because the 200 hours is something that might be appropriate for those who are not board certified or who have not gone through residency training. If you remove something that is strict and stringent, it opens up the pathway for those who are not trained in nuclear medicine/radiation oncology to seek a weekend course or a two week course that gets X number of hours in but would not meet our standards for administering radiopharmaceuticals and although 200 hours might seem excessive, it's something that's probably easily met in reality during the residency training and I would advocate that we don't say anything about number of hours if somebody is board

certified. But if somebody has failed to meet board certification, this might not be inappropriate.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: Well, I think it was Ralph's motion, correct, you put in the table? Who put the motion on the table?

MR. MOORE: I don't think there's one on this one.

CHAIRMAN MALMUD: There is no motion on the table.

(Off the record comments.)

MEMBER WILLIAMSON: I would move that we proposed amending the 200 and 300 series of training and experience requirements to include a three-level requirement as proposed by Lynne Fairobent that includes board certification pathway which requires a residency, an approved residency. And with the residency or the certification exam, only the content to be mastered would be specified and the third level would be the alternative pathway II which would be training and experience acquired outside of an approved residency program that would retain the 200 hour requirement. Alternative pathway I would be successful completion of an approved residency program.

So there would be more complicated alternative pathway requirement. Alternative I would be residency program. Alternative II would be the more prescriptive pathway as currently written.

CHAIRMAN MALMUD: Dr. Van Decker.

MEMBER VAN DECKER: I don't know the answer to all of this stuff and as we all know, this has been talked about for decades now. But I'm a little bit concerned about making multiple levels of ways to do things when we're really concerned about how complicated things are right now.

I would suggest that this piece of the topic be thought about some and some thoughtful comments came back after people do some thinking. But I'm a little bit nervous about multiple levels of different things going on. But I do agree that obviously prescription is not necessarily the answer to a lot of situations.

DR. RATHBUN: Dr. Fisher, Dr. Nag and then I have to take a small break because we have to read something into the record.

MEMBER FISHER: This is Darrell Fisher. In my simplistic view, the way the text reads under 35.50 if you simply deleted "200 hours of" the text goes on to read "classroom and laboratory training in

the following areas" and then those areas are well described. I think that's sufficient without being prescriptive on the number of hours.

DR. RATHBUN: Dr. Nag.

MEMBER NAG: I see here seeing 35, 200 and 300, I think the requirement was only 300. The 200 is simple --

MEMBER EGGLI: The 200 is 80 hours. The 300 is 200 hours.

MEMBER NAG: Yes. So I just think we need to have 200 in there and then being 35.39 in fact should be 35.39 -- if I'm correct.

CHAIRMAN MALMUD: Someone else who had a comment?

DR. ZELAC: Yes.

DR. RATHBUN: Ron.

DR. ZELAC: A quick one. It's more of a comment and a question. Dr. Eggli, what would you think of 120 hours? No, I'm serious. There is a basis for my asking this.

MEMBER EGGLI: I understand this is a little bit of Let's Make A Deal that the requirements should be -- I can see where you're coming from that the requirement ought to be greater than Part 200, but maybe then, you're bowing to the 300 hours for Part

390 being excessive. You know, the bottom line is I guess we work with what the regulation is. But for me, again, I thought 80 was excessive for Subpart 200 training in 290.

I can put together a nice training program that I think meets all the needs of Part 390 in 80 hours of training or so. I don't advocate specifying the number of hours, but if we could get there, I'll take some relief.

DR. ZELAC: The reason I asked it in that way is that there was when the 2002 rule was being crafted I think a general consensus that 80 hours for therapeutic use was not sufficient and that was going to be raised and the question was what to raise it to and the thought was that an individual who would be spending four months in a department or approximately 700 hours would have ample opportunity to learn hopefully both the radiation safety aspects and adequate number of clinical skills to be able to function effectively and independently. So the 2002 rule, in fact, for the alternative pathway came out with 700 hours, no specification separately for classroom and laboratory.

MEMBER EGGLI: Right.

DR. ZELAC: And that's, in fact, what was

in the proposed change for Part 35 in 2005 as well. The reason I mention 120 hours was when the 2002 rule was being crafted there was a survey done as to just what the length of the classroom and laboratory experience was and it turned out that it was 120 hours and so it was basically going to be "Well, you have 120 hours of classroom and lab and the remainder to get to 700 hours would be in the clinical setting which would cover radiation safety, but other aspects as well."

MEMBER EGGLI: Again, I would favor whatever form of relief from the 200 hours can be obtained.

DR. RATHBUN: Okay. Would you have a motion on the table?

CHAIRMAN MALMUD: There isn't a motion on the table.

MEMBER WILLIAMSON: There is a motion.

CHAIRMAN MALMUD: It's not been seconded. Who made the motion?

MEMBER WILLIAMSON: I made the motion.

CHAIRMAN MALMUD: What was the motion?

MEMBER WILLIAMSON: The motion was that there be a three-level training and experience requirement for 35.300, board certification,

alternative pathway with a clinical approved residency and alternative pathway with non-approve residency training.

CHAIRMAN MALMUD: Is there a second to that motion? Are you seconding it?

MEMBER WELSH: I'm seconding it.

CHAIRMAN MALMUD: Dr. Welsh seconds it. Is there any further discussion of that motion?

(No response.)

CHAIRMAN MALMUD: All in favor of that motion?

(Show of hands.)

CHAIRMAN MALMUD: All opposed?

(Show of hands.)

CHAIRMAN MALMUD: It doesn't carry. May I make a motion?

DR. RATHBUN: Yes.

CHAIRMAN MALMUD: That the number -- That we, first of all, not use the word "excessive" with regard to the 200. Two hundred is more than sufficient but it's not excessive. We could never had excessive training.

(Laughter.)

CHAIRMAN MALMUD: That we feel that the training requirements could be met adequately with 120

hours and that that is our recommendation that the 200 be changed to 120 because that is what training program directors feel is more than sufficient to meet the training requirements in the type of physics we're talking about. So that's the motion.

DR. RATHBUN: Does somebody second his motion?

MEMBER EGGLI: I'll second it.

CHAIRMAN MALMUD: Dr. Eggli seconds it. Any further discussion of that motion? Yes. Dr. Welsh.

MEMBER WELSH: Is that 120 hours part of the 700 hours of clinical experience in the field of nuclear medicine?

CHAIRMAN MALMUD: Yes. And the 120, by the way, if you take the average college course, it's about 12 weeks, three hours a week, 36 hours. So we're talking about over a year and a half of a college course in nuclear medicine and physics. I think that's more than sufficient.

MEMBER WILLIAMSON: That's quite a bit.

CHAIRMAN MALMUD: But it's not -- Yes, it's more than sufficient but not so little that somebody could walk through the back door and say, "I took the course in Las Vegas last week and I meet the

hours. I was up day and night doing it." Because there is a risk that the standards are taken to the minimum, that someone may take advantage of them and that would not be in the public welfare. So that's why I suggested the 120.

MEMBER NAG: Yes. I think there is a big difference between the number of hours as part of a residency training program requirement because during that residency training you are also learning other things that help you make the decision and a standalone course where you have no knowledge of what radiation is.

CHAIRMAN MALMUD: There is a motion on the floor. Any further discussion?

(No response.)

CHAIRMAN MALMUD: Anyone in favor of the motion?

(Show of hands.)

CHAIRMAN MALMUD: All those opposed?

(Show of hands.)

CHAIRMAN MALMUD: Any abstentions?

(No response.)

CHAIRMAN MALMUD: I guess two oppose.

DR. RATHBUN: Motion carries.

CHAIRMAN MALMUD: Motion carries.

DR. RATHBUN: All right. I need to do two things. Cindy needs to read something into the record and does this have to be done today?

MS. FLANNERY: Yes.

DR. RATHBUN: All right. Then start reading.

MS. FLANNERY: Thank you. I just wanted to make an announcement for the ACMUI and have this go on public record. Just a very short time ago, you received a couple of letters. They are dated April 26 of this year and June 11. I just wanted to ask that you treat these as pre-decisional and handle them just like you would any other pre-decisional documents that you would get via email or in your binders which is basically to not release them until they have -- until such time that they've been publicly released. So thank you, Pat, for giving me a minute to say that.

DR. RATHBUN: You're welcome. Okay.

CHAIRMAN MALMUD: And Ashley has a very brief statement, too, regarding travel folders.

MS. TULL: Really quickly. There are folders for all the ACMUI members with your names on the front. They have your pay vouchers and your travel expense sheet. If you guys can take a look at those this evening, try to fill them out. Anywhere

that's highlighted needs a signature. I'll need this back at the end of the meeting tomorrow.

CHAIRMAN MALMUD: Thank you.

MS. TULL: Thanks.

MEMBER NAG: Ashley. Yes. For the pay vouchers, it's for the two weeks starting from yesterday which means we can submit that a week from now because otherwise we wouldn't know what we are doing next week. You will have difficulty trying to reconcile it.

MS. TULL: You are correct, but if you can fill in or give me a signature on anything. There are instructions on that. If you can just take a look at it please.

DR. RATHBUN: Okay. As really as a neutral outsider, what I am seeing here is if we had an ACMUI viewpoint on these issues because you were making the motions, I think if we had that, I think the NRC would have a better chance then of going forward and trying to work out some kind of solution. I don't know quite how to do that. I don't really want to backtrack to do this. We could do it, I guess, by letter. I don't know the process well enough.

I also see though that we have an

agreement state issue, not issue, but in other words, challenge. Well, we have a new family that's come on board here in our office and we're trying to work that out. So we're going to need some kind of consensus from the agreement states. Ashley.

MS. TULL: This is Ashley Tull. As far as logistics, ACMUI does have teleconference.

DR. RATHBUN: Okay.

MS. TULL: This is something that needs to carry over. In the past, we have done this where ACMUI would call in and I guess we need to include the agreement states.

DR. RATHBUN: Okay.

MS. TULL: So when we do have a teleconference venue.

DR. RATHBUN: Now is that something that would be agreeable?

MS. TULL: Yes.

DR. RATHBUN: Yes sir.

MEMBER WILLIAMSON: I think to deal with the other nine issues in the next five minutes is obviously a logistic impossibility.

DR. RATHBUN: It won't work.

MEMBER WILLIAMSON: And I think if this is considered important which I think it should be --

DR. RATHBUN: Yes.

MEMBER WILLIAMSON: -- I would recommend that probably a noticed telephone conference which all the same individuals might be willing to convene.

DR. RATHBUN: Right.

MEMBER WILLIAMSON: And we could carry on the discussion for a longer period of time.

DR. RATHBUN: Yes.

MEMBER WILLIAMSON: Rather a separately noticed physical meeting.

DR. RATHBUN: Something like that because we are well ahead of the game because we now have a list of the issues.

(Off the record discussion at same time.)

DR. RATHBUN: And before you really had an amorphous set of comments. So I think we're better off than we were when we started and I think there is a path forward. Yes ma'am. Sally.

MEMBER SCHWARZ: And as a corollary, the public can be included in this conference.

DR. RATHBUN: Sure. So then -- Yes ma'am. I could be wrong because I don't know any procedures. Go ahead.

MS. TULL: The answer is to Sally's question is yes.

(Off the record comment.)

DR. RATHBUN: So having said that --

MEMBER SCHWARZ: I believe they have to email someone to be on the list for the teleconference.

MS. TULL: It will publicly noticed in the *Federal Register*. So that's how everyone could find out about it.

MEMBER EGGLI: Now we have to email you to get the passcode and the number.

MS. TULL: Yes.

DR. RATHBUN: Right.

MS. TULL: So I can control the number of lines.

MEMBER EGGLI: Right.

DR. RATHBUN: Dr. Malmud, is this something that is okay with you?

CHAIRMAN MALMUD: Absolutely.

DR. RATHBUN: Okay. All right.

MS. WASTLER: Actually, you indicated was to control the number of lines. That's not what I'm trying to control is the number of lines. It's to make sure we have sufficient number of lines.

MEMBER EGGLI: To get enough.

MS. TULL: Yes. Obtain.

MS. WASTLER: So that we don't exclude somebody. That's why it's important for us to know you is who is going to call in so we can make sure we have all our bases covered and somebody doesn't keep dialing and going "I can't get in."

MEMBER SULEIMAN: This will require another FR notice. Right?

(Chorus of yes.)

MS. WASTLER: Yes it will.

MEMBER NAG: The only concern I have is that ACMUI has made a number of these statements before and we have been totally ignored. Are we going to be ignored again? If we are, I'll refuse to participate.

DR. RATHBUN: -- and that's what they brought me in because they've selected an outside facilitator and it's my responsibility to make sure that the things you said here get worked on. So as far as I'm concerned, the answer is you are not going to be ignored.

MR. MOORE: I would also say that while the ACMUI's position last time was not accepted in the final analysis by the Commission, its advice and input was certainly not ignored. The staff certainly took the input and has provided that information up and

will diligently continue to do that. So we heard you today say that maybe it's time to readdress this issue with the Commission and ask that the Commission relook at the issue of preceptor statements given the new experience. So we do hear you and I want you all to know that your advice is not being ignored.

I have a few administrative issues.

DR. RATHBUN: Okay. So we've agreed that we're going to continue. I did want to hear from Ron.

DR. ZELAC: That was exactly what I was going to suggest.

DR. RATHBUN: Okay. And in some cases, Ron has done a lot of research on this and so I would like to see you put something into these questions, maybe things we try or something like that, to move us another step forward. Yes sir.

DR. BROGA: Dean Broga. The RSO issue is a looming issue for thousands of community hospitals. We have an ambiguity that if you're an agreement state an authorized user can become an RSO immediately and not in the rest of the NRC states. Will there be time tomorrow morning in the RSO discussion to talk about that?

DR. RATHBUN: If that's acceptable to Dr. Malmud. We could spend a little time in the morning

on that.

DR. BROGA: I mean, this affects radiologists, Society of Nuclear Medicine, cardiologists.

DR. RATHBUN: And the public.

DR. BROGA: It's all of them that's affected by that.

DR. RATHBUN: The health and safety of the public. So if Dr. Malmud would.

CHAIRMAN MALMUD: By all means.

MS. WASTLER: I would point out that Mr. Lieto is already on the schedule to talk about the issue of having one RSO on a license.

DR. RATHBUN: Good. Excellent. Okay.

(Off the record comments.)

DR. RATHBUN: All right. Donna-Beth.

DR. HOWE: I'm also on the schedule tomorrow to talk about some potential changes to Part 35.

DR. RATHBUN: Okay.

DR. HOWE: And there are some issues in there that are included in the potential changes to Part 35.

DR. RATHBUN: So you might have some proposed changes that would resolve some of these

issues. Is that what you're telling us?

DR. HOWE: Into a user need memo that will go to the rulemaking group this summer.

DR. RATHBUN: Okay. All right. Then with that and with Dr. Malmud's permission, I was going to close this part and then go -- I want to go ahead and close this session and -- Yes.

DR. ZELAC: One very, very quick thing. I have to confess that when I was asked about what Dean Broga had been talking about, if I had a response, I wasn't paying attention and that I think had to do with retribution in case you were assigning preceptor statements inappropriately. There is something in the March 30, 2005 rule addressing that specifically. If an individual is authorized as whatever and signed a preceptor statement and the person that he signs for turns out to not be satisfactory, that has no bearing at all on the person's status as an authorized individual. However, if the individual signs a preceptor statement knowingly false, that's another issue entirely.

DR. RATHBUN: All right. This is going to be covered. Okay. Donna-Beth, we'll get it tomorrow. Now again, I want to thank you. This was quite a challenge and I appreciate all of your help, Dr.

Malmud for picking up the ball when I dropped it and everyone. So with that, I'm going to close the meeting and turn it over to Scott.

CHAIRMAN MALMUD: Before you do that, we want to thank you for your help and your participation. Thank you.

(Applause.)

MR. MOORE: Thank you, Pat. Thank you, Dr. Malmud. I have three quick administrative items. In March, the Commission gave staff direction through a staff requirements memorandum which is the way the Commission gives staff written directions to follow up on to work with the agreement states to develop a plan for fingerprinting the recipients of orders of IC, increased control orders, and it tasked the staff to work with the agreement states to develop such a plan and have it in place by and have the requirements in place by September.

NRC has formed a working group with the agreement states to develop such a plan and is moving to do that. It will have some effect on the medical community, especially hospitals that have things like blood irradiators or large gamma knives, large sources, essentially, those hospitals that have received increased control orders or legally binding

requirements from agreement states that have increased controls in them.

We think it would be appropriate to brief the ACMUI on these efforts that are going forward. We need to set up such a briefing at some time in the near future, sometime over the summer and we'll have a follow-on to do that. Sandi and her staff will set such a briefing.

We want to make you aware of it at this point, but let you know that that will have to be done through a separate briefing. It wasn't far enough along when we prepared the agenda for this meeting which was back, I think, at th start of May to get it onto this meeting's agenda.

The second item is this. The Commission recently was briefed in a meeting, we called it the AARM meeting, as part of a review of operational events and data. As part of that discussion, we received direction in that meeting and then we expect to receive written direction afterwards that we're being asked to work towards a goal of or we're being tasked to work towards a goal of minimizing, if not eliminating, therapeutic medical events to prevent injuries from nuclear medicine. We expect that the Commission will tell us to do that.

We will need to engage ACMUI in a discussion of that. There was a discussion that came out during the Commission briefing on those events. The number of such events are fairly low. That came out during the discussion, but as part of the discussion, we were told to work towards a goal of minimizing, if not eliminating, therapeutic medical events and so we will need to engage ACMUI on such a discussion. We'll need to have a further follow-on discussion with ACMUI on that issue. Mr. Lieto.

MEMBER LIETO: A point of clarification. Were these medical events that were classified as abnormal occurrences raising the issue or just medical events in general?

MS. WASTLER: As I recall the specific events that were in question were fetal doses and then what we have seen at the point or I guess what's under potential added discussions of the Commission is I think it's a broader topic and so it's talking about events in general, not necessarily abnormal.

MR. MOORE: Not just AOs but --

MS. WASTLER: Not just Aos.

MR. MOORE: But reportable events. Okay.

MEMBER LIETO: Because I think the committee is already on record as regarding medical

events and improvements that could go towards that issue regarding sodium iodide in 131 therapies which those two fetal dose events were resulting from. So I think we've already made recommendations on that. It's just a matter of those getting --

MS. WASTLER: I would recognize -- I mean the committee has been very helpful.

MEMBER LIETO: Okay.

MS. WASTLER: And they reviewed several INs that we've put out based on events that have taken place. I think the Commission may not be aware of those individual cases. So it's an opportunity to make them aware, but I think in general our goal is always to have the number of events zero. That's a great goal, but we're talking about human nature and individuals and --

MEMBER WILLIAMSON: To insist on a goal of zero means spending infinite resources to preclude error.

MS. WASTLER: But if there are fixes that we can -- But there are always ways we can improve things and if there are things or there are activities out there or processes out there where we could make simple fixes -- we talked about this morning in your presentation potential things that we could do with

regards with Air Kerma and putting an IN out there. That would be an opportunity for us to maybe educate, maybe change someone's thoughts with regards to a QA process that would improve the process and therefore possibly eliminate some of the events or minimize them.

MEMBER WILLIAMSON: But you are already doing that.

MS. WASTLER: I realize that, but the Commission -- I think that's the question that we have to raise, that the Commission is asking us to look at.

MR. MOORE: In raising it with you, I wanted you to be aware of the meeting that was held with the Commission. It went over events, not just medical events, events across the board in the whole materials area and as part of that discussion, it came out that the staff should work towards a goal of minimizing, if not eliminating, events in general, but also therapeutic medical events. So they gave us specific feedback in that area and we want to work through the ACMUI to do that.

We already, we believe, we the staff believe, that we're already working through the ACMUI to do so. We brief you on events. We receive

feedback from you on how we can do that. But as we move forward on such direction from the Commission, we want to make sure that we do that in coordination with the ACMUI and that the staff not just develop something independently and go back and answer the question.

MEMBER NAG: Why is it only for nuclear medicine? I mean, that's the same for any other radiation application with quality for --

MR. MOORE: I think the Commission intended that broadly. I didn't think they meant it specifically.

(Off the record comments.)

MR. MOORE: Okay. The third issue is this. The committee asked about a briefing. There was a question from Dr. Eggli through Dr. Malmud if you could be briefed in a closed meeting on the petition for rulemaking from the AAPM.

At this point, we're still looking into it. We raised the issue with our legal counsel. They are looking at it. There are some things they have to look at regarding the Federal Advisory Committee Act. The ACMUI is a federal advisory committee to the agency and they have to look at it and make sure we don't violate the FACA rules.

But the staff's preference is that we would be able brief the advisory committee in some manner on it in a closed session, if possible, if we can legally do that. So we will try to find a way that we can give a briefing to either the ACMUI or a subgroup of the ACMUI which may be possible under FACA and if we can do that, we would like to do that. So we will pursue it with our legal counsel and find out if we can. But we will go forward and continue to look into that.

Unfortunately, I will not be able to meet tomorrow. I'm out of the agency tomorrow and Sandi will be here for you as your Federal Official. Thank you very much, Dr. Malmud.

CHAIRMAN MALMUD: Thank you.

MS. WASTLER: Dr. Malmud, I'll turn the meeting back to you, sir.

CHAIRMAN MALMUD: I'm going to just ask to adjourn the meeting and hope to see you all here at 8:00 a.m. tomorrow morning. Thank you for a very intense, long day. Off the record.

(Whereupon, at 5:08 p.m., the above-entitled matter was concluded.)