UNITED STATES NUCLEAR REGULATOR COMMISSION

MEETING WITH ADVISORY COMMITTEE ON THE

MEDICAL USES OF ISOTOPES

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TUESDAY

APRIL 29, 2008

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The Commission convened at 1:30 p.m., the Honorable Dale E. Klein, Chairman presiding.

NUCLEAR REGULATORY COMMISSION

DALE E. KLEIN, CHAIRMAN

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LEON S. MALMUD, M.D., Health Care Administrator, Chairman, Advisory Committee on the Medical Uses of Isotopes (ACMUI)

RICHARD J. VETTER, Ph.D., Radiation Safety Officer Representative, Advisory Committee on the Medical Uses of Isotopes (ACMUI)

DOUGLAS F. EGGLI, M.D., Nuclear Medicine Physician, Advisory Committee on the Medical Uses of Isotopes (ACMUI)

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

CHAIRMAN KLEIN: Welcome. We're going to hear from the Advisory Committee on Medical Uses of Isotopes. I think this is an area that probably the public really understands more than any other activity because when they flip the switch on electricity they may not think about where they receive it, but when they go for a medical application they understand why they're there and what the purpose is. We appreciate the advisory work that you all do.

Any comments or questions before we start? Dr. Malmud, it's yours.

DR. MALMUD: Thank you. First, let me express our appreciation to the opportunity to meet with the four Commissioners. We have been trying to do a diligent job on behalf of the NRC via the ACMUI and have had a very fine collaborative working relationship with your staff. I appreciate that as well.

Today, we want to present to you two topics. The first will be presented by Dr. Eggli, who is by virtue of his training a nuclear physician and a radiologist and who represents that area of interest within the committee and he'll discussing the 10 CFR Part 35 training and experience implementation issues. Dr. Eggli?

DR. EGGLI: Thank you. As a nuclear medicine physician,

in the pre distributed materials I made reference to clinical nuclear medicine. Please, though, substitute mentally diagnostic and therapeutic procedures using radioactive materials as a broader sweep whenever I referenced clinical nuclear medicine.

The issue today that the committee would like to present to you is really twofold. The first is a discussion of ACMUI's recommendation concerning the use of the term "competence" or "competency" in a preceptor attestation and the second is a discussion of the unintended consequence of the training and experience regulation that functionally requires recognized specialty boards to train their trainees to the requirements of the alternate pathway.

This results from a gap in time between the completion of training and when any one individual can actually take the board certification examination. That time may be as little as three months in some specialties and as much as two years in other specialties that the NRC recognizes.

The competency is the first issue that I would like to address with you this afternoon. There are a number of problems associated with the attestation of competency as opposed to the attestation to mastery of a body of knowledge.

Competency is really fairly subjective and difficult or impossible to

quantitatively define. Competency cannot be taught. A curriculum or a body of knowledge can be taught. Likewise, competency is difficult to measure.

Mastery of a body of knowledge can be tested and measured repetitively throughout a training program and ongoing competency is difficult to guarantee.

How long does an initial competency attestation last? What is the impact of recertification which recertifies a body of knowledge, but doesn't really address competency?

And finally, competency has a legal liability associated with it which many individual preceptors are becoming progressively reluctant to accept.

The board certification pathway we would recommend should eliminate that competency as to attestation altogether. Approved boards have agreed to meet NRC's training and experience requirements and the certification process involves NRC reviewing and recognizing those boards.

A curriculum or body of knowledge that is pre defined is taught and part of that defined and predetermined curriculum involves radiation safety. The board certification indicates that the T&E requirements have actually been met by the individual and maintenance of certification,

which virtually all boards now have, provides ongoing evidence of current mastery of a fund of knowledge.

It seems that additional attestation to mastery of that body of knowledge is superfluous.

Part of the justification for using the residency program in lieu of a specific attestation of mastery of a body of knowledge is that the entire residency training faculty has input into the progress that a resident is making toward the graduation requirements.

Progress is measured; mastery is routinely tested throughout a residency training program. As an example, at the institution where I am faculty approximately 35 clinical faculty provide input into the performance of each trainee and in the radiation safety arena, that includes five authorized users, the RSO and three additional health physicists or a group of nine people contribute to the collective determination of whether or not an individual trainee has mastered that body of knowledge.

The training director certifies to the credentialing board that the resident has successfully completed all of the training requirements of the board and this certification to the board occurs on behalf of the entire faculty and this includes all of the radiation safety training and experience requirements and includes the assent of all the authorized users and

trainers as a group.

Although the boards are unwilling to attest to competence, they do maintain records that document the resident's completion of graduation requirements including these radiation safety requirements. No one faculty in any program provides all of the training and supervision experience.

The collective opinion of the nine individuals providing the radiation safety training at my institution, I believe is far more accurate than the opinion of a single preceptor who may only have partial and incomplete knowledge of what the resident has actually accomplished as far as training.

The problem of preceptor attestations is particularly acute for Radiation Safety Officers. Since there is only one RSO on any one license as opposed to potentially multiple authorized users on a license, there is only one potential preceptor at any training institution.

The current regulation requires an RSO preceptor for any RSO and more and more RSO's are reluctant to preceptor individuals they did not personally train.

As an example, the Radiation Safety Officer at Mayo Clinic has recently informed the nuclear medicine chair that he is no longer comfortable preceptoring nuclear medicine fellows -- nuclear medicine

fellowship trainees to be Radiation Safety Officers.

The primary impact will be a shortage of RSO's for small and medium-sized community practices where a physician often has to serve in the role of the Radiation Safety Officer.

Although the regulation has been interpreted to allow preceptors to attest to indirect knowledge of a candidates training and experience, the legal liability risk discourages this practice.

Both the certification boards and individual receptors are adverse to the risk associated with the statement of confidence. The risks are two fold.

One is failure to attest to competence leaves the preceptor at risk for a lawsuit by the trainee and on the turn around site attestation of competence then leaves the preceptor at medical legal liability risk in a malpractice lawsuit.

As a result, the ACMUI recommends that the NRC should remove the attestation requirement for board certified individuals. And to recap the justification for the position, the training director certification to the board that a resident has successfully competed all of the training requirements for board certification which by definition include radiation safety training and experience requirements, fully meets the threshold recommended by ACMUI for qualification for authorized user.

The attestation is implicit in the board certification process for boards recognized by the NRC. ACMUI believes that competence cannot be certified and further believes that the collective judgment of an entire residency faculty is far superior to the judgment of any one individual preceptor.

If I could turn now to the alternate pathway. The alternate pathway is also broken into two parts. This is where the discussion will depart a little bit further from the prepared materials.

The training consequences of the lag time between completion of residency and when board certification exam can be taken can be, again, as little as a few months to as much as two years.

Again, this de facto requires the boards to train to the alternate pathway requirements so that between graduation from residency and when an individual can take the certification exam they cannot work as an authorized user via the board certification pathway.

Therefore, they have to certify by the alternate pathway which requires, then, the boards to train all trainees to the alternate pathway and that was not the initial intent of the regulation.

The intent was to allow the certification boards to use some judgment in how to present the materials to their trainees to accomplish the task of mastery of a body of knowledge.

Secondly, is the true alternate pathway which involves trainees that were not trained in recognized training programs and their certification. A solution needs to be found for both of these sets of trainees; both the recognized specialties between completion of residency and the board exam and the willingness of preceptors to certify the true alternate pathway candidates.

Although the alternate pathway was designed to allow individuals who are not yet or do not train by a certified pathway to achieve user status, the current pathway functionally limits the availability of preceptor certification.

For the trainees in recognized training programs who are in the gap between completion of training and final board certification, a possible solution would be to create a third pathway for trainees who have successfully completed the training program, but are not yet able to take the board exam.

In this case, the program directors certification of completion of all of the training programs could serve -- of all the training requirements could serve as the documentation for the training.

As in the case of the board certification pathway, since this is functionally the board certification pathway, the certification includes documentation of all of the radiation safety training and experience since

this experience is required for board certification.

All of the considerations of the board certification pathway then apply to this in-between group of people waiting to be able to take the board exam. And the expectation is that this group of people will in fact become board certified after the time delay required between the end of training and board certification.

There is actually a precedent for this approach. The state of Florida has a program for individuals between residency and board certification. They call it AU in Training. What it's called, I don't think is critical, but they have a process in place to allow individuals who have completed their residency training, but who are not yet able to take the board exam to work as authorized users.

If a solution is not found for those who have successfully completed their training programs, but cannot yet become board certified because of the delays built in between the completion of training and board certification, there could be an adverse impact on both individual practitioners and the ability to deliver patient care.

Inadequate numbers of authorized individuals may be available to support diagnostic and therapeutic applications of radioactive materials.

If graduates are unable to work until they achieve board certification, particularly small and rural practices are likely to be

underserved. The diagnostic and therapeutic procedures which use radioactive materials may actually become unavailable in some areas because they are not authorized users.

This third pathway or interim pathway approach would solve the problem of the time gap between completion of residency and the board certification process.

If I can turn now to the actual intended alternate pathway, the nature of the attestation is also relevant in this pathway. It provides that the training and experience for individuals not trained in recognized programs have achieved.

In this case, the ACMUI agrees with the prescriptive requirements for training because there is no certification board watching over that training. But ACMUI does recommend that the attestation be limited to having completed the requirements for training and experience for authorized user status.

Again, as opposed to assertion of competence since preceptors are going to be progressively unwilling in the current medical legal environment to attest to anyone's competency.

There is actually already a shortage of authorized medical physicists for therapy and AMP's frequently use the alternate pathway to obtain authorized individual status. So, this could exacerbate any

potential shortage of authorized medical physicists for therapy.

So as a summary, ACMUI believes that individual preceptor attestation is less reliable than the collective judgment of an entire training faculty and is superfluous for board certified individuals.

ACMUI recommends that the attestation statement be eliminated for board certified individuals. The board's certification process attests to the fact that the trainee has successfully completed the training and experience requirements for radiation safety.

Secondly, the ACMUI proposes that the training director certification that a resident has completed all of the training requirements for board certification can serve as an interim solution to the unintended consequence of the training and experience regulation that functionally forces the board's to train to the alternate pathway requirements.

Thirdly, ACMUI recommends that attestation of the preceptors for the true alternate pathway trainees be limited to the certification of meeting the training and experience requirements.

These changes will help to reduce the shortage of authorized individuals which the ACMUI believes is on the near-term horizon while assuring adequacy of training. Thank you.

DR. MALMUD: Shall we move on?

CHAIRMAN KLEIN: We'll ask questions after both

presentations.

DR. MALMUD: Thank you, Chairman.

DR. VETTER: Good afternoon. I'm Dick Vetter. I'm here to discuss with you the issue of fingerprint orders. I'd like to also extend my thanks on behalf of my colleagues and the Committee for the opportunity to be here.

In fact, I hope that you all understand that we covet the opportunity to interchange with you and we'll do whatever we can to help you understand the issues that we are dealing with.

DR. MALMUD: Excuse me. I didn't introduce you. I'm sorry.

DR. VETTER: I noticed that that's why I started right in.

DR. MALMUD: Dr. Vetter is the radiation physicist at the Mayo Clinic and is Professor of Radiology in the School of Medicine associated with the clinic. He is nationally known and quite an expert in his area of expertise.

Excuse me for not having introduced you more formally and I apologize for disrupting you.

DR. VETTER: No problem. The issues I'd like to discuss with you regarding fingerprinting are cost, justification, grandfathering and ACMUI input.

First of all, just briefly on the cost. I just want you to understand for the average hospital this is a significant additional cost in the radiation safety program. This slide that I have here shows the cost for -- I'll tell you which licensee -- it's the Mayo clinic.

This is what it's going to cost us to implement the fingerprinting program. Local fingerprinting is variable depending upon the municipality or the jurisdiction where you're working. For us, it's less than $50.

The NRC/FBI costs are $36, so that total is about $90. We have 400 employees, so that's about $36,000 direct costs.

One of the members of ACMUI is from a medical institution, an academic medical center, where they have nearly 1,000 employees who have passed the trustworthy and reliability determination for unescorted access and will need to have fingerprints in order to continue that access.

In addition, there are indirect costs. Time away from work. For us, it's about an hour by the time the individual is pulled from the clinic, they walk down to get their fingerprints, they come back, they waste five minutes talking to each other about the experience, et cetera. There's about an hour of work lost.

One member of ACMUI indicated to me that he lives -- his closest area -- jurisdiction where he can get fingerprints is 20 miles away. So, he has to drive 20 miles in addition to being pulled out of the clinic, et cetera.

So, you look at the indirect costs there's another $40,000 according to my computation for us, bringing the total to $76,000 in order to maintain the trustworthy -- in order to maintain the unescorted access which our employees already have.

Just to compare that with a couple of other items in my radiation safety budget. The annual license fees for our broad scope license for $29,000. Dosimetry services $33,000 and now the fingerprinting is another $76,000. Mayo Clinic's margin the last two years has averaged 2.4%. So, that means we need to earn $3.2 million to pay for the fingerprinting.

And I might add that the American Hospital Association estimates that 25% of hospitals in the U.S. will lose money in 2008. And then there may be the requirement that we have to repeat this periodically.

As to justification, many members of the Radiation Protection Community that I visited with about this consider this to simply be an unfunded mandate. The fingerprinting does not increase security of irradiators.

The RSO on the other hand must justify this to management. I can't go spend $76,000 without some justification. So, I have to justify this to my management.

Two years ago we did a vulnerability analysis of our irradiators at

Mayo Clinic. I involved local law enforcement in that and we actually did increase the security of our irradiators. And then I reported to management after spending that money that our vulnerability analysis now shows that we do not have any security issues.

Now, I have to go to management and say I need this money to do fingerprinting in order for more people to have access, even though there are no security issues as determined by our own vulnerability analysis and local law enforcement.

I looked at the NMED database to determine whether there had been any security issues reported. There's only one event involving irradiators in NMED and that has to do with an irradiator that apparently was lost by a high school sometime between 1986 when the license expired and 2000 when it was inspected.

They had indicated that they first thought it had been shipped to a waste disposal site. The waste disposal site doesn't have any records. They also said maybe it got shipped to the manufacturer. The manufacturer doesn't have any records. We don't know what happened to it. That's not a security issue. It's an oversight issue. That's the only incident that was in the NMED.

Let me introduce you to a typical immunologist doing research at Mayo Clinic. He's been there 25 years. He has over 400 scientific

publications. He has grants totaling millions. His current research -- I won't read through that list, but it's very significant and distinguished.

So, now I'm going to have to go to this distinguished researcher who's been using this irradiator for 25 years and I'm going to have to tell them he can no longer have access to that unit unless he agrees that we do fingerprinting and send in those fingerprints for an FBI criminal background check.

In my opinion, this researcher should be grandfathered. The fingerprint requirements actually disqualify him and disqualify others who have been determined to be trustworthy and reliable.

All current users, in fact, should be granted unescorted access -- I'm sorry; all current users who have been determined to be trustworthy and reliable and are granted unescorted access now simply should be grandfathered because we've already determined that they are trustworthy and reliable.

As to ACMUI input, this today is the first opportunity that ACMUI has had to provide input to the Commission on this issue.

When I became aware of the fingerprint requirement approximately a year ago, I sent an e-mail to NRC staff who assured me that they were interested in our input and they made an opportunity for Ralph Lieto, another member of ACMUI and me to meet with the NRC Implementation

Task Force on July 31st.

There were two surprises at that meeting. The first was when Ralph and I were told that we could not comment on justification; that the only issue open to discussion were implementation issues; that the decision had been made by the Commission that fingerprinting was going to go forward and we had no opportunity to argue one way or another on the issue.

The second, there were at least two members of the task force who's jaws dropped when we told them that the average academic medical center had several hundred people who would have to be fingerprinted then. I think several members of the implementation Task Force simply had no idea of the scope of the issue.

So in conclusion, I just want to emphasize that the initial costs are significant. As I mentioned, American Hospital Association indicates that by their estimate 25% of hospitals will actually lose money this year, so this is not an insignificant issue for many.

And the money, in fact, could be much better spent on security issues if, in fact, there were any. Take the $40,000 that we're going to spend on fingerprinting, put that into security issues to improve security if in fact it needs to be improved would be money better spent.

There is perceived to be a lack of justification for medical category

two sources. If you look at any of the irradiators I'm familiar with, it's simply inconceivable that someone could get into one of these without attracting a lot of attention.

Those employees who have been determined to be trustworthy and reliable, if we were to grandfather them that would ameliorate this burden significantly.

And then finally, there's been a lack of opportunity for ACMUI input up until this point. I think that the decisions regarding fingerprinting could have been better informed, if, in fact, we had been asked a long time ago when this requirement was being discussed.

And finally, I would strongly urge the Commission to engage the ACMUI on the impact of fingerprinting if, in fact, you are even thinking about expanding this to category three sources. Thank you again for the opportunity.

DR. MALMUD: That completes our presentations.

CHAIRMAN KLEIN: Thank you very much. As you know, the NRC is procedurally based and so we rotate the starting of the questions. So, I get to start today and we'll refer to my other Commissioners.

Let me just start in reverse order, since fingerprinting was just talked about. I assume you heard of our 535 advisers that live nearby?

DR. VETTER: I know about them.

CHAIRMAN KLEIN: There are some things that obviously have been passed that give guidance as to what's required. And so, in terms of justification, don't feel that you're the only one with unfunded mandates. That's impacted a lot of individuals.

I think we are in a different world after 9/11 and those are some of the issues that we have to deal with as well. So, when you look at some of the requirements that is being forced upon the medical community, don't think that they always just originate with us.

We do carry out the law. That's a minor requirement that we feel that is an obligation, so we do that. I think all of us are aware of the cost of a lot of these activities.

What I would encourage you to look at in your own institutions are ways in which you can minimize those costs by procedures that you have. Each person will have to do that, but just keep in mind that there were some laws passed that we definitely have to follow and that's just the way the system is.

In terms of the irradiators when you had your local law enforcement come in and do that, did they have any background in terrorism?

DR. VETTER: I can't articulate what that background is. They were aware of the cell activity in the upper Midwest and we talked

about that as part of the analysis; where they were located, what they were doing. That's about all I know about that.

So, I don't know specifically what kind of training they had in anti-terrorism.

CHAIRMAN KLEIN: There have been -- just for your information -- some of the National Labs have done scenarios where they have looked at what people with bad intentions could do. You just have to keep in mind that we are in a different risk environment today.

I think we all suffer that every time we fly with the requirements. I think a lot of this -- you're seeing the evidence of that now of a lot of the Energy Policy Act issues that require additional activities.

Let me move on to another area. On the RSO activities that you had mentioned on slide seven, I think about some of the direct knowledge or indirect knowledge. Can you do testing?

In other words, you indicated some people were a little reluctant to affirm knowledge without involvement in the actual training. Can you do some testing that would document that?

DR. EGGLI: I think most training programs do some degree of testing, but not everything in training and experience can be objectively tested.

There is a subjective component to mastery of skills and knowledge

that I think the collective judgment of a training faculty helped to address, but in direct answer to your question, yes, many of these issues can be tested and test results are recorded and saved.

CHAIRMAN KLEIN: One thing that's of interest in the medical community, have you been following what's occurred in France with their medical procedures?

DR. EGGLI: I'm not sure I understand what you're referring to.

CHAIRMAN KLEIN: In France, recently the regulator has gotten -- has the responsibility now to look in the medical community. Prior to that it was primarily on reactors. And so, they now are looking at cases where there has been a lot of misuse of medical applications.

And I was just curious how you might interface with what other countries do with training procedures and activities of that nature?

DR. EGGLI: I think that the general outline of the requirement for training is specified in the regulation and the boards designed a program to meet that in the United States. It's designed to comply with U.S. regulation. I'm not sure how that interfaces with activities of other nations.

CHAIRMAN KLEIN: My question was are we more rigorous or less rigorous than other countries?

DR. EGGLI: I can't answer that. I cannot answer that from direct knowledge.

CHAIRMAN KLEIN: The other question would be if we're more or less rigorous how does our safety record lie? I think those are some of the things that we --

DR. EGGLI: I think if you look at medical events or abnormal occurrences compared to the number of procedures performed on an annual basis, the numbers of the events are in single digits or low double digits. Certainly, 15 or less a year compared to on the diagnostic side hundreds of thousands of procedures performed every year.

And on the therapeutic side, probably approaching hundreds of thousands performed every year so that the fractions are a fraction of 1%, usually with one or two leading zeros after the decimal point. So, one hundredth of a percent, four hundredths of a percent in that range so that the numbers are of incidents related to radiation safety or misuse of -- medical misuse of radioactive materials is extremely small given the very large denominator.

CHAIRMAN KLEIN: So the percentage is smaller. Do you know what the numbers are?

DR. EGGLI: The incidents last year there was a report -- I believe that there were fewer than 15 nuclear medicine incidents. In total

medical use incidents, I think the number was close to 35.

CHAIRMAN KLEIN: Okay. On slide nine, you talked about the alternate pathway. How many -- what percentage use the alternate compared to the other techniques?

DR. EGGLI: I think now a fairly small number are using the alternate pathway. The way we are handling it currently is we're telling people they simply have to wait until their board certification happens; that we won't write an alternate pathway preceptor statement.

So, at least in my institution, the pathway is defunct because preceptors won't write an alternate pathway preceptor and require people to attain board certification.

Right now for diagnostic radiology, they are board certified before completion of their residency; however, that's going to change. By 2010, American Board of Radiology is going to put a two-year gap between completion of training and when you can finally take the board exam.

Some of -- our shortest is three months. That's not usually much of a handicap by the time you get licensed in a state to practice and you go to work at your first job after training. A three month lag which would typify American Board of Nuclear Medicine doesn't impose a handicap.

But if you look at statistics, a large proportion of clinical nuclear medicine is done by diagnostic radiologists and not in fact by American

Board of Nuclear Medicine certified individuals. And once that ABR requirement rolls in, they're going to be a large number of people who are caught by the need for some solution to fill the gap between completion of residency and board certification.

I have right now cardiology trainees who yell at me because they can take the cardiology certification exam in their fellowship, but they can't take the actual cardiology board until sometime afterwards.

The CNBC, the Cardiology Certification Board, will not actually give them their board certificate until they actually pass the underlying cardiology board exam, which can be as much as a year later. And these people are unable to work as authorized users in that interval.

Our position to them is as soon as you send me a board certificate, we will write you a preceptor statement. But in the gap, they're unable to perform the functions of an authorized user.

CHAIRMAN KLEIN: Thanks. Commissioner Jaczko?

COMMISSIONER JACZKO: I guess I would just follow up on those questions from the Chairman. I understand this and Commissioner Svinicki will perhaps appreciate this. This is one of the big rules that I think the Commission approved right when I started the Commission. And I, thankfully, in my vote said that I'm not responsible for any of these decisions because in the month or so that I was here, I

didn't really have time to read the rule.

So, I guess I can say I'm not -- while I did support this, I'm not necessarily bound by that decision at this point in many ways.

As I understand it, the board certification is certainly one pathway and then we have the alternate pathway. The attestation statement is required in both cases?

DR. EGGLI: It is.

COMMISSIONER JACZKO: Based on the last comment I think that you made, if there is board certification, that statement is easier to make. Is that a fair statement?

DR. EGGLI: That is a fair statement.

COMMISSIONER JACZKO: The challenge right now appears to be the fact that in many cases there's a time lag between the residency period or the completion of the residency at which time for all practical purposes education is completed --

DR. EGGLI: And clinical practice starts.

COMMISSIONER JACZKO: -- and clinical practice starts. At which time you'd want to be an authorized user and be able to begin doing things.

Maybe you could help me understand then what is the cause for that two year delay between board certification and the completion of

residency?

DR. EGGLI: Many of the boards have taken the position that board certification requires some clinical experience prior to granting that board certification where the trainee's entire experience has been supervised with no independence and that board certification requires the development of some clinical competence independent of that supervised process.

And more and more -- essentially, the American Board of Radiology is the last board to grant board certification as the trainee finishes their program.

COMMISSIONER JACZKO: You said that's going to change?

DR. EGGLI: That will change for the incoming class of 2010. For many of the other boards like the American Board of Internal Medicine, it's been a longstanding practice. For most surgery boards, they -- actually, candidates have to go into their final board exam bringing in a list of their surgical experiences and that clinical experience contributes to the board certification process.

COMMISSIONER JACZKO: That's helpful. That's certainly an area where I was trying to understand why there was that time lag and I guess it comes down then to a question then of how we would modify

this in that interim period when you have finished your residency to the time in which you had board certification.

Is there another -- you mentioned that the collective judgment of the entire faculty is better than an individual attestation -- an individual preceptor attestation. Is there another group, you think, that could make sense for how we redefine the preceptor?

DR. EGGLI: I would -- again, I think in a training program the collective wisdom of all of the educators is the best approach.

COMMISSIONER JACZKO: How would you specify that in a regulation?

DR. EGGLI: I think that the function of that is the letter that the training director writes to the board on behalf of the entire training faculty saying it is the collective judgment of the faculty that this individual has met all of the residency training requirements.

COMMISSIONER JACZKO: When is that -- if you have two years from the end of residency to the time at which you get board certified --

DR. EGGLI: That is at the end of the formal residency.

COMMISSIONER JACZKO: That comes in early? That doesn't have to wait?

DR. EGGLI: No, that doesn't wait.

COMMISSIONER JACZKO: In your view, then, would that be an acceptable alternative to the preceptor?

DR. EGGLI: I believe it is not only an acceptable alternative, but a preferable alternative.

COMMISSIONER JACZKO: I know just having reviewed material for this meeting that this is not a new issue.

DR. EGGLI: No, sir, this is not.

COMMISSIONER JACZKO: The Commission, I think -- the committee certainly weighed in with the Commission specifically on this issue and I think the Commission, again, for reasons that I'm not accountable to necessarily decided that this was an appropriate requirement and that it would make sense.

Perhaps you could fill me in a little bit on what your understanding of the sense of where the Commission was at that time a little bit better and what specifically they were trying to address.

DR. EGGLI: I think the Commission was looking for an individual that could be designated as responsible. I understand the desire to be able to say you are responsible, not as an individual rather than the collective view of 35 or 40 people.

I think the Commission was looking for how do you deal with someone who truly isn't able to perform those duties? I think the answer

to that is not to look toward an individual preceptor, but then to hold the individual authorized user accountable for their performance and that the remedy for someone who may turn out to not be able to perform as anticipated is to revoke that individual's credential.

So, I think what the Commission was thinking about initially is the remedy to apply when an individual becomes an authorized user, but yet really isn't up to that task.

COMMISSIONER JACZKO: Do you know of any situations where that has happened?

DR. EGGLI: I have no personal knowledge of a situation where an authorized user has had credentials revoked because of inadequate performance in the radiation safety arena.

I would think that most of the questions would occur in the medical judgment arena as opposed to the ability to handle radioactive materials in a safe fashion for both patients and the public.

COMMISSIONER JACZKO: Thank you. I appreciate you expanding on the comments you made earlier. It's certainly an interesting area and I think one we should continue to look at. Certainly, at this point would be open to looking at alternative ways to achieve that statement.

I think it's important to have some acknowledgment of someone

having completed that training and experience requirement, but I'm certainly open to looking at that is more easily done by a group of individuals rather than any single individual as an alternate approach.

DR. EGGLI: I think the ACMUI would fully support anything which documents that an individual has received the appropriate training.

COMMISSIONER JACZKO: As well as the statement to the effect that they have achieved some competency?

DR. EGGLI: That they have -- again, if we could not use the word "competency" because I think you'll have trouble getting people to sign a competency statement, but they have achieved -- they've completed the requirements. That they've achieve mastery of a body of knowledge. Those are all things that we can attest to comfortably and defend in a litigious process.

And if I might answer a question you didn't ask, which is why are we resurfacing this after the Commission has spoken? I think the answer to that question is we are beginning to see some of the impacts and fear the potential of shortage of authorized individuals that could result in the shortage of availability of diagnostic and therapeutic procedures.

COMMISSIONER JACZKO: I'm over my time. If I could just follow up to the question that I didn't ask by saying -- I think it was a good one.

DR. EGGLI: Thank you, sir.

COMMISSIONER JACZKO: In that shortage, you're saying is, I guess, because we have people who have finished their residency are not yet able to start or is it in fact just fewer people completing residencies?

DR. EGGLI: It is in part because in some cases because we have people completed residencies who are not able to start. And in part it's a function of the attestation process, which discourages preceptors from actually being willing to write preceptor statements because of the legal risk associated with the writing of that statement.

COMMISSIONER JACZKO: Thank you. Appreciate the insights.

CHAIRMAN KLEIN: Commissioner Lyons?

COMMISSIONER LYONS: Thank you for the briefing. I've certainly benefited not only from the briefings, but also from the discussion from our Chairman and from Commissioner Jaczko.

I think you've made some very, very good points which I personally found quite convincing. And I think as Commissioner Jaczko said I, too, would be quite interested in reopening this question of how to better address some of the challenges that you've laid out. I understand the difficulty of someone certifying another individual's competency as

opposed to certifying a mastery of knowledge. To me, that's an important point.

And also your point about relying more on the collective judgment of a number of individuals who've being involved in evaluating as one develops abilities. That, too, to me is a very convincing argument.

So, I don't know if Commissioner Jaczko quite said it this way or not, but I would be very interested in having the staff work further with ACMUI and develop some suggestions back to the Commission to try to address some of the concerns you've raised, Dr. Eggli.

DR. EGGLI: Thank you. We look forward to that opportunity.

COMMISSIONER JACZKO: That's just my view.

COMMISSIONER JACZKO: I didn't ask the one question and I didn't quite say that, but I certainly would agree as much as I agreed that that was the good question.

COMMISSIONER LYONS: And for Dr. Vetter, I do share many of the concerns that you raised, but I also strongly recognize the point that the Chairman made about 535 advisers.

I think we're acting in line with the direction of Congress in what we've done. I personally don't see that we have the flexibility to grandfather people in. I don't think that was part of the thinking in

Congress at the time.

I do think, following up on one of the Chairman's comments, that there may be areas where you can imagine substantially shortening or changing the impact that you outlined, perhaps by something as -- what sounds simple to me at least of bringing the fingerprinting capability on site for a day or two instead of having everybody traipse off 20 miles to find somebody who can fingerprint them. But I honestly don't see that we have the flexibility.

And in fact, I think Dale somewhat alluded to this, we have -- there are a significant number of studies going on right now. The National Academy has reported and the Defense Science Board is, I believe, close to reporting or maybe has reported their very, very strong concerns with cesium chloride based irradiators.

I think as a Commission we're going to be faced with some substantial challenges in terms of how to evaluate both these concerns that are being raised by knowledgeable groups like the National Academy along with the impact on patients that might happen if we actually took some of the National Academy's suggestions.

Frankly, this strikes me as an area where ACMUI can make extremely valuable contributions to the Commission as we're faced with these concerns, particularly on the use of cesium chloride.

The National Academy made statements to the effect that alternative cesium chloride irradiators are equally effective. I don't know if that's true or not, but I would think ACMUI would be in an ideal position to provide information to the Commission on whether those statements are really correct.

Maybe that can be a question. Could you comment a little bit on that, Dr. Malmud?

DR. MALMUD: The person who is most expert in that area is actually Dr. Vetter. As a nonexpert, my understanding is they are not equivalent techniques. The cesium method irradiates the blood in its entirety. The external x-ray beam does not irradiate the blood uniformly and therefore there is the risk of the purpose of irradiating the blood being defeated by using a technique which is not equal to the cesium technique.

I'll ask Dr. Vetter if he would pursue that in greater detail.

DR. VETTER: We as a committee don't know what the efficacy of the x-ray versus cesium procedure is. There is some literature that suggests that the x-ray technique is not as good and that's for reasons that Dr. Malmud pointed out.

X-ray energy is lower and therefore it doesn't penetrate the blood as well as the cesium does. The cesium is going to irradiate it much

more uniformly.

And if you only have a few white cells survive, you have the risk of graft versus host disease which can be fatal in a patient. So, it's not something that we should take lightly.

I appreciate your suggestion, Dr. Lyons, that we take a look at this and I appreciate your invitation to provide input to the Commission because it's easy to say because of the dispersability of cesium we ought to just get rid of it.

If, in fact, we did that, we could in fact be threatening the lives of some patients. So, we need to be sure that any alternate technology is as efficacious as the cesium.

There is also the issue of cost. X-ray will be much more costly than cesium. So, there are a number of issues that should be addressed before any action is taken that would suggest we get rid of cesium.

COMMISSIONER LYONS: I think it would be extremely useful for ACMUI to take that on and provide perhaps some written feedback however you want to provide the feedback. I think it would be very, very useful and certainly those comments were very useful.

The National Academy did in their report make some -- I think they would agree -- preliminary attempts to look at costs. They looked at costs for the existing x-ray irradiators which are, as you said, fairly low

energy compared to the gammas and cesium.

I'm quite willing to believe one could always come up with a higher energy x-ray source, but the cost and complexity and the maintenance and everything else is going to go up.

I don't know if it's linearly with voltage or not, but it's going to be probably some power of the voltage. In any case, I think this kind of guidance from ACMUI is extremely useful to the Commission and we are going to be faced with some challenges.

There are other approaches and you mentioned the potential of improving security. That's certainly another approach. Alternative forms of cesium are another approach. And then there's the one that the National Academy pretty much suggested, which was just get rid of it.

I think the Commission had serious questions on whether or not it was a wise course. Anyway, I'm over my time. Thank you.

DR. MALMUD: Commissioner Lyons, in response to your suggestion, we will take that task on. We will assume that task to do a review of the cesium technique versus the x-ray technique.

COMMISSIONER LYONS: That's just one of us speaking. We need to see if there's some more that agree.

CHAIRMAN KLEIN: I think you'll probably have a unanimous view from that standpoint. If you look at the Academy report,

there is really a weakness from the medical users. In other words, the people who are out there and if we don't hear from that community its going to make it difficult for us to take actions that might have negative impacts on the health and care of people.

DR. MALMUD: The radiation oncologists who are on our committee have the ability to poll their colleagues with regard to the use of the cesium technique as well as finding out who's using the x-ray technique and what efficacy is currently. We will assume that task if Mr. Chairman wishes us to do so.

CHAIRMAN KLEIN: I would encourage you to do so.

DR. MALMUD: Thank you. I'd also like to, if I may, make a comment since Commissioner Lyons has spoken. There's one little line in this document which isn't quite correct and that is that I did have the opportunity to meet with Commissioner Lyons. We did discuss the issue of fingerprinting and I did communicate it back to the committee.

As you can imagine from what you've heard, the committee was not happy with what they heard and for that reason I wanted to make a presentation to the entire committee. But the Commission was not remiss in not hearing from us earlier.

Commissioner Lyons did hear from us earlier and did give us the same response that you are delivering to us today. I appreciate that.

CHAIRMAN KLEIN: Commissioner Svinicki?

COMMISSIONER SVINICKI: Thank you, Mr. Chairman and in addition to nodding my head I will verbally associate myself with Commissioner Lyons charge or encouragement to you to look specifically at the cesium chloride issue.

I think the interaction we've heard just in the last 60 minutes or so is perfect evidence of the tremendous value that all the committee members bring to the agency and the Commission's consideration of issues such as this. So, I thank you.

I know that you sitting here at the table with us and your fellow committee members all have so many other competing demands on your time. So, I thank you for your public service as I reflect on what the Chairman -- his opening comments and the public we serve here benefits so directly from the work done by you and the other committee members and the field that you represent.

So, I think it's important that we be informed by the very practical day-to-day considerations that you've presented on these topics and other topics. I appreciate your work.

I don't have any specific questions, Mr. Chairman. Thank you.

CHAIRMAN KLEIN: Thanks. Just a couple of follow up questions. On slide 12, you talked about the potential disadvantage in

the small and rural practices. Is that mainly from the medical diagnostic or from the actual treatment?

DR. EGGLI: Both, sir. The primary people who are providing that service in the smaller and underserved communities are in fact diagnostic radiologists frequently rather than board certified nuclear medicine physicians. Again, it would be the issue of that two year time gap delaying the entry of individuals into clinical practice until they can obtain their board certification.

Frequently, these are one-person shops where there is only one person who's providing this service. If there is no authorized user, then the service can't be provided or patients have to travel extended distances to have availability of those sorts of diagnostic and therapeutic services, at least for the Part 300 therapeutic services.

On the radiation oncology side, the Part 400 and Part 600 services are generally less of an issue because those people are pretty nearly board certifiable at the end of their training. Again, we're looking at more of diagnostic services and unsealed source therapeutic services.

CHAIRMAN KLEIN: You made a comment about the collective documentation is sometimes better than a single person. How do you document the collective evaluation?

DR. EGGLI: There are two ways. At least in my training

program there are quarterly faculty meetings where each -- the performance of each resident making progress toward completion of residency is discussed and documented by minutes of the meeting and a progress record with specific, effectively checked boxes, are kept on each person.

That's one form of documentation that is maintained internally. And then subsequently, the final documentation is the letter that the training director writes to the board which attests to the fact that the resident has completed all of the board's requirements for board certification. That document is a written document signed by the Program Director on behalf of the entire faculty.

CHAIRMAN KLEIN: You probably understand as a regulator if we can do it better and easier and -- we certainly want to hear that. We often time look for documentation. How do we verify? And so if there are things we can do to make it easier, we certainly would like to hear that, but we will need some kind of documentation.

DR. EGGLI: I think for the board certification pathway, that board certificate serves as the document because the board would not issue that certificate if the individual had not met all of those requirements.

For the people who are in the in-between status, between

completion of residency and board certification, I would think that a copy of the training directors' letter to the board attesting to the successful completion of all training requirements could serve as that documentation for NRC or an Agreement State.

DR. MALMUD: If I may, at our own institution we have a computerized data entry in which we evaluate each resident's performance each month as they rotate through various services: interventional radiology, chest, bone, nuclear medicine. It is a check box system. It's computerized.

We enter the data, sign it electronically and it becomes part of the permanent record of the resident for each month of his or her rotations through the four years of the radiology residency.

The residents also have an opportunity to evaluate us at the same time on a different form. So, there is a record. In addition to that, there are standing conferences in all academic radiology departments in which the residents are required to attend those conferences on a daily basis. Each day they have a different subject in which they’re given ongoing lectures, whether its physics, radiation safety or the specialty areas of ultrasound, CT, MRI, et cetera.

There are adequate records maintained which are then gathered by the chairman or the director of the training program if the director of a

training program is a different person from the chairman, and then summarized when the chairman writes his or her letter regarding the resident's performance and the mastery of the fund of knowledge.

CHAIRMAN KLEIN: With all that documentation, I guess I'm a little surprised that the RSO would be unable to take all that database and then sign off.

DR. MALMUD: This is for the residents in the radiology program. For the RSO, the RSO might be a physicist or of another specialty. I can't address that issue as to how the physicist addresses these issues.

DR. VETTER: May I respond?

DR. MALMUD: Please do. You're the RSO and the physicist both.

DR. VETTER: What the regulations are asking me to do is to attest to the competency of these radiologists to serve as an RSO. Most of them I haven't met personally. I may have given some lectures to them.

Much of the training that we provide is provided by one of my assistants or online, radiation safety training. Certainly, the regulatory material is mostly on line. So, I could attest that they have completed all of the training requirements, but I don't feel at all comfortable attesting

that they would be a competent Radiation Safety Officer.

I don't have any knowledge or personal experience with them. The whole issue is the competency. Are they going to be -- the previous regulation simply allowed us to sign and say that they basically had seen the right number of I-131 patients and all these things. It's simply documented their experience, their training and experience.

Now, it's asking me to attest to their competency. I don't know them adequately to be able to do that.

CHAIRMAN KLEIN: I think from our perspective it would be good if you could work with our staff and give recommendations of how we can do it better and still meet the needs of protecting the public in their regard. Commissioner Jaczko?

COMMISSIONER JACZKO: I don't really have any other questions. Just a brief comment on the cesium chloride and I certainly would be interested in reviews from you all about what's out there in the literature. Perhaps not as much of a believer that the Academy didn't look at that issue. I think they did. I certainly would be interested to see what you do find in regard to that.

I'm also not necessarily convinced that x-ray is the right direction that we're going to go one way or another. I think that is certainly one alternate approach to address this issue, but I'm not sure that it's

necessarily the only one or even the best one.

I certainly think in the end the Commission is going to need to do rulemaking on this activity for this very reason because we're going to need to solicit information from a wide variety people to figure out what the right path forward is.

As Commissioner Lyons said, if it's an issue of energy level, the x-ray, that to me seems like a technologically solvable issue. Now at what cost or what kind of effectiveness and efficiency, that may be a broader issue. But the discussions I've had with people about the Academy report are a little bit more comfortable to some extent they did look at some of the issues in regard to what the impacts would be of other technologies.

DR. MALMUD: The issue may boil down to what is available in current x-ray equipment to do this versus what could be created to do this. Therefore, the issue becomes one of expense.

COMMISSIONER JACZKO: I think that may be some of the difference in opinions here as well. As I think the Chairman and Commissioner Lyons mentioned, I do think these are issues that we're going to have to address and we're going to have to deal with them in the end to the extent that we can do them in a rulemaking, I think, is the most effective way because it will allow for solicitation of different views, in

particular, people in the medical community who have to ultimately use these and also in the research community. I'm sure a large body of the work is not in clinical, it's not an irradiation of blood for clinical purposes, but it's an irradiation of blood or other activities for research purposes.

There may also be some kind of difference in terms of the ultimate end use and what technologies are useful depending on the type of work that's involved. That's all I have. Thank you.

CHAIRMAN KLEIN: Commissioner Lyons?

COMMISSIONER LYONS: I don't think I have any more questions. I found this to be a very useful discussion and very much appreciated the time and effort that you folks put into it.

CHAIRMAN KLEIN: Thank you very much for your comments. They've been very helpful and continue to work with our staff and give us solutions when there are problems out there that we can do it better.

We'll have to live within the constraints that we have as well with the requirements that our advisers give us, but we would like to hear from you, certainly on the cesium chloride because that is going to be an issue that we will need to address. Thank you very much for your participation.

DR. MALMUD: Thank you. If I may in closing, I've been doing this now with the committee for a little over five years. Each year

the NRC staff with whom we work seems to be increasingly collegial; challenging, but collegial and helpful in every way. We very much appreciate it. It's made our roles as a consulting group that much easier.

CHAIRMAN KLEIN: Thank you for your comments. The meeting is adjourned.

(Whereupon the meeting was adjourned.)