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 25, 2005

Work Order No.: NRC-686 Pages 1-226

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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

EXECUTIVE SESSION

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TUESDAY,

OCTOBER 25, 2005

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The meeting was convened in Room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:19 a.m.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

EDGAR D. BAILEY, Member

DAVID A. DIAMOND, M.D., Member

RALPH P. LEITO, Member

SUBIR NAG, M.D., Member

SALLY WAGNER SCHWARZ, Rph, Member

ORHAN SULEIMAN, Ph.D, Member

WILLIAM VAN DECKER, M.D., Member

RICHARD J. VETTER, Ph.D, Member

JEFFREY F. WILLIAMSON, Ph.D, Member

SPEAKERS AND PARTICIPATING NRC STAFF:

DOUGLASS F. EGGLI, M.D.,	ACMUI
THOMAS H. ESSIG	NMSS/IMNS/MSIB
CINDY M. FLANNERY	NMSS/IMNS/MSIB
SANDRA L. GABRIEL	DNMS, Region I
PATRICIA K. HOLAHAN, Ph.D,	NMSS/IMNS/MSIB
ANGELA R. MCINTOSH	NMSS/IMNS/MSIB
MOHAMMAD SABA	NMSS/IMNS/MSIB
SAMI S. SHERBINI, Ph.D,	NMSS/IMNS/MSIB
JOHN SZABO	OGC
RONALD E. ZELAC	NMSS/IMNS/MSIB

ALSO PRESENT:

CHARLES L. MILLER, PhD

JOHN SZABO

DONNA-BETH HOWE

LYNNE A. FAIROBENT

JEAN ST. GERMAIN

ROBERT FORREST

I-N-D-E-X

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

CHAIRMAN MALMUD: It's yours, Mr. Essig.

MR. ESSIG: Okay. If other members would kindly take there seats. Mr. Leito.

As designated federal official for this meeting, I am pleased to welcome you to Rockville for the public meeting of the Advisory Committee on the Medical Use of Isotopes.

My name is Thomas Essig. I am Branch Chief of the Material Safety and Inspection Branch and have been designated as the federal official for this Advisory Committee in accordance with 10 CFR Part 7.11.

Present today as the alternate designated official is Cynthia Flannery, Team Leader for Medical Radiation Safety.

This is an announced meeting of the committee. It is being held in accordance with the rules and regulations of the Federal Advisory Committee Act. The meeting was announced in September 20th and October 4th, 2005 editions of the Federal Register.

The function of the committee is to advise the staff on issues and questions that arise on the medical use of byproduct material. The committee

provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the Commission. The NRC solicits the views of the committee and values them very much.

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

As part of the preparation for this meeting, I have reviewed the agenda for members and employment interests based on the general nature of the discussion we're going to have today and tomorrow. I have not identified any items that will pose a conflict. Therefore, I see no need for an individual member of the committee to recuse themselves from the committee's decision making activities.

However, if during the course of our business you determine that you have some conflict, please state it for the record and recuse yourself from that particular aspect of the discussion.

At this point I would like to introduce the members of the committee that are here today. Dr. Leon Malmud, Chairman, our health care administrative

representative.

Dr. David Diamond, radiation oncologist.

Dr. Subir Nag, radiation oncologist.

Dr. William Van Decker, nuclear cardiologist.

Ms. Sally Schwarz, nuclear pharmacist.

Dr. Richard Vetter, radiation safety officer.

Dr. Jeffrey Williamson, therapy physicist.

Mr. Ralph Leito, nuclear medicine physicist.

Mr. Edgar Bailey, state representative.

Dr. Robert Schenter, who is not here.

Dr. Orhan Suleiman, of the Center for Drug Evaluation and Research of the U.S. Food and Drug Administration are those who are present.

Dr. Douglas Eggli will not be attending this meeting. Dr. Leon Malmud, Acting Chairperson, will conduct today's and tomorrow's meeting.

Following discussion of each agenda item, the Chair at his option may entertain comments or questions from members of the public who are participating with us today.

CHAIRMAN MALMUD: Thank you, Mr. Essig.

The opening remarks will now be made by

Dr. Miller.

DR. MILLER: Good morning. I'd like to welcome everybody to beautiful, sunny Rockville, although for Dr. Diamond, I'm sure that he has been through a little bit more than we have in the last few days. So I was happy to see that he made it.

I would like to welcome the members of the public to the meeting. I think Tom has said out the protocol for the meeting and so that we have a very aggressive agenda this time. So in order to try to stay on schedule as much as we can, Dr. Malmud, I will without further ado turn the meeting over to you.

CHAIRMAN MALMUD: Thank you.

The next item on the agenda is the status of Board applications and the presenter will be Cindy Flannery, and with her Dr. Ronald Zelac and Dr. Dona-Beth Howe.

Dr. Flannery.

DR. FLANNERY: Thank you.

Good morning. Thank you for the opportunity. I will be opening up the discussion on the status of the review process for recognition of the specialty boards.

As you know, on March 30th of this year, the Federal Register announced the change in the NRC

requirements for recognition of the specialty boards. These changes related to the training and experience requirements that the boards have placed on the candidates who are seeking board certification.

Six months in advance of when Subpart J was due to expire, which was yesterday, letters were sent out to 12 different specialty boards and regarding applying for industry recognition of one or more of their certification processes. Nine of those 12 specialty boards responded during the period of July and August applying for recognition of the certification process.

And the last slide, I have a list of the status of the review process for each of the specialty boards, but I first just want to go over the definitions for the four different categories of the status.

The first one is approved, and the status of approved means that the certification process for the specialty board has met NRC's criteria for recognition. The board was contacted. A formal letter has been sent to the board, and that specialty board is listed on the Web site.

And for your information, I do have copies of the Web site that lists the boards that are

approved up to date.

Approvable means that the certification process meets the criteria for NRC recognition. However, NRC staff is still waiting for a response from the specialty board on the date in which the specialty board will meet or has met to NRC's criteria for recognition.

Under review means that the NRC has requested additional information from the specialty board. The information has been received and is currently under review by NRC staff, and awaiting input means that the NRC staff is still waiting for additional information from the board before it can continue the review process.

And in conclusion, this table summarizes the status for the nine of the 12 specialty boards that have applied for recognition of their certification process.

That's all I have.

DR. NAG: One question. The certification of the radiologist London, is that from U.K.? Are they requesting certification?

DR. HOWE: Yes. Am I on?

Yes, it is from the United Kingdom, and we sent letters out to those boards that were listed in

Subpart J, and they were listed in Subpart J. They did respond to us back in the summer and asked us, "What are you sending us this letter for? Will it benefit our fellows?"

And we responded back to them. So at this point we haven't received an application from them, but we have received communication from them.

And I think Tom Essig would like me to address one of the questions that you may have, and that is as we're reviewing the applications, we're finding that most of the boards are having to make minor modifications or codifications of their process that may not be in the information that's available or that they sent into us.

And so to determine a date at which the board meets the criteria, we're not looking and seeing when they made the change. We're looking to see if the change was a substantive change or a codification of what they were already doing that had not appeared in writing anywhere.

And so if you look at the boards that we have recognized, we recognized the Board of Pharmaceutical Specialties for their certification process for board certified nuclear pharmacists. They made some changes to their Web site that indicated the

information that they were requiring of their candidates. But they went back and they looked to see because our rules were more specific than what they had upon their Web site, and they went back and looked at the actual candidates that they had taken the test and had been certified. And they found that all of their candidates met our criteria, and so they were able to go back to March 1996,to show when they were in compliance with our rules, although they made minor changes to what they're putting on their Web site requiring candidates.

And I think you'll find the same thing is true with the American Board of Nuclear Medicine. They now have additional information that matches our regulations up on their Web site, and they have made slight revisions to their certification process to make it easy for us to identify those members that are certified that meet our criteria.

In this case there is a 'Canada' at the bottom underneath the name of the certification for those that did not receive their training under an authorized user from the U.S.. And there is a 'United States' for those who did receive it under the U.S., and they're also going back to look at their candidates that aren't already authorized users, and

if they're not authorized users, then they'll take special efforts to make sure they comply with our regulations and issue them a new certificate.

So there are a number of ways that we're addressing the fact that changes are being made to the criteria, but those changes may not be really new changes to the people that are already certified and methods to distinguish those people that take the test that meet our criteria, for maybe others that take the test that don't meet our criteria, which are normally the foreign applicants.

DR. NAG: Since the Subpart J expired yesterday, what is the exact status of those boards here who are either under new or awaiting for their input? I mean, where does this place us today? If the Subpart J expired yesterday, someone who was approved or who is board certified by, let's say, the American Board of Radiology or American Board of Osteopathic Radiology where most of your use, what is the exact status today?

MS. FLANNERY: You know, as far as the boards, I mean, if they can demonstrate at a later date that they met the criteria at an earlier time, we can indicate that on the Web site. So just because they're not listed today, when Subpart J expires,

doesn't mean that they can't be listed at a later date.

CHAIRMAN MALMUD: Dr. Miller.

DR. MILLER: Dr. Nag, I think your question was, "given the fact that Subpart J expired yesterday, what is their standing as of today."

DR. NAG: Today, yes.

MS. FLANNERY: Sorry. I didn't understand the question.

PARTICIPANT: It's not that they can't go back and become in good standing, but I think since it expired yesterday if they're not in good standing today and had been approved --

DR. NAG: Then let's say -- exactly. If today someone is applying, what are you going to do today because, you know, maybe three months from now they will send in applications that will meet the criteria, but today if someone is applying, what can you do?

MS. FLANNERY: If somebody submitted, say, an amendment request asking to add this individual who is certified by the ABR, they would not be able to, you know, get approved under the certification pathway. They would have to get approved by the training and experience pathway until such time the

ABR can be listed.

DR. NAG: Now, since all sent out at least 80 or 90 percent of all the authorized users will be coming to the ABR certification, I don't think this is an acceptable condition to be placed then because you are going to be by default trying to do everyone by the alternate pathway rather than the board certification pathway.

DR. HOWE: I think the assumption is that we're currently reviewing the ABR application, and that we will be eventually approving it, and when we do approve it, we'll find a date at which it is in compliance with our rule, and that date may be prior to October 24th, and we're expecting it to be a short period of time between October 24th and when the approval comes through.

And it is only those individuals that are applying in that short period of time that are affected, but Subpart J, when we did the new rule back in April, was scheduled to disappear on October 24th, and --

DR. NAG: But we have at least from August 10th and July 26th and July 29th -- these are the three when you are going to have a lot of applications. Is there any way we can either speed it

up between about two or three months?

DR. HOWE: We sent them a letter requesting additional information, and they did not submit that additional information til the last week.

DR. NAG: Do we have an example of what these additional information are? We may be able to push some of these things also through our own direct connection if we know what some of the concerns are because this is a very, very important thing where the Subpart J has already expired.

MS. FLANNERY: Some of the examples, they would list some topics for required training or some topics for work experience or number of hours, and they just weren't specific enough.

CHAIRMAN MALMUD: Dr. Williamson?

MS. FLANNERY: That's a common example of additional information. It's just more of a clarification.

CHAIRMAN MALMUD: Go ahead.

DR. WILLIAMSON: From what I'm hearing, it sounds like not all individuals who are board certified, who have been certified by the American Board of Radiology, will be included in this pathway, and that there are certain segments of the certified professional community that will be excluded from this

pathway.

Could you explain case by case within the ABR framework which individuals or groups of individuals are going to so be excluded and what the issues are? Because, yo know, numerous concerns have been expressed to me by members of the community about this process.

DR. HOWE: I don't think we're far enough in the review to know what groups will be excluded, but I can give you an example of the American Board of Nuclear Medicine. In the American Board of Nuclear Medicine, there is a residency program, and the residency program in our requirements, there are two accreditation boards for the residency program.

They had a third accreditation board, and then if you look at the requirements for 100 and 200, the actual work experience that's also required under the board certification pathway had to be given under the supervision of an authorized user, and those individuals that were receiving their training in Canada were not getting their training under an authorized user.

So the Canadian group is open to take the examination, but they don't meet the requirements in 35-190 or 290. So the board put a notation on the

bottom of the certificate, one United States, the other Canada so that we would see exactly who met our requirements. So we are not holding the boards to any requirements other than what's in our regulation.

Another example would be the cardiology group. They have foreign individuals that take their examination, but they issue two different certificates. One certificate is for those cardiologists residing in the United States. They meet the criteria of coming under the supervised work experience of authorized users. The ones that do not reside in the United States don't meet that criteria. They take the same examination. They pass, they fail, but we have a way of telling who meets our criteria and who doesn't.

So that is an example of distinction between groups, but we can't discuss the American Board of Radiology.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

Dr. Zelac.

DR. ZELAC: Yes. To answer your question specifically, additional information was requested from that particular board, the American Board of Radiology, after the application was submitted and reviewed. In turn, the board did supply additional

information, but just very, very recently.

We are in the process of reviewing the additional information to be sure that, in fact, it does satisfy the requested need to show conformity of the program or programs actually with the current regulations.

The presumption that there may be certified individuals who will not be accepted is premature. If the program in effect as described meets the criteria and if it is essentially, as pointed out by Dr. Howe earlier, one that has been in effect for a considerable period of time, all of the diplomates since the program that is described was established will be eligible.

So that's part of the process in dealing with the boards, to find out when the program which is being described which we deem to be acceptable in terms of matching the regulations requirements was established, and that's the date that gets put into the Web site along with the recognition of that board's certification process.

So in summary, we cannot presume at this time that there will be individuals certified by the ABR whose certifications will not be acceptable. Until we get some information back from the ABR as to

when its program as described was established, it's premature to presume anything.

CHAIRMAN MALMUD: Mr. Bailey.

MR. BAILEY: Since I come from a segment that licenses 80 percent of the radioactive material users in the country, am I correct that agreement states who put someone on the license as an authorized user, those people will automatically be accepted as authorized users by NRC?

DR. HOWE: Right now the agreement states have three years to implement the revisions to Part 35 that were made final in April of 2005, and so until April of 2008, the agreement states, unless they revise their regulations to conform with the current Part 35, can still use Subpart J or what they're using to recognize authorized users, and NRC recognizes people that are recognized as authorized users as authorized users for the same medical use.

So if you are a physician on an agreement state license for the same medical use, then you can be recognized by the NRC.

MR. BAILEY: And does that also apply or how will you take into account those states that, for instance, license physicists? Will those automatically be recognized if it's a state licensure,

as opposed to a board certification?

DR. HOWE: We have a definition of an authorized user, an authorized medical physicist, and an authorized nuclear pharmacist, and those definitions include individuals that are currently on licenses that recognize them for that use for the materials which they're authorized.

So if you have a medical physicist on an agreement statement license that's recognized for 600 uses because that's where we name medical physicists or for Strontium I applicator, then we would accept them as existing authorized users or a medical physicist or pharmacist.

MR. BAILEY: I was referring to a different type of licensure. I was talking about professional licensure, not named on a materials license necessarily.

DR. HOWE: This only addresses board certification routes.

MR. BAILEY: So you would not recognize state licensure, say, in medical physics?

DR. HOWE: Medical physicists are not required to be stated licensed, and so we would not.

MR. BAILEY: They are in some states.

DR. HOWE: By the NRC.

MR. BAILEY: Right.

DR. HOWE: The criteria to be an authorized medical physicist does not include licensure. Some states do license them, but not -- so they would have to meet our requirements or be listed on an agreement state license or already listed on an NRC license because the training and experience rule grandfathers those individuals that are already recognized.

CHAIRMAN MALMUD: Does that answer your question, Mr. Bailey?

MR. BAILEY: Yeah, but not very satisfactorily because if you have a state law that says somebody is something in that state and then you pass a federal regulation that says they have to meet some other requirement, I think there's a little bit of conflict there.

DR. HOWE: But does your state, when it calls someone a medical physicist, does it include normal diagnostic physics? Does it include brachytherapy physics? Does it include things that are outside of what we're looking at?

We can only judge a physicist based on how we list an authorized medical physicist. There are many, many areas that a physicist can function in that that are beyond our authorizations.

MR. BAILEY: I think in different states there are different categories in how those are broken down, and I would assume, although I don't know specifically, that someone who is licensed as a therapy medical physicist should be able to meet the requirements.

But are you going to go do each of the state boards that do license physicists, some of whom may not be board certified?

And I would give an example. There might be someone, for example, in the State of Texas, which does license physicists, who's working at a VA hospital in Texas as a therapy medical physicist.

DR. HOWE: And if there is a physicist that's working at the VA, that physicist needs to come under our NRC requirements to be listed as an authorized medical physicist on that VA permit because the VA is a master materials licensee, and so they have to follow the NRC requirements.

So they would be listed on an NRC license as a medical physicist if they met our requirements. But we don't require our medical physicists to be licensed.

MR. BAILEY: Oh, you do not?

DR. HOWE: We do require our doctors to be

licensed. We require our pharmacists and our physicians to be licensed. They don't have to be licensed in the state in which they practice, but they do have to be licensed. That's in our definition.

CHAIRMAN MALMUD: Does that clarify the issue for you, Mr. Bailey?

Thank you. Thank you, Dr. Howe.

Dr. Nag.

DR. NAG: Since the states have three years to comply, how does this ruling apply to the states? I mean, October 24th the Subpart J expired for the NRC. You know, if you are board certified in one of the agreement states, do you have until October 24th of 2008 for this thing to be applicable or how does it apply in the agreement states?

DR. HOWE: It depends on what the individual agreement state has done. There are some agreement states that may be implementing the new rule quicker than 2008. There may be other agreement states that won't be able to implement the new rule until 2008. So it depends on what the agreement state is doing.

If they have not implemented the new rule, then Subpart J still exists with that agreement state.

DR. NAG: So in many agreement states

there may have until October of 2008 or is it October of 2008 or April --

DR. HOWE: April

DR. NAG: -- of 2008?

DR. HOWE: April of 2008.

DR. ZELAC: Essentially, an individual applying for recognition in addition to a license in an agreement state has to satisfy the requirements in that agreement state. In most of the agreement states, the regulations do mirror what was in Subpart J.

CHAIRMAN MALMUD: Dr. Williamson.

DR. WILLIAMSON: Could you describe what subgroups of certified health physicists are excluded from the recognition pathway, the board recognition pathway?

DR. HOWE: I think it's too early to say. We're currently working with the American Board of Health Physics, for them to give us a date at which they meet the requirements in the current Part 35, and we are expecting that they may be able to do as some of the other boards have done. They may change their requirements to meet the new rule, but they may also be able to go back and look at who is certified and see that those individuals may, in fact, meet our new

rule, and so --

DR. WILLIAMSON: What is the requirement that they don't meet, since every effort was made to craft this new regulation so that it would match, you know, the current practices of the boards?

This was the underlying intent. So I'm very concerned when you tell me now that there are potentially large segments of certified professionals that will be excluded from this pathway, you know. Reports have come to me from various representatives of boards and the scientific societies involved in these processes that, you know, excessively literal interpretations of the regulations, including, for example, refusing to recognize radiological sciences as being a medical physics degree and so forth. Concerns like this have been raised.

I just would like some assurance this is not the case.

DR. HOWE: I don't believe we have said radiological sciences was not a physical science. The criteria for certification under what we would call the health physics pathway because there are two different pathways for a radiation safety officer. One is the diagnostic nuclear medicine medical physicist. The other is the health physics, and that

is that they have a Bachelor or graduate's degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science.

So physical science is a very general term, and we have been asked in the past to look at a list of things that you may not be able to make a determination whether it was a physical science or not, and we've got back to that particular board and said, "We can't make that determination. We're assuming that the board,when it looks at the transcripts from that group,will be able to tell whether that particular degree really is physical science." Because the title itself just does not allow us to make a broad category decision.

But the boards are supposed to require that they be in physical science, and if it's in a physical science no matter what its name is they should be able to recognize it.

MR. LEITO: So if I interpret what you're saying, that you're leaving it to the board to make that decision that it meets that requirement, and if they do and they accept the candidate, then you're deferring to the board. You're not trying to say, well, we disagree with you and we don't consider that

a physical science. Therefore, we don't recognize that candidate.

DR. HOWE: I think it's very clear that we do not consider engineering a physical science, and we do not consider biological science a physical science, and you'll see that in those areas where an engineering degree is appropriate, it says engineering. It says physical science, engineering, and then biologic with hours of physical science.

So that hasn't been an issue yet because those are in the radiation safety officer. They're also -- I don't know if they're in the medical physics one or not.

CHAIRMAN MALMUD: Mr. Leito.

MR. LEITO; Well, two points. One, I've got to really underscore what Jeff said, that we made every effort in crafting the words and the intent so that this would not set into a new criterion, that we'd have this transition that would be as smooth as possible and as general as possible. There was no intent that these were meant to be extremely prescriptive interpretations of the words.

The second point is that I'm getting real mixed signals here because what Ron had alluded to was that if a board that has existed, let's say the

American Board of Radiology now comes in and provides the criteria to demonstrate that, the new criteria are met; that any previous candidates that may have not been listed as authorized users were going to be -- that certification would be recognized.

What I'm hearing from you, Dona-Beth, is that if a person was board certified, let's say by the American Board of Radiology in the year 2000, was not listed as an authorized user, now comes and applies via their board certification to be an authorized user because of the new criteria, and let's say the board's criteria are established, let's say, as of today; they aren't going to be recognized as an authorized user via the board certification, and that is really 180 degrees from whatever was intended in this process.

So I don't know. Like I said, I'm getting mixed signals and I don't know which ones were supposed to be followed here.

DR. HOWE: I think Ron can answer this, but I think we're both saying the same thing.

DR. ZELAC: Just to answer both your concern and what was expressed by Dr. Williamson. We all know that a huge amount of effort was put in both by the Advisory Committee and the staff to craft a rule that would satisfy the need for recognition of

those individuals who were board certified by the existing boards, because those people who had been board certified and were users had certainly been recognized to be qualified and competent and certainly adequately prepared to do the jobs.

So, first of all, just to acknowledge, yes, there was a huge amount of effort and, yes, the intent was to have a regulation in place that would in many cases mirror the requirements of the existing boards. I think that's kind of a given from the past.

The thing that we're trying to do with the boards is to have them indicate to us when the programs, which were the ones that were in effect at the time the regulation was being established and upon which the regulation was mirrored, when those program were established. Was the program, for example, the ABHP that we reviewed and will probably -- it's an approvable status at the moment, isn't it? Yeah, it's not up as approved, but it's approvable.

When was that program established? Last year, five years ago, 15 years ago?

DR. HOWE: Two years from now.

DR. ZELAC: Yeah. Well, whatever it is --

DR. HOWE: It's a spectrum.

DR. ZELAC: -- that's what we're looking

for so that that date goes in as well as the name of the board's process, and so all of the diplomates from that date forward will be recognized as long as that's the process that the board uses.

It's very possible that there will be individuals -- you gave the example -- who came in under a program that didn't meet the criteria that are in effect now by that board and are not reflected in the regulations. If those people come in, they'll have to be by the alternate pathway if they're not already authorized individuals.

MR. LEITO: What you're saying is that you're basically disenfranchising those people that met board certification requirements at the time. So if they met the board certification requirements at the time that those rules were in effect, you're now saying, "Well, because we didn't list you on a board or on a license, you can't be listed as an authorized user." Is that correct? That's correct. Oh, boy.

DR. NAG: I would like to introduce a motion.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: Yeah, I would like to introduce a motion. I am very much concerned that the expiree of Subpart J yesterday we need to avoid, and we

haven't solved some of the problem. In fact, nine out of the 12 boards have not internally solved. They're under review. Others are awaiting further input.

So I would like to make the following motion: that Subpart J, although it expired October 24th, be extended by a period of either six months or one year.-- we can discuss that -- to allow the NRC officials and the boards to resolve some of the problems. Otherwise we are going to be faced with multiple problems.

You know, this is the motion I'd like to place on the table.

CHAIRMAN MALMUD: Dr. Nag has made a motion. Is there a second to his motion?

(No response.)

CHAIRMAN MALMUD: There being no second to the motion, the motion doesn't carry forward.

Mr. Bailey had his hand up for a while.

MR. BAILEY: I was disturbed by the statement that engineering was not a physical science.

DR. HOWE: Engineering is an applied science

MR. BAILEY: I would beg to differ with you, having two engineering degrees and having courses that were listed as either physics or engineering,

depending upon which school you were enrolled in and chemistry courses that were the same way.

DR. HOWE: I think you'll find that where we have a requirement for a physical science, we also add "or engineering," and so you are not disenfranchised. You are included in the particular area where those are addressed.

MR. BAILEY: I thought you said for RSOs, “engineering” would not count.

DR. HOWE: No. For an RSO it can be in physical science or engineering or biological science with 20 --

MR. BAILEY: Okay.

DR. HOWE: -- credit hours in physical science. So the engineers are included.

DR. WILLIAMSON: But not biologists who have engineering courses instead of physical sciences.

MR. BAILEY: Right.

DR. WILLIAMSON: Is that what's disenfranchised?

DR. HOWE: That's disenfranchised.

DR. WILLIAMSON: All right. Well, I think I do have a motion I would like to make.

CHAIRMAN MALMUD: Dr. Williamson.

DR. WILLIAMSON: I think that I would like the details of the process to be made clear on the presumption that an excessively literalist and narrow minded interpretation of the words in this rule have been made by the NRC staff, and that needlessly, you know, various segments of the certified professional population are going to be excluded from the board certification pathway.

So I think that you've been very circumspect, and it seems to me reluctant to give us any details of what's going on, and I'm very concerned.

So my motion is to the effect that, you know, I think the process you're going through needs to be reviewed by us in some more detail so that we can, you know, verify whether there really are, in fact, some substantial efficiencies and discrepancies between the board certification process and the rule or is this just sort of an artifact of excessive literalism?

CHAIRMAN MALMUD: Dr. Williamson, would you care to rephrase your --

(Laughter.)

CHAIRMAN MALMUD: -- motion with fewer adjectives?

DR. WILLIAMSON: Yes, I'll try. It's a very difficult one. The ACMUI requests that a more detailed explanation be given for each form of board certification that when deemed approvable excludes past or current diplomates of that board from the board certification pathway.

CHAIRMAN MALMUD: Dr. Williamson has made a motion. Is there a second to that motion?

MR. LEITO: I'll second.

CHAIRMAN MALMUD: Mr. Leito seconds the motion.

Is there discussion of the motion?

DR. VETTER: I'm not sure whether you can answer this because it depends on what the boards have told you, but if an individual was originally certified, let's say, in 1975 and the board requires recertification every six years and they have been keeping up to date on that, when was it that they were last board certified? Which date are you using? Is it the '75 date or is it a more recent one when their certification was renewed?

CHAIRMAN MALMUD: That's a question to NRC staff.

DR. ZELAC: That question has not come up.

DR. VETTER: Well, I would contend that

they have been -- you know, you had talked about dates. How far back does the process go? I would contend that it only needs to go back no more certainly than six years ago when they were renewed. So, you know, whether they were certified, it doesn't matter when they were certified in the past. It was renewed, and the last renewal date. So I don't think boards have to go back and include all of these people forever. That's why I don't think we need to worry about Subpart J. I think people who have been recertified are, in fact, qualified under the new Part 35.

DR. ZELAC: I wouldn't necessarily disagree with you, but I'm not going to say that that's going to be the interpretation that our General Counsel has. Are you looking for any feedback at this point? I mean, we're all around the table. Are you looking for any feedback from us as to what's going on here?

PARTICIPANTS: Yes.

CHAIRMAN MALMUD: Dr. Zelac, you've hit right --

DR. WILLIAMSON: That's the point of my motion.

DR. ZELAC: Rather than too much formalism

here, why don't we just get into what's going on?

DR. WILLIAMSON: Well, please, we've been trying to step around the question and pry information from you. That's why I made the motion.

DR. ZELAC: The Federal Register notice for the revisions to Part 35, the training and experience, were published on March 30th in the Federal Register to be effective one month afterwards, April 29th.

As soon as the publication came out in the Federal Register, the procedures that would be utilized by staff in reviewing applications were sent out in written form to all of the boards. That was in Cindy's first slide on April 4th, I believe, or 9th. Very early in April letters went out to all the board with about seven pages, which had to do not only with reviews of the applications that would be put in and what should be in those applications and the format for making those applications, but also the procedures that would be followed in reviewing any changes to board procedures in the future, when a particular board might be delisted and the reasons for doing so. All of that was made available in early April.

Along with that was a suggestion that boards, particularly those whose programs were not at

that point recognized, but all of the boards that were interested in being recognized submit their applications ASAP, but 'please' by suggested August 15th at the latest.

So that's kind of where we stood in terms of how we would do. So the procedures that would be followed are in written form. They were reviewed extensively and revised, and they're out there and they are, in fact, up on the Web site and have been since early April.

So what we do in terms of looking at and reviewing applications from boards is there to be seen.

Secondly, the applications come in. They are initially reviewed. If there are obvious deficiencies in the information, it simply doesn't address the requirements that exist in the rule. Then the board is so notified. If an application comes in and it is apparent that the board is attempting to satisfy or at least provide information relating to the requirements in the rule, but there are some questions as to when something came into play, when it was established, what it actually means, you know, the requirement for the hours or whatever, then the board is contacted for supplementary information, and then

when supplied, that information is reviewed.

Oftentimes this back and forth between staff and the board takes place initially verbally, direct telephone conversations or via E-mails. At the point when the board is satisfied that they have sufficiently complete information to supplement their initial application, then they send it in in a formal letter to Mr. Essig. That along with the original letter or that as a substitute for the original letter serves as the basis for that board's process being recognized and that board being listed on the Web site.

Is there anything else? Yes.

CHAIRMAN MALMUD: Dr. Williamson.

DR. WILLIAMSON: The point of my motion is to learn more of the details of why segments of board certified or subgroups of board certified professionals are being excluded from the certification pathway.

DR. ZELAC: Well, that was my point initially.

DR. WILLIAMSON: I would like to know --

DR. ZELAC: They're not.

DR. WILLIAMSON: -- precisely which groups are being excluded in each of the categories and why.

In what form, what is the reason that they fail to meet the stated criteria in the rule?

That's what I'm asking because I'm concerned that you are dismissing and disenfranchising groups for essentially silly reasons; that, for example, I teach a transport theory course that in most institutions with a nuclear engineering program would be a nuclear engineering course. In my institution it's a physics course.

It is essentially hard core radiation physics at a very abstract level, and I think by anybody's estimation would be a reasonable course to bring forward for satisfying a course requirement in physical science.

And so if these are the reasons why, if your other reasons are like this, I'm going to be and my whole community will be very distressed that for essentially silly little reasons, you know, some harm is being done to a subgroup of professionals, and so I've heard nothing to dispel my concern.

DR. ZELAC: What we go on in terms of reviewing an application is what the board says. Now, if the board says that we are going to satisfy the requirements in 3050(a)(2) and they specifically outline that, yes, we are going to satisfy this, this,

this and the other thing, and what's up on their Web site, because most boards do have a Web site, reflects that, they're good. There's nothing more to be said.

We're not going to look at specific courses from particular candidate individuals. The board has made a statement that we will meet your criteria, and this is what we're telling our candidates you have to have in order for us to accept you as a candidate for recognition, and you know, that's it.

And if the board says that to us and the board says that to its candidates, that's it. End of story. Their program is recognized.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: Yes, I'd probably like to ask Tom perhaps. We are discussing details of what mechanism and what are the points made by some of the boards may not have met the requirement and so on. On a broader picture what I would like to know is, is it possible to have a temporary fix until all of the approval percents have been resolved so, that the board certification pathway (being the default pathway) still continues to exist because my major concern is that expired yesterday; and yes, we will have a lot of problems still going on. But we need

something that is a temporary fix that will allow a board certification person to be a default pathway until the issues are resolved.

Can you suggest some mechanism to temporarily fix that?

CHAIRMAN MALMUD: Dr. Diamond.

DR. DIAMOND: So if I can understand you correctly, your concern is what happens if next year at this time ABR has not been approved and what happens to all of the diplomates?

DR. NAG: Or even tomorrow.

DR. DIAMOND: Okay. Let me just -- I want to make sure I understand it clearly. So let's take the example of the radiation oncology trainees who are going to be finishing up their programs in May and June of 2006. Those individuals, provided they have passed their written examinations, will sit for their oral examinations in the fall of 2006, and provided those individuals pass, at that point they will become diplomates of the American Board of Radiology.

Do we have any reason at this point to be concerned that the American Board of Radiology working in good faith with the staff is going to have any problems before the fall of 2006 such that the crop of ABR candidates could possibly be board certified, but

not become AUs?

I think that's the main issue that Subir and I would have on this particular issue.

And then to continue that, I'm not really sure what's going on with the American Society of Clinical Endocrinologists, but again, let's say they have a crop of candidates finishing their fellowships in May and June of 2006. I don't know when they take their boards, but you know, are they working with you in good faith to resolve that or are we going to have a situation where we have a whole crop of new endocrinology fellows who are not going to be authorized for their iodine uses?

DR. ZELAC: Let me speak to the latter portion of your question. The American Association of Clinical Endocrinologists does not at this point have a board certification program. They had inquired when they became aware of the direction that the regulations were going about the possibility of establishing such a board and asked us to provide them with information as it progressed on the process involved so that they could consider it and make a determination.

DR. DIAMOND: So if I understand you correctly then, the endocrinologists that use I-131

for uses that we discussed, they go through essentially an alternate pathway to become AUs. Is that --

DR. ZELAC: That's correct.

DR. DIAMOND: All right. So that's really a non-issue then.

DR. ZELAC: That's right, and that's why there isn't concern at this point that there's been no response back from them.

DR. DIAMOND: Because I'm a practical guy. I'm interested in practical issues. So, again, getting back to the ABR, do we have any concern that the ABR working in good faith with the staff would be in a situation whereby in the fall of 2006 they're not listed as approved and then we have a real mess on our hands regarding a whole crop of, for example, radiation oncologists that could not be authorized users.

DR. NAG: And we don't even have to go as forward as the fall of 2006. What about the problem of someone who became board certified as of this year, 2005, has not applied, and is now applying, subs like they have now expired, and we really have --

DR. DIAMOND: But, again, they became diplomates if they passed their oral examinations. A

few months ago they would have become diplomates of the ABR prior to the expiration of Subpart J.

I guess the only issue is, and I remember it, if some condition in the oral examination has to retake it, that would be a problem.

DR. NAG: Right. There are people who, you know, may be taking a repeat exam later this year. So, I mean, I think we do need a temporary fix right now until all of the board certification problems have been resolved, and need a temporary fix today

CHAIRMAN MALMUD: Mr. Bailey.

MR. BAILEY: Yeah. What I wanted to do was emphasize that if I had decided to quit working for California and go be a hospital RSO, yesterday I would have been acceptable under Subpart J. Today I'm not acceptable; is that right, as a CHP?

DR. ZELAC: If you were going to assume your responsibilities in an agreement state --

MR. BAILEY: No, I'm not. I'm coming to work right here in D.C.

(Laughter.)

MR. BAILEY: So there's no question. At a VA hospital.

DR. ZELAC: The answer to your question is if you had on October 23rd put in an application and

you were using as the basis for your recognition your CHP, it would have been acceptable.

MR. BAILEY: Right.

DR. ZELAC: If you put it in today, it will not be. You'd have to come in through the alternate pathway.

CHAIRMAN MALMUD: We have a representative here from the AAPM who would like to make a comment.

MS. FAIROBENT: Yes, Lynne Fairobent with AAPM.

Dr. Vetter, I just wanted to follow up on something you brought up a few discussion pieces ago, which was on certification and renewal. Remember there are quite a few people that have lifetime certificates and don't recertify. That's true for medical physics. That's true for physician authorized users.

And the other comment that I did want to make goes back to the four states that do require licensure for a medical physicist because those four states, we have been working with them, and there is a disconnect between the state licensure laws and NRC's regs.

So, in fact, you could be licensed in the State of Florida to be a medical physicist practicing

in therapy and not be able to qualify at the moment or once Florida should adopt these regulations, and not qualify as a therapy physicist without them coming to some agreement between the materials program in Florida and the board's state licensure folks.

So there is a potential problem there, and in order to be licensed in one of these four states you do have to have board certification first.

CHAIRMAN MALMUD: Thank you.

So it appears that we have some current problems.

Dr. Miller?

DR. MILLER: Yes, I'd like to bring up an issue that Donna-Beth brought to my attention as a matter of protocol. Specifically with the ABR, right, Donna-Beth?

You know, we've recently received their response. We've reviewed it, but there are some things that we still need to discuss with them. We haven't had a chance to discuss it with them, and the question that she was raising is if we discussed it in this form, we're discussing some specifics that yet the board hasn't received from us with regard to, you know, deficiencies yet in the application.

And I guess the question from the

committee is: do you want to get into those kinds of things, recognizing that the board yet hasn't heard it from us?

CHAIRMAN MALMUD: Dr. Diamond.

DR. DIAMOND: Sure. Again, I just want to respond to that for a pragmatic fashion. What we're trying -- what I'm trying to do at least is I'm trying to think through all the different permutations that are going to be transpiring and prevent preventable problem if we can.

I have every reason to believe that the ABR is going to be working in good faith with the staff and that these issues will be worked out in the near future and that will be the end of that particular issue.

Again, I am a little concerned that there is a potential for some delay transpiring, and that we could potentially have a situation of candidates, let's say, who took, let's say, the October 2005 oral examination, radiation oncology. There's a built in fail and condition rate around what, 25, 30 percent, Subir?

DR. NAG: Yeah.

DR. DIAMOND: That means you have a lot of good people that fail. That's just what they do, I

guess, and they retake it in six months, I believe.

I just want to do everything that we can to make sure that we can work out these detail issues so that there's not a whole crop of individuals that have now become board certified, but because of the timing of their certification, are in sort of a limbo.

That's my specific issue on that.

CHAIRMAN MALMUD: Dr. Zelac.

DR. ZELAC: I don't know that there would be an issue even if these individuals were not able to get authorized under the board certification pathway. The requirements under the alternate pathway are no more -- well, in one respect they are, but I don't think -- sorry.

In one respect they are, but I don't think that individuals would have a problem, and it all really relates to the training that they've had and the preceptor statement that is supplied. A huge amount of importance is placed on the preceptor statement, and recall that by the change in the regulation, the preceptor does not have to be the individual who provided the training and experience, but simply can be an individual who verifies that all of it was provided.

CHAIRMAN MALMUD: Okay. Thank you.

Is there a motion on the table now? It has been a while since we had discussion on that.

DR. WILLIAMSON: Yes, I was going to remind the group that I had made a motion that basically asked the responsible staff to provide the details in any case where a board certified professional was omitted or left out from the board certification pathway and that, you know, the detailed issues, in fact, could be examined at least at some point.

DR. NAG: And I would like to remind that I had made the request is there any way to have a temporary fix until these result? Is there any simple solution from an administrative way to say, well, we'll continue this until these are fixed?

Something that you can do administratively so that we don't end up in this limbo thing.

CHAIRMAN MALMUD: These are two separate issues, if I may. There's Dr. Williamson's motion, and can we once again have you express it concisely without excessive adjectives and adverbs?

DR. WILLIAMSON: Yes. What do you call your group, the certification review group?

DR. HOWE: Actually it's the entire medical radiation safety team.

DR. WILLIAMSON: Okay. That the MRC staff reviewing applications for recognition of board certification by the U.S. NRC provide detailed explanation in any case where a board certified individual fails to be included in the certification pathway because of a change or discrepancy in requirements.

CHAIRMAN MALMUD: All right. Was that motion seconded?

MR. LEITO: Yes, I seconded it.

CHAIRMAN MALMUD: Your second stands?

MR. LEITO: Yes, it still stands.

CHAIRMAN MALMUD: Any further discussion on Dr. Williamson's motion? Dr. Vetter.

DR. VETTER: Correct me if I'm wrong, NRC staff, but I don't think they're reviewing the qualifications of individuals

DR. WILLIAMSON: No, they're reviewing the qualifications of the boards as a function of time, and I understand what they are doing is because of possible semantic issues, they're getting the board to prospectively change and refine their requirements which creates the potential that past diplomates of a certification process will not be recognized with the future diplomates; that, in short, they're placing

cutoff dates and dividing the certified population into two parts, one part that will be recognized and one part that will not.

And so I'm asking that whenever the second part is non-zero, that a detailed explanation be given.

CHAIRMAN MALMUD: that is the motion before this committee. Any further discussion of that motion?

(No response.)

CHAIRMAN MALMUD: All in favor of Dr. Williamson's motion?

DR. SCHWARZ: I do have one question. How would you suggest that this information is provided?

MR. LEITO: Do you want it to come back to us?

DR. WILLIAMSON: Yes, to be provided to the ACMUI for discussion.

CHAIRMAN MALMUD: Dr. Williamson's motion requests that the information be provided to the ACMUI.

Shall we call it? All in favor --

DR. SULEIMAN: I have another question.

CHAIRMAN MALMUD: Oh, excuse me, Dr. Suleiman.

DR. SULEIMAN: The intent of this is to identify people that are going to be disenfranchised, right?

DR. WILLIAMSON: I think the intent is to determine whether, you know, the reason for excluding not individuals, but groups, of individuals, is warranted or not or whether it, in fact, maybe is an overzealous or over literal interpretation of the language in the room.

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

DR. SULEIMAN: Sufficiently.

CHAIRMAN MALMUD: All in favor of Dr. Williamson's motion?

(Show of hands.)

CHAIRMAN MALMUD: All opposed to Dr. Williamson's motion?

(No response.)

CHAIRMAN MALMUD: Any abstentions?

(Show of hands.)

CHAIRMAN MALMUD: All in favor and one abstention.

Now, may I ask a question as a member of the committee? Why would anyone's prior certification be removed without cause, simply for the change of a

regulation?

DR. ZELAC: It wouldn't be -- as an example, if the board simply went out of business, stopped certifying, then it's only those individuals recognized up to the date that the board disappears, or if the board decides they want to go in a different direction in terms of what they require of their candidates for whatever their reasons are and they make a change in their certification requirements for candidates and now what they require of a candidate does not satisfy what exists in the rule as a requirement, then from that point on that board's certification process will be producing diplomates whose certifications cannot be recognized as being adequate for following the certification pathway to their own individual recognition.

CHAIRMAN MALMUD: So may I ask why couldn't that simply be stated, that if the board changes its regulations and no longer conforms to the new standards, that that board's future individuals who are certified would not be recognized?

DR. ZELAC: That is there. It's not part of the regulation, but it certainly is in the procedures that we have placed on the Web as being available. So any of the boards that want to be

taking various actions or not have that to review as a consideration of potential consequences of the actions they are considering.

CHAIRMAN MALMUD: Wouldn't that statement though achieve the same goal without raising the anxiety among all certified practitioners that their current certification may become insufficient to allow them to practice?

DR. ZELAC: This has nothing to do with current recognized individuals. If they were recognized under a process that met the requirements of the NRC's regulations, they're good. As long as those regulations are not changed, they're good.

If the board changes its process, then future diplomates of the board may not be.

DR. HOWE: The only issue here are those individuals that are not recognized on a license or broad scope permit or a master materials license permit as authorized users, as medical physicists, as pharmacists, as RSOs. It's those certification folks that have not gotten into that stream that are the ones that come into question.

CHAIRMAN MALMUD: Is it the individuals who are currently not recognized as authorized users or who have never been recognized as authorized users?

DR. HOWE: The regulations read that they are listed on a license. So there is an "is" which is kind of a present tense. So if you're one of these individuals and you're on a current license, the concept is that you met the requirements for when you were put on the license and you're still practicing and, therefore, you're current and that is easy to transfer to the next liense.

CHAIRMAN MALMUD: But if you quit a week ago and you're no longer on that license, you're not on the license.

DR. WILLIAMSON: A good example might be someone, for example, a medical physicist who became certified, say, in the year 2000, has worked in an institution for four or five years without HDR brachytherapy, moves to an institution where there is HDR brachytherapy and seeks now to become an authorized medical physicist for that modality, but maybe because of some SNAFU over wording, the board, the ABR or ABMP has had to change its language effective 2005 to meet the NRC regulations.

This notch group of physicists that weren't authorized medical physicists may be disenfranchised from the process and will have to go through the alternate pathway route.

CHAIRMAN MALMUD: I think what -- I'll recognize you in a second, Dr. Nag -- I think what you're hearing is the bases for the anxiety among current users and potentially new users for interpretations of the new regulations, which are highly legalistic and, therefore, perhaps precise, but which in the process will exclude current practitioners from the privileges which they currently enjoy or would otherwise enjoy, and this has had reverberations throughout the country for which reasons we are receiving phone calls from currently certified authorized users.

Dr. Nag.

DR. NAG: Yes. I think in addition to my previous request for a temporary fix that would allow board certification by the way in the default pathway, I would like to add to that a grandfathering clause that people who were already existing users, even though there may be tenure in their new board requirement, they would still continue to be authorized users or authorized medical physicists, et cetera.

So, again, I would like to request for some type of temporary fix to allow the board certification pathway and to be a grandfathering

clause.

CHAIRMAN MALMUD: Mr. Bailey.

MR. BAILEY: I'm a little concerned because I got to thinking about it, and I know several institutions that have more than one certified health physicist on it, but they only have one RSO, but they've been working as an RSO, but they are not listed on the license, although they're certified.

So how are -- I mean, that's one example. I think you will also have with medical physicists who are not necessarily --

MR. LEITO: I would just as a corollary to Edgar, you only allow one RSO to be listed on the license. So even if you had three or four individuals of equal capabilities to function independently, they're only allowed to have one on the license.

CHAIRMAN MALMUD: In a department with multiple physicists or multiple radiation oncologists or nuclear physicians or radiologists, there's one authorized license?

DR. ZELAC: No, no. It only applies to radiation safety officers listed on the license. An individual license can have as many authorized users as they wish or as many authorized medical physicists or authorized nuclear pharmacists as they wish, all

listed on the license.

CHAIRMAN MALMUD: So the situation you describe applies only to the physicist.

PARTICIPANTS: The RSOs.

CHAIRMAN MALMUD: The RSOs. Excuse me.

MR. BAILEY: I think it can also apply to a physicist who is in training.

DR. WILLIAMSON: I think it can apply to a physicist who is not in training, who happens to be, you know, temporarily engaged in employment that doesn't involve use of the particular byproduct materials over which NRC has jurisdiction.

So I'd say there's a lot. Take myself, for example. I function for the last three years largely as an administrator and researcher. So if I chose to go back to clinical practice, maybe my board certification would not be recognized, and that would be, you know, considerable hassle and expense for me, even though I've had many years of experience doing this and have written textbooks and hundreds of articles on the subject, that I would not be able to be recognized as an authorized medical physicist for HDR.

So I have concerns. I only want to make sure that if a segment of the certified population is

being excluded from this pathway, there are very good reasons for it, and you know, not a debatable semantic issue.

CHAIRMAN MALMUD: So in summary, it sounds as if the current regulations as being reformatted have the unintended consequence of at least potentially, if not actually, disenfranchising some current authorized users.

DR. WILLIAMSON: Disenfranchising some individuals who previously would have been eligible to be authorized users or physicists or pharmacists, but who now, due to various time blocks of certificate not being recognized can no longer be so recognized.

DR. HOWE: I think you can exclude the pharmacists because they're recognized back to '96, and I think they have a seven-year cycle.

CHAIRMAN MALMUD: So we need to craft some language to make certain that we don't create an unintended consequence which will have an impact on the community which serves patients.

DR. ZELAC: Excuse me. Can I interrupt at this point?

CHAIRMAN MALMUD: Dr. Zelac.

DR. ZELAC: I think it's important to recognize that we look at what's submitted from a

particular board. We try to get from that board sufficient information to be able to approve the program that they discuss as far back as it existed, but it's really the board that needs to supply the information

As Dr. Howe mentioned earlier, in some cases the practice of a board doesn't necessarily agree totally with the information that it had available to their candidates or on the Web site or whatever else, but if the program itself, the process has not changed, it will go back in terms of the approval to when that particular program was established in principle, not specifically a word-by-word definition of the program.

So it relies very much on the board and what it says in response to the call for information.

CHAIRMAN MALMUD: I think we recognize that this is not a problem which is solely the responsibility of the NRC. However, the outcome may be one which will limit the marketplace and, therefore, patient care by virtue of disenfranchising some people who could have or currently are providing service.

DR. ZELAC: Let me just remind everyone of what Mr. Bailey said earlier on and it's correct, that

80 percent of the licensees are in agreement states. They have three years from April to come into conformity. So first of all, we're talking about the 20 percent.

Secondly, any individual who wants to achieve authorized status can certainly submit their credentials and those credentials will be considered and, if necessary, an exception or an exemption from the current requirements can be granted if it's appropriate to do so based on the circumstances of what they intend to be doing, what their background is, and their credentialing.

So it's not as if there's a wall over which there are no possibilities for penetration or for jumping over.

CHAIRMAN MALMUD: Does Dr. Zelac's last assurance satisfy your concerns, Dr. Williamson and Mr. Leito?

MR. LEITO: Well, if you're in an agreement state, sure, but I'm not in an agreement state. So the answer is no.

DR. WILLIAMSON: Nor am I.

MR. LEITO: I have a question as a follow-up to what Ron had just talked about. These boards that are either under review or are awaiting further

input. Are there issues where the board is saying, "Well, we've got to change this in our certification process to meet your requirements for new diplomates. Are there any like that or are they all saying, well, the back-and-forth between NRC and these boards, that we're trying to make this sort of retroactive to our certification dates when we were first established?

DR. ZELAC: I think probably the answer to the question ought to be provided by each of us because we've been -- although every application is reviewed by us as a group, there is a principal person in the group that really is fostering and working it through.

To those that I have been reviewing or are involved with, I have not seen anything that has to be changed now which would make all previous diplomates of the boards ineligible for recognition under the certification pathway.

MR. LEITO: Is that true across all of the ones that you guys have reviewed? I'm raising this question to everybody that's up there because my concern gets back to the very issue that Jeff has brought up in that if there are boards that are changing their certification criteria to make NRC happy for future, I'm wondering if they are aware of

what they're doing to their past diplomates.

MR. SABA: Yeah, the American Board of Health Physics, they have to change. They have to exclude some degree things, like mathematics, from their original requirements in order to comply with the new requirements in order to comply with the new requirements.

CHAIRMAN MALMUD: There is a representative here from the American Board of Health Physics who would like to speak. May we?

MS. ST. GERMAIN: I'm sure they would appreciate that, but on the American Board of Medical Physics.

CHAIRMAN MALMUD: American Board of Medical Physic.

MS. ST. GERMAIN: Although I do have both certifications, but I'd like to say a few words.

First of all, with regard to the number of boards that were solicited, the Canadian College of Medical Physics is not listed, and that is certainly a board that has been approved in the past by various state agencies and a board whose diplomates function in some of our border states to the north on both sides of that border.

So I would suggest that perhaps they might

be solicited for their input on this as well, and if it doesn't happen here, will from AAPM sine the many Canadians belong to the American Association of Physicists and Medicine, taking it as the North American Association. We will make sure that they are aware of this.

With regard to the American Board of Medical Physics, Dr. Howe and I have been having an interesting discussion both on the telephone and by E-mail and there are certain criteria which we are deciding whether or not we're going to change, and they have to do with the acceptability in our case of certain graduate degrees and also the amount of years of experience that can be substituted for graduate degrees and an understanding of what the CAMPEP certification process is.

Now, the problem will be that if we change our requirements going forward, what happens to the people who met those requirements previously under the old rules and are those people who are currently certified going to be accepted going forward once we change the rules, and I think that's one of the reasons that we're still awaiting further input on that.

And so to answer your question which was

raised previously, if we change our rules, are the people who were certified under the old premise going to be allowed to be recognized or is there going to be a date, meaning people certified after this date when our rules change or our criteria change, if they do, accepted whereas people who are certified previously were not accepted.

And I think that's one of the questions that Dr. Williams and others were referring to, and I think it's something that we are wrestling with right now.

DR. HOWE: Could you identify yourself, please?

MS. ST. GERMAIN: I'm Jean St. Germain. I am representing the American Board of Medical Physics. Sorry.

MR. BAILEY: Both Dr. Vetter and I, and maybe some others, have been on the American Board of Health Physics, and I remember when we changed the mathematics degree to require I think it was 20 hours of physical science if you had -- or engineering or whatever -- if you had a degree in mathematics.

My concern though goes back to the days when you did not have to have any degree at all to get certified, and that's going to be a very difficult

cutoff point, I think.

And I know we did discuss concerns about whether or not our exam itself covered all of the aspects that the NRC was looking for in a hospital RSO, and I don't know if they've changed those or if you have changed.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: I have a question for Ron.

Is it possible -- and it's similar to what I had asked before -- is it possible for the NRC to continue under the Subpart J until some of these issues have been resolved? Is there any objection to that? I mean that will at least solve the problem temporarily until we have solved these.

This is becoming a relatively big issue that we haven't solved, and you know, you're having a big problem.

CHAIRMAN MALMUD: Dr. Miller.

DR. MILLER: Okay. I'll speak for the NRC on this one.

You asked if it's possible. Of course it would be possible. The issue here that we're debating, there's a number of things I wanted to bring into it.

One, to continue under Subpart J would

require an act of the Commission. We had to go to the Commission last year to get approval to extend Subpart J for one year. The rationale for extending Subpart J for one year was to allow the T&E rule to get in place and to allow the board sufficient time to submit applications.

The question to my staff: did any of the boards come back and say they didn't have sufficient time to submit an application?

DR. HOWE: I didn't have in.

PARTICIPANT: Nor did I.

DR. MILLER: Okay. So from our perspective, I don't want to find ourselves -- as the regulator, I don't want to find ourselves here at the same time next year in the same situation. I don't think any of us want to find that. From my perspective, I want to do everything that we can to get the boards in good standing as soon as we can so that they become, you know, recertified.

That said, we want to make sure that the boards have met the current requirements in what they're doing, and a lot of the anxiety here is centered on people who are currently board certified who may get disenfranchised as a result of the promulgation of the new regulations. And I think

that's the issue that we have to work ourselves through.

To be quite honest with you, Dr. Nag, if we were to go up and seek extension to Subpart J, that would require the staff to craft a paper to do so. It would have to come up for Commission approval. That might take a number of months before that happens, and my question becomes if they took that long -- and simply because how fast the process can work if it took that long -- you know, I want to make sure we continue to plow forward full steam in trying to get these boards in good standing.

DR. NAG: Right, but the other question was: is there any other way of doing a temporary fix? I mean, is there any way of saying we will -- I mean, I don't know the hierarchy and, you know, your administrative methods. Are there any administrative methods to delay this for a few months?

DR. MILLER: Obviously it has been discussed. The one way is you can always go the alternate pathway. I know that that's problematic. I know that that's burdensome, but that is an alternate way.

CHAIRMAN MALMUD: Dr. Holahan.

DR. HOLAHAN: Yes, we're talking about a

short time span. So we want to get the boards approved quickly, and as Dr. Miller and Dr. Zelac said, we can always go the alternative pathway, and I'd like to know, you know. I think we're looking at a few applications being done. We're talking about disenfranchised, but as Dr. Howe said, if they're currently listed on the license, they're still going to be listed on the license, and it's only those few that may not be listed on a license at the moment and in this time frame they can come in under the alternative pathway, and basically we made the rules that the board certification pathway mimics the alternative pathway.

So I'm asking the ACMUI: how big a problem is it in this time frame?

DR. WILLIAMSON: As I recall, we made the alternative pathway rather more rigorous and detailed and prescriptive than the board certification pathway so that it's, indeed, quite possible that it would be a significant hardship for those who were board certified once we're AU or AMP eligible, but no longer are.

CHAIRMAN MALMUD: Dr. Suleiman.

DR. SULEIMAN: First off, I think I want to clarify. The regulation went into effect

yesterday, today? So it -- right, right. So it's done. So obviously thank you for the clarification, but there's been a whole long process here.

The other thing is I'm wondering. There's clearly a lot of anxiety, but what's the real magnitude of the problem? So, again, I would like to see the boards collect real cases of people being disenfranchised, and if, in fact, there's an epidemic, I would expect the NRC either through internal policy, discretionary enforcement or a whole multitude of things, and you've got 80 percent of the country already under. So they've got a three-year grace period in effect.

So what are the actual numbers of the remaining 20 percent? I want to see the numbers instead of continuing to debate the anxiety, and probably some people are going to be, but you've got alternative pathways, exemptions. There are other ways to address that. Let's see the facts before and I think give the NRC the opportunity to respond, you know, from a policy point of view.

CHAIRMAN MALMUD: Dr. Suleiman, I would first state that to the best of my knowledge thus far there are zero, and from the concerns that have been expressed to me via telephone, I have responded that

there are zero. That doesn't seem to allay the anxiety, but your statement about let's see what comes out of this is certainly a valid one to consider.

Dr. Williamson.

DR. WILLIAMSON: Yes. I think that the motion that I made, which was accepted, that the staff, in fact, carry through with this and provide, you know, a detailed report will give us the basis for determining the magnitude of the problem, and so I agree with you that I think at this point there seems to be little that can be resolved in this forum until that information is available.

DR. SULEIMAN: I have a question. How is the staff going to determine that? Wouldn't it be the boards that would collect? I mean who's going to enforce?

Are you going out right now? How is --

DR. WILLIAMSON: Hold on. Let me try to explain. What they will do if they follow the motion, is they will tell us exaCtly what the cutoffs are in terms of time periods or durations, epochs during which various board certifications are recognized for what. We will also be given the rationale and a reason for epochs that were excluded

We can then go to the boards and we can

find out, I think, how many diplomates are in those different categories and begin to address the magnitude of the problem.

But first we have to understand, you know, the conditions under which the various boards are accepted and the rationales for excluding certain time periods. Then we can go and find out how many individuals are affected by this and in what way.

CHAIRMAN MALMUD: Dr. Williamson, do you mean how many individuals are potentially affected by it?

DR. WILLIAMSON: Potentially affected. That's correct. Thank you for the correction.

CHAIRMAN MALMUD: Is that an achievable administrative task? I ask this of the NRC staff.

MR. ESSIG: Yes.

CHAIRMAN MALMUD: Mr. Essig indicates the answer is yes.

CHAIRMAN MALMUD: Dr. Schwarz.

DR. SCHWARZ: I just would like to ask a question in terms of the boards that are currently being reviewed or are awaiting input. In your estimate, how much longer will it take in terms of being able to have this information finalized from the boards?

I mean, do you think months or another year?

DR. HOWE: I don't think we can tell you an estimate of how long it will take, but I think if you look and see who came in and who's approved now, you'll see that we've gone from August to October and we've approved three boards, and we've done -- some of those boards have been fairly simple with maybe one or two interactions. Others have been more complex with a lot of interactions.

But we're working as quickly as we can, and we're working as closely as we can with the boards to resolve the issues. So I think that is kind of a reasonable expectation for things that have come in recently.

We're going to be working as closely as we can, and we're going to be working as quickly as we can with the boards.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

And with that, may we recognize that it is now 12:35, and we do have a lunch hour which has been delayed a bit? So may we resume instead of at 1:15 at 1:30? Does that give everyone enough time?

It's less than a lunch hour, but it's still time for lunch.

(Whereupon, at 12:39 p.m., the meeting was recessed for lunch, to reconvene at 1:34 p.m., the same day.)

CHAIRMAN MALMUD: We are a few minutes behind right now and we hope to catch up if there are subjects of less controversy to be covered.

It now being one-thirty, the next item on the agenda for this open session is a presentation by Dr. Eggli, which will be regarding the unauthorized injections of radiopharmaceuticals.

Dr. Eggli will present a case history of unauthorized self-injections of radiopharmaceutical by a nuclear medicine technologist for the purpose of acquiring unauthorized imaging studies on themselves.

Dr. Eggli?

DR. EGGLI: Thank you, Dr. Malmud.

I am here today representing the Pennsylvania State University. The Milton S. Hershey Medical Center to present a case history of an unauthorized diagnostic pharmaceutical administration.

In April of 2004, a staff nuclear medicine technologist at the Milton S. Hershey Medical Center asked a student technologist both to perform an unauthorized injection of radiopharmaceutical, which was Technetium-99m HMPAO. And subsequently to perform

a brain tomograph imaging study on herself.

Initially when the student technologist expressed concern, the staff tech said don't worry about it. If anything happens, I'll take the heat for this.

Several weeks earlier, that staff technologist had approached me and relayed a medical history that she thought justified brain imaging. At that time, after discussion, we determined that brain imaging was not justified in that we could not approve it.

And she was specifically warned that if she chose to do it on her own, that it would be a violation of NRC regulation. And that there would be disciplinary consequences as a result of that administration.

At that point, I thought the incident was probably over. However, it wasn't. And the technologist had a student inject her and the scan was performed. The self-injection was discovered when the student began to worry about having done the injection and reported it to our chief technologist.

The staff technologist was within minutes suspended by me after consultation with hospital administration and our radiation safety officer. That

suspension was confirmed in writing by the RSO and subsequently made permanent by the Radiation Safety Committee within 24 hours of the incident.

The incident then was self-reported by Penn State Hershey Medical Center to the NRC. And in May of 2004, Region I initiated an investigation.

An internal investigation was also performed and the results of the investigation that I'm going to share with you represent both the results of the internal investigation at Penn State Hershey Medical Center and the investigation performed in Region I.

In our internal investigation, the technologist never expressed any remorse for her action. In fact, when she came to me to speak about it at the time of the incident, she promised that if I went ahead and reported it, that she would take me down with her and as many other people as she could.

In defense of her action, however, to the NRC she alleged that unauthorized self-administration of diagnostic radiopharmaceuticals was common practice at the Hershey Medical Center. To our knowledge, she never addressed the specific prior warning against the planned self-administration.

Based on that, the NRC launched a somewhat

more than a year long investigation at Penn State Hershey Medical Center. Most of the incidents were discovered to be -- that she reported were discovered to be legitimate medical uses for people who had medical indications and physician requests for their studies.

One incident was so old that it couldn't be tracked down. And two incidents, however, looked like they may have been unauthorized self-administrations of radiopharmaceuticals, one in 2001 and one in `97.

There are timeline issues with the event in `97 and ultimately Hershey Medical Center agreed that it may have occurred. In 2002, the incident involved a technologist who actually had a physician's order for a test but didn't go through the process of getting the approval of the authorized user before injection.

So he essentially had a physician's request in hand and self-injected the radiopharmaceutical.

The 2002 and the 1997 events were not detected by the administration of the Division of Nuclear Medicine or the Health Physics Department at the Milton S. Hershey Medical Center. And they were not detected until they were discovered as part of the

NRC's investigation of the incident which we did discover and report.

If we look at the question of unauthorized injections, I don't know what the incidence of unauthorized injections is but in discussion with Region I staff, their feeling was that this was not an isolated occurrence. Only those incidents which are detected by the licensee actually end up being reported. And neither Penn State nor multiple regular NRC inspections after 1997 before 2004 had detected the two incidents that were detected on the Office of Investigation activity.

And as it turns out, it is actually easy for a technologist to make this sort of incident invisible. The two prior incidents at Hershey again would not have been detected if the incident that we did detect and report had not occurred.

Sort of as a bottom line, you don't know what you don't know.

The dilemma here is for the technologist -- nuclear medicine procedures are considered low risk even by NRC. Nuclear medicine diagnostic procedures are considered low risk procedures. That's part of the design in the Part 35 and the risk informed regulation is these are low-risk procedures.

No adverse outcomes medically can be expected for the technologist who self-administers an unauthorized dose of radiopharmaceutical. The rub in this is that it is nonetheless a violation of the NRC regulation, a misuse of licensed materials.

And effectively Milton S. Hershey Medical Center had to deal with the fact that we had probably three unauthorized misuses of licensed radioactive materials that we were responsible for as the licensee.

We believed that we had a rigorous radiation safety program and that we had adequate policies and procedures in place to protect such an incident.

In fact, each and every one of our technologists to the person when interviewed on the internal investigation stated that they were aware of that prohibition. And that was a core part of their training as a nuclear medicine technologist. And they were fully aware that these sorts of administrations were a violation of NRC regulation.

Again, although we thought we had an adequate radiation safety program, we were obviously wrong because we are now confronted with three incidents of self-administration of

radiopharmaceuticals by technologists.

And as we look at this, a technologist intent on violating NRC regulation for whatever reason can probably do so with a fairly small risk of discovery. And, in fact, the earlier two incidents, had the third incident not occurred, would have never been discovered.

The question is raised how do we prevent that. In a position of having agreed that we violated the regulation, part of the process is to determine how do you prevent recurrences in the future. The obvious statement is to create a culture of respect for NRC regulation. We, in fact, thought we had such a culture of respect but obviously didn't.

I think what wasn't clear to our staff is that willful violation of NRC regulation would result in swift and certain disciplinary action. We have one example of that now which did, in fact, result in swift and clear disciplinary action.

I think the other key point in this is complicity of other staff technologists has to somehow be avoided. All three of the cases at Penn State Hershey Medical Center involved more than one technologist, the technologist who had the administration and another technologist who performed

the administration.

You have to be a little bit more talented to self-administer radiopharmaceutical under a camera and start the camera and get the study going. In each of the three cases, it appears that the technologist who administered the radiopharmaceutical believed that they were administering an authorized injection.

So that appears to be a key. The second participating technologist appears to be a key to prevention. If we can have a process that prevents another technologist from participating then maybe we can prevent the episode from occurring at all.

We now require a written directive as part of our revised safety program for diagnostic administrations on all radiology staff members. We require the technologist who is performing the injection to actually see the written directive. And not only to see it but to discuss it with the responsible authorized user. That is the authorized user whose signature appears on the written directive.

We also have initiated new employee training and annual staff training which emphasized this specific incident and the consequences associated with an unauthorized injection of radioactive material which is then classed by NRC as a willful violation,

which then places it -- can place it as high as a Level 2 violation, which is not something that I think any institution wants to have to defend.

At this point, I would like to comment that in the process of the resolution with NRC, we participated in NRC's new ADR process which is the alternative dispute resolution process, which is a mediation process.

Although the contents of the goings on in the room that day are confidential and everyone signed a confidentiality agreement, I can tell you that it was an open and cordial dialogue with Region I administration. And that although I would not like to have to live through one of these again, that the process was a very positive one, that the ADR process allowed Hershey Medical Center to present its position, the NRC to present its position.

The initial investigative report was modified based on the discussion we had in the ADR process. And I would really commend the NRC senior administration in Region I for the way they handled that ADR process.

At this point, I've completed the case history. I'll be happy to answer any questions that the committee members may have. And then this is to

be open for discussion by the committee to determine if there is anything else that needs to be done.

CHAIRMAN MALMUD: Thank you, Dr. Eggli. I see Dr. Diamond has his hand raised.

MEMBER DIAMOND: Dr. Eggli, why? Why would a technologist do this?

DR. EGGLI: Her comment ultimately was that she felt she needed the study and she knew better than the doctors who didn't think she did.

CHAIRMAN MALMUD: There was another hand raised on this side?

MEMBER NAG: Yes, well, I had a similar question. And how it is different from a nurse or somehow who is going to be administering a drug to a patient taking it herself or himself or a doctor who having pain meds at his disposal taking the pain meds himself?

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: One question then a couple of comments maybe.

Was the study evaluated?

DR. EGGLI: No, it was not.

MEMBER BAILEY: Okay. And second of all, our comment is that I think the agreement states for a long time have argued that the NRC regulations sort

of missed the mark because they do not address technologists. And since most of the times the technologists are the ones that are actually administering the material.

I know we, as a state, have taken disciplinary action against technologists who willfully or stupidly do something -- gross negligence I think is what the lawyers call it -- do something as an effective way to emphasize to the technologists the need to follow some procedures.

I'm a little curious as to how any facility can prevent a deliberate illegal act by an individual. And this is one of the things that we faced in industrial radiography was that we had a community where at least reportedly individuals, not companies, took an illegal action.

And so we addressed that by certifying radiographers. So I'm wondering how do you get to that from an NRC standpoint if someone deliberately does something?

CHAIRMAN MALMUD: Dr. Miller?

DR. MILLER: In an attempt to try to answer your question, I don't think any of us can absolutely prevent someone who deliberately wants to do something. I think the message here that Dr. Eggli

has so succinctly raised is I think it is important that technologists know that such activity is an unacceptable practice.

You know if somebody wants to go down the highway at 100 miles an hour, I don't think any laws can prevent that from happening other than enforcement of the regulations and the laws. But I think it is important that everyone understand that deliberate violation of the regulations is not acceptable.

And I think the concern here is that, you know, Dr. Eggli has very accurately pointed out Hershey Medical Center feeling that they had a very solid program. And we have no reason to dispute they had a solid program. Nevertheless, we find in all aspects of nuclear regulation that, you know, there are very solid programs.

Someone does something you could declare stupid, not intelligent, thinking that they know more than those who are authorized to administer such activities. And there's nothing you can do to absolutely prevent something like that other than making sure that people are aware of what is right and what is wrong.

CHAIRMAN MALMUD: Dr. Suleiman?

MEMBER SULEIMAN: I know there is a

radiation issue but this is really a medical issue. I mean it's no different than the improper administration of a medical drug. So doesn't the oversight inherent in the institution be sufficient?

I mean it is interesting you had to bring in the NRC. Couldn't the hospital handle that? Aren't there enough regulations to say this was improper, this was inappropriate?

DR. EGGLI: I can't address that question directly, Orhan, other than that the decision to report it was made by our hospital administration. And the report was to determine -- to ask NRC to determine in a sense did we need to report it. So it initially went to NRC as an inquiry. This event occurred. Do we need to officially report it? And that's how the process started.

MEMBER NAG: Is the question a medical event?

DR. EGGLI: I don't think this -- because a patient -- no patient was involved so I don't think this qualifies under a medical event rule. But there is in the regulation, and I wish I -- over in that binder over there I have the portion of the regulation that basically deals with appropriate medical use of licensed materials. And the NRC determined that this

was not an appropriate use of licensed radioactive materials.

MEMBER NAG: Right. But this was an injection without a written directive.

DR. EGGLI: This was injection not only without written directive but without authorization of an authorized user. In our diagnostic studies, there is an implicit authorization that goes from me to the technologist every time they inject for a medical indication.

CHAIRMAN MALMUD: Dr. Vetter?

MEMBER VETTER: This is not a medical event. Number one, it doesn't require written directive. The regulations don't require it.

And second, even if it is the wrong patient, in this case, the effective dose is less than five rem.

MEMBER DIAMOND: So really this is outside of our purview. I think it is interesting. I never knew that this type of problem occurred. But as was mentioned earlier, this is something really outside of our purview. Hopefully the frequency is very, very low. It does require basically one individual plus a second conspirator, if you will, to make this happen. So there is some oversight. I think if people

understand and it is reinforced --

DR. EGGLI: And I think our observation was these were unintended co-conspirators if you want to use that sort of phrase.

MEMBER DIAMOND: Well, in this particular example, it was obviously pressure between a teacher and a student relationship, which is another issue altogether. But I think that's really all we need to do on this particular committee.

And obviously the person probably has a lot of other issues going on.

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Yes. I guess I have a question for the NRC staff. In a situation like this where a radiation safety program has undertaken all reasonable steps to ensure adequate safety and oversight, if an employee willfully and illegally -- you know willfully and knowingly commits an illegal act or infraction of the regulations, is NRC's how should I say -- juridical response limited to punishing the licensee or do you have an option for actually pursuing criminal litigation or fines against the individual perpetrator?

DR. MILLER: The NRC's responsibility is certainly with the licensee number one. And in

certain instances, NRC will pursue action against individuals.

MEMBER NAG: But this --

DR. MILLER: But it depends upon the position that the individuals occupy. I see Susan, you're here from the Office of General Counsel.

PARTICIPANT: (Speaking from unmiked location.)

DR. MILLER: Could you come to the microphone? From a legal perspective.

PARTICIPANT: Sorry. Yes, we have our deliberate misconduct rule in all the regulations. That gives us the authority to take action or to, you know, take enforcement action against an individual who deliberately violates NRC requirements. Does that answer the question?

MEMBER NAG: Yes but this is not the problem of the licensee. It's the problem of one individual. So why would or why should the licensee be penalized? Let it happen at my institution. I or none of our people it is a problem, it's one particular individual. So why would my institution be penalized?

DR. MILLER: Let me answer that from a regulator's perspective, okay? If it happened to you,

it's you, the licensee, that hired that individual, okay? And you hold an NRC license. And those that work under that NRC license are culpable under that license.

I recognize that in the case that somebody decides to do something deliberately that there is sometimes nothing you, as the licensee, can do about that.

But I think it comes back to, you know, it is left up to you to determine the people that you hire and what the credentials, the honesty, the integrity of those people that you hire are. And that those people clearly, as does the licensee, you are responsible for the regulations that you are bound under.

DR. EGGLI: Subir, if I can comment. We asked sort of the same question. It's kind of the captain of the ship. We hold the license. And, therefore, we are, in fact, responsible.

But we decided to sort of give up that question as non-productive. And to try to ask -- the other question is is there anything we can do to further mitigate the risk?

And in our program, we thought there were a couple of things that we could do to further

mitigate the risk. Again, one of them is a self-preservation issue. These are not fun processes. And although it was a perfectly fair process, it wasn't fun. And I would just as soon not have to do it again. And if we can mitigate the risk further as the license holder, I think it is incumbent upon us to construct a safety program that to the best of our ability does mitigate risk.

You know we can't, you know, who is to say a technologist won't take a vial of radioactivity and go up to the cafeteria and throw it on the floor? But, you know, what can we do to mitigate that kind of risk?

And I think if we make sure the technologists understand that certain classes of activity which, in our case, occurred more than once over a period of about ten years, will not be tolerated. One, if they know there are consequences and two, if we introduce whatever safeguards we can to attempt to mitigate which is, in our case, dealing with the unintended accomplice by making sure that we have a process that asks the second technologist to verify the legitimacy of the administration, then I think that we are taking the next step as licensee.

And I think a point will come where we

have done everything we can. But as we looked back on our program, even thinking we had an outstanding safety program, there was clearly more we could have done. But again, you don't know what you don't know. And you learn from these events.

And part of the reason that I'm here sharing this is to share this experience so somebody else doesn't have to learn the hard way the way we did.

MEMBER NAG: Now this was a diagnostic procedure using radioactive material. Now similar to that, if a technologist has an x-ray, it fell down and without having a doctor's prescription just took the x-ray himself or herself, where would that place that situation?

DR. EGGLI: That actually violates Part 210 of the Pennsylvania Code.

(Laughter.)

DR. MILLER: NRC has no jurisdiction on that. But it's a similar kind of thing, yes.

CHAIRMAN MALMUD: Ralph?

MEMBER LEITO: Question for Doug. Has the NRC indicated anything to the effect that they are taking any action against the technologist in terms of willful, you know, disregard for the licensee's

direction?

DR. EGGLI: The NRC has not indicated to us as the licensee what their intentions are with respect to the individual technologist involved. I don't know if that's a privacy issue. I assume that once the NRC makes a decision one way or another, like our notice of violation, I assume that turn up on the website as well once it becomes -- if there is something that happens.

But certainly nothing has been shared with us as licensee.

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: Yes, one of the things that is sort of disturbing is that tech can now go to New Jersey and go to work in a hospital whereas we've seen in some of the other activities under the NRC where they actually issue an order to an individual who intentionally violates regulations.

And that order then goes out to all of us as sort of a hey, by the way, you ought to look at this person.

DR. EGGLI: Again, I don't know that NRC doesn't have other action planned. It's just that I have no personal knowledge of what the regulatory plan is.

CHAIRMAN MALMUD: Is there a question before this group?

DR. MILLER: I think the question that the staff would ask the committee is based upon Dr. Eggli's presentation and the discussion, is there anything that the ACMUI would recommend needs to be done on the part of the NRC to help, you know, try to minimize or prevent the occurrence of such activities?

CHAIRMAN MALMUD: Dr. Vetter?

MEMBER VETTER: There was an information notice wasn't there? I'm trying to recall. It seems to me I read an information notice on this. Maybe I'm wrong about that. But a reminder somewhere about -- relative to our own programs reminding technologists what their responsibilities are. Does anyone else remember that?

MEMBER LEITO: Yes.

MEMBER VETTER: You do?

MEMBER LEITO: There is an information notice dated July 16th, 2002, unauthorized administration of byproduct material for medical use. That might be it.

MEMBER VETTER: Okay.

CHAIRMAN MALMUD: Well, if you're looking for a response, I'll give you a personal response not

on behalf of the committee. I don't know what else you could have done. And I don't know what else any of us can do.

If an employee is intent upon harming himself or herself, there's little that we can do outside of making certain that all the rules and regulations are adhered to.

I would have difficulty personally finding you, as a licensee, the least bit guilty for what happened since any individual can at any time do something like that despite all the rules, regulations, and understanding about the risk of radioactive material.

MEMBER NAG: I would like to be on record as saying that I support the institution's handling of the case. And I would like to be on the record as an ACMUI member and perhaps making an ACMUI resolution that we support the handling of the case that has been presented.

DR. EGGLI: If I might make one final comment, an e-mail circulated in the nuclear medicine community critical of Penn State's handling of this incident, describing me as the lilly-livered licensee without the courage to stand up to NRC for this incident.

So there is some feeling in some of the nuclear medicine community that Penn State overreacted. I personally disagree with that. I mean we clearly violated the regulation. We accept the fact that we violated the regulation. And we've tried to modify our program to prevent recurrence.

But there is an opinion out there in the nuclear medicine community that we overreacted.

CHAIRMAN MALMUD: Well, I must say I haven't seen that. And I don't agree with that. But I think that Dr. Nag, you have a motion on the floor, don't you? Was that a motion Dr. Nag?

MEMBER NAG: Yes, I was going to present it as a motion that, you know, as the ACMUI, we support the institution's reporting of the case and also taking action to prevent potential incidents in the future. And commend them for that. And we support them for that.

CHAIRMAN MALMUD: Is there a second to that motion?

MEMBER VETTER: Second.

CHAIRMAN MALMUD: Dr. Vetter seconds it. Any further discussion?

(No response.)

CHAIRMAN MALMUD: All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any abstentions or opposition?

(No response.)

CHAIRMAN MALMUD: It's unanimous.

Thank you very much.

DR. EGGLI: Thank you.

MEMBER BAILEY: I just want a clarification. You said there was an information notice that went out in 2002. Has there been one that has gone out since then? Like since this incident came to light?

PARTICIPANT: No, not to my knowledge, on.

CHAIRMAN MALMUD: Sally?

MEMBER SCHWARZ: There was -- at the bottom of this e-mail, which actually was distributed, that went out from one of the members of the community, I think there is a publication coming out in February of `06 that's talking about unauthorized injections, technologists -- I mean there is a publication that is actually mentioned that is addressing this.

Probably just the fact that it is out in the community, that people are aware that this has happened.

DR. EGGLI: We actually have submitted a publication --

MEMBER SCHWARZ: Right.

DR. EGGLI: -- in one of the Radiation Safety Journals --

MEMBER SCHWARZ: Correct.

DR. EGGLI: -- that will be published. We're submitting another article in the Journal -- probably more importantly -- in the Journal of Nuclear Medicine Technology to get this out to the nuclear medicine techs as well.

MEMBER SCHWARZ: And I think that is excellent in terms of just raising the level of awareness that this has occurred. And that often can at least help to stop considerations, you know, to alter behavior.

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Well, I guess I would like to say that it would be unwise to take the moral of the story too much to heart you know in the sense that I think this is a very low probability event. And if one, you know, considers I suppose risk and view it as somehow the product of frequency and severity of effect, it is quite small of this happening. Both the probability and the consequences.

So, you know, recommending even that all licensees move to a very strict protocol for treatment of employees of a hospital, you know, because of such an incident would seem to me not to be a good societal use of resources for quality assurance that could be better expended in the higher risk categories of clinical care.

So I guess I would say there is a negative consequence regulatory -- or negative consequence to health and safety for reacting too strongly in terms of, you know, insisting or encouraging widespread and expensive practices for low probability, low severity events.

DR. MILLER: You lost me on that.

MEMBER WILLIAMSON: Oh, sorry.

CHAIRMAN MALMUD: Dr. Eggli?

DR. EGGLI: My purpose in presenting today was to do with the fact that you don't know what you don't know. Before April 29th, 2004, I would have told you there was a zero percent probability that this would happen at Penn State Hershey Medical Center.

My primary goal in making this presentation today is to try to create some vehicle for raising awareness in the nuclear medicine

community so you don't live through what I lived through. Because the answer still is you don't know what you don't know.

And I would never in my life have believed that this could have occurred three times in ten years at Penn State Hershey Medical Center. I just would have never believed that until I have to deal with in my face.

So again one of my main purposes is to share the information that it does happen. And you don't know what you don't know. And it is easy to bury it until some really serious digging around happens.

CHAIRMAN MALMUD: Well, Dr. Eggli, we thank you for sharing that with us. It seems to me the simplest thing to do is for every licensee to go back to his employees and say if you ever give yourself radiopharmaceutical without a physician's order, you're fired. Period. End of discussion.

I don't think it requires the intervention of a federal agency. I saw that only on behalf of our income tax bill. So the people will do things that are very strange that we can't anticipate.

Your participation in this was quite honorable and we respect that.

DR. EGGLI: Thank you, sir.

CHAIRMAN MALMUD: And with that, if we may, we'll move on to the next subject. And that is the revision of NRC Form 313A. This is an open session. We thank Sandra Gabriel from the NRC for giving us her time.

MS. GABRIEL: Thank you, Dr. Malmud. I've invited Dr. Howe to join me as she has worked closely on this project with me.

As you know, Form 313A is an available method for licensees to use to submit the training experience and preceptor statements for proposed authorized individuals. The form was revised in 2002 with the Part 35 revision and also with the initial publication of NUREG-1556, Vol. 9.

Again, earlier this year when the Part 35 training experience requirements were revised, and NUREG-1556, Vol. 9 was revised, the form was revised again.

The initial version of Form 313A was made to deal with relatively simple Part 35 training experience requirements. The form was relatively easy to use. And it addressed authorized users and radiation safety officers only.

The 2002 version was intended to deal with

the somewhat more complex training and experience requirements in the new portion of Part 35. The form was, therefore, more complex. Authorized medical physicists and authorized nuclear pharmacists were added so one form was intended to address four different types of authorized individuals.

And our experience in the region reviewing applications was that licensees had difficulty determining which sections of the form to complete for each type of authorized individual and the correct way to complete the applicable sections.

We also found that Form 313A was used relatively infrequently at that time because Subpart J was still able to be used. So most licensees submitted applications in accordance with Subpart J.

In the new 2005 version of Form 313A, the instructions on the form provided more direction about which sections to complete but we found that licensees still found the form to be confusing as did the regional license reviewers.

We also noted that the need for a user friendly form, user friendly to both licensees and license reviewers becomes more urgent today with the expiration of Subpart J and also with the limited number of approved specialty boards, meaning that at

least for a period of time, we'll be evaluating more applicants based on training and experience rather than on certification.

The regional participants in the Part 35 working group, which consists of representatives of both headquarters and each of the regions, proposed revision of the 313A into separate forms for each type of authorized individual to try to simplify things.

Region I was assigned to coordinate the project. And the team working on this revision includes representatives from Regions I, III, IV, and from INMS and headquarters. We've been working by e-mail and telephone to expedite the process of updating the form.

Current proposal is for there to be six different versions of the form to reflect six different sets of requirements. One for radiation safety officer, one for authorized medical physicist, one for authorized nuclear pharmacist, and one for the diagnostic authorized user categories, 35100, 200, 500, one for unsealed therapies 35300, and then one for authorized user for the sealed source therapies 35400 and 600.

And the project also includes an update of the guidance in Appendix D of NUREG-1556, Vol. 9,

which instructs applicants how to use the forms.

Copies of the latest draft were distributed to you to review in advance of the meeting. And we would like to open this up to discussion now if you have any comments.

CHAIRMAN MALMUD: The subject is now open for discussion. Ralph?

MEMBER LEITO: I'd like to commend staff because I think it is a big improvement separating out the different groups. And just also for the committee's information, the 300 applies to all 300 uses, not just .300 but the 390s also which is good.

I've asked some people to, you know, look at this also and get their feedback. And the only comment that I got back, which I think was a good comment, has to do with the authorized user training and experience for the diagnostic uses, the 100, 200, and 500s, that the different parts have sign offs because authorized users for like say the diagnostic uses, they may get their training -- the training and experience -- this would be for the non-Board certification route. I should clarify that.

They may get the physics and the didactic portion in one area and the clinical at a different institution altogether. And if there could be maybe

-- the suggestion was that authorized users are willing to sign off for those portions they provide but they're not willing to necessarily be the preceptor that everything is there.

So in other words, they may go through for like cardiologists, they may go down to nuclear medicine and get a certain portion of their training in nuclear medicine. And the nuclear medicine authorized user is willing to sign off for what they did. But they're not necessarily willing to be the preceptor that attests to the whole ball of training, okay?

And if there could be -- like on -- if you look at authorized user under the diagnostic -- under number three where they attest to the total hours of experience, if there could maybe be a sign off line that that portion was done under the, you know, for the authorized user for that portion.

Then I had one question. When you have that the supervisor meets the requirements below, it says check one. Would there be an objection to check all that apply? I mean if they had more training --

MS. GABRIEL: That's a good suggestion.

MEMBER LEITO: -- experience rather than just the one piece, in other words, they might be able

to address a larger range of training experience. It's like well, I've got diagnostic and I've got therapeutic. And why can't I check them all off that apply in terms of the users' training. Because basically you want some record of what the user's training and experience is that is providing this. And I would just suggest rather than saying check one, check all.

MS. GABRIEL: We will update that. Thank you.

MEMBER LEITO: Those are the comments that I had gotten back.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: Is there a way to easily address the situation where a trainee has trained in more than one center. They did the first year in a separate center, second year or third year in a separate center. And no one preceptor can certify for the whole thing. But, you know, it may have been 80 hours in one place and another 100 hours in the other place. Is that possible?

MS. GABRIEL: I believe our intention is that multiple copies of that page could be submitted, each one completed by one supervising individual to reflect the portion of the training that involved

them.

DR. HOWE: And you need to remember that the preceptor now is essentially verifying the training and is not the one that was responsible for giving the training. So we would still expect one preceptor statement at the end for the whole batch of things. But there can be many different supervising sheets to add up to one.

MEMBER LEITO: I would suggest that when you put together the instructions that go with these that maybe you indicate that so that people know that this is what they can do? Because I think there is maybe the impression it's all got to be on one form.

MEMBER VETTER: If I could just underscore that. It's really common in training programs, especially radiation oncology, where a training program might not have HDR, for example, or Gamma Knife stereotactic radiosurgery in their institution so the resident goes to the university medical center to get that portion of the training.

And in order to avoid confusion, some instructions need to address. All of that needs to be incorporated somehow into one submission and signed by the authorized user where the resident is trained.

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: I notice that Table C, if I'm not mistaken, is --

DR. HOWE: Which form are you talking about? There should be a designation at the top.

MEMBER BAILEY: RSO.

DR. HOWE: Okay.

MEMBER BAILEY: Table C, the instructions in Part 1 are choose one of the four methods below. But then Table C, which is included in Method One, in each of the other three methods, you have to go back and complete that part of Part 1. So I would suggest that it be brought out right on top and not included in the choice.

DR. HOWE: We included it in number one. And then to avoid having to repeat it, we refer people back to it in number one.

MEMBER BAILEY: Well --

DR. HOWE: Do you want to see the table in all sections?

MEMBER BAILEY: No, no. What I'm saying is that table should be before number one because you're going to make everybody fill it out so you should fill it out right up front and then go to choice one or two or three or four.

Right now you've got a yo-yo going. I

choose two but I've got to go back to one and fill it out.

DR. HOWE: Okay. We take your point.

MEMBER WILLIAMSON: Or put it at the end as a common appendix.

MEMBER BAILEY: Yes, something.

DR. HOWE: I think we're concerned if we put it at the end then the Board certification folks may not realize they need to fill it out also. So we'll try to do something that makes it obvious.

CHAIRMAN MALMUD: Sally?

MEMBER SCHWARZ: This is under authorized user training and experience and preceptor attestation.

DR. HOWE: Which form? We have six.

MEMBER SCHWARZ: AUT.

DR. HOWE: AUT? Okay.

MEMBER SCHWARZ: Now I know we have kind of draft changes. This is what we had gotten sent out. The first part there are typos where it says 35300, 300, 300, 300.

DR. HOWE: We'll take care of the typos.

MEMBER SCHWARZ: Then under Board certification on one, the question was raised why is documentation needed in C and D below if the Board is

recognized as meeting the NRC training and experience?

DR. HOWE: In the regulations, the Board certification has been separated from the specific training on devices. And so that's why one thing is separated. And also your attestation. Let me make sure where you are addressing.

MEMBER SCHWARZ: I think this is something different.

DR. HOWE: Okay. Where are you?

MEMBER SCHWARZ: AUT.

DR. HOWE: I'm on AUT.

MEMBER SCHWARZ: Part One, Training and Experience.

DR. HOWE: Yes.

MEMBER SCHWARZ: Board Certification.

DR. HOWE: Yes.

MEMBER SCHWARZ: That was why is the documentation needed in C and D below, which is Board Certification C and D where they refer to the tables for completion for the -- if the Board is recognized as meeting the training and experience? It has to be reiterated?

DR. HOWE: If the particular -- well, we'll be looking at this once we have our -- all of our Board certifications up. But if the Board

certification meets either for 490 -- oh no, this is a 390 one. Okay. Oh, C is because the clinical experience has been separated out from the Board certification process. And so there needs to be the clinical experience plus the preceptor statement for those individuals coming under 390.

The Board did ask that the clinical experience be separated from the Boards. And so it was. And so that has to be provided under C as a separate part.

And D is for those individuals coming under a different Board, the 490 Boards or the 690 Boards. And they have to provide the additional documentation for 396. Does that help?

CHAIRMAN MALMUD: Dr. Vetter?

MEMBER VETTER: Relative to that particular section, it is elsewhere, too. For instance under RSO. But under Board certification A, provide a copy of Board certification if Board certification is older than seven years. Now is that the renewal or is that the original?

For instance, ABHP requires you to renew every four years or you are no longer an active certified health physicist. So if I was re-certified three years ago, does that satisfy that requirement?

Or are you going to go back to my original certificate from the `70s?

DR. HOWE: This is an area we haven't really discussed among ourselves. But my personal view is that if you are re-certified, you have provided evidence of continued training and experience. So I think we would take your re-certification date as an indication that you are.

MEMBER VETTER: Thank you. I think that's -- I personally would do the same thing.

MS. GABRIEL: And the requirement for training and experience within seven years is not a new one.

MEMBER VETTER: No, I know that, right.

MS. GABRIEL: And that's been part of the regulation for some time.

MEMBER VETTER: That is the recentness of training -- that's the recentness of training issue.

CHAIRMAN MALMUD: Bill?

MEMBER DIAMOND: Before I start on my question, I was going to say I thought Dr. Vetter you trained in 2002, not the 1970s.

(Laughter.)

MEMBER DIAMOND: I'm going to get confused here. Can I ask three questions if I could on Form

AUD, Authorized Training and Experience for .200? I guess my question revolves around .3, which is the outlining of the training and experience, both classroom and laboratories A, and then supervised work experience for B, noting the detail in the preceptor form as far as this -- what I would consider the old Subpart J breakdown for didactics. Asking whether that is still a breakdown that we want since the current regulation reads 80 hours and doesn't read that breakdown.

The only reason why I ask -- and I don't particularly mind except we don't have a standard for what goes -- in Subpart J, we had a fairly good standard for what went into each of those parts for the total of 200. We don't have a current standard right now.

And I'm not sure that across programs -- I'm not sure whether we want that standard, don't want that standard. We haven't set it up so far but you have a chart in there and somebody is going to put numbers into it. What does that really mean to us I guess is the question at this point in time. Other than, you know, the total.

DR. HOWE: I guess I'm a little confused because if you look at 290 in the regulations, you'll

find that you have to have classroom and laboratory training and they indicate a minimum of 80 hours. And they list these subjects. These are the subjects that are under the first part. And then they say you have to have work experience.

MEMBER DIAMOND: Right. That's correct.

DR. HOWE: And then these are the topics under the work experience. And then the total adds up to 700.

MEMBER DIAMOND: That's correct. But my question is is this 20, 20, 20, 20? Are you going to get things from different ones with different numbers in there?

DR. HOWE: Absolutely.

MEMBER DIAMOND: Do those numbers mean differences to you? Or you just want to know that there were numbers in each one?

DR. HOWE: We want to know the numbers that are in each one. And it's a performance base. And so if you end up with a total of 80, we are satisfied. If you end up with -- then you add up to a total of 700, we're satisfied.

There is no set divide by the number of blocks and that's the number of hours or any other algorithm to give you specific numbers.

MEMBER DIAMOND: Right. But in Subpart J, there used to be a breakdown and it was not equal across these parts as far as what most people did for that training for that 200 hours.

And that's the only reason why I asked, you know, it doesn't -- we didn't proscribe how those 80 hours got broken down. So I'm just trying to figure out when you go out to explain it to the community, what we consider as a reasonable curriculum we'll have to re-talk about and re-deal with.

You may see different numbers. I'm just trying to figure out what that means.

MS. GABRIEL: There are times in the region when we may receive applications that just show a bracket and the total number of hours confirming that all topics were covered.

MEMBER DIAMOND: That all topics were covered. Right.

MS. GABRIEL: And we generally find that acceptable.

MEMBER DIAMOND: Okay.

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: On the AMP page 3 --

DR. HOWE: He had three questions. Were those your three questions?

MEMBER DIAMOND: No, my second --

(Laughter.)

CHAIRMAN MALMUD: Oh, I'm sorry. I apologize.

DR. HOWE: Are we still in the AUD?

MEMBER DIAMOND: We're still on the same one. That was question one.

Question two is just a subpart of that which had to do with the clinical experience documentation which I guess you just answered which is it is a block of 700 hours. And now we have all these subtypes here as far as how we add them up. And is it just good enough to say that we've done 700 and covered all the subject areas which is, you know, obviously the gestalt of what we're trying to get to.

So I guess those two answers to together.

And I guess the third question had to do with the statement that these forms are available but not required. So I guess my question to that means is when a Board on the other pathway takes a statement from a preceptor that that preceptor has fulfilled all of the categories to be considered for authorized usership status, that they can do that in a letter format that outlines all of these categories without using these forms?

Or are these forms something that need to be in place somewhere? In somebody's pocket.

MS. GABRIEL: Let me answer again as a regional license reviewer. We would accept the information required by the regulation in whatever format you wish to submit it.

DR. HOWE: Provided it is all there.

CHAIRMAN MALMUD: Does that complete your three questions Dr. Van Decker?

MEMBER DIAMOND: Sounds like three to me. Thank you.

CHAIRMAN MALMUD: Thank you. I apologize for having interrupted you after the first.

Mr. Bailey?

MEMBER BAILEY: And me, too, I apologize.

AMP, page three, the footnote I found interesting. It says training and work experience must be conducted in clinical radiation facilities that provide high energy external beam therapy (photons and electrons with energies greater than or equal to 1 mev) and brachytherapy sources.

Why? Why do they have to have external beam electron therapy before they can do -- it has nothing to do with leak tests or decay calculations or calibration or anything else.

MS. GABRIEL: It is taken directly from the regulation. 3551 --

DR. HOWE: B1.

MEMBER BAILEY: You mean so if I don't have an accelerator, I can't get an NRC license -- I can't be named on an NRC license?

DR. HOWE: Okay, the -- no -- well, okay. The requirement is that -- in B1, which is the alternate pathway, to hold a masters or doctor's degree in physics, medical physics, other physical science, engineering, applied mathematics, and completed one year of full-time training in medical physics which an additional year, or full-time work experience under the supervision of an individual who meets the requirements of authorized medical physicist for the types of use for which the individual is seeking authorization.

So if you're not seeking authorization for some of these things, then it doesn't have to be there. The training and work experience must be conducted in clinical radiation facilities that provide high energy external beam, energies with greater than one mev, or brachytherapy must include.

I think if you're not applying for an external beam, then --

MEMBER BAILEY: What if I was applying for any of the isotope external beams? Why do I need to have worked at an accelerator facility?

CHAIRMAN MALMUD: Are you going to answer that question Dr. Williamson?

MEMBER WILLIAMSON: Well, I think just to underscore, there is a problem. The fact that it mentions electron beam seems to be irrelevant. Had it just been limited to photons, then I think -- because I think the intent was to say there is megavoltage beam therapy of some form or another so as not to limit the practice to just cobalt-60 because so few training programs have cobalt-60 nowadays.

But it does seem that putting in the qualification -- electrons seems unnecessary though I would imagine there are very few training facilities that wouldn't have electrons.

DR. HOWE: Is it sufficient to want it removed?

MEMBER WILLIAMSON: No.

DR. HOWE: No?

MEMBER WILLIAMSON: I think it certainly is an additional requirement that doesn't really make sense.

MEMBER LEITO: I think what Ed's point is

that it is not under the purview of the NRC whether there is electron beam therapy or not. I think for the purposes of this form, I think striking out and electrons still would achieve the NRC's intent on revision of this form.

CHAIRMAN MALMUD: All right? Oh, Sally?

MEMBER SCHWARZ: Sorry. One more question on AUT.

DR. HOWE: AUT? It takes us a while to get forms.

MEMBER SCHWARZ: That's all right. And this is that question that was raised was for 3B calculating, measuring, and safely preparing patient or human research subject doses. The question was diplomats of ABNM shouldn't have to fill out this section. Or comment as it was. Is that correct?

DR. HOWE: Okay. You're in --

MEMBER SCHWARZ: This is AUT -- Authorized User Training and Experience and Preceptor Attestation.

DR. HOWE: We -- and you're talking about the American Board of Nuclear Medicine? Okay. The American Board of Nuclear Medicine is recognized. The clinical case experience has to be provided because that's been separated out from the Board

certification.

They would need to fill out 3C, which is the clinical case experience.

MEMBER SCHWARZ: Right. This is 3B.

DR. HOWE: But 3B does not have to be filled out because --

MEMBER SCHWARZ: Does not have to be filled out, okay.

DR. HOWE: -- because that's part of the supervised work experience that comes -- that the Board certification takes the place of.

MEMBER SCHWARZ: Okay. Good.

DR. HOWE: Okay? And if you look up the Board certification, we do not send you to there.

MEMBER SCHWARZ: Okay.

CHAIRMAN MALMUD: Thank you. Do we have a question?

MS. FAIROBENT: Yes, Lynne Fairobent, AAPM. On AMP, page 5 of 6 under the preceptor attestation, I'm curious to know why you're asking for the preceptor to attest the individual is Board certified. When you look at the regulation, we decoupled that.

And under 3551(b)(2), it says obtain written certification that he has completed (B)(1).

It doesn't tie to the Board certification.

I'd just like clarification. We had had discussions that the preceptor may or may not know if they have been certified.

DR. HOWE: Excuse me. Give us a chance to find the right place. So you're talking about the preceptor attestation.

MS. FAIROBENT: Right.

DR. HOWE: And which section are you on?

MS. FAIROBENT: Part 2, check one of the following Board certification or 2 education and training. And you're asking I think that the preceptor attest to the individual being Board certified.

And if I remember correctly and in looking at the regulation, we only ask that the preceptor attested to the alternative pathway training and experience and any of the other -- the specific modality training. Not that they were certified.

DR. HOWE: They do not have to attest that they are certified. But they do have to attest that they have satisfactorily completed the requirements in -- I've got the right one -- A1 and A2. And what they wrote was that A1 and A2 are that you are under -- that you have the full-time practical training and --

you have the right degree. And you have the right experience. But we do not make the authorized user attest that they passed the examinations.

They do not attest that they pass the examination. They have to attest that they hold the right degree and that they have completed the practical training and supervised experience.

MS. FAIROBENT: Isn't A1 coming in under the Board certification pathway?

DR. HOWE: Yes. A1 does.

MS. FAIROBENT: I'm confused if it is. So you are attesting that they are certified? Because they're coming in under the certification pathway?

DR. HOWE: No.

MS. GABRIEL: The header is labeled Board certification to direct you to the statement to complete.

MS. FAIROBENT: I think it needs clarification then.

DR. HOWE: You're coming in under the Board certification pathway. And if you're coming in under the Board certification pathway, then the preceptor must attest that you have completed A1 and A2. They do not have to attest that you have satisfactorily passed the examination. Only that you

have the prerequisites to be a candidate.

MEMBER LEITO: I see what you're saying.

CHAIRMAN MALMUD: Ralph?

MEMBER LEITO: I see what they're saying but it is very, very confusing. I think if you look at it from the standpoint that the preceptor is in and of itself its own entity, instead of this -- because it does -- first reading this, I was getting the same impression, that you are wanting the preceptor to attest to the Board certification.

And really what you want is them to attest that the whole package is there. And that's the way that I would put this together. Not all the ors and ands. Just -- because this has to be filled out regardless if you are Board certified or the alternate pathway. So I think these headings are making it look like you can, like, pick and choose. And really the whole thing has got to be done. They've got to just make one attestation to the whole piece.

DR. HOWE: There is a different attestation if you're coming the Board certification pathway than if you are coming the alternate pathway. Because you are attesting to something different in many of these. And that's why there is a difference on the attestation for Board certification and for the

alternate pathway.

And then you'll find other sections that are the same for both. And you'll see instructions that say complete all of the following. And then you have those things that are common to both pathways.

But there are different attestations depending on which pathway you're coming through. And it's in the regulation.

MEMBER LEITO: What this looks like is that the preceptor is making four separate attestations.

DR. HOWE: They are. They are attesting whether they met the training and experience, either under the Board certification pathway or under the alternate pathway. So there's a choice there for one or the other. They are attesting that they have training for the types of use that are being sought. That's paragraph C.

MEMBER LEITO: So what this looks like is that four different people can make attestations.

DR. HOWE: Part of the -- the fourth attestation is -- he's essentially attesting that he meets the requirements to be a preceptor. That's the fourth block down there. The other three are the ones in the regulation.

MEMBER LEITO: Now I'm more confused than when I started talking.

DR. HOWE: A preceptor has to meet certain requirements. And so that's the fourth block.

MEMBER LEITO: Well, I understand that. But it's the attestation piece here that is extremely confusing. Because the preceptor is making the attestation that all these training and experience components have been achieved.

So why not just have that -- the pieces that they're attesting to and then there's one signature? It's like you're making them repeat the same thing four times -- five -- four times and then signing off. And I just don't understand what is it that we're trying to achieve by making them attest four times?

MEMBER WILLIAMSON: I think if you read the section two in the strikeout language, which is the only clear -- the strikeout version of the T&E, it indicates that there are four different things effectively -- well, actually about three different things in any give case that preceptor must attest to. That A1 and A2 or B1 and C were done -- one or the other.

Then has achieved a level of competency to

function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized physicist status. So is that right? That's sort of three things.

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: This is confusing to say the least. And I don't see why you can't simply have a statement that the information on this form is true and accurate. And get away from all of this other stuff.

If you've already had to put down the hours and everything, which they probably can't attest to, I'd like to see somebody attest to when I got training in radiation physics and instrumentation. No one alive today can remember that.

So I mean --

DR. HOWE: But as a preceptor, your preceptor can verify versus being the one providing you with the training back in the Dark Ages.

MEMBER BAILEY: but the records are on rocks.

(Laughter.)

DR. HOWE: So he can check the rocks out.

MEMBER BAILEY: I mean -- there are some

things that ought to -- it seems to me ought to stand for themselves. Board certification, which is current, should be able to stand for some of these things. You know if I went down and said where did I get my training on 35100, do I put down ACMUI meetings? And would that be a legitimate place to have learned it?

I mean I have to tell you, I have not gone through a course on any of these topics here. But somebody here would attest that I stayed awake, you know?

(Laughter.)

MEMBER BAILEY: So I'm not sure how these really relate to fundamentally knowing how to do a program. They relate to -- that somebody has put the regs in front of you? Or have you sat through a session on it? And it doesn't guarantee you anything.

DR. HOWE: That's a different question.

MEMBER WILLIAMSON: It is in the regulation though. There's an attestation for the device-specific training, an attestation for the modality-specific training, kind of a general attestation to competence -- level of competence to function as an AMP, and then attestation that the A1 and A2 or B1 has been completed.

CHAIRMAN MALMUD: All right. Ralph and then I have a question.

MEMBER LEITO: Jeff, if you look at the form, okay, they have --

CHAIRMAN MALMUD: Which form?

MEMBER LEITO: The form AMP, the last page, the attestation on Part 2, okay? You've got to complete all of the following. There's I attest and then you fill in the blanks and check the boxes.

Then you go I attest again and you go like that. Why isn't there just I attest to each of these just as a bolded item and there's one signature. I mean the signature is there but it seems like we've made this whole page on something that could just fit into a matter of five lines. And why make it so difficult?

MEMBER WILLIAMSON: It's worse than that because, you know, it is quite possible that this might have to be filled in by three different people -- three different forms, partially filled out forms may have to be signed by different individuals. It might have been better to create one form with several signature blocks.

MEMBER LEITO: You can only have one preceptor. There is one preceptor form.

DR. HOWE: No. You can have more than one preceptor. But you have to have a form for each preceptor. And if you look at the top of the preceptor attestation, it says if more than one preceptor is necessary to document experience then, obtain a separate preceptor statement from each.

So there is a possibility that there is more than one preceptor. And that's why the form is the way that it is. And the preceptor has to attest to what the preceptor can attest to.

MEMBER LEITO: Then you need a signature for each piece then?

DR. HOWE: And so -- yes -- and so you put a check in the block and then the blocks that are checked, the signature is at the bottom.

MEMBER LEITO: But you only have one signature box. What I'm saying is if that's what you're saying, that you could have potentially four different preceptors --

DR. HOWE: But that's what the check is. The check is I attest that -- and you've checked that I attest block. Or say got the hands on device operation safety procedures clinical use and then the next one is you attest that the individual has gotten a level of competency. And then you fill out what

your requirements are and you sign.

You are signing for all the blocks you've checked. And someone else may have to sign for other blocks. Or for the same blocks for a different piece of device.

DR. MILLER: So if I understand you, Donna-Beth, what you're saying is then if there are multiple preceptors, then there would be multiple forms signed for those portions that the preceptor --

DR. HOWE: Could sign for.

DR. MILLER: -- did.

DR. HOWE: That's correct.

DR. MILLER: And in the end, you have to have a collection of signatures and attestations that cover all four.

DR. HOWE: That's correct.

CHAIRMAN MALMUD: Okay. I have a long question.

DR. HOWE: Tell us which form.

(Laughter.)

CHAIRMAN MALMUD: That's why I've been so patient with everybody.

DR. MILLER: Can you divide it into three parts?

(Laughter.)

CHAIRMAN MALMUD: It's actually more than three parts. Let's say that I had not attended this meeting, did not have the advantage of all the questions that were asked and answered. And I now take a look at Form AUD, 313 AUD. It's four pages long.

DR. HOWE: Yes.

CHAIRMAN MALMUD: I have just completed training. I'm young again. I just completed training in nuclear radiology in a Department of Radiology. And I know that I'm going to have to get Form 313 AUD and AUT and one more form signed, right? In order for me to fulfill Sections 190, 290, 390, 392, 394, and 590, I'll have to have about three forms filled out.

DR. HOWE: You could fill out one -- well, you might need multiple copies yes for 190, 290 --

(Laughter.)

DR. HOWE: -- but 390 should suffice. You would not -- if you're going for the full 390, you would not need 392, 394.

CHAIRMAN MALMUD: But I would need 590.

DR. HOWE: If you wanted to do 590, yes.

CHAIRMAN MALMUD: Sure. And what about

190 and 290?

DR. HOWE: 190 and 290 you probably need separate forms. But there is also a provision that if you are authorized for 290, you could be an authorized user for 190. So you could select to just go for 290.

MS. GABRIEL: Speaking as a reviewer, I think we would accept one form to cover the 190, 290, 590.

CHAIRMAN MALMUD: So actually you would accept one for 190, 290, and 590. But 390 would be separate?

MS. GABRIEL: Correct. When we tried to construct one form to cover all of those together, it became yet more complex.

CHAIRMAN MALMUD: So I will not need to fill out 392 and 394 if I do 190, 290, 390, and 590. If I do those four --

MS. GABRIEL: Correct.

CHAIRMAN MALMUD: -- I'm okay. And I don't have to do 392 and 394 separately.

MS. GABRIEL: Correct.

CHAIRMAN MALMUD: Okay. So here I am, I'm young again, just coming out of training as a nuclear radiologist. And I need to have these forms

filled out. So I take a look at Form 313AUD, page 1. Name of the proposed authorized user. That's me. I'm requesting 100, 200, and 500.

I'm just finishing training. I may or may not have Board certification yet. But let's say that I have Board certification. I'm okay.

And then -- so I check off Board certification. I'm certified.

Now I go to the next question. Question No. 2, current authorized user seeking additional -- that doesn't apply to me because I'm not a current authorized user yet. Is that correct?

DR. HOWE: Yes, you're not an authorized user yet.

CHAIRMAN MALMUD: So I don't have to do that?

DR. HOWE: No.

CHAIRMAN MALMUD: Now I said this is going to be a long question. Now what if I'm Leon Malmud who is here physically today, older, do I need to go through this process again?

DR. HOWE: If you are currently listed on a license --

CHAIRMAN MALMUD: Yes.

DR. HOWE: -- you do not need to go

through this process. If you are --

CHAIRMAN MALMUD: So I'm Board --

DR. HOWE: -- if you are asking for the ability to be an authorized user for the same materials that you are authorized for use on a current license, you can go to another facility, use the fact you are an authorized user on an existing license to show that you meet the training and experience criteria. And you do not fill out the 313A.

The 313A is for new people that are not listed as authorized users, medical physicists, pharmacists, RSOs, and that's who it is for.

CHAIRMAN MALMUD: So if I were to leave my current institution after 33 years and move to another institution down the street, I would not have to do anything except say I've been an authorized user at Temple where I am now and that's sufficient to get me authorized user status at the new institution?

DR. HOWE: For the uses that you had before and then we would probably ask for maybe the permit at the broad scope that indicated --

CHAIRMAN MALMUD: I'm sorry. I didn't hear the last -- you would ask for what?

DR. HOWE: The permit at the broad scope licensee that said you were an authorized user.

CHAIRMAN MALMUD: Okay. So that -- all right. Now we'll get back to this young fellow. I'm now back to my youth again.

DR. HOWE: Oh, but you could ask for -- you could already be an authorized user and under the new rules, it wouldn't apply to you because diagnostic nuclear medicine included I-131 under -- over 30 micro curies but under 33 in the old part.

But if you were a brand new person, then 200 does not include whole body I-131 scans for patients that have already had thyroid carcinoma or other treatment. So you would come in under this Part 2.

CHAIRMAN MALMUD: Right.

DR. HOWE: You might.

CHAIRMAN MALMUD: But if I were to move to another institution, all I would need is evidence that I was already an authorized user and just move my authorized use permission to the new institution.

DR. HOWE: And the new institution would review it and approve it, if it is a broad scope. If it is a limited specific, they would then forward that information to the NRC and we would then list

you on a license.

CHAIRMAN MALMUD: Okay. So now we're back to this young man whose just finishing training. He could be a young woman, but I don't want to go through a sex change right now. So at any rate, they've now checked off Box 1 Board certification.

Now we go -- no need to check off Box 2 because he's currently not an authorized user. He's just finishing training.

He now turns the page and goes to training experience. And these boxes will be filled in by his training supervisor? His authorized user?

DR. HOWE: No, if he's Board certified then he provides his Board -- it says you have to select one of the three methods.

CHAIRMAN MALMUD: Yes.

DR. HOWE: And you have selected Box 1.

CHAIRMAN MALMUD: Right.

DR. HOWE: So once you have selected Box 1, you do not select Box 2 or Box 3. But -- no -- and this is a 200 user so there's no clinical experience there. That's already incorporated under your Board certification. But you do have to go to Part 2, the preceptor attestation.

CHAIRMAN MALMUD: And where does that

appear?

DR. HOWE: That's the very last page.

CHAIRMAN MALMUD: All right. So it seems to me that if I select Board certification, there should be a parenthesis there which says if you have selected Box 1, skip Box 2, skip Box 3 -- the same way it does on our 1040 forms where it tells you what to skip.

DR. HOWE: Well, we thought select one of the three methods below would do that but --

CHAIRMAN MALMUD: I don't think it's optimal.

DR. HOWE: -- it's not doing the trick.

CHAIRMAN MALMUD: It's not optimal.

DR. HOWE: And we just said A and B.

CHAIRMAN MALMUD: No one has had more experience in dealing with the public than the IRS. I think they're a good role model for this.

(Laughter.)

DR. HOWE: Okay, your point is taken.

CHAIRMAN MALMUD: So I would do that.

And now, naive as I am, have skipped Boxes 2 and 3 and gone to --

DR. HOWE: Part 2.

CHAIRMAN MALMUD: -- Part 2. Now you'll

notice at the top of page 2 of 4 has Box 3. And then it has under it an A and a B. And then we go to page 3 of 4 and there's a 3 again. Does that mean 3 continued?

DR. HOWE: Three continued, yes, it does. And the table, supervised work experience, is continued on to page 3 of 4.

CHAIRMAN MALMUD: Okay. So I can still skip that because I'm skipping 2 and 3. I've followed your directions on page 1.

DR. HOWE: Yes.

CHAIRMAN MALMUD: And now I'm on the preceptor attestation statement.

DR. HOWE: Yes.

CHAIRMAN MALMUD: And here it says Board certification. So my supervisor has certified that I have satisfactorily completed requirements.

DR. HOWE: Yes.

CHAIRMAN MALMUD: That doesn't mean that I'm certified does it?

DR. HOWE: No. He does not have to -- you can get the preceptor statement. This was -- goes back to her question. You can get the preceptor statement that you have completed the training requirements for the certification before you pass

the examination. So you could get the preceptor statement before you take the test.

Now when it comes to the NRC, we're going to look to see that at least when it comes to us, you've already got your certification which indicates you passed the exam.

CHAIRMAN MALMUD: Yes.

DR. HOWE: and then we'll look at this attestation that says that the person attests that you had the training --

CHAIRMAN MALMUD: Okay.

DR. HOWE: -- and the work experience.

CHAIRMAN MALMUD: So my preceptor has attested to my Board certification. Or he has attested or she has attested to my training and experience.

DR. HOWE: You're Board certified so he's just going to attest to your Board certification.

CHAIRMAN MALMUD: Okay. But let's say I haven't passed Part 2 of the boards yet. I've only taken the written but not the orals yet. Or I haven't passed a section or it, God forbid. So now he has to attest to my training and experience.

DR. HOWE: He could. He doesn't have to.

CHAIRMAN MALMUD: He doesn't have to

obviously. He's not obligated.

DR. HOWE: You may hold this form in abeyance until you've got your certification. And that's what would happen. You would provide this form once you got your certification.

CHAIRMAN MALMUD: Okay. Now I am also applying for 290. So we go through the same thing there.

DR. HOWE: Yes, that's correct.

CHAIRMAN MALMUD: And that completes that form.

DR. HOWE: The preceptor has to complete the bottom that says that the preceptor meets certain requirements. And then he signs it and provides the information. The form is complete.

CHAIRMAN MALMUD: That's not very difficult at all. That's pretty straightforward.

DR. HOWE: We thought so.

CHAIRMAN MALMUD: Now we go to 313AUT.

DR. HOWE: Okay. Wait a minute. AUT.

CHAIRMAN MALMUD: It's the next page. Page 1 of 8. Now do I need to do that having done 313AUD? Must I now do 313AUT?

DR. HOWE: 313AUD only authorizes you for those unsealed materials that require no written

directive. If you want to administer greater than 30 micro curies of I-131, then you will need to fill out AUT.

CHAIRMAN MALMUD: And I certainly do wish to.

DR. HOWE: So you're now working on AUT.

CHAIRMAN MALMUD: I want to work with as little as one millicurie up to 300 millicurie, 300 if necessary.

DR. HOWE: Okay.

CHAIRMAN MALMUD: So I'm now going to fill out --

DR. HOWE: Do you only want to use iodine or you want permission to use other materials?

CHAIRMAN MALMUD: Other materials as well.

DR. HOWE: So then we would -- you would come under the full 390. Okay?

CHAIRMAN MALMUD: Okay. So --

DR. HOWE: So you would check 35300, use of materials for which a written directive is required.

CHAIRMAN MALMUD: And now we go down to the next -- Part 1 T & E, we check off Board certification because we all assume that I'm Board

certified.

DR. HOWE: Okay. And your certification is recognized under this, yes.

CHAIRMAN MALMUD: Now it says current authorized user seeking additional authorization. Now we go back to the older man. And I may be seeking additional authorization for something that I haven't done before.

DR. HOWE: Yes.

CHAIRMAN MALMUD: So I would then fill out this form --

DR. HOWE: Yes.

CHAIRMAN MALMUD: -- but who will have -- who will attest to that for me?

DR. HOWE: The person that is providing you the new -- the person that is verifying that you had this new training and experience.

CHAIRMAN MALMUD: Just the new training and experience?

DR. HOWE: Yes.

CHAIRMAN MALMUD: Great. Okay. So that is easily accomplished.

Now we move to the next page, page 3 of 8. Supervised work experience. That relates only to those who are not Board certified? Or do those who

are Board certified require that to be filled out as well?

DR. HOWE: The Board certification people do not require the supervised work experience or the classroom and laboratory training.

CHAIRMAN MALMUD: Therefore -- oh, excuse me.

DR. HOWE: Yes?

CHAIRMAN MALMUD: Therefore, if we go back to page 1 of 8, it should say if you've checked off Board certification, skip Section so and so and so and so.

DR. HOWE: We could certainly put that in.

CHAIRMAN MALMUD: The same way --

MEMBER NAG: Except in 396.

DR. HOWE: But you do have to come down to -- well, the 396 part. You do have to provide C, supervised clinical case experience because the Board certification has been decoupled from the clinical cases. So you would have to provide the information and clinical case experience.

CHAIRMAN MALMUD: So it would say if you are checking off Board certification, skip Section 2A and B but complete Section 2C?

DR. HOWE: Right. And under C, we say for 390 provide documentation of supervised clinical experience. So that's C.

CHAIRMAN MALMUD: Okay. So we're now up to page 5 of 8.

DR. HOWE: Yes.

CHAIRMAN MALMUD: Now we turn to page 6 of 8. Now comes the preceptor attestation.

DR. HOWE: Correct.

CHAIRMAN MALMUD: And this is just the attestation for 390, which is unsealed byproducts, 392, which is oral administration of I-131 --

DR. HOWE: But you've indicated that you are coming in for the full 390 authorization.

CHAIRMAN MALMUD: Right.

DR. HOWE: So once you check 390, you do not have to check 392 or 394 or 396.

CHAIRMAN MALMUD: Okay. Then I would suggest with --

DR. HOWE: And we told you to check one of the following for each requested authorization.

CHAIRMAN MALMUD: I would suggest that where it says on page 6 of 8, if you're checking 390, you need not fill out 392, 394, or 396.

DR. HOWE: Okay. We can do that.

CHAIRMAN MALMUD: All right. Then we go to page 8 of 8. And that's just a part that requires some signatures.

DR. HOWE: That's correct.

CHAIRMAN MALMUD: All right. Now that completes it really.

DR. HOWE: Yes, that completes it for you.

CHAIRMAN MALMUD: I beg your pardon?

DR. HOWE: That completes it for you.

CHAIRMAN MALMUD: So having gone through this as a naive individual who did not attend this meeting and did not hear any of the intelligent questions asked or responded to, this is not very challenging.

(Laughter.)

DR. HOWE: We hope that's true, yes. That's our objective.

CHAIRMAN MALMUD: I had you to lead me through it but you have now recommended that there be some parenthesis next to some of these Board certifications to indicate which sections can be skipped. And you've created forms which I think are not very demanding of a program director.

Now we have already told our residents a

long -- well, some time ago, you better keep track of every therapy patient by some method so that you can prove to us that you really had that experience since we're not going to track those patients for you. And they're doing that. Meaning the I-131 therapy patients and so on.

So I think this is not a burdensome role for a training director. Now I'm no longer a training director. So I can't speak for them. I did it in the past but not now. But it doesn't seem to me that it is onerous.

Does anyone on the committee feel that this is onerous with this explanation having been offered to us?

DR. HOWE: I think I'd also like to mention that we are planning on providing guidance in NUREG-1556, Vol. 9, so that you will have a little bit more to help you through the forms than just the forms.

But we do think Sandy has created forms that you can pretty much go through without a lot of additional --

CHAIRMAN MALMUD: Well, even I could work through them with your help in the space of a few minutes. So I'm certain that they are efficient.

And my hat is off to both Sandy and to you for having created these forms which with a couple of little tweaks are understandable even by me.

So I thank you. And since the committee agreed with me -- I didn't see any opposition --

MEMBER SCHWARZ: I'm sorry. I'm not opposing. I'm asking. In this AUT form where you are doing training and experience for 396, where it says fill out Tables 3B and 3C, should it just be 3C?

CHAIRMAN MALMUD: Yes.

MEMBER SCHWARZ: So there is listing a direction of 3B on there as well.

DR. HOWE: For 396, you have to provide evidence that you have -- you are Board certified through the brachytherapy certification pathway or the therapy device pathway. And so you have to provide documentation of your 80 hours of training and experience in unsealed materials. And so you would have to fill out these forms, yes.

And if you go to 396, I think you'll find out that you've got 80 hours and you've got to do the A part, which is the classroom laboratory, because those subjects, radiation, physics, instrumentation is what you have to fill out.

And then you have to have work experience

under somebody. And then you have to fill out the B one for the work -- because of that work experience. And involved is also your three cases. And your three cases are over in C I believe.

So you do have to go and fill out the tables for the alternate pathway for 396 because your Board certification is coming from 35400 and 35600 uses.

CHAIRMAN MALMUD: Mr. Leito?

MEMBER LEITO: I'd like to go back over this form that you just went over.

CHAIRMAN MALMUD: Yes? Which form?

DR. HOWE: The AUT?

CHAIRMAN MALMUD: Which form? Which page?

MEMBER LEITO: AUT.

CHAIRMAN MALMUD: AUT?

MEMBER LEITO: It says at the top okay request authorization, check all that apply. All right? So is that supposed to be 390? You told me these were typos here but is it supposed to be --

DR. HOWE: Oh, no, I'm sorry. These are not typos. This is 35300. And the first one is if you're going for all uses under 35300, you check that box.

If you're going for just oral administration or oral administration greater than a certain activity, you're going for the parental administrations of the betas and the gammas, then you check that block. And if it is the others, then you check that one. So those are not typos. I'm sorry. I hadn't seen the form quite quickly enough. Those are not typos. And --

MEMBER LEITO: That's, I think -- because I think this is supposed to be training and experience. And I think it indicated here the training experience that you are supplying, which identifies the use, wouldn't it be 35390, 392, 394, 396? Right there --

DR. HOWE: The actual uses are up in 300.

MEMBER LEITO: Okay.

DR. HOWE: And the training and experience with those uses is in 390, 392, 394, 396. We could --

MEMBER LEITO: Well, then I guess I'm --

DR. HOWE: -- we could put something in here that maybe more clearer explains which training route you're coming through.

MEMBER LEITO: Because I think under the Board certification route, okay, it's like, okay,

what Board certification satisfies 394?

DR. HOWE: Right now? None. The American Board of Nuclear Medicine is authorized under 390 because they get the whole ball of wax.

MEMBER LEITO: Okay.

DR. HOWE: So they come under 390. You don't have to provide anything additional.

MEMBER LEITO: All right. So -- and then 490 therapy would be --

DR. HOWE: To use unsealed materials would then come under 396. Or we might have some 400 or 600 physicians that may also want to deliver therapeutic I-131. So they may come under 394.

MEMBER LEITO: Okay. Under Board certification 1A, if Board certification is older than seven years. I mean you could have a Board certification longer than that. Don't you mean recentness of training? Or I mean it's not the Board certification that's the seven year requirement. It's recentness of training. Am I making my point?

DR. HOWE: It is the recentness of training. And I think we put it in there and we may have to write it a better way.

MEMBER LEITO: Yes, it's just that it makes it a Board certification from the Dr. Malmud

from the 70s, I mean you're still going to meet that as long as you demonstrate --

MEMBER NAG: Recentness of training.

MEMBER LEITO: -- recentness of training and continued use. And I think that's what the intent is here. But it's not what it states.

MEMBER NAG: Right.

MEMBER WILLIAMSON: Yes, I guess to add to what Ralph just said, in this case where the Board certification there was gap or interruption and you had the Board certification. It was older than seven years, what exactly do you have to provide? Which parts of this form do you have to fill out to document recentness of training?

DR. HOWE: We get a few cases every few years of people that were Board certified. And this is not under the new rule but under the old rule, that are Board certified 26 years ago, never listed as an authorized user, went into the administrative area of medicine and stayed there. And now they're ready to retire and they want to get more into the clinical side of things.

And we treat those on a case-by-cases basis. And that we pretty much consider the alternate type of pathway. We don't require them to

fill out these forms. But we do require them to provide information on their training and experience in the last seven years.

MEMBER WILLIAMSON: Okay. So maybe you might want to put a line here that -- instructing them perhaps to prepare a separate letter or somewhere in the instructions to these forms indicating that that class of authorized user applicants should not fill out these forms.

MEMBER NAG: Donna?

DR. HOWE: Well, we do have guidance that we'll be developing in the NUREG and we can go into more detail there.

MEMBER NAG: Donna, do you mean that the interruption is for more than several years. And we can go into more detail there.

MEMBER NAG: Donna, do you mean that the interruption is for more than seven years? Or the --

DR. HOWE: Even if the interruption is less than seven years, then we look to see what your experience was in the last seven years. And if your experience in the last seven years was you weren't on a license for one of those seven years, we don't expect you to do much more. And we'll go ahead and put you on a license.

But we do have to look to see how long you've been away. Most of the ones that we really get into are those that have been out of field for significant periods of time.

CHAIRMAN MALMUD: With that, may we take a break because we have the public session that is supposed to be getting -- at 3:15?

I want to thank you both, Dr. Gabriel, Dr. Howe.

Dr. Suleiman?

MEMBER SULEIMAN: Yes, one question. These haven't been OMB cleared yet?

DR. HOWE: No, they have not.

MEMBER SULEIMAN: So that will take another --

DR. HOWE: We are distributing them to the Advisory Committee for your comments. We'll be developing the guidance. And then we'll be putting both the guidance and the forms out for public comment during the OMB clearance process. So the forms cannot be used until they have OMB clearance.

MEMBER SULEIMAN: So these may not see the light of day for at least six to twelve months if not longer unless you get through --

DR. HOWE: Six months is what we're

hoping.

MEMBER SULEIMAN: You don't bet do you?

(Laughter.)

DR. HOWE: Well, we have revised -- we did revise the 313A that was up on the web that's the official document. We just got a new OMB clearance for the last 313A.

We took out all the Subpart J requirements because that went on the web today. Subpart J is no longer in effect for us. That's the only change we made to that 313A form. But these will have to go through OMB clearance.

MEMBER BAILEY: Could we get a copy of what became official today?

DR. HOWE: Yes. I can print it out for you. It's up on our website.

MEMBER BAILEY: I don't have a computer.

DR. HOWE: That's okay. I'll print it out for you.

CHAIRMAN MALMUD: Thank you. We'll resume at 3:25. Thank you.

(Whereupon, the foregoing matter went off the record at 3:14 p.m. and went back on the record at 3:29 p.m.)

CHAIRMAN MALMUD: The next session will be

– the presenter for the next session will be Dr. Sami Sherbini, and the topic is the status of guidance on reducing doses to members of the public.

Thank you.

DR. SHERBINI: Thank you.

We had discussed at a previous meeting the guidance is now finished. It's just about to be issued. It's probably in a couple of days in fact.

We have put the guidance out for comments, and we received a lot of comments, most of them favorable comments. And we've incorporated most of them in one way or the other.

Some of them we were unable to incorporate either fully or in some cases maybe partially. Just to give you some idea on why we did not incorporate some of the comments, the reasons why we did not do so.

So this is one of the comments that we did not incorporate fully. Several commenters objected to the fact that we refer to using such treating facility as a cheap easy-to-use alternative for monitoring visitors.

We modified the risks and softened that statement somewhat by saying that in some cases it might be an expense that is not justified, but some

other way could be found to provide real-time control of the doses.

So that was just partially adopted.

Please be consistent with use of radiation terminology. Use SI units. And so forth. And do not interject TEDEs.

We incorporated this partially. The NRC policy is to use both the old and the new units. The new units followed by the old ones in parens.

Unfortunately we have to use TEDEs because that is the quantity licensees are required to show compliance to, which is the sum of both internal and external. So since there is always a potential for external dose, then it is necessary to show that the TEDE does not exceed this.

TEDE is the name that currently being used in the industry for the sum of the external and internal doses. Unfortunately ICRP did not define this or give it a name, so each agency essentially names its own quantities using TEDE.

And so the use of TEDE is inescapable.

We also used Rankin in that guidance. And the reason we used Rankin is that a lot of the survey instruments and the subtreating dosimeters, et cetera, are still calibrated to Rankin. So this

being the practical guidance, we thought it would be appropriate to discuss this in terms of units that are normally seen on the instruments.

The use of the rakin is also still allowed by the ICLU, so it's not such a big issue from the SI system.

It was suggested that measuring excreta should be deleted from the guidance. We had something that the intention was not to actually do bioassays or anything like this. The intention was that if there is any data on excreta that sometimes urine is collected in shielded bottles and surveyed.

This is the kind of data we have in mind. It would help us if we had to do those reconstructions if we had this kind of data available.

And so we modified the write-up slightly to indicate this.

It was suggested that the retrospective dose reconstruction be removed from the document. The intent wasn't to discuss how to do dose reconstruction, but merely to indicate what kind of data should be collected if such a reconstruction was to be done. So we clarified this point. Just tell us what kind of data we should have in hand. It does

not tell how to do the reconstruction.

The suggestion was made to change from the first to the second. Although the proposed rheolite is good, it changes the meaning of the sentence. The first sentence intended to highlight the fact that control is paramount. And that is why we say they were inadvertently permitted to exceed the dose, indicating that control was not as good as it should have been.

The second sentence does not have that thought in it, and so we decided to leave the first sentence as is.

MEMBER VETTER: Doesn't the first sentence imply that the licensee knew, a priori, that the member of the public would receive a dose in excess of the limits?

DR. SHERBINI: Well, either knew or should have known, either way it was permitted. In other words, the licensee is in control. The failure of control could be because the licensee didn't know, or because the visitor did not cooperate.

But in either case, the licensee should be control in the sense of knowing what is going on. And that was the thought we wanted to highlight by putting "permitted" in there. Because whatever

happens at the licensee's facility is either permitted by the licensee, or at least it is done with the knowledge of the licensee at the very least.

We realize sometimes the licensee can't do anything about it, but at least we know about it. So that is the point here.

CHAIRMAN MALMUD: Dr. Sherbini?

DR. SHERBINI: Yes, sir.

CHAIRMAN MALMUD: Even with the wisdom of hindsight, how would you have prevented that individual from receiving doses in excess of the regulatory permit?

DR. SHERBINI: You probably couldn't help, in the risk that if this situation is seen to be approaching, then the NRC should be notified. And the notification implies two things, that something might be done by the NRC about it, or at least that the licensee is in control and knows what is going to happen imminently. So that's basically it.

CHAIRMAN MALMUD: The committee certainly agreed, and in fact, discussed the fact that had NRC been notified in a contemporaneous fashion that perhaps this incident would not have escalated to the level.

However, those two sentences don't relate

to that. They relate to how the member of the public received the doses. And I prefer your second sentence to the first one, your second introduction to the first one, quite frankly.

DR. SHERBINI: I see your point.

There was an item that had to do with internal contamination. We did not delete preference in front of contamination, but we softened it and clarified it a bit.

The point is, there is always a potential. And if there is a potential the licensee is required to do a survey.

By survey we mean that at the very least to be aware or to state that there is no protection. That is all that is intended here.

Of course if there is a potential, then appropriate measurements would have to be taken.

Another suggested change was – I personally didn't like the second, because it puts the onus on the visitor, whereas really the onus is on the licensee. The visitor doesn't comply with anything except maybe directions of the licensee if they had to comply with them.

But the idea of compliance does not really apply to a visitor.

Yes, sir.

MEMBER VETTER: Excuse me, but yes, certainly the licensee is in the final analysis responsible, but we as licensees don't have the authority to throw a visitor out of a room. If a patient walks out of a hospital, regardless of whether they have radioactivity in them, if they simply walk away that's in violation of a joint commission regulation.

There are some things that are beyond the control of a hospital, and so to say we lack sufficient control of visitor activities, I'm just thinking that is a little strong.

DR. SHERBINI: We're not implying control in the sense of physically restricting the activities of a visitor. By control we mean, as I said earlier, the very lowest level of control is awareness, and we can take it to that level. We recognize that the visitor can say, no, I'm not going to do what you're telling me, and you can't do anything about it.

MEMBER LEITO: That's not what you're saying. You are saying that even though the awareness was there, okay, the physical barriers, physical signs, instruction, that lack of compliance by the visitor with all those requirements, or those

guidelines, that that's not what's here. You're basically throwing that out again. You're just saying that lack of sufficient control of visitor activities.

DR. SHERBINI: No.

MEMBER LEITO: The controls were there. The instructions were there. The visitor consciously, that is sort of analogous to what Dr. Eggli's example was about you have all these – you have all these proper instruction and everything is in place, and if someone willfully decides not to comply, you can't necessarily say that the licensee didn't have control of the problem.

DR. SHERBINI: But we can in the sense of, at least in the case we had in mind, that the licensee did not really know that the dose was going to be exceeded by quite a few of the visitors, and that is from our regulatory perspective, that is lack of control.

Control may be an unfortunate word, but implies physical restriction or something of the sort. Control in this sense means that the situation doesn't run away from the licensee, meaning that people don't get doses when they don't know about it. They can get doses when they know about it, call the

NRC, get exemptions, et cetera.

But you need to know what is going on.

DR. WILLIAMSON: That may be a good point to make, but I think you should then expand that sentence into a paragraph that makes the different subtle distinctions between different forms of control, rather than assume everybody understands that. Because what you're hearing is that that is not the common ordinary language and interpretation of the word, control.

MEMBER NAG: At our previous meeting with the commissioners, I think the commissioners were very much aware, and they were very much sympathetic, to the fact that there may be a loved one who, even though the licensee is under control, the licensee has told the person. That person consciously decided to – I would do something – but decided to go above the limit, and I think the commissioners were very sympathetic that this is something that we should find a way to permit the visitor to do without violating some rules.

DR. SHERBINI: Yes, we are working on that. As I would indicate in a few minutes. But even under this provision, even if there was a provision, the provision will require the licensee

to request from the NRC some kind of exemption from the default limits, which means call the NRC and say, we have this person who is about to exceed the default limits. We need to increase to another limit.

It still doesn't get away from the control issue, which is, in order to do that, you need to know what is going on. You need to know that this person is about to go over 100, and therefore call the NRC before you do.

MEMBER NAG: But many times we may not know what those limits are going to be. We know that it may be potentially a problem. For example, I treat children all the time. And the mother of the child may say, I want to be with that child. I wouldn't know beforehand what that dosage would be, but I would know potentially it will be over the limit. So we will ask potentially – we see the potential problem. We want to be allowed to exceed the limit.

DR. SHERBINI: That would be acceptable. That would be what we are looking for basically.

CHAIRMAN MALMUD: Dr. Sherbini, we have a visitor from the University of Pennsylvania who wishes to make a comment if he may.

DR. SHERBINI: Oh, sure.

MR. FORREST: Hi, Rob Forrest, University of Pennsylvania.

When the outpatient guidance came out, the NRC issued something to the effect that, I don't know if it was in a RIS (phonetic) or something else, that the licensee would not be held responsible if the patient did not follow their instructions, which would potentially lead to the same situation you're discussing.

So I'm a little concerned that the same principle doesn't apply to an in-patient, if a visitor, you give them instructions, you give them training, you give them whatever, they choose purposefully not to follow those instructions, why the same principle doesn't apply.

DR. SHERBINI: Because it's not the same situation. The example you give would be analogous to a situation where the licensee did not realize that the patient needed to be given instructions, and just was let go basically, because the licensee was not aware that the dose did not meet the criteria, or did not require provision of instructions or something.

This would be the analogous situation.

In other words, if the licensee knows what is required of them, provide instructions. The patient goes out, doesn't follow the instructions; that is one situation. If the licensee releases the patient when instructions should be given, but the licensee fails to give that instruction, that is a wholly different situation. That is a loss of control.

That is what we are talking about here. We are talking about the visitor who is in the room. The licensee has the responsibility to recognize at least there is a potential there. The doses are high, there is a potential based on the behavior of the visitor, that this dose is going to be exceeded. But there is not going to be a way to keep it within, say, 100, and therefore action is called for. Call NRC, get the higher dose limit, get an exemption, whatever.

And that is what we mean by control.

MEMBER FORREST: I think I would have to agree with Dr. Vetter. You are asking us to do things we can't do. There are positions where we can say, you sit in this chair, and if we come in the next morning and they are on the other side of the shield, how could we possibly have known without doing some psychoanalysis on the person that they

weren't going to follow our instructions? It's impossible.

DR. SHERBINI: That is your responsibility as a licensee.

MEMBER NAG: No, I'm telling you, I don't agree with that. Our responsibility is to instruct the patient and the visitor. We have to instruct them. We have to let them know potential problems. And if they willfully desire to exceed that, that is not under our control.

We can tell them and advise them. And that is all.

DR. SHERBINI: There is a factor that we are not mentioning here. And that is the dose rate. And this example is really important. The dose rate is important, because it will tell you what is likely to happen.

We have somebody sitting in the room overnight, and the dose rate is two millirem per hour, it is unlikely by the morning it will have exceeded 100 millirem. But if the dose is 50 or more per hour, then I would think the licensee would have to do something about it, even put somebody up all night to make sure that this person doesn't go behind – because the dose rate controls how quickly the

situation can run away from you.

MEMBER NAG: Right, but the dose rate depends whether you are sitting on the other side of the lead shield, or whether the placing of the visitor had gone on their own away from the shield. That's not up to the control of the licensee. The licensee can instruct and say, you do not go around the other side of the shield. But if the visitor decides to go on the other side of the shield, there is really nothing I or my safety officer can do other than physically pulling the visitor out.

DR. SHERBINI: Okay. I guess we are going around here in circles. Basically the situation that elicited all of this was that the visitor was actually going behind the shields, and was actually approaching the patient, and the dose rates were notably quite high.

So even back of the envelope multiplication would have quickly alerted anybody that this patient is no way going to stay within the dose limit; no way. It doesn't take much to do even in your head.

But despite all of that, despite the existence of those rates of a couple of hundred per hour, nobody could know.

Now, we can't say --

MEMBER FORREST: It's not true.

DR. SHERBINI: Well, the overexposures were discovered several days or weeks afterwards, at least the records indicate that that is what happened. But that was our concern.

CHAIRMAN MALMUD: Mr. Bailey.

MEMBER BAILEY: Earlier we talked a licensee being responsible for an employee who violated, directly violated procedures and everything else.

And now it seems as though we're taking it a step beyond even the employee; we're taking it to a member – to someone that the hospital or the licensee does not employ, does not have police power or anything else, and making nit a violation of the licensee.

And to me that is going at least one step too far.

DR. SHERBINI: No, I think there is a step which you left out, which is that if the licensee notifies the NRC before this happens that there is not going to be a violation.

MEMBER BAILEY: But how would you know that the person was going to go around the shield?

DR. SHERBINI: The person is in the hospital. There is stuff there. And if the dose rates are high, and if the visitor shows that they are not about to obey instructions, then you know that the dose is going to be high.

MEMBER BAILEY: Well, I would pose a hypothetical situation. The person is there in the room, outside the shield. They perceive something is going on with their loved one, and they say the heck with the instructions you gave them, and they run around the shield.

DR. SHERBINI: And many of them do it.

MEMBER BAILEY: Would that be something that the licensee could logically assume is going to happen and therefore they should ask permission in case it did?

This seems to me to be a medical event; not a violation.

CHAIRMAN MALMUD: Dr. Williamson

MEMBER WILLIAMSON: I think I have to agree with Dr. Sherbini on part of this. I think that it is reasonable to make a distinction between being responsible for a visitor's behavior versus being responsible for making a reasonable effort to ensure that the visitor is following instructions

while in the licensee's facility.

And I think that it is a reasonable injunction to make in an RIS to say that licensees should be aware, and make an effort to be aware of whether visitors are complying with the procedures or not.

And if they are not, and it looks like there is a significant chance of exceeding limits, then the user has some recourse to ameliorate the regulatory fall out from that event. I think that is reasonable.

I think part of the problem we have is that the specific incident at the hospital that we keep returning to, there is a lot of – there was sort of a nasty incident in the sense that there were very different stories told by different people, by the people in the hospital, by the inspectors who inspected the facility.

And I don't think we should be arguing too much over the particulars of that incident. But what is reasonable guidance in a situation like this, in general, quite apart from that incident.

DR. SHERBINI: I think we are – Dr. Williamson is well taken, that maybe we should take away the control word, and explain what we mean.

MEMBER WILLIAMSON: I think that would be very wise. Because you do have to make a distinction between somebody that is an agent of the licensee, an employee, who is responsible, whose behavior and performance the licensee is legally responsible for, and a patient or a visitor over whom no such corporate control exists.

DR. SHERBINI: We'll make a change.

Yes, it was suggested that we move a substantial – we weren't sure what to put in its place, so we ended up leaving "substantially," hoping that most people will understand that substantially means you are getting close to where you shouldn't be.

Substantial also will change depending on the dosage. If the dose rate is high, then a substantial fraction might be 20 percent of the limit. If the dose rate is very low, then it might be 80 percent of the limit.

So it is open to interpretation by the individual licensees. That is probably appropriate.

We left the discussion of nonuniformity and variation with time of dose fields -- only because we thought this was useful information. The licensee take it or leave it, depending on whether

they think it would be useful for them. And that is certainly something that does happen, so it should be considered at least.

We did not change dose assessment to dose estimates primarily because for the NRC dose assessment is a much broader term, and it is not necessarily mean cascading numbers. It could mean reviewing what happened, deciding whether you should calculate numbers or not, deciding whether to use sophisticated models or not, and so on.

So it's a much broader term that encompasses a lot more activities than to estimate the dose. And so we decided to leave it as assessments. It doesn't really matter one way or the other.

But it also fits in with a lot of our other documentation which uses assessments rather than estimated dose.

Delete the section on biological dosimetry. We weakened that section considerably, but left something in there, because it is sometimes useful, if for nothing else, put some people's minds at rest if they think they got a high dose. We have run into that situation many times where people don't believe our sophisticated models and calculations.

They want to see a test, and so in situations like this we found that doing biological dosimetry cytogenetics analysis puts their minds at rest when the result comes out negative, below detected limits. So that helps a lot in many situations.

And so it is certainly an option. Licensees don't have to take that option if they don't want to, but it's there.

MEMBER VETTER: Excuse me, just a point of clarification. You are talking about biological dosimetry on the visitor.

DR. SHERBINI: Yes.

MEMBER VETTER: I'm just wondering in my mind how am I going to capture this visitor and get a urine sample.

DR. SHERBINI: Well, the chances are that the visitor will express concern to somebody saying, I got a high dose and I don't believe your numbers. We have run into that situation many, many times, even for people whose dose estimate was just a few hundred millirem, and they insisted that they got a big dose. And so the only way to settle that was just to draw a blood sample and send it for cytogenetic analysis. And the test comes back that whatever dose they received was below detectable

limits. And so it kind of settles the issue.

CHAIRMAN MALMUD: Mr. Leito.

MEMBER LEITO: I have a general question for Dr. Miller. The RIS doc itself. That stands for regulatory issues summary?

DR. MILLER: Yes, issue summary, correct.

MEMBER LEITO: Could you just for the education of the group here, what is the purpose of an RIS? It might help in the context of some of these things, and also my next comment.

DR. MILLER: A regulatory issue summary can involve a number of things. The one thing it cannot do, it cannot set new requirements.

What it's intended to do is to provide information that will allow licensees to be able to meet their requirements, and sometimes it's helpful hints. Sometimes we give information with regard to events that have taken place, so that people can be aware of them and prevent them themselves. Sometimes it gives helpful hints on things you may do to prevent violation of the regulations.

Did I miss anything?

MEMBER ESSIG: I was just going to add to it that it's one of four types of generic communications we have. The top tier is the bulletin

in which we can actually request information from the licensee because of the severe safety significance of the issue.

The next step down is a generic letter, which conveys a strongly worded message and may or may not request information.

And then a RIS is third, and then an information notice is the bottom of the tier.

The information notice merely conveys information, maybe on an event. It might be a lesson learned from an event that we had.

And so those are the four. So this is the next one up from the bottom if you will.

MEMBER LEITO: When we had the teleconference over this RIS, there were a number of things that I think were pretty well consensus of the ACMUI members that participated of things that were bothersome.

Were there any of those issues that you did take and adopt in totality into this RIS? Because in looking at these here, it seems like almost everything that was objected to or we had problems with has been either kept in or modified slightly.

That's kind of --

DR. SHERBINI: I don't really have a tally of what fraction was adopted whole, and what fraction was partially or not adopted.

The hope and objective of this presentation was to try and show you, and give reasons why we did not adopt certain accommodations that you provided.

And hopefully the reasons that I presented were convincing.

MEMBER LEITO: From this member's standpoint, I think keeping in biological dosimetry as, well, you want to do it, you don't, in a document like this basically is saying, you know, if you are going to put it in this document, then what you are doing is you are telling a licensee this is something that you should be considering doing. And I really can't find any need to do biological dosimetry on a visitor.

I mean there is no way that they are going to get a dose, even in a situation that precipitated this whole event, that would warrant anything like this type of dosimetry.

So to even keep it in there, because it is not a standard of practice, it is not a consideration in any of these events. And I don't

know of any case to date involving a medical exposure of a visitor or a worker where they have done this.

DR. SHERBINI: Well, no, that's true, they haven't. But there are some cases where they could have, that could have settled a lot of questions without --

MEMBER WILLIAMSON: What is the lower threshold for biological dosimetry to be able to detect with any certainty?

DR. SHERBINI: You can go down to five rads with sufficient number of cells.

MEMBER SULEIMAN: Well, it depends on what you're looking for. A bioassay, if you are looking for a radionuclide in the blood --

MEMBER WILLIAMSON: That's if you have a background.

DR. SHERBINI: Yeah, if the – some of the labs will analyze up to 2,000 metaphases. And if they do that, you can go down to about five rem. So in some cases there have been cases where the dose was above this.

MEMBER VETTER: I think if you are going to make the suggestion of biological dosimetry, you should either by reference or by a little paragraph

maybe indicate what some of the limitations and strengths of this tool are, such as where it breaks down and where it's not applicable; at least give references.

DR. SHERBINI: Yes, I think we have done that to some extent. We haven't given references, but we have weakened to the point where it's sort of an oh-by-the-way kind of thing.

CHAIRMAN MALMUD: Dr. Vetter.

MEMBER VETTER: This is kind of on the edge of my knowledge of IRBs, but I don't think that we have the authority to get a blood sample from a visitor without going through our institutional review board.

DR. SHERBINI: No, that is true.

MEMBER WILLIAMSON: It's assault and battery.

MEMBER VETTER: So I'm just really having a lot of difficulty with this, how we would ever implement this.

DR. SHERBINI: This is the situation where this is used, it's almost always initiated by the exposed person. Because the exposed person is generally the person who is concerned with the accuracy or the reliability of the dose estimates

based on analytical methods.

MEMBER VETTER: I think that is a different matter. If the visitor came to us saying I'm concerned, that is a different matter. I don't think we would be arguing about this.

This implies that we should have in our program some prospective thought about biological dosimetry on visitors.

DR. SHERBINI: No, I will make sure that this is not written this way. I'm sure it isn't, but I'll make sure it isn't. It does not imply that you should do anything of the sort.

DR. MILLER: Sami, let's see if I can help or hinder this discussion.

The concern here would be that if a visitor felt that they got a higher dose of radiation than they really received; is that correct? And therefore the biological – if you took a sample and did a biological analysis on it, then that could show that it didn't reach a threshold, which means it is something below that.

As a regulator how would we use that?

DR. SHERBINI: The way it usually comes – first of all, the exposed person generally does not know about biological dosimetry. So if the person

has doubts about the licensee or whoever does the assessment of dose, then this could be offered as an option, okay, do you want to do biological dosimetry? Here is what is involved, and here is what it can do for you, and here is what it can't do for you.

It's an option that the licensee or the exposed person can use if he or she decides to do so. That's all it is.

DR. MILLER: But from a regulatory perspective, for we as regulators, okay, we would only use that if a member of the public voluntarily submitted to such a test for lack of a better word.

DR. SHERBINI: Yes.

DR. MILLER: And then the licensee presented the results of that test as evidence that the licensee – that the individual did not get a dose of radiation.

Other than that, we wouldn't have a stake in it as regulators.

DR. SHERBINI: Well, there are situations where this is your only option. In other words there are situations where there is no data, and we have had such situations. And the only option you have left is biological dosimetry, since there are no numbers, there is no measurement, there is nothing.

MEMBER VETTER: Well, another IRB issue is that the information – if the visitor is coming for simply their own edification that the dose is okay, that is going to be privileged information, and we would not be – we wouldn't have the authority to share that with anyone.

We probably wouldn't even know. I mean that is going to be – that is a visitor issue. They essentially become a patient at that point, and that is privileged information.

Perhaps they'd be satisfied, well, you couldn't detect it, I'm okay with that, and that will be the end of the issue.

But suppose they do get a number, suppose it does say 10 rem, the patient has to be – that visitor has to want to share that information with us.

DR. SHERBINI: There is always a release form.

MEMBER VETTER: I'm sorry?

DR. SHERBINI: There is always a release form. And the form says that the results will be shared with the licensee, and often with the NRC.

DR. MILLER: But he would have to consent to that.

DR. SHERBINI: Oh, yes. That's standard. That's standard like anything else.

CHAIRMAN MALMUD: We have a comment from a member of the public.

MS. FAIROBENT: Lynne Fairobent, AAPM. Actually I have a question. Because of other meetings I've been in recently, how many facilities are there even in the U.S. that can do this type of biological dosimetry that you are looking for, and at what cost to the licensees?

DR. SHERBINI: Right now, there is one. It is very expensive. But very soon we will have another one that is not as expensive.

MS. FAIROBENT: It's still relatively expensive?

DR. SHERBINI: Yes. $500 typically.

MEMBER NAG: On a similar issue, if you have let's say a nurse or someone who has to take care of that patient, has a badge, but complains that I'm feeling faint. I may have gotten too much radiation, what are the avenues that the licensee has to, A, either confirm or deny that that worker did or did not get an excessive dose of radiation? That itself shows no radiation?

DR. SHERBINI: There are several ways.

You can calculate the dose and ensure that it was small, or there it is, biological dosimetry.

There are situations where the reading of the dosimeter is suspect. It could be defective, the dosimeter could read high because somebody spiked it, or whatever.

So there is something about the reading of the dosimeter that makes me believe that it might not be as reliable as you would like it to be. So you do calculations --

MEMBER NAG: But you know calculations can vary by a huge fraction depending on the assumptions you make. Where is your hand? Is your hand close to the implant area? Is your body 10 centimeters away or 100 centimeters away? I mean those things are very difficult.

DR. SHERBINI: That's why we left this in here, because this gives an additional option. You don't have to take it. You don't have to use it. But it's an option; it's there, in addition to calculations and measurements and everything else. It's the whole slew of options that you have when you are faced with this situation.

Most situations won't need such things, but some situations do.

It's a piece of information. I'm not understanding why providing more information to the licensee is viewed negatively. We are not suggesting that they should do it, or that they should be prepared to do that analysis themselves.

We're suggesting that here is another option by which you can assess where the dose lies.

MEMBER WILLIAMSON: I guess from having heard everything, it sounds like it's so far out of the mainstream, and because it's a medical procedure done on a visitor, its use is so restricted that it seems to me to hardly be useful enough to include in a mainstream report of this nature.

DR. SHERBINI: We can revisit this. We can revisit it to see if maybe it might be appropriate to just remove it if it's causing such difficulty.

CHAIRMAN MALMUD: Are there any other comments? Dr. Suleiman.

MEMBER SULEIMAN: Yes, I'll just repeat this, because I've repeated several times previously. Again, I don't understand why the NCRP – I think it was commentary report #11 which addresses this very issue of caretakers – is only a few pages long and

very clear and simple. And I think this entire exercise is really taken a lot of extra effort.

And I also – I noticed in your journal article that you used SI units consistently, so the journal apparently required that. I don't understand why as a minimum the NRC can't use SI units along with the TEDEs and the Rankin and whatever.

DR. SHERBINI: We have to do that. It's required.

CHAIRMAN MALMUD: Dr. Nag?

MEMBER NAG: From the ACMU side, I would like in your report to make sure that an emphasis that you do emphasize that the licensee has a responsibility to explain and warn the visitors, but that the licensee itself cannot be held responsible for making sure that the visitors comply with that. Because that is really not up to the licensee's control. I would like to emphasize that.

CHAIRMAN MALMUD: Any other questions or comments for Dr. Sherbini on this issue?

MEMBER SCHWARZ: My comment is on this biological dosimetry. Since it really is such a – I mean it's a test that is certainly not routinely performed. And as far as data that would be available once a visitor might have such a test

performed, there is not really a lot of correlate information that is going to reassure them that something bad hasn't happened to them.

I think this is probably not the best route to go to assure a person that essentially they have not sustained damaging effects.

DR. SHERBINI: It hasn't been a situation, especially when people do not have much confidence in complex computer programs and things like this. People don't feel that these programs are really producing good numbers that they can believe in. But a test is stronger. A test is – I'll rethink this and maybe remove the whole thing since it is taking such --

CHAIRMAN MALMUD: Mr. Bailey.

MEMBER BAILEY: I would have to agree with some of the people who have been talking about the biological testing.

Number one, we have historically years and years and years of bioassay performed on nuclear med techs, and about the only time we got anything measurable is when somebody was really messing up.

As far as going to cytogenetics, we too had a case recently where basically it was 150 whole body equivalent dose. We sent it to two different

centers. We got widely varying results. And the one in the United States was the most unbelievable, because it didn't correlate with either the film badges or the clinical symptoms of the patient.

To me that is one of the most disturbing things that can happen to an individual is to have two results, and they are different, and so they say, you don't know anything.

To me it is not reassuring to necessarily have bioassay data of any kind.

DR. SHERBINI: Well, we learned that the hard way. We had some bad experiences.

But that does not really – this is not a critique of the method; it's a critique of the lab. It's a fine distinction, but it's important to keep in mind that this would apply to any kind of medical test you do.

Yes, some labs will give you wrong test results, but that doesn't mean the tests shouldn't be done or that they are bad.

MEMBER BAILEY: Well, I guess I would argue, if you can't trust the test results, you are worse off with bad results.

DR. SHERBINI: I agree.

MEMBER WILLIAMSON: So maybe you

shouldn't take a position advocating its use in this instance.

MEMBER SULEIMAN: Well, last I knew there were no commercial labs who did this sort of thing. Are these commercial labs or are they private labs?

MEMBER BAILEY: They are governmental.

MEMBER SULEIMAN: Okay. But the cost of a personal dosimeter would be how much compared to one of these tests?

DR. SHERBINI: Much less. Okay, I will remove it.

CHAIRMAN MALMUD: May I summarize what I suspect the feelings of the committee are, since we've discussed this for a long time, Dr. Sherbini.

I think that the committee feels that the licensee in this case, was unduly punished for something that was not under the licensee's control at the time.

We recognize that the regulations require the licensee be held responsible. Once having said that, the next question is not how we measure the dose to the unauthorized member of the public who is receiving more than he or she should have, but how do we prevent this from happening again.

And I've thought about it. Other members of the committee have thought about it. There are some things we simply can't control.

Calling the police would not have resulted in a response either, and it's unlikely that a police officer is going to drag a daughter away from her dying mother in a room which is known to be radioactive by virtue of the mother's presence. He himself would be anxious about entering the room.

Nor would hospital security be able to do it, nor would the radiation safety officer.

We agree, I think you and we agree, that the way this should be handled should such an incident, which is extremely rare, occur in the future, is for a timely notification of the NRC that the problem exists.

Now how would we know that the problem existed? Probably the only way that is practical would be for the nursing directive, the order to be written that someone monitor the room every two hours, let's say, to make sure that the visitor is behind the lead shield. And if the visitor is not on the right side of the lead shield to notify the radiation safety office who would then notify the local NRC office, that would constitute a prompt

notification.

And then the NRC office with the licensee could scratch their heads and try and find out a way of convincing this noncompliant visitor of the merits of not being noncompliant.

Other than that I think there is little that we as human beings, who are concerned for one another both in terms of radiation safety and humanity, could do about a situation such as this.

Now clearly there is an exception. The exception is, if the behavior of the individual puts someone else at risk, someone other than the individual himself or herself, then we have every right and every responsibility in the world to protect others.

This was a sad situation for all individuals concerned – the patient, the daughter, the radiation safety officer, the hospital administrator – for all. And it's been a very time consuming on the part of many skilled people who devoted many hours to this.

I would hope that what we have learned from this is that should such a rare situation occur in the future that it be dealt with with closer monitoring, visual monitoring, and that could be done

from the door of the room, just looking through the door to see if the visitor is compliant. And then prompt notification of the RSO and the NRC.

From there on in it becomes a conjoint issue, and probably would not generate the kind of response that was forthcoming in this case.

And I would hope once again, on behalf of the public, and on behalf of the taxpayer, that this kind of effort would not be necessary in the future for an incident such as this.

And lastly, I think that we sitting here would wish that you would be a little more understanding of the clinical issue involved, and soften the language, as you have shown examples on the slides, but use the softer language.

Because being a clinician and having the responsibility for the patient, and indirectly, the responsibility for the visitor, is very different from being a scientist, and looking at this as an issue of dosimetry and physics.

We very much respect your scientific skill, and would hope you similarly recognize that physicians and individuals taking care of patients have other things to take into consideration as well.

And perhaps with that we could close the

subject for this committee, which has been extraordinarily time consuming on our behalf. And I think we've learned something from it. We've learned many things from it. And we thank you.

MEMBER ESSIG: Dr. Malmud, there is a small part two, which is a fast forward.

CHAIRMAN MALMUD: That's the next 15 minutes, and we've consumed a few minutes of it. But Dr. Sherbini, you're on again.

DR. SHERBINI: This is very short, just two slides. Basically we are working on the caregiver dose limit, which was the first opportunity for discussion.

These are just steps we are pursuing. The first step has been completed with us the regions for input basically. But they are going to be the ones who will implement this policy.

So they are going to tell us what they think the policy should look like. And two of the regions have already done that. We're waiting for the third region to do this.

Once we get these, we are going to develop these thoughts and put them into the form of a RIS. We'll give it back to the regions to review. And once we've taken care of all the comments, we

will put it out for general comment including ACMI members, state licensees and so forth.

And once these comments are resolved, then the RIS can be issued, hopefully by the end of next year. And that should take care of that.

CHAIRMAN MALMUD: Thank you very much.

That was one of the most succinct presentations, and we thank you for that.

MEMBER WILLIAMSON: This is a very factual question. Are there two RISs now?

DR. SHERBINI: Yes.

MEMBER WILLIAMSON: So there is an RIS that in general goes over – it's more focused on this one case and the lessons learned. Then there is this RIS which is actually going to be a load of propagating policy?

DR. SHERBINI: Yes.

MEMBER WILLIAMSON: I think it's very good you've separated them. That I think was one of our recommendations at the telephone meeting we had.

CHAIRMAN MALMUD: Thank you again.

Oh, Dr. Vetter.

MEMBER VETTER: I've got a question which is sort of post-RIS. I assume that this second RIS talks about the – what licensees would need to do is

we saw a visitor in the room and couldn't control them, and we know they are going to go over the limit.

And it would mean calling our region or headquarters to get permission for that visitor to go over the limit, it becomes a license amendment, as I understand it.

And the question I have is, is the NRC prepared to issue that license amendment immediately without sending someone out to confirm what we're seeing? That is a little cloudy in my mind. As a licensee I'm going to call you and say, I've got a visitor in the room. The patient is dying. I cannot control that visitor. He or she wants to be next to their parent or child who is dying, and I know they are going to get five rem. You are going to give me that license?

DR. SHERBINI: Yes.

MEMBER VETTER: Just like that?

DR. SHERBINI: The way it's structured is that everything will be prepositioned, the kind of information that the licensee needs to provide to the region would be given; the kind of information that the region would be expecting would be established; the procedure they have to go through, the form of

the exemption, the kinds of controls that we would expect the licensee to have in place; everything would be known and documented.

MEMBER VETTER: And now what happens when that visitor gets 10 REM?

DR. SHERBINI: Well it's a progressive thing. The approach is that there is no limit.

MEMBER VETTER: Okay, all right.

MEMBER VETTER: As long as we are doing whatever we can, there basically is no limit?

DR. SHERBINI: That's right.

MEMBER NAG: Now maybe a hypothetical question, what if the NRC or the agreements they have imposed say, “No we are not prepared to increase your limit?”

DR. SHERBINI: No, that is the whole purpose of this thing.

CHAIRMAN MALMUD: If I may, the NRC would have been notified, and would be a participant in attempting to help you find a mechanism for reducing the dose to that individual, and would share in the problem.

It's different from letting the NRC know retrospectively that this occurred, and that no attempt that the NRC recognizes as having been

substitute was made, whether or not it was made.

So I think there is a difference. And the contemporaneous notification of the NRC is probably the lesson that we've learned from this.

Mr. Bailey.

MEMBER BAILEY: I have to respond to that. To me this whole issue is form over substance, and I find it very unlikely that an agreement state program, particularly those based in a health department, would be able to do anything to that hospital. When we took it to our lawyers, they would just laugh at us, and I think that that would not be an uncommon finding in most of the agreement states.

You would call up and say, yes, we understand the problem, or if you told us the next day. I mean there is an implication that if this occurs at midnight, you're going to phone NRC and tell them this is occurring.

So again, I think, and I hope, that my colleagues in the agreement states would have an appreciation for the problems that are being confronted by the patient and caregiver and the hospital and the physician and everybody involved in it.

DR. SHERBINI: I think it's important to

point out that what the RIS is going to do is nothing that is not already happening. The whole process of exemption is already in place; it's just going to streamline it. That is all the RIS is trying to do anyway.

MEMBER DIAMOND: Again, excuse me, let's just keep the context straight. As Dr. Malmud said, these are extraordinarily rare events. In fact they should never, ever happen.

But the practice of medicine is outside our purview. However I can tell you if I ever found the physician who gave this ministration to his dying patient, I would speak to that person privately and say, what is wrong with you? Because this makes no medical sense at all.

It is time for this issue to be put at rest, and let's be done with it. It's really not a useful expenditure of your time or our time, because the frequency of the event is so rare.

MEMBER BAILEY: I have to disagree. It's – I would say that once every two to three months we get a case where a patient dies with radioactive material in them. And the family wants to cremate the body. And we end up with cases where essentially they've either got to be buried before sundown, or

they have got to be cremated, and we have to give exemptions. Because if we look at the dose level coming off the urn, or whatever, there are some pretty heavy doses that can come off.

But the patient dying with a radioactive source or pharmaceutical in them is not infrequent.

MEMBER NAG: The other problem that I sometimes face is that when you start the radioactive implant doses, the patient is in fairly good shape. But sometimes during that three, four or five days that the implant is in place, because of medical problems, the patient deteriorates suddenly in the middle.

And that is a problem that you do face, if you do enough implants.

CHAIRMAN MALMUD: If we may, we'll move on with the agenda, to the next item. And it looks as though Dr. Howe is back on. We'll take a short break.

(Whereupon at 4:29 p.m. the proceeding in the above-entitled matter went off the record, to return on the record at 4:40 p.m.)

CHAIRMAN MALMUD: Dr. Howe has been ready, and I think the audio-visuals have caught up with her.

MS. HOWE: They have indeed.

CHAIRMAN MALMUD: Okay, Dr. Howe, you're on.

MS. HOWE: Okay. Recently – well maybe not so recently, about a year ago, we did an inspection at one of our medical licensee facilities. And it is essentially the first time that we have run into a licensee in which they had electronic written directives.

What we are used to seeing is that there are electronic records; there are electronic treatment planning systems; but people print out the directive, and then they sign it, and then they put the piece of paper in the patient's folder.

In this case they said they are electronic, and they are keeping all the patient records electronically, and the written directive is electronic. And they also print a paper copy of the electronic written directive and put that in the folder.

And the issue is, this is kind of the first time. So where are we in our regulations, and what is it we're going to be looking for, and what is it we're going to be accepting?

And if you look in 35-5, it says that you

can maintain records stored in an electronic media if you have the capability of producing a legible, accurate and complete record during the retention period. For a written directive that's three years.

And then other records such as letters drawings, specifications, must include all pertinent information such as stamps, initials and signatures.

So those are our general performance criteria that we will be evaluating different licensees against. And as we bring this issue up to our IT folks, they are looking for very prescriptive things, and we don't have prescriptive regulations. We have general guidelines. And so we will be comparing them against these general guidelines.

And then the licensee also has to maintain adequate safeguards against tampering or loss of records.

So that's our general baseline for keeping electronic documents.

Let's look and see what you have to have in a written directive. It has to be dated and signed by the authorized user, before the administration, and it must include specific information.

When we develop written directives and

put them in the regulations a few years ago, we made it clear that it's not – it doesn't have to be in a prescription. It can be in any kind of document, as long as it has somewhere in it the minimum information we need for a written directive, and the authorized user has dated and signed it.

It doesn't have to be generated by the authorized user; it just has to be dated and signed by the authorized user.

So if we have an electronic written directive, we are going to be looking to see if it has been dated and signed by the authorized user, and if it has the minimum specific information that is required in a written directive.

You can also have an oral directive, provided a written directive is prepared within 48 hours.

You can also have a revision, as long as the revision is dated and signed by an authorized user, and it is before the administration with unseen material, gamma, sterotactic, teletherapy, et cetera.

So when you go to an electronic record of this, if there is a revision to a written directive, then we need to be able to see both the revision and the original electronic record.

And one of the things that we found out is that an electronic written directive has to be audited in the electronic mode.

If you print out a copy of an electronic written directive, it's now a piece of paper. It's no longer in electronic mode, and you can't use that for auditing purposes.

If you are using a treatment planning system, and you print it out and then sign names on it, that's fine. That is now a paper written directive, and it's got a real signature on it.

If you were keeping this totally electronically, you would have some kind of electronic signature process. And we would have to inspect the electronic written directive in the electronic mode.

If you printed that piece of paper out, it would no longer be an electronic written directive.

MEMBER DIAMOND: I'm a little confused. So let's say you were inspecting my office, and I had an electronic medical record. And you were inspecting online, and you wanted to review the electronic written directive, can't – I would assume that in each of these systems there is a methodology

to print out a true copy of the electronic record as it existed at that time that you could go and put it in your folder and take back with you.

In other words, don't these records indicate any annotation to show that a record has been changed? I mean that is the whole purpose of it. If they were changeable, then they would not be true medical records. There would be no way for them to be valid as recordkeeping instruments for medical purposes.

MS. HOWE: I think we have to verify on the electronic system that it was the written directive. And then once we printed it – but you have to be in the electronic system. Otherwise you could have – you could have almost anybody create something that looks very much like what you had, but it wouldn't really be your electronic written directive. That is the guidance we're getting.

MEMBER DIAMOND: Are you talking about a forgery? Is that what you are referring to?

MS. HOWE: Forgery, or generation in some other manner.

MEMBER DIAMOND: Well, I mean the same could be said for a paper record. Of course if someone wanted to make a false copy, the statement

could be true.

So I'm just not really understanding what you are getting at.

MS. HOWE: The issue is that when you are reviewing electronic written directives, you need to review the electronic version of it. So you need to do an electronic audit in order to ensure that it is there in the system.

CHAIRMAN MALMUD: If I may, what you are saying is that in reviewing the electronic record, the reviewer wants to look at the electronic record in the computer if you will, in the same way that the reviewer will want to have seen the original hand signature, not a Xerox copy of it, when reviewing the written record.

Does that help you?

MS. HOWE: Yes.

MEMBER DIAMOND: That's understandable.

CHAIRMAN MALMUD: Then you can print a copy of it if you wish for a hard copy, or you can Xerox a copy of the original handwritten. But you want to see it in its original form.

MS. HOWE: Yes.

CHAIRMAN MALMUD: Is that a fair analogy?

MS. HOWE: Yes, it is.

MEMBER SULEIMAN: So you can look at it on the screen.

MS. HOWE: Yes.

MEMBER SULEIMAN: You have to look at it on the screen is what she is saying. But once you print out a paper copy it doesn't void the electronic version.

MS. HOWE: No, it doesn't void the electronic. It's just that is not the official record that you are looking at.

MEMBER SULEIMAN: Now let me ask a third way to look at this. What if you have a paper copy with a signature, and you want to scan it in and get rid of the paper copy?

MS. HOWE: If you have a paper copy with a signature and you want to scan it in --

MEMBER SULEIMAN: And throw away the papers and have an electronic copy of that, an electronic image of it.

MS. HOWE: I think the electronic image of the paper copy is fine. Because then it is not really an electronic written directive; it's a facsimile of the paper written directive. We do that

in audits all the time.

CHAIRMAN MALMUD: If I may, the reason that that would be valid is that your handwritten sheet which is then read into the computer will be timed by the computer as to when the computer received it.

So if there was a desire on the part of someone who had less than honorable motives to alter the original record, they could not do that beyond the point that it was entered into the computer as the original record.

Dr. Nag?

MEMBER NAG: Do you have any methodology for the electronic signature? For example there are some where the electronic signature, you type in your password, and some where you type in your password and the computer will almost hand sign it as if it were your signature.

Do you have some way of documenting that this was that person's electronic signature?

MS. HOWE: To do that, it's part of our inspection audit process. We're in the process – you know this is the first time we've run into electronic signatures for documents that are generated internally, but NRC has a requirement for you to

keep. So they are not documents that you send to the NRC.

And so we're new in this, and we're feeling our way through as to what we're going to be looking for, and what is going to be acceptable.

And we're coming to the ACMUI in a very, very early part, and one of the things we're going to be looking at is, what is the function of your normal written signature? Your normal written signature actually is a biometric. The way you sign, even if it's a straight line, can be tied back to you.

So we may in some cases have to find out more about the software to see how that signature is generated.

The signature does authentication. It does nonrepudiation, where you can't repudiate you signed the document. And it also – there is a function of data integrity.

And electronic signature we would expect to do many of the same things that you have in a written signature. We expect it to perform the functions of a written signature. We think the individual ought to know that they are signing. We think the document has to be unchangeable; that is kind of a function of an electronic signature.

Now electronic signature is a big umbrella. It is a huge umbrella. There can be many many ways of doing an electronic signature.

One of those is a digital signature. If you are submitting information to the NRC for NRC to review, we have a digital signature system that you have to use. And there is encryption, and there are certificates, and it's a very elaborate system.

That is one form an electronic signature. When we look at the requirements in 35-5, it doesn't say you have to have a digital signature. It just says you have to keep things in a complete and accurate method.

And if you look at 35-40, it says you have to date it and sign it.

So we are not holding people to a digital signature. And what you were describing is kind of part of what --

MEMBER NAG: In most radiation oncology specialties, they have a data verification system, and therefore, that electronic record is part of that. And usually what they will do is, you have the dictation, and then when we put in our password, the dictation becomes official, and you can not change any dictation after you put in your electronic

password.

So those are things that are involved in electronic signatures that I know of.

MS. HOWE: And we looked at related documents to try to understand more about electronic signatures and what was happening. Most of the documents we find have to do with commerce, because commerce is really the big elephant in the middle of the room.

MEMBER NAG: The what?

MS. HOWE: Commerce is the big elephant in the middle of the room. It is how do you transact business electronically. And health care is just one small part of it.

But there seems to be an ASTME standard for electronic authentication of health care information that most of the health care systems seem to be subscribing to, and it seems to be the standard that they are trying to meet.

And that is one that we're looking to for a lot of guidance. We are in an interesting situation. We can't enforce other people's regulations or standards unless we adopt them in rulemaking, and we haven't done rulemaking yet.

But we can look to the ASTM to see the

standard the health care community seems to be adopting, and seeing what its asking of its people. And then try to compare what we see with our performance-based regulations, looking to see what we're requiring in 35-40, what we were requiring for the recordkeeping part, and what in 35-5.

Right now, we're still in a data collection mode, for this particular licensee that we're looking at. We have had information technology people get in touch with the software manufacturer to see what the capabilities of the software, because there may be things that are just transparent to the users but are important for understanding the electronic signature.

And then we're also, one of our inspectors went out to visit this facility after our initial inspection, and got to see more of a real-life demonstration or real-life electronic audit of what they were capable of doing, and how they could safeguard different information.

So we are pulling all that information in, and we are going to be coming up with a determination of whether this particular licensee's electronic signature was an electronic signature, and the way they are keeping their electronic records is

acceptable to us.

But we have not reached a conclusion on that. We're still in a data collection mode.

And I think what we're coming to the ACMUI for is to see your experience in your facilities with electronic recordkeeping, how you are handling electronic signatures and things.

Trip, do you want to say something? The microphone is over there, but right now we're not in rulemaking space.

MR. ROTHCHILD: I'm Trip Rothchild, assistant general counsel at the NRC.

The question that really comes up is when you don't have an electronic signature and you have an electronic system, and you go to your computer, and you have a password, and so you put your password in, your initials whatever it is, and you log in and you then type in your instructions, and then you electronically transmit it to someone, you have no signature on the page at all.

The system has no signature, because there is no requirement that you then make a paper copy of it, and you sign it.

And I guess the real question as I understand that you want to present to the ACMUI is,

is that acceptable to us? Do we have enough certainty that someone didn't give the password, these systems are secure enough to where the nurse didn't get into it, or someone else didn't know your password that wasn't authorized to do so, and could just go in and tamper with the system, or someone goes down the hallway and the computer is sitting there, and someone then starts typing stuff up and sends it, because all we know is that someone had access to that computer, and we have no real signature that says, this was me.

When you go to some of the digital signatures and everything you're talking about, you do have that kind of assurance. And I think the real question the staff is raising is, we get in this electronic world, and more and more people move into that kind of system, is that going to be acceptable to the NRC? Should it be acceptable to the NRC? What are the medical community's standards when you don't really ever have a physical signature that you can go look at, and you're not using digital technology.

MS. HOWE: Not using a digital signature, you are using a broader electronic signature instead of a digital signature.

MEMBER WILLIAMSON: Could you define the difference just as a point of information. What is the difference between an electronic signature, and using the password?

MS. HOWE: Password could be a method of electronic signature, but the – if you go to – if you go to the ASTME standard for health care, then the electronic signature is an act of attaching a signature by electronic means.

After the electronic signature process. It is a sequence of bits associated with the electronic document which binds it to a particular entity.

And supposedly when you add an electronic signature, the information that you are adding the electronic signature to now becomes frozen in time.

MEMBER WILLIAMSON: Okay, so it's the act of freezing it and rendering it uneditable; that's the difference between the password-protected system and the electronic signature of a document.

MS. HOWE: Now there are password systems --

MEMBER WILLIAMSON: That's different than the situation Mr. Rothchild raised, the situation where someone else could happen to know the password,

which I guess is the biometric link between an individual and the electronic signature.

MS. HOWE: And if you go further into the ASTME, you will see user authentication with passwords. Passwords have proven to be a very effective means of providing identity when used properly, and used properly means, the password is not shared with anybody else, and you keep it.

But they have severe limitations in the realm of electronic signatures, because they are not the top level, but they certainly are one of the levels.

CHAIRMAN MALMUD: Dr. Howe, you made the point early in your presentation that the place to look is in commerce. And in fact most banks today encourage their members to use electronic signatures, and to bank over the Internet. And this has proven to be not terribly much more subject to forgery than handwritten signatures.

Our hospital, and I don't propose to be an IT expert, but our hospital is using electronic signatures. About every three months, they require that we change our signature. I'm looking over to Dr. Van Decker, because he is in a different department, and I assume he has the same problem.

So they require us to enter our --

MEMBER VAN DECKER: You mean I can't remember my password when they change it every month?

CHAIRMAN MALMUD: Exactly. That is the problem I'm referring to. They surprise us one day, and it says it rejects our password, and we have to enter a new password.

But the point is that it's very effective. The hand signature is irrelevant, because in order for me to enter a facsimile of my signature, I'd have to type in an electronic signature to generate the hand signature.

It's an irrelevancy. It's no longer important on a document if it says electronically signed.

So that is the method we're using for signing our reports. We have not gotten far enough long in that transition for me to electronically sign my orders, so when I order a dose of I-131 for a hyperthyroidism it's a hand signature. In fact it's three signatures, and one set of initials, all for the same dose.

MS. HOWE: And that's typical of what we're finding. We're finding that facilities have electronic patient records, but they haven't

necessarily gone to electronic written directives.

CHAIRMAN MALMUD: At our institution we haven't because we have not been budgeted to go that far yet. But that will be on the horizon.

And with respect to leaving the computer open, the signature on an order has to be an individual order. So if I were to write an order for Patient X, I sign it then.

The computer is still on. It's still on my page. But another order cannot be written without my signing it. My signing it means I have to enter my password. So I'll enter MalmudLS which was my identification, then I'll put in my password, let's say my password is magic – it isn't, but let's say that it is.

So they'd have to – and then every three months to have to change it, to magic1, magic 2, or tragic, or whatever I can remember.

MS. HOWE: Well, the session that we looked, the physician initially enters their log in and their password, and then there are certain screens that just the physician has access to. And so he gets access to that screen, he inputs his information, and then he has an A or an E button to push.

CHAIRMAN MALMUD: Exactly.

MS. HOWE: And he either accepts or he edits.

CHAIRMAN MALMUD: In the example that Mr. Rothchild cited, if I were to enter my computer to do a report, I'd have to enter my name and then my password. I know have access to the screen that allows me to dictate or type in my report.

But the report can't go out until it's signed, so the password has to be reentered as the electronic signature.

So if I left it open and unsigned, no one else could sign it for me unless they knew my password.

MS. HOWE: In the facility we're looking at, you do not reenter your password.

CHAIRMAN MALMUD: That could be troublesome.

MS. HOWE: You just push an A or an E.

CHAIRMAN MALMUD: That can be troublesome, because that leaves the opportunity that Mr. Rothchild alluded to of my having been called out to an emergency, leaving my screen on with orders partially written, and someone else could complete the order for me, or complete the dictation and it

would not be a valid document.

So we do require that the signature be reentered for each entry.

Now if I am dictating a series of 20 cases, I can dictate all 20, sign none of them until the very end. Then it will show me a list and I can sign them all at one time. I don't have to sign each one individually. But no one else can sign them; only I can sign them with my password.

Now I don't know that that is the best system in the world, but it works very well at our institution, and it has worked very well for us.

MS. HOWE: And I think it's easier for us to accept the second password entry as kind of, you understand you have to take another step that includes your specific password and ID, but that we have to look at the other ones too. And we don't know exactly where this line is, and that's one of our difficulties right now.

So we're in the beginning of it. I was out on a site visit at a very big facility. And I thought, okay, while we're at this sophisticated high therapy device thing, I'll ask about their electronic written directives. And I said, do you have electronic written directives? No.

It's not broken yet, so we're not going there.

And what they do is, they use the treatment planning system to develop a written directive, and then they sign and date it, and it's a paper written directive.

So I didn't get a chance to see one at the facilities.

Anybody else have experience?

CHAIRMAN MALMUD: Dr. Vetter.

MEMBER VETTER: We are using, we are generating written directives electronically, but as Dr. Malamud mentioned, it does require the physician to go back in and reenter the password as a signature.

And we've had a couple of times when that was missed, and the technologist said, it's not a completed written directive, and called the physician. The physician had to go back in, reopen it up, and sign it.

MS. HOWE: So both of you are using password entry twice.

MEMBER VETTER: Password entry twice.

CHAIRMAN MALMUD: And the other element of this is, with a computer at home, and the ability

to access the computer at the hospital from home, if we did forget to sign it, we could even sign it – we can review it at home and sign it at home, in the example you cite.

MEMBER VETTER: I just wanted to mention one other thing, the reason we caught – we were aware of this is because the computer system keeps track of when the written directive was written, and when the signatures were placed.

So we caught the fact that the signature was a different time than the written directive. So we asked why are they different? We wanted to ask that before the NRC inspector saw it.

MEMBER NAG: Also it allows any authorized user to sign using his or her name. So let's say with my patient, for whatever reason, we wouldn't do it, so we can call up and tell them, and they can enter the system using their password, using their name, the signature will come under that authorized user's name. So that also is possible.

But you will be able to keep track of who exactly signed it.

MS. HOWE: Right.

MEMBER VAN DECKER: I was just going to make a comment. I don't envy you your task right now

of trying to delve into this from a smaller piece of it.

Obviously looking at the large global health care electronic medical record issue, there are lots of different ways things are being done. There are arguments for going to proprietary mechanisms versus nonproprietary electronic records, and cost issues and a variety of other things that go on.

So I think you are going to see a variety of electronic options out there, and trying to decide what may be useful for your issues as opposed to general health care is obviously not going to be an easy line to put in the sand. Because as usual, I would probably suggest that if you look at all the different models out there, looking at the physician order entry systems for the hospitals, where physicians are doing physician order entry, that whatever mechanisms they have in place would be the same type of mechanism you want for a written directive, which I suspect is, you want an identifiable order, separated from all other kinds of medical information with an attached identifier timed and can't be changed without an annotation modifier put to it at the same time.

And I think that is kind of what you want to be looking at. Most of those are double password protected.

MEMBER LEITO: Is the NRC looking just at electronic signatures for written directives? Or also electronic records for other nonwritten directive purposes? In other words, there are a lot of records, QC records, survey records, things like that, that require names of individuals that are – you can buy commercial packages that has – provides the NRC record of compliance.

MS. HOWE: There are other documents that require signatures. A fair number of our documents now only require initials of who did the check. An initial in this case, it doesn't quite carry the weight of a signature.

MEMBER LEITO: Well, you are kind of alluding to my next questions, because Part 35 says that the records have the name of the individual performing it. But a lot of the commercial packages, like Rio (phonetic) pharmacy packages and so forth, they only allow initials.

So there has been a question amongst a lot of RSO types that the fact that you can only by the fact of the software itself, only put I think a

three-letter initial in there, does that still meet the recordkeeping requirements of the name of the individual?

And we've gone back to these commercial vendors, and they aren't going to change it, because they say they have to go back to the FDA – no offense, Orhan – go back to the FDA to make these changes in their software.

So we're kind of in this quandary where one way we've done it, and we haven't been challenged on it, but we don't necessarily wave it in front of the inspectors, is the fact that we have this sort of cheat sheet where we have – each person has a unique mnemonic that belongs to them, has their signature, and so any record or signature is identified by this, you know, this shall I say this standard if you will that can be referenced.

But it still doesn't meet the literal part of the record in terms of the name of the individual.

MS. HOWE: I think in the past we have accepted a system that is similar to what you describe. There is a difference between naming who did it, putting initials of who did it, and having to have something signed and dated.

So right now we think the written directive is probably our most important document where you really have to – and it has to be a specific person that signs and dates it and it has to be signed and dated before the administration.

So that's why we're looking at this one very closely right now. But we have accepted I think in the past a cheat sheet that says, DBH is Donna-Beth Howe, and you can't have anybody else use those initials.

Sandy, is that your experience as an inspector? And Sandy is nodding yes, that is her experience as an inspector.

CHAIRMAN MALMUD: Does that complete the presentation, Dr. Howe?

MS. HOWE: He seems to have a question. Oh.

Yes, that completes my presentation.

CHAIRMAN MALMUD: Thank you very much. It's 10 after 5:00. We agreed to adjourn at 5:00. We're only 10 minutes late.

Is there a motion for adjournment of today's session?

MALE VOICE: So move.

CHAIRMAN MALMUD: Second?

MALE VOICE: Second.

CHAIRMAN MALMUD: All in favor? It's unanimous, thank you.

(Whereupon at 5:12 p.m. the proceeding in the above-entitled matter was adjourned)