# Official Transcript of Proceedings

# NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the Medical Uses of Isotopes: OPEN SESSION

Docket Number: (not applicable)

Location: Rockville, Maryland

Date: Tuesday, October 24, 2006

Work Order No.: NRC-1277 Pages 1-239

**NEAL R. GROSS AND CO., INC.**
**Court Reporters and Transcribers**
**1323 Rhode Island Avenue, N.W.**
**Washington, D.C. 20005**
**(202) 234-4433**

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

OPEN MEETING

+ + + + +

Tuesday, October 24, 2006

+ + + + +

The meeting came to order at 10:30 a.m. in room T2B3 of Two White Flint North. Leon S. Malmud, M.D., Chair, Presiding.

PRESENT:

Leon S. Malmud, Chairman

Richard J. Vetter, Vice-Chair

Edgar D. Bailey, Member

William Van Decker, M.D., Member

David Diamond, M.D., Member

Douglas F. Eggli, M.D., Member

Ralph P. Lieto, Member

Subir Nag, M.D., Member

Sally W. Schwarz, Ph.D., Member

Orhan H. Suleiman, Ph.D., Member

Jeffrey Williamson, Ph.D., Member

ALSO PRESENT:

Thomas H. Essig, Designated Federal Official

Charles L. Miller, NMSS/IMNS

Cindy Flannery, NRC

Angela R. McIntosh, NMSS/IMNS

John Szabo, Esq., OGC

Lydia Chang, NRC

Donna-Beth Howe, Ph.D., NRC

Duane White, NRC

Neelam Bhalla, NRC

James Firth, NRC

Ronald Zelac, Ph.D., NRC

Cindy Flannery, NRC

Ken Brown, M.D., ASNC

Paul Goldberg, NRC

William Ward, NRC

Mohammad Saba, NRC

# I N D E X

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

10:39 A.M.

CHAIR MALMUD: We will resume and call together our regular session. The session will begin with opening remarks and we have a very tight schedule today and therefore we will ask Mr. Essig to introduce Dr. Miller. And Mr. Essig has some opening remarks.

Tom?

MR. ESSIG: Thank you, Dr. Malmud. As Designated Federal Officer for this meeting, I am pleased to welcome you to Rockville for the public meeting of the ACMUI. My name is Thomas Essig. I am Deputy Director of the Division of Intergovernmental Liaison and Rulemaking and have been designated as a federal officer for this advisory committee in accordance with 10 CFR Part 7.11.

Present today as the alternate Designated Official, Federal Officer is Cynthia Flannery who is the team leader for Medical Radiation Safety within the Medical Safety and Event Assessment Branch of the Division of Materials Safety and State Agreements.

Both of the aforementioned divisions are part of the Office of Federal and State Materials and Environmental Management Programs which was established on October 1, 2006.

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

The meeting was announced in the October 3, 2006 edition of the Federal Register, Volume 71 at page 58443.

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

I request that whenever possible we try to reach consensus on the various issues that we will discuss today, but I value the minority or dissenting opinions. If you have any such opinions, please allow them to be read in the record.

As part of the preparation for this meeting, I've reviewed the agenda for Members and employment interests and based on the very nature of the discussion we're going to have today. I've identified any items that would pose any 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 such a conflict, please state it for the record and recuse yourself from that particular aspect of the discussion.

At this point, I would like to introduce the Members that are here today: Dr. Leon Malmud, Chairman, Health Care Administrator; Dr. Richard Vetter, Vice Chairman, Radiation Safety Officer; Dr. James Welsh, Radiation Oncologist; Dr. Subir Nag, Radiation Oncologist; Dr. William Van Decker, Nuclear Cardiologist; Dr. Douglas Eggli, Nuclear Medicine Physician; Dr. Sally Schwarz, Nuclear Pharmacist; Dr. Jeffrey Williamson, Therapy Physicist; Mr. Ralph Lieto, Nuclear Medicine Physicist; Mr. Edgar Bailey, State Representative; and Dr. Orhan Suleiman of the Center for Drug Evaluation Research of the U.S. FDA.

I would note that although Dr. Welsh's appointment has received management approval, his security clearance is being processed at this time. Therefore, his appointment will not be official until the security processing is complete.

I would also know that the Patient Advocate Representative on the Committee is currently

vacant and nominations are under consideration.

Dr. Malmud, as Committee Chairperson, you will conduct today's meeting and following a discussion of each agenda item, you may at your option entertain comments or questions from members of the public who are participating with us today.

Dr. Malmud?

CHAIR MALMUD: Thank you, Mr. Essig. We'll move immediately to the next item on the agenda which is the opening remarks by Dr. Miller.

Dr. Miller?

DR. MILLER: Good morning. I'd like to welcome all the members of the public to the open session of the meeting.

What I wanted to cover today was the recent reorganization of NMSS and the Office of State and Tribal Programs and to walk you through what the new organization structure will be and who the players will be.

But before I do that, I just wanted to touch on a couple of things. First, I'd like to welcome Dr. Welsh to the Committee. I'm sure you'll find the discussions invigorating and enlightening and we look to you to help us in the radiation oncology area in providing advice.

Secondly, I'd like to congratulate Dr. Vetter on his appointment as Vice Chair. He's been kind of informally helping in that capacity. Now we have formalized the process, so with Dr. Malmud as Chair and Dr. Vetter as Vice-Chair, and with the participation of the full Committee Members, we feel that the Committee is in very good hands.

Thirdly, I'd just like to touch on the fact that as Tom mentioned, the Patient Advocacy position is currently vacant. We are very anxious to fill that. It's very important for us to make sure that the patients' concerns and the patients' views heard at this forum, so we will be trying to fill that position as quickly as possible.

Finally, before I get into the reorganization, I wanted to acknowledge that for those of you who have known Tom for a long time, this will be Tom's last meeting. Tom is retiring in early November and so Tom is moving off to bigger and better things. He's bought a home on the West Coast and is going out to live in the Seattle area so he can be near his children and grandchildren and I'm sure that that's something that he's looked forward to for some time. We're going to miss Tom. I've worked with Tom for a long time and I'm going to miss the dedication

that he's given, not only to this Committee, but his expertise in the health physics area.

With that, I'd like to go into the reorganization and kind of show you how things fit together. The Commission had made a decision as a result of a lot of future activities to reorganize the Agency and what they have done is they have divided the Office of Nuclear Reactor Regulation into two offices. That reorganization will take place on January 1st and it will include the Office of Nuclear Reactor Regulation which will focus on existing reactors and it will have a new office devoted to new reactors. The Agency is expecting to receive a number of orders for new reactors over the next several years, based upon the renewed interest in nuclear.

So to position ourselves for doing that, the Agency has decided to reorganization the reactor area. In addition, to support that and all the associated things that go along with the potential resurgence of the nuclear industry and to look at some additional challenges that we have is the Commission decided to reorganize the Office of NMSS and to combine portions of NMSS with the former Office of State and Tribal Programs and create a new office which is titled the Office of Federal and State

Materials Environmental Management Programs which is a very long title that came about through Commission deliberation.

And I have been asked to lead that new office. Our office was stood up on October 1st, the beginning of the fiscal year and we are currently functioning. As a result of my new assignment, I will be transitioning off of my current position with regard to the Committee and I'd like to introduce Janet Schlueter who is going to be replacing me in that capacity. For those of you who don't know Janet, Janet has worked with the Agency for a number of years and she started out in the health physics and medical areas, so she's got a lot of experience in this area. Janet was the former Director of the Office of State and Tribal Programs and she will continue to have oversight for those activities in her current capacity.

George Pangburn will serve as my Deputy. George is currently the Director of the Division for Nuclear Materials in our Region 1 office and George is going to be transitioning down here to headquarters over the next month or so.

The chart that I've got up on the screen also shows the full complement of my office and I will

talk in more detail about the division for which ACMUI's these activities will be included, but I'd like to first touch on the other divisions that we have which are the Division of Intergovernmental Liaison and Rulemaking which will be led by Dennis Rathbin. Dennis has served many years either in the Chairman's Office or as the Director of Congressional Affairs in his former capacity, so he brings a lot of intergovernmental experience. We've put the rulemaking function in that group so as it pertains to these activities, any changes to Part 35 will be promulgated through that division's activities.

Also, the Division of Waste Management Environmental Protection pretty much came intact from NMSS. That division will focus on decommissioning activities, environmental reviews and will also focus on some of the waste issues that are other than high level waste. And in addition, Uranium Recovery has been added to that and I'll briefly mention with the price of uranium skyrocketing, there's a lot of renewed interest in possibly techniques to recover uranium for uses in the nuclear fuel cycle.

Janet -- and I'd like to focus really on Janet's division -- Janet is assisted by Scott Moore. Scott will be Janet's deputy in this organization and

many of you know Scott from his rulemaking activities.

In addition, if you look over to the left side of the chart, you'll see the Medical Safety and Event Safety Branch. That's going to be the group led by Sandy Wastler. Sandy is sitting over here at the side. Many of you know her. And for those of you who are regulars at this meeting, you'll see that the players that you're familiar working with will all be part of Sandy's branch. In addition, Sandy will be replacing Tom as our Designated Federal Official for the future activities of this forum.

The State Agreements and Industrial Safety Branch is currently -- Patricia Rathbin is acting as Branch Chief. We are in the process of selecting a permanent person for that. They're going to focus on the agreement state activity, so there will be a lot of synergy as well as the materials safety activity which has been formerly in the division that I led, IMNS. So there will be a lot of interchange between the State Agreements group and the Medical Safety group as it relates to interaction between agreement state activities in the medical area and the federal activities in the area and there are a lot of issues that I know that come before the Committee, especially in things like the training area that have a synergy

between agreement state activities and federal activities.

On the right is the Source Safety and Security Branch led by Tim Harris. Tim has got responsibility for this and source securities will overly with the medical activities. I mean we've done a lot since 9/11 to try to increase the security of sources and the medical area is no exception. And so we have to make sure that the three branches work in concern under Janet's leadership.

And I guess with that, that's about all I wanted to say on that. I'll quickly flip through the other divisions, as I mentioned. Tom has been serving as Dennis' deputy in these few weeks prior to his retirement. We have an Intergovernmental Liaison Branch which will focus on liaison with other federal entities and with our tribal functions that we have. As many of you know, the Indian tribes in the United States are considered sovereign nations so we have activities with them as another government entity. The rulemaking activities will pretty much stay intact as they have been with Rulemaking Branch A and Rulemaking Branch B. The one thing I'll mention is that Charlotte Abrams, who was the chief of the rulemaking, what was Section A and now Branch A, has

moved over to our Office of International Programs as part of these activities to kind of broaden her horizons. So we're in the process of trying to pick a chief for that group, but the rulemaking branches will be focused on activities that I know that will interface with this group over the next several years.

That's about all I wanted to say, Dr. Malmud. I'll entertain any questions if anyone has any at this time.

CHAIR MALMUD: Thank you, Dr. Miller. If I may, on behalf of the Committee, we would like to express our thanks and our best wishes to Tom for his service with us and for his guidance with us and to both of you simultaneously, to Tom with best of luck in his retirement from government service here and his relocation to Seattle and for you with regard to your additional responsibilities. It's been a very collegial experience working with the two of you. We have enjoyed it and we have been able to accomplish some things that could only be accomplished with the collaboration of the NRC and this Committee. We wish you both the very best in the future.

(Applause.)

DR. MILLER: I'd just like to say on my behalf, I've really enjoyed working with the Committee

and again, I'm not going to be a stranger. The Committee's activities will be within the authorities that I have in my office, so I don't plan on being a stranger. I plan on coming down and observing some of the Committee's activities from time to time on special topics. So I'm sure I'll be seeing all of you and I appreciate the willingness of the Committee to work collegially with Tom and I on many of these activities. I think sometimes we've had good debates. I think debates are healthy. I think they're productive and without diverse views. I don't think that a lot of the problems that we solve can get solved and I very much value the diverse views presented by the various members of the Committee. So I wish you well. I wish the Committee a good future and I hope that we continue to resolve the issues that come before us that come under the Committee's purview.

And with that, I will transition my activities to Janet so that she can fill the chair that I've filled for the last number of years and I wish you all a good meeting. Thank you.

CHAIR MALMUD: Thank you again, and welcome to Janet. And if I may I'll move right agenda with the agenda and introduce Lydia Chang who will

present the subject of NARM legislation update.

MS. CHANG: Today, I just want to give you a quick status report of the NARM rulemaking. We are still working on common resolutions, so we do not have a lot of decisions made at this time. So my status is basically on what we have done since the last meeting in April.

Since last ACMUI meeting in April, we have issued a SECY paper 06-0069 for the proposed rule. We did make the SECY paper publically available as soon as possible. The Committee also has briefed the Commission back on May 15th, along with some stakeholders from the medical community and the OAS and CRCPD.

On June 28th, the Commission did issue a final SRM and with the SRM, the Commission did direct the staff to be flexible in working with the states, especially with OAS and CRCPD regarding the compatibility designation of health and safety for byproduct material definition. The Commission also approved the staff's proposal for implementation strategy.

In addition, the Commission has directed the staff to include some kind of exemption to antique collector facilities and repair shops for time pieces

including radium. So as a result, the Commission direction we revised the proposal to include the repeat activity of 10 time pieces within a year.

On July 28th, we finally published a proposed rule in the Federal Register and I've included a citation here for your convenience. On August 22nd, we also held a public meeting in Las Vegas. We had quite a few medical communities show in support of the proposed rule and we really appreciated that. They also gave us some comments to improve our proposed rule. The proposed rule was published for a 45-day comment period which ended on September 11.

We have received a total of -- actual around -- right now it's 29. We just received another comment letter last week from NEI, so right now we have a total of 39 comment letters received on the rulemaking. Most of the comment letters were received prior to the September 11 due date. There were two or three that were submitted post that and we are considering those comments as well.

Fourteen of those 29 comments were comments submitted by the states and I have listed all of them here. Four comment letters were from federal agencies including EPA, Air Force, Navy and Veterans Affairs. The remaining letters are from citizens. We

had seven letters from citizen groups, eight from professional organizations including the Health Physicists Society, the ASTRA, the ASNC, the CORAR, the SMM, AAPM, ACR, NEI, National Watch and Clock Museums, quite a few people. We also have comments from two universities and four industry groups.

In addition to those 39 comment letters, we also received a letter for extension requests from the Nuclear Information and Resource Service and Sierra Club, requesting us to extend the comment period until the end of October. Since we have been making most of the draft proposed rule available for the public and we have included all the background documentation within our website, NRC decided we would deny the request. So on September 21st, NRC sent a denial letter to the Nuclear Information and Resource Service and Sierra Club, denying their request of an extension.

In addition, this rulemaking has such tight statutory deadlines. We really cannot afford to grant any extensions at this time.

I just want to kind of quickly summarize the type of comments that we have received. Of course, compatibility designation is a huge one from the agreement states and also from the organizations

from agreement states.

The health and safety identification is really an adequacy determination to ensure a central objective of the program elements are adapted. Many of the agreement states are concerned that we might require change of their definition within their statute and also in their regulation. And in their mind, it is really no benefit at all and would be very time consuming and resource intensive, so they recommend to NRC to really clarify the intention of the health and safety identification and how that would be implemented within the impact review. And NRC under the direction of the Commission, we are going to be as flexible as possible in the implementation stage in defining -- I guess in implementing the definition of byproduct material.

As far as for the definition of discrete source, we got quite a few comments. Most of the comments are related to the term physical boundary that we were -- that was included in the definition of discrete source. So we are evaluating that.

We also had one commenter indicated that whether the material is going to be used for radiological purpose or not should be irrelevant in defining the definition of discrete source. So we are

having some working group discussion regarding the definition of discrete source and try to streamline the definition to be as simple as possible and as less ambiguous as possible. Right now, we don't have a final decision yet. It's under discussion.

As far as the regulation, items containing radium, 226, we have a lot of different comments from one extreme to the other. Very broad opinions. A lot of the agreement states indicated that they have not found any health issues with radium items and then we also have some individuals that indicated that most of the collectors do not know what they are dealing with and there are huge health and risk significance that they may not be aware of.

Of course, a lot of people indicated that they doubted that there are any consolidated source information the NRC could use and come up with technical basis in supporting changes to our proposed regulation. We also have quite a few commenters recommended that we should do a very systematic study and evaluation to come up with a regulatory framework.

So as a result that we actually did request our research folks to do a more detailed analysis. We submitted a user need memo back in July to our research people. In turn, they also have

tasked the Oak Ridge Institute of Science and Education to help us in at least gathering the information with radium-containing items and also to do some kind of dose modeling to see what kind of dose, public dose that might have. Right now, that work is still ongoing. We did discuss the priorities on what they can support, so right now they will be focusing on supporting technical basis for any kind of exemptions such as exemptions of one microcurie of radium, time pieces and also repair items, no more than 10 radium time pieces per year, as the Commission has directed us to do.

So based on their technical study, we might need to revisit what we have proposed within those two areas and as far as the more broader materials such as antiquities and other material that contains radium sources, they may not be able to come up a whole lot of technical information to support any changes. So it may look like that we must proceed with the general license because it's a really a happy medium to at least let people continue to use the material, but still have some minimum control of leakage and disposal.

There were also a lot of comment letters related to contaminated sites. Most of them are

related to old radium sites, especially for Navy and Air Force type of facilities. Office of Facilities supported Air Force operations in the past. There were some discussions on whether we are going to come up with de minimus, whether previously clean up sites, whether or not NRC is going to accept that or not. How are we going to be working with EPA. EPA is already involved in cleaning up those sites for base closure. So there are a lot of questions regarding how we're going to be interacting with the other agencies and what type of authority NRC has. Right now, we're still working on responding to those comments.

There are a couple of questions regarding clarification of licensing practices. They indicated whether one license was needed for some activities or multiple licenses would be needed; whether how that's different with agreement states. So it's just a little reminder, a clarification on NRC licensing practice that's needed.

There's quite a few comment letters related to specific values for ALI and DAC for nitrogen-13 and oxygen-15. As you know, being a proposed rule, we did a quick and dirty calculation and was including the proposed rule, even though we

did not propose to change the regulation, but there were overwhelming numbers of the medical community that would like us to include a specific value, even though the value, it's only maybe one to two magnitude larger than the value in the Part 20.

We did ask Research to work with Oak Ridge National Lab to come up with the number, with a specific number that's consistent with Part 20 methodology and also consistent with the common practice in those calculations. So we should have the final report from Oak Ridge National Lab through our research folks, hopefully by this week.

It is highly likely that we will include specific value within the final rule and based on what I heard from our research folks, the number is still very, very consistent to what the comment letter has submitted and also our preliminary calculation within the proposed rule.

There were a few comment letters regarding the grandfathering of Authorized Use or Authorized Nuclear Pharmacists, Radiation Safety Officers, Authorized Medical Physicists. Some of them just want us to clarify what does that include and also wants ut to include some cyclotron operators and engineers within the grandfathering clause, not just in Part 35,

but also in Part 30. There are also some comment letters that indicated that we should resolve the issue related to Radiation Safety Officer and Authorized Medical Physicists within this rulemaking instead of the other effort and I believe Ron has already drafted the Commission paper in that area.

There are one or two comment letters regarding clarification on noncommercial distribution, whether the noncommercial distribution within Part 35 that we have included within the proposed rule that should also be included in Part 30. And also the terminology of consortium, what do we mean by consortium within a medical institution, for noncommercial distribution.

There are also some discussions on decommissioning of accelerators. There was a mixed bag of comments on accelerators. There were some comments related to nonproduction accelerators and what kind of decommissioning requirements are needed. Based on our preliminary discussion within the working group, NRC is not going to be regulating nonproduction accelerators. Therefore, replacing components or replacing the accelerators, it's not under NRC jurisdiction as far as we are concerned.

For protection accelerators, I guess there

are some discussions on -- I guess on the activated material, what needs to be included and what does not need to be included, depending on the energy level. There are quite a few commenters that were concerned with financial assurance for decommissioning, especially for cyclotron since I guess the shielding, the buildings, that could potentially be activated and decommissioning costs based on the comment letter indicated that could be very, very huge. So there were some comments indicated that perhaps NRC should exempt financial assurance for accelerators that's less than 16.5 MEVs since they don't believe the activated material is going to be a huge concern.

There were also some concerns regarding fee categories. A couple comment letters indicated that they don't believe we need to separate fee category for accelerator production, no, production facilities using accelerators. Right now, we are still having discussions with our fee group and also within the working group in that aspect.

The last thing, waiver termination and transition plan. There were quite a few comments indicating that we should maintain the waiver until the medical and scientific communities are ready to implement the rulemaking instead of using the phased

approach to terminate the waiver early.

As I say, we are still working on comment resolutions and we don't have the final response to all those comments. We are still working on it.

Our next step is to continue to address public comments, revising the regulatory requirements. Right now, I think we probably will be revising the definition of discrete source and depending on results from research and their contractor, we may need to revisit some of the regulatory framework for rating sources.

I think besides that, there are just some minor adjustments and clarification that's needed. Once we have the comment resolution, then we'll start drafting the Federal Register for the final rule and then sending the draft proposed, draft final rule to the states for review, also drafting the Commission paper and then initiating the office concurrence process.

Right now, our goal is to submit the Commission paper and the rulemaking package to the EDO by December 22nd and once the EDO signs off, then we will have Commission paper and we will release to the public once that's signed. That's all I have for today.

CHAIR MALMUD: Thank you. Are there any questions for Ms. Chang?

Dr. Schwarz?

MEMBER SCHWARZ: Sally Schwarz. I'm just curious about when you think you'll be sending the draft to the states and at the same time will you be sending it to the ACMUI?

MS. CHANG: Yes. Right now, I'm hoping to be able to send it in early November, early to mid-November.

MEMBER SCHWARZ: Will it also go out to ACMUI at that time?

MS. CHANG: Yes, it will.

MEMBER SCHWARZ: Okay.

CHAIR MALMUD: Any other questions? If not, thank you for the presentation. Thank you.

If we may, we'll move on to the next item on the agenda which is the NARM guidance. The presenter will be Dr. Howe, with Duane White from the NRC. And the speakers will provide the Committee with updates on the NARM guidance.

(Pause.)

MS. WASTLER: Donna-Beth, why don't you go ahead and get started. They have the slides in their book, while they try to fix the technical

difficulties, PowerPoint.

MS. HOWE: Actually, it's a Corel presentation. Most people aren't used to using it. I only have three slides.

(Laughter.)

Basically, on the first slide, for the changes, I'm going to be talking about the changes to Volume 9 which are the -- which is the guidance for submitting an application for medical use license and the first slide shows changes that really aren't part of the NARM rulemaking, but we believe that this was the time to make some of these generic changes. So the generic and general changes quickly are really simplistic things. We're adding some MSI units. We're updating the agreement state map. Probably the most important one is that we're beginning to add information about sensitive information. And so we've modified the section about sensitive information and we've sent people to the website to get the most recent guidance on submitting sensitive information to the NRC.

As part of our increased awareness of providing sensitive information to the public and not having it out to the public, we're also revising the format of our sample licenses so that they contain the

same information, but they don't really look like real licenses so it would be more difficult for someone to use our sample licenses to produce forged licenses. So you'll see some changes to the licenses. A lot of the watermarks, standard wording and other things are removed, but the information that's in the license will remain the same.

Now we also have made some very minor changes to Part 35 since the 2005 T&E rule. The new Volume 9, Revision 2 will remove all references to subpart J. We've also revised the RSO guidance and attestation to incorporate the minor changes that we made back in the fall -- the winter of 2006, with regard to the pathway for authorized users, authorized nuclear pharmacists, authorized medical Physicists to become recognized as Radiation Safety Officers.

Now we'll get to the body of the changes that were made to reflect the new NARM rule. One of the things we really did a surgical type of change to Volume 9, so we just went in and looked at the NARM rule itself and the minimum changes that we could make to bring this guidance up into conformance with the new rule.

So you will see references to the Energy Policy Act, an explanation that the Energy Policy Act

now increase our jurisdiction over accelerator-produced radioactive materials and also Radium 226, discrete sources. And there will be reminders throughout the document that these are now part of byproduct material.

We've -- I've also got a discussion in a number of places about the effects of the multiple waiver determination because this waiver determination will be spread out from when the rule becomes final in 2007 through August of 2009.

Now we also in the rule grandfathered medical Physicists, nuclear pharmacists, physicians, podiatrists, dentists and RSOs who only work with accelerator-produced materials. So you'll see information in the new reg that will explain the grandfathering provisions for these individuals. You'll also see that we have now made it clear the documentation that's needed to meet the grandfathering conditions and in that case, they just have to document that they use this material under the waiver and it is for the same uses that they are going to be asking to be put on a license for.

The Radium 226 clarification. In this case, we don't believe Radium 226 is being used for medical use. There could be somebody out there doing

it. We have not forbidden it in the new regulation. So we've essentially put a disclaimer that we will be adding Radium 226 in the guidance even though we don't think anybody is using it for medical uses and we will address how we believe it fits into our regulatory scheme.

Radium 226 was used in past years for manual brachytherapy. It someone came in and said that they were going to use Radium 226 for manual brachytherapy, we would just apply the 35.400 requirements to them. If someone comes in and says they're going to use unsealed Radium 226, we're thinking right now we're going to put that over in 35.1000 because we don't believe that was a use that was -- we don't believe it was being used for that purpose before and that's something we would certainly want to have additional information on before we authorized it.

I've added a new subsection to talk about discrete sources or Radium 226 other than sealed sources. We also recognize that there may be sources, sealed sources for Radium 226 out there that -- and I'll cover it later in some of the technical issues that are not -- don't have sealed source and device registrations or the sources that they have are so

small that they really can't tell who the manufacturer was or what the model number is. So we've addressed that in some of our technical issues.

For PET radionuclide production clarification, I have a few paragraphs in the introductory part of the new reg that essentially indicates that Volume 9 does not authorize the production of radioactive materials using an accelerator and that if you are intending to have those activities, then you need to go over to Volume 21 which Duane will talk to you about later for guidance on how to submit an application for that process.

I have a description there of what we consider a consortium and I have also a discussion that if you are a medical licensee and you have accelerator -- are going to be producing accelerators, you're going to go to Volume 21 for the production part. If you're going to use the isotopes internally, you don't need an additional license. If you're going to also be involved in the commercial distribution, then you need a commercial distribution license and you need to go over to Volume 13 for that authority. So I've provided references to other NUREGs to where people can find information on the licenses that they

would need, depending on the activities they're getting into.

I've addressed the fact that the facility diagrams, if you're going to have an accelerator and you're going to deliver products directly to 35.100 and .200 rooms, you need to include these transfer tubes or direct transfer delivery lines. And on technical issues, we recognize that there's a higher potential for increased doses to workers in the public because of the increased energy and so we're expecting that licensees may have additional discussion or information about shielding in the area of these higher activity, higher energy level sources.

In technical issue, I indicated that we think that there may be some devices out there that don't have SSDs. If that's the case, we're going to handle those on essentially a case by case issue and have the applicant essentially go to the regions and ask for guidance on what to do in those cases. We're not going to prohibit it, we're just not going to be able to get the same kind of information we normally get.

Jeff?

MEMBER WILLIAMSON: Are you going to expect individual accelerators and synthesis modules

to have SS --

MS. HOWE: No, we are not regulating the accelerators and so we will not be listing model numbers or manufacturers for accelerators. And synthesis kits are under either production or under commercial nuclear pharmacy processes and we are not looking for models or additional information on that. We would be looking for shielding, if you were doing it, because you do need more shielding than you would use for normal preparation of radioactive drugs.

MEMBER WILLIAMSON: So what sorts of devices are you thinking of including in the registry?

MS. HOWE: We're thinking maybe there's some old radium devices out there that are being used for some purpose.

MEMBER WILLIAMSON: You're not thinking of accelerator-produced -- other than the typical sources that we already use in radiation oncology, sealed sources.

MS. HOWE: No, I think for the -- we would expect the palladium sources to have manufacturers and models. There might be some Cobalt-57 sources that a licensee might have that might be fairly old. Most of the half lives are fairly short, so that's not going to be a factor here.

Ed?

MEMBER BAILEY: I think in looking at the NARM sources, there was Idaho Nuclear that was doing it, but I think most of the modern accelerator sources have been brought in under the SS&D system.

I would be surprised to see if there's any medical radium sources that have an SS&D, because 20 or 30 years ago we tried to do that and nobody was really manufacturing them at that time and they were just using the old ones.

Most of the agreement states do not have anybody who still uses that modality of treatment, although some facilities may have them in storage.

MS. HOWE: I think that's the point. The older sources that -- we believe right now most sources are coming through the agreement states if they are NARM material, but for the older sources that you may not have the information available, is to cover them. We didn't want to exclude them. We don't think there are very many there.

Let's see, we wanted to make it clear that in the guidance, if things have SS&Ds, seal source and device registration certificates, there's normally a discussion about leak testing and we wanted to make it clear that if there were any of these old devices out

there, that you could not tie to an SS&D, that the license conditions for leak testing would still apply to them. So to make sure there was not a gap.

The old Volume 9 did not address alpha emitters because they weren't believed to be very many of the old type of byproduct material that would be alpha emitters, but with the advent and the addition of accelerator-produced materials we are going to see more alpha emitters being used for medical use, so we've provided a quality factor. We've discussed the difficulties associated with alpha counting. We've advised people that it's probably better to use unit dosages or volumetric measurements compared with the manufacturers' activity values because we have seen quite a few problems on the betas and we expect it to be even worse for the alphas as far as people measuring things in their standard type of dose calibrators or other instrumentation and coming up with accurate numbers. So we think the manufacturer is probably a better source for that information.

Let's see. We're reminding people that their facility diagrams may change because now they may have additional areas that they used NARM material in that they didn't use byproduct and these are now parts, these are now areas that we regulate.

I think in the Radiation Safety Program changes what you'll see is a constant reminder that within NRC's new authority under the Energy Policy Act, that areas that you may not have included in your NRC license before are now under NRC regulation to remind you that your procedures that you may not have been evaluated on for your NARM, the NARM material now comes under those and will be part of the NRC inspection. So it's more of a reminder to people that we have this additional jurisdiction and those materials that you used to use that were outside of our purview are now part of our purview. And so it's nothing more than really a reminder.

Sally?

MEMBER SCHWARZ: You talked about facility diagrams and lines running to 100 and 200 areas, would need to include those transport systems, but what about lines -- I mean you want them to other -- the PET areas that are not necessarily current 100, 200 areas, right?

MS. HOWE: Right now, there's essentially -- there's an exemption for the broad-scope licensees to even identify changes to 100 and 200 areas and we're saying that in the new rule that if you do change to a 100, 200 area because of moving an

accelerator around in that particular area or moving a transfer tube in that particular area, we want to know about that. And then licensees before could just notify us if they made these changes and we're saying no, you need an amendment now just for the very special case of being associated with movement of the accelerator that's used for producing these materials or the transfer line, because we think that's a different radiation safety hazard than normally seen in 100 and 200.

MEMBER SCHWARZ: So now that's requiring amendment?

MS. HOWE: Yes.

CHAIR MALMUD: Mr. Lieto?

MEMBER LIETO: You're saying that this requirements an amendment even for broad scope licensees?

MS. HOWE: Yes. It's a change to your facility diagram and that's not exempted for broad scopes.

MEMBER LIETO: But you're allowed to make changes to 100 and 200 areas under a broad scope.

MS. HOWE: A broad scope license can still make changes to 100 and 200 areas if it doesn't involve actively moving an accelerator around in those

areas or moving a transfer tube from an accelerator that's directly piping radioactive material to the 100 and 200, so it's a very, very limited change in the rule and it's only associated with those cases where you're sending a pipe for oxygen directly from the accelerator up to the 200 room because we think those are radiation safety changes we'd like to see.

Yes, Dick?

VICE-CHAIR VETTER: Is that clearly spelled out in this rulemaking? Because I don't think most broad scope licensees would recognize that.

MS. HOWE: I believe it is. It's under the broad scope exemptions. It says that that's not included in the exemption and it's also in the notification process.

Ed?

MEMBER BAILEY: That reminded me of a question. Does that mean that you are de facto accepting existing accelerator shielding and transfer lines?

MS. HOWE: Under the waiver, licensees or nonlicensees are allowed to continue to do what they were doing under the waiver, once the rule becomes effective. They can continue those operations until they have received final NRC licensing action on an

amendment or a new license. We don't believe everybody is going to need an amendment. We've written licenses in very general terms for like 100 and 200 uses. If you're just using -- if you're also using PET materials, the authorization currently stands as any 100, 200 material, that's covered by any -- any radioactive material covered by Part 35.100, .200, well, PET would fall under those categories.

But there are some other cases that you would need to provide information. So if your facility diagram changes, you need to provide that. That could be an amendment. There would be new areas of use.

MEMBER BAILEY: We repeatedly used PET, but there could be other accelerator-produced materials. And those are lumped in when we're using the phraseology PET?

MS. HOWE: Those are lumped in. If we have written the authorization in a very general term, then they are included. For the 400 users we do require that you list the manufacturers and model numbers. And so for the palladium sources, that wouldn't require an amendment to list those.

CHAIR MALMUD: Mr. Lieto?

MEMBER LIETO: Yes, just a caveat here in

terms of licensing actions. In the agreement states, you're probably correct, there's not going to be a lot of changes, but there are in NRC states, a lot of mobile, PET-only registrants I'll call them because they're not licensed right now that exist. And they go to multiple sites and I think you should be a little careful here because I think you're going to see a fair number at least in the NRC regulated states licensing actions regarding these PET operations. And some of them are just on the mobile trailers themselves, but we're seeing at least in the State of Michigan an increasing number of areas being constructed where patients are going to be injected and in what we'll call the prep areas before they go to imaging on the trailer.

So there's going to be these use areas, if you will, that will require updating of specific licenses in NRC states, so I would be kind of -- just a caveat that there may be more actions going on at your regional level than you may realize.

MR. JAMES: And I think one of the things that we built into the regulation to recognize that we don't know exactly how many licensing actions we're going to have, is that we tied the ability to continue to use materials in the manner that you're using them

under the waiver to NRC's final licensing action, provided you got your amendment requests or your new license within the time frame, so that if NRC is inundated with a lot of requests for licensing applications that it takes its time to get through, people can continue to do what they're doing until we take our final licensing action. And that gives us an opportunity to go back and negotiate and talk to licensees and new applicants about what they're doing. So we've built that in case we have a tremendous flood because we didn't want anybody left out.

CHAIR MALMUD: Mr. Lieto?

MEMBER LIETO: Just a follow-up question. I would also encourage you to in your discussions with the regions because some of them have time metrics for licensing actions, that you give them more latitude in that metric or possibly suspending it during this transition time, just simply to be sure that we don't have some things fall through the cracks.

MS. HOWE: And we do have an additional concern that in the past we could essentially withdraw a request, therefore clear the boards, and in this case people are still using materials, so we're not going to have that flexibility.

CHAIR MALMUD: Dr. Schwarz?

MEMBER SCHWARZ: And in that same line of thought in terms of time lines, with older facilities, specifically university facilities that don't move quickly, thinking in terms of the long-range time line for that group of people because certainly it's very difficult for universities to come into compliance quickly and the longer the time frame allowed is better and that way if one of your largest facilities is the older facilities, it seems like looking at that full length of time for each of these licenses to come into compliance might be a good thing, so that you're looking at the worst case as the end of it, you know?

MS. HOWE: The one I will stress is that when the waiver is terminated for each licensee, that licensee is required by regulation to meet all the requirements in the regulation. What they are being given relief from is the fact that they may not have a license that authorizes the use of the material and so we've given them additional time to apply for an amendment or apply for a license, but we expect them to apply Part 20, the reporting requirements, the record-keeping requirements, as soon as the rule is effective for that particular licensee and there will be different time periods that the rule will come into effect for the federal and tribal groups that will

come into effect 60 days after the NARM rule is published in final form. For other licensees, it may be later.

If you don't have any other questions, Orhan?

MEMBER SULEIMAN: I just want clarification. You're going to license the facility for the positron nuclides that will be produced, but your stance on the actual accelerator or cyclotron is what?

MS. HOWE: We will issue a license for the production of radioactive materials using an accelerator. We will not license the accelerator itself. We will license activities associated with the radioactive material produced by the accelerator. In other words, if you have maintenance on the accelerator and you have to deal with a contaminated part, we will license that. But we will not license the accelerator's operation, turning the buttons on, adjusting the knobs. That's not our purview. Our purview starts at the production of the radioactive material.

MEMBER SULEIMAN: I know you don't want to hear this and I think to ignore -- I'm just speaking from a common sense perspective, to ignore the source

itself and somehow not keep track of it when source itself may be more hazardous from a radiation point of view than the products that they're going to be producing, that you now do have legal jurisdiction over is -- may be strictly legal, but I think from an operational radiation safety point of view, causes me some concern.

I would reconsider that or rethink that or --

MS. HOWE: We are restricted by the authority that was given to us by Congress in the Energy Policy Act and we were not given authority over the accelerator. We were only given the authority over the radioactive materials. So we don't believe we have an option, nor do we want to go there.

CHAIR MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: So a university hospital or medical school would be licensed under Part 30?

MS. HOWE: If the university or the hospital were producing radioactive materials, it would be licensed under Part 30.

MEMBER WILLIAMSON: Only if they intended to use it for what purpose, any purpose, like if they were doing physics experiments, would it be licensed?

MS. HOWE: If they have an accelerator that's being used for physics experiments in which the beam is being used to do things, but not produce radioactive materials for commercial, medical or research purposes, then that accelerator will -- that accelerator and the radioactive materials produced by that accelerator, the incidental radioactive materials will not be licensed by NRC.

So your linear accelerators in which the therapy is being delivered by the beam and not by activation products inside the person will not be regulated by NRC. If there were a neutron accelerator that produced activation products and the activation products we used were the therapy implement, we would get into that.

MEMBER WILLIAMSON: And so for a broad-scope licensee there would be the latitude to add any FDA or radioactive drug committee approved radiopharmaceutical or would everything have to be done by individual license amendment? Would you prescribe limits on --

MS. HOWE: I think Duane will get into this, but we've kind of drawn a boundary around the radioactive material production and that will be under a Part 30 license and then as that material moves into

a different use, it may come under the Part 35 use as taking that radionuclide and converting it into a radiopharmaceutical. That's already authorized under Part 35. It may go into a commercial nuclear pharmacy whose purpose is to distribute, commercially distribute radiopharmaceuticals. And so it would go from this license into the 3272 license and the same thing with the manufacturers.

MEMBER WILLIAMSON: So I guess I'm asking because I haven't had to ever deal with Part 30 before, in Part 35 there are well-defined ways of specifying the limits as to what radioactive source products and radiopharmaceuticals could be used in the medical use environment. How is the range and levels of activity that a university or hospital may produce defined?

MS. HOWE: It's not.

MEMBER WILLIAMSON: It's not.

MS. HOWE: The regulatory --

MEMBER WILLIAMSON: It's anything they want.

MS. HOWE: The regulatory requirements for a Part 30 license are in 30.32 and they are very broad statements. You can use -- you can have licensed material for things that are in the regulations. You

have to have people with training and experience to use it in a safe manner to protect the public health and safety. Very broad-brushed statements. So there aren't --

MS. HOWE: So a license, a Part 30 license doesn't resemble Part 35 in that it has strictly specified possession limits?

MS. HOWE: Our licenses do have specified possession limits, but those limits are essentially given to us by the licensee, what is it they expect to do? One reason they do put limits on them is for financial assurance and decommissioning purposes and we've now in the security of materials, we've sent out a number of orders because people had very general global statements and they come back and said yeah, I have the general global statement, but I don't really hold radionuclides up to those levels at all and so they're backing away from using the general statement.

Ed?

MEMBER BAILEY: I think how the states have handled that in the past is that they'll go ahead and say any radioactive material in any amount as activation products in the accelerator are shielding or structures, rather than trying to necessarily put you may have up to five microcuries of this or

whatever.

MS. HOWE: Yes, for the activation products I think we will have -- Duane can talk more clearly to that because it will be in the guidance that he's developing, but we'll do it in very general brush strokes on small activities.

MEMBER WILLIAMSON: I guess, can I express my concern is that I think for a busy and large academic medical center, a noncommercial manufacturer of these things. You need something analogous to a broad-scope Part 30 license that allows the Radiation Safety Committee to have juridical authority over developing new radionuclides -- producing new radionuclides if that's what they need to do instead of constructing a bureaucracy that requires submission of many license amendments that do not contribute materially to patient safety.

CHAIR MALMUD: Mr. Bailey?

MEMBER BAILEY: I think that, in essence, what you're saying is exactly what happens. In the states, we tend to authorize radioactive material with atomic numbers 3 to 83 and then in some cases 84 to 106 or 107 or whatever, particularly for those cases where you have an accelerator because you don't know -- they're not going to be producing this one thing

today and decide tomorrow they're going to produce this and you get them in a Catch-22 because accidentally also, oh yes, we produce this.

So I think that's the way it's been handled, whether or not it will be called a broad license is another situation and it's dependent upon more conditions than just what materials you're authorized for.

MS. HOWE: Orhan?

CHAIR MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I'm going to ask you again. We've worked -- I've worked with lawyers at FDA as well and sometimes some say how do you want us to interpret the law for you? Some of us say this is how it's going to be. I would really urge you to maybe go back and ask your lawyers. I think you've got a little bit of regulation that's going to be worse than no regulation or too much regulation. But -- it's neither going to protect the public safety, you know, if you ignore the source of the radiation from the cyclotron and worry about the materials. I'm not saying go ahead and regulate the machine, you know, prescriptively in a very ridiculous manner, but somehow there's got to a more logical way to just sort of say we need to know how many cyclotrons or

accelerator machines you have that are going to produce, have the potential to produce. So yeah, you don't use it one day to produce nuclides and another day for some other function. You may have some -- you forget what the status is right now, but anticipate what's going to happen in a couple of years. So reconsider that.

MS. HOWE: We do have our lawyers involved in everything we do from the ground floor up, so they're actively involved.

CHAIR MALMUD: Dr. Vetter?

VICE-CHAIR VETTER: Just in response to your concern, I think that is handled by the states. I mean states -- you can't just build an accelerator and start using it. You have to register with the state. You have to file the shielding plan with the state. So -- and then you have to demonstrate that your personnel are protected. So I think your concern is currently taken care of by the state.

MS. HOWE: Not all states regulate accelerators or radioactive material.

MEMBER SULEIMAN: In a nonagreement state.

MS. HOWE: We have a state that doesn't regulate anything.

(Laughter.)

MEMBER BAILEY: But do they have an accelerator?

MS. HOWE: They may not.

MEMBER SULEIMAN: Actually, I had meant to precede my statement by in a nonagreement state that does -- because all states are not equal. So you leave that option, that possibility open.

CHAIR MALMUD: Mr. Lieto?

MEMBER LIETO: Just a follow-up question which wasn't clear on this guidance document. This is the guidance document that you and Mr. White are going to be discussing, so it tends to be what's perceived by the regulated community as the devil in the details.

Is the guidance document intended to be out prior? Well, let me ask this. Is there going to be a draft form of this that's going to be discussed before the rule becomes finalized? Are you just coming out with the guidance document in its form and that's it?

MS. HOWE: The intent is to publish the guidance documents and we're only revising three of them at this point and that is the medical use Volume 9, well, we're not revising three, we're revising two. And the commercial nuclear pharmacy which is Volume 13

and we're developing an entirely new document for the production of radioactive materials with accelerator and that will be Volume 21 which Duane will speak to.

Our plan is to put these documents out as draft for public comment when the rule goes out, but we have to bring the documents up into compliance with any changes we make from the proposed rule to the rules, so we can't put them out before that, but we intend to put them out for public comment.

And then the idea is that in that 60-day period in which you go from publishing the rule to its effective date, that's the comment period and then we'll try to get the guides out as final after that.

MEMBER LIETO: Dr. Schwarz?

MEMBER SCHWARZ: I was wondering since you will make the regulation available to the states and to the ACMUI at that same time will you make the guidance available? Can you?

MS. HOWE: I think I will let Torrie Taylor, who is the project manager for the guidance speak to that?

MS. TAYLOR: Yes, for the record, I'm Torrie Taylor in the new FSME, rulemaking A, we'll go to the lowest level, I can remember that. The current schedule is the document will be published for public

comment as Donna-Beth said when the rule is released by the Commission to be available to the public. We hadn't, with the schedule, we didn't really factor in a time for it to go out earlier than that because of what she's indicated. There may be some changes with the final rule that we have to incorporate into the final draft documents before we can put them for public comment.

We have state representatives involved with the guidance that are bringing in the state perspective on that, but --

CHAIR MALMUD: Thank you. Another comment?

MEMBER SCHWARZ: I just wondered would that be available when you're sending out the draft rule?

MS. TAYLOR: To the states in November?

MEMBER SCHWARZ: The states. Can that be available to go out?

MS. TAYLOR: At this point, we haven't planned it because I don't know that they'll actually even be finalized in a good draft yet at that point. We can talk off-line with our management to see if there's something we can work out into that, but it's not factored into the schedule at this point.

MEMBER SCHWARZ: It would be helpful if it could be.

CHAIR MALMUD: Thank you, if we may, Dr. Howe, may we move on to Mr. White's presentation?

Thank you, Dr. Howe.

Mr. White?

MR. WHITE: This is good morning, almost good afternoon. Dr. Howe mentioned a lot of the generic changes and items that will be changed in Volume 13 and Volume 21. From the major changes for Volume 13, basically the biggest thing I guess would be adding PET radiopharmacies so that is a new item for the NRC. So we're still staying with the initial structure as far as the radiation safety, but we are bringing more attention to now we have higher emitting radionuclides, higher energy radionuclides, so we expect more shielding and instrumentation changes. And so we will cover that as a recommendation in the guidance.

As Dr. Howe mentioned, we have decided, the writing team decided to have a separate production license and that everything that the accelerator produces is going to only -- everything -- once the accelerator is turned on and material goes to the target, that will be the production license and then

from there, once it is transferred to let's say in PET, in essence, to a chemical synthesis unit or to the other side that now will become the radiopharmacy, so we decided that instead of trying to have a radiopharmacy or research for broad scope that you would have this -- have a production license that would stand alone and would only license the activities of actually, basically the activation products and just the primary material that is produced.

And that is what Volume 21 talks about. Basically, Volume 21 just gets into, for example, how we have the individuals that perform maintenance and repair on the accelerator, so we will put a little bit more emphasis on safety aspects of that and general training. Again, in 10 CFR Part 30, we do not have specific training requirements, so it's not like 35 where you say you have to 200 hours of training. But it is going to be based on your general experience and in training that will be looked at by the license reviewers.

CHAIR MALMUD: Dr. Vetter?

VICE-CHAIR VETTER: May I interrupt and please ask a question about that?

The bullet says, let's see, wrong slide up

there now, but the bullet on that item that you just discussed says "ensure applicants realize that individuals that perform maintenance and repair on the accelerator should be licensed as authorized users." So two questions. One is individual don't get licensed, they're listed on a license. And second, authorized users refer to -- in our case, it's physicians who are using the material. So if you could clarify that. I'm not sure what you mean there.

MR. WHITE: Generally, when we look at authorized user we're not looking at the -- to the level of a physician, let's say. Generally, a small category, authorized user where this is a person who is -- has all the experiences required to handle material and in this case, it's a specialized case in that maintenance of the cyclotron say is -- they're pretty much the professionals on how to do that. In this case, they would be considered authorized users because you couldn't say a nuclear pharmacist necessarily had more.

VICE-CHAIR VETTER: Well, it's one thing in the regulations to describe the kind of training that an individual might need to perform a certain task, but it's a totally different thing to require that people meet some test and then we have to send

the name in or the licensee has to send a name in to the regulator, the regulator has to approve that they be listed on the license. And I would submit that an expectation that these people have certain training requirements is quite reasonable. But to require them the licensee to go through a process, I'm not sure what that would add to safety, a process to add them to the license, I'm not sure what that would add to the safety here.

MR. WHITE: Well, when looking at, let's say, for example, PET operations as Dr. Williamson mentioned, the accelerator, in general, just going in and now you're dealing with higher activity, so it's not a standard -- it's not a standard radiation safety practice. So the training could vary. So you should have some experience just out of a one-year of experience or what have you. So a nuclear pharmacist couldn't do the same job as a -- if you understand. So because of the potential for problems, as far as safety issues, it's recommended that the individual who performs maintenance also is listed so that we can make sure, ensure that individual has the proper amount of experience in working around accelerator, working with those higher energy-emitting radionuclides. So that was the thinking there, and

states do that currently and that was another --

MS. HOWE: If I could clarify, this is Dr. Howe, this will be a Part 30 license and we have authorized users for all licenses. You, as an ACMUI are used to seeing an authorized user being a physician. But in other licenses we have authorized users that could be gauge users. They could be radiographers. They could be well loggers. And so this is just the generic term for an authorized user and that is the person that handles the radioactive material, essentially by themselves and we recognize that this individual does meet radiation safety training experience and we have not put specific training guidance on them, so they need to meet the requirements for Part 30. I hope that clarifies a little bit.

CHAIR MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: This seems irrational. You say you don't license accelerators, yet you're going to declare accelerator repairmen and engineers to be authorized users. It makes no sense. Why can't they simply be covered under Part 20 which would require anyone who works with controlled radioactive byproduct material, I guess as you've more broadly defined it, to be under the appropriate jurisdiction

of the Radiation Safety Officer and to have the radiation safety training needed to do their job. It doesn't seem to me to make sense to license or authorize them for some specific activity.

MR. WHITE: And the word license might be taken in the wrong -- I mean, we're not expecting them to take a certified test and say okay, you know, like a technician would do, let's say. We're just saying that these individuals are the individuals who basically supervise this type of work.

MEMBER WILLIAMSON: But you know, you wouldn't -- you don't declare, for example, a radium or source curator to be an authorized personage. I still don't understand why, if you're not regulating the linear accelerator or cyclotron itself, why you have to make a special category of authorized personnel to do maintenance of the accelerator. That seems not rational at all.

MR. WHITE: And what we're looking at, we're not looking at the maintenance of the accelerator, but we're looking at the fact that they're handling radioactive material during their maintenance and repair of the accelerator.

CHAIR MALMUD: Dr. Schwarz was next.

MEMBER SCHWARZ: One problem I want to

point out to you in terms of this process, you're talking about authorized users. You're talking about a specific license. We have cyclotrons and we have people from the companies come in to service our machines. We, as the licensee, are not managing the people that come in to repair our cyclotrons. I understand the training criteria will need to be met, but it won't be necessarily defined by the licensee because we don't have any say over who comes in to service our machines. These people are employees of the company who we buy the machines from and so -- I mean I think that you need to think about this presentation of training requirements differently than the word "authorized user" which is associated with license which really won't be under our control.

I understand that we need -- I mean the individuals may need to adhere to training requirements, but you're kind of looking at this -- we do also have people internally who work on our machines as well, so that's a different story and those are possibly, in our case, cyclotron operator who is trained and so there can be criteria that are met. But again, as Dr. Vetter pointed out, authorized user probably needs to be, the word needs to be changed. Again, training criteria for these

individuals, but again, this will -- it needs to be kind of presented differently, I think.

CHAIR MALMUD: Mr. Bailey?

MEMBER BAILEY: Duane, I'm thinking that there's a little bit of confusion about what goes on with regard to an accelerator in a production facility. As has been suggested, yes, there will be people, there will be training set up. They have to meet certain requirements and I would differ a little bit with Sally on how we would handle that in that those people coming in typically are working under the facilities license as far as safety and radiation exposure and so forth are concerned.

I would compare what happens typically at an accelerator with what happens at a large irradiator. There are lots of people who come in and do various jobs at a large irradiator, for instance. Not all of those people are named on the license, but they all have to meet certain training requirements and they're under the radiation safety program of that particular facility when they come into the facility to work.

So to me, when you say authorized user, that equates to a named individual being on there as opposed to a category of people. Just as we don't

name all of the janitorial staff that go in some place, likewise, we would not name all of the electricians or whatever that might come in to work on the accelerator.

MEMBER SCHWARZ: But you do actually have training requirements that those people would have to meet in order to come in?

MEMBER BAILEY: Typically, in my experience, the way they're set up is the company or university, whatever, provides -- here is the training program we're going to have for these people. And often, it's a very small program.

If you have in-house people, yes, they would be people that would be designated by the Radiation Safety Committee to work in that area or to enter restricted areas.

Generalized training for people who work in restricted areas.

CHAIR MALMUD: I think next was Dr. Eggli.

DR. EGGLI: I wanted to sort of emphasize the point that Sally was making which was largely my point, but if I have a cyclotron that's manufactured in Tennessee and we have a problem with the cyclotron and the company in Tennessee has to send in the field service engineer, I have no way to document the

training of that individual who comes in from the vendor who happens to have a headquarters in Tennessee. It may be a senior engineer, perfectly well trained, but again, I don't think you can hold the licensee responsible for vendor training of their people in the safety practices. And I think particularly with cyclotrons, these aren't going to be local field service engineers. It's not going to be the guy that lives 20 miles down the road who comes into my site every week to repair my gamma cameras. He's probably going to fly in from somewhere way out of state and come in to look at the cyclotron. I'm going to have no way of verifying that guy's credentials.

I think that in this case if the credentials of the individual for safety training have to be verified, it's going to have to be the vendor of the system that verifies those credentials and we may have to ask that vendor to provide us a certificate that their people are trained that we can put in our files, but I don't think we can be responsible for their training.

CHAIR MALMUD: If I may, under the slide Volume 21, the second bullet, would this wording be acceptable and practical, "ensure applicants realize

that individuals that perform maintenance and repair on the accelerator should have received radiation safety training certified by their employer." Employer may be the manufacturer of the equipment. The employer may be the institution in which the accelerator is located, but someone has to assume responsibility that that individual has been certified and trained.

Is that wording acceptable? And does it meet the requirements clinically of those of you who already have accelerators on board.

I'll repeat it: "ensure applicants realize that individuals that perform maintenance and repair on the accelerator should have received radiation safety training certified by their employer.".

Dr. Howe?

MS. HOWE: Dr. Malmud, I'd like to clarify that NRC also has another category of licenses which are service providers and those service providers are the people that go in and do radiation type of things on equipment and we license them and we look at their training and experience. So we already have a mechanism for covering people that are dealing with the radiation safety parts in the radioactive

materials that are coming in as a repair maintenance, but we aren't really involved in maintaining the accelerator.

What Duane is trying to get to is people that change out the targets or have to go in and do things where they're in a radioactive environment and making sure that those people are trained to the materials that they're using and handling them and maintaining safe radiation safety. And a lot of times those individuals work alone, work after hours and are not under anyone else's supervision. So the idea was to ensure that they can work alone.

CHAIR MALMUD: May I ask a question, Dr. Howe, and that is let's say that the person is sent by the manufacturer. That would have been the manufacturer's responsibility to make certain that that person is competent to do the task before that person.

MS. HOWE: Absolutely.

CHAIR MALMUD: If the person is based at the home base of the university that's operating the accelerator, then it's the university's responsibility to have assured that training.

So in either case it would be the employer with respect both to the radiation safety for those

who work around the instrument as well as for the individual himself or herself.

Now there already are regs -- the NRC already has regs for such employees.

MS. HOWE: That's correct.

CHAIR MALMUD: So is this sentence not consistent with what the NRC already has?

MS. HOWE: I wasn't really addressing the sentence. I just wanted the Committee to be aware that we have another type of license.

CHAIR MALMUD: Right.

MS. HOWE: That is out there.

CHAIR MALMUD: Mr. Lieto?

MR. LIETO: I'd like to answer your question in that your statement is very consistent with other license types. Specifically, the examples of blood irradiators. They allow -- it says that the -- that any servicing addressing the radiation safety or safety operation has to be done by the vendor. And there's no requirement that has -- that we have to license or have any type of amendment to a license that lists the service people working on these blood irradiators.

Also, your statement, Dr. Malmud and what Sally has presented, is consistent with what is going

on right now with nuclear medicine operations. Why is there a requirement for these people dealing with radioactive sources from an accelerator different than a technologist milking a one to two curie generator? It's just not consistent. And we have, I think, years, decades of experience with handling these large amounts with -- by technologists and individuals not named on the license, okay, that use much larger or as large sources as are going to be involved with these accelerators, but are not required to be named on the license. And so you're really setting up a whole licensing mechanism that really is not necessary. Okay.

The onus is on the licensee regarding the safety and so if that -- are individuals that are being brought in from the outside, the statement that Dr. Malmud made would answer that issue of documenting. They have acceptable training regarding the radiation safety operation of working around this machine.

I would think universities and broad-scope licensees would be very hard pressed to come up with a mechanism to looking at the credentials of every individual that comes in and works on their accelerators?

MS. HOWE: I agree.

CHAIR MALMUD: Dr. Nag.

DR. NAG: I think the same thing for HDR, I mean we have the HDR on our license. This is a similar issue.

MS. HOWE: Dr. Nag, the HDR repair person that comes in is licensed by the manufacturer and has a licensee that are in an agreement state or NRC state to handle radioactive materials at temporary job sites. And so that's the mechanism for licensing those people that are in the mobile service sector.

CHAIR MALMUD: If I may, once again, is the wording that I suggested acceptable and does it satisfy the user's needs, the public needs, the patient needs?

MS. SCHLUETER: I think that we would like to take your language under advisement as we regroup internally because I'm not sure that we're clear on the intent of that bullet. I'm concerned about the words "licensed" and "AU" before all this discussion began. I'm even more so now. And so I'm reluctant to place the staff in the position of agreeing to your suggestion until we have had time to go back.

CHAIR MALMUD: All right. Would you like me to repeat the wording I suggested or is it

acceptable -- or is it in the minutes already?

It's in the transcript.

MS. SCHLUETER: We have it. I would like to -- I will go back to the staff in response to your earlier comments, Sally, to see what opportunity we can build into our guidance development process to allow the ACMUI an opportunity to review those volumes before they go public.

MEMBER SCHWARZ: That would be tremendous.

CHAIR MALMUD: Dr. Williamson?

DR. WILLIAMSON: Well, I think that actually Dr. Suleiman's point has just reared its head here. I think there's a difference between the accelerator repair man and the HDR repair man because the nuclotron and barium are licensed under Part 33. I'm sure to distribute these radioactive sources and these devices. So they have a license on which their repair men can appear as authorized personages to do whatever they have to do. But since you don't regulate the linear accelerator, I see your dilemma that you're trying to impose upon the end user, the hospital or university, the responsibility for licensing these individuals that they have -- or authorizing these individuals they have no control of. This seems to be part of the problem.

I would also say that it seems like maintenance is the wrong word. I think perhaps it might be more proper to call the individual who removes the targets an operator.

MR. WHITE: Only my concern with operator we have is we don't want to confuse it with the operation of the accelerator. That's the reason we didn't use the word operator.

MEMBER SCHWARZ: Excuse me, but the persons who do operate those accelerators do change the targets and work on the machines.

DR. WILLIAMSON: And this isn't maintenance, this is a routine usage of the device. That's what it's intended to do.

MR. WHITE: And I understand that. Because we do not regulate the operation of the accelerator, those people would be still -- be looked at as far their maintenance roles, but the word operation, we were just trying to avoid the actual use of the word, basically. But those people would still be included, as I do know that those operators might at some time do some maintenance.

MEMBER SCHWARZ: Often.

MR. WHITE: Right, and it's usually basic maintenance. Then usually you have a field service

engineer who would do more advance maintenance.

CHAIR MALMUD: Dr. Suleiman?

DR. SULEIMAN: Again, I'm just trying to clarify in my mind. So if an operator gets accidentally exposed to the radiation coming off of the source and as a reportable medical event, would that be reported to the NRC or not?

MR. WHITE: Yes, one thing to still note is that the NRC still does look at dose. So we're still looking at nonlicensed activities as well as licensed activities. So the radiation safety --

DR. SULEIMAN: Is Part 20.

MR. WHITE: Right.

DR. SULEIMAN: Kicks in.

MR. WHITE: Right. So if a person gets overdosed, whether it's from the accelerator operation or from doing maintenance, that still will be seen and that still needs to be reported and it still needs to have the proper radiation safety in place to ensure that it doesn't happen.

DR. SULEIMAN: Again, I'm strongly suggesting that there's going to be unanticipated consequences down the line that I can't necessarily predict, but I see that this thing is illogical and in terms of assuring the safety of the operators of the

people at the facility, you take a step and carefully look at this before you promulgate the reg. Then it's going to be more difficult, obviously to change things. But your charge is to protect the health and safety and I think you should consider that and figure out how to work that into some sort of meaningful, useful regulation.

CHAIR MALMUD: Mr. Bailey, did you have a comment?

MEMBER BAILEY: Yes. I have to respond to that. It's an improvement over when they used to go in and not look at NARM at all, when it was used in the same office. So it's a step forward in that regard.

But what I raised my hand for initially was that we've been talking basically about production facilities. But if you look at research facilities where you have multiple people that may use the machine and they may be coming in for a week or two weeks or whatever, I think this really poses a problem for research accelerators an din particular at universities and so forth.

CHAIR MALMUD: May I, Mr. Bailey? When you say it presents a problem, what's the nature of the problem that it presents?

MEMBER BAILEY: Well, if your wording is not accepted --

CHAIR MALMUD: Okay.

MEMBER BAILEY: You do have a lot of people coming as researchers who actually go into the target areas. They exchange samples. They take specimens in. They take the material out. If they're producing material. They're actively involved in working with the accelerator. They may not physically be operating the accelerator, but if they're doing experiments, they definitely in the target area where generally the higher doses are going to be -- or the larger amount of radioactive materials can be accumulated.

CHAIR MALMUD: And your point is that they should have received some training?

MEMBER BAILEY: They should have received some training, but not be named as authorized users.

CHAIR MALMUD: May I ask how those individuals currently require, Dr. Howe or Mr. White, are those individuals currently required to have training?

A researcher who goes to a cyclotron -- to an accelerator and is doing research there for a period of several weeks and handling the isotopes that

are produced?

MS. HOWE: Let me handle that in a different manner, because at this particular point, the cyclotrons are under the waiver and the material being produced by cyclotrons are under the waiver.

Let's take a look at a university that brings someone into the laboratory where currently regulated NRC materials are being used. The structure that we have now is that that person comes in and works under an authorized user. And only if the facility wants to make them an authorized user, do they go through the process of being -- their training and experience being reviewed, so that they can operate independently. And I think that would be the same thing that we would be doing in a production facility. In other words, we would have an authorized user. And in this case, I'm using a very broad term of the word authorized user. I'm not talking about a physician, a pharmacist or those. I'm talking about a Part 30 that we recognize as the individual that can handle the radioactive material, can use it and can be responsible for the other people that work under his supervision.

So we would handle it the same way. And if you were a broad-scope licensee, then you would be

given a little bit more flexibility.

CHAIR MALMUD: Thank you for clarifying that.

Dr. Schwarz, you had a comment?

MEMBER SCHWARZ: Right, at George Washington University Hospital (Saint Louis [SIC]) we do have the situation that you're just describing. We have many people who come in who are licensed to work, who are not authorized on our license, students, post-docs, visiting scientists, who essentially do work under authorized individuals who then supervise. They again must comply with the radiation safety guidelines of our institution and they are receiving radiation exposure under our license. But they are under the direction of an authorized individual, not a physician. This would be an authorized individual. But again, this authorized user has implications for medical licenses. So the wording is just not a good choice.

MS. HOWE: And that was one of the things we were trying to make clear. This is a Part 30 license. This is not a Part 35 license at all.

It may be in a facility that also has a 35 license, but the production itself is a Part 30 activity and not a 35 activity.

Its use and the materials that are coming out of it, then will flow into a different license for its use in patients or human research subjects.

CHAIR MALMUD: If I may, for the sake of time, Ms. Schlueter has indicated that this proposed rewording will be reviewed and will come back to us. Am I correct? It will be reviewed and come back to us?

MEMBER NAG: Yes. I'd like to make a motion that --

CHAIR MALMUD: Please do.

MEMBER NAG: -- in agreeing to what you said. The motion would be that the NRC official will reword this and ensure everything realized that the individual that handles the accelerator should have received training by their employer and the NRC official will revisit this and bring it back to ACMUI.

CHAIR MALMUD: Dr. Nag has made a motion. Is there a second to the motion?

Dr. Schwarz seconds the motion. Any further discussion of Dr. Nag's motion?

All in favor? Any opposed? Any abstentions? Carries unanimously and it's now in the hands of NRC staff.

Will we be notified of your review by

mail, by email or will it wait until the next meeting?

MS. WASTLER: This is Sandra Wastler. We'll have to get back to you on that. I think we have to look at, have a discussion among the staff and look at what our options are and then we will let you know at least how we're going to get back to you and when by email, but we will let you know. Hopefully, we won't let it go to the next meeting.

CHAIR MALMUD: Thank you.

MS. SCHLUETER: I don't think it can because of the --

MS. WASTLER: No, it can't because of the time line.

MS. SCHLUETER: We're obligated to issue the guidance.

CHAIR MALMUD: Thank you. Mr. White, I think we interrupted your presentation.

MR. WHITE: And I kind of jumped a little bit because Dr. Howe mentioned a lot of -- but that was basically my presentation as far as the general comments. Again, looking at -- one thing I did not mention for facility layouts, we will ask for Volume 21, production volume. We would be asking for diagrams of delivery lines and seeing how -- or what mode of transportation from accelerator to the other

processes, manufacturing, how would you get the material from the accelerator to the -- I guess you'd say the manufacturing area or distribution area.

So we will be including that and as a general, we have asked that the applicant provide information on the accelerator, but this is not a tie-down condition as we don't regulate it. But just to -- so that the reviewer understands all that would be produced, as far as give the idea of activation products, gives you an idea of making sure the proper shielding and everything is in place, so we do ask that that is provided, but it's not going to be a tie-down condition in the license.

CHAIR MALMUD: Thank you. Dr. Schwarz.

MEMBER SCHWARZ: In regard to the first bullet where you say include accelerator-produced activation products, to list -- the list of radioactive materials, will you be requiring something such as Ed suggested that a range of potentials or what are you looking for?

MR. WHITE: Right now, what we plan, what the thought is is that we would have a 1 through 83 request. You can request it. We prefer that you provide a general list, but yes, there is -- you can request a 1 through 83 permission and you just have to

give the maximum activity produced by any one of those isotopes and then you have to give a maximum total quantity activity as far as what you think would be.

And then any isotopes that go above that, that threshold, let's say, would need to be listed out separately. But as we do that, currently, the way NRC words, once that is put in place there's automatically assumes right now that some type of financial assurance will be needed as you do that. If you do the 1 through 83.

MEMBER SCHWARZ: Some type of additional financial assurance?

MR. WHITE: Well, not additional, but just, in general, so you wouldn't be excluded from financial assurance. So you would have to provide financial assurance and that would be based on what the license reviewer decides.

MEMBER SCHWARZ: Certainly within our license we have significant decommissioning assurance already, so I'm just concerned too, how you want this defined.

MR. WHITE: That would -- well, again, the production and say for example, ~~brochoscope~~ Broadscope license, it would all fall in. As far as saying additional, it wouldn't be --

MS. HOWE: I think, in part, there's a balance. We can put 3 through 83 and we can give you megacurie quantities for each isotope and a total very large activity for everything. That will throw you into serious financial assurance. And so most licensees won't pick that option. They'll pick something that is what they can work well within without having to do amendments, but also takes them down into something that's more realistic as to what they're handling.

So I think it's kind of like a broad-scope medical where you'll see small activities for the 3 through 83 and then you'll see a line item for the technetium or the molybdenum the I-131 or those isotopes that you really know you're going to have high numbers for. And we expect the same thing for the production. In other words, the activation or the things that they may be playing with, may be in the 3 through 83, but if they're really in production and they're putting out large quantities of palladium or fluorine 18 or oxygen, we expect those to -- they'll be listed as line items, so that they don't trigger into financial assurance and heavy decommissioning things.

CHAIR MALMUD: So if I may then, under

that first bullet, Mr. White, you really are suggesting that the topic would be include accelerator produced activation products and anticipated quantities to a list of radioactive materials? Anticipated maximum quantities or anticipate quantities?

MR. WHITE: Yes.

CHAIR MALMUD: And that would allow for the institution, individual, to weigh the - -what they expect to produce versus what it's going to cost them by way of assurance to produce it?

MR. WHITE: That's correct.

CHAIR MALMUD: Okay.

MR. WHITE: And I do want to note that the slides here are not the exact wording that's in the guidance. These are just slides just to get a general point across, but that's not going to be the exact words, but I'm glad that you're providing input.

CHAIR MALMUD: Thank you. Mr. Bailey?

MEMBER BAILEY: Yes. I think -- in looking at financial security for these accelerators and in particular the PET accelerators and so forth, you're really going to be looking at the accidentally-induced radioactivity as the decommissioning costs because most of the production items you -- no matter

how many curies you have there, they're not going to be there long. So it's almost immaterial how much they produce in terms of radioactive material that's not activation products.

MS. HOWE: And the point here is to just clearly show that what you are producing is such short half life that it's not going to trigger anything, but the 3 through 83 has a lot of long half life isotopes in it and so if you put big numbers on there, then it's going to look like you're making lots of long life isotopes. So it's kind of a clarification type of thing so that when people are looking at the licensee and say clearly this is not an issue for financial assurance.

CHAIR MALMUD: Thank you, Mr. White. Does that complete your presentation?

MR. WHITE: Yes, it does.

CHAIR MALMUD: Thank you very much. It stimulated some great productive discussion, thank you.

(Laughter.)

CHAIR MALMUD: If we may, we'll move on -- it's 12:30 and I imagine that it's your gastrointestinal tract that will help you make the decision as to whether or not you want to go on to the

next item or go on to the next item after lunch?

The -- I hear a groundswell of suggestions that this will be done after lunch and if I may, we'll move for lunch now.

What time should we rejoin? Dr. Vetter suggests 1:15. Everyone looks in favor of 1:15, 1:15 promptly. Thank you all.

(Whereupon, at 12:33 p.m., the meeting was recessed, to reconvene at 1:15 p.m.)

CHAIR MALMUD: Well, good afternoon, everyone. It's now 1:17 and we have a presentation regarding petitions for rulemaking. The presenters will be Neelam Bhalla, James Firth, and Ron Zelac, I assume in the order that you are listed. First is Neelam Bhalla.

MS. BHALLA: Thank you. I hope everybody had a good lunch and we can get started. I am going to give a status of Peter Crane's petition for rulemaking. What he is petitioning is he wants us to do a partial revocation of the patient release criteria rule.

What he is asking us to amend is the regulations related to patient release criteria to not allow patients to be released from isolation with more than the equivalent of 30 millicuries of radioactive

iodine in their bodies. This rule, as you all know, was promulgated in 1997 and then retained in 2002 major revision to Part 35.

We have here labeled it as PRM 35-18 and just go quick stats on this. This petition is dated September 2, 2005. We noticed it in the Federal Register of December 2005 with a 75-day comment period. The comment period ended March 6th. Then resolution of this petition is anticipated by the end of December of this year.

For the comments we received 48 comments. Fourteen comments are in support of the petition and these were mostly from the patients. However, there was one medical physicist who is in support of this petition. Thirty-one commenters opposed this petition and these commenters included physicians, medical physicists, RSOs, and professional organizations.

Then there was one commenter supported for reasons other than those raised by the petitioners. In particular, the commenter raised waste issue. Then there were two comments from the petitioner himself.

Professional organizations that commented were ASTRO, AAPM, AB&P, American Thyroid Association, the Endrocrin&Society, ACR, SNM, National Association of Nuclear Pharmacists, American Pharmacists

Association, and CODAR which is also to do with radiopharmacists and radionuclides.

In his petition Mr. Crane also made assertions that this 1997 rulemaking was a sham and that it was tainted by collusion between the NRC staff and a petitioner. Not this one but a petitioner.

Then he said the petition asserts that a former member of the NRC's Advisory Committee on the Medical Use of Isotopes, ACMUI, submitted a petition for rulemaking in 1991 requesting the patient release criteria rule at the NRC staff's request and that the NRC did not follow its rules on disclosure of assistance.

I am going to petitioner's sort of technical concerns. He's saying those two family members -- his concern is those two people during patient transport, contamination, and those concerns due to vomiting, hyperthyroid patients are not able to fully comprehend or remember instructions.

And he talks a little bit about NRC has allowed for reduction of exposure to hospital employees at the expense of elevated exposure to family members, and particularly children. Again, he reiterates children are more radiation sensitive than adults and deserve more protection than less.

I'm going to skip over this slide 8 in the interest of time. Basically it's what the rule is based on TEDE of 5 mrem or 500 mrem and that written instructions are needed if the TEDE is likely to exceed 100 mrem. Then there are rules on guidance if breast feeding and TEDE is likely to exceed 100 mrem. I am sure you are all familiar with this.

Now, prior to 1997 measured dose rate from patient criteria for release was that it should be less than 5 mrem per hour at a distance of 1 meter, or that the activity in the patient or human research subject is less than 30 millicuries. This is what the petitioner wants us to go back to.

I just want to give you an update on the status. There is a working group reviewing the petition. What we are reviewing is since the rule came about in 1997, from 1997 to present time we are looking into what the implementation experience is and we are looking at that for both NRC as to what our inspection experience has been, and the licensees. The licensees have had considerable, almost nine years of experience.

In that regard licensees have in some cases measured exposures. They have published papers so we are looking at all those papers to see what kind

of exposure the family members have received from these type of patients. We are gathering data on that.

Then we are also looking at the current ICRP and NCRP recommendations. We are also going back to the statements of consideration when the rule was promulgated in 1997 and then again in 2002. Then at the end we want to make a recommendation to our petition review board as to if there is any need to amend the current regulations. That is where we are on this.

CHAIR MALMUD: Thank you.

MS. BHALLA: I'm done and this way I'm saving time for what we lost earlier.

CHAIR MALMUD: Thank you very much for a straightforward and concise presentation. This does not require any action on behalf of the Committee. This is for information only?

MS. BHALLA: That is correct.

CHAIR MALMUD: Does anyone have a comment to make? Dr. Williamson

MEMBER WILLIAMSON: Well, yeah. My reaction to this is the NRC staff is taking Mr. Crane's petition very seriously which, from my perspective, seems most unfortunate because I think

the 35-75 patient release rule is a very beneficial rule. I wonder if this group ought to not go on record supporting the existing rule and insisting that we be included in the review of any effort to modify the rule.

CHAIR MALMUD: Dr. Eggli.

MEMBER EGGLI: As a practicing nuclear medicine physician who has literally treated hundreds of patients under this current release rule, this has been a real benefit to the practice of medicine. Isolating people in the hospital who are not sick is a waste of precious healthcare resources. Many patients, in fact, don't want to be in the hospital.

The issue of people forgetting instructions, we give everybody written instructions and the class of patients that he suggested are going to forget their instructions are hyperthyroids who are going to be treated with less than 30 millicuries most of the time anyway.

This would be a giant step backwards for the delivery of quality healthcare in the United States if we were to go backwards to the previous rule. As a practicing nuclear medicine physician who does this work every day I am very opposed to going backwards.

CHAIR MALMUD: Dr. Welsh.

DR. WELSH: As Dr. Eggli has pointed out, there are some positive advantages to the current setup. The petitioner points out one concern, contamination and dose concerns due to vomiting. I'm not personally aware of any episode since the regulation changed where this was a problem. Is there any instance where this has been a problem? Otherwise, why would he mention that? It's a theoretical concern but I have never heard it in practice.

CHAIR MALMUD: Dr. Eggli.

MEMBER EGGLI: There's a drug called Zofran which is an excellent anti-nausea. Anytime I treat a patient who may be at risk for nausea for vomiting, I pretreat them with oral Zofran. It's a very powerful central anti-nausea drug and it literally has been a magic bullet and changed the experience of radioactive iodine patients. In patient doses up to several hundred millicuries I can completely block nausea with Zofran.

CHAIR MALMUD: We've had in the last 30 some years one patient vomit after getting I-131 in a dose less than 30 millicuries in the patient's car. It happened off the hospital campus. The patient's

husband called. We told them to come back to the hospital property where the radiation safety office met their car, cleaned it out, decontaminated them and the automobile off of hospital property, actually on a back street.

There was no way of knowing in advance this patient was going to vomit. She had no complaint of nausea. She just vomited. We now give each patient a plastic bag in the event that they do vomit instructing them if they do that they should return the bag to us and we'll dispose of it for them. It is a rare occurrence. With respect to the patient's behavior regarding children, we generally advise patients who have children to separate themselves from the children if the children are young since young children can't keep a six-foot distance in a disciplined fashion.

Usually the mother, because of the frequency of hyperthyroidism among women, isolates herself from the children for a period of several days by moving out of the house or having the children move out of the house to that of a relative. There is an enormous sense of responsibility on the part of a parent toward his or her children. The advantages of treating patients on an outpatient basis far exceed

the theoretical liability.

MS. WASTLER: Dr. Malmud, Sandra Wastler. I just wanted to clarify something based on Dr. Williamson's comment. Just to remind the Committee members and Dr. Welsh who knew that a petition for rulemaking is what we are dealing with here. We take all requests and petitions seriously.

We will look at them and the process is when somebody sends in a letter requesting, you know, petitions us for some technical medical rationale for making a change to the regulations, we take this and will accept a petition outright. We will publish it as for comment. It is all part of our consideration.

At this point in time this petition we have not made a decision that we are going to make any changes to the regulation. Should we make that decision, that would be the time during the normal rulemaking process when the ACMUI would get involved. I just wanted to remind you of that. This is early stage. A decision hasn't been made by the agency as to whether we are even going to do anything with the petition that has been requested. Just a reminder.

CHAIR MALMUD: Thank you. We realize the responsibilities of the NRC with respect to the petitioner and we are supportive of the current

rulemaking and supportive of your efforts.

Dr. Eggli.

MEMBER EGGLI: Just one last comment to help you think about the process. Again, the most prolonged exposure to young children are going to come from patients under 30 millicuries because they still have a thyroid gland. The thyroid cancer patient that we are treating with 100 or 150 on an outpatient basis have clearance halftimes of less than 18 hours on the average.

Some as short as 12 hours for a clearance halftime of the bulk of the radio iodine dose. Again, some of the arguments made in favor of returning to the old rule only apply to patients who would not be affected by the old rule. I would like you to consider that in your consideration of whether to engage in rulemaking on this.

CHAIR MALMUD: Thank you. Once again, we thank Ms. Bhalla -- is it Ms. or Dr.? I'm sorry.

MS. BHALLA: It's Ms. Bhalla.

CHAIR MALMUD: -- Ms. Bhalla for the presentation and keeping us informed. We will move on to the presentation of Mr. Firth, if we may, because we are under a significant time constraint. If you feel that there's an issue that requires further

discussion, we can call a telephone conference call with 15 days notice and deal with it then. Otherwise, we run the risk of not completing our agenda for today.

Thank you for your patience, Dr. Suleiman.

MEMBER SULEIMAN: My question would have been less time than your --

CHAIR MALMUD: But it would have generated another comment from someone else.

Mr. Firth.

Mr. Suleiman, while we are waiting for the images you can make your comment.

MEMBER SULEIMAN: I was just wondering if anybody knew off the top of their head what the dose rate would be for a 30 millicuries.

MEMBER EGGLI: It's going to be under the old 5 RMR limit.

CHAIR MALMUD: That's how it was derived. That's how it was derived. It was derived from the 5 RMR.

MEMBER EGGLI: At one meter.

MR. FIRTH: Okay. Good afternoon. I'm going to quickly run through the highlights of petitions for rulemaking which we have designated as 35-19 submitted by William Stein. This deals with

training and experience for the use of radio isotopes.

It was written in March of this year, published in the Federal Register on June 14th. The comment period closed in late August. We have formed a working group. We have not started deliberations in terms of considering the petition and the comments.

Basically the petition requests NRC to establish training and experience requirements in a limited sense for authorized users for parenteral administrations requiring written direction on the following: $^{153}$Sm-lexidronam (Quadramet), $^{131}$I-tositumomab (Bexxar) and $^{90}$Y-ibritumomab tiuxetan (Zevalin).

They are requesting that NRC recognize the following as adequate training and experience for this limited authorized user status: 80 hours of classroom and laboratory training, supervised work experience, and written attestation.

The basis that they used is that the risk associated with these FDA approved agents is less than that of sodium iodide through oral administration. They are making a comparison to those other NRC requirements. That was the assertion of the petitioner.

The comments on the petition, we had

comments from three states, the states of Alabama, Arkansas, and Iowa. They span from qualitatively supporting the petition to opposed to the petition. Four organizations expressed views. All of the organizations opposed the petition.

We had a number of physicians comment on the petition. A number of these are hematologists, oncologists. They were supporting the petition. There were other physicians that were opposed to the petition.

That is essentially the summary of the petition where we are. I know the Committee has been actively involved in the experience so we would be interested in any views that you may have.

CHAIR MALMUD: Thank you, Mr. Firth. I think the first hand up was Dr. Nag.

MEMBER NAG: These are unsealed isotopes and basically if you are going to take this down to 18 hours the entire 390 would be the same. Unless you are going to hold up 390, then the people in 490 why not hold up 490. I think there is really no basis for changing this.

CHAIR MALMUD: The second hand, I think, was Dr. Eggli.

MEMBER EGGLI: The first comment is the

same. Basically you take these three isotopes out of 390 there's nothing left in 390 so you might as well throw 390 away. Secondly, there are significantly greater risks of bone marrow suppression with these intravenous radiopharmaceuticals than with radioactive iodine.

In fact, Bexxar requires a permanent form of dose symmetry. One might argue that maybe Zevalin should because there is a significant experience that said there is bone marrow suppression with the Zevalin as well. Clearly Quadramet has the risk of bone marrow exposure suppression if you don't adequately evaluate the metastatic burden in the patient.

I think these three isotopes are higher risk than iodine. I would argue that for the typical iodine patient, except those that we do high dose on and we do formal dosimetry with those, iodine is clearly lower risk than any of these intravenous radiopharmaceuticals.

I can only think of one case in 18 years of experience of a patient that did not go through a dosimetry process with radioactive iodine who had significant bone marrow suppression from that.

Again, probably over the last 20 years I've treated thousands of patients with radioactive

iodine. I would disagree with the petitioner's assertions about the relative risk. Again, if you change it, there's nothing left in 390 and, as Dr. Nag said, you might as well throw 390 away.

CHAIR MALMUD: Dr. Welsh.

DR. WELSH: To follow up on that point, I would ask why is Metastron not included in this list, strontium-89, because it is a glaring omission and raises the suspicion of an ulterior motive with pharmaceutical industries. Does anybody know why the strontium-89 was not included?

MR. FIRTH: I cannot add in terms of why it was not. One of the comments from the State of Arkansas indicated that if NRC were to pursue rulemaking in response to this petition, that they would recommend including Metastron.

The petitioner in phrasing their petition gave these as examples. They also cited that there's other drugs that are becoming available so they actually offered three alternatives in terms of how to address the training and experience of which they said one approach would be NRC could do it on an individual basis or to do it more in a generic sense that would include like Metastron and the others in an envelope for the rulemaking.

CHAIR MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: First off, I think iodine which is usually used to oblate the thyroid so the dosimetry is of questionable accuracy. I think these are used for non-hotchkins lymphoma.

MEMBER EGGLI: The dosimetry with iodine is to calculate bone marrow exposure on high-dose patients.

MEMBER SULEIMAN: But what I'm saying is I think you need much better dosimetry for the Bexxar and the Zevalin than you do what they are comparing it to. They aren't comparable and the risks are -- just to remind people, we are dealing with a therapeutic -- where the organs are internal and much more critical.

CHAIR MALMUD: Thank you. Dr. Williamson.

MEMBER WILLIAMSON: Who are the four organizations that commented?

MR. FIRTH: The organizations were the American College of Radiology, the American Society for Therapeutic Radiology and Oncology, the American College of Radiation Oncology, and American Association of Physicists in Medicine.

CHAIR MALMUD: Thank you. The information for us was for information only?

MR. FIRTH: It is for your information but

if you have any other views, we can consider them as we work in resolving the petition.

CHAIR MALMUD: I sense no contrary views from the members of the Committee.

MEMBER NAG: I'm wondering if to help you if even at this point we can make a motion that we have advised this in the ACMUI and I make the motion that the ACMUI rejects the argument. That would give them a stronger hand.

CHAIR MALMUD: There is a motion on the floor. Is there a second to the motion? Dr. Eggli. Any further discussion of Dr. Nag's motion which has been seconded by Dr. Eggli? If not, all in favor of Dr. Nag's motion? Any opposed? Any abstentions? It's unanimous. You have the sense of the Committee.

MR. FIRTH: Okay. Thank you.

CHAIR MALMUD: But you can use the interrelations as well. Thank you.

I believe Dr. Zelac is next on the agenda.

DR. ZELAC: I was asked to be the third because this is the petition about which we know the least in that it was received more recently than any of the others. It was submitted by E. Russell Ritenour, Ph.D., and it was submitted on behalf of the American Association of Physicists in Medicine, the

AAPM.

When a petition comes in an initial decision is whether or not to accept it as a petition or whether something as a request is simply frivolous and should be disregarded. This is not frivolous. This has been accepted by NRC as a petition. It has been docketed and has been assigned the number that appears at the top of the slide.

This petition has not yet appeared, been published in the Federal Register, although that's expected in the very near future. Once it is published the comment period will extend from the date of publication for 75 days. Resolution of this petition if we follow the usual course of events at the agency is anticipated within one year after the date that it is noticed in the Federal Register but it might be much sooner.

We would attempt to get it done as promptly as possible. We meaning the agency. I am not directly involved yet, if at all. I'm already serving as a member of two of these petition review boards. I think it's probably likely that I am going to be assigned to this third one as well.

There are two requests that appeared in the petition. The first was to revise 10 CFR 35.57

which is the grandfathering provision of the medical use rule to grandfather as authorized medical physicists all medical physicists certified either by the American Board of Radiology or the American Board of Medical Physics on or before October 24 of 2005 for the modalities that they were practicing as of that same date.

Just for information, the second request also relates to 10 CFR 35.57 which is titled in the regulations, "Training for experienced radiation safety officer, teletherapy, or medical physicist, authorized medical physicist, authorized user, nuclear pharmacists, and authorized nuclear pharmacists."

The second request again deals with the same provision, 35.57, and it is to grandfather as radiation safety officers all individuals certified by the boards named for radiation safety officer training and experience requirements in the former 10 CFR 35 Subpart J who have relevant work experience providing appropriate preceptor statements are submitted.

Just for information, Subpart J did expire and was removed from the regulations as Donna-Beth Howe mentioned earlier. It expired on October 24th of 2005. Therefore, the magic date that appeared in the first request.

The boards that were listed as recognized for radiation safety officer training in the section of Subpart J dealing with radiation safety officers included the American Board of Health Physics Comprehensive, the American Board of Radiology, the American Board of Nuclear Medicine, the American Board of Science and Nuclear Medicine, Board of Pharmaceutical Specialties in Nuclear Pharmacy, American Board of Medical Physics and Radiation Oncology Physics, Royal College of Physicians and Surgeons of Canada in Nuclear Medicine, American Osteopathic Board of Radiology, and the American Osteopathic Board of Nuclear Medicine.

Now, that whole list of boards that I just mentioned that appeared in Subpart J, three of them have applied for recognition in the radiation safety officer training category under the new Part 35 training experience which became effective in April of 2005.

They are the American Board of Health Physics. It is currently recognized and diplomates and its certification process is recognized from January 1st of 2005 to present. The American Board of Radiology, specifically in radiologic physics, medical nuclear physics, and diagnostic radiologic physics,

from June of 2007 forward. And the American Board of Science and Nuclear Medicine in the specialty for nuclear medicine physics and instrumentation from June 2006 forward.

That's all in the way of information and background. Again, this is not even been noticed in the Federal Register yet so we have not received any comments on it, although clearly they are welcome as soon as notice has been published.

I will not say too much more unless there are questions because this is a reasonable seque into the next talk which I'm also presenting.

CHAIR MALMUD: There is a question from Dr. Nag.

MEMBER NAG: Would a similar petition like that solve the problem with the board certified radiation oncologist who was board certified in 2005 and before 2007? We are having that problem with some of the people who are going to be board certified now and before 2007 who would have a problem being recognized as an authorized user. If a petition like that for the radiation oncologist is given, would that solve the problem?

DR. ZELAC: A petition submitted would, of course, follow the same course of consideration that

this petition is following. Whether either of those petitions would result in and of themselves in a solution to the issue is another question but it certainly could be entertained. I am certain there are other boards that are looking to see how this petition is handled to make decisions as to what, if anything, to do on their behalf.

There is a mechanism which I will discuss in the next talk which I think could work around the issue that you have just mentioned with respect to not only radiation oncologists but all diplomates of boards whose certifications were obtained in times other than those for which that particular certification process is recognized.

CHAIR MALMUD: Thank you, Dr. Zelac. I believe you are on again.

DR. ZELAC: Indeed I am.

CHAIR MALMUD: I believe your slides are on the white on black. Is that correct?

DR. ZELAC: Black and white. That's correct. That is the way they appear.

CHAIR MALMUD: White on black, yes. They are a handout. They are not in your book.

DR. ZELAC: This talk has been allocated in a relatively appreciable amount of time for

discussion. I noticed in this morning's talk by Lydia Chang that she mentioned it was a status report and, on that basis, it didn't seem to be a whole lot of feedback. I might suggest this is also a status report. Not because I'm trying to save time but because you'll see when I get to the last slide that, in fact, that is exactly what it is.

There are a number of considerations which have already been made, actions which have been or will be taken, but there are other things coming up which are also under consideration, not the least of which is the petition that we just discussed.

I thought it would be a good way to start by reviewing the pathways to authorize status, to recognize status for radiation safety officers and for authorized medical physicists that exist in the current Part 35, again, which became effective as of April of 2005.

Certification pathway, which we have started to discuss already, for radiation safety officers. There are, in fact, two in 35.50(a) and also in 35.50(c). For authorized medical physicist the certification pathway is 35.51(a). A pathway which does exist involves the grandfather provisions in 35.57 as I was just discussing a little earlier.

Those appear for RSOs and for authorized medical physicists in 35.57(a).

In quick summary, if those individuals who were named on licenses, be it NRC or agreement state licenses as of the effective date for the T&E rule, April 29, 2005, are grandfathered. If your name is on a license, there is no need to modify your training and experience to match the current requirements. What you did before to get authorized is sufficient.

The third pathway is the notification provision pathway which relates to authorized medical physicists only, not to radiation safety officers. It centers on the definition for an authorized medical physicist in 35.2 which includes not only those that are certified by a board recognized by NRC or an agreement state, but also those individuals who are named on licenses or permits by NRC or an agreement state.

Those people that are named on permits or licenses can begin work at another licensee's facility without that license being amended. Those individuals can within 30 days have their credentials submitted to the agency, NRC, or some of the agreement states. That is sufficient. At some later time when the license is being worked on, either for amending or

renewing, that person's name will be added onto the license.

This provides the notification provision pathway, provides an easy path for those essentially either who are certified during a period when the process is recognized, or named on a license to begin work at another licensee's facility easily.

The last pathway to mention is the alternate pathway, the requirements for which appear in 35.50(b) for radiation safety officers and 35.51(b) for authorized medical physicists. These are the training and experience requirements more specifically spelled out than those in the certification pathway.

MEMBER WILLIAMSON: I'm sorry. May I ask a question of clarification?

DR. ZELAC: Certainly.

MEMBER WILLIAMSON: I am not certain I understand the difference between the grandfather and notification provisions. They seem --

DR. ZELAC: Grandfathering only applies to those individuals who are named on licenses as of April 29th of 2005. If you are named on a license, there is nothing further that you need to do in order to continue work. You are authorized.

You can continue being authorized even

though the now training and experience requirements differ from those that were in place when you were recognized. The notification pathway does not have a time associated with it. It's at anytime that you become named on a license as dealing with that aspect of it.

Anytime that you become named on a license as, for example, a medical physicist or an authorized medical physicist you can begin work at another NRC facility and at least some of the other agreement state facilities without the license being amended. Essentially it's a ticket to begin work at another licensee's facility.

MEMBER WILLIAMSON: But the prerequisites aren't the same. You have to have been named on a prior license as an AMP or teletherapy physicist. That's why I'm not sure I

appreciate --

DR. ZELAC: You need to be named on a license but it doesn't have to have been prior to April 29th of 2005. It can be from that day forward, for example.

MEMBER LIETO: I'm a little confused because in order to get named on the license you either have to meet the certification pathway or the

alternate pathway. The only way they could notify a license that you have been on a license already is that say a broad scope and they approve and the AMP. They have to use one of those two criterias unless there is a difference in broad scope licensing that I'm not quite aware of. They have to use one of those pathways in order to approve them in-house.

DR. ZELAC: What I am basically trying to say is that if you were interested in becoming an authorized medical physicist at some particular licensee's facility, there are four ways that you could achieve that status. One is if you were certified and your certification was obtained during a time when the certification process of the board was recognized.

The second is you have training and experience and you simply document that training and experience. If it matches the requirements in 35.51(b), you should be good to go. Those qualifications would have to be submitted for review prior to your starting work.

However, if you were either named on another license previously, you can continue on that license in your current capacity. Or if you were named on another license, you can go to another

licensee's facility and start work on that as well, again, either named on a license or a permit.

MEMBER WILLIAMSON: So it's basically the same group of people except the notification pathway encompasses those between April 2005 and the current date.

DR. ZELAC: That's essentially correct. That's correct. So I'm going to try to focus this on questions and try to hopefully provide answers that are intelligible to the various questions.

Why is this authorization a medical physicist as AMPs and RSOs a concern? I'll just put out everything on the slide and then we'll just talk about them. First of all, as we have been discussing, medical physicists not named on licenses or permits as of April 29th, 2005, are not grandfathered.

Secondly, some agreement states previously, and still to this date, don't list medical physicists on licenses. All of them list radiation safety officers but typically there is only one per license. Third, in terms of why this is a concern, the certification pathways are now time restricted. When a board was recognized in Subpart J it was recognized period.

Now, there had been criteria under which

that board's recognition was considered in terms of the adequacy of the program at the time it was recognized, but there were no time restrictions. Whereas with the 2005 training and experience rule, the direction that was given to staff from the Commission was that each board, each and every board including those that appeared in Subpart J, should have their certification processes reviewed.

It would be only those boards whose processes met the now current training and experience requirements for recognition of a certification process who could remain recognized or become recognized. There is a time frame now for a particular board's certification process.

The second bullet that you see there talking about agreement states really relates to the notification provisions pathway which, as I mentioned earlier, is available in many jurisdictions but not all. I'll speak to this in the next slide.

So how large an issue is this concern about medical physicists seeking AMP status? I'll cover AMP and then go into RSO. NRC conducted a survey of the agreement states to gather information that would relate to this particular question.

The survey took place this summer and the

results indicate that 28 of the 34 agreement states have been or are now listing medical physicists or AMPs on limited specific use licenses. Of course, for broad licenses they are not listed. That is up to the Radiation Safety Committee to consider the qualifications and to provide permits.

The other six agreements states, which will remain nameless until someone asks, will list medical physicists on licenses or AMPs on licenses by April of 2008. Why April of 2008? That is three years from the effective date of NRC's current training and experience rules and the agreement states are typically allotted three years to come into conformity wherever that is required in terms of compatibility.

MEMBER BAILEY: Can I ask a question?

DR. ZELAC: Certainly.

MEMBER BAILEY: I didn't understand that who you named on a license was an item of compatibility.

DR. ZELAC: That's the point. That is exactly the point, that it hasn't been previously but the new training and experience requirements have compatibility beat, which means they have to be essentially identical so if it now a requirement for NRC to list medical physicists on licenses, unless I'm

mistaken it will be a requirement under compatibility for the agreement states to do the same.

MEMBER BAILEY: I would disagree. I mean, I agree that the training requirements are items of compatibility.

DR. ZELAC: Thank you.

MEMBER BAILEY: But I don't necessarily know that listing it on a license --

DR. ZELAC: You are correct. That relates to the notification provision and that is not a compatibility. You are correct. I stand corrected.

MEMBER BAILEY: And you said unless somebody asked. May I be the devil's advocate and ask so I can perhaps get back to them? Which states are not now doing it?

DR. ZELAC: The six states which are not now listing medical physicists and who have indicated they probably are not going to do this before they really need to in April 2008, or they will have accomplished it at that point in time, are Kansas, Louisiana, Maryland, Mississippi, New Hampshire, and Tennessee.

MEMBER WILLIAMSON: May I ask a question?

DR. ZELAC: You certainly may.

MEMBER WILLIAMSON: Well, the fact that

the agreement states may be doing this now is I think perhaps not of much help to those who would like to be grandfathered since the grandfathering clause, as I read here --

DR. ZELAC: I understand what you're saying.

MEMBER WILLIAMSON: -- before October 24, 2002.

DR. ZELAC: You are absolutely correct. It's not the grandfathering that this relates to. It's the notification pathway because if individuals were listed on licenses, then they would have a clear and easy way to start work at another licensee's facility in an NRC state or in at least some of the agreement states.

MEMBER WILLIAMSON: And I also don't really see where in the letter of 35.57 serving as an authorized medical physicist or authorized medical physicist in a broad scope licensee would provide grounds for grandfathering.

DR. ZELAC: It does under the notification. It's not grandfathered.

MEMBER WILLIAMSON: That's under the notification pathway but I don't see that, you know, it satisfies the grandfather.

MS. HOWE: This is Dr. Howe. If you look at 35.57(a) you will see that you can also be listed on a permit issued by a commission or agreement state, broad scope license or master material's license permit, or a master material's license permittee of broad scope so it does cover the broad scopes.

MEMBER WILLIAMSON: Okay. All right.

DR. ZELAC: I knew the wording was there but I wanted to give it to you directly. No, it does apply to permitees as well as licensed persons.

Since we are talking about who does what with respect to the agreement states, might as well mention that California currently only lists physicists for gamma knife. However, if a physicist request to be listed, they'll do it. Illinois, Nevada, and Texas do list medical physicist except for strontium-90 eye applicators which is one usage in Part 35 that does require input in involvement of an authorized medical physicist. And North Carolina will list physicist but only on request.

The last bullet on this slide simply says what we have already discussed. Once a medical physicist is listed, that person can achieve authorized status on another license in NRC states definitely and some agreement states via the

notification pathway.

There are more considerations to this question about how large an issue this concern is for medical physicists seeking AMP status. First, there are certification pathways. I mentioned -- I didn't mention for medical physicist but there are certification pathways that do exist now and they may expand both in terms of numbers of boards as well as possibly the time duration under which a certification process is recognized.

Medical physicists also, of course, can seek authorized status via the alternate pathway. It is simply, again, filling out a form that relates, or not even a form, providing information about training and experience in an attempt to show that it matches the current requirements in the alternate pathway.

The third and the fourth bullets simply fact and just give you a status of where we are. There haven't been any reported problems from NRC's regions with medical physicists getting authorized since almost a year ago, October of 2005. We have not received any problem reports either from agreement states that have been operating with revised training and experience requirements that match Part 35's requirements.

How big an issue is this relating to this concern? First of all, as I'm sure everyone on the Advisory Committee recognizes, many medical physics uses do not require an AMP. These include all diagnostic uses, for example, nuclear medicine, and some therapeutic uses, for example, manual brachytherapy.

MEMBER BAILEY: You mentioned eye applicators awhile ago as something they were not listing medical physicists for. Are eye applicators not considered manual brachytherapy?

DR. ZELAC: The specific requirement in the rule that calls for the involvement of an authorized medical physicist is for the decay corrections only. That is the only place that an authorized medical physicist is called for with relation to a manual brachytherapy activity. It is only for strontium-90 eye applicators.

DR. ZELAC: The second point -- well, I should say then -- I've said what medical physicists as AMPs are not required for but I should just remind you what they are required for. They are required for the teletherapy unit use, for remote after-loader unit use, for gamma knife and other stereotactic radial surgery use, and for strontium-90 ophthalmic

applicators.

Again, in terms of the scope of the approximately 6,000 medical use licensees in the entire United States including NRC and the agreement states, 5,000 of these licenses do not require authorized medical physics services.

Now, to switch gears slightly, how large an issue is this concern about medical physicists seeking RSO status? The considerations are as follows. First, anyone who is seeking RSO status must submit credentials for review. There are no automatic authorizations based on certifications from boards recognized under any of the sections of 10 CFR Part 35.

There is no notification process that applies. You are changing RSO. The credentials must be submitted. Secondly, there are certification pathways to radiation safety officer for all three main types of certified medical physicists, therapeutic medical physicists, diagnostic medical physicists, and nuclear medicine medical physicists. The pool of medical physicists who might be seeking RSO status is largely than those that are AMP eligible medical physicists.

And, as I mentioned earlier, there are

additional boards that may be recognized currently. It's only a certification process from the American Board of Radiology which is recognized by the American Board of Medical Physics, has submitted request for consideration of recognition of the certification process or processes, and the agency is currently awaiting additional information from that board.

More considerations. These I will note before I even start to put them up are important information but I think it is generally not recognized. For medical physicists that are seeking RSO status via the certification pathway, there are training and experience requirements listed in that pathway and that training and that work experience requires that there be a certified supervisor, meaning someone who is certified but that person does not have to be an AMP, that supervisor.

That supervisor does not have to be an RSO and that supervisor does not have to be certified in years that the board's processes are recognized. Simply has to be a diplomate of a board which has been recognized by NRC or an agreement state so that very much opens up and broadens the range of individuals who can serve as supervisors for those gathering their required training and work experience to seek

certification as a medical physicist.

Secondly, AMPs, medical physicists who have been named on licenses as authorized medical physicists, have a pathway, an easy pathway to RSO status, it's in 35.50(c)(2) regardless of whether that individual AMP status was achieved via the certification pathway or the alternate pathway. In other words, it doesn't require an AMP who is certified. It simply requires an AMP to have an easy pathway to RSO status.

The certified supervisors that are mentioned here relate to the two years of full-time practical training and/or supervised experience in medical physics. That's a direct quote from the rule.

CHAIR MALMUD: Mr. Lieto.

MEMBER LIETO: Ron, could we go back to just your previous slide there on that supervisor question? The certified supervisor statement there, is this applying to the AMP or the RSO or both? It sounded like your comments were referring to the AMP, not the RSO. I guess the second part of that this is to the component of the preceptor, right? The attestation statement?

DR. ZELAC: No, this is not the attestation. I am not speaking here of the

attestation and the preceptor statement at all. I'm speaking to the requirement in the rule section itself that lays out the qualifications that a board's process must have in order for it to be recognized.

MEMBER LIETO: So this would be for medical physicist seeking AMP status?

DR. ZELAC: Well, the certification pathway for an authorized medical physicist, the AMP designation, in order for the board to be recognized that it require of its candidates that they have two years of full-time practical training and/or supervised experience in medical physics under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an agreement state. That is pretty clear.

MEMBER LIETO: It's not just RSO status. It would be RSO or AMP status.

DR. ZELAC: And if we go to the certification pathway requirements that apply to a medical physicist seeking RSO status, that is in 35.50(a)(2), "Have two years of full-time practical training and/or supervised experience in medical physics under the supervision of a medical physicist who is certified in medical physics by a specialty

board recognized by the Commission or an agreement state."

Yes, it applies to both the training requirements for RSO and for authorized medical physicists. I spoke of it here in discussing the RSO but it also applies to the medical physics.

MEMBER LIETO: All right.

DR. ZELAC: There's been a statement, and that's the reason I'm putting it here under the considerations, that in terms of the size of this issue I really need to emphasize, and that's why this first bullet is there, if a medical physicist is not able to apply via the certification pathway, they are not disenfranchised.

They are not being kept from practicing their profession legally. They can also achieve RSO status via the alternate pathway because, again, there is a specific pathway there that some may consider onerous but it does provide another way to achieve recognized status as an RSO.

Secondly, that alternate pathway is not a second class pathway. It's not a lesser path. A radiation safety officer for a given use is considered just as capable and just as qualified of carrying out the responsibilities if they achieve that status via

certification pathway or an alternate pathway.

Now, big question. What is NRC doing to reduce the impact of this issue? Clearly, we are not just saying there isn't an issue. There is an issue here but what are we able to do? What have we done? What will we be doing to lessen the impact of this issue.

The principal thing that I can say is we are encouraging, we are putting out encouragements. First, to medical physicists to get listed on licenses or permits. As we discussed earlier, then the notification pathway is available to them.

Secondly, encouragement to agreement states to do just what we've been talking about, listing medical physicists whenever a licensing action occurs. Not retroactively to go and look at all licenses but if a license is being handled anyway for renewal, for amendment, now would be a good time with very little additional cost and effort to add the name of the medical physicist whose credentials were considered before that usage was authorized to begin with.

MEMBER BAILEY: Could those be approved under preexisting requirements? What I'm thinking is that medical physicists if there were regulations

regarding their being named may have simply said board certification by these groups without reference to years or anything else.

DR. ZELAC: Well, recognize, of course, that the agreement states do have until 2008 in April to make the conversion so they still have their equivalence to Subpart J available and their equivalents simply name the boards

MEMBER BAILEY: Or some other pathway.

DR. ZELAC: Or some other pathway.

MEMBER BAILEY: Okay. So you would accept those. They do not have to be equivalent.

DR. ZELAC: If the agreement state has a path that it uses in considering the qualifications of a medical physicist and it uses that path and the result is that individual is considered qualified and is named on the license, that is good.

The third thing that we're doing is to speak to the boards themselves in attempts to broaden, if possible, the recognition times for their certification processes.

MEMBER WILLIAMSON: Could I ask a question about the previous bullet before you move on?

DR. ZELAC: Certainly.

MEMBER WILLIAMSON: What is the difference

between permittee and named on a license?

DR. ZELAC: Say that again?

MEMBER WILLIAMSON: Can you tell us the difference between a permittee and one who is named on the license as an authorized person?

DR. ZELAC: For these purposes none. There is no difference at all. They are considered equally because in any --

MEMBER WILLIAMSON: Why are there different words used if they mean exactly the same thing? What is the distinction?

DR. ZELAC: Because they are not identical but for these purposes there is no distinction.

MEMBER WILLIAMSON: Could you define what they are?

DR. ZELAC: Sure. An individual --

DR. HOWE: Let me get a quick one in here.

DR. ZELAC: Here. Go ahead. I was going to but go ahead.

DR. HOWE: You have the board scope. The broad scope issues permits to authorized users, medical physicists, whoever, in order to authorize them to use the material. We also have a category of licensees that the NRC call the master materials license.

The master materials license, which is the Air Force, the Navy, and the Department of Veterans Affairs, has a central regulatory type of group that will issue what is equivalent to an NRC license but what is called a permit so we recognize those permits and people identified on those permits because they have to meet the NRC requirements as being equipment. The broad scope NML permitees also can issue permits to their individuals.

MEMBER WILLIAMSON: What's it called?

DR. HOWE: Master materials license.

MEMBER WILLIAMSON: Okay.

DR. HOWE: They can also issue permits to their broad scope permitees to recognize physicians and medical physicist and nuclear pharmacists and RSOs on their permits. That is the meaning with respect to our master materials licenses.

MEMBER WILLIAMSON: Is broad scope licensee AMP considered to be a permittee or named on a license?

DR. HOWE: The terminology we use is if the broad scope has recognized that individual to be an authorized medical physicist, we consider that to be a permit, a broad scope permit.

MEMBER WILLIAMSON: And the evidence for

that are the minutes of the Radiation Safety Committee?

DR. HOWE: Whatever documentation that the broad scope has.

MEMBER WILLIAMSON: So this pathway does not exist for specific scope licensees?

DR. HOWE: That's correct because a limited specific licensee has to have individuals. The training and experience is reviewed by the NRC. I'm just talking for NRC licensees. It's reviewed by the NRC and the individual is named on a license, or uses the notification pathway if they are already recognized by definition as an authorized user, authorized medical physicist, and then gets listed on the license later.

DR. ZELAC: So, in summary, to answer your question very succinctly, for these purposes there is no difference. It doesn't matter whether you are named on a license or named on a permit, the same pathways are available to you.

The first two bullets on this slide, to MPs that get listed on licenses or permits and to agreement states to list MPs whenever licensing actions occur, will first prevent any rushed efforts and backlogs and agreement states that are not

presently listing MPs to do so to list AMPs as the April 29th of 2008 deadline approaches.

Second, will facilitate the review and approval process of those certified MPs who are not presently listed on licenses and for whom the grandfather provisions do not apply because the Subpart J equivalence, as I mentioned, can be used as a bases for these determinations.

Third, these actions will facilitate relocation when sought to another facility by a medical physicist who is practicing in an agreement state licensed medical use facility but isn't listed on the license or on a broad scope license permit. In other words, this will be good for the medical physicist who may want to change locations.

The third bullet that is up here now to broads to broaden their recognition times, applies not so much to medical physicists. It applies specifically to the American Board of Health Physics but not to the American Board of Radiology for radiologic physics process because that process was recently changed and it is unlikely that time frame for its recognition will be, or can be expanded. The process was changed. The recognition time reflects the process that exist now.

Here is what I think is a big, big opportunity to handle a lot of the concern. NRC is also encouraging the certification boards to identify upon request from a diplomate, those diplomates from years when their certification process wasn't recognized who do meet the current requirements for certification pathways, to authorize medical physicists and/or to radiation safety officer.

In other words, you have a diplomate of a particular recognize board. However, that diplomate's certification came at a time when the process wasn't recognized. Why wasn't the process recognized? Perhaps because not all diplomates for that particular time frame met the requirements.

Most did but not all. Those diplomates who did -- whose qualifications at the time did meet the current requirements could approach the board and as a service to their diplomates, the boards could if they wished to issue some kind of a revised certificate or equivalent, letter perhaps, indicating this fact and such documents could be used by diplomates seeking recognition via the certification pathways. We are certainly open as an agency to that approach.

VICE-CHAIR VETTER: Excuse me, Ron. Has

that process been approved by NRC and communicated to the boards?

DR. ZELAC: We have been discussing it internally to see if it was workable and we have been in touch with boards and are continuing to be in touch with boards to make this fact known to them.

CHAIR MALMUD: Mr. Bailey.

MEMBER BAILEY: Assuming some board chose not to do that, would NRC be willing to do the same thing? In other words, I'm sure one of the concerns are the degree requirement. If I as one of these who didn't get certified afterwards submitted my certification and the fact that I had the degrees required, would NRC then accept that rather than all this other stuff?

DR. ZELAC: Well, under the best of circumstances the board, which granted the certification, would give you a letter and that letter would be submitted. Failing that for whatever reasons, you have asked a question which we have talked about but we don't really have a position at the moment.

I think we should and can and will consider it but I can't say with certainty that would meet the requirement that exist in the rule and that

is where we have to have Office of General Counsel involved interpreting what we can do and what we cannot do. That individual could certainly use his or her credentials, whatever they might be, and apply for recognized status via a certification pathway and through an exemption. We prefer not to --

MEMBER BAILEY: You prefer not to regulate by exemption.

DR. ZELAC: Absolutely.

CHAIR MALMUD: Dr. Nag.

DR. ZELAC: The other alternative -- excuse me, just to finish, is they could just define and explain their training and experience in ways other than, "Here is a copy of my certification," and apply via the alternate pathway.

MEMBER NAG: I think this is similar to what we were discussing before when I mentioned that NRC do something to rectify the problem itself. This is a problem basically we ourself unknowingly or unwittingly. I think we should bend backwards to try to prevent individuals from getting into trouble because it is not their fault that they happen to graduate in 2005 or 2006.

DR. ZELAC: This is why I mentioned earlier that what we were discussing here in terms of

what our available options for providing relief to medical physicists could well apply to other professionals seeking authorized status.

MEMBER NAG: I would very highly push for NRC to provide a solution like this rather than asking either the board or ask the applicant to show the burden of proof.

CHAIR MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: Ron, could you remind me what is the cause of condemning all the prior medical physic certifications to this eternal purgatory?

DR. ZELAC: The 2005 rule using guidance from this Committee, and specifically the Subcommittee on training and experience -- I'm not pointing fingers, just stating facts -- did come up with recommendations for requirements that did differ from those in the previous rule, the 2002 rule significantly enough that the Commission wanted to be sure that all boards who had interest in being recognized did, indeed, have certification processes that matched the new requirements that were placed upon boards in order to be recognized.

It was on that basis that the direction that we got from the Commission was to ask each and

every board including those who were named in Subpart J to seek re-recognition or initial recognition if they didn't appear there previously.

MEMBER WILLIAMSON: I think you misunderstood my question. I'm asking specifically what aspect of the American Board of Radiology for certification and therapeutic radiological physics failed your criteria.

DR. ZELAC: Oh, I'm sorry. That particular board, that particular path involved where the training and experience was acquired and under whose supervision, as well as, I believe, where the degree was obtained.

Cindy, did you -- can you comment further on that?

Those of us on the medical team had responsibility for reviewing applications from boards. This particular application was reviewed by Cindy Flannery.

MS. FLANNERY: Cindy Flannery. The change that ABR, the radiologic physics specialty, had to make in order to meet NRC's current training and experience requirements was the medical physicist getting the work experience under an authorized medical physicist. That was the change that they had

to make in order to meet our criteria.

DR. ZELAC: That doesn't quite sound right because the rule requires it to be under a certified-

MS. FLANNERY: I'm sorry. Thank you. Certified medical physicist. In the past they had not required that work experience to be obtained under a CMP.

CHAIR MALMUD: Dr. Eggli.

MEMBER EGGLI: I think what Cindy's comment points out is that the boards probably have gone as far backwards as they can. I don't see how any board can go backwards and guarantee that an individual training program, in fact, met requirements that weren't requirements at that time. I don't think you are going to see boards lining up to do this. I think you are going to see boards running like crazy away from that option. I don't see that as a viable option.

I think in all good faith the boards have tried to go backwards as far as they can and where they didn't meet requirements, they don't have a mechanism for documenting that any individual program may have met those requirements independent of what the board actually required at the time. I don't see that as a viable effective pathway because the boards

would have done it if it's viable. They understand the pressures.

DR. ZELAC: The only option available to a board at this point in time when they sought their recognitions was that each and every diplomate that was granted recognition during a particular year either followed a program that met the current requirements or did not.

In some cases it was a situation that a board's process wasn't recognized only because one or two or a very small number of the diplomates from that year didn't meet the requirements, not that all of them didn't. They had ways of understanding and recognizing that there were such individuals whose training and experience did not meet the requirements from the vast majority of those who did.

It was because of those few that they couldn't be recognized for a particular year. Again, should that -- I hate to use the word disenfranchise because it doesn't totally apply but should that prevent individuals who did meet the qualification for whom there may be easy recognition of that fact from following the certification pathway.

We think not and we expect that the boards will think not, too, and will be willing to do a

service to those diplomates. Again, perhaps those few diplomates who will be in the situation of first seeking to be authorized medical physicists where a medical physicist is required who are not grandfathered, who are not currently named on licenses for notification. The feeling is that there are not a whole lot of people that are in that situation. But for those that are, the boards ought to be willing to do a little bit for their diplomates.

CHAIR MALMUD: May I suggest that we allow Dr. Zelac to complete his presentation and move ahead and if we need to, we can have a telephone conference call adequately notified to clean up some of these issues if there are still issues for you. Otherwise, we will not get through our agenda.

DR. ZELAC: Thank you. I'll be more than happy to move ahead judiciously.

The next slide indicates -- this slide was talking about what we are doing in terms of encouraging medical physicists, encouraging agreement states, encouraging boards to do things. The next slide talks about how we are accomplishing this, what kind of contact with these individuals and organizations are we using to achieve these objectives.

What is NRC doing to encourage these actions by individuals, agencies, and organizations? First, we did issue an all agreement states letter this summer encouraging the listing of medical physicists on licenses. Secondly, we will soon be issuing a regulatory issue summary, RIS, encouraging medical physicists to request being listed.

Third, we are providing copies of this RIS to medical physics professional organizations and boards suggesting that their members and diplomates be notified of this document so that they can examine it and decide if it's in their best interest to do something with it.

For these second and third bullets, again, I will note that these are actions in progress, that the RIS will be published and distributed when complete and will then be provided to these medical physics professional organizations and boards.

Was there a question?

MEMBER LIETO: Just real quickly. That is all fine about the RIS notifications and summaries but what's missing is that the agreement states MPs are not going to know about this. They are the ones that need to be notified so what really needs to happen is that the agreement states need to notify the medical

physicist to request this.

DR. ZELAC: The RIS will be going out to the agreement states as well. This is general practice. Certainly any covering letter that would go with such a distribution could encourage their actions as well as the actions that we are hoping the boards and professional organizations will take with respect to their members.

CHAIR MALMUD: Thank you. And you have one more slide, Dr. Zelac?

DR. ZELAC: I have one more slide. We are doing additional things including developing revised and considerably simplified NRC forms 313A. Again, not required for use but available for possible use by individuals that will be applying for AMP or RSO status via either the certification or the alternate pathways.

As those of you who have had anything at all to do with this process recognize, the current 313A tried to gather information for all pathways, for all individuals, and it is difficult to say the least to follow. The new 313As are broken down so there will be an individual form for those seeking RSO status, AMP status, AU status, etc. That should help considerably in making that pathway more viable.

Finally, NRC is continuing its discussions with the boards about either broadening their recognition times, as well, as we discussed, identifying earlier diplomates whose documented training and experience at the time they made application for certification satisfy the current requirements.

In fact, there was one additional thing, what's coming up. There are two things and that's why I called this a status report when I first started. The Commission will be receiving a paper soon providing a staff summary on the results of our actions, staff actions, to identify these problems relating to medical physicists and recognition under the new current 10 CFR Part 35.

The Commission will receive the paper and when they do there may well be something other than, "Thank you very much," that we get back from the Commission in terms of what we are doing, what they think we should be doing.

MEMBER WILLIAMSON: Are we going to see this paper?

CHAIR MALMUD: Dr. Williamson asked if he'll get to see the paper.

MS. WASTLER: At this point in time I

believe it's still with the EDO.

DR. ZELAC: That's correct. I suspect --

MS. WASTLER: It has not gone to the Commission to date.

DR. ZELAC: The Commission may choose to once it receives the paper permit publication or availability of it prior to any decision that it might make with respect to the paper as it did for the NARM rule.

MS. WASTLER: As we have with other documents, since it is a predecisional document, we can send you a copy for your information but you just have to remember that it currently is predecisional.

MEMBER WILLIAMSON: I think that's what I was asking.

MS. WASTLER: Oh, I'm sorry.

MEMBER WILLIAMSON: The ACMUI first could see a copy of the document.

MS. WASTLER: Yes, you may. Yes, you may. We will get you a copy of that. It's just fair to say that Ron's presentation today was basically a summary of that particular paper actually but we will get you a copy.

CHAIR MALMUD: Thank you. Does that

complete --

DR. ZELAC: And the last thing, of course, where we started, there will be action on the petition for rulemaking PRM 35-20 that was submitted by the AAPM with respect to revising 35-57, the grandfather provisions pathway. That will follow the process that I mentioned earlier. There will be due consideration including consideration of all comments that may be received once it is published in the Federal Register.

CHAIR MALMUD: Thank you, Dr. Zelac.

We actually have a representative here from the AAPM, Gerald White, who has asked for a few minutes to make a statement.

MR. WHITE: Thank you, Dr. Malmud. I'll try to make my statement brief. I apologize in advance to Dr. Zelac for a lack of diplomacy that is necessitated by the brevity. I have great respect for Dr. Zelac's work.

Grateful, actually, for his providing an extensive list of possible work-arounds for the problem, but I call to your attention that it's a mixture of hopeful speculation and staggering complexity and I ask everyone on the Committee to contrast that with the simplicity of the solution proposed in the petition for rulemaking.

In his first slide he talks -- in the second slide talks about establishing the 2005 date initially intended to allow practicing physicists to become licensed prior to the expiration of this old Subpart J. In fact, the duration of the process, the negotiating with the boards and such, took much longer than that.

If the process was important before 2005 to allow these physicists to be licensed, it is certainly important after 2005. I think that we should honor that. The agreement state issues were also not solved before 2005 and we did not anticipate the issue of the effective date problem.

I had been an attendee at a great many ACMUI meetings and I don't believe that was ever aired at a ACMUI meeting, this effective date issue. I don't think it was the intent of the ACMUI to have that problem arise, although I don't certainly want to put words in your mouth. I've heard other people mention that at this meeting.

MEMBER WILLIAMSON: Clarify what you mean by the effective date problem.

MR. WHITE: The effective date problem is diplomates of the boards were approved on a particular date and diplomates of the board prior to that were

not deemed to have the board's status.

I'll note that ACMUI meetings there were numerous discussions of how archaic certificates would be handled, certificates that were no longer offered by boards. It seemed to be the assumption that this was not going to be an issue, although it certainly has become an issue and I don't think it's likely to go away.

Dr. Zelac talks about the agreement states and a large number of the agreement states have begun to deal with this problem which is true and helpful. The mechanisms, there are 38 states. We have to follow these regulations in 38 different states.

How many of them are going to do it right? How many of them are going to be consistent with NRC regulations? What happens to physicists who move from jurisdiction to jurisdiction as these regulations are changing shape in different states? You might find yourself licensed in one state, move to another where you're not or vice versa.

What we need, and I think what this Part 35 was intended to do, was a uniform set of national criteria, high compatibility criteria for authorized medical physicists and RSOs. I also note that the NRC seems willing to accept AMPs and RSOs who are on

agreement statement licenses who don't meet the current NRC requirements, that an agreement state could accept board certifications going back to the beginning of the board.

That person could be licensed in an agreement state on that license and then get licensed in an NRC state but could not become licensed de novo in the NRC state. That just doesn't make any sense from a regulatory point of view and I think it's indefensible from a public safety point of view.

Dr. Zelac talked a little bit about the boards expanding their date range. Certainly for the American College of Radiology, as he acknowledged, that is highly unlikely. I'll mention a slide that the NRC is not aware of significant number of problems. I'll say to the credit of RSOs and medical physicists, one of the reasons that occurs is because we don't submit the license applications if we are not going to meet the criteria.

There are a great number of people who would like to be licensed and have not submitted applications because they don't feel they are going to meet the criteria. He notes that 5,000 of the 6,000 medical use licenses don't require the use of an AMP.

That leaves a 1,000 licensees who do. At

our AMP licensed institution we have four AMPs who practice actively and another three who are associated with other institutions. There are thousands of physicists who fall into this category.

The board certification serves as a surrogate for basic training. There is no doubt that the alternate pathway is available but it doesn't make any sense to go through that process. It's far more cumbersome than we might assume from the slides.

I have recently licensed several physicians under the alternate pathway because they fell into the notch and a 15-minute process has turned into, in one case for a board certified radiation oncologist who is faculty member at an academic institution, four months it took me and at least two days of full-time work equivalent.

Another physician, nuclear medicine fellowship trained, took three months to get all the documentation. It's a 15-minute procedure. It can be done. One can travel from Washington to New York by way of San Francisco and Seattle but it's not necessarily the best path.

I would also like to say that the burden should not fall on the boards to evaluate individual applicants to years past. There are thousands of

these people and the boards simply do not have the resources. We have discussed that with the boards and talked specifically to the ABR about the 2006 notch baby physicists and they are willing to look at those 120 physicists individually potentially but even that took great negotiation.

Let me also say that the RSO issue if it's to be solved by the pathway of getting on agreement state licenses will require the creation of the entity of alternate RSO so you can have more than one individual on the license.

This is a problem that is going to follow our people, not just for now, not just until you get on your first license, but for the rest of your career it's going to occur over and over and over again. What we need is to honor the board certification process of people who fell prior to the effective date and we don't see implications in public safety or radiation protection. We see it as an incredibly simply solution and we hope that the Committee will agree.

CHAIR MALMUD: Thank you. Any comments? Your comments have been heard, Mr. White. If we may, we'll move on to the next item on the agenda. Dr. Zelac.

DR. ZELAC: The only comment that I would make is with respect to the numbers. When I spoke earlier in the talk about perhaps a 1,000 licensees that fall in the category of needing AMP services, in the entire country including the 44 of the 50 states where medical physicists are recognized and are listed on licenses there are only about 1,000 units about 700 of them being remote after-loaders.

That is the current situation. It doesn't mean the things like gamma knife aren't going to increase but that is the situation we're in now. Most of the current users in terms of the medical physicists' names do appear on licenses.

Activities are not being affected significantly to our knowledge in terms of provision of medical services by the current rule, although, again, there is an issue and we are trying to deal with it.

MEMBER WILLIAMSON: I'm sorry for not waiting to be recognized but I would wager those 700 or 1,000 licensees probably represent the vast bulk of radiation therapy services which, I believe, according to current statistics is used in at least 60 percent of cancer patients who receive some form of radio therapy during their treatment course or history of

their disease so I would not minimize it. I think it's a substantial fraction of the market.

DR. ZELAC: I agree. The only distinction I was trying to make is between the numbers of licensees and the numbers of devices. There are only about 1,000 devices totally in the entire United States.

MEMBER WILLIAMSON: There are only about, I believe, 2,500 megavoltage beam devices in the country. This is, I think, still a substantial fraction if not a majority of all the radiation therapy facilities in the country.

CHAIR MALMUD: Thank you.

MR. ESIG: Mr. Chairman.

CHAIR MALMUD: Yes.

MR. ESIG: Just back to the agenda. Since we have Dr. Brown from the outside, I don't know if he's facing a time constraint. Is he or not? We can reverse the order of the presentations if you are facing a constraint. If not, I was going to suggest we go ahead with Cindy Flannery's presentation, take a break, and then, if it's okay with Dr. Brown, we would have him right after the break.

CHAIR MALMUD: We'll go ahead with Cindy Flannery's presentation followed by a break.

MR. ESIG: Did I hear an objection? Okay.

MS. FLANNERY: Okay. This presentation here is just an informational presentation to provide the status of the recognition of the certification boards, as well as to provide follow-on actions taken by the NRC staff to recommendations made by the ACMUI at the April meeting.

This is a list of the boards that are recognized thus far. I have mentioned previously there are nine specialty boards that have applied for recognition. Currently eight of those nine are recognized. The American Board of Medical Physics is still outstanding and NRC has requested some additional information from the ABMP and we are awaiting input from them. That status has remained unchanged for a little over a year.

This slide here is giving the exact same information but just in a different format. This was taken directly from our website. I realize it's difficult to visualize this on the slide so I have printed a full-page version that was handed out this morning as well as there is a copy in the back.

As I said, this is taken directly from the website so you can also get the information there. The only difference with the format here is that it is

listing the different sections of the regulations and the boards that are recognized for each of those sections.

The last two slides that I have here are related to the discussion and recommendations made by the ACMUI about contacting the boards. This recommendation was made at the April meeting. The recommendation was made back in April to send letters to the American Board of Radiology for two different specialties; that is, the radiation oncology as well as diagnostic radiology.

NRC staff has sent letters to those two specialties and we have taken a step further and also have sent a letter to the radiologic physics specialty of the American Board of Radiology. Prior to those letters being sent out, contact was made with the American Board of Radiology to also discuss the options.

I will talk about the radiation oncology specialty first. The reason why the radiation oncology specialty has a future effective date of June 2007 is because they had to make changes to the certification process under 390 to meet NRC's current T&E requirements under the board certification pathway.

The question is since they didn't have to make changes to the certification process for the 490 and 690 could they be listed with an earlier effective date. That question has been posed to the ABR.

They have indicated to me that, yes, they can give an earlier effective date but they are still determining what that date can be so we are waiting to hear back from them. But for the 390 the effective date will have to remain as of June 2007 because of the changes that they had to make to the certification process.

Now, for the other specialties, namely the diagnostic radiology, radiologic physics, and then the 390 of radiation oncology, these specialties had to make changes to their certification process.

The question has been posed to them what can you do for your diplomates to recognize those who got certified prior to the effective date. What we have discussed is having the ABR do a review of the qualifications of these diplomates on a case-by-case basis at the request of the individual.

If the board determines that this individual meets NRC's current criteria under the board certification pathway, then they would either issue an addendum to their certificate or issue a

letter of some sort that would serve the same purposes of the certificate which is to let the NRC know that they meet NRC's current T&E requirements.

The American Board of Radiology actually has a board of trustees meeting being held this month so they were not able to give an answer to provide any response until after that meeting but the feedback that we have received from them is that this is going to be proposed to the board of trustees meeting this month so all I can say right now is this is under consideration by the ABR.

That is all I have for the status of these specialty boards.

CHAIR MALMUD: Thank you, Ms. Flannery. Questions? Hearing no question, it's coffee break time.

MS. FLANNERY: Thank you.

CHAIR MALMUD: Let's please be back in approximately 12 minutes so 3:20.

(Whereupon, at 3:10 p.m. off the record until 3:22 p.m.)

CHAIRMAN MALMUD: Ladies and gentlemen, it is now 3:20, and we must get back on track again if we are to get out of here at the appointed hour; because if we stay too late, they will lock us in the

building, and we will be stuck here overnight.

The next item on the agenda as we move forward is the presentation by Chris Ghallager, the American Society for Nuclear Cardiology. I'm sorry, we have Ken Brown next. We moved the agenda a bit. Sorry. And, Ken, you are representing the American Society for Nuclear Cardiology?

DR. BROWN: Yes, I am. Thank you. Thanks for allowing me to be here. I promise my statement will not be more than really a few minutes. I'm hoping I can get some discussion.

The American Society of Nuclear Cardiology appreciates the opportunity to comment before the Advisory Committee regarding necessary training requirements for authorized medical users to serve as radiation safety officers.

As you may know, the American Society of Nuclear Cardiology is a greater than 5,000 member professional medical society which provides a variety of continuing medical education programs related to nuclear cardiology, develops standards and guidelines for training, promotes accreditation and certification within the nuclear cardiology field, and is a major advocate for furthering research and excellence in nuclear cardiology.

My name is Ken Brown. I am a past President of ASNC as well as a professor of medicine and Director of Nuclear Cardiology and Cardiac Stress Laboratories at the University of Vermont. I am also an authorized user.

The American Society of Nuclear Cardiology is here today, because we have heard from a number of our constituent nuclear cardiologists across the country who are extremely concerned over the new requirement that an authorized medical user must obtain written attestation signed by a preceptor radiation safety officer stating that he or she has the necessary radiation safety experience should that authorized user wish to serve as a radiation safety officer on their laboratory's license.

As you know, a critical mandate of the NRC is to regulate the medical use of radioactive byproduct materials in the field of nuclear medicine, radiation therapy and research, to ensure that both patients and health care workers' health and safety and protected.

While no one can argue against being too cautious when it comes to radiation safety, the American Society of Nuclear Cardiology is concerned that the NRC is interpreting and implementing this

specific radiation safety officer requirement in a manner that is in direct contrast to previous long standing Commission policy on this issue.

For years, authorized medical users involved with diagnostic procedures, those that involve the relatively small amounts of radioactive materials to facilitate imaging of bone, heart, and other organs, have allowed to function as both an authorized user and a radiation safety capacity.

Nuclear cardiologists seeking authorized user status under Section 35.290 for diagnostic purposes must complete 700 hours of training, including radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use in radiation biology.

In addition, nuclear cardiologists are required to know about ordering, receiving, unpacking radioactive materials safely, and performing the related radiation surveys, performing quality control procedures on instruments used to determine the activity of doses, and performing checks for proper operation of survey meters, calculating, measuring and safely preparing patient or human research subject

dosages, using administrative controls to prevent a medical event involving the use of unsealed byproduct material, and using procedures to safely contain spilled radioactive material, and using proper decontamination procedures, administering doses of radioactive drugs to patients or human research subjects.

Nuclear cardiologists that choose the certification pathway must complete a minimum of four months of specialized training in this specialty and pass a rigorous examination administered by the Certification Board of Nuclear Cardiology, CBNC, which devotes roughly a third of its exam questions to radiochemistry, instrumentation, and radiation safety issues.

The American Society of Nuclear Cardiology, which is a co-sponsor, is proud and pleased that the Certification Board of Nuclear Cardiology is one of the first boards to be recognized by the NRC under the revised Part 35 regulations for satisfying the Commission's 35.290 authorized user requirements.

The second concern of ASNC revolves around the practicality of having authorized medical users obtain a preceptor statement from a radiation safety

officer. The preceptor statement required for Board eligibility or the statement required for those individuals applying on the basis of training and experience -- the criteria is adequate documentation for this purpose.

We believe that the end result of this additional preceptorship requirement would be limited patient access to nuclear diagnostic imaging, particularly in small facilities in suburban or rural areas where it is just not feasible or financially possible to employ a full time radiation safety officer, as is the case a large urban or university multi-modality facility. Should this requirement continue, it is likely that patients will have to wait longer, travel further to receive these critical diagnostic services.

Finally, ASNC believes that this additional mandate possibly resulted from a clerical error between the December 9, 2003 proposed rule and the drafting of the March 30, 2005 final rule. In reviewing transcript of past ACMUI meetings as well as the language of the 2003 proposed rule, ASNC is fairly confident that members of the ACMUI did not intend for authorized medical users in the 35.290 category to secure an additional preceptor statement from a

radiation safety officer to serve in this capacity.

Thank you for allowing me the opportunity to present this important issue before the Committee, and I would be happy to answer further questions.

CHAIRMAN MALMUD: Any questions for Dr. Brown? Dr. Van Decker?

MEMBER VAN DECKER: Maybe I can just start out with a clarification for the Committee practicing in this realm.

I think, if everyone harks back to Subpart J, which was the rule of the land for decades, one of the sub-clauses for becoming a radiation safety officer was being an authorized user on the license in the modality with which you had appropriate training and experience, and somehow that "or" clause has been lost in the current revised 35, such that somebody in a very small outpatient operation with limited employees dealing with very low level materials essentially would need to have a preceptor statement from both an authorized user training them and from a radiation safety officer in addition, to be able to serve both functions.

Obviously, that becomes a lot more prescriptive in what we are trying to accomplish. I think, if I remember back to when all this started in

1996, the goal was really to be less proscriptive and more risk based. The current requirements certainly make it more difficult for diagnostic people to be involved in this type of setting in the smaller areas.

Obviously, not every authorized user wants to be a radiation safety officer. I could tell you, at Temple I am glad that Lily is around and it is a large modality set-up, but I think on an access to patient care, where we are trying to create a wide variety of venues in the United States, that there has to be some flexibility in how we allow this to occur.

You know, I think that Ken's appearance here has been generated by some phone calls. We are talking about who are people who have been denied. There actually have been instances of authorized users denied the ability to be RSOs at very small facilities because of the current wording of the rule.

I guess the question being brought up here is was that indeed the intent. You know, what was the transformation between the proposed rule and the final rule where that clause got lost, and what are possible ways to be dealing with that, if indeed we see that as a national access issue to some of the diagnostic studies?

You know, I don't see this as just a

nuclear cardiology perspective issue. I see this as a general radiology issue and a general nuclear medicine issue out in the community as well. I think it goes across all the authorized user providers in the 100 and 200 classes.

You know, certainly, I would be the first one to tell you that I look at therapeutics a lot differently than I look at the diagnostic realm, but I think that this discussion was just meant to generate people's thoughts in how the rulemaking pizza got made and how we are where we are now, and is this an issue for the future.

Obviously, if you look at the training programs right now, if you look at me as an authorized user being involved in people's education, you know, I am certainly not the institutional radiation safety officer. Dr. Vetter is a radiation safety officer who may be seeing a large number of people involved in training as authorized users, and how we put all of that together so that the right thing gets done, I guess, is a part of the question.

CHAIRMAN MALMUD: Dr. Eggli?

MEMBER EGGLI: I think the issue of the attestation has become a very personal one for the attestor. The radiation safety officers authorized

users are reluctant to do this on behalf of an institution for someone that they do not have detailed personal knowledge of the competence of the individual, I think, which is where the authorized users who want to perform radiation safety functions in small practices are running into a problem, is finding an authorized RSO who knows them and is aware of their level of competence well enough to be willing to assign an attestation.

I think, since the new rule went into effect in October of 2005 in the final version, individual preceptors feel that there is an increased legal burden to that attestation than there previously was in a preceptor statement which sort of detailed the previous experience.

We know say -- Effectively, we say I personally know this person; I personally know what they can do, and essentially I accept responsibility for them. You are going to find that there are a whole lot of authorized individuals out there, whether they be authorized medical physicists, authorized radiation safety officers, authorized users physician-wise, who are just not willing to put their signature on that piece of paper.

I agree with the comments made, that in

small freestanding practices there is going to be a problem.

CHAIRMAN MALMUD: You are agreeing with Dr. Brown and with Dr. Van Decker?

MEMBER EGGLI: Yes, indeed.

CHAIRMAN MALMUD: Thank you. Dr. Vetter.

VICE CHAIRMAN VETTER: Well, I would also agree with him. Coming from a training program where residents go through four years of training, they are around a long time, but they spend very, very little time with me. I mean, I interact with them a matter of hours. They go through some formal training which my staff interacts with them as well, but again it is only a matter of hours for each of them to interact with these residents. At the end of four years, I don't know them.

If I were to sign an attestation statement, almost certainly it would have to have been pre-signed by the preceptor, who can guaranty to me that, in fact, they would be a good RSO. So the whole thing is really rather problematic.

I'm sorry. Then just to tag on there, for most residents they are not interested in becoming a radiation safety officer when they leave. They don't care, but every now and then one will call back and

say I just joined a practice, we need an RSO. In the past that's not been a problem. We go rescue their preceptor statement, which they had left a copy in the graduate school. We make sure it is okay, and we can help them out. But today, that is a little bit different.

CHAIRMAN MALMUD: Thank you. Mr. Lieto.

MEMBER LIETO: We don't have a training program at the institution I'm at right now, but I would like to kind of, first of all, agree with my colleagues and Dr. Brown in that this is an issue.

I think, in some of the previous submissions it has been indicated that these are not problems that occur. What happens is that these fellows do not submit applications. They find work-arounds.

One of the work-arounds is that they will hire consultants to be named on the license. Now I guess I would have to ask the NRC, is it better to have someone who is on site who is using the materials as the RSO or somebody who is geographically removed and not on site to be the RSO?

I would also ask the question, in that if you are willing to approve them as an authorized user for those uses, why wouldn't you consider them to be

competent enough to be the RSO for those same types of uses?

I think this process of approving them as a user and then they have to come back and then resubmit as an RSO is really a bureaucratic waste of everybody's time, the regulatory staff in having to do amendment changes, as well as the people making the application.

CHAIRMAN MALMUD: Thank you, Mr. Lieto. Other comments? Once again, Dr. Brown, thank you. Oh, I'm sorry, I didn't see your hand up. Dr. Nag?

MEMBER NAG: Can I make a motion -- Well, maybe I will make another motion.

CHAIRMAN MALMUD: Thank you.

MEMBER NAG: I would like to make a motion that the officials in the NRC consider that, if someone is an authorized user, that person can automatically serve as an RSO -- authorized user or AMP.

CHAIRMAN MALMUD: There is a motion by Dr. Nag that an individual who is already an authorized user or AMP be automatically qualified to be an RSO.

MEMBER EGGLI: I would like to offer a modification to Dr. Nag's amendment, and add in there "for Part 190 or Part 290 uses." I would second his

motion.

CHAIRMAN MALMUD: Is that agreeable to you, Dr. Nag? For Part 190 --

MEMBER EGGLI: And 290 uses, which are the very low risk uses.

MEMBER NAG: Okay. No, but what would happen then for Part 390 and 490? There would have to be a separate RSO? Can you clarify what you meant?

MEMBER EGGLI: From my point of view, I guess I deal with the work I do. For at least Part 190 and Part 290 users, those are very low risk, and any authorized user should be able -- again, when you do risk informed evaluation, should be able to be an RSO for those uses.

I guess I might go as far as to do something similar for 390, although I worry a little bit more about that. For 490, I would ask Dr. Vetter to address the question of whether any AU should be an RSO for 490 or 690 uses, and he is shaking his head, no.

DR. VETTER: Just briefly, my personal recommendation would be to support the motion as amended, because 190 and 290 are what we have considered to be low risk uses, but not support it for 390 or 490. These are therapeutic uses. I wouldn't

support that.

MEMBER NAG: I agree with the amendment.

MEMBER EGGLI: And then I will second Dr. Nag's motion as amended.

CHAIRMAN MALMUD: So there is a motion that any authorized user or AMP is qualified to be an RSO for 190 and 290 uses.

MEMBER EGGLI: If they are an authorized user.

CHAIRMAN MALMUD: If they are an authorized user.

DR. HOWE: Dr. Malmud.

CHAIRMAN MALMUD: I'm sorry.

DR. HOWE: This is Dr. Howe. Once you pass on that, I'd like to ask if you would consider the ANPs to be in that category also, the Authorized Nuclear Pharmacists.

CHAIRMAN MALMUD: All right, we will consider that next. Dr. Vetter?

DR. VETTER: This wouldn't exempt them from being -- from having to meet other parts of 3550, such as, in addition, they have to have appropriate radiation safety training to do that material. It's just basically eliminating the preceptor statement for 190 and 290 for RSO.

CHAIRMAN MALMUD: There is a motion which has been seconded. Is there discussion? Dr. Williamson.

MEMBER WILLIAMSON: Well, I am wondering about eliminating the preceptor for the ANP as well to be an RSO. I think the same sorts of arguments can be made, although our community is somewhat smaller, but finding an RSO is not always straightforward, even for a physicist.

MEMBER SCHWARZ: And as Donna-Beth suggested, for the Authorized Nuclear Pharmacists as well, they are essentially are completely trained to be able to handle these situations.

MEMBER EGGLI: I would certainly accept that as a modification, as the second.

MEMBER WILLIAMSON: So perhaps we should just generalize it and say drop the preceptor statement entirely from 3550.

MEMBER EGGLI: For 190 and 290 uses.

MEMBER WILLIAMSON: For everything.

MEMBER NAG: I think the problem was, if someone is an authorized user for 290 and --

MEMBER WILLIAMSON: The preceptor statement doesn't solve that. There are separate requirements, you know, already that I think basically

would limit the authorized person. It is to practice only in certain areas. So I think that that is the -- The preceptor statement is not what is preventing a 190 or 290 authorized user from being a Radiation Safety Officer for radiation therapy.

CHAIRMAN MALMUD: It's the attestation?

MEMBER WILLIAMSON: The attestation. Yes, it's solely the attestation that is preventing it and not the requirement that the authorized personage can be an RSO only in the areas in which they have experience?

MEMBER VAN DECKER: Only in the area in which they have experience.

CHAIRMAN MALMUD: I'm sorry, Dr. Van Decker. I didn't hear you.

MEMBER VAN DECKER: I was agreeing with Dr. Williamson's clarification, that it is in the modality in which you have training and experience to be an authorized user.

MEMBER WILLIAMSON: That was a question, actually, on my part. Doesn't the regulation as written require that as a condition as well for all the different pathways.

CHAIRMAN MALMUD: The answer to Dr. Williamson's question was yes.

MEMBER WILLIAMSON: So, therefore, we can drop -- We can change the motion to -- So I would propose we amend the motion to the following: The ACMUI recommends that the attestation statement requirement be dropped from all pathways leading to qualification of an individual for radiation safety officer.

CHAIRMAN MALMUD: That's a motion. Is there a second to that motion?

DR. VETTER: Second.

CHAIRMAN MALMUD: It has been seconded by Dr. Vetter, and Mr. Bailey had his hand up.

MEMBER BAILEY: I guess I'm getting sort of wrapped around the axle about the idea. Preceptor statements are attestations for non-practitioners. The preceptor statements used to be sort of a way that we as regulators who were not licensed to practice medicine got out of evaluating the medical qualifications of an individual.

We always felt that we were competent to evaluate the radiation safety training, because most of us had received training in that area, but we realized in most cases we did not have physicians on our staff to evaluate the physicians coming in, and we used the preceptor statement simply to say, okay, his

colleagues, his peers, so forth, have said that this person knows how to practice the medicine.

I think we've gone way beyond that now in all of having preceptor statements for all of these other positions and attestations for them.

CHAIRMAN MALMUD: Having said what you said, Mr. Bailey, are you supporting the motion?

MEMBER BAILEY: Yes.

CHAIRMAN MALMUD: It's been a long day.

MEMBER BAILEY: Obviously, it was not clear.

CHAIRMAN MALMUD: No. It may have been that I didn't hear well. All right. So there has been a motion and seconded. Dr. Vetter?

DR. VETTER: And just to clarify, the current motion is simply eliminating the attestation. It is not eliminating the preceptor statement. That is the documentation that training occurred.

MEMBER WILLIAMSON: That is correct.

CHAIRMAN MALMUD: There is a motion that has been moved and seconded to eliminate.

DR. BROWN: Could I just ask for a clarification. You are saying that -- Nobody is disagreeing that they have to meet certain qualifications, but you are agreeing that the

attestation letter is not necessary. Is that --

MEMBER WILLIAMSON: That is what we are recommending.

DR. BROWN: That's what we were proposing.

MEMBER WILLIAMSON: For all of the pathways to being an RSO, not just the authorized user one.

DR. HOWE: Dr. Malmud, this is Dr. Howe.

CHAIRMAN MALMUD: Dr. Howe?

DR. HOWE: Could I get a clarification. When Dr. Williamson says all the pathways, is he talking about the board certification pathway for normal health physicists and the alternate pathway for the RSO or is he just talking about 35(c)(2), which is the pathway for authorized users, authorized medical physicists, authorized nuclear pharmacists, to be RSO?

MEMBER WILLIAMSON: I was speaking of all pathways.

CHAIRMAN MALMUD: Dr. Williamson is speaking of all pathways, essentially that the attestation requirement be deleted. So there is a motion on the floor which has been seconded. Any further discussion of it?

If not, all in favor of that motion, that the attestation requirement be deleted? Any opposed?

Any abstentions? Motion carries unanimously as a recommendation to the staff. Thank you very much, Dr. Brown.

DR. BROWN: Thank you.

CHAIRMAN MALMUD: If we may, we will move on to the next item on the agenda, which is the interim inventory and national sealed source tracking. The presenters will be Paul Goldberg and William Ward.

Excuse me. Mr. Lieto.

MEMBER LIETO: There is some confusion on this side of the table as to the attestation statement. It was the understanding that this applied to RSOs for 100 and 200 uses. Is that correct?

MEMBER WILLIAMSON: All uses.

MEMBER LIETO: I think we just -- I think we are going to run into some problems with that, because basically what you are saying is that, for anybody to become an RSO, they don't require a letter of attestation, which basically means you don't have to comply with the rule.

MEMBER WILLIAMSON: No, no, no.

DR. VETTER: Under the motion, the NRC would still enforce the rule. They would still have to have appropriate training. It's just that no one -- The preceptor at the institution would not have to

sign an attestation. So the RSO -- So, for example, the RSO will not have to sign that the authorized user would be an appropriate radiation safety officer. The NRC would evaluate that individual's training and determine that on the basis of the training.

MEMBER NAG: And again, for the modality for which you have been trained -- that itself, that is what Dr. Williamson said.

MEMBER LIETO: I just don't want it to jeopardize what the original intent was, which is that the 100 and 200 users, which are the low risk ones, where the problem really exists in large numbers.

MEMBER WILLIAMSON: I think that -- If I could speak to that, regardless of whether the motion has a narrower scope or broader scope, no pun intended, I think it would involve a rule change. So, basically, implementation of our suggestion at any level requires the rule to be changed, simply that.

I think I was fully aware of that, and the recommendation doesn't mean violate the rule. It is a recommendation to NRC to change it.

CHAIRMAN MALMUD: Thank you. In the interest of time, we will move on. It's Paul Goldberg and William Ward. Mr. Ward will go first.

MR. WARD: Good afternoon. I am William

Ward. I am going to go first on this. I am going to go kind of fast to try and gain back a little time for you and, of course, there is the chance to catch up with questions at the end.

There's going to be a little bit of assumption that you are somewhat aware of some of the things that are going on. If not, let me know at the end.

In the past we have been -- past three years, we have been doing an interim inventory of radioactive sources. The reason for this is that we have an interest in eventually tracking IAEA Category 1 and 2 sources, and in order to gain data on that and be able to design a system that Paul is going to talk about later, for the last three years we have been doing an interim inventory of sources, contacting NRC and agreement state licensees to find out what sources they have and information about the sources.

So the first year was Fiscal Year 2004, and we repeated it in 2005 and 2006, and we are about to start Fiscal Year 2007. 2007 will be a little bit different than the previous years, and I'll go into that in a second.

A little bit of background: The initial impetus for this was a working group between NRC and

DOE where we evaluated the radiological dispersal devices, the risks proposed by them, and one of the recommendations out of that working group was to develop a national source tracking system of high risk sources and, in order to develop that system, do an interim inventory.

The initial thought was it would be a one-time-only inventory. We later, per Commission direction, went on to perform the inventory every year. Later, the IAEA issued a Code of Conduct, and as part of that there was a new list generated, and in the interest of international cooperation and trans-boundary issues, NRC and the U.S. government adopted the IAEA list. So that was the major change.

We developed the interim inventory, and we have been doing it annually, as I mentioned. It provides a snapshot of high risk sources. In other words, what the licensee submits on the day they present the information -- that's what they have. We don't track. They don't tell us they gained a source or they lost a source over the next year. On the day that they submit the information, that's what they have. So we know what each licensee has on the one day that they submit.

It includes NRC and Agreement state

licensees and, as I said, it is only category 1 and 2. From a medical perspective, the most likely sources to be included a teletherapy sources, blood irradiators, and gamma knives.

Currently, we have -- We have about 2300 licensees that we contact, about 1400 of which actually possess a source, at least one source. But we contact those that are authorized to possess sources. So we find out every year, because as I said, it's a snapshot. They may or may not have one at the time that they put the data in.

We update annually. I keep saying that. We have also used the database not only for designing the National Source Tracking System, but it has come in handy for the recent hurricanes in 2005 where we wanted to make sure that all the high risk sources were accounted for.

There are other instances where law enforcement or FBI, etcetera, have some knowledge of something, and they just want to make sure that all the sources in a particular area may be accounted for. So we have used it as well for law enforcement.

It was also -- This list was used as a base list for the recently issued Increased Controls orders. When we developed the list, we based it on

what licensees authorized to possess Category 2 quantities, and that was the base for the orders that were issued.

As I said, there's about -- Well, in Fiscal Year 2004 we contacted about 2600 licensees, and we had all but five of our data. That particular year, we also did some aggregation of Category 3 sources. There was some confusion about the aggregation process, and it didn't work out very well. Being the first time around, the data was a little bit suspect in various ways. There were some people that didn't take the inventory very seriously.

We also had questions that year on import/export and disposal plans. That was to satisfy planning for the import/export rulemaking that our Office of International Programs did, and also some questions that Department of Energy had about potential disposal.

In FY '05, we contacted about a little over 2300. We had all but six respond. We had streamlined the process. We got rid of some of the questions. We no longer did aggregation of Category 3 sources, and we used a streamlined process where we had a simple web based interface where people could enter data. Most licensees chose that. If they

wanted to use a hard copy,. they could mail in the form that we sent them.

We mailed everybody, using FedEx or Certified mail with their user name or password so they could enter the data, and there was a hard copy provided that, if they wanted to use that method, they could FAX or mail back the hard copy, and we would enter it manually.

FY '05 was the second time around, and the data was much improved. There was a lot of ways I could cross-check the data internally. In the end, we ended up with about 16,000 source reports, and I say that because, for example, a gamma knife with 201 sources, we allowed that to be reported as one source, although we know it is 201, and we just had the total quantity.

Similarly, for the large industrial irradiators that could have anywhere from 400 to 1,000 sources, and they didn't have to report all the sources. They just reported it as one large source, told us how many pencils they had. So when I took that data and broke it down, there were about -- a little over 48,000 Category 1 and 2 sources. We had about 16,000 source reports. I won't go into much more detail.

I am going to go quickly. You may have seen these before but, hopefully, the slides you have have it a little bit better, but these show some of the data screens. The first one is the basic name, address, phone number, contact information that we have. That allows us to send out the packages each year.

We also had a question about the basic business type, and it helped me to do some cross-referencing, cross-checking of data internally.

The second screen gives you an idea of the way the sources are listed in the system. We have the isotope, the activity, manufacturer of the source, the model number of the source, serial number, and then date of activity. That allowed me to do DK calculations, and the manufacturer, model number, along with the business and sometimes the business name allowed me to do the cross-referencing of data for internal checking.

This is a screen that shows how that data that was presented in a previous screen was actually entered. Some of the screens had dropdown lists -- for example, the activity type and things like that.

In 2006 we used the same process we used in 2005, and my initial look at the data is that it is

fairly similar to what we had in 2005. I haven't had a chance to analyze it. We just closed it a couple of months ago, and we have been working toward opening up for 2007.

In 2006 we had a few more licensees. We contacted a little over 3,000, and in 2005 we had not quite 16,000 source reports. In 2006 a little over 17,000.

Response rate was a little bit lower this time. We had two state agencies that were going to contact their own licensees and enter data, and they did not. So their rate is a little bit lower, and we are going to make sure we get their data first in 2007.

One major change in 2007 is the Commission has directed that we contact licensees down to what we call Category 3.5. Now Category 2 was the threshold previously. Category 3 is one-tenth of that. Category 4 is 1/100th of Category 3. The Commission has chosen 3.5, which is one-tenth of category 3 and is 1/100th of Category 2. It is significantly lower than what we have been doing before.

There's going to be quite a few more licensees that we need to contact, and certainly more source reports in the system.

Because of the level, we are not forgetting about generally licensed devices. There aren't really any in medical use, but there is another group of licensees that NRC and Agreement states have to deal with, and that information we are going to obtain directly from the various general license tracking systems that the states or NRC have. So we won't be contacting any of those licensees.

Now how does it affect medical licensees? I think brachytherapy is the biggest new category that is going to be included when we go to Category 3.5. So there will be medical licensees added primarily because of brachytherapy.

The purpose of going down to Category 3.5 is to (a) consider adding Category 3 to the National Source Tracking System, which Paul will talk about in a second, and (b) it is because we are considering tightening the general license regulations.

That was very fast, I know. Hopefully, I have covered the high points. Anybody have any questions at the moment? If not, you can -- you will have a second chance after Paul talks to ask either one of us.

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: You said 3.5 was one-tenth

of Category 3. Did you mean ten times the limit?

MR. WARD: No, one-tenth. It is going to be a lower threshold in terms of activity.

MEMBER BAILEY: Okay.

CHAIRMAN MALMUD: Dr. Vetter.

DR. VETTER: While they are getting the next set of slides up: If you go down to Category 3, you may capture a number of cesium inventories that are sitting out there in safes that aren't being used anymore. I don't know how you would do this, but I would encourage the NRC to explore some mechanism to help medical licensees dispose of those sources.

MR. WARD: We are planning to ask a question about disposal plans in this next round. There are some initiatives being considered concerning cesium sources in particular and sources in general, and Department of Energy has some things that they are considering. So we hope to take that data back and share it with Department of Energy. I'm not sure what will come of it.

CHAIRMAN MALMUD: We have a question from the floor.

MS. FAIROBENT: Yes. Lynn Fairobent with APM. Dr. Vetter, we are working with the Conference of Radiation Control Program Directors and DOE LANL

right now on a new program called Scatter, which DOE is funding and the contract either has just been signed or will be signed shortly between CRCPD, and the intent of that is to be able to geographically aggregate these sources that are below the threshold for the Orphan Source Recovery Program right now, and in a region collect all of these sources that have been involved.

The other thing APM is doing is we are also working with the Department of Homeland Security to look at a grant separate from the CRCPD to supplement that one in order to perhaps move these from Commerce at a quicker basis to the Nuclear Sector Coordinating Committee on Radioisotopes.

CHAIRMAN MALMUD: Thank you. We will move on to the next presentation by Mr. Goldberg.

MR. GOLDBERG: Okay. I will discuss the National Source Tracking System. I am Paul Goldberg.

Bill has gone over some of this information already. So this should be pretty quick, but please let me know if you have questions as we go over it.

The background: As Bill mentioned, these sources for the Interim Inventory in the National Source Tracking System, the Joint NRC/DOE report, and

the IEAEA Code of Conduct. There is also the Energy Policy Act where the Source Tracking System is concerned, which codified the requirement for the rule and did place some requirements on the system and gave us certain additional isotopes to include.

Bill has discussed the interim inventory. You know about that.

We have tried to cooperate with a variety of agencies, including the states, other Federal agencies, to design the Source Tracking System. We had a working group that included NRC, DOE and agreement state membership. We had a steering committee involving NRC, DOE and the agreement states.

The system will be designed mainly to provide information for NRC, for DOE and for other Federal agencies and for the agreement states. Licensees will be able to use it in some cases to keep track of their own inventory. It may be useful to some extent for those purposes also

The system will include sealed sources from NRC and agreement state licensees and the DOE facilities. It is intended to be a comprehensive, nationwide system. There may be some sources that move between NRC and the -- excuse me, between DOE and the commercial sector, and we want to be able to keep

track of those, too.

For the most part, it won't include special nuclear material, with a couple of exceptions. The aim is to have a life cycle account of each source. It will track transactions of the sources from their origin, which would be creation/fabrication of the source, or import, to disposal, export, destruction in some cases of the source.

These are the isotopes involved. There are not too many that are of interest for medical purposes. Bill discussed gamma knives. Of course, teletherapy and irradiators are of indirect interest, also for blood and for sterilization.

These are the transactions that we expect to capture: Manufacturer, transfer, receipt, disassembly and disposal. The tracked sources are the same ones Bill mentioned, IAEA Category 1 and 2 with a couple of additions, a few additions that the Commission wanted to include, particularly for DOE.

One of the requirements is that to be able to track these is that manufacturers must assign a unique serial number. In some cases, older sources do not have a serial number or, in some cases, they have a serial number that is not legible. That may pose a bit of a challenge.

The aim is to improve accountability of these sources, which are of concern for security purposes, and give better information to decision makers. The information as it is aggregated in the system will be considered Official Use Only, in NRC's term, security related information, and licensees are obligated to handle it that way also.

The system is designed to be relatively user friendly. It will be primarily web based, the reporting, and most of the viewing of the system will be done over the Web. We will have additional options for reporting and a Help desk will be available.

The proposed rule was published. The final rule will be published sometime this year. We've got a contractor working on development of the system. We expect to have workshops for licensees to train them in the use of the system, and we expect operation sometime in 2007, and with a second phase that will have additional user features being issued by summer 2008.

That's all we have on the National Source Tracking System. Are there any questions? Yes?

MEMBER WILLIAMSON: Yes. What are the levels of interest or thresholds for iridium-192 and cesium-137 at the, I guess, 3.5 level?

MR. WARD: For iridium, the current Category 2 threshold is 21.6 curies approximately. So it is about 1/100th of that, so 216 millicuries.

MEMBER WILLIAMSON: For 3.5?

MR. WARD: For Category 3.5, yes.

MEMBER WILLIAMSON: I thought you said it was a tenth.

MR. WARD: It is a tenth of Category 3. It is 1/100th of Category 2. Category 2 is the current threshold, and that is 21.6 curies. Category 3 is 1/10 of Category 2. Category 3.5 is 1/10 of Category 3.

MEMBER WILLIAMSON: What about iodine-125?

MR. WARD: Iodine is not one of the isotopes of concern.

MEMBER LIETO: What would the radium be at the 3.5 threshold?

MR. WARD: Iridium?

MEMBER LIETO: Radium.

MR. WARD: Radium. I think that is 16.2. So it is about 162 millicuries.

MEMBER LIETO: I thought 11 was Category 2.

MR. WARD: For radium? Okay.

MEMBER LIETO: Radium was 11.

MR. WARD: So it would be about 110 millicuries, if it is 11.

CHAIRMAN MALMUD: Does that complete your presentation?

MR. WARD: Yes.

CHAIRMAN MALMUD: Thank you very much, Mr. Goldberg.

If we may, we will move on to the next item on the agenda, which is the status of medical events. For that, we have both Donna-Beth Howe and Ralph Lieto.

MS. WASTLER: Donna-Beth, could I ask you maybe to go from the slides. We are having a PowerPoint problem. So it is actually not operator error. There is some kind of issue with the software, and so we are not sure why. So if you could just go ahead and talk from the slides, and we will try to catch up.

DR. HOWE: That's what I was going to do. I am going to be talking about the status of medical events, and Ralph will be talking about the status of other reportable events from medical use licensees.

The first thing I wanted to do is -- I gave a status report at the last ACMUI meeting where we all got together, and that was essentially the FY

2006 half-year point. So I thought I would just throw this slide up as a reference point to start and to show how we ended up at the end of the Fiscal Year.

The major differences are that we went from 02000 35.200 which are the Diagnostic Administration's medical events to three, and we had a greater variety of 35.600s in HDR, and I specifically bought out the mammosite, because we seem to have a number of medical events that involve the mammosite. They are not necessarily specific to the mammosite this time as they are to treatment planning programs and coordination between treatment planning programs and computer systems in the HDR, and then also we had two gamma knife experiences.

So if we are looking at the 35.200s, it is not a surprise that all of our 35.200s involved I-131 and cases where diagnostic procedures were prescribed, and the greater than 30 microcurie activities were administered.

In a number of cases you had failure to follow procedures. You had an endocrinologist ordering 5 microcuries, and then it just says a physician -- it came from the agreement states; we are not sure who the physician is -- then ordered 2 millicuries, and then the 2 millicuries was given.

We also had a physician that intended to give 10 millicuries but wrote 10 microcuries. So those are our diagnostic medical events.

For the 300, we are starting to see -- And of course, the 200 ones we've seen a trend in before, and we have an information notice that we are getting ready to go out with that may include some of these, making licensees aware of checking for written directives if you measure greater than 10 milli -- 30 microcuries in the dose calibrator and making sure that you give what you intend to give.

For the 35.300, what we are beginning to see is a lot of capsules left behind in the vials, and it appears as if people are dumping the vials upside down. They are giving people the capsules, but the capsules are sticking to the vials, and they don't find out that they are in the vials until they go back to the pharmacy.

In one case, we had a situation where the pharmacy providing the capsules was not the normal pharmacy providing the other unit doses. So it was kind of a second tier pharmacy, and they let the original pharmacy know there was a problem, but the original pharmacy didn't get back to the medical use licensee, and a month later they had another medical

event. We believe that the pharmacy had made the right effort to get back to the medical use licensee. The licensee could have corrected its programs and prevented the second medical event.

The first case that you see here is a patient intervention. That was a case in which there was an elderly patient that didn't want the procedure. The procedure was given. The technologist gave the patient the pill, gave him water, watched them drink the water, and then about two weeks later found out that the family found that the capsules was underneath the sofa cushion that the patient sat on for hours every day, and that the patient had put the pill in their shoe on the trip home from the hospital to their residence, and that was several hours. So the source was sitting on the patient's skin for about four hours and delivered a hefty dose to the foot.

So we gave that patient intervention, but it looks like there will be probably some permanent tissue damage to the patient because of the very high exposure to the surface of the capsule. That particular licensee is going to be a little bit more careful about the elderly patients that have dementia to make sure that pills that are given are actually ingested. So that was one of our reportable events.

Ralph, did you have a --

MEMBER LIETO: It was just the one where they found it under a pillow?

DR. HOWE: They found it under the cushion of the sofa, yes, weeks later.

We actually had a Samarium-153. It was from the agreement states. We don't have a lot of information on it. Most of our Samarium-153s have to do with medical use licensees that believe they can measure the Samarium better in their dose calibrators and, in fact, they cannot, and they don't go with the manufacturer's number, and they end up giving significantly less dose than they are supposed to.

So those are our 300s. For the 400s, we basically have two groups of patients. We had eight cases. We had a total of 14 patients involved. One case involved five patients. Two of them, I think, involved two patients each.

The gynecological ones, we ended up with the wrong seed activity being selected or the wrong source-bucket combination where the sources just weren't compatible and, therefore, didn't put the dose in the right location.

For the prostate, we had two wrong sites. We are continually seeing problems with physicians

interpreting ultrasound images, and that seems to be reoccurring.

We are also having problems with the fact that many of these treatment planning programs are in air kerma, and the orders are in millicuries, and then the information getting put back into the computer systems gets put back in the wrong unit. Since we are seeing quite a few of those cases, we are actually thinking about developing an IAN with respect to that to make the medical community aware.

MEMBER NAG: I'd like to make a comment there. Many of the manufacturers -- Some of the manufacturers only accept orders in millicuries, whereas the treatment planning -- Most of the modern treatment planning softwares are in air kerma, and I think NRC has to give a strong recommendation to the manufacturers to be able to accept -- You know, when we tell them that we are going to order in air kerma, they say, oh, no -- I think you need to send a strong statement there.

DR. HOWE: I'm not sure exactly what strong statement we are going to send, but we are going to make everyone aware of the problem of ensuring that they are looking at the right units and that they are putting the right units into the

programs, and they are ordering the right materials, and that they are checking things when they come back.

For 35.600 we ended up with a number of errors that were based on either delivery tubes or catheter lengths not being the lengths that they were expected to be. So we ended up with a lot of -- with a number of medical events to the wrong site.

We ended up with three mammosites. We have seen a number of mammosites earlier. Most of these, though, appeared to be more of getting information from treatment planning correctly into the HDR computer software in that transition phase between putting in information parameters.

In the past, we have seen the mammosite problems be associated with fluid build-up around the area and then aspiration to remove the fluid, and then rupturing the balloon and, therefore, not getting the right dose.

MEMBER WILLIAMSON: Is this because the mammosite treatment time calculations are based upon a manual kind of milligram? Do manual programming -- I mean, what is the reason for the problems in transferring information for this particular clinical scenario?

DR. HOWE: I have to look a little more

carefully. Let's see.

MEMBER NAG: And why mammosite --

DR. HOWE: Mammosite is one, but we have been noticing that it is a fairly new device, and we have in the past had more problems that were associated with the use of the mammosite versus the HDR. It appears like most of these are HDR problems that happen to be mammosite.

So we have a sensitivity to the fact that people were having difficulty with this device.

MEMBER NAG: Perhaps one of the reasons for that is many of the people who are doing mammosite are very new to HDR. Other people who have been doing HDR have been doing HDR for years, and therefore, they are familiar with it, where many of the new mammosite users are new to HDR. So I think it is more a question of their being new to HDR than mammosite being the problem.

DR. HOWE: In the last group that we looked at, it was more of a physical problem with the mammosites, because they were deflating the -- They were puncturing the balloons and, therefore, the seed was not in the center where it was supposed to be.

In this one we had, they blamed the treatment planning for the fractionalization problems.

They stopped the -- They had the wrong length catheter. So they stopped the source about 6 centimeters short from where it was supposed to be, and we have had problems with length of catheters before.

Then another was the interface between the treatment planning and the HDR control computer where they put the wrong information in. So we are seeing those interface problems.

One had a magnification error, and we had a number of catheters that moved. For --

MEMBER NAG: If a long catheter moves and that's because the patient coughed it out, that should not be a medical event.

DR. HOWE: It wasn't because the patient coughed it out. They would check at one point, and then when they go back to check, the catheter had slid out for so many centimeters. So they hadn't really checked to make sure that when they put the source in, it was in the right place.

For gamma knives, we had one that was a wrong site. I think this was a case between left/right type of problem. We had another one with a three pin in which you had an elderly patient that was given the three pin procedure, and then moved, and

the pins did not adhere to where the patient's head was. So we ended up with a medical event. That licensee has now gone back and looked at its procedures and realizing now, based on our information notice we put out this summer about the gamma knives, patients being able to move within the gamma knife helmet, they are now looking more carefully at their patients and making sure that, if they see somebody moving, then they go and look and check to make sure that the gamma knife is still set where it is supposed to be set. So I think we are having a positive impact with evaluating and preventing medical events in that case.

Then we had a Yttrium microsphere medical event in which there was -- well, they completed the procedure. They thought they had delivered all the dose. They looked in the V vial. A significant percentage remained in the V vial. They also had some spillage out of the hepatic port where they were entering into. So they had a number of problems and delivered significantly less dose to the liver than they had expected.

You will see in your books that I also have some other documents or things that were retracted for medical events, and I put those in there

just for your information, to give you a complete picture of what I had looked at. Ralph? Ralph is up next.

CHAIRMAN MALMUD: A question for you from Dr. Vetter.

DR. VETTER: While you are switching slides here, do you recall or do you know what the previous experience is of that licensee with the use of the V vial? Had they much experience in administering microspheres? This is another one of those modalities where experience makes a huge difference.

DR. HOWE: It certainly is. This was an agreement state in Houston, and so generally for the agreement states we don't get a lot of information, but we can check, follow up on that.

Yes, Dr. Welsh?

DR. WELSH: Regarding that Yttrium-90 microspheres case, often the prescription is written to a certain dose or until stasis is reached. Sounds like stasis was reached.

DR. HOWE: No. In this case, I don't believe it was a stasis case, because they believed that they had delivered everything from the vial, and then they were surprised to see that they still had

liquid left in the vial.

We wrote the guidance to allow stasis, because we understand that is a typical endpoint for the spheres, and so we made sure that those would not be medical events. But in this case I don't believe that was the case.

MEMBER EGGLI: But if they observed spillage, doesn't that imply stasis? Your comment was that they observed spillage from the hepatic artery, and that implies some degree of stasis, or either that or catheter misplacement which is a separate problem.

DR. HOWE: Yes, I believe it was the separate problem.

MEMBER EGGLI: Okay.

DR. HOWE: Because there was no discussion of stasis, because we would accept stasis as a legitimate endpoint for any Yttrium-90 microsphere. Yes, Dr. Welsh?

DR. WELSH: I was just reading the item number, and it says the retention fluid for the microspheres had become backed up from the site of injection in the hepatic artery with some spillage on the surface occurring.

DR. HOWE: As observed on the gauze.

DR. WELSH: May be Dr. Nag can answer that better, but this is 35.100 Yttrium-90.

DR. HOWE: Near the end of the package.

DR. WELSH: Yes, it's the last page before it says retracted.

MEMBER NAG: I think -- I mean, I have investigated quite a few of these -- some of these. This is not one I have examined. If it is something, I will be glad to investigate it in detail, if need be.

DR. HOWE: Well, I'll check in the Texas documents and see if we have any other clarification on it. Ralph?

MEMBER LIETO: When this first came up as an agenda item, Donna-Beth and I were talking about how we would try to present these events. The source of the information for both our presentations comes out of what is called the NMED database. Now that stands for the Nuclear Materials Event Database. It is not just medical events that are reported in this.

We both looked at the Fiscal Year, the Federal Fiscal Year from October 1, 2005, to October 1st of this year. Donna-Beth, because she had been presenting previous presentations on the medical event definitions as they apply or are found in Part 35,

continued that presentation.

So what I am presenting is basically, I guess, the first time are other medical events involving related -- or involving or related to the medical use of radioactive materials.

There were -- I think Donna-Beth had about 34 events in her presentation. I found another 42 events related to the medical use of radioactive materials. Now I wasn't sure, basically, how to separate and present this. Donna-Beth, I think, had a little advantage in that she could use the Part definitions in 35.

So this is my first blush effort at presenting this and trying to put them into some overall categories. So you see that I broke these out as to lost sources, either sealed or unsealed, leaking sealed sources, landfill alarms, and I broke this out because this was the largest number of events that were reported in my presentation, and I broke this as to where the description could present that it was either decay-in-storage waste that had been improperly disposed or we didn't know where it came from other than that it was medically related, and then also those events that were identified as related to patients who had been released under 35.75 and a

report had been filed in the NMED database; and then miscellaneous, basically exposure events that were reported.

Also I am going to present, since this was my first blush at this, some concerns and issues with the reporting, and ask for some input from the members.

Under lost sources there were six events that were reported. One was a flood in the basement of a hospital where the radioactive waste storage area was, and basically washed out the radioactivity that was stored down there. Principle isotopes were I-131 and some I-125 waste.

The second event was a Strontium-90 eye applicator that was stored in a nuclear medicine laboratory that basically became dormant for a couple years, and then was reactivated. They went back in, and the other sources were there except the strontium-90 eye applicator, and the activity involved was 28 millicuries.

Another event was a cartridge for a Mick applicator containing 10 seeds of Palladium-103 for a prostate implant was left in the Mick applicator. A survey was not properly done, and when an inventory was done after returning the sources to the storage

area found that the one applicator -- excuse me, one cartridge was unaccounted for, they went back and did surveys and found three of the missing seeds. So seven of those are still missing, for a total activity of 8.75 millicuries.

Another one was an inpatient cesium-137 brachytherapy treatment were a capsule was lost and later found in the hospital laundry. The other was a reported incident of -- These were calibration and reference sources that basically a technologist was going through the laboratory and basically cleaning out decay-in-storage waste, had several of these sources, calibration and reference sources, and threw out three sources, for a total activity of less than 10 microcuries.

I think individually they were less than the exempt quantities, but they still were not at background levels. So these were reported as lost sealed sources.

Another was a cobalt-57 flood source that was used for transmission studies in nuclear medicine was placed on a patient gurney; when the study was done, transferred the patient back to the room. The gurney went out in the hallway, and with the source still in it, and they went and picked up another

patient and realized that the flood source was missing and later found it where it was on the gurney.

So this was not only a lost and found source, but also reported as an exposure of a member of the general public. I think the exposure was less than 10 millirems total, I think, is what they --

MEMBER NAG: What do you mean by a flood source?

MEMBER LIETO: It is for doing uniformity evaluations of gamma cameras. These are large circular or rectangular disks of about 10 to 20 millicuries that is used for quality control the gamma cameras. In this case, they were using it underneath the patient as a transmission source.

The next has to do with leaking sealed sources. I am going to probably call on Jeff Williamson here to kind of explain for the last two. But the first involved a shipment of cesium-137 seeds for brachytherapy application.

One of the seeds was damaged at the vendor packing location, resulting in contamination of the inner packaging, which was discovered by the licensee upon receipt of the package. The cause was later found to be problems with the vendor and their quality control and survey process, but did not result in any

contamination at the licensee's site.

I am going to ask Jeff, if he would, to kind of explain the Mick applicator and cartridge. This is a slide of the Mick applicator. This is the Mick applicator longitudinally here, and the cartridge is this little vertical piece here. Is that right, Jeff?

MEMBER WILLIAMSON: Yes. Yes.

MEMBER LIETO: Okay. That's the extent of my knowledge, and I'll turn it over to Jeff.

MEMBER WILLIAMSON: It is a commonly used device for permanent seed implantation for implanting loose seeds in, hopefully, a linear array which are a preloaded cartridge with the seeds stacked horizontally is inserted. The seeds are pushed out one by one, and in between the user has to retract the needle in order to achieve the desired spacing.

MEMBER NAG: Perhaps I might comment. I mean, I do this almost every day. What happens is that, those who are not properly trained, if that seed is not totally aligned, there will be a little resistance. So the one who is uninitiated keeps on pressing on it and, when you keep on pressing on the plunger, the seed can lock here, and that way you have -- So the way to solve it is (a) take the -- out

immediately, realign the seed in the cartridge, put it back; or you are not used to doing that, you have to take that cartridge out and, you know, dispose it --

MEMBER WILLIAMSON: I might add that these seeds -- The titanium cladding on these seeds is extremely soft and very easy to rupture and bend. So, you know, rough handling procedures can easily violate the integrity of an iodine seed.

MEMBER LIETO: There were two separate incidents that involved iodine seeds rupturing when the cartridge was jammed in the applicator. Another report involved palladium seed being sheared when the cartridge became jammed and the user improperly removed the cartridge and sheared the seed upon removal.

Now I know that there has been, I think, an information summary. I don't know if that's the right --

DR. HOWE: Information notice.

MEMBER LIETO: Information notice on this that went out from the NRC in the spring. Is that about right? Early summer?

DR. HOWE: I'm not sure when it went out.

MEMBER LIETO: Earlier this year. But some of these incidents have occurred since that

summary or notice had gone out. So it was another reason for reporting it here. So these events still are occurring, even though the notice has gone out.

The next category of reports or events that were reported involves landfill alarms. These involved basically improper disposal of medical radioactive waste from licensee. All the events involved the isotopes listed there: Technetium-99m, Iodine-131, Thallium-201 and Gallium-67.

Now there were eight reports in which the origin was unknown as to whether it was residential -- in other words, it might have came from a patient that had been properly released under 3575 -- or possibly even just improper disposal. So we categorized them under this category of unknown or improper decay-in-storage waste.

There were 19 reports total. When I looked at where these were coming from, basically there were three from two non-agreement states and 16 from five agreement states in terms of the total reports, and the agreement states are listed there.

So there seems to be --

MEMBER WILLIAMSON: Go ahead. Sorry.

MEMBER LIETO: I was just going to say: So there seems to be very few of the states that are

using NMED as a mechanism for reporting these events, even though these may occur -- From my own personal knowledge, an event may occur in a landfill. It is probably that very few of these events are going into the NMED database.

MEMBER BAILEY: Yes. I think there are two factors there. One is, looking at those states, I know that they have a lot of landfill alarms set up. Secondly, there are in some states procedures set up that you don't report them or you don't count them as incidents if they are a certain category.

MEMBER LIETO: If they are the low half-life materials, and I'm sure that is probably the case. And in fact, many of the events that were reported -- In fact, I think I rank ordered these states, agreement states, and the number of reports. Interestingly enough, several reports from Alabama were the result of waste transferred from Tennessee.

So I think, when you put those two together, that is where most of these events are being reported.

Now whether these should still be reported via NMED, I guess, is a question for maybe future discussion. I don't know if the NRC encourages these events being reported into this mechanism or not,

especially when they know what the isotope is; because many of the stations that reported this had identified the isotopes, because they have portable detectors that can identify the specific radionuclide involved.

Now the second category of landfill alarms: There were nine reports, and I put this category separate, because I felt these should not have been in NMED. They came from patients that had been released or hospitals where the patients would have been released under 3575.

When I say the hospitals, for example, there was, I think, one case that stands out in which they determined that the radionuclide involved was Technetium-99m, and it was a Foley bag, a contaminated Foley bag with urine that was triggering the alarm.

All but one of the reports were from agreement states, and the point that, I think, I would make in reviewing these reports, especially these alarms, is that I think the biohazard risk of identifying the source so greatly exceeds the radiation risk involved with identifying these.

I think either the state people or whoever is doing the dumpster diving here at the landfills are probably at much greater risk from biohazards than the

radiation risks that are involved with these.

MEMBER BAILEY: Ralph, the problem is that the waste sites don't want it, and somebody has to go out -- some of us feel, has to go out, and we try not to do dumpster diving and try to identify it outside the container or have them dump it somewhere. Only we have a bad actor that we suspect do we ask them to go out and dive in the dumpster and recover their stuff.

MEMBER LIETO: What was happening in some of these -- and I guess I'll maybe emphasize this again toward the end -- is that, at least from the brief reports in the NMED database, it appears that in some cases they are identifying where this waste comes from, either in a previous slide the hospital, and they are asking them to modify procedures, which probably would be appropriate if it is a decay-in-storage waste that shouldn't have got out.

In some of these residences, or in the case of the Foley bag type of thing, they are asking the licensees to modify their procedures or install expensive monitors to monitor all the trash going out. I think we are kind of trying to shoot a fly with a shotgun here, and I'm a little -- I think there's some area of concern, and I don't know what the solution is to this, if there is something that ACMUI might

recommend or that NRC staff might have some suggestions in going back, or whether these are appropriate to be even in the database also. I don't have a recommendation for that right now.

In terms of some of the miscellaneous things that we found in terms of the reports, one had to do with a prostate seed implant that was removed 90 days post-implant by a non-licensee who reported this, and I'm not really sure how it got into the NMED, being a non-licensee, but anyhow it was reported as a potential overexposure to the surgery staff because of the removal of the prostate with the seeds.

NRC in follow-up stated that this was not reportable, since the patient had been released in accordance with 35.75.

Another event was an event in which a licensee was doing emergency training exercises with an HDR, which are done on an annual basis. They did not follow the vendor's procedure in using a dummy source set-up, which resulted in the actual source going out, resulting in an exposure to the users in a training exercise and resulted in some exposure to them, nothing in excess of dose limits or anything like that; because as soon as the alarms went off, there was a very hasty exit.

Another event, which I think was an event that was reported -- also the same event reported earlier by Donna-Beth, but this was also indicated in the description in the database as a possible noncompliance with release criteria for an iodine-131 patient.

This was the patient who had dementia and was administered an I-131 capsule, and this capsule was later found several days later at another location under the patient's pillow or cushion, as Donna-Beth described earlier.

So the description in the database indicated that this might be some issues with the licensee in not complying with 35.75 in that they released a patient who could not be assured -- there was not some reasonable assurance that they could comply with the release conditions.

Another event that was found and was still reported as a medical event was a diagnostic radiopharmaceutical of Technetium-99m that was given. It was the wrong pharmaceutical given to a patient. It does not meet the dose criteria for a medical event, but there was no retraction in the database.

So it was still in the there as a medical event, although it really does not meet that criteria.

Some general observations and issues: In a couple of conversations that Donna-Beth and I had regarding identifying events, we found that in querying the database that there were events that she didn't capture and neither did I capture. I think we looked at four different query criteria in trying to capture all these events, both for medical events and these other material events.

These three or four that are listed here were ones that I found in the quarterly report of the NMED. They make quarterly reports on their event summaries, and these were described in the actual report.

Again, one of them was a leaking stopcock valve during a Technetium-99m stress study. It was classified as an equipment failure under heart-30 -- Would that be right? -- which I guess I don't have to probably -- Maybe Dr. Van Decker might probably want to even guess at the number of leaking injections that occur during nuclear stress studies.

I find this one kind of very surprising in its report, because this is -- I don't want to say it is a common occurrence, but it is not rare either.

Another couple of events -- Another was a leaking dose calibrator standard for Cesium-137. I

have to admit, I've never seen a report of a leaking dose calibrator source before. So I was very curious about this, but yet couldn't find any follow-up information as to was it really leaking and, if so, was it something that was just a flaw in the design of the standard; because these are used in almost every nuclear medicine department with a dose calibrator.

So if it happens once, you kind of wonder where else is it happening and not being reported or is this basically something else going on here that is not really a problem with the standard.

Another event was the cremation of a body shortly -- a prostate implant, I-125 implant, shortly after -- There was a cremation shortly after implant. I'm sorry, I don't have the total activity on this, but obviously, probably in the range of about 30+ millicuries of I-125.

This was reported under Part 20, I believe, although if you -- In the NMED database a query of Part 30 events -- excuse me, Part 20 violations, if you will, or medical events involving this type of thing, it did not come up under that type of query.

Another event had to do -- which was reported as an exposure, was an inpatient, cesium-137

patient, that went into -- I don't know if it was cardiac arrest, but I'm assuming that it was a Code Blue which required immediate emergency care of the hospital team, and the exposure reported as a result of this. This was reported under Part 20 exposure events.

So there were some issues that came up that did not capture all the events involving radioactive material use. The landfill alarms regarding patient waste were categorized in some cases as either lost, stolen or missing radioactive materials under Part 20.2201.

Really, these are patients that are meeting the criteria for release and, really, they are not lost, stolen or missing. You know, it is probably a contaminated toothbrush or linen or something of that from the house, and it is not really lost, missing or stolen. They put it out there.

One of the things, I think, regarding NMED was a real problem, and this may be from my accessing it, and I don't know if that's the case, is that in the reports they give reference documents which may or, hopefully, will provide more detail on the events.

Many of these, you couldn't -- They were

totally unavailable or simply the original cryptic report that resulted in the NMED event narrative itself.

Leaking sources were classified as equipment failures, not under Part 25 or a leaking source criteria. I couldn't find any follow-up assessment that was documented with these reports, and again I think this is a concern that maybe might be for future improvements in that one of the things that, again from the query process and in developing these reports, is that it was very difficult to find things that were medically related.

There is not in NMED any type of a data field that indicates where the license field -- who the licensee is that is involved with this. So if you wanted to, say, do a query based on all medical licensees, you can't do that.

In fact, some of the events that came up in the queries captured medical -- exposure events that resulted in medical care of the individual that was overexposed, even though the individual had nothing to do with the medical use of radioactive materials.

Is there a way to -- as I say, to determine whether the reports are accurate. As I

mentioned with the leaking sources, was it really the source that was leaking. Was there some failure with that, or was there something that, in terms of how the source was handled, stored, whatever, that resulted in it leaking?

Medical events: There were, I think, several medical events that were reported. Some were retracted. Some were not. I think there was one that was retracted in which, from the narrative, indicated that there was no medical directive, written directive. So I didn't quite understand the reason for that.

I think, you know, the other thing is that, should any reported event be included in these quarterly reports? If there is no assessment into the accuracy or the fact that it was later retracted, does that still go into the quarterly reports as statistics of these types of events?

I don't have an answer for that, and in looking at the quarterly summary reports, I couldn't determine if there was any type of, for lack of a better term, QC of the reports in terms of, well, this really shouldn't go into the statistics or not.

I guess the last one is a question in terms of do the members find value in reporting these

other medical radioactive material events that are not medical events in the definition of the Part 35 regarding the patient definition of dose and dosage?

CHAIRMAN MALMUD: Thank you, Mr. Lieto. Are there any questions for Mr. Lieto? Dr. Vetter.

DR. VETTER: Just a comment. Do we find value in this? I think personally I would find more value if we could somehow group them -- if we perceive there might be a problem that needed to be communicated to the user community, if they could group them and then come up with a recommendation to staff on what that might be, on how to advise the user community.

MEMBER NAG: Exactly what we did in the IC recommendations for HDR. We took all the NRC administration at that time. We -- them why it happened and explained. I think that is more beneficial, and in future I think, if we do this, we should take some time beforehand to -- and maybe give a 15 minute presentation, not on all of these, like maybe five of these and a,b, c.

CHAIRMAN MALMUD: Mr. Bailey.

MEMBER BAILEY: I notice that several of the events involved accelerator produced material, and I would speculate that those probably came from

agreement states, although I don't know that for sure. I don't know that NRC licensees would necessarily report accelerator materials that were lost or whatever.

So those who are watching the number of incidents that are occurring should remember that you are getting a whole bunch of new sources in that probably will put a spike in the number of reports that you get.

CHAIRMAN MALMUD: It seems then the answer to your question is that it would seem useful to the committee if you could group these perhaps with external beam radiation, brachytherapy second group, third group perhaps nuclear medicine issues.

I don't think that the committee needs to be informed of every leaky valve during a stress cardiac study, but we are interested in knowing the number of events. Does that summarize it pretty well? Thank you for a very thorough description of what has occurred.

If we may, we will move on now to the patient release issue, which is being presented by Cindy Flannery. Thanks, Ralph.

MS. FLANNERY: Okay. In the interest of time, I will try to summarize this as much as possible

here.

This is just an informational presentation to explain an effort between the NRC and the AHRQ, which is the Agency for Healthcare Research and Quality, which is part of the Department of Health and Human Services, and the Center for Disease Control. This is an effort on collecting information on release of patients who have been administered radiopharmaceuticals or implant who have been stopped at security checkpoints.

Earlier this year the AHRQ noticed in The Federal Register a project, information collection on security at checkpoints and patients with radiopharmaceuticals, and there are several comments that were received in response to this Federal Register notice, and many of these comments had to do with how this information collection really falls under NRC's jurisdiction.

So that began a dialogue between the NRC and AHRQ and CDC, and we decided to collaborate with these agencies on this information's collection. This topic really will become of increasing importance as it is expected that there will be more security checkpoints, and these detectors will grow in number.

Patients who have been administered

radiopharmaceuticals or have implants are released in accordance with 10 CFR 35.75, and medical facilities are not required to provide patients with information that could be presented to law enforcement personnel. Oftentimes, when these patients are stopped at security checkpoints, many of these individuals are unaware that they have received a procedure involving radioactive materials and, therefore, sometimes cannot adequately communicate that with the law enforcement.

So a few years ago, 2003, NRC issued an information notice about the heightened awareness of patients containing detectable amounts of radiation from medical administrations. The bottom line message in this IN was that NRC urged medical facilities to provide patients with information or documentation to present to law enforcement or security personnel at these security checkpoints.

Now NRC has recently issued a temporary instruction. A temporary instruction is intended for inspectors of all medical use facilities, and a temporary instruction gives direction on gathering information in addition to what is collected during -- or inspected against during the routine inspections.

It is not the goal of the study to evaluate the adequacy of the existing regulations, but

rather just explore the range of practices among the medical facilities. So I have listed here the objectives of the temporary instruction.

Of course, the inspectors will be evaluating the compliance with 35.75, but this TI also has as objectives to gather information concerning whether the medical facility is implementing the information notice and, if so, how are they doing that.

Ultimately, the data will be used and evaluated by AHRQ or CDC, and an article will be published in a peer review journal.

So the goals of the study are, as I said, to explore the range of practices across facilities. What the TI is looking at is determining what methods facilities are using to determine when patients can be released from care, also what type of information is being provided to the patients, including documents to present at security checkpoints, and lastly how this information is being communicated to the patients.

In your binders you have a copy of the draft TI, and since the time that these binders were sent out and the meeting here today, the TI has become final. It went into effect. It was signed, finalized and went into effect October 13, and it is planned to

be implemented for a period of three to six months, however much time is needed to gather an adequate statistical sample. The goal is to try to get the information from 60 different facilities.

What we are trying to gather information on is facilities ranging all the way from your small, private offices up to your broad scope programs. So we are not just targeting one type of licensee or one group.

Lastly here, I have just listed the points of contact with the agencies outside of the NRC. The AHRQ actually administers the contract, but the technical expertise actually comes from the CDC.

I don't have any data to provide at this point, because this was just published less than two weeks ago. So, of course, we don't have any data to present, but we plan to present some data at the April meeting, because we should have collected all the information that we need by that time or are close to the end, and we plan to have Dr. Ansari from the CDC present at the April meeting the data that has been collected up to that point.

So that's all I have to present. This is more just a heads up of what you will be hearing about more in the future as we have collected the actual

data.

CHAIRMAN MALMUD: Thank you. There is a question from Dr. Vetter.

DR. VETTER: A couple of quick questions. First of all, will the 60 facilities be NRC licensees?

MS. FLANNERY: Yes, they will be.

DR. VETTER: Okay. Now this looks like a good set of questions to ask what patients are being told. Will there be any plan to try to assess whether patients are actually following the instructions?

MS. FLANNERY: No. It's more just how the medical facilities are implementing, say, for example, the IN.

CHAIRMAN MALMUD: Thank you. Dr. Eggli.

MEMBER EGGLI: There are actually starting to be articles in the literature about patients being stopped at security. It looks like the worst group is actually the hyperthyroids who are getting under 30 millicuries, because they retain so much of the dose for so long. Patients have set off airport detectors as long as six to eight weeks after their therapy.

I used to -- I give instructions in my written documentation when patients leave. I used to tell them to avoid government buildings and public transportation and airports for a week. Then I was

doing it for two weeks, and I'm not sure what the answer should be now, but hyperthyroids are setting them off six to eight weeks later.

I guess I will modify it for hyperthyroids, but they also carry -- I ask them to carry a copy of their consent form in their wallet, and I tell them brutally that, if they are stopped at security, they will be treated like a terrorist, and the odds are security will be rude to them, and it is better to carry their consent form than to go through that experience.

CHAIRMAN MALMUD: Thank you, Dr. Eggli. We give the patients a business-size card which indicates the isotope that they received, the amount of the isotope and the date, and tell them don't cross the bridges or tunnels into New York City, don't enter any Federal office buildings. If the President comes to town, stay home, and indicate that they will be regarded as terrorists until they show the card.

This always is met with amusement by the patient, since they don't see themselves as looking like terrorists, whatever terrorists look like. But they remember, and I tell each patient that I treat with radioiodine that that's the case.

Now we do not do that with all of our

patients who receive isotopes -- for example, thallium which will trigger off some of these monitors -- but it is routine for our therapy patients.

How often does this really happen? I mean, we hear all of these apocryphal stories. How often?

MEMBER EGGLI: I have one personal experience. It was actually in the early days. I got called by U.S. Customs in Toronto. A patient was not screened leaving the country but screened coming back into the country, and I had to tell Customs exactly what I treated the patient with and when I treated. So I have one personal incident.

CHAIRMAN MALMUD: Is there any magnitude? Is it 100, 1000 incidents per year?

MEMBER SULEIMAN: I think it is very prevalent, because there are more detectors being put out there. Some of them like will detect 2 MR per hour.

CHAIRMAN MALMUD: Well, we think it is probably. I mean, is there any quantification?

MEMBER EGGLI: A recent article in the literature was about -- was somewhere between six and eight patients.

CHAIRMAN MALMUD: In a year?

MEMBER EGGLI: No. It was just reporting a small series.

CHAIRMAN MALMUD: Mr. Essig seems to have some.

MR. ESSIG: I have just one rather large number to share, but it includes everything that is passed through the ports of entry into the United States, and Customs reported that over a three-year period they had 318,000 alarms.

CHAIRMAN MALMUD: But not from patients treated with radioisotopes.

MR. ESSIG: It would include them, but they would be a small subset of that. But that's the only data I have.

CHAIRMAN MALMUD: But we have -- Currently, we have no idea of the magnitude.

MR. ESSIG: The alarm population is large and growing, because the sensitivity detector is getting better, and there are more being deployed, not only at ports of entry but in the interior of the United States.

CHAIRMAN MALMUD: Of course, in Philadelphia we have a lot of Federal buildings, and we tell the patients to stay out of the Federal buildings, and also not to fly within a week. But

that is a pearl. I didn't realize we could be as long as six weeks for these hyperthyroid patients. I didn't know they were monitoring that closely. I'll warn the patients about that as well. Thank you.

The next item on -- Oh, Ralph?

MEMBER LIETO: I just had a question regarding this information collection. Was this -- The document for the data gathering, was that developed by NRC or by AHRQ?

MS. FLANNERY: Are you referring to the questionnaire, the attachment with the questions?

MEMBER LIETO: Yes, the statistical data gathering report, Attachment A. Is that theirs or--

MS. FLANNERY: The questions were drafted by the CDC and their contractors. However, they were screened and reviewed, revised by NRC staff.

MEMBER LIETO: Because I think it is a gross underestimate in how long it is going to take to complete this. I think there's like over 50 questions. Some of them are multi-part, explain and so forth. I think 30 minutes is kind of a gross underestimate in time, but this is just data gathering or is the inspector -- If he gets an answer that he doesn't like or thinks is not right, are they going to be cited for how they respond to this?

MS. FLANNERY: What the inspector is really evaluating the licensee on is compliance with 35.75. So these questions really are in addition to what they are being inspected on, if that makes any sense.

MEMBER LIETO: Yes, it does, but I just see a real danger, because there is going to be an -- There is a lot of room for interpretation on some of these, and I'm just kind of wondering if someone doesn't answer right or says I don't know, does that constitute that they weren't instructed?

MS. FLANNERY: There aren't any questions on the Attachment A there that would really put them in an area of noncompliance.

CHAIRMAN MALMUD: If I may, we have a comment from a member of the public.

MR. WHITE: Hi. Gerald White, AAPM. I would just like to comment. I think this is going to come up over and over again before the ACMUI, and I would like to inform you that the AAPM objected strongly to the AHRQ process, and I'd like to just do one brief paragraph from our letter where we said that their goal, which was "to assure that patients who activate radiation detectors understand why they emit radiation and carry the appropriate documentation to

validate the statements" -- that's their words -- is troubling.

Patients should not bear the burden of "understanding the medical technical issues related to their emission of radiation" nor should they be required to educate security personnel on the subject.

We note that creating secure, authenticated documentation to allow security personnel to verify the medical nature of the patients' emissions is at best impractical and most likely impossible.

Rather, the Federal government should require that radiation detectors used at security screening locations be capable of identifying the isotope within the patient, thus allowing the security staff to verify the medical nature of the emissions.

Such detectors are widely available, and we went on to encourage AHRQ to, in fact, gather data on the frequency of use of their detectors -- those detectors and their efficacy. I think we should place the emphasis on the security personnel and not on the patients to solve this problem.

CHAIRMAN MALMUD: Thank you for that advice. It certainly does make sense that the patient not be given the burden, but in the meantime we had

best give the patients some identification so that at least they can defend themselves when they are accused of being potential terrorists.

We have another item on the agenda, and that is the administrative closing and the action item review. Mohammad Saba. Thank you, Ms. Flannery.

MR. SABA: I am going to highlight the actions and recommendations by the Committee during this meeting.

The first -- There are several actions and two motions that I have on this paper. But I ask the Committee and the staff to add anything I have missed.

The first action is to send a copy of the NMS reorganization to the members. I already gave everybody a copy of reorganization.

The second action was the ACMUI agenda should be amended to add a standing agenda item that allows the ACMUI a period of time to discuss emerging medical issues such as imaging agents for breast cancer. This item was suggested by Mr. Bailey.

The third -- Go on.

MS. WASTLER: No, this is Sandra Wastler. I just wanted to clarify. I know that was suggested by Mr. Bailey, but I'm not sure whether the Committee agreed that that was a viable recommendation. I

personally would think it would be a great idea, but from my notes I did not see that it was called for by the Committee as a whole. Just for clarification.

CHAIRMAN MALMUD: You are correct. There was no motion. We could take the motion now, if you wish. All in favor of having the informational item on the agenda for each meeting. Is there a second to the motion? All in favor. Any opposed? Any abstentions. Carries unanimously.

Thank you for bringing it to our attention. It is officially a motion. Mohammad?

MR. SABA: Okay. The third action was NRC should consider workshops regarding non-implementation for licensees. This was suggested by Mr. Lieto.

The fourth action item was NRC should consider listing the ACMUI on the main NRC web page and add ACMUI to the FSME organization chart, suggested by Mr. Lieto.

The fifth action --

CHAIRMAN MALMUD: That also was not a motion.

MEMBER NAG: It's action -- Those were all action items.

CHAIRMAN MALMUD: Yes.

MEMBER NAG: There were three or four

motions, but these were all action items.

CHAIRMAN MALMUD: Please go ahead, Mohammad.

MR. SABA: The fifth action was send ACMUI a copy of the pre-decisional paper to the Commission regarding the results of the step actions to identify problems in authorizing medical physicists under 10 CFR 35. This was suggested by Dr. Williamson.

The last -- No, not the last, the sixth action is the draft non -- The draft not rule should be sent to the ACMUI at the same time that it is sent to the agreement states, as well as the non-related guidance.

The last action item is consider revising the language in Volume 21 guidance.

As far as I have, I have two motions. The first one is NRC should reword guidance in NUREG 15-6, Volume 21, to state that people who repair the accelerator be trained by the employers.

The second item was the attestation requirements for all pathways for being RSO be deleted, i.e., deletion of 35.50(d) from the regulations.

CHAIRMAN MALMUD: Dr. Vetter.

DR. VETTER: Yes. There was also a motion

to not support William Stein's petition.

MR. SABA: Oh, yes.

CHAIRMAN MALMUD: Thank you, Dr. Vetter. Were there any other items, Mohammad?

MR. SABA: That's it. Oh, the next item is, as usual, the dates for the next meeting. I have two suggested dates. Let me get the calendar, the 24th and 25th of April.

MEMBER NAG: Would it be possible to have this meeting along with the meeting with the Commissioners?

MR. SABA: Sure.

MEMBER NAG: We would like to try one with the Commissioners.

CHAIRMAN MALMUD: Do we know when the commissioners are meeting?

MS. SCHLUCTER: No. At this time, we would not know the dates of the annual opportunity for the Committee, but that would be determined probably about three to four months in advance.

So what we will do, through our own internal process, is to -- if you have a preference of what month you would like to have your opportunity to meet with the Commission, we would then base the meeting around those dates. So we will have to work

around their schedule.

CHAIRMAN MALMUD: Thank you.

MEMBER SULEIMAN: April 24th and 25th is fine with me.

CHAIRMAN MALMUD: That will be April 24-25. That's a Tuesday-Wednesday?

MEMBER NAG: Yes. What was the other option? You said you had two dates.

MR. SABA: Oh, that was 25th and 26th and, if it doesn't work, the week before.

MS. SCHLUCTER: Well, as long as you understand that it will move based upon the availability of the Commission.

MEMBER EGGLI: And, Mr. Chairman, I don't use a paper calendar. Mine is electronic and, since I don't have Internet access right here, I can't get to my calendar to confirm availability for those dates.

CHAIRMAN MALMUD: Okay.

MEMBER EGGLI: So I would like to see the proposed dates come out by e-mail for a response back to Mr. Saba.

CHAIRMAN MALMUD: April 24-25. Thank you. We will ask Mohammad to do that. Also, will this room be available?

MR. SABA: Well, we don't know, but we try.

CHAIRMAN MALMUD: You will try? Okay, because we have had some venues that were less than satisfactory.

MEMBER NAG: Would any of the hotels be available?

CHAIRMAN MALMUD: The Ritz-Carlton in Virginia is available, but not to us.

MEMBER SCHWARZ: I think we are waiting for the Commission dates are available before we confirm anything. Correct? Is that what we are also wanting to do?

CHAIRMAN MALMUD: Well, we are booking these two dates temporarily, yes. I didn't mean to be flip, Dr. Nag.

We have had a problem, as you know. This turns out to be a very fine arrangement in a government building with a fine conference room. We have had less than ideal arrangements. We have had one meeting in a hotel, but I was told it was expensive by comparison to this. So we are trying to conserve our tax dollars.

MEMBER NAG: No, what I meant was even hotels in the area are not available, even when we

hold it here.

CHAIRMAN MALMUD: Yes, that is a problem. We are having difficulty booking rooms for ourselves, and the sooner that we can set the date, the better off we are in terms of trying to book a room at government rates.

Does that complete your agenda, Mohammad?

MR. SABA: Yes, that's all I have.

CHAIRMAN MALMUD: Well, I would like to point out that, because of the cooperation of all the members of the Committee, we were able to conclude the meeting at 5:20, which is not far off from our goal.

In addition, besides thanking all the members of the Committee, both NRC staff and members, for their cooperation and productivity today, to thank the members of the public who took the time to be here to give us their advice and opinions as well.

Also, we welcome aboard Janet, and we once again wish Tom every success in his move to the West Coast, a home which has a hot water faucet, a cold water faucet and a Starbucks Coffee closet, being in Seattle.

MS. WASTLER: And, I believe, a gorgeous view of Mount Baker.

CHAIRMAN MALMUD: Yes. Well, that's the

way it is.

Are we supposed to leave these with you today?

MR. SABA: Yes, please.

CHAIRMAN MALMUD: We will. Those of you who are able to fill these out, leave them with Mohammad today.

Thank you all. We will look forward to seeing you in the spring, and wish you all a happy Thanksgiving, a Merry Christmas, a Happy New Year, and everything else that goes between now and then. Thank you.

(Whereupon, the foregoing matter went off the record at 5:24 p.m.)

## CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission in the matter of:

Name of Proceeding: Advisory Committee on the Medical Uses of Isotopes

Docket Number: (Not applicable)

Location: Rockville, Maryland

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and, thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

Charles Morrison
Official Reporter
Neal R. Gross & Co., Inc.