Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Medical Rulemaking Workshop

Docket Number: (n/a)

Location: Houston, Texas

Date: Friday, August 12, 2011

Work Order No.: NRC-1054 Pages 1-192

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NUCLEAR REGULATORY COMMISSION

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MEDICAL RULEMAKING WORKSHOP

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FRIDAY

AUGUST 12, 2011

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HOUSTON, TEXAS

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The Workshop convened at the Marriott Houston, 6580 Fannin Street, Houston, Texas, at 8:30 a.m., Susan Salter, Facilitator, presiding.

PANEL PARTICIPANTS:

SUE LANGHORST, Ph.D., Washington University in St. Louis

RALPH LIETO, M.S.E, American Association of Physicists in Medicine

EDWARD LOHR, US Nuclear Regulatory Commission

HOMER MACAPINLAC, M.D., American College of Radiology

DAVID WALTER, Organization of Agreement States

RONALD ZELAC, Ph.D., US Nuclear Regulatory Commission

NRC STAFF PRESENT:

SUSAN SALTER, Facilitator

MICHAEL FULLER

MICHAEL WEBER

GRETCHEN RIVERA-CAPELLA

A G E N D A

P R O C E E D I N G S

(8:30 a.m.)

MS. SALTER: Okay, welcome. Welcome back for some of you, welcome for the first time to others. I'm curious to know, I think we still have some people outside, but I'm curious to know how many people here were not here yesterday, just from a raise of -- raise your hand if you were not here yesterday. Okay. So pretty much, we have a very similar audience than we had yesterday, which is good because you're familiar with the process.

But just before we get started, I want to remind everyone to please put your electronic devices on silent mode. And, again, if you need to take a call we certainly understand that. We just ask that you leave the ballroom and go out to the reception area.

Today's process is very similar. This morning we're going to have panel presentations, panel dialogue, and then we'll open it up to audience participation, including folks on the webinar. I would just remind you that if you want to speak, please fill out a blue card and just keep it with you. And then when we get to the audience participation point you can hold up your blue card if you want to speak, and I'll collect that from you and bring you the mic.

Again, you don't have to put what your comment is unless you don't want to read your comment, and you'd like me to read it.

Folks on the webinar, we ask that you type your question in and throughout the day we will be touching base with Gretchen Rivera-Capella, our webinar moderator, and she will read the questions for us. Please remember to put your affiliation when you type your question into the webinar.

So, to get us started this morning I'm going to turn the meeting over to Mike Fuller. And Mike is the lead for the Medical Radiation Safety Team in NRC's Office of Federal and State Materials and Environmental Management Programs.

MR. FULLER: Thank you, Susan. Can everybody hear me? Okay.

As I and others have stated, this workshop is a very good opportunity for NRC Staff to hear what our stakeholders believe are important issues that we should consider as we begin to amend our medical regulations. We, the NRC Staff, feel it's important to share with you what we believe were the key messages we received yesterday.

Now, we provided you with the key messages that we received while we were in New York, so I won't

take the time to go over this morning all of those things. But rather, I'd like to take this time to share with you some of the things that we heard yesterday that were different from what we heard in New York, and some things that were in addition to what we heard in New York. Now, there's no particular order. I'm just going to kind of go through what we heard, what we felt were the key messages.

First of all, we heard that none of the states that responded to the OAS questionnaire, and I think David told us there 14 states that responded to that questionnaire, but none of them advocated for a medical event definition that is based on total source strength or activity.

Secondly, we heard in New York that for unintended tissues and organs an absorbed dose criteria for defining a medical event is appropriate. Now, contrary to that yesterday we heard from some of those representing the medical community that the dose to unintended sites should not be under the purview of the regulators, and that the related section in 10 CFR 35.3045 should be eliminated.

We also heard from several stakeholders that for prostate implants, in particular, absorbed dose is very difficult to quantify in a subjective

value.

Now, we heard from one of our panelists that there are two things that we should consider when developing a definition for medical event based upon source strength, or total source strength. The first thing that we should consider is the percentage of seeds that are implanted outside the treatment site. And the second thing to consider is the distance that a seed or some seeds are implanted away from the intended treatment site.

Now, I will note that there was quite a bit of discussion on this point, and consensus was not reached on this amongst our panelists.

We also heard that the D90 value poorly predicts clinical outcomes, it lacks precision, and should not be used for regulatory purposes, not even for under-doses.

Another key message that we heard yesterday was that the whole patient-doctor relationship is changing. Our patient's rights advocate panelists explained that many patients these days view themselves as medical service consumers. And that fact implies more and more individuals wish to share in the decision making process when it comes to their medical care. Therefore, more information and

not less information should be shared.

I also want to take this opportunity to clear up any confusion that may exist about what the current rules allow for and don't allow for regarding who must implant radioactive sources or seeds. The current NRC rules do allow individuals working under the supervision of an authorized user to handle and implant such sources.

Now, if you feel that there are other messages that were provided to us yesterday that are in addition or different from what we heard in New York, and different from what I just went over, please feel free to approach me on a break, tell me what you think. I'll try to take good notes.

Also, I want to let everyone know my email address if you want to send me an email with any other points that we should consider, or things that perhaps I didn't capture the way you think maybe I should have. My email address is michael.fuller@NRC.gov. That's Michael, M-I-C-H-A-E-L.fuller, F-U-L-L-E-R@NRC.gov.

Now, before I turn the mic back over to Susan, I want to remind everyone that our last session today will be an opportunity for you to provide us with your comments, suggestions, recommendations

related to the other 20 or so items that were published in the Federal Register Notice. Now, that Federal Register Notice, for those of you on the webinar -- the Federal Register Notice is in your packets if you're here in person. But the Federal Register Notice is 75 FR 29171. So, the last thing we're going to do today, it's Topic 5, and it's titled "Additional Items Under Consideration for Rulemaking."

Now, we're not going to have any formal presentations by NRC Staff on this issue. This is an opportunity for you to provide us with your comments, suggestions, and so forth related to those items that are published in that Federal Register Notice. These are things that are already part of what we've been referring to as the expanded Part 35 rulemaking.

Also, we have the Part 35 preliminary draft proposed rule language. It's dated May 16th. That's the document that's on the table outside. It's also referenced in that -- for those of you on the webinar, it's also referenced on the last page of the FRN. And it is the -- it can be found at www.regulations.gov, and you can search on the docket number. The docket ID number is NRC-2008-0175.

So, again, at about -- let me get my

agenda here. I've got it right here, yes. At 2:45 we're scheduled to begin Topic 5, and that's the point in time when we will just simply open it up for folks to provide us with their comments and recommendations on those things that were published in the FRN, and also in the proposed -- I mean, in the preliminary draft rule language.

All right. So, again, I want to thank you for your comments and suggestions yesterday, and we are looking forward to another day, another very productive day for us here at the workshop. So with that, Susan, I'll turn it back over to you.

MS. SALTER: Okay. Since almost everybody was here yesterday you're kind of familiar with our format. We're going to open it up with some presentations from our panelists. Then we're going right into the panel discussion. And, again, that is an opportunity for the panelists to have an open dialogue on any topics related to this particular Topic 2. You can take that discussion in any direction they would like. And immediately following that we're going to go right in and allow the audience to jump in on that discussion, including folks on the webinar.

And we are planning to wrap all that up

about 10:30, and then we will have a break, come back at 11, and move on to our next topic, Topic 3. And there won't be a panel for that, so the rest of the afternoon after this part of the program will strictly be brief presentations by NRC Staff, and then open dialogue with the audience. So, that's kind of our agenda for the day.

So, to get us started with Topic 2, I'm going to ask Ed Lohr to come up and make his presentation. Ed is Health Physicist in the Division of Intergovernmental Liaison and Rulemaking in the NRC's Office of Federal and State Materials and Environmental Programs.

Mr. Lohr has worked in the Radiation Protection field for over 30 years, including 20 years in the Army Medical Department where he served as the supervisor of the Kentucky State Radiation Control program, the Kentucky State Radon Coordinator, and the Operation Officer for the Conference of Radiation Control Program Directors.

He is a registered Radiation Protection Technologist and holds a Bachelor's of Applied Science as well as a Master in Public Administration. And we welcome Ed.

MR. LOHR: Thank you, Susan. Good morning,

all. I'm going to tee up the subject matter this morning, and as Mike has said many times, as NRC Staff, I'm going to sit back and listen, as well.

I'll start out with the acronyms that you will see in my presentation. You've probably seen most of them yesterday, but there's a few new ones, such as PRM, Petition for Rulemaking, and probably, I don't know if SECY was defined for you yesterday. It's the Office of the Secretary of the NRC.

For everybody in this room, you're probably aware that Part 35 has been revised on many, many occasions; the last major modification occurring in 2002. Training and experience was one of the main components of the 2002 rulemaking, and final points of the T&E were clarified in the 2005 rulemaking that followed.

One of the items or the requirements that was included as part of the rulemaking in 2002 was the requirement for an attestation, or in 2002 we called it certification of an individual to be authorized on a medical license. Prior to the 2002 rulemaking only nuclear pharmacists were required to have this certification or attestation.

The regulations have two formal -- well, actually three pathways, although we only have two

listed here for individuals to become authorized on a medical license. One is by presenting a certification given by a board whose processes have been recognized by the NRC or an Agreement State. We refer to this many times as a certification pathway. They present their documentation that shows the individual has met the specific training and experience requirements, and through the alternate pathway for those people who are not board certified.

The alternate pathway has required an attestation, or again certification as we called it prior to 2005, since the 2002 rulemaking. Prior to the 2005 we'll call it a tweak to T&E, a candidate for certification had to obtain a preceptor attestation as part of their process, the board process. The 2005 rulemaking changed that and put the onus on the individual to get the attestation.

And, of course, the third pathway that is very commonly used is if an individual is already listed on a license, an NRC license or an Agreement State license, they can be recognized on an additional license, for example when they move to a new job.

During a meeting that was held in 2008 with the Commission, ACMUI, the Advisory Group to the NRC on medical issues, provided the following

recommendations to the Commission. And the first recommendation was that the NRC should eliminate the attestation requirement for board certified individuals seeking authorization status via what we call the certification pathway.

The rationale that the ACMUI provided to the Commission was that the boards have agreed to meet the new NRC requirements in the 2002 and 2005 rulemakings, and that the certification process reviewed and recognized by the NRC at this stage of the game in 2008. And that having an attestation in addition to the board certification was redundant, basically.

The second point that they brought to the Commission, or recommendation, was for the alternative pathway, that the attestation standard should be both measurable and achievable. And that they did not -- and wanted to see change to how the NRC defined competency. So, that will be, hopefully, part of our discussion this morning, is some ideas on what we can work with that.

But do note that the NRC's intent for requiring competency statement from preceptor was never to address the applicant's competency to practice medicine, but instead to indicate that the

applicant successfully completed the required training and experience, and was capable of independently fulfilling the radiation safety responsibilities.

The third and final recommendation was that the NRC should accept attestation from residency program directors, even if that individual was not an authorized user.

Based on these recommendations from ACMUI, the Staff sent a paper in November of 2008 to the Commission recommending adopting the ACMUI recommendations. And in January of 2009, the Staff -- or the Commission approved the Staff recommendations in an SRM to the Staff. So, that's the background on attestation.

The next topic I want to key up is what we refer to, and you'll see referred to in many places as the Ritenour Petition. In September of 2006, the NRC received a petition for rulemaking from the American Association of Physicists in Medicine, AAPM, signed by Dr. E. Russell Ritenour; and, thus, we always refer to it as the Ritenour Petition. Generally, the last name of the petitioner is what we assign to that.

The petition explained that Part 35 offered the three pathways, two of which I've already covered, the certification pathway and the alternate

pathway. It goes on to talk about there are actually three pathways. And, of course, I've talked about that one, as well, if you're already on a license.

The petition asked that the NRC consider grandfathering additional individuals. And that is for individuals who are certified by a specialty board recognized by the NRC through the certification pathway would be recognized, of course, for RSOs. But they have a number of certified individuals who in the 2005 rulemaking were not named on a license, Agreement State or NRC, and, therefore, were not grandfathered, the term that the petitioner used, in the regulations to be an RSO.

And because of that, if they had held a board certification, they now had to have an attestation. Prior to the 2005 final rulemaking there was not an attestation requirement. The board certified individual could either come in under the new provisions, or use what we call Subpart J provisions.

So, the petition under the certification alternate pathways, an individual seeking authorization for byproduct material had to now have an attestation signed by a preceptor. And the attestation had to state about competency and those

sort of things. And, again, as I mentioned earlier, prior to 2002 the only one who had to have that was the nuclear pharmacist.

The specific concerns, though, raised by the petitioner was that there was a group of board certified professionals that were inadvertently affected by the rulemaking. Most of these were board certified individuals who worked as medical physicists in radiation safety positions when the rule effected, when the rule went into effect that were not named on NRC or Agreement State licenses. Therefore, they were not grandfathered.

They also pointed out, if you will, that these individuals now had to apply under the alternative pathway. It's not that they were not allowed to practice, and they were not allowed to be an authorized user, but the board certification process, in other words, if they had a certificate, was no longer accepted by the NRC.

There were several issues that the petition asserted. I'll summarize them very quickly; and that is that the medical physicist demonstrated competency to practice medicine through their certifications. There was no evidence to support that the rulemaking assertion that the T&E requirements

prior to 2005 were any greater safety significance with them. As a result of the present rule, the individuals with certified dates prior to the effective date of 2005 were now having to use the alternate pathway and creating a burden to them. And that a number of the authorized medical physicists and RSOs available to provide preceptors were actually in short supply.

The petitioner specifically requested two items, and I want to really zoom in on these two items. First, they requested that the NRC amend 10 CFR 35.57, what we call the grandfathering clause, to recognize medical physicists certified by ABR or the ABMP, I can say these, on or before October of 2005 as grandfathered for the modalities they practiced. This change should be independent of whether or not the medical physicist is named on license, NRC or Agreement State, at that time.

The second thing they asked for in the petition was that to, again, amend 10 CFR 35.57 to recognize all diplomats that were certified by the named boards in the old Subpart J for RSO who had the relevant time work experience, even if they, again, were not named on a license.

The NRC resolved this petition and

published in the Federal Register in May of 2008, and from the Federal Register Notice it said, "In its review and resolution of the petition, the NRC concluded that the revisions made to the regulations in 2005 may have inadvertently affected a group of board certified professionals."

The FRN went on to state that, "The issues raised in the petition will be considered in the rulemaking process." The NRC is now in this rulemaking process and considering this petition.

I want to touch on how the NRC resolved the petition because this is a very important point. In resolving the first request to recognize medical physicists certified by the ABR or the ABMP on or before 2005, the NRC resolved the petition by concluding that if appropriate preceptor attestation would be needed in addition to the individual's board certification. And I'll go into that rationale here in just a second.

The second part of the request that the petitioner asked for, to recognize all diplomats that were certified by the named boards in Subpart J, was resolved by accepting the petitioner's statement that, "The diplomats need to be grandfathered as RSOs by virtue of the certification providing the appropriate

preceptor attestation is submitted." And that's from the petitioner's request.

And what's important is the rationale that the NRC used for resolving this petition. The NRC looked at the rationale that was put in the Federal Register for why we grandfathered originally in 2002. In doing that, the credentials of the people who were grandfathered, the NRC concluded their credentials had been reviewed, and they had functioned as to establish an acceptable record of performance.

In resolving the petition, the NRC took those two same principles and applied them; and that is that the board certification could be accepted as a review of the individual's credentials, and the appropriate preceptor attestation could serve as a verification for establishing an acceptable record of performance.

Additionally, although the petition did not specifically mention other professionals who may have been adversely and inequitably affected by the revisions, the NRC intends to consider them in this proposed rulemaking.

However, as I stated earlier, the NRC is also considering eliminating the attestation requirement for all board certified individuals

seeking authorization status via the certification pathway. And this appears to be in conflict with the basis for resolving the Ritenour Petition.

And that's all I have for teeing this up, I believe. Back to you, Susan.

MS. SALTER: Thank you, Mr. Lohr. As Mike goes up and pulls our next presenter's presentation, I want to introduce David Walter.

Mr. Walter was a panelist for us yesterday. I want to remind everyone that you do have detailed bios in your packets, and there are copies of the presentation out front. But Mr. Walter is currently the Chair of the Organization of Agreement States. And he is currently the Assistant Director of the Alabama Office of Radiation Control, and the Director of the Radioactive Material Licensing Branch for that office. And I will turn it over to Mr. Walter. Thank you.

MR. WALTER: Thank you, Susan. Yesterday I was here representing the OAS. Today I'm not here for the OAS, I'm here as representing one of the Agreement States. But I will say that everything that I'm going to say has gone through the OAS, has been through the Board. It's nothing new, it's just that I didn't get the official go forth and talk for us statements.

So, let's start off under the current system that we have. We could support the removal of an attestation for individuals using the board certification route as long as the NRC regularly reviews the board certification process to assure an adequate knowledge of radiation safety is required to sit for the boards.

When using the classroom, and laboratory, and supervised experience option, attestation should be kept. Now, one of the questions that's come up has been whether or not a residency program director could sign as the attestor. And it was always the intent, having been a member of the original working group for Part 35, it was always the intent that -- to allow the residency program director to attest, as long as they have verification from the actual supervising individuals. And that verification or documentation should be a part of the residency program process.

We can also support the grandfathering of board certified individuals when certification occurred before the rule went into effect. In fact, one of the things that I tried to do was to make sure that information went out to all of the regulators to remind them that all of the people who aren't currently listed on a license, in particular the

physicists, need to be notified that if they don't get put on that license before that rule goes into effect, they're out in the cold. And we were lucky, and we were able to get all of them in Alabama on the licenses before we made -- went into effect with our new rule. But that doesn't help the people that were coming in from outside of our state, because they're not listed on a license. So, it makes it difficult for us, as well.

So, we can support that grandfathering when certification occurred before the rule went into effect, because we believe this would reduce the shortages of authorized medical physicists.

Now, the next subject I want to talk to you about is an alternative method that I, in fact, brought up in the `97-`98 time frame during the original rewrite of Part 35, but because of the short time constraints that we were under at that time, it was discounted as it's going to take too long to do it, and it may be too costly. Here we are 14 years later still talking about it, and what we're going to do.

I also brought this up as a member of the OAS Board during a Commission meeting in the fall, and I think we already have precedent set for this, so

it's something that we need to seriously consider. And that would be to set up a National Radiation Safety Examination Program.

Since the precedent has already been set in industrial radiography where they must successfully complete a nationally recognized exam before they're authorized to use licensed material, such a system could also be created for medical users, physicists, and RSOs.

For authorized users there could be say three examinations from which combination exams could be prepared. The RSO exam could be separate, but more likely appropriate questions could be included in all of the authorized user and authorized medical physicist examinations to allow successful completion of those exams to also suffice to be an RSO.

Approval by passing the exam would be for a predetermined period of time after which the individual would need to retake the exam. And why? Because that would assure that they've been keeping up-to-date with all the changes in rules and requirements.

There are some advantages to doing something like this. It could do away with classroom and laboratory training hour requirements, and

minimize required documentation. Preceptoring, not attestations, would also be minimized and would only be required for the more risky therapy operations, just as we have now where you have three supervised cases in each of the various types of therapies.

Now, there are some disadvantages, but they're more or less time consuming. It would take time to develop a valid pool of questions and getting the proctors and locations necessary to offer the exams in enough places and times across the country. And we would need to refine the delivery of exam, grading, and dissemination of the results system. But we've already done these on a smaller scale with industrial radiography. And I don't see why we couldn't do that now.

I believe that something like this could be completed up and running in less than three and a half to four years. We've already been constantly tweaking the current system for nine years, and every time there's a tweak it costs the states millions of dollars to keep up with the compatibility requirements. So, there's also a lot of expense that's been involved in this, as well.

So, that's where I'd like to leave with you guys, and thank you for listening.

MS. SALTER: Thank you, Mr. Walter. Our next speaker is Dr. Susan Langhorst. And Dr. Langhorst is currently the Radiation Safety Officer at Washington University in St. Louis, and is a faculty member at the Mallinckrodt Institute of Radiology.

Dr. Langhorst is also currently serving as the Radiation Safety Officer representative on the NRC's Advisory Committee on Medical Uses of Isotopes. She received her BS in Nuclear Engineering from the University of Missouri-Rolla, and her Master's and Ph.D. in Nuclear Engineering Health Physics from the University of Missouri-Columbia.

Dr. Langhorst is certified by the American Board of Health Physics, and is a council member of the National Council on Radiation Protection and Measurements. Welcome, Dr. Langhorst.

DR. LANGHORST: Thank you very much. Good morning.

I appreciate the opportunity to serve on this panel and provide you with perspectives on these issues from the NRC's Advisory Committee on the Medical Use of Isotopes, also known as the ACMUI.

The NRC Staff asked the ACMUI to first review the Ritenour Petition at its June 2007 meeting. The Committee's discussions on issues raised continued

in its August 2007 teleconference. Since these first discussions, the NRC Staff has continued to brief ACMUI on the status of the Ritenour Petition, and at its April 2011 meeting, the Committee again discussed and voiced its opinions on the specific issues surrounding these topics.

In regard to the attestation requirement, ACMUI recommended in 2007 and continues to recommend that this requirement be removed for board certified individuals. In the Committee's 2007 discussions, Committee members carefully deliberated the topic of grandfathering to ensure that the recommendations did not inadvertently exclude board certification individuals, or board certified, excuse me, individuals from recognized boards. And so decided on this statement here to grandfather all board certified individuals of the currently recognized boards, and for many recognized boards listed in Subpart J of the previous edition of Part 35.

The NRC -- excuse me, the ACMUI reconfirmed its recommendation in April 2011 that the written attestation be eliminated for board certification pathway regardless of the date of the individual's certification.

The ACMUI agrees that the attestation

requirement be retained for the alternate pathway. In 2007, the Committee strongly recommended that the attestation should not include the word "competency," because of concerns that this word implies medical competency, and strays into the area of medical practice. And because it could be used to potentially hold the preceptor liable for future acts of this authorized individual. Instead, the Committee recommended that the attestation should read, "Has met the training and experience requirements."

In 2011, the ACMUI again discussed wording for the alternate pathway attestation statement, and revised its recommendation to say, "Has received the requisite training and experience in order to fulfill the radiation safety duties required by the licensee." This revision was made again to clarify that training and experience requirements for Part 35 refer to the radiation safety aspects of medical use of radioactive materials, and not to the individual's medical training and practice.

Also in 2011, the ACMUI voiced its support that residency program directors can sign the attestation documents even if they're not themselves an authorized user, or an authorized individual, as long as at least one faculty member is an AU in the

given authorization status category, and there's no objection from that authorized user.

Again, I want to thank you for allowing me this opportunity to share these topics.

MS. SALTER: Thank you, Dr. Langhorst.

Our next speaker is Ralph Lieto. And Mr. Lieto is currently a Medical Physicist and Radiation Safety Officer for the St. Joseph Mercy Health System in Ann Arbor, Michigan. He received his Bachelor and Master of Science in Nuclear Engineering from the University of Michigan, and then completed a radiological physics residency at Henry Ford Hospital in Detroit.

He has over 30 years of nuclear medical physics experience and radiation safety experience as a radiation safety officer for a large community hospital, medical center, and broad scope medical programs. Welcome, Mr. Lieto.

MR. LIETO: Thank you. I'd like to thank the NRC for the invitation to participate in this panel discussion on these topics, and also to represent the American Association of Physicists in Medicine.

First off, regarding preceptor attestation discussion, the AAPM has always been a strong

proponent of eliminating the attestation requirements for board certified individuals. It has opposed this ever since it was proposed when the rulemaking was first established in 2002, and has been very consistent in this along with other members of the medical user community.

The AAPM would like to see NRC eliminate the attestation requirement for individuals seeking the authorized status via the board certification pathway, as well as all those boards whose processes have been recognized by the NRC or Agreement States and individuals grandfathered under 10 CFR 35.57.

The AAPM feels that the requirement for attestation, especially for board certified individuals is redundant. It turned out to be, essentially, a unnecessary paperwork burden, and has not demonstrated any observable health or safety benefits since it was implemented.

Regarding some questions that were posed in the Federal Register, we have some specific responses to those questions. For the alternate pathway should the NRC amend the language and remove the terminology, "has achieved a level of competency to function independently," with some other language. There were two suggestions in the Federal Register

that were proposed. The AAPM feels the phraseology for alternate language should be "has received the requisite training and experience in order to fulfill the radiation safety duties required by the licensee." And would support that change in the attestation documents.

A question, should residency program directors and/or medical institution administrators be allowed to provide the attestation -- fulfill the attestation requirements for individuals submitting via the alternate pathway? For those that are submitting this residency program directors, as well as authorized individuals who have been authorized for the same uses should be allowed to provide this attestation requirement.

The administrator individual "might be familiar with the applicant," but that could be someone who is quite removed and is most likely not going to be familiar with the requisite skills that the individual has, as well as monitoring that individual on a routine basis in their program, which the program directors are required to do.

We would like to -- AAPM would like to make one additional comment regarding the attestation discussion. We would support residency program

directors attesting for applicants via the alternate pathway, but it's important to recognize that the applicant may not be just an authorized user, i.e., physician. It may also be someone who is applying via -- as an authorized medical physicist. There are an increasing number of medical residency -- physics residency programs that are occurring, so also for AMPs as well as RSOs. So, the -- and also to point out that the director, regardless of the applicant type, AU, AMP, RSO, may not be authorized for the same uses. So, we still support the program directors, but it's important that the NRC recognize that, and not hamper that route for preceptor attestation.

Regarding the Ritenour Petition, I think Mr. Lohr provided an excellent background. A couple of points that we would like to add, is that during the comment period there were 166 comments that we received. The overwhelming majority supported the petition being granted at that time.

A year and a half later, as was pointed out, the NRC stated that it will attempt to develop a technical basis to support the rulemaking. The AAPM feels that until the proposed rulemaking is out there, this petition is still unresolved and in limbo.

There are two groups of individuals, as

Mr. Lohr pointed out, that this petition, the AAPM petition addresses, that's recognizing medical physicists who are certified by the American Board of Radiology, or the American Board of Medical Physics prior to this October 25th deadline -- excuse me, October 24th, 2005 deadline. And, also, that it address recognizing all diplomats who were board certified in those boards that were recognized up until October 2005 in Subpart J.

I think it's important to emphasize the issues that were created by this effective date of the rules; basically, that before anyone board certified before that date who had not already been listed on a license as an RSO or an AMP had to go and submit via the alternate pathway. So, from our perspective it impacts medical physicists for both radiation safety officers and authorized medical physicists.

Now, the authorized medical physicists or AMP issue is compounded because this did not exist before 2005. So, these were not listed on licenses prior to that date.

Now, there was the old terminology of teletherapy physicists that was used on the licenses, but not all states, and I think hopefully Mr. Walter will correct me, but in a lot of Agreement States they

did not list medical physicists that performed those functions on their licenses. So, there -- as he pointed out, some states started to rectify that before 2005, but there were a lot that didn't.

So, should AMPs and RSOs grandfathered before the petition -- only AMPs and RSOs be grandfathered before the petition request. This was one of the question in the Federal Register. No, the AAPM can't speak for other professional organizations, such as those representing authorized users and authorized nuclear pharmacists, but we would most strongly support those being recognized regardless of the year of certification who have been adversely affected by this regulation.

Another question in the Federal Register for this workshop is, should the NRC recognize all individuals certified by boards that had been listed in the regulations, and who had not been named on a license prior to 2005?

We most definitely support this. It's forced these individuals to seek approval via the alternate pathway simply because they were not named on a license, or the date of their certification. Neither of these issues have been shown to be any health or safety issue.

If the NRC adopts the ACMUI recommendations to remove attestation requirements for board certified individuals, does this resolve the grandfathering under the Ritenour AAPM petition? These are two separate issues.

The petition, the AAPM petition addresses the date of board certification and the date that that certification was received. The preceptor attestation, even if it goes away, does not resolve this issue. Okay? So, these are -- we want to emphasize that these are -- very importantly, that these are two separate issues to be resolved.

Should the NRC require preceptor attestations for grandfathering all individuals, no individuals under the grandfathering, or only RSOs per the petition? We strongly support that no preceptor attestation should be required for any grandfathering. It's critical for the NRC to remedy this situation for qualified individuals, medical physicists, RSOs, authorized users have not been recognized because of the year of their certification.

Should the NRC require some other means other than attestation to establish an acceptable record of performance? We're opposed to any added methods or documentation. There really has not been

anything that's come out ever since preceptor attestation was initially required in 2002 that's been less burdensome, and some have -- so, we feel that this issue has been pretty well vetted in the original rulemaking process, and there's really not anything out there that the AAPM would support as being better or in addition to. And I think that's what I have to say. Thank you.

MS. SALTER: Thank you, Mr. Lieto.

Our next and final presenter is Dr. Homer Macapinlac, and Dr. Macapinlac is the James E. Anderson Distinguished Professor of Nuclear Medicine and Chair of the Department of Nuclear Medicine at the University of Texas-M.D. Anderson Cancer Center in Houston, Texas, and holds a joint appointment in the Department of Experimental Diagnostic Imaging.

He is Director of Clinical Radiotracer Production and Development at M.D. Anderson Center for Advanced Biomedical Imaging Research. Dr. Macapinlac is also an expert consultant to the International Atomic Energy Agency, a member of the International Association for the Study of Lung Cancer, and an International Visiting Professor for the Radiological Society of North America. Welcome.

DR. MACAPINLAC: Thank you very much. I

would like to thank --

MS. SALTER: Excuse me, just if you could pull the mic as close as you can to you. I'm sure -- there you go, so our folks on the webinar can hear. Thanks.

DR. MACAPINLAC: Can you hear me now?

(Chorus of yes.)

DR. MACAPINLAC: Yes, thank you.

So, again, I would like to thank the NRC for inviting me to participate in this panel. And I am here on behalf of the American College of Radiology. This is a professional association representing 34,000 radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists. You see our mission here is to serve our patients, and to maximize the value of our subspecialty practice.

We do this to improve -- we do this by improving the quality of the patient care we deliver, influencing the practice of radiology, providing continuing education to radiologists and allied health professionals, and conducting research for the future of radiology.

In terms of the preceptor attestation recommendation -- the recommendation of the ACR is

that the attestation requirements should be eliminated for individuals with board certification, as well as grandfathered individuals under 10 CFR 35.57. This is because board certification proves mastery of knowledge. The preceptor attestation and certification is unnecessarily redundant. The attestation is useful to the NRC, perhaps, only for the alternate pathway, and the board certification process has a maintenance of certification requirements which requires us to keep up with our knowledge regularly.

We recommend, also, that there be modification of the requisite language in the attestation statement. We should replace the language, "a level of competency to function independently," again because of the word "competency." Instead we use language specifying that "base training and experience regulatory requirements have been met." Residency programs can review the individual's record to provide this attestation.

The term "competency," again, has specific or very vague sometimes implications in the practice of medicine. The liability of the preceptor is not clear. Some may be wary of serving in this role because of the medical-legal possibility of liability

within the current language. Qualified and willing preceptors then could be very difficult to find for some of these alternate pathway individuals.

In terms of the Ritenour, the NRC -- we recommend that the NRC should grandfather appropriately board certified individuals who have not been named on an NRC or Agreement State license prior to October 25, 2005. This should include authorized users and others in the fixed, not just AMPs and RSOs. Do not require additional documentation or attestation for grandfathering board certified individuals.

This is because, again, board certified individuals should not be required to invoke the alternate pathway to achieve authorization. The alternate pathway is prescriptive by design only because it's meant to verify knowledge in the absence of certification.

With that, I'd like to thank everybody for the opportunity. Thank you.

MS. SALTER: Thank you, Dr. Macapinlac.

So, we are right on time. Actually, we have about five extra minutes, so that means we'll have a little bit more time for our discussion. And I am right now going to move to the back of the room so I can see everyone.

And just listening to the presentations, seems to be a lot of consensus in the attestation area, so I guess I would ask if any of the panel members has a question, or a comment to pose. I know Mr. Walter submitted an alternative solution with the exam. I don't know if anyone wanted to comment on that.

I do have the questions in the Federal Register, and I have some other questions from NRC that I can throw out to you, if you want me to, or if there's something that you want to start the discussion with, I'll refer that to you, to let you do that.

All right. Well, one of the questions that I have been given was in looking at removing the attestation, which it seemed like most people were in favor of for board certified individuals, and the grandfathering of board certified individuals, the question is, what would the NRC -- if attestation is removed, what modalities would the NRC -- should they authorize these individuals for? Similar to what the attestation would be authorizing them for, or are there limitations?

Ed, do you want to --

MR. WALTER: Can you rephrase that question

in a manner that we can understand exactly what you're asking?

MS. SALTER: That's the way it was given to me, so --

MR. LOHR: I think I understand what Susan is asking, and that is, an attestation provides more information than simply attesting of the competency or whatever word we're going to use. It also shows the experience the individual has the modalities. For example, when they have HDR background, or Gamma Knife, those sort of things. So, I believe the question is, if the attestation is no longer available to the NRC in licensing space, what would the NRC -- what would you think the NRC should use then to gather that information that's necessary to put the individual on the license?

MS. SALTER: Dr. Langhorst?

DR. LANGHORST: Well, let me suggest this, because I was looking at the regulations, and when a licensee puts someone on the -- or requests to put someone on the license, they have to provide information on their training and experience. So, you already have that in 35.12, and that's what the NRC can use to decide if that person meets those requirements. The licensee has to provide that

information.

And I was kind of wondering in the discussions this morning if really anything needs to happen even beyond what's required in 35.12 for applications to put AUs, ANPs, AMPs, or RSOs on the license.

MS. SALTER: Mr. Lieto?

MR. LIETO: Well, I guess I would echo what Susan has just said. And I'm assuming that the issue that you're addressing would be for new applicants. And if this was someone who had not -- in other words, someone who not been on a license, there was no regulatory trail to identify what type of training and experience that this individual had.

And it's not unusual for -- I come from an NRC state, it's not unusual for a license reviewer to ask for additional information on an individual. And if there wasn't enough there in terms of their board certification for what they were applying for. Generally, these are pretty straightforward as far as AUs, AMPs in terms of what they're applying for. And as far as the HDR applications go, they've always required additional documentation for an AMP applying for authorized medical physicists for those uses.

MS. SALTER: No other comments?

DR. MACAPINLAC: Yes, I agree with the previous two speakers that, again, the board certification should provide the necessary background when they do apply as a new authorized user. If there is anything else, then I think the NRC should be free to ask for that, but I think it should be sufficient the processes we have in place, the supervision for all these -- both the trainees is well documented, and the board certification is the document which should provide the trail for which they begin with. And, of course, this is aside from the people who actually had a previous trail already, but were just left out by this process.

MS. SALTER: Mr. Walter?

MR. WALTER: I just want to make sure I'm clear on something here, because I'm thinking as I listen to this a little bit more, what I'm hearing is perhaps the NRC is asking right now if you are applying for authorized medical physicist status for an HDR you have to tell them which computer software information and devices they have experience with, which would not be on the certification. So, is that meaning that that would be the additional requests that would come from the NRC as to what specifically do you have experience with? Is that what you guys

were saying?

(Off mic comment.)

MR. WALTER: Okay.

MS. SALTER: Dr. Langhorst?

DR. LANGHORST: And let me clarify what I'm trying to propose here. Because as we're discussing this, to me, the licensee is stating we want this person on our license, and they have met the training and experience requirements. And they provide what documentation is required under 35.12.

Now, a licensee, the management may want additional information from their existing authorized users, or authorized nuclear pharmacists and so on on the specifics of that person's training, but maybe that doesn't even have to be in NRC's regulations, because it's already in 35.12, that the licensee is saying we have reviewed this training and experience of this individual. They meet the requirements, and we want them put on our license. So, that's a specific of what I was throwing out there.

MS. SALTER: Mr. Lieto?

MR. LIETO: Yes, I would -- just to add to the way the question was posed from Mr. Lohr. I could see an easier solution to this, not being in regulatory space, but rather that when an applicant

makes this, that rather you severely update your regulatory guides to say that when you submit -- this is the training and experience requirements that is expected when this individual is making this application.

I mean, it's similar to what you do right now, but at least you would not have this very specific issues of concern about having an individual address this from the preceptor attestation route, having it that the licensee is providing that -- either provides or has that information on site for regulatory review.

MS. SALTER: Dr. Langhorst?

DR. LANGHORST: I did -- excuse me, summer cold, forgive me. I did want to go back to this national testing, if we could?

MS. SALTER: Absolutely.

DR. LANGHORST: I'm concerned that going that route separates radiation safety from the board certification route, and makes it too -- okay, now you're talking radiation safety, now you're talking use of radioactive materials. And I think they're -- it's already well covered in the board certification. I'd hate to have to sit as an RSO for another test when my certification board exam is all about

radiation safety. So, I don't think that's the right route to go, and I don't think that the cost that would take, and the additional studying and so on periodically. I'm not supportive of that.

MS. SALTER: Mr. Walter?

MR. WALTER: Such a system would definitely separate the practice of medicine from radiation safety. And the test that would be given would be radiation safety-based only. And it's -- don't get me wrong, I don't think there's a regulator in here who has seen, unless they are a board certified individual, who's seen the radiation safety questions on any given exam, but we know what would be on an exam. And since that's our purview, is radiation safety, and our sole purview, not -- when I say "sole purview," I mean that's the only thing we're dealing with, not that we're the only ones that deal with it. Then it would make sense for us to be concerned with the radiation safety aspects in the use of medicine.

We constantly are treading on what is considered to be the practice of medicine, because there is no defined line that separates the practice of medicine and radiation safety. There's just no fence there. So, we have to get into that gray area.

This is a way to separate it. It's another

test, yes, one of many, many, many that certified individuals would have taken, or anybody, any physician or anyone that's in the status would have taken. So, I don't really see where it would be onerous for them to take a 100 to 125, we'd have to put some additional questions in there for testing each time, but say 100 to 125 question radiation safety exam.

It would do away with the 80 hours, the 200 hours, the 700 hours, and all of this. We would rely on the practice of medicine and the fact that medicine is going to assure that only the right people are doing this work. To bring it down simply to if you can take this test, and you can pass this test, then you can be approved as an authorized user, or physicist in the area in which that test was planned.

MS. SALTER: Anyone else want to comment on this suggestion, or how it might be revised? Mr. Lieto?

MR. LIETO: Well, I think it's a very interesting proposal. I'm very much setting on the fence on it, because I think the devil is in the details on how this would be set up, and administered. I'm not really sure if an exam would be -- a "national exam," is necessarily the mechanism. I was pondering

whether maybe a set of training or topic modules that an organization could provide for its residents or physicists, and maybe there would be some type of a national or professional organization that would provide these, and then when you successfully complete these within a period of time, you provide the certificates or something like that. But the onus is on the individual to get the training.

So, there might be different ways to skin this cat. It's, like I said, a very interesting concept. There was, I think, how you would set up a training board who would provide these questions. I think a lot of what is required in current NRC regulations is archaic and outdated, as far as what medical -- especially for authorized users, and what they do. So, I think you want something that would reflect more the current practice of what the responsibilities and duties are. So, I'm not necessarily for it, but I'm not necessarily against the concept.

MS. SALTER: Dr. Macapinlac.

DR. MACAPINLAC: Among the practicing physicians I think one should realize that we do have maintenance of certifications. What I'm trying to say is we have a process in place, and perhaps radiology

may not be the best example. I would give you a better example because it involves different kinds of physicians. It would be the practice of cardiovascular nuclear medicine. You have interventional radiologists, cardiologists, nuclear medicine physicians, and radiologists who practice this.

We are, actually, mandated to take an exam to recertify, which specifies specific parts of it dealing with radiation safety and the handling of isotopes. We even have courses specific outside of the actual stress testing, interpretation of the studies, but particularly for the radiation safety and handling of pharmaceuticals, instrumentation, et cetera. This is actually happening in about September of this year.

It happens annually, because we get recertified. And the website itself, less physicians who are certified or not, or people who have not recertified, or do not want to get recertified. And you do not have to have any part in enforcing it, because it's self-enforcing. We will not be paid as physicians if we do not get certified. You cannot practice.

So, what I'm trying to say, this is part

and practice of our practice of medicine, particularly in the area of nuclear medicine, and sealed with radiation oncology.

We take ownership in that this involves the administration of these nuclides, or these isotopes, or these radioactive materials to patients. It is our responsibility, and it involves part of our practice, and part of our maintenance of certification. So, what I'm trying to say is you have this process already in place. We have to take a written exam for this, and it's there. It's well documented.

MS. SALTER: Any other comments on that?

Well, I know -- I think that in your presentations you covered the questions, at least in the Federal Register around attestation. The first was should only AMPs and RSOs be grandfathered. And I think I heard support for that.

In addition, there were some additional people that some of the panelists felt should be grandfathered in. I don't know if there are any additional comments on that topic. No? Mr. Lohr?

MR. LOHR: I'd like to hear the group's thoughts on the idea of the authorized nuclear pharmacist, which has had to do a certification or an

attestation for many, many years before 2002.

MS. SALTER: Okay. Any of our panel members want to weigh in on that? Let's go to Mr. Walter, and then Dr. Langhorst.

MR. WALTER: Frankly, in our state at least, we've not seen the kind of problems that have cropped up with the new rule with the pharmacists. It's been business as usual with them.

MS. SALTER: Dr. Langhorst?

DR. LANGHORST: I guess I would ask the question as to why that requirement was there in the first place, and does it need -- why couldn't that be eliminated as we were discussing with all of them. Just because it was there before this most recent change, you know, it doesn't mean it needs to continue. So, I'd ask why it was placed there in the first place?

MS. SALTER: Did you want to respond to that?

MR. LOHR: I can take a stab at it. Remember, I am from the rulemaking group and not from the technical office. But I believe that there were some issues in the past with the nuclear pharmacy, I don't want to say programs, but with the field. And the Agency in response to that had developed the

attestation.

I'm not suggesting that those problems are still existing today. I'm not suggesting that we should or should not keep the program, but I have not heard that in any of the presentations this morning from any of our panel members on the nuclear pharmacists. So, I was curious, were they intended in their statement to also include them with the removal of the attestation?

MS. SALTER: Dr. Langhorst, and then we'll go to Mr. Lieto.

DR. LANGHORST: Yes, we meant to include them.

MS. SALTER: Mr. Lieto?

MR. LIETO: Ditto. Yes, we did mean to include them. And I think if a board want -- preceptor attestation is a part of their board, I believe part of their board certification process, if I'm not mistaken. I don't want to speak for nuclear pharmacists, if there's one in the audience, but -- so, this preceptor attestation for the radiopharmacists was well -- was in play many, many years, probably a good decade and a half before the rule rewrite in 2002. So, it really was not an issue for them whether it stayed or didn't stay.

I think that was going to be maintained as a part of their certification process regardless, but the requirement for applying to the NRC for a licensee to get approval for an authorized nuclear pharmacist on their license, the preceptor attestation in addition was not meant to be part of that.

MS. SALTER: Any other comments from -- Dr. Langhorst?

DR. LANGHORST: I had a question about how often -- and I just don't know this. How often NRC reviews the boards and their requirements? They get initial recognition, but is there a re-review of their requirements periodically?

MS. SALTER: Mr. Lohr, can you answer that question?

MR. LOHR: I cannot.

MS. SALTER: Okay.

MR. LOHR: But I believe we have a Staff member who can.

MS. SALTER: Okay. Because I know this -- I think, Mr. Walter, you had something in your presentation about how you felt that this could work if the NRC kept up on that. So, let's go to Dr. Zelac.

DR. ZELAC: Certain certification boards that were interested in having their certification

processes recognized by NRC or Agreement States made application to NRC. I don't know of any that made any applications directly to Agreement States. Made application to NRC to describe what their processes were, and indicate where there was compatibility between their processes and the requirements in their respective sections of the regulations.

Once any omissions or contradictions were satisfied, those board processes were recognized. Part of the process of recognizing the boards was to make clear to them what their additional responsibilities would be for the future with respect to maintaining those processes that had been approved. And the requirement that's been placed upon all the boards is to notify the NRC in advance of any modifications to those processes that have been reviewed and approved in sufficient time that the changes can be reviewed and determined to either be acceptable or not.

There is not a recertification process, re-recognition process for these board certification processes, but there is an outstanding and continuing requirement for those boards with recognized processes to notify NRC, as the recognizing agency, of any changes. And this is published information up on the website.

MS. SALTER: Did you want to -- Mike Fuller?

MR. FULLER: Yes, I was just going to clarify that the process that Ron just described where the certifying boards are expected -- not only are they expected to come in and notify us when there's change and we have an opportunity to review that. That has been exercised a number of times. Things have changed, and we have reviewed it, and so forth.

MS. SALTER: Thank you. So, does that generate any comment from the panelists, clarification? Mr. Lieto?

MR. LIETO: I guess just a comment. I think the whole aspect of going at the boards to address training and experience is kind of trying to push the water uphill. The boards do not train applicants. Okay? They reflect the requisite knowledge of the training that is provided to them in the training programs.

It seems to me what should be addressed is that the -- are the training programs providing the information in their training programs. Do they feel that this is what's necessary to put out good AUs, AMPs, authorized nuclear pharmacists?

The practices change because of

technology, as we saw yesterday in a lot of the discussion, and I think a lot of the specificity of some of the training and experience requirements really are not in concert with what the practices of these individuals are in these various areas.

MS. SALTER: Mr. Walter, did you have any -- one of your concerns, I guess, on eliminating the attestation requirement for board certified individuals was would the NRC evaluate or review boards periodically? Would this current process that's in place meet your needs in that area?

MR. WALTER: Yes, that's exactly what I was referring to when I was discussing that, is that any changes that would be considered by a board would have to be reviewed for those areas that are covered in the rules, would have to be reviewed and accepted by the NRC.

As Dr. Zelac had stated, the boards had the option of going to the Agreement States, but the fact of the matter is, none of them ever came to any Agreement States that I'm aware of, that they all more or less were probably used to working with the NRC more than they were with individual states. So, that's why they chose to go that direction, more than likely. But, at the same time, I don't know what -- if someone

came to me in Alabama, I probably would say I really don't have the expertise in doing this. I think you ought to go to the NRC, or someplace else. Okay? Because I'm not going to -- I'm not proud. If I don't know how to do something, I'm not going to try and do it.

MS. SALTER: Dr. Langhorst?

DR. LANGHORST: I wanted to bring up another little twist on this. As I was reviewing transcripts of past ACMUI meetings and so on, the topic of physicians, in particular, trained in Canada came up, and whether that was allowable for people to get board certification here in the U.S. And I know there are still some of the recognized boards that have to have certain types of wording on their certifications that say, like physicians trained in the United States, or says United States on it. And I just wanted to bring that topic up, if an individual gets -- passes a board certification that is a U.S. board, I think they have to alert the U.S. regulations, and I don't see if they're trained in Canada or here if that would make much difference. So, I wanted to bring that topic up.

MS. SALTER: Mr. Lohr?

MR. LOHR: That particular topic is under

Topic 5 for this afternoon's discussion.

MS. SALTER: Okay.

MR. LOHR: If that's okay if we defer until then.

MS. SALTER: Sure.

DR. LANGHORST: Okay, thank you.

MS. SALTER: Bring it back up when we get to Topic 5.

Any other -- this is your opportunity to take this discussion in any direction that you would like. We have about five minutes left for the discussion part, so let's go to Mr. Lieto, and then Mr. Walter.

MR. LIETO: I have a question for NRC. It was mentioned that boards have come back to the NRC to, I'll say re-approve their process, or amend their process for board certification. Could you kind of give an example of what you mean by that, or specifically what was done, and what it addressed?

MS. SALTER: Do we want to answer that now, or do we want to --

MR. FULLER: Most of the time when these changes are made, they have to do with changes to the certificate, for instance. There may be some changes in nomenclature that the board wants to make with

regards to what they call their board certified individuals, and so forth. So, that's been the main -- most of the cases. And then there may have been others that were more substantive and so forth, but, anyway, we can -- I can get that information for you and get back to you, Ralph.

MS. SALTER: Is there a concern in that area that you want to provide, or something that the NRC should consider? This is really your time to --

MR. LIETO: Well, I'm just kind of -- I'm just curious as to this whole board -- the whole Agency approval of a board process. I am not familiar of any other regulatory agency in the federal government that does this. Okay? That approves a board process. So, I think why is -- why does the NRC have to be so unique in this? And I think it's created some real difficulties with this whole recognition of diplomats, the date of certification, and so forth. So, I just would like to know what are some of the specifics of what the boards are actually doing with the regulatory agencies in this process.

MS. SALTER: Okay. Mr. Walter, did you have a --

MR. WALTER: Well, I didn't have a comment on that. I had another question.

MS. SALTER: That's fine. That's fine.

MR. WALTER: Okay. We're on six years now since the 2005 changes that we're looking to make amendments and changes to. And it's possible that it will be at least seven years after the last major changes in the training and experience to where we get to the new one.

Let's assume that we drop the requirements for attestation for board certified individuals. Are we still going to keep the evidence of having been active within the last seven years?

MS. SALTER: Dr. Langhorst, did you want to comment? I see you shaking your head, but the folks on the webinar can't see that, so --

DR. LANGHORST: Yes. I mean, I don't think that has been brought up as anything to change, or proposed to change in this regulation. And board certified individuals have to maintain their certification well within a 7-year period, and I know how painful that can be for me in my certification. So, yes, I don't think there's any proposal to change that.

MS. SALTER: Well, with our last five minutes for the panelists' discussion before we get the audience in, I'm going to go to Mr. Lohr, and just

see if there was any question he wanted to throw out to the panel members for comment.

MR. LOHR: I was interested in hearing the panelists' thoughts, specifically during one of the presentations they were talking about the residency program directors providing attestation. And one of the slides talked about the idea that the -- on the residency program staff there would need to be an AU who had similar background of what was being requested, and would also have the ability to disagree; and, therefore, the attestation would not be issued by the residency program director. So, I was interested in the thoughts of the panel on that approach.

MS. SALTER: Okay. I don't remember whose presentation that was, but if you would like to elaborate on that, or if someone else would like to comment on that. Dr. Langhorst?

DR. LANGHORST: Thank you. I think as far as board certification, a residency director probably would not recommend an individual to sit for a board if one of the authorized users or other authorized individuals did not agree that that individual was ready to sit for a board.

I would hope that a licensee before they

put a person's name forward to be placed on their license, if they had an authorized individual under their license who did not agree with this, that that would be part of their process of well, we're not putting this person forward until we have this resolved.

It just seems like a very practical, this is how you would do business kind of question. And I think that NRC doesn't have to get down to, necessarily, that detail. But if a licensee is putting forth an individual that they need -- that they have this training and experience, then NRC looks at that individual and holds the licensee responsible for insuring that that training and experience has been met.

MS. SALTER: Mr. Lieto?

MR. LIETO: I don't know if it was my slides that Mr. Lohr is referring to, but maybe just to clarify. One of the points that I was making is that besides program directors, that an individual who is already an authorized user for the same uses that the applicant is applying for to be authorized by the regulatory agency, that person could also be a person that could provide the preceptor attestation, not just the program director.

My other point was that in some, especially with authorized users, some program directors may not be someone who is an authorized user for radioactive materials. He could be someone who does, basically, diagnostic x-ray as his primary practice, but is the director of the residency program which encompasses the nuclear medicine residents. So, that program director may not be an authorized user, but he has all the information to make the judgment based on the information from the other authorized users and individuals in the training program to provide the preceptor attestation.

And, similarly, that could also be the same case with an authorized medical physicist. You could have an authorized medical physicist whose board certification is in the diagnostic imaging modality, yet they could be part -- their training program may encompass individuals that are applying via the alternate pathway for authorized medical physicist status on a license. So, obviously, along the therapeutic medical physics avenue. So, I don't know if that provides the answer to your question or not on what I was trying to make, or was it a --

MR. LOHR: It was not a question. I was looking for the thoughts of the panel on it.

MS. SALTER: Perspectives. All right. Well, we are at the time when we'd like to invite the audience to join in on this conversation. And I would ask if we could bring the standup mic to the front of the room. However, if I can reach you, I can bring you a mic so you don't have to crawl through the tables and the other participants. And I have a card from Dr. Herb Mower, so I'm going to start over here. If you have a blue card and you want to talk, just raise it. If you need a blue card, I'll bring you one.

DR. MOWER: One of the things that was noted was if you had your name on a license on the magic date of October 25th, 2005 you were then okay to go forward. And I believe Mr. Walter commented that at least in his state they suggested that people get their names on the licenses prior to that date. I did that to my staff, all my physicists who were not listed on our license were put on there.

One of the problems with this, though, I believe is that at that time in most, if not all licensing bodies only one RSO could be listed on a license. Therefore, it was not possible to get other people who had served as RSO up until October 24th when they happened to hand the reins over to somebody else,

on October 25th they were no longer an RSO and, therefore, are not eligible now to be an RSO without going back through the process.

I was wondering if you have any comments on that, and then we'll hit the real good questions.

MS. SALTER: Mr. Walter.

MR. WALTER: You're absolutely right. The RSO has been a little bit of a sticking point in that while we have allowed -- in my state we've allowed multiple RSOs, particularly when we have multiple sites, most of the time when we have multiple RSOs they are one for diagnostic use, one for therapeutic use, rather than one that can handle everything at one location. We would generally just have one RSO on there, so you're correct in that assumption. And that has on very rare occasions, at least in my state, been a problem. But most of the time, it hasn't been when it comes to the physicists, at least, and the authorized users, we haven't had too much trouble getting them into the RSO position.

The biggest problem has been that attestation request, which if an RSO has already left 29 days before, and maybe they didn't leave in the best of intentions, and didn't have the best feelings towards their past employer, they're not willing to

write an attestation letter. So, that -- politics gets into everything, so it doesn't matter what we do, and how we try and fix it, politics will screw it up one way or another.

But you're right on that, it was difficult. And one of the things that I tried to do as the OAS representative on the working group is, I sent out at least two, I think three emails to all of the director members at the time imploring them to make sure that their licensing staff got all of the physicists on to the licenses before they adopted the new regulations, which as you know can take three years after the NRC's regulations go into effect. And even so, I was getting requests to add people on the day before our's went into effect. And I, essentially said if it was dated before that June 6th date of 2006, I'm going to accept it. And luckily they all came storming in there at the very end.

And I also was very liberal in my authorization process. I didn't authorize them just for the things that are listed in the rules as to what they had to be listed in. I listed them for everything on that license that they were using or working with regardless of whether or not they currently under the rules had to have their name on a

license to use it, because what's going to happen in the future?

So, we tried to be as proactive as possible in doing that, and that's what I encouraged other states to do. Some did, some did not.

DR. MOWER: The other topic I would like to see the panel really address in some detail is this recommendation of a National Radiation Safety Exam, which I see several problems with.

First, as Dr. Langhorst mentioned, this is already covered to a real extent in the board certification processes, at least through the ABR and the ABMP with a specific section on that.

Second, I think as recommended, it really weakens the systems. It's not asking for anywhere near the training, and experience, and knowledge that we had there before. And then there is the question that if this exam were to come about, would that group performing the exams be something which would be recognized by the NRC such that they would accept this person as a radiation safety officer?

MS. SALTER: Okay. Well, barring what the NRC would do if this was approved, let's ask what would you like to see the NRC do in this case, or respond to Dr. Mower's -- I'm over here behind you --

Dr. Mower's concerns regarding that particular proposal. And that can be from Mr. Walter or any of the panelists. We'll start with Mr. Walter.

MR. WALTER: Yes. This was a situation that struck me, in particular, back in the late `90s when we started the rulemaking process, because my state has had no luck in getting certification or training requirements specified in the rules in any way, shape, or form for techs or anyone who actually handles materials a lot. It was being shot down right and left every time we tried.

So, one of the things that I suggested was we can simplify these rules by saying that if they know the radiation safety component of the type of use that they're wanting to do, then take the exam that shows that they understand the concepts and understand what needs to be done. We can do away with the number of hours of classroom and laboratory training which, as all of you know, was a fight. Well, it doesn't need to be 200 hours, well, it doesn't need to be 80 hours, it doesn't need to be 8 hours. You know, how much is right? Very subjective. We talked about subjective and objective yesterday.

If you know the stuff, you know the stuff. If you don't have to take any additional training to

know it, then you don't need to take any additional training.

What constitutes an approved, accepted training program? NRC does not review or accept any of those training programs that are giving you the 200 hours, or 80 hours, or whatever. That's all left up to the Agreement States.

Every Agreement State is going to look at them in their own way, no consistency. We're in the process right now, the OAS and the Conference of Radiation Control Program Directors are in the process right now of working -- putting together a working group that is going to address just that issue. What is the best way? What do you always need to do when you're reviewing these training programs to assure that they're adequately providing the information necessary to safely handle radioactive material.

In particular, that's going to be for those training programs that are not specified as to what has to be covered in the rule. But, at the same time, everybody has wanted to go on line. What's an acceptable on line training program? Taking it and passing it, or oh, you need to go back and look at this part of this module and just memorize it long enough to say -- to get the right answer so you can

move on to the next one? Where is the retention? What is acceptable? So, let's do away with that. Let's do away with the incongruencies and inconsistencies that we have at this point in time.

My intent in having a national training or national testing program would be that it would be accepted by all regulators. And in order to do that, it's not going to be the easiest thing in the world to do, but you have to remember, again, like I said, every time there is a small change in the Compatibility B Category license or regulation, 37 Agreement States have to make changes, not just the NRC.

Now, it may not cost us much more than just the NRC by themselves to go through the long process that it takes to do this for us to get it, but it costs money, and a lot of FTE to make a rule and not be out there in real world making sure that radiation safety is being done. And I'm not talking about just medical, I'm talking about the majority of other licensees that we have.

So, the cost in manpower and money, itself, for even the smallest changes is easily in the millions of dollars. And we're having to bear that,

as well. So, why don't we get a process that doesn't have to be constantly tweaked, doesn't have to be constantly reviewed, and changed, and overhauled in some small to large manner? So, that was my premise for bringing this up back in `97, and again this year.

MS. SALTER: All right. I have a comment here. I'm going to ask you to stand up so folks can see you, and introduce yourself, and your organization.

DR. MAHMARIAN: Sure. I am John Mahmarian. I'm the Director of Nuclear Cardiology and Cardiovascular CT at Methodist Hospital right across the street, and also professor at Weill Cornell. I've been training fellows for the last 25 years, so I have somewhat of an interest in all of this. I'm also here representing the American Society of Nuclear Cardiology, and the Certification Board of Nuclear Cardiology.

And I'd just like to make just a few comments. First of all, I'd like to say I agree with all the comments from my esteemed colleague from the American College of Radiology. I think we're on the same viewpoint in terms of where we think the comments should be going in terms of attestation, in terms of accreditation and certification.

And in that regard, we certainly agree with the issue of not having to need attestation for people who are already board certified. We certainly agree with the issues regarding the alternative pathway. And we do feel, and I personally feel that a program director should be able to attest to the completion of a program by an applicant, as long as it's under advisement by either the authorized user and/or another faculty member who has been a preceptor for the individual, so we certainly agree on that.

We also agree with excluding the language of competency in the requirements. As was referred by Mr. Lieto, boards look at competency, training programs attest to completion of materials and going through and doing the proper -- getting the proper training. So, I think that is an important thing -- an important concept to remove from the verbiage.

I would like to say one last comment about this issue of national safety examination. In cardiology and internal medicine, if you're a cardiologist, you already take a recertification exam -- initial certification and then recertification exam in internal medicine in cardiology. If you're in nuclear cardiology, you take another one. If you're in cardiovascular CT you take another one. If you are

in echo cardiography or electrophysiology, you take another one. If you're in MRI, that's coming up, too, very soon. And right now every 10 years our fellows and people out of their fellowship program have to take recertification exams, including myself, which I don't particularly like doing every 10 years.

And, in fact, if I were to recertify, it's getting to the point where every single year you would end up taking a new recertification examination. You'd never be able to practice medicine any more. You'd be just recertifying and doing those sorts of things.

Right now, I know -- I'm not sure about the other certification, the recognized certification boards, but I can tell you that CBNC, 30 percent of the exam is on radiation safety. So, this is already incorporated within the certification examination.

And, at this juncture, it seems like we're trying to expand; whereas, ABIM is actually trying to consolidate because they realize how onerous this is on everyone to constantly taking not only initial certification exams, but recertifications at such frequent intervals. And, in fact, there's now some thought about going to ongoing certification so you don't have to have this constant retaking of tests

every 10 years. So, it seems as though where ABIM is getting maybe more toward consolidation, here we're talking more about expansion. And I'm not sure that's necessary.

Now, maybe from my own personal viewpoint, maybe the best way to approach this would actually be to have NRC advise the certification boards in terms of what type of material they would want on a test, so as to satisfy the regulatory needs or the presumed regulatory needs, rather than offering a completely new examination that someone might have to sit for. And I think those are all my comments. Thank you.

MS. SALTER: Okay. Thank you, Dr. Mahmarian. I'm going to go back here again. I'd ask you to stand up and introduce yourself.

DR. BEASLEY: Hi, I'm Charles Beasley, and I'm on the faculty of UT Health just down the street here in the Medical Center. Also, I'm the Radiation Safety Officer for Memorial Hermann, so I have some operational experience.

Very briefly, back in the `80s it used to be that all we needed to do was get a photocopy of an ABR certificate and that was it. After the rule change, basically, I had to tell newly minted residents that that wasn't worth the paper it was

printed on, and they needed to fill out some rather lengthy forms.

My experience was many of these people decided not to pursue getting the authorized user status because they either didn't want to take that trouble, or they had difficulty in complying with the requirements.

On the educational experience, I'm involved with the Radiology Residency program at UT. We have over 50 residents in the program, and we participate, our physics group participates in the education part of it.

It's been our experience when the attestation is required prior to taking the ABR, that when we have that filled out by our proctoring group, that they are hesitant on two aspects to sign it. One, they were not participating with the 80 hours, that was the physics group that did that, so they were concerned about just being shown the information, and want to know why doesn't somebody that actually did the education, such as the physicists, sign off on that instead of the position.

The second thing, as Dr. Langhorst mentioned, is they don't like the wording, and they're very confused by the aspect that what they're

attesting to. Are they attesting to their clinical expertise, or are they attesting to their general training and knowledge? So, that's what I want to say.

MS. SALTER: Thank you, Dr. Beasley. I'm going to go -- I'd like to, before I go to our next speaker, just want to remind everyone on the webinar that although we can't hear you here, other individuals participating in the webinar can hear you if you don't mute your phone. So, please mute your phone and use *6, and also not to put your phone on hold because when you do that, if you have music it's coming through to other folks on the webinar. Of course, if you're on hold right now you're not hearing this, but --

(Laughter.)

MS. SALTER: -- don't put your phone on hold in the future.

With that, I'm going to go over to Dr. Welsh for a comment.

DR. WELSH: Hi, I'm Jim Welsh with the ACMUI. And I'm going to just comment on the concept of national safety, national state safety -- radiation safety examination.

I know that we've already heard comments

on this, but since I and I believe many others have strong opinions on this, I thought I'd echo those sentiments, and perhaps reinforce them by stating that I disapprove, in general, of the concept of any federal or state agency intruding too much into the practice of medicine. I think we're all in agreement with that.

Analogously, I'm not in favor of the concept of a federal or state agency going overboard and kind of approving a board certification process, and examining that with a fine tooth comb. I think the board certifying organizations know what they're doing, in general.

So, just as nobody would be in favor of the idea of the NRC or the states intruding into the practice of medicine, I think that we're walking a very fine line here when we talk about this concept of a national or state radiation safety examination.

Granted we're not talking about the practice of medicine per se, but the American Board of Radiology, for example, as one of the certifying organizations, certifying boards, certainly knows what they're doing in terms of radiation safety. And I believe that the radiation safety issues are fully addressed, and these concerns are fully addressed by

the board certification process.

So, while the concept of a national or state radiation safety examination is an intriguing concept, I, for one, am quite opposed to it because I believe that what we already have in place does, indeed, adequately address this issue. And that's just my statement.

MS. SALTER: Thank you, Dr. Welsh. We have one quick comment on the webinar, so I'm going to go over to Gretchen to get that. And it's like one sentence, so we're not going to put it up on the screen.

MS. RIVERA-CAPELLA: Thank you. This comment is from Steve Mattmuller, and he's from the ACMUI. And he's saying that, "Yes, attestation is part of the BCNP process."

MS. SALTER: Just a clarification there. Anyone else in the audience want to make a comment? We have a few minutes left. All right. Well, with our last -- I'll go back up to the panel. Is there anything that the panel has heard in these last couple of comments that they would like to respond to, or make a comment on? Oh, quiet.

All right. Well, with that, I'm going to take our last couple of minutes and turn it back over

to NRC to see if there were any particular issues on this topic that they would like clarification or any more information on before we close it up. So, I'll go to Ed Lohr.

MR. LOHR: I was interested in hearing the panel's thoughts on, I believe -- I'm sorry, sir, I don't recall your name, the cardiologist, with the idea of having the boards incorporate the radiation safety aspect into their exams that are recognized rather than independent panel or board at a national level for this sort of thing. And I guess this would be a question not only to David, but to the other members of the panel.

MS. SALTER: Okay. So, on Dr. Mahmarian's comments, any panel members want to weigh in on that? Mr. Walter?

MR. WALTER: I don't want to be presumptuous and speak on behalf of the NRC, but having been on the original working group, the intent was that if the board came to them and did not indicate that there was -- I don't remember the exact percentage, but they were talking percentages, and we never made a decision as to what would be an acceptable percentage. Again, they were looking at subjective numbers here of the test questions being

radiation safety-based. If it weren't adequate, they weren't going to be accepted. So, that's part and parcel of the requirement to get accepted by the NRC in this case.

MS. SALTER: Any other panel members? Dr. Mahmarian, did you -- okay, Dr. Mahmarian.

DR. MAHMARIAN: And, again, I understand that in terms of having a certain percentage of the examination having the content of radiation safety. And I'm not speaking on behalf of CBNC now, I'm just speaking on behalf of myself. But it might -- as was suggested by Mr. Lohr, and as I have suggested, maybe the content would be more of an issue rather than the percentage of the material that's on the examination. And working with boards in that regard may offer a better solution than offering yet another examination to individuals.

MS. SALTER: Okay, thank you. Mr. Walter?

MR. WALTER: That was turned down when it was first talked about back in the early 2000s period. There may have been some other contentiousness going on at the time, because the boards didn't want to be taken out by name from the rules to start with. And I think that was the point that was being pressed home by the boards at that particular time, and it was not

a welcome topic to even consider a regulatory agency to recommend the types of questions that should be on the board. That was a no-no, but the -- again, my point here is, you indicate that you got 30 percent of your exam, of the CBNC exam on there. I'm not saying to take it all off. But every percent you free up for medical gets you more into the medical competency, where the boards are supposed to be, into the medical competency section of it, as well.

And I understand it's well-rounded, that they need to feel -- the board needs to feel that you're well-rounded in all aspects necessary to have a competent practice, which includes radiation safety. But it -- that's just something that would free up a little bit more percentage possibly on that, but it also -- and, again, the biggest thing, it separates, as much as possible, the concept of getting involved in the practice of medicine.

DR. MAHMARIAN: Okay. This is John Mahmarian, again. Just one final comment I'd like to make on that. Having taken the certification exam, having taken the recertification exam, having written questions for the certification exam, I can tell you that it's an extremely well-rounded examination, and that removing radiation safety isn't going to make it

any more well-rounded. If anything, keeping radiation safety on the exam makes it much more well-rounded, and well-balanced.

MS. SALTER: Thank you. All right. So, we are at 10:30, time for our morning break. We will come back at 11:00, and we will talk from 11 to 12 on Topic 3, which is Naming RSOs on the NRC Medical Licenses. So, come back recharged and prepared to engage in a dialogue on this topic.

(Whereupon, the proceedings went off the record at 10:30:07 a.m., and went back on the record at 11:01:04 a.m.)

MS. SALTER: All right. It's 11:00, and I would ask for our panelists, Mr. Lohr and Dr. Zelac, to make their way up to the front table. Oh, let me go get Ron.

All right. Welcome back, and welcome back to our participants on the webinar.

The rest of today is going to follow a little different format. We're not going to have panelists per se. We have a NRC Staff person who is going to kind of tee up the issue, give some background, and then we are going to open it up for audience participation to comment, provide suggestions, perspectives, your positions.

And the topic we're going to be talking about now, which is going to take us to lunch is, Naming Associate/Assistant Radiation Safety Officers on NRC Medical License. And our two panelists that are going to be here the rest of the day are Dr. Ron Zelac and Ed Lohr. And I'll just briefly introduce them.

Dr. Zelac is a Radiological Health and Safety Specialist who has been active in educational research in applied areas of the field. He is currently employed as a Senior Health Physicist by the U.S. Nuclear Regulatory Commission, and is presently focused on medical use of radioactive materials, including regulations, guidance, and implementation issues. And Dr. Zelac is certified by the American Board of Health Physics and the American Board of Medical Physics.

And Ed Lohr is a Health Physicist in the Division of Intergovernmental Liaison and Rulemaking in the Office of Federal and State Materials and Environmental Programs at the NRC. Mr. Lohr has worked in the radiation protection field for over 30 years, including 20 years in the Army Medical Department, where he served as the Supervisor of the Kentucky State Radiation Control Program, the Kentucky

State Radon Coordinator, and the Operation Officer for the Reference of Radiation Control Program Directors. He is a registered Radiation Protection Technologist and holds a Bachelor's of Applied Science, as well as Master in Public Administration.

So, there you have our panel members. And with that, I am going to turn it over to Mr. Lohr to give us some background on this topic, and then we will open it up to audience participation. Again, please fill out a blue card if you have not done so already, just hold it up. If you need a blue card, raise your hand and one of us will bring it to you. For folks on the webinar, again you'll be typing in your question into the webinar.

So, with that, Mr. Lohr, you want to get us started?

MR. LOHR: Thank you, Susan. Everybody hear me okay with this? Thank you.

Welcome back to Topic 3, and the NRC's interest in public input on our proposal to add to the regulations. The acronyms you will see on my slide I believe you've seen before, but just worth always repeating for anybody who is new.

Part 35.24(b) of our current regulations requires a licensee's management to appoint a

radiation safety officer who in writing agrees to be responsible for implementing the radiation protection program.

The current regulations are written in terms of singular individuals who are responsible for the radiation safety program. This singularity for one RSO is repeated in multiple places in Part 35. In addition, in the 2002 rulemaking in the supplementary information, the NRC states that, "Part 35 does not allow licensees to have more than one permanent RSO."

Section 35.24(c) does allow licensees to temporarily name replacement RSOs, if necessary, but that is to make sure that the licensee has an individual who's qualified to be an RSO for each of the different types and uses of radioactive material permitted by the licensee for a short period of time.

As further explained in the 2002 rulemaking, even though we've added a provision for a temporary RSO, a licensee is expected to fill the position of permanent RSO as soon as possible. The intent is to have one person responsible for the radiation protection program.

The ACMUI in June of 2007 identified that perhaps the restriction of having one RSO on a license was becoming problematic. Specifically, it appeared

that this restriction is contributing to a shortage of available RSOs to serve as preceptors, and creates a situation where an individual who is qualified to perform the same duties as an RSO cannot be recognized or listed on an NRC license.

In addition, they expressed a concern that there are many RSOs who are working as contractors serving several hospitals, and they were not able to have the actual day-to-day oversight of the programs.

During this meeting, the attestation ununanimously voted in favor of changing -- proposing change to the regulation. The Committee believed that having the ability to name associate or assistant RSOs would increase the RSO pool, recognize qualified individuals, and allow licensees to more quickly appoint a replacement RSO.

The proposed change to the regulation would allow licensees to appoint qualified individuals with the expertise in certain uses of byproduct material to serve as associate or assistant RSOs who would be responsible for overseeing the radiation safety operations of their assigned sections of the program, while primarily reporting to the RSO.

The primary RSO would continue to be the individual named on the license responsible for

implementing the program, as it says in 35.4. This would allow licensees with multiple operating locations to have qualified assistants or associates for each of the location, and additionally, and I think very interesting to most of you folks out there, the idea they could also be listed on a license.

I do want to note that this proposed change is intended only to apply to Part 35, and not to any parts of the regulation.

Our discussion -- one of our discussion points is, of course, that we're considering to do this to name them on the license. We would like to get input on the qualifications of this individual. We'd like to know if anybody feels there should be a limitation of the number that a licensee would be able to actually list on license. And are we using the appropriate term "associate/assistant," or is there some other title that would be more appropriate?

With that, Susan?

MS. SALTER: Thank you, Ed. And what we're going to do is kind of go to this first discussion point, and go to the audience to review that. And then we'll go to the other, so if you have comments on the others, we're going to try to keep some order here, and keep us focused on one topic before we move

to the next.

I would also refer you to the Federal Register Notice that's in your folder. There are a number of specific questions that the NRC is looking for input on. You certainly are not limited to just these particular questions, but they may help guide you in providing feedback to the NRC.

So, in looking at what the NRC is considering here, are there any particular comments on this discussion point from folks in the audience? I have one over here. And I'll just ask you to stand up and introduce yourself.

MR. WILLIAMS: Gary Williams, Veterans Health Administration. My organization has 120 locations where we try to maintain an RSO, and it's a continuing challenge. The idea or concept of having an associate or assistant radiation safety officer is strongly supported by the Veterans Health Administration, in particular if it provides a pathway or a documentation route for us to qualify persons to, perhaps, be the official radiation safety officer at some point in the future.

The qualifications, from our perspective, for the assistant can be of a lesser nature than the full-time or the named Radiation Safety Officer, and

that would give an opportunity for additional individuals; in particular, sometimes a nuclear medicine technologist might be in a position to replace a physician authorized user as the RSO. So, the qualifications should be not as stringent. It should be done with a concept of a pathway, but also more importantly from the Veterans Health Administration to insure that we have continuous coverage for the RSO position so that we don't have any loss of continuity for health care for the veterans.

MS. SALTER: Thank you, Mr. Williams. I have a comment over here. Dr. Mower.

DR. MOWER: Herb Mower with the -- oh, she knows I'm going to put the card back up again later, the AAPM.

I would strongly support, and I'm not sure what the name should be, an associate or an assistant RSO on the license, because I would assume, and would promote that this person be allowed to do all the functions of the RSO in the RSO's absence, such as should the RSO get hit by a mack truck on Thursday morning at 8:30 and you have a radiation safety committee meeting scheduled at noon that day, certainly in many places at present, since the RSO

probably would not make that meeting, it's not legal to have that meeting on that day, because one of the requirements is that there be somebody from administration who can authorize spending money, bottom line. And the RSO is one of the ones that has to be there, as well as quorum. And if for some reason at the last minute the RSO cannot make it, this invalidates the meeting. And we had this happen once when we had five very good meetings in a year, and missed one in a calendar quarter because the RSO could not make it at the last minute, and we were cited for that. If we had an assistant RSO, that person could take that position and the meeting could happen that day.

MS. SALTER: Thank you, Dr. Mower. We have a comment here from Mr. Walter.

MR. WALTER: Yes, David Walter, State of Alabama. We already have situations where we have what we call co-Radiation Safety Officers. We don't -- I'm not saying that's the right term to use, it's just what we use right now.

If we're in a situation where for unforeseen circumstances happen to the main RSO, and you have the assistant coming in, they have to meet the same qualifications. If they're going to be the

RSO at any given time, they've got to meet the RSO qualifications. Lesser qualifications mean that they are able to do lesser things and, therefore, couldn't take over the program as the RSO.

And as far as I'm concerned, the way we look at it as an inspector, if I come in there and you have 12 people named as Co-RSO, I can go to any one of those 12 and they better be able to give me all the information I need. So, not only is it going to be a matter of them being trained, but kept up-to-date on what's going on, because at any moment they could be thrust into the limelight and have to take over.

MS. SALTER: Thank you, Mr. Walter. I want to go to Dr. Langhorst.

DR. LANGHORST: I fully support the ability--

MS. SALTER: Could you just hold that a little closer.

DR. LANGHORST: Sorry. I fully support the ability to have multiple RSOs listed on the license. I agree with you that there needs to be one who is that main radiation safety officer.

I think it should be left flexible enough that the RSOs named, whatever they're called, on the license fits the licensee's programs. So, I can see -

- I have an associate RSO who works with me. I would have his name on my license, if we were allowed to. I would probably have my most senior HP on there who is board certified. But I could see an instance where you would need another RSO, an assistant RSO to perhaps cover an area where the RSO is not yet up to speed or up to training on.

For instance, when I went to Washington University in St. Louis, I had never been an RSO for a Gamma Knife facility, or for an HDR facility. And it is not clear if the current regulations would even allow me to be named RSO since I'd never had experience with those. But I knew regulations, I know how to read regulations. You get trained. But there may be a time when a new RSO comes in and you need that kind of overlap to get that person up to speed on a given approved section of their license with someone else acting as the primary RSO for that section.

So, I would just urge you to make it flexible enough that people named in this manner are -- their duties are defined by the license, and that you allow different types to be named, as long as it's described in the licensee's license application.

MS. SALTER: Thank you, Dr. Langhorst. Are there any -- anyone else in the audience that would

like to make a comment? Mr. Lieto?

MR. LIETO: I'm definitely in support of this, since when I was on ACMUI I was one of the -- I was the individual that presented this to the ACMUI as a suggestion for implementation.

One of the things that I think, as far as the titles go, I would -- my recommendation would be that if they have the same requisite skills as the RSO, they're listed as an RSO on the license.

Now, the question might come up, okay, you have two or three people that are listed as the RSO. And I think this is one -- I think the answer to that is that -- that needs to be addressed is that -- I think one of the biggest, I think, issues that needs to be addressed is the management who makes the decision on who is the person that has the ultimate responsibility.

I think licenses -- I personally feel that there should be a designated person from management named on the license who is responsible for the radiation safety program. They're the ones that are in charge. They're the ones that have the ultimate responsibility for the license; yet, there is absolutely no one named either by title or specific name on the license with that responsibility.

And I think the suggestion I would make is that if they have the same skills as the RSO, and the same qualifications, then they should be listed as an RSO on the license. And management determines, just like you, I would suggest, maybe where in the Part 35 regulations where management designates the responsibilities of the RSO, they can just put a line item into that responsibility that designates Dr. So-and-So, or Mr. So-and-So as the primary responsibility for the radiation safety officers in the program.

Now, that being said, there have been a number of situations that licensees have an RSO that meets the overall arching responsibilities, but would like to have individuals that have maybe just specific area responsibilities, such as nuclear medicine, or radiation oncology to oversee the HDR program, and brachytherapy programs; yet, there's no comfort level by either one of those individuals in the other areas.

For example, you could have -- I could see, basically, a physician being named as an RSO in the nuclear medicine areas, or the radiopharmaceutical areas, but would not have any comfort level with doing radiation oncology. And I think maybe that's where you come up with a different designation.

I like the term radiation -- I never liked

the term "officer." I would maybe call them maybe a radiation protection supervisor, but a different designation that would indicate they have just a limited -- what I'll call maybe, for lack of a better term, a limited scope of responsibilities within that area.

MS. SALTER: Thank you. Are there any other comments? Do we have any comments from the webinar? No.

Well, I know we're kind of getting into a number of issues, but we can flip to the next one. And I'm not sure if we have any additional comments on this topic. We have a little bit of time here, folks. This is your opportunity. Dr. Mower?

MR. LOHR: Well, thank you for the promotion. It's Mr. Lohr.

MS. SALTER: Oh, Dr. Mower is --

MR. LOHR: Oh, I'm sorry.

(Laughter.)

DR. MOWER: You don't really want me back up on the platform again. Herb Mower with the AAPM.

I'm not sure what insight to give on this. I can see an institution which has multiple sites, and their assistant/associate RSO at a particular site should certainly have knowledge of what is happening

at that site, but not maybe globally for the whole program. So, we need to figure out a way to address that. And, yet, if you have say -- well, in our case we happen to have two sites really close together, so it's not as big a problem, but there the RSO would have to be involved with anything and everything in the program, and the assistant RSO likewise. So, I'm not sure what kind of guidance to give relative to qualifications, but I think that as we look at this in the regulatory space, we need to remember that there may be instances where the assistant RSO is working with a small portion of the program, possibly remotely located from the main facility and, therefore, might have a very narrow perspective of what's needed; whereas, one who is involved with the major program and everything that's going on might have to have a different series of qualifications.

MS. SALTER: Thank you, Dr. Mower. Are there any other comments on this discussion point? Oh, there we go. On my way.

MS. REVELL: Sylvia Revell, UT Southwestern. The term "associate" at my facility implies that you would be able to work at the same level as say, in my case, the Environmental Health and Safety Director. As an associate, you would be able

to perform those same functions, so as an RSO if you're going to use the title of Associate RSO, it would imply that you should have the same qualifications.

The assistant RSO is at a lesser level, and I think implies that there should be some training associated with it over several years. And I'd also like for the consideration of when you use the term or title of associate RSO, there is some compensation that goes with that. So, I just want the board to be aware of that, that that might be a deterrent for some facilities to use the word "associate."

MS. SALTER: Thank you. Any other comments? Dr. Langston -- Langhorst. I'm sorry.

DR. LANGHORST: I think your point is good as far as what you call it. And I would suggest for NRC to steer clear of what you call those additional RSOs, just in the regulations say that there can be additional RSOs, and then one has to be named as the primary RSO, or whatever you want to call that. But then that's part of what a licensee has to submit to you to tell you this is what these additional RSOs' requirements, duties, whatever have to be for them to meet our radiation safety program, and under our license.

So, I think it's best to be as flexible in the regulations and have the licensees define how they may use multiple RSOs, and what their requirements -- like, for instance, in my case my associate RSO can step in and do the whole program. But I could see where we may have someone that we'd really like to give the primary -- primary is not a good word. To give the responsibility of maybe overseeing an HDR facility, and I say that as just an example, that we want them to really focus on that, and they may not be able to know the whole rest of the program. But having someone in that position, if you have only one additional RSO is better than having no RSO in your license, you know, when that RSO gets hit by the bus. And I'm going to steer clear of the trains later this afternoon.

(Laughter.)

DR. LANGHORST: Thank you.

MS. SALTER: Thank you. All right. Let me go over here to Mr. Walter.

MR. WALTER: One of the things I think we need to recognize here is the difference between a medical licensee and a broad scope licensee. In a broad scope licensee, you're going to have a main radiation safety officer, and then every sublicense or

permit that's issued is going to have an RSO on it, as well.

When you're talking about the standard licensees out there, the standard medical licensees, for instance, you may have -- we may have three radiation safety officers that are specified as to what they are the RSO over by the list of the isotopes that's on that license. And they're not going to be expected to know everything from all the rest of the places that they're not the RSO over. But if you're going to have a single radiation safety officer for your regular everyday diagnostic use facility which makes up some 65 to 75 percent of the licensees out there, medical licensees, you can have one RSO, you can have two RSOs, you can have six RSOs, but they need to meet -- if you're going to call them the RSO, or co-RSO, or associate RSOs, or equal in value RSO, however you want to say it, then they need to have the same training, understanding, and information to be able to take up for whatever -- you know, if -- it's up that licensee to say okay, RSO Number 1, 2, 3, and 4. Number 4, as long as numbers 1-3, any one of them is here, don't worry about it, just keep up-to-date. But that's not for us to decide.

For us to decide is to who gets to go on a

license. And saying assistant RSOs or having someone with a lesser training requirement means that at some point in time if they're not -- if they have a lesser training requirement, and they're the only ones there, and they're the only ones there for a while because of an unexpected heart attack of the only other person who's specifically the RSO, is unfair to everyone involved.

So, I would urge that if you're going to name a person as one of the radiation safety officers for any given area, that they must meet all of those qualifications or requirements in the rules.

When it comes to having techs as RSOs, I've got a few. They make great RSOs, as long as you get a document from the administration that says I'm giving them that full authority to do the duties of the RSO. That means that they get to do what's necessary if there's a spill and say no, we're not doing your patient now because we've got to clean the place up. That's a problem sometimes. So, while I won't ever have a problem, generally, with a certified nuclear medicine tech being a diagnostic nuclear medicine radiation safety officer, it's again the politics that sometimes gets in the way, so you have to get through those politics.

But I would urge that all of the radiation safety officers who are doing full radiation safety officer duties for any part of a license meet the requirements of the rules to be a safety officer. If you're going to go some other way, I don't see a reason to put them on the license. Let that be something done internally.

MS. SALTER: Thank you, Mr. Walter. We're going to go back here to Dr. Welsh.

DR. WELSH: So, the question is, should the qualifications for this additional RSO be the same as the RSO. And this may sound like a tongue-in-cheek comment. My answer is going to be no, because this additional RSO should be exempt from the requirement of a preceptor attestation, and should be grandfathered in if he or she is board certified prior to 2005.

What I mean, of course, is that this topic and the prior topic are intimately related, and if there is currently consideration of amending Part 35 to allow additional RSOs on a license, and there is also consideration of the Ritenour Petition, whichever one of these two things comes first is going to be critically important. And I would recommend that if this topic number 3 possibly be addressed prior to

resolution of the Ritenour Petition, that we incorporate our comments regarding that prior topic, the Ritenour Petition, into the qualifications of this alternate, co, assistant, associate RSO rather than wait for the Ritenour Petition resolution.

MS. SALTER: Thank you, Dr. Welsh. I think we have a comment from the webinar, and I think we fixed it so we can put this up on the screen. Okay, so you can read along.

MS. RIVERA-CAPELLA: Steve Mattmuller from ACMUI. "Since the recommendation for a single RSO is not in the regulations, but in a guidance document as pointed out at the last workshop, is this appropriate to discuss in Part 35? Since this would be a brand new regulation, if one follows the typical regulatory process, shouldn't there be some sort of justification analysis that would support adding this to Part 35? Has that been done? Since this resides in guidance, wouldn't it be more appropriate to address this with new guidance?"

MS. SALTER: All right. That was the only comment we have from the webinar right now. I'm going to turn it back to the audience here. All right.

Can you get that off the screen so we can get back to the presentation? Thanks, Gretchen.

All right. So, I think we're kind of going through these topics. You want to go to the next slide, Ed? I'm going to -- oh, you have control of it. Oh, okay, very good.

All right. I have a comment from Dr. Mower, so I'm going to go over here.

DR. MOWER: Herb Mower with the AAPM. And I would put forth a suggestion that's the same as we limit the number of authorized users and authorized medical physicists on a license, we should limit the number of RSOs on a license, i.e., we do not limit the other two. Uh-oh, another physicist speaks.

(Laughter.)

MS. SALTER: Are you done? All right. Mr. Lieto.

MR. LIETO: Can you hear me? I saw a lot of wrinkled noses by the Staff at the podium up there as a result of Mr. Mattmuller's suggestion. And I would definitely endorse the statements that he made.

It is not a limitation of the regulations, and this was brought up at the last workshop, that only one RSO has to be on the license. The regulation says that the licensee must have "a radiation safety officer." It doesn't say only one, it doesn't say the radiation safety officer, it says a.

And one of the issues along this issue, NRC Staff has stated that in some very obscure one-sentence statements of consideration in 2002 that NRC had established a policy of only one RSO. Well, where was the policy for the previous 35 years that was in existence and followed?

There has not been any information that has been supplied prior to that time that states that this was a policy and/or a regulation, so I would reinforce the comment that Mr. Mattmuller made on the webinar that this definitely could be moved into guidance space, and would not require rulemaking.

MS. SALTER: Thank you for that comment. Dr. Langhorst, can you -- okay, good.

DR. LANGHORST: Not that I'm disagreeing with Ralph at all, but my understanding was the part in the regulations, and please forgive me for being a regulatory geek, 35.12(b)(1), it talks about you have to give information for experience, qualifications of the radiation safety officer. And that, I think, was just an unfortunate name to put on it, the. And that's what I understand NRC is saying, that means it can only be one.

I don't believe it has to be one. I think the big push to have multiple RSOs on the license was

to relieve licensees -- I mean, there aren't enough RSOs out there, and I think that maybe some of the other discussions we've had on attestation, and board certification requirements, and so on, may help relieve this problem of not having enough RSOs, but still getting a fully trained RSO out there who is board certified who can follow -- who can do -- manage a radiation safety program for a licensee.

Now, I know we haven't gotten into the topic about -- too much about authorized users, or authorized medical physicists, or authorized nuclear pharmacists who could also be named as RSOs, and I think in certain licensee situations, that's a very appropriate thing to do again with, as Mr. Walter had said, management's letter that says this person has this authority. And also importantly, that that person signs it and says I accept that authority.

MS. SALTER: Okay. So, looking at is there a limit, I mean, is there -- could you get to too many? I mean, is there -- should there be a high end limit? I mean, we're hearing that just restricting it to one, but --

DR. LANGHORST: No, I'm saying we should restrict it to one.

MS. SALTER: Correct.

DR. LANGHORST: I'm saying this is in the regulations where I believe NRC thinks that this limits it to one.

MS. SALTER: Okay. So, if they said it's not limited to one, is there a number that you think would be too many to have on there?

DR. LANGHORST: I think there's probably a practical limit, but if a licensee needs multiple RSOs I think they can define that in their license application, and in the exchange between NRC and the licensee applicant, they can decide what's reasonable for that case.

MS. SALTER: Okay. Any other comments? Do we have anything from the webinar? Okay.

So, one more slide on here I think, Gretchen, if you want to go to the next one. And I think we've had some discussion on the title. I'll open it up again. Dr. Mower? You have the microphone behind you.

DR. MOWER: Herb Mower with the AAPM. I think this is something which should be left up to the institution, and not something which should come through regulatory space. And that the institution should determine relative to what they expect a particular individual to do, how they should be named.

MS. SALTER: Okay. All right. So, I'm going to pitch it back to Ed, if there's nothing that anybody else wants to offer up, and see is there anything that you were specifically looking for clarification or input on, a particular area that possibly you haven't heard yet, and you'd like to throw that out to the audience to get some feedback on.

MR. LOHR: One of the things that we are considering is the idea of allowing the associate, co-RSO, whatever name we're going to use to also have the ability to do a testing for other RSOs for the modalities, for example, that individual will be responsible for on a license. For example, in Dr. Langhorst's example of the HDR or the Gamme Knife, have an RSO who has that background named on her license, we would be very interested in knowing the thoughts of the community on that individual as an associate, or assistant, or co-RSO to be able to attest for other RSOs who are not board certified.

MS. SALTER: Give you a minute to think about that. Mr. Lieto, do you want to --

MR. LIETO: I would say yes, I would use the analogy of an authorized user that would attest for a physician for the same types of uses that

they're currently authorized for under a license. So, I would say that the analogy is already -- we already have what I would say maybe some type of a -- I don't want to use precept, but existing type of mechanism in place that already allows that for the case of an authorized user. I would think that this would be just analogous to a specialized case of an RSO.

MS. SALTER: Thank you. Mr. Walter?

MR. WALTER: If a person is named as the RSO for any given uses, how are you going to keep them from being an attestor? I don't think there would be any way for the NRC to justify stopping them if you've named them as an RSO on a license to be an attestor for that same -- to be an RSO for the same uses that they're already the RSO. I just don't see how legally there would be any way for you to stop it, anyway, without -- well, just leave it at that.

MS. SALTER: Any other comments on this suggestion? Anything from the webinar? No? All right. We do have a few minutes left. This is your opportunity to provide any comments on Topic 3, but if I don't see any, I'm going to go back and just ask the NRC Staff, Mr. Lohr or Dr. Zelac, if there's anything that they would like, again, to throw out to the crowd to get some feedback on.

DR. ZELAC: The issue of what the qualifications should be for these additional people named as RSOs on licenses has been discussed, and there is not a consensus. We have some positions suggesting lesser qualifications for those, and we have others who feel that the individuals should have full qualification to be named as any type of RSO.

I think it's kind of instructive to look at our current regulations, and this is just a comment for your consumption, our current regulations with respect to temporary RSOs, where we do permit the naming. In the case of an absence of the RSO, of temporary RSOs for a limited period of time in, essentially, the specialty areas. You could have a separate temporary RSO dealing with nuclear medicine, from the temporary RSO dealing with radiation oncology. So, there is a precedent for having people who have more limited background and training assuming responsibility for RSO duties in a limited area.

And with that in mind, I'd like to ask, I guess Mr. Lieto and Dr. Langhorst for just a little clarification on what has been said. Mr. Lieto, I believe you had said that each of the persons named as RSOs should have full qualifications, but some of them might have limited responsibilities, either based on

specialty, or geography, or whatever. Is that correct?

MS. SALTER: Mr. Lieto, I think I gave you the microphone.

MR. LIETO: Yes and no. Regarding the individual being designated as an RSO should have the same qualifications as the RSO, but I also stated that there may be situations like you were using in terms of the temporary RSO analogy, but I think that should have a different name associated with it. In other words, it shouldn't be -- they should not be called RSOs, but maybe there's another name that would designate that they would have, for lack of better terminology, a limited scope radiation safety responsibility, such as a nuclear medicine tech in nuclear medicine, maybe a medical physicist in radiation oncology, maybe a researcher, investigator, user in a research application in that type of a situation. Does that clarify what you're asking?

DR. ZELAC: That's half of what I'm looking for, and the other half is going to come from Dr. Langhorst. And, Dr. Langhorst, you indicated there should be -- I'm not sure what your position is with respect to qualifications. I think I missed that. Should they all have equal qualifications?

DR. LANGHORST: Well, I'm really glad you brought up the temporary RSO because, quite frankly, I had not -- I didn't have that in my brain as I've been here at this workshop in regard to this topic.

I am away from my licensee. My associate RSO, I granted him the temporary RSO duties, and he is fulfilling what I would be doing while I'm gone.

I think the point about naming RSOs on the license is to have that recognition by a regulatory body that this person has been named as an RSO on a license. So, it may be, as I was talking and thinking about this, and you brought up temporary RSO, that you have in the regulations already, that that could be used to provide that transition for getting hit by the bus, the RSO being hit by the bus, or as the example that I had said, the new RSO coming in and maybe not having the full experience with say an HDR unit, so we have a temporary RSO over that part that gets that RSO up to speed on it.

Maybe we should limit the people who are named on the license as RSOs to only those who would have the background, the training, and the experience to take over as the RSO for that license. And that would be dependent on the given license.

So, to answer your question more

specifically, Ron, is to -- it's -- yes, they should have the full requirements of an RSO for the given aspect of the program, be it all, or be it only a small section that is required for that use that the licensee defines, and works through with NRC as they get licensed.

DR. ZELAC: Then my follow-on question, and this relates to what I thought I had heard earlier, that I needed some clarification for, I believe you said that the duties that the RSO, whatever the name of the person might be, is going to assume -- should be identified, named in the license along with the individual. Mr. X is going to have responsibility for radiation oncology, and radiation oncology only.

DR. LANGHORST: Well, if they are named on the license, we have to provide NRC with that person's name and training qualifications, and what their duties would be. I mean, I think if you're going to have multiple RSOs listed on a license, you need to understand how is that licensee applying that to maintain the radiation safety program. So, you would have that naturally when you name that person to the license.

Now, as far as temporary RSOs, and I know I utilize that available regulatory allowance, I don't

-- I mean, that person has to be fully qualified to take over the radiation safety program. And that's how we utilize that.

But I think there's other aspects that you can carve out a certain aspect of your radiation safety program, and that strengthens a licensee's ability to maintain radiation safety in whatever they're doing. I'm not sure if I answered your question.

DR. ZELAC: So, what I think I'm hearing, and I think I'll just throw out for general comment by anyone, is that if the individual who is going to be named as an RSO on a license has full qualifications, that essentially that should be so indicated on the license, that they have full responsibility. Or if they are going to have limited qualifications, that would also be named on the license as a limited scope of responsibility as an RSO. Is that --

DR. LANGHORST: That's what I'm trying to say but, I guess, I would ask that you not get rid of the ability to have a temporary RSO.

MS. SALTER: I think we have a comment from Dr. Mower on this -- I'm assuming on this topic.

DR. MOWER: Well, sort of. It's on -- Herb Mower from AAPM. It's sort of on the qualifications

of an RSO, or others. Assuming they were in a program which has several things, nuclear medicine, radiation oncology, et cetera, et cetera, I don't think that the -- I do believe they should appoint an RSO person, whatever that institution or regulatory body decides that person should be named, same as you have a Chair of radiation oncology.

I don't think that person needs to really be fluent in all aspects of all the departments which might handle radioactive materials. The basic radiation safety criteria and philosophy carries through all of those, and the person would certainly have that knowledge.

In the specific areas where that person is not a super expert, then that's a good place for the role of some kind of a subsidiary, an assistant, or an associate radiation safety officer. And in radiation oncology which, of course, is the only department in a hospital which matters --

(Laughter.)

DR. MOWER: Darn. The person who does an excellent prostate permanent brachytherapy implant might be absolutely useless when it comes to the Gamma Knife, and yet -- so we need to talk about it and say well, yes, you're working with radiation oncology. I

don't fully understand every little intricate thing which happens there, but sort of the basic radiation safety aspects I would know of your program because I'm from nuclear medicine. That person should still be able to serve as RSO, but would delegate specifics relative to that section of the facility, or the practice, which would then require maybe additional expertise beyond the normal knowledge of radiation safety principles.

MS. SALTER: Okay. I'm going to go to Dr. Langhorst.

DR. LANGHORST: In a practical sense, that's already done, especially in a big medical use broad scope license. It's whether a person needs to be named on a license or not. And where that becomes important is if that person -- it makes it easier then for that person to become an RSO on another license. So, I don't think that the delegation of who can be overseeing parts of your radiation safety program, they all have to be named RSOs, or some derivation, but I think the important thing is what's the importance of being named as an RSO on a license, and how can that be trans -- moved from license to license.

MS. SALTER: I'm going to pitch it back to

Ron to see if you have any follow-up on this, on what you've heard here. Do you need any more clarification, or --

DR. ZELAC: I do need a bit more clarification from Mr. Walter. I could get you off line, but I think this might be beneficial to others, as well, so I'm asking you in public forum.

You mentioned in what you said in your earlier comments that at a broad scope licensee, the permitees of that broad scope would each be naming their own RSOs? I mean, that's quite different from my experience as RSO at a broad licensee.

MR. WALTER: Okay. Yes, we have a -- in our largest broad scope we have everything from diagnostic and your labs, to Gamma Knife. We have them then issuing permits to labs, to nuclear medicine, to therapeutic areas, and what they do in their permit is they name a radiation safety officer, or a person responsible for all of the stuff that they need to go and do an inspection of for that particular section.

The radiation safety officer for the broad scope is the only one that's on our license, our license. And that's who we go to when we come to do an inspection of their program. So, yes, they -- you might call it a responsible person, call them green

for all I care. They're a person who is the permitee's RSO. They're responsible for all the -- making sure that all the radiation safety aspects of that program are being performed the way they're supposed to be done. They're the responsible person for radiation safety for that investigator, for instance. So, when that broad scope's techs go out to do inspections of that permit, that's the person that they first go to, just as I would try and go to the RSO first.

Now, one of the -- if I might, one of the -- I'm hearing it on both sides here. And I want to make sure that I'm straight in what I'm hearing. I have a licensee that has three radiation safety officers. These are not called co-radiation safety officers because they're the radiation safety officer for diagnostic use, the radiation safety officer for therapeutic use, and the radiation safety officer for HDR, because I don't have any one person who meets all qualifications at that facility for all of it. So, I've got three individual radiation safety officers that are specified, So-and-So is designated radiation safety officer for uses specified in Sub-items so forth, which is all the diagnostic uses.

What I'm hearing is -- and what I think

we're trying to address here is the shortage of radiation safety officers that meet the qualifications to be named safety officer under the current regulations, and how can we increase that number, because we lose attestors when they move off.

So, if that licensee that I just described decided that they wanted to have three more radiation safety officers, a second one for diagnostic, a second one for therapeutic radioisotopes, and a second one for HDR, I would have six people named on there, and it would specify what they are the safety officer for. Is that what I'm hearing from both sides here?

MS. SALTER: Dr. Langhorst?

DR. LANGHORST: I'll go back to what I said at first. There has to be one person named that is the primary, or the RSO that you go to. And, quite frankly, I don't know it all. Well, maybe I shouldn't say that in front of all these regulators.

(Laughter.)

DR. LANGHORST: I mean, I don't know all the day-to-day details that my staff knows. So, they -- I mean, I have to know what they're doing, but I don't know all the day-to-day stuff. So, I would say -- I guess it really does come down to what are the qualifications required for a radiation safety

officer.

Now, my Region III folks know that I whined to them as this regulation was being developed and so on, that had it been in place when I went to Washington University, I couldn't be named as the RSO because I had not experience in Gamma Knife and HDR. So, I had experience in reading regulations, interpreting regulations, managing an overall radiation safety program. I can learn that very easily, and it's not that it's that big a detail to then okay, now I have to look at those regulations for HDR.

It is a big detail to make sure you're compliant, but that's something, given my radiation safety background, I was able to do. And other than doing the emergency training that our license had established for that, HDR, Gamma Knife, I mean, that's really easy for me then to take over. So, how fine a detail do we need to get in the regulations for doing this?

I mean, in my license the NRC knows I have a staff of health physicists, and technologists, and so on that help me do my radiation safety program. And I think it really comes down to who needs to be named on the license to help, perhaps, move from one

license to another much like authorized users do, authorized medical physicists, authorized nuclear pharmacists to be able to make sure there is not that shortage just because the rules are very prescriptive in who's allowed to become a radiation safety officer. Did I answer your question, Dave?

MR. WALTER: For a large licensee, yes.

DR. LANGHORST: Yes.

MR. WALTER: Okay? For the vast majority of medical licensees out there, no. We deal with — probably 35 percent of my medical licensees are private practice cardiologists, and the RSO is one of the authorized users. Okay? They don't have physicists. Most of these people are -- most of them are just plain diagnostic. Most of our medical licensees are nothing but diagnostic licensees. Therapy is consolidated into the larger facilities for the most part.

So, what I'm trying -- I would -- the concept of having a main radiation safety officer is, in my mind, the responsibility of management of the licensee, not the regulators. I would not be in favor of the regulators getting involved in tiering radiation safety officers, so this person can be the radiation safety officer, this is a radiation safety

officer in training, this is a newbie safety officer. I don't want us to get into that. I want us to just say okay, let's keep it simple. We have a radiation safety officer. We need to have a second one because we need to build in case there's something that happens in the future. We want a third one.

Well, let those people all meet the same qualifications, and be interchangeable in that license. All of them be named on the license, but be interchangeable on that license as the safety officer. Management then says, you know, Dr. Smith is the primary safety officer according to our internal organizational chart. So, when we show up as inspectors, we're going to know -- well, first off we're going to be told well, Dr. Smith is the primary person, but he's not here today, so Dr. Jones is the one. He's here at this office today, and he's one of our radiation safety officers, also.

I don't need to go away and try and come back only when Dr. Smith is there. I need to be able to go ahead and do my inspection, and Dr. Jones should be able to help me in doing that. And that's where I'm kind of coming from on this.

I don't want us to get into this big -- gosh, man, when I first got into this business it was

six pages for Part 35. That was it. That was all done on the licenses by condition, so the licenses were like a tome, but now we're up to 120 some odd, 130 some odd pages in our license -- in our rules for the equivalent Part 35. I don't need another few pages.

If were just to make one change and just say in the rule put a parentheses (S) next to radiation safety officer, and call it a day, I'm happy.

MS. SALTER: Thank you, Mr. Walter. I know we're a couple of minutes over into our lunch time, but I do want to make sure that we finalize the discussion. And Mr. Williams had raised his hand, and wanted to make a comment.

MR. WILLIAMS: Yes. Gary Williams, Veterans Health Administration. I guess I would just voice strong disagreement with your comments. They appear to be from an inspector, what's easy for an inspector. I have a Master Materials license. I have licensee and regulator responsibilities, so my focus on recommendation to having an assistant person who can step in when the primary person inadvertently loses the contract, and I can't get an interim situation taken care of, because that's restricted to

60 days in a calendar year. So, my focus, my recommendation is continuity of health care, focus to keeping patients treated and diagnosed, rather than what's good or easy for the inspection process of a licensee and a regulator.

I don't have circumstances where at a facility I've got three or four people who are fully qualified. Sometimes I'm lucky that I have one. I have only one facility, I think, where they have sort of an assistant RSO who is fully qualified, and he's waving. Stan, hi. But in every other circumstance we struggle to have one person, and often we have gaps. We're trying to fill those gaps because we want to have continuity of health care.

At that point, my focus is not what's easy for me as an inspector or regulator, my focus is on health care and continuity of operations. So, that's the reason I disagree with the perspective that's being offered by several, that this is important for us regulators. I think it should be more focused to what's good for continuity of health care.

MS. SALTER: Thank you, Mr. Williams. I think we're going to give Dr. Langhorst the final comment on this, and then we're going to have to wrap it up.

DR. LANGHORST: I agree with Dave Walter that there are different licensees and that's, again, who can become a radiation safety officer. And we talked a little bit earlier today about board certified authorized users, AMPs, ANPs, that may be someone who could be a radiation safety officer for a given license.

I totally agree with you that gosh, if the NRC could just put (s) behind radiation safety officer, that would help greatly, and then licensees and the regulators could decide how that works for each situation.

And is it true that if NRC comes in to inspect me and I'm out of town my staff can tell you to go away?

(Laughter.)

DR. LANGHORST: No, they still do that, but, again --

(Off mic comment.)

DR. LANGHORST: Your point is, is can those other radiation safety officers step in at that point and provide the regulators the access they need to do their inspections. Thank you.

MS. SALTER: Thank you. I think we're going to to wrap it up.

I also neglected, I apologize, after the panel session this morning to thank our panelists, so I wanted to make sure that we did that. We thank you for serving on the panel this morning. We thank Ed and Ron for helping to lead this discussion, and I hope everyone got some good information from it, and got to share their perspectives.

We are going to break now for lunch, and we will come back at 1:30, so please be ready to start at 1:30. And I believe this room will be locked once everybody leaves. But, again, if you have something particularly valuable you may want to take that with you. Thank you.

(Whereupon, the proceedings went off the record at 12:07 p.m., and went back on the record at 1:33 p.m.)

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

1:33 p.m.

MS. SALTER: On the record. All right. So we -- hope everyone had a good lunch. I would just like to take a quick minute to remind you to put your electronic devices on silent mode in case you were using them over the lunch break.

We are going to continue our format that we started right before lunch. And we are going to move to topic four. And like we do for the discussion on RSOs on NRC medical license we are going to approach Topic 4 the same way, brief introduction from the NRC staff, Ed Lohr and Ron Zelac, and then go right into audience participation.

If you've already filled out a blue card, you do not need to fill out another one. Just raise your hand so I can see that you want to make a comment. We have some microphones around the room. So I will either bring one to you.

If you're close to this mike in the center of the room, then of course, just walk up to that one. But please wait until I acknowledge you and call you up.

For those of you in the audience who don't go up to the stand-up mike, I would still ask that you stand up so people can see where you are talking from

and to introduce yourself so that both our transcriber and the folks on the webinar are aware of who is speaking.

We have about an hour for this session and then we're going to take a break. Without any further delay, I am going to ask Ed Lohr to get us started with some background information on Topic 4.

MR. LOHR: Thank you, Susan. Welcome back, everybody. I hope your lunch was as good as mine. That really wasn't a very good lunch. I went across the street to the Chinese place. Buffet and they serve you and -- Anyway, I'm sorry. Let's get back on topic.

Acronyms that I may use that you're not familiar with, IN for information notice and Mo-99 for molybdenum-99 (Mo-99). I think I'll use Moly the rest of the time I speak about it.

Under the current regulations in Part 35.204, one of the first eluate from a Mo-99 generator is required to be tested for breakthrough. Our regulations in the past had required that each eluate was to be tested. But because breakthrough was considered a very rare event, the NRC regulations were changed in 2002 to require only the first eluate to be tested. Please note though that testing the first

eluate is an NRC requirement and that the manufacturer has always recommended testing each of the eluates.

During October of 2006 through February 2007 and again in January of 2008, medical licensees reported generators had failed the Moly breakthrough test in that the ratio of the Mo-99 to technetium-99 metastable was exceeding regulatory limits. Some licensees were reporting the failure detected from measuring the first elution. And other reported normal or a first elution in the sequential elution ratios failed on the second, third and fourth and not necessarily in those orders but at various times.

In January of 2009, the NRC responded to the situation by issuing Information Notice 2008-22. The information notice strongly encouraged all licensees who used the Mo-99 generators to measure eluate for the breakthrough before the tech-99 metastable was administered to patients and to report any concentrations that exceeded the regulatory limits described in our regulations. It also encouraged voluntary reporting of each generator manufacturer to the NRC of notifications provided to them by medical licensees who had these issues.

The information notice also stated that the NRC staff would consider initiating rulemaking to

require Mo-99 breakthrough measurements of each elution to demonstrate compliance with the regulations rather than just the first elution as it is now. Also the NRC is considering an initiative and rulemaking to require reporting of noncompliance of the concentration limit.

So the NRC's proposing to amend Part 35 to require licensees test each elution before administration to a patient. This would be similar to what the regulations require prior to 2002. Also this would be in concert with the manufacturers' recommendations.

Additionally, the current NRC regulations do not have requirements to report when a test result exceeds the regulatory limits. The NRC was only made aware of the Moly breakthrough appearing later than the first elution because the licensee reported having difficulty in getting a replacement generated from a manufacturer when his generator elution failed to meet the breakthrough limits.

And so we had two speaking issues. We have the idea of amending the regulation to require the testing after each elution. And then we'll have a second discussion point of reporting requirements if they're adopted and how should we go about regulating

them if that's something that we would take the initiative to do.

With that, Susan.

MS. SALTER: Okay. So thank you, Ed. Again these are topics unlike yesterday where the NRC is a little further down the road. But they still need some comments and feedback as they continue the rulemaking process. And so we would open this up to comments either on these discussion points or other points related to this topic from both the webinar and folks in the audience. Don't be shy.

Dr. Mower and then we'll come back to Dr. Beasley.

DR. MOWER: Herb Mower AAPM addressing the second point. This appears to be more something which the manufacturers should be reporting through the FDA and other places. And I would recommend that it not become a reporting requirement for the licensee.

DR. BEASLEY: Charles Beasley. I was surprised years ago when you changed this. I didn't really understand. There's been a lot of rules that we've always wondered why they were there.

But this one, the test is so straightforward and simple. It doesn't take much time at all to perform. But it's I think going back to that original

requirement of doing it on each and every elution is the way to go.

As far as reporting, if I was going to put some sort of standard, I would probably be comfortable with just a telephone to the manufacturer and if you deem it necessary to the NRC.

I also wanted to make a comment on whether or not you're going to be proposing anything related to the strontium-rubidium generator especially in light of the recent problems that it's had.

MS. SALTER: Do you want to make a suggestion on that?

DR. BEASLEY: I suggest that a similar requirement be put into the regulations.

MS. SALTER: Thank you.

Sir, I'm going to give NRC. Did you need any clarification on those comments? I think they were pretty clear.

Any other comments? This is your opportunity. Dr. Langhorst. I think there's a microphone up there.

DR. LANGHORST: The manufacturer recommends that you do a breakthrough each day, breakthrough test each day. I don't think NRC has to go back to that. It's already being done. It doesn't

need to be put back into NRC regulations.

The manufacturer is a licensee. If they get reports of this problem, they're the ones that need to report to NRC or agreement state, whatever regulatory body that they report to.

I think as far at the medical use and the licensees at that end if something is wrong they go to the manufacturer. If there's an overall problem, the manufacturer notifies the regulatory body. So I'm in agreement with Herb Mower on this requirement.

I would also say that maybe the regulation is too prescriptive in only saying moly-tech generators. And, yes, we have the strontium-rubidium generator. But there could be other generators that are coming. And so this might be an opportunity to put a requirement in as far as a generic generator and then look to the manufacturers to be required to report problems to the regulatory authorities.

MS. SALTER: Okay.

Dr. Beasley.

DR. BEASLEY: Going along with that suggestion, maybe the requirement to be more generic would be to say that you are required to follow the manufacturer's recommendation on testing frequency.

MS. SALTER: Again this is your

opportunity to provide any thoughts or positions on this topic. Do we have anything on the webinar? We do have something on the webinar.

All right. Whoa. All right. That's up on the screen. Hopefully -- It's a little small. Can you make it a little bigger? There you go.

MS. RIVERA-CAPELLA: Okay. This is from Joseph Haepers. Lantheus Medical Imaging is one of the two North American generator manufacturers. Although our experience with actual Mo-99 breakthrough test failures are rare, there are many variables introduced during customer use that warrants testing each elution. Therefore, LMI supports the proposal that every generator be tested for Mo-99 breakthrough. The current USP test limit should be based on 12 hours post-elution as this is the eluate expiry.

We do not support the proposal to report failing Mo-99 breakthrough tests to NRC. It is important for the users to immediately report product's failures to the manufacturer. It is then the generator manufacturer's responsibility as required by the drug product license, FDA, to investigate each complaint and implement CAPAs as appropriate.

We believe the current system is

sufficient to ensure patient safety due to FDA reporting requirements and frequent audits. Having two regulatory agencies investigate drug product failures should not be necessary.

MS. SALTER: Thank you. And thank you for that comment from the webinar.

Anybody want to follow up on that or make another comment? I've give you some time to read that.

All right. What I'm going to do then is ask Ed and Ron if there were particular issues on this topic that they would like to hear and receive feedback on.

MR. LOHR: I'd like to --

MS. SALTER: It's Ed Lohr.

MR. LOHR: Yes. I'd like to comment on our webinar commentor. The particular instance that the NRC experienced with the Moly breakthrough was not reported to the FDA and then shared with the NRC. Our experience was that one of our licensees shared it with us. And we tracked it back. And we informed the FDA there was an issue.

And so I'm not familiar with the FDA reporting requirements as maybe some other of our tech staff is. But I know that somehow that system did not

function properly. Therefore, the NRC's proposing since we have control on our licensees the idea of having licensees either report to us directly or report to the manufacturer's distributor who would then report to the NRC directly.

So really my comment and question to the audience is if we are going to pursue that -- and I say if because this is all preliminary -- is it better for the licensee to report it to the NRC or is it better for them to report to the manufacturer and have them required to report to the NRC?

MS. SALTER: Okay.

Question to the audience? Mr. Lieto.

MR. LIETO: I would say the latter that you want the licensee to inform the manufacturer as soon as possible because there's obviously going to be other potential licensees that are going to be affected. And I think since the cause was with the manufacturer I think NRC influence should be on the manufacturer not the licensee to bear the responsibility of appropriate reporting.

And I think it was Dr. Beasley brought up about the PET generator issue and that seems to have worked right. I mean a problem was found by the user. It was reported back to the manufacturer. That was

then reported to users. And notices came out through the professional societies.

So I think the mechanism would appear to work. And I think reporting back to have the licensee being responsible to report to the NRC I think it's just an added mechanism that doesn't really solve the problem. I think it needs to go -- I think the responsibility is reporting to the manufacturer. Because if you have the licensee report to you, then the onus is going to be on the NRC to get back to the manufacturer and that just simply puts in more delays than are needed.

MS. SALTER: Any other comments on this?

(No verbal response.)

Any clarification requested from the NRC staff?

MR. LOHR: Can we have the slides back please?

MS. SALTER: Okay.

Thank you, Gretchen.

Which one did you want? Well, you have the remote so you can --

MR. LOHR: Right.

Dr. Zelac was indicating that it would be a good idea for us to perhaps get some feedback and

hear if we do adopt reporting requirements how much time should we allow if we went with as Ralph indicated the manufacturer/distributor notifying the NRC. Should it be a 12 hour notice? A 24? A three day? What sort of time frame would be appropriate? And we want to get the public's input on that.

MS. SALTER: Okay.

Dr. Mower.

DR. MOWER: Herb Mower with the AAPM. I'm not really sure what kind of time frame there should be. But I would recommend that if the reporting goes from the licensee, medical licensee, the user to the NRC with time frame A NRC should then write into the regulations that the NRC will notify the manufacturer within an equivalent time frame and not be longer in reporting to the manufacturer.

Because what we're worried about is word getting back through whatever avenue to the manufacturer to make sure that things do not go out to other institutions and get missed. And I think it becomes a little bit onerous to say that the licensee has to start calling up the manufacturer, the NRC or the state and da-da-da-da-duh on something which they noticed but was not something which they created.

MS. SALTER: Thank you, Dr. Mower.

Other ideas on this? Mr. Williams, I think you can get the mike. There you go.

MR. WILLIAMS: Gary Williams, Veterans Health Administration. If there's any required report, I strongly suggest it not require the licensee to call the NRC operations center such that a report is posted publicly identifying a licensee as perhaps having a problem when really the licensee is, might I say, the victim.

So I would not support any report the operations center. Excuse me. And also say that because in general as a medical licensee when we have called the operations center unfortunately the staff there has no medical expertise. And they tend to ask a whole series of questions which aren't pertinent to the health physics or health and safety circumstances because they're poorly trained in medical issues. And that just becomes a difficult circumstance. And then there's demands for additional information which really aren't appropriate for the licensee to have.

So I strongly support any reporting requirement to not involve the operations center and not to be identified as a public issue for the licensee given that the licensee really is a victim of circumstances and has actually done the appropriate

thing to make the report.

MS. SALTER: Thank you, Mr. Williams.

I believe we have a comment from the webinar. So we're going to give Gretchen a moment to pull this up on the screen so you can see it.

Do we have any other comments from the audience? Mr. Lieto, do you want to go ahead while we get this question up?

MR. LIETO: Regarding the timing of reporting, I think you have to take a step back and look at the practicality of this. If somebody gets an elution that fails, they're basically dead in the water. They can't do any diagnostic imaging.

They are going to report that asap. I mean if they're not you kind of wonder about the practice itself.

The recommendation I would have would be that this is really a practice of radiopharmacy. And that I would encourage and suggest to the NRC that they either through the Society of Nuclear Medicine's Radiopharmacy Council or one of the other professional radiopharmacy organizations get their recommendations. And I think that should be what the NRC should go with.

MS. SALTER: Thank you, Mr. Lieto.

Are we ready with the question, Gretchen or?

MS. RIVERA-CAPELLA: This is Joseph Haepers again. Once again, the generator is a drug product that is under FDA license. The incident cited should have been reported to them. A reporting phone number is provided to all of our customers.

MS. SALTER: Okay. Thanks for that comment from the webinar.

Any other comments from the audience so far on what we've been talking about?

(No verbal response.)

All right. Then I will go back to Ron and Ed to see if there is another area that they are looking for some feedback on.

(Off the record comment.)

That's it. All right. Well, we're a little too early for a break because we've only been here for half an hour.

So I'm going to turn to Mike Fuller and ask if he wants to go into the fifth topic which is really a discussion on the 28 or so other remaining items. We can start that discussion and then take a break in about a half an hour or we could take a break now and come back and do that. But that wouldn't give

us much of a break later.

MR. FULLER: I think Gretchen has something.

MS. SALTER: Oh, do you have another comment? That gives Mike time to think.

MS. RIVERA-CAPELLA: All right. This is Steve Mattmuller. Ralph is right. Ralph is right.

(Off the record comment.)

This problem was first found by a pharmacist who already performed the check of a per elution basis in accordance with the manufacturer's recommendation. If the limit is exceeded, the elution can't be used. So patients are not at risk. Everyone should know when this happens, users contact the manufacturer immediately.

In essence, they have lost their source of technetium-99m. They now need a replacement generator as soon as possible. Appropriate reporting is already in place. Additional reporting by the licensee direct to the NRC would be duplicative.

And then he says, "Sorry. Trouble with my cut and paste. I didn't mean to say Ralph is right twice."

(Laughter.)

MS. SALTER: All right. Any comment on

that comment? Dr. Zelac.

DR. ZELAC: Not a comment. Just a question. Am I correct that there appears to be a consensus that reporting by the licensee to the manufacturer as is already required or recommended by the manufacturer is the way to go and that reporting by the manufacturer to the FDA should be left as is without NRC being involved at all? Is that what I'm hearing? I guess so.

MS. SALTER: How many people say that's what he's hearing?

Mr. Walter.

MR. WALTER: And one more follow-up question on that. Since right now the rules state that you have to do the first elution. And while it may be recommended by the manufacturer to do every Eluate but they don't, what happens when a patient gets one that, gets an injection that, has a high level? Now we're not talking about the same thing, are we? Are we talking about something that needs to be? The NRC needs to know about? I mean I'm just asking. I don't know.

MS. SALTER: All right. Anybody want to follow up on that or on Ron's question? Is what Ron heard what you all were saying for those people that

spoke up?

DR. LANGHORST: Sue Langhorst, Washington University in St. Louis. This may be a licensing topic with the regulators and the manufacturers where that reporting requirement is in their license. I don't know. It may not be necessary to put it in the regulations. I offer that up as a potential suggestion.

I would say again that this I think is an opportunity for NRC to have the regulations be prepared to go further in the future and talk about this in a more generic sense than just naming every generator system. Because there may others that will be coming up and then they're not listed in the regulations. So that's my strong suggestion.

MS. SALTER: I'm looking to some of the folks that had commented on this. And since I'm not hearing any I'm going to say that what Ron thought he heard was what you wanted him to hear. I'll go to Mr. Lieto. Did you have a --

MR. LIETO: Well, yes. I think that what my understanding is is reporting to the manufacturer and the manufacturer reports to the FDA. I think a suggestion, just a takeoff on what Sue was just recommending, would be to contact the manufacturer

licensees and clarify "Is it your understanding that a generator breakthrough regarding if it's Moly or other generator -- Is it your understanding that a report back to you requires you reporting to the FDA?"

And if they come back and tell the NRC that "No, that's not the case" or "Yes, that it is" because I thought from the Lantheus representative, the impression I got, was that they are required to report back to the FDA. But if they tell you as a licensee that they're not required, then obviously I think that would be somewhere where NRC could take action with the manufacturer licensee. But I think the user licensee needs to be out of that loop altogether.

MS. SALTER: Dr. Beasley.

DR. BEASLEY: And one more comment about that is what is their time that the manufacturers require to notify the FDA. I mean if it's a long period of time it's not going to help us. It's not going to help the nuclear medicine community. So that time needs to be inquired about how soon they're supposed to close the regulatory cap.

And I'll say I agree with Sue about trying to make a more generic policy on generators that would be inclusive.

DR. LANGHORST: Sue Langhorst, Washington

University in St. Louis. The manufacturers need time to investigate the issue because it may be just a problem with that generator licensee not milking something correctly or not seeing something. So they need some time to really see if there is a problem.

But I think that if they find a problem, I don't know what FDA -- if there is a time frame with FDA. But I know the manufacturers are very interested in getting that particular licensee back on track and have a new generator there as soon as possible. And they want to make sure that their other customers have working generators.

So I don't have a good answer for what that time frame should be. But just an acknowledgment that the manufacturers need to have some time to review it. They shouldn't just "Oh, we have a notice." And then it shouldn't be assumed that oh they pass that notice on to the NRC right away without investigation.

MS. SALTER: Follow-up, Ron?

DR. ZELAC: Just on what I just heard at the very end. Pass that notice onto NRC or to FDA?

DR. LANGHORST: Yes.

DR. ZELAC: Okay. And if I could ask one more question.

MS. SALTER: Sure.

DR. ZELAC: My impression is that there is consensus among this group anyway and the people on the webinar that testing of each eluate is an appropriate thing to be required. Is that? Okay. Thank you.

MS. SALTER: Anything else from the webinar?

(No verbal response.)

Do you have a comment or? Okay.

While as Gretchen works to get the comment up on the screen which I think is really helpful to be able to see those in writing, I will give this audience one last chance to add to the discussion that has already taken place.

(No verbal answer.)

Once we get the webinar comment up, we'll probably close out this topic and we're going to go into the fifth topic which is actually multiple topics. And it's opportunity -- Although we had picked specific topics like attestation and the Ritenour Petition and naming RSOs on NRC license, there were a number of other areas that the NRC is also looking at and we wanted to be able to provide time for individuals to provide the NRC their

perspective positions, feedback, input on those topics as well. So we're going to get started with that once we finish closing out this discussion with the comment from the webinar.

MS. RIVERA-CAPELLA: Okay. Joseph Haepers. We have to report to the FDA if patient safety is at risk. Most of our high Moly complaints have been measurement errors and not an actual problem. We need to investigate first.

MS. SALTER: Okay. So I'll give one last opportunity for anyone to comment on that. I'll ask Ed or Ron if they have any -- need any further clarification. Anything that they heard.

MR. LOHR: I'm interested in the group's thought of time frame. If I'm understanding and I believe that Dr. Zelac fed it back to you the idea that the current system that's in place for the manufacturer to report to the FDA, the FDA investigates and then sends on to the NRC, I can't tell you the time frame. I could guess that it's not days. I would guess weeks.

Is that acceptable to the medical community not to have a feedback on an issue? What is the acceptable time frame is really what I'm asking. Is 24 hours? Is it three days? Is it two weeks?

What sort of time frame is acceptable?

MS. SALTER: Anybody have a position on that? Ideas on that?

Mr. Williams.

MR. WILLIAMS: I would recommend 24 hours after discovery which is consistent with making a report of a medical event. I think as a practical matter as Sue mentioned people are going to be having to contact the manufacturer rather soon anyway to get a replacement generator. So 24 hours would be more than enough time to allow people to make a report and not be considered deficient in their reporting given that as soon as they can't use their current generator they're most likely going to be asking for a replacement.

MS. SALTER: Thank you, Mr. Williams.

Any other suggestions on this or comment? Does that work for everyone?

(No verbal response.)

I see some heads shaking. All right.

Anything else on this topic, Ed or Ron?

(No verbal response.)

Anyone else from the audience?

(No verbal response.)

Nothing else from the webinar?

(No verbal response.)

All right. So we're on to our final topic. You guys didn't have a presentation for this though. Correct? Or did you?

MR. LOHR: I do have a slide or two or three or four or seven.

(Laughter.)

MS. SALTER: Okay.

MR. LOHR: Thank you, Susan.

Our last topic of the day is what we call the additional items under consideration for rulemaking. Many of these items the NRC considered minor in nature and such.

I guess first do we have new acronyms and, yes, we do. The SSDR, the sealed source and device registry. So I want to make sure everybody is aware when I say SSDR what I'm referring to. But we are considering rulemaking additional items in Part 35 to be changed.

I think Mike put this out yesterday morning and again this morning that the preliminary language has been published and made available in the back of the room or at registration rather as of yesterday morning. And it's been available to the public for a number of weeks.

Not everything that was in the Federal Register notice has preliminary language. But what we want to do is really open this up to your folks after I briefly run through this to tell us what you'd like to talk about. And, for example, I know that Dr. Langhorst want to talk about the Canadian issue with the physicians.

So let me go through these few slides. And we'll get on with things.

Just some of the highlights of the additional items are to lower the paperwork burden for certain license applications, to do clarifications of certain T&E requirements. One of the items that I consider very important is the expandability of used sealed source and devices approved, the SSDRs.

We also want to talk about the expansion and clarification of the alpha emitter categories. And again as I said there are other minor changes.

I do want to say as always that public comments are welcome on these proposed rules. Now this is preliminary language that we've asked for comments on. And I believe that runs through September 6th. That's available for you to comment on.

We encourage written comments. Although

today's meeting is transcribed and we will capture what you have today, many times when you have a chance to write them many other points come out. And we really appreciate that opportunity to see those.

And as Mike also said earlier and I have it on the slide here, you can submit those comments at regulations.gov using the docket number NRC-2008-0175. And it's September 15th. Thank you. My slide tells me my date.

I do want to not caution you necessarily but to remind you that the preliminary draft rule language is subject to significant revision based on the comments we receive today, the public comments, and, of course, the NRC's working committees before this will go out as a proposed rule.

And with that then I'm really going to bump it back to you, Susan, to any particular items that the audience would like to bring up from that preliminary language that we have published or that was in the items in the FRN.

MS. SALTER: All right. And you do have a copy obviously of the FRN in your packet.

Dr. Mower, get us started.

DR. MOWER: Herb Mower with the AAPM. I am looking at 35.14, Notifications. I'm looking at

page five of the document that was handed out, specifically Item No. 6. And I would raise the question to the NRC. Do we really want to have something which only applies to manual brachytherapy rather than any sources which are coming out?

And I would also raise the question that I am concerned with the last statement there. "The notification must include the manufacturer and model number of the sealed source" -- maybe no real problems there -- "the isotopes" -- certainly yes -- "and the quantity per sealed source."

I may have in the license that we're going to use I-125 of certain activity for a prostate implant. And for whatever reason for next week that activity may not be available. The doctor doesn't wish to put in quite as high an activity per seed. And all of a sudden I come up and am I going to have to say to the doctor as a result of this regulation "I'm sorry you cannot do your implant next week because that is not the activity of per seed that we have in our license." And I think we need to look seriously at that wording there and strike "the activity per source" in there because it will pose some real problems there.

MS. SALTER: Okay.

Ron. And also if you -- I have some extra documents of what Dr. Mower was referring to, the proposed rule language. If you didn't get a chance to pick it up, I have it back here.

MR. LOHR: Susan.

MS. SALTER: Yes.

MR. LOHR: Could I ask when they speak to the preliminary language they would give us the actual section number and not just the page number please? That will help the people who are also on the webinar. For example, I believe he was referring to 35.13. Is that correct, Dr. Mower?

MS. SALTER: Fourteen.

MR. LOHR: Fourteen.

DR. MOWER: Actually, Dr. Mower did in his comments. And if we would play back the tape stating it was 35.14, that it was on page number five, and it was Item No. 6. So I think I really did cover all of those things. And I guess my suggestion would be thank you.

MS. SALTER: Thank you.

A clarification or further comment on that from the NRC staff? Dr. Zelac.

DR. ZELAC: The purpose of this section 35.14 is to permit the licensee to go ahead and do

certain things even though they may not agree in totality with what appears in their licenses. This permits them to go ahead and do something and then after the fact let NRC know that this has been the case.

So with the example that you had given there would be nothing to preclude your licensee from ordering seeds of a different strength and utilizing them as long as notification was made within 30 days later.

DR. MOWER: In that case the way it's proposed in the regulation it looks like it's a rap of the knuckles rather than allowing you to do it and then making a correction afterwards to the NRC. And the language needs to be changed.

MS. SALTER: All right. I have a comment over here. I'll just ask you to stand up and introduce yourself.

DR. POSTON: I'm Jay Poston from MD Anderson. We had this come last week. We wanted to order some iodine seeds or 15 millicuries. Our license said it was 10 millicuries. So we did a lot of talking back and forth to the state and with the physician and with the physicist. And through our wonderful state agency we were able to get an

amendment made Monday afternoon so we could do the treatment yesterday.

So this would have been nice. If this was in the rules, we could have gone ahead and proceeded with that order, let the state know what's going on and got the amendment made in maybe not such a rush fashion. So I like the words here where it allows you to deviate a little bit from what you're allowed to have.

MS. SALTER: Thank you for that.

Did we have a comment? Mr. Williams, I think there is a mike over there.

DR. ZELAC: Susan.

MS. SALTER: I'm sorry. We have some clarification. Dr. Zelac.

DR. ZELAC: Possibly. When I made my response to Dr. Mower I had presumed that the activity that was going to be ordered was less than the limit on activity that was already indicated in the license. However, in this case, that was just described of wanting to receive sources of a greater strength than were indicated in the license was a little different story.

Our licensing folks should be able to comment on that. But I would think that as long as

the activity was less than that was listed in the license that would be okay. If you wanted to exceed it I'm not sure that notification would be the appropriate way to go.

MS. SALTER: Follow-up? Mr. Williams?

MR. WILLIAMS: Gary Williams, Veterans Health Administration. I refer to Section 35.12 beginning on page two and continuing on page three. This is a general comment.

I recommend the section be revised to provide an opportunity for amendment requests or notifications to be made electronically and that there be a specific discussion and statement that it can be done rather than the way we've done it for these many years where NRC requests and demands in fact that it be in writing and it has to be in a letter. It has to be faxed. I think it's a good opportunity to change the regulations to allow us to go into the more modern forms of communication.

MS. SALTER: Thank you, Mr. Williams. Oh, Mr. Williams again. Well, first let me -- Are you going to go onto another topic?

MR. WILLIAMS: Yes.

MS. SALTER: Okay.

MR. WILLIAMS: I was going to the next

page.

MS. SALTER: Okay. Before we do that, did anyone want to follow up on that? On his first comment?

(No verbal response.)

No. Okay. Why don't you go to your second one.

MR. WILLIAMS: My next comment is on page four under the section 35.13. There's a new subsection added, Subsection H, and it provides an opportunity for someone to use something that is listed in the sealed source and device registry.

Unfortunately, licensees don't have access to that registry. So my recommendation is you delete this section as being impractical since it doesn't save the licensee any time. They have no basis or method to confirm something is in the SSDR.

Now often as in the past you might get a copy of an old version of something that was in the SSDR from the vendor. But as the licensee you have no way to prove that that actually continues to be listed that way. So NRC is providing an opportunity for someone to do something which is as a practical matter they can't do.

MS. SALTER: Thank you, Mr. Williams.

Did we need any clarification or follow-up on this?

MR. LOHR: I would like to address that if I could, Susan.

MS. SALTER: Okay. Mr. Lohr.

MR. LOHR: As you're aware, Gary, the SS&D library is not available to the general public. However, if you as a licensee are considering buying a source or a device, the distributor or manufacturer can provide you with the current SS&D for that device or source. They have that information.

MR. WILLIAMS: My comment is that you say that I have to know that it is listed there. Getting a copy of something which a salesperson tells me is from the SSDR is a bit problematic to make sure that I am in explicit compliance with this regulatory requirement since I would have no firsthand basis to confirm that.

I will stipulate that as a master materials licensee I do have access to the SSDR. So this is not a problem for the Veterans Health Administration. But it was a problem before we did have such access. I didn't have a lot of confidence in what a product or vendor salesperson would give me because often the information wasn't really current

since SSDR information changes over time.

MS. SALTER: Okay. Any other comments either on the proposed rule or any of the items in the FRN?

(No verbal response.)

Nothing on the webinar?

(No response.)

Dr. Mower.

DR. MOWER: Going back to 35.14, the notifications, again number six on page five, and relative to the comment that was made from Texas that they were ordering a higher activity per seed and this was indicated as possibly not being what was meant by section six, as long as the licensee does not exceed what their license allows them to have for a total quantity in any given category I don't see why we should be restricted whether we go up or down in the amount of activity per seed as long as we have not exceeded our license requirements.

MS. SALTER: Any clarification needed on that? Follow-up?

(No verbal response.)

All right. Next comment. Kind of quiet. I'm going to get you some snacks in a minute. But I'm going to make you work a little bit more.

I'm going to go back up to Dr. Zelac and Mr. Lohr and ask them if there were specific areas that you were looking for feedback on.

MR. LOHR: If it's okay at this point, I'd like to address the issue that Dr. Langhorst brought up on the Canadian physicians.

MS. SALTER: Okay.

MR. LOHR: First we have no preliminary language for this issue. The Canadian residence programs are recognized by regulations. But our problem is that they do not have an authorized user.

And an authorized user in Part 35 is defined as a dentist, a physicians, a podiatrist, etc. And it's further in our regulations defined that these doctors must be licensed in the U.S.

And so we have problem with our regulation right now in the sense that the authorized user to provide the supervised work experience must be U.S. trained. We are struggling to try and work this issue and are soliciting input from the public on how we may best address this issue.

MS. SALTER: Okay. So I'm going to give the NRC staff another opportunity to pose a question to this audience on any of these issues that you're struggling with or that you're looking for additional

feedback on.

Mr. Lohr.

MR. LOHR: I'd be glad to -- Another issue that came up is in the preliminary language on page seven. It's 35.65 and you'll see it in red little letter a-12. And this is the issue of transmission sources in use with patients.

We are attempting to clarify that transmission that are used in various pieces of equipment are to be used under the supervision of an authorized user when a patient is in the beam, not when the transmission source is being used for calibration or other functions.

In addition, we have proposed a change that would prohibit a licensee from bundling or aggregating single sources into a much larger source. We have received one comment back from the public on that. And because of that I wanted to see what the audience here felt about those issues.

MS. SALTER: Dr. Langhorst.

DR. LANGHORST: In the summary that you gave us from the New York workshop, I was very glad to see that my comment that came through on the webinar was included in that. If you're making that change for transmission sources and now putting that under

authorized use of 35.500 that the training and experience portion of 35.590 include that a person could be authorized for this use if they were already authorized for 200 level uses.

I'd like to amend that to say also that it should include users that are 300, that are approved for 300 uses, 390 I should say. And I say to put that in there explicitly so that it relieves those physicians from having to get experience in eluting a generator which they have to do if they're going from 300 to 200. So I would add 300 in there.

On the topic of elution of generators, I really wish that requirement would be dropped from 290. I know I jumped around there, but that's just -- I thought it was a pertinent point to put in there as I was talking about it.

Thank you.

MR. LOHR: Can I get a clarification, Dr. Langhorst?

DR. LANGHORST: Sure.

MR. LOHR: Are you suggesting that the language, what we put in the preliminary rule language be struck or the entire provision be struck on having the generator training?

DR. LANGHORST: I think it should be

struck as far as they have to have that experience of eluting a generator. I don't think it's necessary for an authorized user.

MR. LOHR: Thank you.

MS. SALTER: Any other comments? Do we have anything on the webinar?

(No response.)

No. Then I'm going to take the liberty to go to the NRC staff. Dr. Zelac, you had also wanted to make a comment I think when Mr. Lohr was making his comment.

DR. ZELAC: Lost now.

MS. SALTER: Sorry.

All right. So let's do this. It's 2:30 p.m. Let's take a break.

Mike, we had a 15 minute break scheduled. Do you want to give a 30 minute break? To give folks time to look over this or do you want to stick with the 15 minute break?

MR. FULLER: Let's go ahead and I think unless somebody wants to talk me out of this my way of thinking is to go ahead and take the 15 minutes.

MS. SALTER: Okay.

MR. FULLER: And then if we finish up a little bit early we finish up a little bit early.

MS. SALTER: Okay. Mike says we'll take a 15 minute break. So we'll get back at 2:45 p.m. and we'll finish this topic. And if we get finished a little early we get finished a little early.

But please come back. Take a look at the information and see if there's anything else that you want to bring to the NRC's attention. Off the record.

(Whereupon, a short recess was taken.)

MS. SALTER: On the record. All right. Welcome back. I hope you got some coffee and some snacks. Got some energy back after lunch.

As you know before the break, we started Topic 5 a little early and had some comments and some discussions.

And we are going to jump right back into that discussion. And these are the additional items that are under consideration for rulemaking as outlined both in the draft proposed rule language. I have some extra copies here if you need one as well as the Federal Register notice outlines the additional topics.

So although we had some specific topics that we really wanted to have more in-depth discussion we also wanted to use this time to allow you the opportunity to provide feedback on all of the issues

that are under consideration for rulemaking.

I will pitch it back out to the audience to see if there are any additional comments. Again this is your opportunity to comment on anything. But I do know that NRC staff also has some specific areas. So I'm going to give them an opportunity to do that after I open it up to the audience to talk about what you want to talk about.

(No verbal response.)

All right. So I will go back to NRC staff, Dr. Zelac and Mr. Lohr, and ask you to throw something out to the audience for consideration.

MR. LOHR: We are very interested in getting some feedback. This will be in the preliminary rule language. It's actually on page 13, 12 and 13. But it begins on page 10. It's 35.390(b)(1)(ii)(G). Got to love these regulations.

But it has to do with the categorization of isotopes or I should say use of isotopes that require additional cases be done by an authorized user. And we are proposing to expand and clarify these categories of cases that an authorized user must have experience with to demonstrate your ability to use this particular by-product material in therapy.

The current regulation has categories such

as "Other" that includes many things. And we are proposing to expand those out. The primary reason is, for example, our alpha emitters right now. We think these are inappropriately categorized. For example, a radium-223 source is categorized with beta emitters such as P-32 where the primary use is actually the alpha emission.

And so these new categories we're proposing we want to reflect the specific safety and training considerations for the administration thereof. And we're interested in feedback from you folks on whether we got it right, we got it wrong, we're out in left field somewhere.

MS. SALTER: Mr. Williams, I think you had a comment.

MR. WILLIAMS: Gary Williams, Veterans Health Administration. I ran this by my physician advisors and their concern about this is that you appear to be requiring someone to have case experience that they would likely have gathered in a residency program for procedures which aren't now commonly completed in all different types of facilities.

So it might be better and our recommendation is that you continue with a more generic requirement rather than having this

specificity which is exceedingly difficult to conform to in order to get an authorized user especially on something that might be more investigational.

The practical outcome of this might be that there would be a lesser ability to have new procedures at some facilities because you couldn't qualify an authorized user unless that person in a very expensive way went off to one of the two or three places that actually did that procedure. So I think in general we would want to depend on the local facility's clinical staff to approve users and look at some more detailed requirements rather than that being regulatory space.

MS. SALTER: Thank you, Mr. Williams.

Dr. Langhorst.

DR. LANGHORST: I know when this topic came up with the Category I think it was D of the all others I had no idea that meant alphas or that NRC had intended that to mean alphas. The only time I learned about that was reviewing ACMUI transcripts about past meetings. So what is there is already confusing.

I think when NRC redid the regulations of Part 35 in 2002 they got it right. You guys got it right in specifying moving the I-131 diagnostic procedures into meeting written directives and then

the I-131 therapy.

And my perspective on that has always been those were called out separately because there are many physicians who want to just use one or maybe both of those categories. And they don't want to know all this other stuff. So that made sense to me.

But parenteral administration, why doesn't that just cover all the rest? I mean if it's parenteral just as Gary was saying make that generic and I think it's good that that individual has to have both the levels of I-131 -- Well, they don't have to have experience in the lower level of I-131. Because if they get it in the higher, they already count for the lower.

I get very confused about all this. So I think I would say get rid of (d) and put (c) as all the rest of the parenteral administrations. My recommendation.

MS. SALTER: Mr. Walter.

MR. WALTER: My understanding or guess on this is that the reason that they've added this is risk-based. Correct?

MR. LOHR: That is my understanding, sir.

MR. WALTER: Okay. And so what they're doing is they're just equating that there's a higher

risk to or different risk to the alpha compared to the beta low energy gamma. Correct?

(No verbal response.)

Okay. Back long ago when we first started this we talked about the fact that there's going to be alpha emitters that are going to start being used. They had already begun testing in fact for cancer therapies. And the discussion was "Well, there isn't anything now. So we won't just be worrying about putting it in the rules."

I'm just trying to give you a little historical perspective involved in what was going on in that rulemaking process. Because there wasn't anything they said "Well, we're going to put in a thousand. We're going to put it in 35.1000 when it comes out." And that was how we moved past that and went onto another place.

It sounds to me now like they're coming back and saying, "Okay. We know it's there. We need to address it now based on risk." And that's I think why we're seeing what we're seeing here.

And I would like to hear what others have to say about is this correct in assuming that that risk is higher or different for the alpha emitters than it would be for the other parenteral uses.

Because that I think would help the NRC considerably.

MS. SALTER: Mr. Lieto, are you going to follow up on this comment?

MR. LIETO: Yes.

MS. SALTER: Okay. Good.

MR. LIETO: To follow up on Mr. Walter's comment, the risk issues are different. But the radiation safety aspects on high energy particulates from radionuclides to me fall into the same category of risk.

The real safety issues here is the parenteral administration. It's getting this stuff from the vial or syringe into the patient. Okay. That's a very -- It's a one-time-only shot. You can't risk subbing this or any of those aspects. And so that's the real safety aspect in the administration of these.

I would support Mr. Williams' and Dr. Langhorst's comments that the items in three, four and five there should be grouped together as parenteral radionuclides with primarily high energy particulate emissions or something along that nature might be a suggestion. But I think they should all be grouped together.

I am very glad that when this was first

discussed you did not put it in 1000. And I think that one other comment along that line is I would really, really strongly encourage you to please keep it out of 1000. But I think that as far as the risk and safety issues go that you could lump all three of those categories together and I think that it would be perfectly appropriate.

MS. SALTER: Okay. I'll go back to NRC staff just to see if you need any clarification on those two points.

(No verbal response.)

Okay. And we'll go to Dr. Langhorst.

DR. LANGHORST: If we lump it together, I don't -- we're not saying we don't need to be trained on what alpha emitters do and what the risks are for that. I think that's covered by the licensee's requirement to provide training for that individual on what they're doing.

And so I'm not saying that "Oh well, it's a higher level of risk and we're not recognizing that." We definitely are recognizing it. But we think we've got that covered in the licensee's requirement to make sure that it's users, physicists, whatever are trained in what they are specifically doing. So that would be my suggestion on that.

MS. SALTER: Dr. Welsh.

DR. WELSH: Thank you. I recall when this was first discussed at the ACMUI. Part of the reason for the discussion in addition to the reasons that are being discussed presently, one of the reasons was that the language in existence at the time did not cover some of the newer radiopharmaceutical therapies that are exploiting the alpha radiation or Auger electron emissions, etc. So it was recommended that additional language be added. And that's what has been done.

However, I would agree with some of the statements made here earlier that the more generic and all-encompassing the wording the better. So instead of having section four, section five and section six that as Dr. Langhorst said keeping this generic might be preferable.

If NRC does wish to keep them separate, I would not advocate insisting on three cases in each one of the categories but perhaps adopting something similar to the footnote in the section right above it saying that experience with at least three cases in category (g)(2) also satisfies the requirement in category (g)(1). Meaning that if you have experience with the higher activity iodine-131 it is sufficient for use with the lower activity I-131.

I would first recommend that we lump these together. But if not it might be preferable to say that if an individual has experience with beta or high energy photons that would be sufficient for any of the other newer modalities such as alpha emission and Auger emission that might come along.

MS. SALTER: Follow-up from NRC staff on that or request for any further clarification? Mr. Lohr.

MR. LOHR: Dr. Welsh, I think I understand your comment. My question would be if we look at how we have proposed the breakout and if we take the path of keeping them broken out so to speak -- and I'm not saying we will -- what would you suggest would be the higher risk of these items that would then say if you are three cases in that particular higher risk then the lower risk one then also follows such as we did with the iodine.

MS. SALTER: Dr. Welsh.

DR. WELSH: I would probably respond that the highest risk would certainly be the high energy photons of 150 or more with the beta being a close second in terms of radiation safety issues. And as I think Mr. Lieto pointed out it's the parenteral administration that is the most challenging and

technically difficult and important aspect of this in terms of radiation safety aspects. And if high energy photons and beta and low energy photon experience has been documented, I believe it should suffice for the others that might come along.

MS. SALTER: Thank you.

Did you want to follow up on that or?

MR. LOHR: No. Thank you very much.

MS. SALTER: Okay.

Dr. Langhorst.

DR. LANGHORST: If we keep them broken out as what you all have provided in the draft regulatory language would then that be the fine point that's listed for authorized users that you're approved to do this and this one but not this one as far as parenteral administrations go? That again is a paperwork burden that I think is already covered that a licensee has to provide training for its users and so on in the specific uses that they're asked to perform.

I would hate to have to have that finer distinction on licenses. It would be very confusing to me.

MS. SALTER: Follow-up on that?

(No verbal response.)

Do we have anything on the webinar? No.

All right. Further comments on what we've just talked about or any other item under consideration for rulemaking?

(No verbal response.)

This is your opportunity to provide your comment. Mr. Lieto.

MR. LIETO: There was something I wanted to address, but it's not in the marked-up rules that we've been following. It was in the Federal Register.

MS. SALTER: Correct. That's absolutely fine. We want to hear on those items as well. So please go ahead.

MR. LIETO: This is actually the number one item under Topic 6 in the Federal Register. The issue had to do with an authorized medical physicist to perform decay corrections for strontium-90 sources. Now granted these aren't very common utilization of brachytherapy. But it's the only 400 use that specifies an authorized medical physicist.

And the question I think being posed by NRC staff is to remove authorized medical physicists and make any qualified medical physicist for lack of a better term if I'm not reading too much into this be allowed to do these decay corrections. And the AAPM

has some real concerns with that on two fronts.

One is there were a number of misadministrations several years ago with these sources that got to improper calibrations, a number of other aspects associated with their use. Although the decay correction in and of itself seems like a minor issue, a lot of brachytherapy physicists are concerned about not requiring an authorized medical physicist involved with this. Because when they look at a strontium-90 source it isn't just the decay correction. They look at the calibration, the currentness of the calibration, leak testing, a number of other aspects that go along with these sources.

And the other reason that I would like to state a concern about this proposed deletion of an authorized medical physicist is that there is a new device out there in investigational mode that's used for age-related macular degeneration that uses a strontium-90 source for treatment. And we would be a little adverse of changing the requirements for an authorized medical physicist not being necessary for this kind of a device also. That's one thing that I would like to bring up in terms of a suggestion non-change if you will.

MS. SALTER: Any clarification needed or

question for Mr. Lieto?

MR. LOHR: I have a clarification, Susan.

MS. SALTER: Okay.

MR. LOHR: And that is, Ralph, we are not proposing to remove the authorized medical physicist but rather to add a second category of the physicist who can do limited task for those licensees who are in geographically remote areas. I just wanted to clarify that point.

MS. SALTER: Any further comment on Mr. Lieto's suggestion? Dr. Zelac, did you need any further?

(No verbal response.)

All right. Any other topics either in the proposed rule or again in the Federal Register notice as one of the additional items under consideration for rulemaking? I see some folks reading. So I'm going to give a couple more minutes.

Anything on the webinar?

(No response.)

Mr. Williams.

MR. WILLIAMS: Gary Williams, Veterans Health Administration. I refer to Section 35.400 and similar language in 35.500.

MS. SALTER: Is this in the proposed rule

or is this in the --

MR. WILLIAMS: Proposed.

MS. SALTER: Okay.

MR. WILLIAMS: And I'm on page 16. And if you look at 35.400(a) there's a statement in there related to sources should be used specific to the radiation safety conditions and limitations in SSDR. I believe that statement has been inserted in order to allow physicians to use a device for other than the specific medical uses that might have been stated in the SSDR.

My recommendation is that this wording be revamped to say exactly what the physician is allowed to do. That is the authorized user shall use it as described or in any other acceptable medical use rather than having this statement that I think is subject to interpretation because it says you have to use it according to the radiation safety conditions and limitations.

However, if you look at an overall SSDR, there are other limitations that aren't specifically radiation safety which might be more health and safety or something like that. So I think this could be clarified if you really say exactly what you're trying to accomplish by having such a statement.

MS. SALTER: Okay. Does the NRC need any follow-up to that comment?

Dr. Langhorst.

DR. LANGHORST: I wanted to bring up the issue of who trains the authorized individual. For authorized users, it's required to be an authorized user. And I know that I believe it was in the Federal Register where you asked the question about whether an authorized nuclear pharmacist can be a supervising individual. And I would argue whether an RSO listed on the license could be a supervising individual even for authorized users because we're the ones that know that aspect of the program.

For instance, my name isn't listed anywhere as a supervising individual on a residency 313A form because I'm not an authorized user. But I'm the one that does training for the radiation safety aspects of things and especially the regulatory aspect of things.

So I think that's a good thing to be able to have an authorized nuclear pharmacist be able to supervise certain aspects of a person's training like checking in packages, you know, some of those requirements that you have. I think it should be recognized that it could be another authorized

individual to provide that part of the training. And obviously that's for the alternate pathway on these training and experience requirements.

(Off the record discussion.)

MR. LOHR: If we may, Dr. Langhorst, I want to clarify that indeed you were speaking to our 35.290 language on the NRC's proposal to allow the authorized nuclear pharmacist to provide the training on elution of generators. And you were -- And I want to make sure I understand. You're proposing that that actually be expanded to allow as you said RSOs to provide training in that realm, not necessarily generators, but in that sort of vein.

DR. LANGHORST: I think if that's who's providing the training for that authorized individual I think it strengthens the training documentation that someone who is actually doing this part of the radiation safety program is giving these individuals the training.

Now I will state again that I do not think authorized users have to have hands-on experience of eluting a generator. But an authorized nuclear pharmacist may supervise their training of receipt of packages and doing surveys and so on or an RSO could do that. I think I like that aspect of what you all

were asking that it be recognized that there are certain other authorized individuals that can provide aspects of the training even for an authorized user.

Did that clarify that for you?

MR. LOHR: I believe so. And in response I would like to clarify that we are only -- our only attempt here was to allow the nuclear pharmacist to provide the training for elution of generators. It was not to go into other realms of radiation safety that the authorized user normally provides that supervision over. So I just wanted to let you know that's our limitation of our proposal at this stage.

DR. LANGHORST: I understand that. And my suggestion was that you could have other what you consider authorized individuals and I hope people consider an RSO named on a license as an authorized individual. I mean I think that strengthens what training they got, who supervised that aspect of receipt of radioactive materials. That's a requirement that has to be gone over in the training aspects. So that's my comment.

MS. SALTER: Did you want to follow up on that before we go to Mr. Walter?

MR. LOHR: No, madam.

MS. SALTER: Okay.

Mr. Walter.

MR. WALTER: Under the current rules you're allowed to do this anyway because it doesn't say under the supervision or even in the physical presence of an authorized user. It just says under the supervision an authorized user.

So if any authorized user deems you as being an adequate person for training or for that matter a pharmacist that they know -- so you wouldn't even have to add this in there -- then you can go ahead and do it. There's nothing that I know of in this rule that would preclude you from doing that right now.

DR. LANGHORST: This is Sue Langhorst again. My name isn't on their training and experience form. It has to be a supervising authorized user's name. Otherwise they will not be approved.

MR. WALTER: I understand that. But the supervising authorized user is not the one doing every single one of these minutia either. And so it's not a person who -- You've got a lot of people who are not on that list, but they are answering to the authorized user who is on that list.

DR. LANGHORST: I agree with that. It just would be nice that other authorized individuals

who do that aspect of the training and the supervising authorized user isn't necessarily -- I understand what you're saying. And, yes, a lot of people get involved in the training. But I think it should be allowed if they get that training from the RSO or they get that training from an authorize nuclear pharmacist they could list that person as one of those supervising individuals.

MR. WALTER: My personal thought is that the way it is taking out the nuclear pharmacist, not adding that additional text in there, gives more latitude to the licensees than if you were to start adding individuals that have to be listed in some way, shape or form. So I am all for giving the greatest amount of latitude to you in this case. That's the reason I'm saying that.

MS. SALTER: Thank you.

Any further clarification the NRC needs?

MR. LOHR: Just one clarification and that is the proposed language doesn't say that the training must be given by an authorized nuclear pharmacist. It says it may be given. So it's another option that is being provided.

And I do believe, David, that your interpretation is the one that the NRC is using as

well. It's under the supervision of. And I believe also at this point that individuals who are receiving this training right now some of the licensees are taking -- I shouldn't say taking -- but are actually the trainee. I don't want to use that word. But the person being trained is actually being done at the pharmacy. And it's being done under the supervision of an authorized user from wherever that licensee is at.

What we were attempting to do here is to make it very clear that an individual may actually get that training directly from an authorized nuclear pharmacist rather than under the supervision of. Just to offer another option. That's what our intent was.

MS. SALTER: Mr. Walter.

MR. WALTER: I understand that they've got a contract with the pharmacy to do that. And that contract should spell it out I think. And I don't think we need to get involved with this.

MS. SALTER: Any other comments on this issue or again any of the issues under consideration?

(No verbal response.)

Anything from the webinar? No, the webinar is quiet this afternoon.

(No response.)

I'll go up to the NRC staff, Dr. Zelac and Mr. Lohr, and ask if there are any particular questions you would like to throw out to the audience. Not throw out.

MR. LOHR: I have no further issues to bring forth.

MS. SALTER: All right. Well, I'm going to give the audience one last chance to bring up any issues or the webinar. Type fast.

(No verbal response.)

Going once. Going twice. Nope. All right. Well, we're a little bit early about a half an hour. But I want to thank Mr. Lohr and Dr. Zelac for spending the afternoon in the hot seat by leading these discussions. I'm sure they appreciate and got lots of information that will be helpful to them as they go back to NRC and continue to work on these items.

I want to thank everyone here for participating. And a special thank you to those on the webinar. I know it can be a little difficult participating in a two-day meeting. But we appreciate you hanging in there and all the comments you made. All the NRC staff, everyone here.

I want to remind you that you do have an

evaluation form in your packet. So if you can fill that out and drop that off at the registration desk.

And with that I am going to turn it over to Mike to summarize some of the things that NRC heard today and give us some closing remarks. And you can go up to the podium or you can stand here, whatever you're more comfortable with.

MR. FULLER: Thank you, Susan. I'd also like to thank everyone here and all our panelists for taking the time from their busy schedules to attend and participate in our workshop. And I think I can speak for everyone when I say the workshop is a really good I think term for the last two days because I think we did a lot of work. I really do.

I know from my perspective and the folks that are working on this expanded Part 35 rule and those that will be working developing the regulatory basis for our medical event definition rule gained a lot of information and a lot of insight over the last two days. So I know for us it was a workshop and I do appreciate everyone's participation. I really appreciate the benefit of your experience and your insight. And again it was just very, very valuable to us.

I'll go over a few things that we heard

today, but I'm not going to attempt to try to get into a great deal of detail because it was just a lot of information that was exchanged. And I'm going to tell you just sort of generally what I think I heard, but also as I said this morning I am available by email. And I really would like to hear from anyone who thinks that they would like to provide me with more details and suggestions as we move forward in this process.

Again, we're very, very early in the rulemaking process. There's a lot of opportunities here for people to provide us with your insight.

But anyway talking about attestation, I think we had a good discussion this morning on the relaxation of some of the attestation requirements, especially for the elimination for the attestation for board certified individuals. One of the things that I got clarification or we got clarification on is that the elimination of those attestation requirements for those board certified individuals does not make the Ritenour Petition issue go away. So we need to make sure that we keep in mind that these are for the most part two separate issues that we need to deal with. That was a message that I heard today.

Moving onto the RSO and assistant or associate RSO discussion, again we had a good

discussion on this issue. One key point that I heard that I think we need to take away is that even though we didn't come to a resolution on what we should call these additional individuals we need to make sure that we're mindful of the fact that the name or the term does matter. Because whatever term we pick will have some connotation that perhaps right now we can't predict. But certainly we need to exercise care.

With regards to the moly breakthrough topic that we discussed, one key message that I heard today was that again we need to exercise care as we move forward in rulemaking. And something that I thought was very compelling and something we need to really think about is this whole concept that rather than simply change a rule for molybdenum-technetium generators we really ought to think more holistically, more generically and try to come up with a rule change that could perhaps anticipate future radionuclide generators or radiopharmaceutical generators and try to make this more generic so we don't find ourselves again in rulemaking space.

So again very good point. It's something we will have to consider. And maybe something like have some generic requirement that says that our licensees are required to follow the manufacturers'

recommendations or something along those lines. Something very performance-based.

And again we heard loud and clear just like we did in New York there seems to be a pretty strong consensus that we should not pass new notification requirements for our licensees to report to NRC of failures. But again there are more things to consider along these lines.

When we got to the more generic topics, rather than going in to trying to capture a lot of things that I heard because there were a lot of things going around I'll just say this. We appreciate your feedback and your comments. And I'd like to remind everyone that if you go to www.regulations.gov you have until September 15th for those things that have already been published to provide us with written comments.

And as Ed said earlier we're all scribbling taking notes. We have transcripts. I mean we have everything we need to make sure that we capture what we heard the last two days. But if you would be so kind as to sit down and thoughtfully think about what comment you would like to make to us and send it in through that system that's another good way, not the only way, but another good way for us to

capture your recommendation and your comments. And then we'll have them as part of the record to deal with.

And as we go through the process and as the working group develops new preliminary draft rule text my assumption is -- and, Ed, you can correct me if I'm wrong -- that we will put more preliminary draft rule language out on regulations.gov. Is that a fair assessment? A fair assumption?

MR. LOHR: I believe that is the intent.

MR. FULLER: Okay. When we do, we will make every effort to notify folks especially those that are on our medical list server. Gretchen manages that list server for us. And so if you're on that, if you're listed on the medical list server, we'll try to get timely. We'll do our very best to get timely notifications out through that process. It's very informal but sometimes very effective process for notifying folks if there are things that we would like to have you take a look at or be aware of.

And we've talked about it only briefly yesterday morning, but that's really the purpose for that yellow card. So if you're not on our medical list server, then please fill out one of those yellow cards before you leave today and leave it with the

folks back there at the table. And we will get you on the medical list server.

So that's about what I had. Again I want to thank everyone. I also want to take this time especially to thank our facilitator, Susan Salter. I think she did a wonderful job the last two days.

(Applause.)

I don't think people fully appreciate just how difficult it can be for someone who has really very little technical background in this area to be able to keep the conversations streams going and so forth. And I just think Susan did a remarkable job. And I appreciate all your efforts.

I'd also like to recognize Gretchen Rivera-Capella. She has not only been manning our webinar for the last two days, but for the last four or five months she has been working extremely hard working with our contractors and working with me and working with others in putting together this entire workshop. So I'd like to recognize Gretchen as well.

(Applause.)

And again without any further ado I'd like to thank you all and thank you all for coming. And I would wish you all very safe travels back home. Off the record.

(Whereupon, at 3:33 p.m., the above-entitled matter was concluded.)

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