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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

GREGORY B. JACZKO, COMMISSIONER

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KRISTINE L. SVINICKI, COMMISSIONER

1 PARTICIPANTS:

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

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

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

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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,

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

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

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

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

21 Competency is really fairly subjective and difficult or impossible to

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

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

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

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

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

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

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

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

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

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

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

1 trainers as a group.

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

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

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

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

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

1 fellowship trainees to be Radiation Safety Officers.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 this experience is required for board certification.

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

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

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

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

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

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

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

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

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

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

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

1 potential shortage of authorized medical physicists for therapy.

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

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

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

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

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

20 DR. MALMUD: Shall we move on?

21 CHAIRMAN KLEIN: We'll ask questions after both

1 presentations.

2 DR. MALMUD: Thank you, Chairman.

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

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

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

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

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

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

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

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

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

8 The NRC/FBI costs are \$36, so that total is about \$90. We have
9 400 employees, so that's about \$36,000 direct costs.

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

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

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

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

5 Just to compare that with a couple of other items in my radiation
6 safety budget. The annual license fees for our broad scope license for
7 \$29,000. Dosimetry services \$33,000 and now the fingerprinting is
8 another \$76,000. Mayo Clinic's margin the last two years has averaged
9 2.4%. So, that means we need to earn \$3.2 million to pay for the
10 fingerprinting.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 Task Force on July 31st.

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

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

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

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

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

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

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

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

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

15 DR. MALMUD: That completes our presentations.

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

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

1 DR. VETTER: I know about them.

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

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

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

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

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

20 DR. VETTER: I can't articulate what that background is.

21 They were aware of the cell activity in the upper Midwest and we talked

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

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

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

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

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

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

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

21 There is a subjective component to mastery of skills and knowledge

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

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

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

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

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

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

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

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

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

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

11 And on the therapeutic side, probably approaching hundreds of
12 thousands performed every year so that the fractions are a fraction of
13 1%, usually with one or two leading zeros after the decimal point. So,
14 one hundredth of a percent, four hundredths of a percent in that range so
15 that the numbers are of incidents related to radiation safety or misuse of
16 -- medical misuse of radioactive materials is extremely small given the
17 very large denominator.

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

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

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

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

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

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

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

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

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

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

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

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

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

15 CHAIRMAN KLEIN: Thanks. Commissioner Jaczko?

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

1 didn't really have time to read the rule.

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

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

7 DR. EGGLI: It is.

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

11 DR. EGGLI: That is a fair statement.

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

16 DR. EGGLI: And clinical practice starts.

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

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

1 residency?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

1 DR. EGGLI: Thank you, sir.

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

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

11 COMMISSIONER JACZKO: Thank you. Appreciate the
12 insights.

13 CHAIRMAN KLEIN: Commissioner Lyons?

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

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

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

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

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

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

12 COMMISSIONER JACZKO: That's just my view.

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

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

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

1 Congress at the time.

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

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

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

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

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

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

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

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

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

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

1 more uniformly.

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

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

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

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

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

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

1 energy compared to the gammas and cesium.

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

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

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

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

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

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

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

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

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

10 CHAIRMAN KLEIN: I would encourage you to do so.

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

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

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

1 CHAIRMAN KLEIN: Commissioner Svinicki?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11 DR. VETTER: May I respond?

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

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

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

1 that they would be a competent Radiation Safety Officer.

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

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

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

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

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

1 necessarily the only one or even the best one.

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

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

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

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

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

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

8 CHAIRMAN KLEIN: Commissioner Lyons?

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

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

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

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

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

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

6

7 (Whereupon the meeting was adjourned.)