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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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FRIDAY, MAY 8, 2009

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The meeting was convened in the auditorium of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., Leon S. Malmud, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D., Chairman

DOUGLAS F. EGGLI, M.D., Member

DARRELL FISHER, Ph.D., Member

DEBBIE GILLEY, Member

MILTON GUIBERTEAU, M.D., Representative

RALPH P. LIETO, Member

STEVEN MATTMULLER, Member

SUBIR NAG, M.D., Member

ORHAN SULEIMAN, Ph.D., Member

BRUCE THOMADSEN, Ph.D., Member

WILLIAM VAN DECKER, M.D., Member

RICHARD J. VETTER, Ph.D., Vice Chairman

JAMES S. WELSH, M.D., Member

NRC STAFF PRESENT:

ROB LEWIS, Director, MSSA

CHRIS EINBERG, Branch Chief, RMSB

CINDY FLANNERY

STEVEN BAGGET

NEELAM BHALLA

ASHLEY COCKERHAM

DONALD COOL, Ph.D.

RON ZELAC, Ph.D.

DONNA-BETH HOWE, Ph.D.

DUANE WHITE

GRETCHEN RIVERA-CAPELLA

GLENDA VILLAMAR

LEIRA CUADRADO

CASSANDRA FRAZIER

SANDY GABRIEL

DORIS LEWIS

ED LOHR

PATRICIA PELKE

MARK SCHAFFER

MARK THAGGARD

DARREL WIEDEMAN

MEMBERS OF THE PUBLIC PRESENT:

GARY BECKER, ABR (PHONE)

MEMBERS OF THE PUBLIC PRESENT CONT.

MELISSA CACIA, AACE (PHONE)

ROBERT DANSEREAU, NY (PHONE)

WILLIAM DAVIDSON, U OF PENN (PHONE)

RICHARD EATON, MITA

EMILY GARDNER, ASNC

LYNNE FAIROBENT, AAPM

BONNIE HAMILTON, MDS NORDION

KAREN LANGLEY, UT (PHONE)

KATRINA MILLER, AACE (PHONE)

MIKE PETERS, ACR

DOUG PFEIFFER, AAPM

GLORIA ROMANELLI, ACR

JOE RODGERS, THERAGENICS (PHONE)

RIAD SALEM, SIR

REED SELWYN, UNIF. SVCS. UNIV. OF HLTH. SCI.

BRIAN STAINKEN, SIR

STEPHEN THOMAS (PHONE)

KEN THURSTON, SIRTEX

CINDY TOMLINSON, SNM (PHONE)

ANN WARBICK CERONE, MDS NORDION

EMILY WILSON, ASTRO

JENNIFER YOUNG, AACE (PHONE)

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P R O C E E D I N G S

(8:12 a.m.)

CHAIRMAN MALMUD: Because of yesterday's extensive discussions, today's program will be altered slightly. However, we are beginning with Dr. Cool, who is scheduled at 8 a.m., and the topic of discussion is "Options to Revise Radiation Protection Regulations."

Dr. Cool.

DR. COOL: Good morning, ladies and gentlemen. Thank you for inviting me down to speak to you again. You will recall that I think the last time we met, last fall; I came down and talked to you about what the staff was, at that time, thinking about suggesting to the Commission in terms of next step for radiation protection regulations and requirements following on the publication of the International Commission on Radiological Protection's recommendations.

Well, I'm back to talk with you today to refresh that, and to move forward. So, I'm going to very quickly go through the first few of these, because we had a chance to talk to them before. As you know, of course, 10 CFR Part 20 was last revised in 1991. It's based on recommendations that went back

all the way to 1977. And some regulations and NRC requirements were not updated at that time, if they had their own separate explicit dosimetric criteria. The one that was catching everybody's attention was not the one you would be so much interested in, but was very important to our friends that run the reactors, because that was the requirement dealing with effluent controls, 10 CFR Part 50, Appendix I. Those go all the way back to the recommendations from 1959. So, there was, obviously, a bit of a question about trying to update the requirements.

In 2001, we had asked the Commission on the next steps, and everyone had agreed that we would wait for ICRP to be done. We didn't quite figure it would take ICRP seven years, but nothing moves quickly, and greatly benefits from the multiple rounds of public comment that transpired during the course of the development of those recommendations. So, those came out in December of 2007.

So, now to catch up to where we were last time, the staff did go to the Commission in December of last year, SECY Paper 080197 is publicly available, as a notational paper. We asked the Commission to provide us with directions on a set of options for moving forward. We provided them some background on

the information, and some of the technical issues, and we -

(Off the record comments.)

DR. COOL: Okay. And, as I said, we recommended to the Commission that the next step be to engage in further discussions with the stakeholders, various groups of licensees, and work on developing the technical basis, because there was much that was necessary before we could actually begin rulemaking.

The Commission gave us direction in an SRM just a month ago. The SRM approved the staff going forward to develop a technical basis and to start interacting with the stakeholders. That's part of the reason that we're here with you today, is to start making that move forward. Our objective, then, is to explore the implications, looking for what's appropriate, what's scientifically justified to move towards a greater alignment with ICRP Publication 103 and the recommendations for radiation protection.

We must keep in mind that the baseline from all this is that the standards do provide adequate protection, so questions become what the benefits and impacts, the pros and cons, different possibilities for modifying the framework to get more consistency with the requirements that might be

associated with that.

You saw this slide last time, I believe. To quickly overview some of the key questions that we are going to be looking for interactions on, this group last time had quite a bit of discussion on the very first item, the use or not use yet of effective dose. Other major issues being the dose limits, the application of constraints, and, of course, some of the numeric values, and otherwise. And I'm going to go into those in greater detail now just to go through those briefly.

On the occupational dose limits, the one that everyone seems to focus on, ICRP both in the current set of recommendations and the previous set of recommendations from 1990 recommended an occupational limit at 10 rem over any five-year period, with a maximum of 5 rem in any one year. That has been translated internationally, in some cases, as a simple 2 rem per year limit, period. Nice and simple, straightforward. Many countries, in fact, have the 10 rem over five-years, sometimes the five years is a rolling average. Sometimes it's a fixed five-year period and you get to restart the clock again every five years, so there are some variations on the theme.

The United States is about the only place

left in the world that still has a limit which is only 5 rem. So that, obviously, poses a question as to whether or not some adjustment needs to be made. As I noted to you last time, of course, since the ICRP recommendations were a maximum of five in any one year, you could argue that we are still consistent with the international recommendations, particularly since most all occupational exposure after you've applied ALARA is very much below that. And, in almost all cases, even below the 2 rem per year average.

So, the key options that we, at least, laid out to the Commission, you could not change, you could move to the ICRP recommendation, you could go to a simple 2 rem per year value. And there are pros and cons associated with that. There are a number of impacts, a little bit of which we talked about last time. That includes record keeping and reporting. Some of us are old enough to remember the days of 5N minus 13, 18, I'm trying to get myself younger, and all of the ongoing record keeping and figuring out where you were, and looking back at dose histories and otherwise, which you no longer needed when you had a simple yearly value. Those would have to come back if you went to a five-year average of some type.

There are also, as we know, some issues

around certain types of uses, industrial radiography being one, nuclear pharmacy being one that was identified here last time. So, we're going to be looking specifically for the views of this Commission, and your various constituent's organizations in terms of the pros/cons, implications, and impacts on that.

Moving on to the next one, which we also had some discussion on last time, dose limit for protection of the embryo fetus for a declared pregnant female. The ICRP recommendation now is a fairly straightforward 100 millirem after the notification of pregnancy, consistent with a generalized statement of protection consistent with that provided for a member of the public. Currently, Part 20 is at 500 millirem for the entire gestation period, which means that under our requirements, you have to go back and assess the exposure that's already taken place before the individual declared her pregnancy to determine what's left, and what you can apply.

So, again, as you can see, there are possible implications of moving to the new system, or retaining the old system. Obviously, again, options would include not changing anything, going to the ICRP recommendation, going to some other single value after declaration, or otherwise, that have been suggested.

Since you know the individual is not going to declare on the day of conception, and it will be somewhere between there and the day of birth. And depending on what the individual wants to do, and it is her choice, it is not a requirement that there be a declaration, the degree of protection then varies. If the declaration is very early, then an ICRP recommendation of 100 millirem after declaration would be more protective than 500 millirem over the duration. But if you get the individual who waits until four, five, six, seven months in before declaring her pregnancy, then, in fact, you could argue that the ICRP recommendation might be less protective. So, there are various pros and cons, and again, there are implications associated with the record keeping and update, and the analysis that would have to be done.

Moving on to what may be one of the biggest points of discussion, that is the concept of constraints. ICRP has in its current set of recommendations emphasized the use of constraints in planning values in the process of optimization of ALARA. This is probably the single greatest feature of the revised recommendations, is the emphasis upon this as a planning tool in optimization. It's not a limit. ICRP doesn't intend it to be a dose limit. It

intends it as a planning value, prospectively used to figure out where you want to be, and where you don't want to be in the process of figuring out what options, and what activities you'll conduct as part of your ALARA program.

Now, the NRC already has constraint defined in the regulations. In fact, there is already a constraint value for airborne effluents from material facilities of 10 millirem per year. That went in as a result of our interactions with EPA under the Clean Air Act. This would go, potentially, substantially beyond that current position.

We know, for example, that many licenses, certainly all of the big licensees, all the reactors, many broad scopes, and otherwise typically and normally use planning values in deciding what their ALARA program is going to be, what their ALARA objectives are going to be for the year, and otherwise. That's a constraint.

The question really becomes, do we see a value in requiring licensees to do that, because some do, and some don't. And antidotal at this point, the evidence would seem to indicate, perhaps, that in those areas where that is not a standard practice, or is not consistently used, those are areas where you

tend to see higher exposure, and potentially have more issues, so there is the possibility that you could be improving protection by having people do a better job of planning. Actually makes a fair bit of sense.

So, the questions really become do we want to put such a requirement in, or is it an overreach of a regulatory burden and a requirement to require them to do such a thing? Do we want to have them make it part of it? And, then, do we want to go so far, if you were to put it in, to suggest to them a numeric value, or, perhaps, a maximum value that they could use as part of the process?

There are, obviously, a number of implications that we want to look at and explore with various groups. Do you or do you not already do this? If you already do this, it's just a matter of okay, now there's a requirement for it. Are the benefits to protection to be seen? As I indicated, many times there is a benefit to making sure your planning is done well, and going back and checking that. But is there a benefit sufficient that you might want to make that part of the requirements? What might be the relationship to the dose limit?

As I briefly outlined to this group last time, one of the things that the staff has explored

internally is the question of whether instead of modifying the dose limit, we could achieve the same degree of protection out there in the field in practice by using constraints, and having people do a better job of planning, rather than by ratcheting down the limit, itself. So, there is some interplay that we would like to explore with groups. And, as I said, is this appropriate or perhaps not appropriate insertion of a regulatory requirement in an area where many people are already doing something?

So, to interact with you, and to move forward, what we're looking for are your thoughts, both the Committee, you folks as individuals, and each of the various types of medical uses that are represented around this table. What are the impacts of the options? What other options may be out there? I, by no means, suggest to you that we've thought of all of the possibilities, nor am I suggesting to you this very quick list today is by any means the entire list of issues that needs to be addressed. This is just the very first wave. There are many, many others. What happens with extremity doses? What happens with the public dose limit? What happens with the numeric values? Do you want to continue to have those available? What are the underlying calculations

and criteria that are used? ICRP raises questions because when you start to underlie this, we know that there are some differences between the risks in males and females. This has a balance. Is that the appropriate balance? Do we continue to move forward? Are there legal implications associated with some of these other decisions? All of that needs to be built into the information that we need to gather in order to be able to make a recommendation for rulemaking in a couple of years. Now, we do, in fact, have a couple of years.

So, the schedule, at this point, now through this summer, at least, maybe on into the fall some, some initial discussion, presentations much like I'm doing for you today to raise awareness and to get people thinking, and starting the discussion process. Starting in the fall through the winter, and into next year, to get into more detailed discussions, to really start digging into the details, getting the pros and cons, debating it back and forth, looking for the issues and impacts. We will, at some point, be looking to try and hold specific interactions with groups of licensees, some workshops, and otherwise. We do not have those scheduled yet. We're looking for your thoughts and inputs on what are the good places,

and times, and groups to be doing that with. Continue that through 2010.

Part of the schedule on this is driven by the fact that the ICRP is still working on revising the dose conversion coefficients that are used to translate a unit intake of radioactive material into an effective dose. That underlies the annual limits of intake concentrations that are in Part 20, Appendix B, and otherwise. The first of those, the first of those will not be available until 2011. The complete set may not all be there in place until more like 2014, so we're going to face a question of when do we have enough to get started, when will we have enough to be finished? How can we work through this process in an orderly manner, meet all of our requirements under the Administrative Procedure Act, and otherwise?

We, of course, all through this process will be continuing our analysis, working on technical basis, interacting with our federal partners, EPA, DOE, OSHA, and others to try and - I was going to say gently move, I'm not sure that's quite the proper word - the whole federal family in the same direction to try and achieve a little better alignment than what's currently present today. Of course, you all know that all of the federal regulations exactly match each

other, not exactly.

We are developing a whole series of things to try and facilitate the discussions. There will be a set of web pages on our public website. They're not quite up yet. You know there are many, many steps in the process of making sure you've got it right, and getting the infrastructure people to agree that you have it sufficiently right that they'll let you post it out there, so that will be a little while. But, in the meantime, we do already have a dedicated email address for people to use, so you don't actually have to send it to me personally. Regs4rp. It does work, we've already tested it. The State of Iowa has already sent us in some stuff, so we know it's working. There was a press release on the 27th that has stimulated a bit of interest. We have a whole series of these initial presentations scheduled. We'll be at CRCPD in just a couple of weeks, the Society of Nuclear Medicine in June, the Health Physics Society in July, the State Liaison Officers, the Fuel Cycle Information Exchange, the list is growing. These slides get out of date almost as quickly as I hit the save button on the PowerPoint presentation.

So, for our purposes today, because I know

that you do not have the time that you might wish to really start talking about the pros and cons, and issues, but what I'm particularly interested in is to get the Commission starting to think about how we can work together over the next couple of years to work through some of these issues, to explore your views on the pros and cons, and options, and how we can engage with your various communities that you represent to get the information from them.

I'm looking for suggestions of particular meetings of societies and other groups of licensees that we might be able to talk to, and explore these issues with. And I would like your thoughts and views on the right mechanism of interaction with this group. I know that with the ACRS we now have a dedicated subcommittee that Dr. Mike Ryan actually chairs, to work with us some of the HP issues. Whether or not you would wish to do a similar sort of thing, or continue interactions with the Committee, we hope to get your views and find the right ways that we can be exploring that with you.

And, with that, I complete this little run-through presentation, and open up for questions and discussions. Thank you very much, Dr. Malmud.

CHAIRMAN MALMUD: Thank you, Dr. Cool.

Are there any questions for Dr. Cool, who has invited questions? Dr. Vetter.

MEMBER VETTER: Not a question, a comment. I really do like the idea of a subcommittee from the standpoint that it takes too long to interact with the Committee, as a whole. As you know, Bruce had trouble with trying to get his Subcommittee to come to consensus, and it had to come here to finally get settled. That's a long time. And if a subcommittee can more actively interact with Dr. Cool and his colleagues on various questions that come up, even if it's not coming to decisions, if it's simply getting information and feeding it back, it can be done much more quickly, than interacting with the entire Committee.

CHAIRMAN MALMUD: Thank you. I, personally agree with you. It's a much more efficient approach to it. Other comments, other than how we might interact with respect to a subcommittee, rather than the Full Committee? Dr. Vetter?

MEMBER VETTER: Yes. I'm speaking a little out of ignorance here, but as I recall in the -- -somewhere in the early `80s time frame, the NRC sent out a questionnaire to materials licensees to voluntarily report their exposures. And it wasn't in

any kind of a regulatory sense. NRC was trying to learn something, and I even forgot why they were doing it.

The reactors send their occupational exposures into a database of some sort, but you don't know what the materials licensees' exposures are, I don't think. I don't think you have a database. And, so, if you were to sample all of us, that's a very, very, very small sampling of what the occupational exposures are. So, maybe it's possible to explore how can you get some real occupational data from materials licensees? That might be useful.

DR. COOL: If I could respond to that? Certain classes of licensees are required to report their information, and that does pick up one or two materials uses, particularly industrial, and radiography has to report. So, we get the information for those that remain as NRC licensees.

We face two things here. First is that we need to explore how to do this, particularly given that three-quarter plus of the licensees now are Agreement State licensees. And, so, the Agreement States may well have some of the information. In some cases, they have even more information than we do, and try to share that and gather. The second is that at

least for NRC, and in most of the states, there are a couple of places where this is not true, the medical licensees do not have to provide their occupational exposure. That is maybe one of the biggest holes in the data set. The third component, of course, related to the interest of this Committee, is that our regulatory jurisdiction goes to the materials. The bigger piece of the pie is the machine-produced radiation, and only some of that would be an interaction as a result of multi-modality, and otherwise. But we need to explore the implications not just for the materials, but for the entirety of the program, if there's going to be anything like consistent national system. So, I would welcome any and all of your suggestions. I know that we've been doing some interactions, but we don't have a lot of data, at this point, and information.

CHAIRMAN MALMUD: Dr. Fisher.

MEMBER FISHER: Don, you take a very complex subject and make it easy for us to understand. And I think you have a nice way of presenting the ICRP concepts, and the challenges that NRC faces. And I concur with your initial recommendations, and request for information.

One question, these changes will impact in

the practice of medicine some elements more than others, cardiology, in particular, and radiopharmacy. Could you state that -- could you give us any information about what the implications of the new ICRP recommendations are on workplace monitoring, assessment of exposure, or even assessment of internal dose from materials? Are there any implications for workplace monitoring that you'd like us to consider?

DR. COOL: I think there are certainly some things that ought to be considered; per se, the recommendations don't go to the level of detail of specific suggestions related to workplace monitoring, or otherwise. But that has to be looked at in the context of what the requirements are. Currently, the requirements are for there to be monitoring sufficient to demonstrate compliance. If you are to change the limits, or otherwise, then almost automatically the threshold levels, which are usually percentages of the limit would change and come down. That could certainly have some implications.

There are changes, we know, in the annual limits of intake, derived air concentrations for at least some radioactive materials. They are not going to be huge, earth-shattering moves one way or another. They will be small adjustments, for the most part, as

we understand them. So, those do not, necessarily, have significant impacts on workplace monitoring, other than the connection back to limits or otherwise.

The other component, which I really don't know how to predict, but I would invite you to think about is, to what extent there's an interface between the issues of establishing constraints, and otherwise, and the values that you would establish associated with monitoring. I would hope that there would be connections between what you use when you plan your program, and where you want to be in terms of your ALARA effort, and the criteria that you would use to monitor, because it wouldn't seem to be of very much use if you set up a lovely program and planning, and then your monitoring systems didn't allow you to detect whether you'd actually achieved it. And that may end up, in fact, being very facility-specific.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I have a few comments. One, I think sometimes when you wait long enough, it gets easier. I think the world has standardized in terms of the effective dose, and the scientific community has accepted that. So, in some ways, your transition actually will be easier in terms of people understanding the difference between effective dose,

and effective dose equivalent. I think the first transition to effective dose equivalent was clearly more difficult, and challenging. That doesn't minimize the effort that's going to have to go on.

My focus the last several years has been more on research, which is really a much minor set of issues. FDA, you guys aren't as outdated as we are. We have some dose limits for some research applications that date back to `75. We intend on changing those at some point. But you don't say anything; you basically do not address human research. You defer to the IRBs, and to FDA, and so on. Would you be willing to readdress, or do you think you'd maintain that same stance?

DR. COOL: I would expect that the Agency would maintain its stance in not getting into the middle of the question of the doses to the individual research subjects as part of the protocol, just as we don't go to the question of what's the appropriate exposure for a patient. Obviously, we would be looking at the question of protection, occupational, public, and all the things that go along with it, but I would not expect us to be trying to open up a new piece of discussion.

On the other hand, we would welcome

continuing to interact with you as you look at those subjects, so that we can be putting all of these consistently together into a federal framework.

MEMBER SULEIMAN: Right. And I really empathize with your statutory constraints, as well as -- because we deal with them all the time, as well. But the body doesn't differentiate how -- where they get the radiation, so I think -- I do think you're going to have to -- you should get -- I suspect you don't collect medical exposures, because some of the doses are from x-ray, and, so, that doesn't cover -- you're not responsible for that, and you can't differentiate between that. But I think from a public health point of view, it would be collect that information and have a little asterisk, and say that some of this radiation doesn't come under our direct jurisdiction, if that's the reason why you didn't collect it in the first place. But, I think, sort of like the states when they -- you don't differentiate.

MEMBER GILLEY: Radiation is radiation.

MEMBER SULEIMAN: That's right.

CHAIRMAN MALMUD: I think first was Ralph Lieto.

MEMBER LIETO: Me? Dr. Cool, sort of a follow-up question, or not question, but comment, to

what Dr. Suleiman just mentioned. There are other federal agencies that have dose limits that are extremely archaic. And I would -- I know that, again, that there are some constraints that the NRC has, but I believe that there is the Memoranda of Understanding. Is this an avenue by which you can sort of encourage these other agencies to sort of come up into the -- out of the darkness and into the light on this subject? I don't know if that's something that you've been looking at, or have been considering. But I think it's important that all federal agencies sort of come up to speed on these dose limits, since many of them are still back in the `70s.

Another question I did have related to the term, to the constraints. And as you go forward, I think this being an entirely new concept, I think a lot of people are going to try to look at this in the context of, is this analogous to the ALARA levels that are set in terms of action levels of dose, responding to dose limits in their various licenses, or is this an investigational level, which is a concept that's quite commonly used in radiology.

I think the biggest problem in going forward with this concept is, if I wrote this down correctly, was that the constraint is considered a

numerical value licensees cannot exceed. I mean, that's a limit. If they can't exceed it, it's a limit, and that's how it's going to be viewed. So, I think as you go forward in conveying this to other societies and agencies, and groups, that if you can kind of put this in a context that they're familiar with, that this might have to be replacing, I think that would be helpful.

DR. COOL: Thank you. The two pieces of the puzzle. First, the other federal agencies. Yes, we are working with them. We've had a number of discussions with them, in fact, through the Inter-Agency Steering Committee on Radiation Standards. We are looking at exactly what each of the agencies has, what each of the agencies is thinking about doing, and looking to try and have a consistency as we move forward. Obviously, we cannot do more than influence, cajole, push, pull, and otherwise, but that is exactly what we intend to do.

On the concept of constraints, yes, you're very right. This is an area where a lot of careful discussion and then very careful wording is going to be necessary if the concept were to be considered to be in the regulations. Because, there is a very fine line between words which become a limit, and words

which are where the licensee would not plan to exceed in their ALARA program, which is not a limit, but which has similar connections to investigation levels, and otherwise. So, there's a whole set of concepts where you might initially plan to be, the boundary of your ALARA process, what your ALARA process might suggest to you is the best place to be, the establishment of the targets or the goals, which might be the result of the optimization, so it might actually be less than their initial plan, and at what point you would go back in and investigate whether or not it was working, or not working. And there's a whole set of things, which does need a very careful understanding and alignment in order to decide exactly what the right relationship is. And it takes a lot of time.

CHAIRMAN MALMUD: Before Dr. Vetter asks his question, I wanted to follow-up something that you said, Ralph. When you said some of the regulations are archaic, in what ways?

MEMBER LIETO: OSHA limits are basically the limits that were set before the NRC modified theirs in the early 1990s. They're basically the limits that were in place in the early `70s, 5N minus 18, 3 rem per quarter, these types of limits that are

still in place.

CHAIRMAN MALMUD: And these limits are excessive compared to current standards? When you say they're archaic, do you mean that they are -

MEMBER LIETO: In some instances -

CHAIRMAN MALMUD: In their definition?

MEMBER LIETO: Yes. In some instances, the numbers are higher, higher dose limits that are permissible. But they're in areas that usually the NRC does not have regulatory authority over.

CHAIRMAN MALMUD: Yes. Thank you. Dr. Vetter.

MEMBER VETTER: In response to Dr. Suleiman's comments, I don't know if he was going there relative to establishing limits for patients, for human subjects. But the ICRP recommendations are justification and optimization for patients and human research subjects, and I really don't, at this point, see anything that would suggest that the regulatory structure go beyond that.

CHAIRMAN MALMUD: Thank you. Dr. Suleiman, did you wish to comment?

MEMBER SULEIMAN: I just want to clarify, most of our research, there are no limits. I think the Radioactive Drug Research Committee is a very

special set of circumstances, where we allow researchers to not actually have to get filed in the investigation of new drug application, and, so, to release them from that additional burden, they have to comply with certain limits. But if they -- they have the option. They can do it under an IND, and then there are no limits. It's up to the expert on the committees.

CHAIRMAN MALMUD: Dr. Welsh?

MEMBER WELSH: I can appreciate that this is a very sensitive and important subject. It's sensitive because we're talking about regulation. And I can appreciate all the thought and effort that ICRP has put into ICRP 103. I know it came out at a very controversial time, 2007, when doses from medical procedures, such as CT, were in the news on a regular basis. And if we are going to be discussing adoption of some of the recommendations herein, the ICRP report, therefore, would have to be very, very carefully analyzed and evaluated.

Questions that come to mind surround the controversy about LNT. I know we don't have time, and this is not the venue or forum for a discussion about that, but can you tell us if the LNT model was used in ICRP 103, as a starting point?

DR. COOL: Yes, I can tell you, and yes, it was. The underlying model of Linear Response continues to be the basic model used for the establishment of an appropriate regulatory regime. ICRP was actually rather careful in their language about appropriate for a regulatory regime, versus an absolute we believe that this is the way the body actually behaves, because there is a lot of things going on, and there are a lot of unknowns associated with that, as you know.

Furthermore, ICRP has backed away from that, or can be viewed as backing away from that, because they have been very careful to say that a collective dose calculation, as in integrating number of people and their exposures for some period of time, is not an appropriate measure for assessing the risk of that radiation exposure in that population, because of the wide uncertainties at the low doses, the uncertainties associated with the exposure. So, ICRP has, in fact, suggested that it not be used in risk assessment, which is one of the places that the Linear No Threshold hypothesis would drive you to, and from a purely mathematical construct.

CHAIRMAN MALMUD: Dr. Van Decker.

MEMBER VAN DECKER: Thank you. I've

served on chaired enough Radiation Safety Committees in 20 years to know that from an occupational worker perspective, the people that are going to be the most affected, obviously, by dose reductions would be people in constant fluoro environments, and interventional radiology in the cardiac cath lab by far and away. To the degree that this discussion will interact on those people who are being exposed by machine-produced radiation, and clearly take them into the realm where a large percentage of those providers will be affected, and the amount of activities they perform in a year, clearly say that you need to be involved with those societies which are not represented at this table right now, Society of Interventional Radiology, which was here yesterday, and the matching one on the other side would be known as the Society of Cardiac Angiography and Intervention, CA&I, known as SCAI in the vernacular. But I think that they would have strong interests in some of this discussion, and understanding the technical and scientific basis for why we would be making this move, when most of those members, obviously, have battled through the badging, and monitoring, and trickiness of those requirements in that environment, and these types of dose levels that

are easily within this realm for -- well, let's see, my partner has been doing it for 40 years, 40 years. So, I think they'd be interested in being part of the discussion, and I could facilitate half of that for you.

DR. COOL: Thank you.

CHAIRMAN MALMUD: Dr. Welsh.

MEMBER WELSH: So, if I could ask Dr. Van Decker to expand a little bit, if we were to change our recommendations from 5 rem per year, to 2 rem per year, do you think that would have a significant impact on some of the workers in those fields you mentioned?

DR. COOL: Oh, in the large centers, this would affect more than 50 percent of the practitioners.

CHAIRMAN MALMUD: Debbie Gilley.

MEMBER GILLEY: Dr. Van Decker, does your facility allow the weighting of badges, or are you using simply a personal dosimeter on the outside collar?

MEMBER VAN DECKER: I leave those types of technical considerations up to Radiation Safety Officers that have battled with this. I've seen it done both ways. A lot of times it's been done by

mathematical calculations for the obvious reasons.

MEMBER GILLEY: And you would still exceed the 2 rem a year, even with an alternate reporting requirement technique?

MEMBER VAN DECKER: I would see it close enough in the realm of consideration.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: Just to sort of follow-up on Debbie's question. On the Radiation Safety Committee, I review these sorts of doses quarterly. If you take the external badge, and then you do the calculations for deep dose, most of our interventional radiologists would be pushing that 2 rem limit, pushing or exceeding that 2 rem limit. It is not uncommon in a quarter to have 2,000 or 2,500 millirem on an external collar badge.

CHAIRMAN MALMUD: Debbie Gilley.

MEMBER GILLEY: My next question is for Dr. Cool. How are the Europeans meeting the 2 rem requirement? Are they simply not doing the number of procedures we have, or is there a better method that they are using?

DR. COOL: That's one of the things that we want to explore more with them. The first blush we get back is, there aren't any difficulties, they've

been complying with it for years. What we do not know at this point is, when we dig under the surface, do we find that they're doing an effective dose calculation from external sources? Are they not wearing badges, or some other combination of possibilities? That is a question that we do intend to pursue, and for which, at the moment, we do not have a real good answer on.

MEMBER GILLEY: Thank you.

CHAIRMAN MALMUD: Dr. Vetter.

MEMBER VETTER: One of the problems that we have in this country at this point in time relative to badges worn by interventionalists, and cardiologists, and so forth, is that we are regulated by 50 different regulators relative to those badges. And, in some states, they're more progressive than others, and they will allow you to correct those mathematically based on more recent computations. Some states say well, we want to take the most conservative point of view, and we will allow you to divide that external badge reading by three. And that's the rule, and you must follow it. It doesn't matter what ICRP has said. So, if we could all get on board with the latest estimates of risk and computations, I don't think we would have a problem with a 2, although there still are some

interventionalists that will become close to that. But we certainly today have a huge problem with meeting that limit if we have to divide the external badge -- the badge worn on the outside of the apron by three.

CHAIRMAN MALMUD: Thank you, Dr. Vetter.

MEMBER VETTER: That's to estimate effective dose equivalent.

CHAIRMAN MALMUD: Thank you. Dr. Suleiman.

MEMBER SULEIMAN: I think the need to standardize, actually using effective dose, or effective dose equivalent, it's conceivable some people could actually get more dose, because you may find out that some of the extremities may be weighted much, much less, and so you could actually -- it would be conceivable to have a high -- to fall below the effective dose limit, and still get some pretty high doses to some other tissue. But the need for standardization, and not to dumb down, sometimes we do to keep it simple, but we pay the price, because then you have people say I'll just use the badge, which is a good health physics principle. It gives you the upper limit, but it's not going to give you an accurate estimate as to the total risk that the individual was subjected to.

In terms of the practice, I think the whole purpose of radiation safety is to constrain, because, in my professional opinion, my doctoral thesis was in fluoroscopy, but I think technology, and how I think modern day medicine can be conducted to meet a lot of these constraints. I think in some cases, technology can help reduce the doses significantly. I don't want to go into a large-scale discussion on that, but I think the potential is really there, and you see variations of that across the country. So, the constraints do what they're supposed to. The limits do what they're supposed to, and, so I think you're on the right approach. But I think the need to standardize would help solve some of those problems.

CHAIRMAN MALMUD: Dr. Cool.

DR. COOL: Thank you. A couple of quick notes. Effective dose is what's now in the NRC regulations, and we do allow the use of the different formulas for calculation. So, that's where the NRC is. Yes, there is the continuing discussion of how that gets implemented in various states and otherwise, the degree of conservatism and things. And noting, of course, that with the new tissue weighting factors, the algorithms that people use are another one of the

things that are being updated. There's already been an article in the Health Physics Society that goes through and updates the algorithms for the new tissue weighting factors.

Secondly, to note that there are also requirements in the regulations now for extremity doses. And while there can certainly be some discussion around whether or not there should be changes in those, the ICRP recommendations don't suggest any changes in those areas, so you have that.

The third piece, which I'd just like to pick up on, is again the issue of constraints, and the interactions of constraints in the optimization process with the limits. The limits as a legal boundary, someplace that we would hope we don't ever actually get people over, because then there are all sorts of ramifications. Part of the reasons I offer the suggestion to you for discussion is, I can conceive of regulatory requirements utilizing the idea of constraints carefully constructed that might allow increasing the protection, accomplishing things for some of these interventional radiologists and cardiologists, and otherwise, and getting them in the place where we might wish them to be from a protection standpoint, but not, necessarily, do that by means of

just taking down the limit, which would put them in a legal quagmire, where it was do I become illegal, or do I take care of this person before they die?

CHAIRMAN MALMUD: Dr. Cool, not being a fluoroscopist, but having observed fluoroscopy in a number of institutions, and having observed human behavior, I would fully agree with your last comment, that lowering the limits will not achieve the goal. The first thing that should be done is, perhaps, to collect a sound database, which we do not have currently. It might be required that before the exposure to a machine, or to a radiopharmaceutical, that there be a timeout, just as there is in surgery, in which there is assurance that the badges are being worn by the individuals who are supposed to be wearing their radiation exposure badges, so that a sound database can be obtained. Right now, it's not at all uncommon for someone to forget his or her badge, or to forget a portion of the badging, the finger badge, the badge on the collar, what have you, and that to tighten the rules in the face of the absence of a sound database, would create problems, which you've alluded to for the population as a whole, particularly those who provide radiologic services. So, my own inclination would be, though I am a firm believer in

ALARA, that a database is the first thing that we need, and we don't have one. And I doubt that the Europeans have one either. I have a number of European colleagues and they have the same beliefs and practices as my American colleagues. And I see it, and this is among very educated people, who just forget the badge on the day that they're going to -- at a moment when they're going to get some exposure. So, I would first argue for a sounder database before the rules are tightened, but that's a personal opinion, and I'm certain that my colleagues in diagnostic and oncologic radiology would have their own opinions with regard to professional behavior in these environments. And, also, this applies to technologists. I don't think we have a database. We'd be measuring the unknown with the unknown under current circumstances.

Having observed the tightening of the rules in the operating room, which have been very effective in reducing a number of untoward incidents in operating theaters, it may be that we need the same kind of practice in the world of radiology, not regulated by the NRC, but within each institution so that we could achieve a database in which we might make some observations. Otherwise, some people will

feel that their livelihood is being interfered with, and there's a natural tendency not to want that to occur, even when it puts the individual at risk, or when the individual feels that he or she can't provide essential patient care on behalf of the lives or the well-being of a patient because of an abstract concept. Mr. Lieto.

MEMBER LIETO: Just to follow-up on your statement there, Mr. Chairman. As you go -- if you do go forward with getting a database of information in medical users, I would encourage you to try to separate, where possible, machine users from radioactive material users, because I think you might find that although there are very high-end machine users in interventional radiology, there is a tremendous amount of what I call psychological monitoring that's done in medical institutions for nursing staff, OR staff, so forth, because they think they might get exposed. So, when you look at the averages of x-ray users, it's going to be maybe low, and when you look at radioactive material users, where you're monitoring the people that are actually handling it, and there's very little of what I call psychological monitoring that goes on, you may find that the numbers are a little bit higher, I'll say

above maybe the ALARA levels. So, if you can, as you go forward, if you can separate out this database by those users, it might provide some differing information on what the exposure levels are in the different groups.

DR. COOL: I think we would very much agree. Yes, we need a database. We need information with which to have a basis to propose or not propose anything. And the better the fine structure that we can get on that database, the better the information and the decisions will be. I think we're much in agreement with that.

CHAIRMAN MALMUD: I think we agree. And my observation would be that we'll never be able to achieve a sound database if the penalties are too great to the individual in the collection of that database. Was there someone else? Yes, Dr. Suleiman.

MEMBER SULEIMAN: I hate to throw in an idea, but why not? Have you ever thought about, if the medical community feels so strongly, would they allow a higher occupational limit for some life-threatening, or for some high-risk procedures?

DR. COOL: I'm going to say first, thank you. Nothing is outside the realm of possible consideration. And, thirdly, today in the

requirements there is, in fact, a special case provision called, "Plant Special Exposure", which would allow, upon a careful set of considerations, to exceed the dose limits, very highly restricted. I know of only one case where someone has ever actually gone through the process, and applied to be able to have permission to use that, and their controls were such that they didn't ever actually do that.

MEMBER SULEIMAN: I think the kind of person that would go for that would probably have good enough procedures; they wouldn't exceed it, yes.

DR. COOL: But we can engage in all sorts of discussions on the possibilities, and back and forth. That's the whole purpose of starting the dialogue now, while there isn't a proposal on the table, so that people don't feel like they have to defend their particular turf, and can rather help us understand what the entire landscape looks like.

CHAIRMAN MALMUD: Thank you, Dr. Cool. Dr. Eggli.

MEMBER EGGLI: I don't think in the materials arena at my institution we're going to have any trouble meeting these limits. But in the machine-generated, we are. And I am absolutely certain that there isn't a single interventional radiologist in our

institution, or interventional cardiologist in our institution that's the least bit worried about their cumulative exposure. And they have the education to understand what those risks are.

The other problem is if this is a patient care issue, not all interventionalists are created equal. Some are more talented than others, and they tend to take care of the most critically ill patients, and they tend to be the more complex procedures, and they tend to get over-exposed in those procedures. And I could name to you the people I consider are most talented interventionalists, both in cardiology and radiology, and I can tell you that when I look at their quarterly exposure reports, they're going to top the charts.

CHAIRMAN MALMUD: Dr. Eggli's observations, my observations from different perspectives are the same. I mean, among radiologists and cardiologists, the interventionalists are really the heroes of the profession. They're the ones who are called on true emergencies. When I provide I-131 therapy, I'm getting some beta radiation, it's scheduled, and all the safety regulations could be employed in a careful, timely fashion. When an interventional radiologist has to do a procedure on a

patient whose life is really at risk for that moment, or the interventional cardiologist, same situation, their natural tendency is to put the patient first and not themselves first. And anything that we would do that would interfere with that would be counterproductive in terms of the welfare of the public. But, we still should have database, so that we understand where we are, and I think we're all pretty much saying the same thing. And all of us, from different perspectives, have made the same observations. We're dealing with an issue that profoundly affects emergency patient care, or could affect emergency patient care. It's very different in my situation.

In my situation, when I'm giving a patient an oral dose of I-131, and the resident shows up with the white coat, but without the badge, I say, "Out. You may not participate in this therapy without your badge." If the excuse is they lost or misplaced the badge, that's fine. They don't participate in that therapy that day. But that's very measured, as opposed to the patient who's brought into the emergency department with acute myocardial infarction who's rushed to the interventional lab, and then a lifesaving procedure is performed, very different set

of circumstances, and a very committed physician, who's performing this procedure without concern for his own well-being, or her own well-being. Dr. Welsh?

MEMBER WELSH: I think most of the points that I was about to make have been eloquently stated. I concur with the idea of having a database. I suspect if we have an accurate database, Dr. Van Decker's prediction might come true, and that we will see individuals who are critically important in medical care approaching the proposed 2 rem per year limit. And if that happens, I would say that from a patient perspective, we have to be cognizant of the potential consequences.

I have the good fortune of practicing at a major academic facility in Wisconsin, but, also, at a much smaller facility, where it's approximately 70 miles between any given radiation oncologist, and maybe 120 miles between interventional radiologists. And we've heard that not all interventional radiologists are created equal, so, therefore, the one that's 120 miles away is the one that's of choice. If that individual exceeds the limit, you might have to drive 500 miles, 300 miles to get to a competent interventional radiologist. And I think that that has to be factored into some of these regulation

decisions, as well.

CHAIRMAN MALMUD: If I may, part of what I'm trying to drive at is, is all these statements are valid. If the database exists, there may evolve from the database a better way of reducing the radiation burden to the provider. But in the absence of a database, there's no urgent need to change the methodology, currently. But the interventional radiology field is filled with brilliant individuals who will respond, if necessary, to changes that are necessary. That's my general observation of these highly trained individuals, so I'm optimistic that a database will generate a better standard of practice, if it's needed. But constraining the current limits will have the opposite effect. Everyone will forget to wear his badge. We have Dr. Guiberteau.

MEMBER GUIBERTEAU: Well, I've been listening to this with a lot of interest. This topic is one that is of major concern to the diagnostic radiology community, primarily from the point of view of the interventional radiologists. I think in our discussions in various organizations, there is, as has been mentioned by various commenter's, the need for an understanding of what interventional radiology consists of.

I do think the average procedure, it's well understood that you can stay within the limits of exposure. But there are studies, outliers, both with respect to the individuals performing them, and to the difficulty of the case, that place them at higher dose levels.

There is also an exceeding interest in if the physician badged is exceeding his limits, then the dose of the patient is exceeding the values that would not be tolerated in most circumstances, and those need to be justified.

There have been numerous articles in the last several years in the literature imploring further investigation of these incidents with patients, and with physicians, and I think we would all agree in the radiology community that a valid database would be the place to start. And I guess my question is, to you, is that where in terms of being a regulatory agency could this information be achieved?

DR. COOL: I think the answer is yes, we are trying to think about the right ways to try and gather the data. There are, of course, two opportunities. One is to try and go back and capture by some voluntary means data that has been collected over the last couple of years, recognizing that it has

the potential for I forgot my badge, and other things, which make the uncertainties greater. There is, of course, always the possibility, I suppose, for trying to do some special effort prospectively for some period of time to try and improve on the quality of that data as we go through the process, as well.

Step one, I think, for us is recognizing that there is a lot of data that is out there, which we do not have access to, is to try and find the right ways to get access to that data. And sadly, that means that we have to go through a series of commotions and steps, including our friends in the Office of Management and Budget in terms of how many people we can ask questions of, and what kind of data we can ask for, and otherwise. But we are exploring, trying to get what's out there, in order to try to start building upon that. My colleague, Vince Holahan, may have something to add to that, as well.

MR. HOLAHAN: Good morning. I'm Vince Holahan. I'm Senior Advisor for Health Effects in the Office of Research. One of the things that our group does is, we set up the REIRS database, that's the Radiation Exposure Information Reporting System. We use that for all of our power plant workers, and a number of material users. With that, we can look at

trends, annual trends, three-year rolling trends, and so forth. Unfortunately, we don't -- at this time; we don't have the authority to collect the medical data from the states, and particularly, the Agreement States.

Fortunately, you'll hear about this in the next hour, the NCRP issued Report 160. And in Chapter 7 of that report, it addresses occupational exposure to include medical. They went to the dosimetry vendors and used the dosimetry vendors to provide information to look at years 2003-2006. And what you find among the 600,000 badged medical workers, there are about 600 that are exceeding the occupational dose limit of 5 rem a year in each of those years. The good news is most of the workers are receiving very little or no exposure.

What we can possibly do is go to those vendors and see if we can get additional information from them, and that will provide us information sooner, rather than later, to address some of the questions you're talking about. If we have to set up an individual database, that's going to probably take a change in statute to give us the regulatory ability to do that, because right now, as was indicated earlier, I think it was by Dr. Vetter, some

institutions report to the state on an annual basis what the exposures are, some do not. They're just inspectible type of reports, so there is no mechanism to obtain that information now. And what we're finding is, in particular with the industrial radiographers, our database is actually getting smaller, because as soon as a state decides to become an Agreement State, they no longer send that information to us, and we put it into our database.

CHAIRMAN MALMUD: Thank you. Dr. Vetter.

MEMBER VETTER: I wanted to point out just one caution relative to interpreting data from the vendors, and that is that all they have is a badge reading. And that will not take into account whether the individual is wearing an apron, so the badge reading, itself, does not, necessarily reflect the effective dose, or effective dose equivalent.

CHAIRMAN MALMUD: It also depends whether the individual is wearing the badge outside of the apron, or inside the apron. Mr. Lieto.

MEMBER LIETO: It's also the aggregate of radioactive material users and machine users lumped together, so you're looking at that cross-aggregate, if you will, of wearers. It's not separating out the radioactive material wearers versus the machine

wearers. And that's something only really I think the licensee or registrant can do.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I think it's a probably soluble problem. The data is out there, and rather than argue the argument like these arguments always are argued in terms of anecdotal stories about individuals, let the data speak for itself. I think most hospital RSOs, I would assume, are looking over their data. It wouldn't take much effort to parse by department and get an idea. If everybody in the group is giving high doses, or whether you've got low doses, collect the data, maybe work through the vendors, maybe work through some of the hospitals or some of the societies. There ought to be a way to get some preliminary information.

There was a global effort to put the NCRP report together. It's just a case of going one level further and trying to parse by the different specialties. And the data will just leap out at you. You'll either get a very broad distribution, or you'll get some clustering. And then you'll have some numbers to make some valid discussions with.

CHAIRMAN MALMUD: Thank you, Dr. Suleiman. I think Dr. Howe was next.

DR. HOWE: This is just kind of a generic comment. As I'm listening to the discussion, I'm hearing that we need to make a clear distinction between machine dose and materials dose. As we move into more emerging technologies, such as intervascular brachytherapy, such as microspheres, we're starting to pick up more of the interventional radiologists. Now, we're clearly not picking them all up, but we are starting to pick up a group that wasn't in our regulatory sphere in earlier days, so I think that's something that the Committee and the NRC needs to keep in mind, as we move forward.

CHAIRMAN MALMUD: Thank you for bringing that to our attention. If I may address Dr. Suleiman's comment, I'm still concerned, Dr. Suleiman, that we don't have an adequate database, and that further constraints on the limits in the face of an inadequate existing database would be counterproductive. The goal is -- we agree on our goal, which is to reduce the radiation burdens, the unnecessary radiation burdens to providers. My concern is that if the limits are reduced, as might an outcome of agreement internationally, that the database will never be achieved. Dr. Lewis.

MR. LEWIS: Thank you for the promotion.

I'm not a doctor.

(Laughter.)

CHAIRMAN MALMUD: Honorary Dr. Lewis.

MR. LEWIS: I would like to make a suggestion to the Committee, and Vince Holahan has already kind of invoked this, that much of this discussion, I think, will be very relevant to the next topic on the agenda, which is what to do about NRCP 160. And just a suggestion, if we want to revisit that, or kick that off now, that's -- I'll leave it for the Chair's discretion.

CHAIRMAN MALMUD: Thank you. Dr. Guiberteau.

MEMBER GUIBERTEAU: Just two comments. One, to comment on Dr. Howe's observation. As we move into hybrid technologies in both nuclear medicine, and diagnostic radiology, where we're performing both CT and materials imaging, there have been a number of reports of occupational exposures, depending on the state, where some states have very strict rules about who can operate these -- perform these procedures, and others do not. We have found that there are large lapses in those who are trained in materials use, technologists, who are now trained to operate a CT unit, but not, necessarily, the radiation safety

aspects of it. And usually vice versa, particularly when you're using high-energy radiopharmaceuticals in addition to this. And that is something that I think this Committee should be very interested in.

Secondly, just a matter of expression of the difficulty in collecting valid data, that I'm certain that the radiology community understands how difficult this methodology is due to compliance issues with those who are performing the procedures, with the methodology of calculating doses, and what is being reported. And, finally, just with deformation of the data due to observational scientific collection of the data, as per the Hawthorne Westinghouse experiments many years ago. So, it isn't very easy, and I think the only way to start is to try to get to the information as broad as possible, and as granular as possible, so that you can separate out what we're collecting.

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau. Dr. Thomadsen.

MEMBER THOMADSEN: Just a potential suggestion. Since you're talking this June to the Health Physics Society, maybe they could bypass the problems that were discussed with having the NRC establish a database, and they might be able to

facilitate a database for you.

DR. COOL: Thank you. That's certainly another possibility. We've also been in discussions with Lynne Fairobent and others in AAPM to try and find some mechanisms that would get us a view of some of this data without it having to appear that the regulatory agency was going to come after you.

CHAIRMAN MALMUD: Thank you. Now, if I may, we'll get back to a suggestion that Dr. Vetter made earlier, and that is that we establish a subcommittee within the ACMUI in order to work with you. Are you receptive to that idea?

DR. COOL: Yes, sir.

CHAIRMAN MALMUD: Then we will come up with a subcommittee for you. Did I interfere with someone asking a question? And we will find a subcommittee of three that can work with you. We're currently in a state of transition here. We have three very experienced members of the Committee who are leaving, and we're recognizing their service and the loss to the Committee of their services today. And I will get back to you with a recommendation.

DR. COOL: Thank you very much. We appreciate that, and we very much look forward to interacting with that subcommittee, and with all of

you. And I would, again, ask - I know that following the last meeting, I had conversations with a couple of you about groups and otherwise. We were not able to follow those up because of the time frame of the Commission decision, and otherwise, but I am very interested to find connections to some of your organizations, and to your respective groups of licensees, because these are the discussions that are needed now, and we look forward to it. Thank you very much.

CHAIRMAN MALMUD: Thank you. We will move on to the next item on the agenda. Ashley, are we sticking to the agenda thus far?

MS. COCKERHAM: Yes, until we get to this afternoon.

CHAIRMAN MALMUD: Who will be the next presenter?

MR. LEWIS: I'd be happy to tee up the topic, if you'd like. But we were really looking for just a brainstorming open session from the Committee about the report, the NCRP report. So, with that, before I start, as Chris mentioned in his opening remarks, the NRC staff is aware of at least three Committee members who were involved substantially in the NCRP 160 report preparation and publication. And

we just need to remind you of the conflict of interest provisions that are in the ACMUI bylaws. And any member who was involved in this report would need to recuse themselves of the discussion. I believe you can just answer factual questions, but any kind of substantive discussion you should recuse yourselves from the areas where you have a conflict of interest in preparing for the report. And if there are any other Committee members who are involved that the staff isn't aware of, they should identify themselves, as they should with any topic.

MEMBER NAG: Excuse me. Could I have -- I know they prepared the report. Wouldn't that be helpful in the discussion? I mean, why would they have to recuse themselves?

MR. LEWIS: Because, legally you're required as a Committee member to recuse yourselves of any discussion if you're trying to influence the Committee on a report you prepared outside of your ACMUI duties.

MEMBER NAG: Oh, outside. I see.

MEMBER SULEIMAN: I want to clarify this. If you look at the preamble of the report, it's just a scientific collection of data. It doesn't make any recommendation. It's just a census, so it's not

advocating any specific position.

MR. LEWIS: Well, let me finish my tee off, and you'll see kind of -- because we are -- the NRC staff is asking the Committee to give us policy advice about what to do about the report. So, from that perspective, it would be a conflict according to our attorneys.

Okay. On March 3rd of this year, the National Council on Radiation Protection Measurements, which we've already referred to as NRCP, held its annual meeting in Bethesda, and they issued a report called NCRP 160, titled, "Ionizing Radiation Exposure of the Population of the United States", which I believe you all have a copy of at this point, at least the pre-publication copy. And we had heard just last week that it went to final publication, so the ring binder that you have.

The report has a punch line finding that essentially says that the increase -- Americans were exposed in 2006 to more than seven times as much ionizing radiation as they were in the early `80s. So, the average dose to the population has increased by a factor of seven over the recent times. They attribute this increase, primarily, to the use -- machine-produced radiation, such as increased use of

computed tomography, and also to diagnostic nuclear medicine procedures.

These two modalities were responsible for the majority of all the increases, so in addition to more minor contributors, such as increased background radiation. I believe the occupational exposure where they had data actually went down over that time. So, the NRC is asking for the Committee to give us policy advice, as is your primary mission, about this report. And we're asking, in particular, does this report contain any information that suggests that there are gaps in NRC's policies and requirements that need to be addressed. And where there are already NRC policies, such as our medical use policy, are those policies serving the public well. For example, should NRC revisit its decision to not intrude in the practice of medicine, as regards to diagnostic nuclear medicine, and protection of patients, given that the increases in diagnostic nuclear medicine are primarily responsible for these dose increases? And any additional issues that the Committee may wish to bring to the NRC's attention, such as the lack of a database for material licensees that we were just discussing.

You have pretty much -- that's kind of the extent of the task we're asking for you. You have

kind of an open book to tailor that task. We have, of course, limited NRC authority over machine-produced radiation, but we do have policies that are related to non-machine-produced radiation, some of which is mentioned extensively in the NCRP report.

So, with that, I'll just turn it back over to Dr. Malmud.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: As a nuclear medicine practitioner, I could talk about some of the increased patient exposure that has arisen in diagnostic nuclear medicine. I think it probably comes in predominantly two areas where we have seen significant growth in the use of diagnostic nuclear medicine over the last several years. One of them would be nuclear cardiology, and then secondly, PET imaging. And let me start with PET imaging first in my comments.

PET is a high-energy photon. There are patient exposures that result from this. However, you have to look at the benefit that that's creating. If you look at all cancers, and the "conventional" imaging modalities, what a conventional modality is, are what other people, other than you are performing. You're the forefront, and they're the conventional. So, if you want to look at CT, it has been the gold

standard for diagnosis and monitoring of tumors for years. And the CT has an accuracy, and a sensitivity and specificity that's always down in the low 60s percent or worse. Now you add PET to the mix.

The diagnostic accuracy, the sensitivity, and specificities rise into the high 80s and low 90s, when you combine with PET CT. It has made a huge difference in the quality of care provided to patients. And then if you look at the cost across the board of diagnosing and managing diseases, the adding of PET CT into the diagnostic algorithm has reduced the cost of diagnosing and following diseases between $500 and $2,500 per patient. So, economically it makes sense, and from a patient care point of view, it makes sense. And anything that is done that reduces the diagnostic efficacy for a cancer patient is morally unacceptable.

CHAIRMAN MALMUD: Thank you, Dr. Eggli. You said that there were two. The first one you mentioned was PET, and the second one was nuclear cardiology, or cardiovascular nuclear medicine. I think that the figures for cardiovascular disease, and we have a provider here, Dr. Van Decker, they speak for themselves, and that is the death rate from coronary artery disease in the United States has seen

a profound change. There are many elements to it; perhaps one would credit the statins more than the interventional radiologists, but both contribute to the change in the mortality and morbidity associated with cardiovascular disease.

MEMBER EGGLI: I thought it would be better for Bill to speak to that, than me.

CHAIRMAN MALMUD: All right. I'm going to introduce Bill. So I'm going to ask Dr. Van Decker, whose life is committed to nuclear cardiology to speak on behalf of that technique. Clearly -

MEMBER VAN DECKER: I like the way I could save my voice here.

(Laughter.)

CHAIRMAN MALMUD: But, clearly, the techniques that you employ have reduced the death rate from cardiovascular disease in the United States. Dr. Van Decker, with that introduction.

MEMBER VAN DECKER: I'll make a couple of comments, also. Obviously, I think that -- first of all, I'd like to say I think that the report is a scientific report. Staying away from anything that this may mean as a useful thing for everyone involved in ionizing radiation. I mean, I think that it's actually somewhat helpful, if it hadn't been such a

long period of time between the look-see, because two points in a line to see where you are, when you look at large decades of time when technology is growing, it gives you a skewed idea, sometimes, of what's gone on. But I think that a lot of people put a lot of work into this, and I think the information is useful for all providers to kind of look at, and try to make some thoughts about.

Now, as far as the cardiovascular disease and nuclear medicine portion of this goes, I guess I would make the following comments. You know, if you look at CDC data from 1980 to 2006, the life expectancy of females has gone from 77.7 years to 80.7 years. The life expectancy of males has gone from 70.0 years to 75.4 years, which means that men have made proportionally a larger increase in the life expectancy over the last 40 years than females. If you want to look at statistics and what they really tell us, that's probably because, unfortunately, men have more coronary disease than women, and men die of coronary disease. And we do a much better job with that situation than a lot of other things we need to focus on.

The second thing -- and, so, the use of diagnostic techniques has not decreased life

expectancy over the last 30 years, that's for sure, or our therapeutics, obviously. The other thing I would point out looking at CDC data is that the death rate from ischemic heart disease from 1980 to 2006 has taken a dramatic decrease. It's gone from about 492 per 100,000 to about 211 per 100,000, which is a reduction of way over 50 percent. And I would agree with Dr. Malmud that obviously there are a lot of things that go into that in the cardiovascular provider community. My cousin is an interventional, the medical work with statins, some lifestyle issues that we've tried to push with the public, but when we recognize the fact that the incidents of diabetes and the incidents of obesity is going up, and up, and up, and that we're dealing with an older and older population with a much, much more higher incidence of the disease process, I think that speaks very, very well for what some of the diagnostic techniques have been able to identify and allow us to do.

I would also point out from the CDC data that if you looked at death from malignant neoplasm from 1980 to 2006, that that number has also gone down, not to the same percentage, from about 198 per 100,000, to about 183 per 100,000. So, I guess we need to be finding it sooner, and doing better things

with it from other ends, but it certainly has not gone up.

MEMBER EGGLI: And if I could add to that just slightly, Bill, the incidents of cancer continues to rise, while the death rates are decreasing.

MEMBER VAN DECKER: Which is probably more a reflection of more people living to elderly ages, and from the cardiovascular provider community, we look it as, if we keep hearts alive longer that somebody is going to have to treat the cancer that will eventually declare itself from bad DNA repair mechanisms, so our goal for the oncology community is, we'd like to try a few peaks going along longer to see where we get. But I think that's all an important piece of the discussion.

I mean, what really has happened here on a treatment paradigm is that the cardiovascular nuclear medicine piece of this has become the seamless major screener in cardiac disease for significance of chest pain symptoms, and significance of who goes on to mechanical intervention in the Cath Lab, or by coronary artery bypass grafting.

I think whatever modality or whatever technology fills the role of what is our screener to our high-risk interventions, what is our screener to

more patient reassurance, and medical management is going to have a very high number in this nation, because that's what we need, and that's what we do, and that functional piece is incredibly important. And I think that you will see multiple competing modalities, and multiple competing thought processes for trying to fill that hole, because that hole -- or trying to compete in that hole, because that is where the rubber hits the road of how we take care of patients. As we've taken care of more and more patients that are going to clearly be where we are.

I would just make a couple of more comments. I don't think that the community is blind to the fact that this is an ionizing radiation technique, just as CT scanning is. And, therefore, on a performance improvement basis, which I always credit Dr. Suleiman for bringing out so well in all our discussions, we need to see if we can do better and better in that regard. I think if you looked at the professional component of this, we see strong evidence that we have been reacting to this over the years.

I think that the protocols of acquisition have been maneuvered around to try to give the least amount of dosing possible to the patient, much more emphasis on maybe doing stress only imaging. There

are clinical appropriateness criteria out there, so that we're only trying to use this in our highest risk chest pain patients, and our highest risk coronary artery disease patients, and maybe use other modalities for the less at-risk patients. And appropriate use criteria have been popularized throughout this nation, both in the provider section, and in the reimbursement section.

I think that the interest of the community in trying to -- and in all of nuclear medicine, not just nuclear cardiology, to reduce dosing has actually pushed for some great science in the realm of camera development. I think for the first time in the next three years we're going to see detector acquisitions that are more solid-state, more efficient. And rather than decreasing the amount of time the patient is under the camera, a lot of that efficiency will probably be utilized to decrease the amount of dose given to acquire in the same period of time. So, I think that there's a variety of things in place to try to improve these dynamics.

And I think that the community has, obviously, worked very, very hard to make sure that the quality of studies is at the highest level, so that the benefit of the patient undergoing the study

really has a quality outcome, and it really makes a decision in the patient decision tree for where they're going in their care.

Obviously, people are living longer, and so sometimes several years later, especially if they've had interventions, they need to get screened again, so the more we carry people along and make this a chronic disease process, rather than dead in Cath Lab with their MI coming in, because the first presentation frequently can be death, the more of some type of study doing this functional assessment we're going to see. This certainly has been our most reliable to-date.

I would also point out a couple of last points that the population that we're studying is mostly in the 50s, 60s, 70s, and 80s, so it is an older population. Other than anomalous coronaries, when people have really been screened for all kinds of things, it sometimes happens in the younger age groups. We're really dealing with people who are more along in their life expectancy, and, therefore, obviously, on a 10-year mark from the exposure, even an LT model becomes less of an impact, hopefully.

And the last part of this I would point out is something that the report kind of alluded to,

which was predicting the growth of studies down the line, which is why I think when you look back, and you're looking over 20 years, and medical technology is rapidly advancing, it becomes very hard. I think that at some point in time you kind of define your population of where your technology has saturated into what you need to do, and then your growth rate slows. I think that if you looked at the growth of nuclear cardiology studies over the past three years, they've actually been flat, if anything, slightly down. And I think that, obviously, they will probably truck along at about that rate, or maybe grow a few percentage points as the population ages. Some here, depending on what other -- depending on how much better the oncology community gets at treating oncology, so that people can develop their cardiac disease, so that we can treat it some down the line. And we would be happy to be able to do that.

And, in that regard, probably on a clinical basis, I'm seeing a lot of care go on around me, probably a growth of CT, which has become such an incredible tool from a large variety of disease processes, probably we'll end up seeing much more growth in that realm than anything in this realm. So, I've probably gone on too long in all this regard, but

it is my passion, and part of what I do. I just wanted to make sure we put this in some perspective. I do think the information is useful. I think that it is understandable, given the prevalence of cardiac disease. It's understandable, given then niche this has filled for us in patient management. I think that the life expectancies and death statistics prove out that this has been a very positive effect. And I'm sure other people will say that diagnostic testing is important in providing good patient care.

My recommendation, if there was going to be a recommendation is, I think that something like this should be updated every once in a while. We should see how things go on a line, and how the medical community reacts to the facts before we decide if there's a regulatory piece to this that's important for interfering with how medicine gets practiced more than other things going on right now, but that's one person's thoughts.

CHAIRMAN MALMUD: Thank you, Dr. Van Decker. Dr. Eggli, and then Dr. Nag.

MEMBER EGGLI: I would like to follow a little further on the PET CT. Unfortunately, cancer is less discriminating than heart disease. The youngest PET CT I've done is a six-month old. But I

think you've actually already seen the high water mark on this exposure. And I think that by the time a report is created, the data is already old.

Machines are better now than they were two years ago. They're capable of dose modulation. In the PET CT arena, some of the radiation exposure in nuclear medicine is from the CT portion of a PET CT. The vendors have figured out how to use modulated doses in the attenuation correction algorithms. Plus, what you begin to look at is a decrease in overall CT use.

Initially, in the era of PET CT, patients would get a PET CT. There would be an exposure for the CT portion of the PET CT, and then the patient would go across the hall and get a diagnostic quality CT, the same day, or within a week in follow-up. We're beginning to no longer do that, as both physicians and payers recognize that there's excess radiation exposure, and excess cost. So now, interestingly, instead of cranking down our techniques on the PET CT, we're cranking them up, giving IV contrast, and we're doing diagnostic quality CT scans with the PET CT, saving the patient an additional CT scan. And, effectively, the exposure savings would have been the equivalent radiation of what we would

have done on a PET CT previously, that wasn't diagnostic. So, I actually think we're passed the high water mark on these radiation exposures on a per individual patient basis, and that we are doing many things to reduce the exposures to those patients.

What Bill was speaking of the better detectors, will allow us to dramatically reduce the cardiac doses. There are newer detector materials out there in PET scanners now. If you look at the difference of what you have to give to get a good scan on a BGO crystal versus an LYSO crystal on a PET CT scanner, we can have some dose reduction of the PET dose on those more efficient scanners. The fact that the algorithms for reconstruction have become more sophisticated, and we're doing 3D PETs rather than 2D PETs, has allowed us to decrease the dose to the patient, while improving the quality of the overall imaging. So, again, I think you've seen the high water mark. And I think you'll see it dropping from this point forward.

CHAIRMAN MALMUD: Thank you, Dr. Eggli. Dr. Nag.

MEMBER NAG: Yes. I'm going to talk from a radiation oncologist point of view, who has treated cancer patients for about more than 30 years now.

There are several risk-benefit determinations for analysis that needs to be made. On one hand, you have patient and the general public who are scared to have a CT done, when that patient is going to get thousands of rem from the radiation from the therapy, and you're going to get an additional million in the order of millirem, they are scared of that. And that fear, we have to educate them about that fear.

On the other hand, you have to promote the ALARA principle that not to have indiscriminate screening CT where the CT may have been done somewhere else, or similar information may already be there, but it may be that for the non-availability of the previously done CT, or the physician did not properly analyze and order the CT for every patient no matter what. It's like a screening CT. So I think that critical cost-benefit analysis has to be done. So, you do have major benefits, as we have heard, from both CT, PET scan, and other studies. But, at the same time, you have to lose so-called unnecessary CTs, and other imaging.

CHAIRMAN MALMUD: Thank you. Are there other comments? Dr. Guiberteau.

MEMBER GUIBERTEAU: Just a couple of comments from the diagnostic radiology community,

which also performs nuclear medicine, and cardiovascular nuclear medicine. And I think in terms of the overall spectrum of ionizing radiation procedures that are performed, nuclear medicine has done an outstanding job in doing what we can to decrease the doses to patients, both with better management of the doses, and better technology.

I do think that the two areas involved are, as we've discussed, primarily the increasing use of cardiovascular nuclear medicine as a screener of high-risk patients, has only increased, and generally to the benefit of our population. And I have to also say, we're doing a better job in PET CT, primarily, better regulation of our doses. You have a high-energy radiopharmaceutical, but it's very short-lived. And, in many cases, there are difficulties in determining what dose a patient will get when that patient shows up. But we're doing a better job with that.

I also think that the protocols that are coming out for the procedure, even though we're doing what we can to manage, the treatment protocols -- as you know, most of these studies are ordered by non-radiologists, or non-nuclear medicine physicians based on the protocols that they use in other disciplines.

And many of the protocols coming out of the oncology community, medical oncology, and the oncologic major hospitals in the United States are using more frequently this in terms in individual patients to determine the success of a treatment regimen they're giving. And, so, if you perform a PET scan and find out that the patient is not responding, you can change the dose to -- you can change the regimen to something that works. So, I think the monitoring of patients has increased somewhat in most of the current protocols, and that, again, contributes to this.

Finally, I also believe that the American College of Cardiology, the Society of Nuclear Medicine, and the American College of Radiology have all cooperated in terms of what we consider the appropriateness of these examinations. And this is a medical practice issue.

The inappropriate utilization of these procedures, and there are various numbers, depending on how you look at it, is something that we are trying to decrease, so that we don't get shotgun medicine being performed, and procedures being done that basically are not indicated. The American College of Radiology has 160 appropriateness criteria, with 700 iterations under that, which we distribute on a

regular basis to payers, and to medical practitioners outside of our discipline, so that they will know what the guidelines are before we will perform these procedures. And I think with, again, the new payment protocols that are coming in from CMS, that these will only increase. So, we're trying our best, and I have to say in terms of both nuclear cardiology, nuclear medicine, and radiology, we're all trying our best to keep these doses down. And I think in nuclear medicine, we're doing really a pretty outstanding job.

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau. Dr. Fisher.

MEMBER FISHER: Thank you. I'd like to address this from a patient perspective, if I might. The NCRP report is really well done. I've read it. I spent a lot of time going through it. It's a fabulous piece of science. A lot of data have been collected. The issues are, at least as you've explained them, one of collective dose versus individual dose, collective risk versus individual risk, and collective benefit versus individual benefit. The increases in medical exams, including pediatric exams, pediatric CT have increased the collective doses to the population of the United States. And the effect on the individual, however, is one case at a time. And some

people who have received these exams, their individual dose has gone up quite a bit. Many others have had no exams.

The collective risk from these doses, there is going to be a calculation of some increment of collective risk. The individual risk, however, as Dr. Nag pointed out, is close to negligible. The collective benefit is difficult to measure. The individual benefit is either going to be zero, or very great.

I have a neighbor, close friend who went in for one of these storefront CT exams, was diagnosed with a very small tumor, had that cancer removed, and is very fortunate today. And I was really quite surprised to hear that anecdotal story, because that's usually not the case. Usually, patients go in for a CT exam on a well-patient history, and nothing is found, and so there's a little bit of dose, and no real benefit. But in that one individual patient where the radiographic, radiologic exam finds something, or helps to find an illness, or helps explain damage to a childhood brain from a sports injury, helps in the diagnosis of that patient, leading to better treatment. I think what needs to be pointed out is that the individual benefit of those

exams is very high. And the individual risk is very small, in those cases.

CHAIRMAN MALMUD: Thank you, Dr. Fisher.

MR. LEWIS: If I could just -

CHAIRMAN MALMUD: Oh, please. Mr. Lewis.

MR. LEWIS: -- respond slightly, because I agree with 99 percent of everything you said. But I would not go so far as to say the individual risk is zero of a several rem exposure. That does introduce, at the minimum, an increased chance of a latent cancer appearing. And that's the basis of our entire regulatory structure, but in cases where the individual benefit is great, that's an acceptable risk. In cases where the individual benefit is zero, as you said, then that's the question at hand.

MEMBER FISHER: Yes. I didn't mean to imply that the risk was zero. Certainly, that would be a foolish thing to state, but the enormous benefit in those cases really has to be taken into account.

CHAIRMAN MALMUD: Thank you. I think, Dr. Suleiman, you -

MEMBER SULEIMAN: Yes. I mean, my takeaway from the report is that first, when you look at the medical doses, you've got to realize those doses are associated with a benefit. So, I look at it

from a point of view that this is just one risk of many that patients undergo, radiation being just one of them, and all the benefits that you get with this.

What I take away from this is, look at all the other components that the public gets radiation from, and they're so much lower. And I think, as a society, the biggest problem is, we just don't understand risk very well. We were talking the other day, the risk of getting killed in an automobile accident is very high. And if you translate the risk, it's very negligible. It's never zero, but it's close to zero, so I think the take away message here is, if you were to exclude the risk where there's a medical benefit from it, how much radiation are people getting, trying to sort of put a better perspective on it. That's what I think the snapshot is intended to do, and not be a debate about what are the values of all these.

I mean, there are societal values from nuclear power, from all these other technologies, and there are benefits, both individual, and societally. But I think this is just one element of that, because we get risk from many, many other things. We probably do a better job in radiation of quantifying than any of the other risks we deal with.

CHAIRMAN MALMUD: Thank you. Dr. Eggli, then Dr. Vetter.

MEMBER EGGLI: I would like to make an additional comment of things that we in the profession are doing to mitigate radiation exposure risk. In many situations in an emergency department, a CT scanner has come close to replacing a stethoscope and a physical exam. A patient comes in with abdominal pain, the likelihood is the ER doctor is going to order an abdomen and pelvis CT. We now run our department with extremely sophisticated information systems, and we've set flags in those systems to trigger an alert when a patient has frequent radiologic exams. That allows us then to go back to the practitioner and say, you know, this patient was in here 17 days ago with the same abdominal pain, and we did a CT at the time, and it was negative. So, the profession is doing what it can, again, to help mitigate. And one of the additional things is the use of these information systems that we can use to track histories.

CHAIRMAN MALMUD: Thank you. I think Dr. Vetter was next.

MEMBER VETTER: Thank you. I agree with what's been said around the table about the scientific

rigor of this report. I think it's an outstanding report, but bottom line is, it's simply a scorecard, and it's a scorecard that was last published in the `80s, and now it's updated. And like Dr. Van Decker said, it's appropriate to update it periodically, but it's simply a scorecard. And it tells -- what does the scorecard tell us? It tells us that the largest increase in exposures, almost all the increase in exposures, due to the application of radiation in medicine, which the NRC does not, in terms of patient doses, does not regulate. And medicine -- why has that gone up, is because of increased availability of technology, and new technology, and increased availability of the technology to a wider variety of patients. More patients have opportunity to be exposed.

Medicine, if you read the medical literature, medicine is very concerned about that, and they are looking at utilization, they're looking at doses, try to reduce doses. They're looking at all of that, so I don't think any of this has been done irresponsibly. So, what the report tells me, and if you look at the other areas of the report, I don't think we have a problem. Where would you go to try to reduce exposures? In the consumer products area,

you'd try to get people to stop smoking. In the background area, you'd try to get people to do something about radon on their homes, but in the occupational area, as you mentioned, Mr. Lewis, actually, the occupational exposure has gone down a little bit. So, if you look at all of the other areas of the report, what the report says to me is that the NRC, relative to these exposures, the NRC and regulators have been doing their job. And I don't see any -- I don't think the report makes any suggestion that regulators need to take any action to reduce exposures.

CHAIRMAN MALMUD: Thank you, Dr. Vetter. Was there another comment? Dr. Welsh.

MEMBER WELSH: I agree with Dr. Fisher's points about the benefits of medical imaging. And I can appreciate the anecdote. I think that any clinician can come up with dozens of anecdotes that they've seen with their patients, and the medical literature is replete with documentation of the numerous benefits.

I don't disagree with Dr. Lewis' comment, that the risk may be non-zero. But I think that we have to acknowledge that the data in this very low dose realm is a bit sketchy, and it's difficult to

fully interpret. While I agree with the ALARA principle, I think that it has to be acknowledged that the scientific data is not complete. And we're all familiar with Kerala, India, Ramsar, Iran where doses from background radiation can be the equivalent of dozens, if not a hundred CT scans annually, so if you look at the epidemiology and life expectancy in Kerala, it's higher than most of India. It's sometimes difficult to put all of this together, and then integrate that with our instinct to say that we should reduce the number of medical imaging studies because of the increase in dose to the public. I think it does have to be tempered with a little bit of common sense.

CHAIRMAN MALMUD: Thank you. If I may, I'll try and summarize what the Committee appears -- what I've heard the Committee say. Number one, there's a consensus that the report is an excellent document, and we're grateful to those who prepared it. Number two, we believe that the NRC should continue to maintain records, keep us aware of radiation exposure so that we can bring that into the thought processes with regard to caring for patients. Number three, it's a medical principle first, do no harm. And the medical community is eager to adhere to that

principle. But the current belief is that given the data with regard to the morbidity and mortality of cardiovascular disease, and the incremental progress being made in cancer, that the benefits currently appear to outweigh the risks. And, lastly, you heard several members of the Committee comment on our continued concern with regard to radiation exposure to children, who appear to be more radio sensitive, and whose life expectancy is such that we need to be continuously aware of the risk to them of unnecessary radiation. Does that summarize what the Committee has concluded? That's our response. Mr. Lewis?

MR. LEWIS: Would the Committee like to comment at all on the -- on whether or not NRC should revisit any of its policies in this area, as a matter of going forward?

CHAIRMAN MALMUD: Well, I believe that one -- my second point was that the -- we would encourage the NRC to continue to keep records of, and keep us aware of radiation exposure, so that that data may be brought into the diagnostic armamentarium and assist physicians in decision making with regard to the advantage, or disadvantage of employing a radiologic technique in the care of patients. But the actual decision should be within the realm of medical

practice, and not NRC. But we're appreciative of the data. In fact, we need the data.

Dr. Eggli, were you going to make a comment?

MEMBER EGGLI: Your question is, did you want that in the form of an official statement from the Committee, in the form of a motion, or is Dr. Malmud's summary adequate for your purpose?

MR. LEWIS: Well, that's a good question. I will defer to the Committee to decide if they want to have a motion, but it will be on the record what he just read.

MEMBER EGGLI: I would propose a motion that because the increase in exposure related to materials was for medical indication, and not occupational, in keeping with the NRC's policy of not dabbling in the practice of medicine, that no new action is required on the part of NRC.

MEMBER VETTER: Second.

CHAIRMAN MALMUD: There's a motion which has been seconded. Discussion of the motion? Mr. Lieto.

MEMBER LIETO: I have a question regarding the policy. Does it state in the policy something to the effect that will not interfere with the practice

of medicine because studies are medically justified, some type of medical justification terminology?

MR. LEWIS: Donna-Beth and Ron have that committed to memory, so I will defer to their expertise.

DR. HOWE: I think the medical policy says that we will regulate the radiation safety of patients when necessary, and the NRC has traditionally taken a position that when you're into procedures that require written directives, that's your threshold, and we do require written directives to make sure the administrations are in accordance with the physician's wishes, and that they're in writing to make sure there are no errors in there. So, we don't get involved in the actual dose to the patient, we use the physician as the gold standard. And that's the point at which we jump into protection of the patient.

MR. LEWIS: And just to be fully clear, being an NRC policy, we do have the legal authority to do it, and we've taken a policy decision to not get into the practice of medicine, so there is an issue of should we revisit that policy, as the Committee has weighed in.

CHAIRMAN MALMUD: Thank you. Dr. Suleiman.

MEMBER SULEIMAN: This is a snapshot of some scientific information. Why do we need to make any kind of motion just for the sake of making a motion? I tell you what I think would be of value in terms of -- if the information is collected both by the NRC and the Agreement States in terms of the occupational doses, that this is the discussion prior to this one, where if that information could be collected somehow, or looked at as an early warning, you may have some new technology creeping in, and get an early warning. Let's say PET with the high gamma is exposing those workers at a higher rate than previously, that would sort of fall in the realm. I think it's more -- that could be useful. I don't know whether they can collect that information or not, but I think we need to use scientific objective data. And if it's being collected, let's use it beneficially. But I don't see the value of having some sort of motion, unless there's a real specific objective to it.

CHAIRMAN MALMUD: Thank you. Mr. Lieto.

MEMBER LIETO: Just a follow-up to my question before. It was pointed out to me that in a policy that states that the NRC will not interfere with medical judgments of authorized users in the

course of their practice. And I think, to me, the current policy is adequate. I don't think there's anything, in light of what's been discussed already, that indicated that either there is a deficiency in the current regulations, or the current medical policy that the NRC has. I think it is of the appropriate scope that this document does not reflect any further action that's needed by the NRC in the area of medical use of radioactive materials.

CHAIRMAN MALMUD: Thank you. Dr. Nag?

MEMBER NAG: Yes. I feel that saying that the NRC does not intrude into the practice of medicine applies here, because we are not trying to intrude into medical practice. We are trying to say to use the best judgment, and to weigh cost-benefit ratios. That's not interfering with medical judgment, so I would not go along with this motion. I think a better response to this would be to say that the ACMUI agrees with -- and the summary you made was an excellent summary, and say this was the response of the ACMUI.

CHAIRMAN MALMUD: Dr. Eggli.

MEMBER EGGLI: To respond to that, my understanding is that Mr. Lewis' question was, should NRC reconsider that policy, and consider engaging in some degree of control. Am I correct, sir?

MR. LEWIS: And are there any gaps in any other policies.

MEMBER EGGLI: Yes. So that's why I think the motion is appropriate to make the opinion of the Committee clear, is that the current processes are adequate, and there is no need to go further into this. That's the intent of this motion, and that's why I think since the question was asked, why it's appropriate to respond specifically to that question.

CHAIRMAN MALMUD: Thank you. Any further discussion of this? Dr. Welsh.

MEMBER WELSH: I'm fully in support of the motion. If I understand the concepts and questions on the table, is NRC -- should NRC take any change in its practice based on information gathered about increasing dose to the public from medical diagnostic procedures involving isotopes. I think to do so would be encroaching upon medical judgment, and that's, perhaps, not within the purview of NRC.

More importantly, or also importantly, yesterday, when we were discussing INES, International Nuclear Event Scale, it really is International Nuclear and Radiological Event Scale. Similarly, today, NRC will be talking about possibly regulating diagnostic studies, therapeutic interventions using

isotopes, and then 50 percent of the medical radiological procedures would, or more than 50 percent would not be under such regulation. And if we were to endorse regulation, we might come to a point where a person can't get a bone scan, but they can get a bone survey, and that just doesn't make any sense to me. So, I think that unless there was an agency that were going to take over all aspects of radiation exposure to the public, and to patients, that NRC probably should not make any changes based on this information.

CHAIRMAN MALMUD: Thank you, Dr. Welsh. Any other comments with regard to the motion that Dr. Eggli has made? Dr. Eggli, may I request that we find a synonym for dabbling?

(Laughter.)

MEMBER EGGLI: I will accept any appropriate synonym.

CHAIRMAN MALMUD: All right. That the NRC and agreement -- by the way, this should also -- we're also looking for the Agreement States to give us a database. Is that possible, Debbie?

MEMBER GILLEY: You can surely make a recommendation, but there is no authority for ACMUI.

CHAIRMAN MALMUD: Regardless of authority, it's just with encouragement. Alright. So that the

second part, number one, I think there were four parts to the issue. The first one was that we commented on the excellence and thoroughness of the report, and are appreciative of it. Number two, that we would hope that the NRC and the Agreement States should be encouraged to keep us aware of the radiation exposure to patients, that we encourage them not to -- to continue not to intervene in the practice of medicine. Is that, intervene?

MEMBER EGGLI: Perfectly good word.

CHAIRMAN MALMUD: Thank you. The third point is that Committee members recognize that as a basic premise in tentative medicine to first do no harm. And the profession is aware of that, and is concerned about radiation exposure. And the fourth one is that we always are reminded of the need for the benefit to the patient to outweigh the risks, regardless of the procedure being performed. And that was the motion. Does that sum up what you said?

MEMBER EGGLI: I'll accept that as the motion. Thank you.

CHAIRMAN MALMUD: Who seconded the motion?

MEMBER VETTER: I did.

CHAIRMAN MALMUD: Is that acceptable?

MEMBER VETTER: Yes.

CHAIRMAN MALMUD: Any further discussion? All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? Any abstentions? Two abstentions. Oh, three abstentions. Thank you. Mr. Lewis?

MR. LEWIS: Yes, if I could make a final comment. I would request that the Committee make its views known to the Commission at the upcoming ACMUI meeting with the Commission.

CHAIRMAN MALMUD: Thank you. We will. We move on to the next item, which I believe is a brief break.

(Whereupon, the proceedings went off the record at 10:23 a.m., and resumed at 10:38 a.m.)

DR. EGGLI: Okay, start again. This is the report of the subcommittee on the board certification pathway for authorized individual status. This report has partially been presented before, where a framework for a recommendation was presented at the last meeting, but I will briefly review the problem.

Basically if there is a significant time delay between the completion of training and final board certification for trainees who intend to become

authorized individuals by the board certification pathway, they may be unemployable for a period of time.

As a result the only way for those individuals to become immediately authorized for materials is to utilize the alternate pathway which effectively invalidates the board certification pathway for those certification boards.

The problem was recognized, and I need to mention and applaud both the American Board of Radiology and the NRC staff, because the problem is not imminent yet, and the time frame for solving the problem is probably quite adequate.

So the subcommittee was charged to recommend a potential solution that would allow an authorized individual - allow a trainee to become an authorized individual prior to that board certification. The subcommittee was specifically charged with developing a recommendation that could apply to diagnostic radiology and the American Board of Radiology.

However, the subcommittee thought it would be important to make a recommendation that could be generalized, and could be utilized by any certification board that perceived a problem with

their trainees becoming authorized individuals between the completion of their training and the final board certification.

It is important to state that this is a framework design and that no board would be required to utilize this framework if they didn't perceive a problem. It's simply a framework available to be used when there is a problem to be solved, and that problem being the time delay between completion of training and final board certification.

The initial proposal to - was that NRC recognize certifying boards could issue a separate certificate at the end of training to attest to the trainee's completion of all the TV requirements and necessary examinations to achieve authorized individual status. So the first recommendation is that the boards separate the training - the certification of training for authorized user status from the rest of the board certification.

The second proposal was that the NRC accept this certification for the board certification pathway to achieve authorized individual status.

This effectively preserves the integrity and utility and intent of the board's certification pathway, while at the same time provides a level of

assurance of the quality and completeness of the individual's training.

The NRC staff asked a series of clarifying questions about the proposal. There were actually four numbered questions, but we divided question three into two parts, so there are five questions we will be answering.

The first was to provide clarification that separate AU certificate issued at the end of training is indeed recognized by the board or in effect stands alone, and is not just a piece of paper. And the subcommittee in this case recommends that the certification of completion of T&E is considered by the board a stand alone recognition; which is to say it is not then dependent on the board's subsequent determination at the end, but that it stands alone and remains in force effectively forever once it's issued.

The second question was that - provide clarification that the proposed certification is indeed separate, which is sort of a further refinement of the first question. And again the subcommittee recommends that the certifying boards clarify that the AU training and experience is not an interim but a stand alone certification, and the subcommittee in response to, again, staff questions, recommends that

the certifying boards specifically state what training this is certifying, whether it be training under Part 200 - training under 290; Part 300 training under 390, 392, 394; or for any other board part, 400 training under 490 or Part 600 training under 690, in a broadly applicable training algorithm.

The next question is to clarify whether or not successful completion of the NRC tailored examination will be required for trainees who do not pursue or do not achieve the proposed authorized individual training. The - in this case the subcommittee understands that different certifying boards may take a different approach to satisfying this concern. There are two possible approaches that I saw in a general basis, and the first path would say all trainees would be required to acquire the necessary training and experience and to pass the required examinations to become an authorized user as part of their board certification requirement; that if they do not complete this first phase then they are not eligible ultimately for board certification.

Alternatively a certifying board could offer two pathways, one that leads to board certification effectively as ABR does now; one that leads to board certification with authorized user

eligibility; and one that leads to board certification without authorized user eligibility.

And the question is, what is the impact of that? And I think that is what the next question effectively answers, which is to say that if trainees do not achieve the authorized user status as part of their board certification program and they subsequently determine that they want to become authorized users then their option becomes the alternate pathway and it is no longer an obligation of the board to go retrospectively and provide them with something so they can get authorized user status.

So that if the board were to offer a dual pathway and the individual did not choose to participate in the training and examinations necessary to become an authorized user, and sometime later determined that they wanted to become an authorized user or authorized individual more broadly, then their option becomes the alternate pathway, and they are no longer eligible for authorized individual status via the board certification pathway.

The final comment from staff, which I'm not sure was a question but more of a comment, is that this represents a change in the approval that - or recognition that NRC has already provided to the

individual boards, and that the boards would have to amend their proposal to the NRC and have that amended proposal recognized.

And again the subcommittee's recommendation would be that the board would do exactly that, which they would submit their modified proposal to NRC for review, for the board certification, and to make it clear to NRC as to whether this proposal represents a replacement of their existing recognition or whether this represented an addition to their existing recognition.

And that is pretty much as far as we could go in making a recommendation. I don't think that we could make a recommendation that is more specific and yet broadly applicable. Again the goal is to provide a framework whereby the boards can provide the opportunity for trainees to become authorized individuals prior to the completion of the final board exam, and when there is a large gap between completion of training and final board certification, a program that is not required to be used by any board, but is a framework available to be used if the board chooses to do that.

If a board does not perceive that they have a problem, then they have no need to utilize this

pathway.

So that I think concludes the subcommittee's report.

CHAIRMAN MALMUD: Thank you, Dr. Eggli.

Questions or comments for Dr. Eggli?

DR. NAG: I have been asked by many of my colleagues in radiation oncology that if this were to come into effect, what would happen to those individuals who got the NRC annual status; they did not appear before the board, or they appeared before the board and they failed; and all they decided that they do not need the board and they would not appear for the board. So would you clarify that?

DR. EGGLI: Yes, again, for the subcommittee's point of view, and I guess this is as much a question for NRC staff, is that if they achieved this authorized user status technically they could apply for authorized status, but the reality is they are unemployable, that if their limited employment opportunities for individuals who do not achieve board certification these days. And that is not an NRC regulation; that is coming more and more from third party payers who are beginning to impose credentialing requirements for payment.

But I think that the way this proposal

stands is that they could conceivably apply.

Now the other thing is if though the American Board of Radiologies, radiation oncology section, did not modify their request to NRC to include this pathway, then it doesn't exist. So it is up to the individual boards to determine whether or not this sort of solution is either viable or useful for them as a board.

So one solution might be that radiation oncology says, we are not going to use this framework; that we are happy with what we have now, and that's it.

So again this is not imposed on any board. The solution is not imposed. It's a framework, and it's not the individual candidate who decides whether or not to use the framework; it is actually the board that determines whether or not they want to implement a program within the framework.

CHAIRMAN MALMUD: Dr. Nag, did Dr. Eggli answer your question?

DR. NAG: Partly, but I still think that it will use the authority of the board if they were to apply -- if they were to rank two separate -- because many people would say I am going to apply for the NRC AU status, but I don't want to take the trouble to

take the exam and get the board certification. On the other hand, I don't really see the importance why would a candidate go through the entire residency clinical plan, go to the board, go through everything else, and not apply for the AU status at the same time. So I'm a little -

DR. EGGLI: The solution is intended is intended for the boards that have a significant time gap between completion of training and final board certification. No board is required to utilize it. This may not be the appropriate framework for radiation oncology at all. They are not required to implement that pathway if it doesn't apply to their diplomates.

DR. NAG: No, it does apply to our diplomate, I thought the solution was that people who are going through the board certification, they finish their residency, and at the end of that residency they are given an AU - NRC AU certificate, that means basically available to them so they don't have to go through the alternate pathway. And then they appeal to the board, and when they appeal to the board then this becomes a permanent situation. That is my understanding.

DR. EGGLI: Okay. What I took away from

NRC's questions, and maybe I read too much into staff's questions. But my - the feeling that I got out of this, and please, the staff should respond to this, was that I saw this as the staff wasn't interested in having to police an interim certification that might have to be taken away. And therefore the solution needed to be such that it was not an interim certification.

CHAIRMAN MALMUD: I believe that Dr. Zelac is able to comment on the subject.

MR. ZELAC: The NRC regulations list specifically particular requirements that an individual board has to satisfy in order for candidates, its candidates, that the board has to require of its candidates in order to have this certification process recognized. In other words the regulations say, if you want a recognized certification process so that your diplomates can follow the certification pathway to authorized status, here are the things that have to be met.

Those are in the regulations now. What they are basically saying is that through this suggestion from the subcommittee is that, as I understand it, that if a board chooses to, at the end of the residency program, provide an examination which

will fulfill that portion of the NRC's requirements and subsequently if the candidate passes that examination the board issues a certificate to that person so stating, and then that individual can follow the certification pathway in seeking authorized status.

DR. EGGLI: That's the impact. Debbie Gilley has been trying to get in here.

MS. GILLEY: I'm a little confused. Don't we already have an alternate pathway for these individuals? And what are the advantages of setting up a third pathway versus trying to make sure the alternative pathway meets the needs of the board eligible authorized users?

DR. EGGLI: I think that the alternative pathway, and I covered it in the four-page single spaced document which would put you to sleep if you tried to read it, but the recordkeeping requirement is significantly different for alternate pathway than the board certification pathway.

The - and many preceptors these days are not willing to write alternate pathway preceptor statements.

The other thing is that the boards have some leeway in how they compose the training to meet

the regulations, where the alternate pathway is significantly more rigid.

So it imposes on the board certification pathway a recordkeeping burden which is very different than if they have to train rigidly to the alternate pathway and keeping all the records that document the alternate pathway than the board certification pathway does.

CHAIRMAN MALMUD: Dr. Guiberteau.

DR. GUIBERTEAU: Just to reply to Debbie, I don't believe this was intended to be a third pathway.

DR. EGGLI: No, it's not. It's still the board certification pathway. It is the proposal of what will NRC accept as evidence of completion of the board certification pathway.

MS. GILLEY: But my concern as a regulatory is that alternative pathway, we put somebody on a license, an authorized user, and they do not pass the board or choose not to sit for the board, I have no regulatory authority necessarily to remove them because of that, because they have already demonstrated that they are capable of doing these procedures without any supervision.

So there is some legalities, regulatory

coordination activities that are very very concerning to those folks who must implement this particular regulation.

CHAIRMAN MALMUD: Dr. Guiberteau?

DR. GUIBERTEAU: May I respond? I realize this, and wisely so, and I thank our chairman, Doug Eggli, for doing a superb job on this, and Cindy Flannery for advising us. But if I might give you what the ABR is willing to propose or would like to propose, to give you an example, not to be put into writing at this point, because there is no reason we would do that quite yet. But what has happened is, the American Board of Medical Specialties, which is a combination of 24 boards of which the ABR is one, we have not been in line with the other boards in that we do not require a clinical year after training before they take their final exam.

So in the past completion of all the training, completion of all the certification including the AU eligible status portion of our certificate, was given at a time when they could apply and use it in that year of practice.

At the moment our final certification is given 15 months after they go into the practice or further training. So if we did not - were not allowed

to give the AU, that is, take the AU portion of our certificate and put that off and give it to them earlier if they complete all of it, they would have a 15-month gap in which they would not be able to function as an AU, even though they were qualified.

Our current process for this that we are proposing is, in the four years of residency, at three years they take a comprehensive examination. This comprehensive examination covers 17 topics, okay. And including in these are the examination on radiation biology, radio-pharmacy, radiation safety, radiation physics, nuclear medicine, et cetera, et cetera.

They must pass this examination at the end of the year - or they must pass this examination before they can then take a dedicated AU examination which is a separate - we propose to be a separate examination.

So together those two examinations by the end of their fourth year when they leave us will qualify them we believe - because it is the same process we are basically using now - so that we might give them documentation that they should be AU eligible under this board certification pathway.

This includes the board collecting documentation in terms of they must have attestation

from their program that they have completed the - to us that they completed the necessary training. They must give us their case logs that were preceptored of their 300 cases. They must pass this extensive core examination, and they must pass the AU examination.

So what we are proposing is, rather than waiting for 15 months to give them one certificate saying that they are ABR certified and AU eligible, we would like to take that off and give it to them earlier.

The examination that they take at 15 months is based on the practice that they are in. They get to choose three of the topics that they are examined on, and the board gives them two standard topics, both of which are clinically oriented, but for noncognitive - many with non-cognitive skills, professionalism, ethics and those sorts of things.

So in effect they have completed all of the necessary training. Everything has been documented, at the time they go into practice, when they leave their programs by the board. And in order not to have a deficit in terms of the number of Aus coming out that are eligible for AU status, we would like to present this as a variation on the certification pathway.

CHAIRMAN MALMUD: Thank you, Dr. Guiberteau.

Debbie?

MS. GILLEY: Currently we are doing this through the alternative pathway. There is a gap now I believe between getting board certification and actually completing your educational requirement. So they are sending to us their alternate pathway attestation clinical cases, some of the same things that the American Board of Radiology is looking at doing to provide this document.

I'm still confused as to where the gap is in alternative pathway to get them on a license -

DR. EGGLI: Debbie, let me try to explain that. As a preceptor I will not write an alternative pathway statement for anybody.

MS. GILLEY: But we are looking at changing those regulations?

DR. EGGLI: Not the alternative pathway regulations we are not.

MS. GILLEY: We are looking at taking the competency statement out of that. Are you not willing to write an attestation letter -

DR. EGGLI: No, what I -

MS. GILLEY: Because that is what you are

doing -

DR. EGGLI: No, that is not quite right. It is the recordkeeping requirement for all the individual components in the alternate pathway. I don't have to keep those records now, and I don't. Because essentially the program director is certifying to the American Board of Radiology that that has been completed. The bottom line is, I'm not willing to put my signature on an alternate pathway document that is supposed to have this many hours of this, this many hours of this, this many hours of this. And if you look at NRC's form 313A it asks for the number of hours in each of those areas. I'm not willing to try to document that and put my signature on it.

MS. GILLEY: But you are willing to do that for the American Board of Radiology to get them -

DR. EGGLI: No, the attestation to the American Board of Radiology is that they have completed the training requirements within the description of the program of the American Board of Radiology. The board certification pathway covers the topics that must be covered, but no real distribution other than the 80-hour requirement; no real distribution efforts.

CHAIRMAN MALMUD: Dr. Welsh.

DR. WELSH: Dr. Eggli, perhaps you could clarify a misunderstanding I might be having. Since this is for new graduates to accommodate that brief interval between completing residency and board certification, does this new proposal in essence obviate the alternative pathway? Is there not going to be -

DR. EGGLI: No, there will always be people who do not graduate from a recognized training program who are qualified to become authorized users. For instance right now I don't believe there is endocrinology training program that is recognized; and I could be wrong on that. But yet, via the alternate pathway, endocrinologists can become authorized users. So there will always be categories of people who have training and experience appropriate for authorized user status, but do not have a certification from a recognized board, even though they may be board certified.

DR. WELSH: But for endocrinologists they wouldn't have this particular problem that we are talking about with radiation oncology and radiology, so this solution is primarily directed towards radiology and radiation.

DR. EGGLI: This solution is directed

toward diplomates or trainees who train in training programs where their program is recognized by NRC for board certification status, but who have a significant time gap between completion of training and final board certification; and that time gap is perceived as causing a problem with either employment or the ability to deliver care to a patient population.

CHAIRMAN MALMUD: If I may, we are under a time constraint in that we must be at the hotel by 11:15. May we pick up this discussion after lunch? Thank you.

DR. EGGLI: Personally, I'd rather just see a motion made to pass.

CHAIRMAN MALMUD: I don't think we are ready for a motion.

We will reconvene promptly at 1:00 o'clock, which means we should leave the hotel around 12:45 to get back here at 1:00.

(Whereupon, the above-entitled matter went off the record at 11:06 a.m. and resumed at 12:59 p.m.)

DR. EGGLI: While people are coming in let me make if I could, Mr. Chairman, make two clarifying points. One is that this is - Steve, we have your briefcase - one of the clarifying points is

that this is a framework. The proposal was that again that the candidates would complete training experience and any appropriate examinations, and each individual board who chooses to use this framework would submit their proposed program to NRC for evaluation, and NRC would need to concur that that proposal met the requirements of the regulation.

So there is no obligation placed on NRC to accept any one proposal if NRC is not satisfied that the requirements and the regulations are being fulfilled.

I think that is the primary clarifying statement. And the other one is, no board is compelled to implement something along this framework if the board has no need for it. We wanted to make this reusable so that the wheel didn't have to be reinvented every time a certifying board came up against a delay if they changed their training paradigm from how it currently exists.

So again the point is that the proposal does say that all candidates or all trainees meet the training, experience and examination requirements; and it says that the board submits a proposal to NRC that NRC would have to accept as meeting the regulations, and qualify it as meeting the requirements of the

board certification pathway.

And then Mr. Chairman, I will turn it back for what residual discussion is left.

CHAIRMAN MALMUD: Does anyone else wish to comment on the issue? Dr. Nag.

DR. NAG: The solution that was passed at the last meeting was something that was applicable to everyone. We then - NRC official asked for a number of qualifications. What I wish to ensure is that radiation oncology has some of the similar problems in that we have the examination at the end of the third year, and they finish residency at the end of the four years. But they do not appear before the board until a year later. So we do have a gap problem.

However we do not have the problem that we need a separate examination because our regular written board has plenty of questions on NRC rule, regulations and so forth. So I wish to ensure or I wish to clarify that if we pass the new regulation or the new qualification it will not require a radiation oncology candidate to mandate a third examination with the NRC examination.

DR. EGGLI: Mr. Chairman, on this, again the program that is adopted is a negotiation between NRC and the certifying board using the framework.

Again, the thing says, appropriate training experience and examinations. There is nothing in the proposal that says that mandates a separate examination. ABR may go that route, but there is nothing in the proposal that obligates an additional examination. If NRC, I would think - I would staff to comment, please, if NRC is satisfied that the examination given adequately tests and separately scores performance in those portions, NRC may or may not require something separate.

Again a separate exam is not mandated, but what it says is this is a negotiation between NRC and the certifying board.

DR. NAG: The reason I am asking for the clarification is that both the diagnostic and the radiation oncology, both are called radiology. With the name, ABR, it is what you have to do because you are certified by the ABR, someone may mistakenly think that it applies to diagnostic and radiation oncology as well.

I want to prevent such misunderstandings in the future. I am trying to look in the future and people - and it has happened before. Just because we have written ABR, people have misunderstood that it means to both.

DR. EGGLI: Cindy, you are our touch point with NRC on this. Could you please comment?

MS. FLANNERY: Yes, with regard to Dr. Nag's concern, I don't think that will be an issue, because there - on our website we have three different specialties of ABR listed. So I don't think that that should be an issue. So just because you have a certification process for ABR diagnostic radiology, that same process wouldn't apply for ABR radiation oncology. So it does differentiate the three different specialties on our website, as well as listing them under the various sections for 10 CFR 45.

And the third specialty being the medical physics, or radiological physics.

CHAIRMAN MALMUD: Thank you.

MS. GILLEY: Again this is a question from NRC. Would this require rulemaking?

MR. LEWIS: We're not entirely sure at this time. But we would have to talk to our rulemaking people and our OGC to decide that.

MS. GILLEY: Okay. The second comment then is the way that currently the situation is set up NRC could make these changes because their compatibility. They would be forced onto the Agreement States, but without better Agreement State

participation I would be a little hesitant to step forward in any kind of support of this activity since they have not really been informed of that activity.

CHAIRMAN MALMUD: Thank you for bringing that to our attention.

Any other discussion of this item? Dr. Eggli.

DR. EGGLI: Again, certainly a vote by this committee to endorse the subcommittee report doesn't mean this is going to happen. This just says that this is recommended as a potential solution. And I would agree with Debbie that the work is clearly not done, once a recommendation is made.

CHAIRMAN MALMUD: Dr. Welsh.

DR. WELSH: Speaking as a radiation oncologist, I acknowledge that there is the very same problem in radiation oncology as there is diagnostic radiology. Therefore a solution has to be sought.

The proposed solution of an AU certificate sounds like a very reasonable solution until those individuals go on a year later or whenever to take their formal board examination. But I would submit that for the radiation oncology residents, that an additional examination might be required.

DR. EGGLI: Yet there is nothing in the

proposal that would require a separate examination. There is nothing in the proposal that would require a separate examination. What it says is that the NRC is satisfied that the training experience and examinations whatever they are that the board submits to NRC for approval meet the requirements.

So I don't think there is anything in this proposal that suggests that necessarily a separate exam would be required, as long as the core examinations met the requirements.

DR. WELSH: And the core examination is the one that would be taken in the future?

DR. EGGLI: The core examination would be whatever the radiation oncology section of the American Board of Radiology defines as its board exam.

DR. WELSH: So maybe there was a misunderstanding. There is no separate examination for the AU certificate?

DR. EGGLI: Right, and there is nothing in this proposal that suggests that there needs to be.

DR. WELSH: In that case, I agree with this.

DR. EGGLI: Offering a second exam would be the American Board of Radiology's diagnostic radiology section proposal for how they would manage

it for diagnostic radiology; that is not imposed on any other portion of any other certifying board.

DR. NAG: When we make the motion, when we are voting on the motion, could that qualification be added into the motion? Because I am always afraid that they will all be lumped into one. So it would help if in that motion you say that a separate examination is not necessarily required.

DR. EGGLI: I guess I think that is overboard, because again NRC has stated that they do not consider these the same board. That statement has just been made, that NRC does not consider the diagnostic radiology board exam of the American Board of Radiology to be the same exam as the radiation oncology exam, and there is nothing in the proposal - there is nothing in the proposal that says a second exam. The second exam just happens to be the way that the American Board of Radiology diagnostic radiology may approach it. But this, all this says is that the patients - that the candidates pass whatever the appropriate examination is. There is no reference to a second examination in the proposal.

DR. NAG: I'm sorry. Let me read it out word by word. Please clarify whether successful completion of the NRC tailored examination will be

required for ABR candidate, not diagnostic candidate, ABR means ABR, for both diagnostic predictions as well as therapy candidate, who do not pursue or do not achieve the proposed certification.

DR. EGGLI: That is the question.

DR. NAG: Yes, I think the qualification that they ask for, and if they do not qualify, which part of it you are recommending that a second exam be required, I am afraid that later on it may be lumped together as ABR.

DR. EGGLI: But the response to that doesn't make reference - and the proposal doesn't make reference to a second exam. The answer to the question does not make reference to a second exam.

CHAIRMAN MALMUD: Dr. Guiberteau.

DR. GUIBERTEAU: The ABR certification process in diagnostic radiology decided on its own to offer a separate examination for several reasons. First of all if the candidates do not - their programs do not submit the proper paperwork, or if they do not pass their core exam the first time, then there is no need for them to take the AU examination because they don't qualify.

If they go forward, or they take the AU examination and do not pass it, or they go out into

practice and decide well, I don't want to be an AU and never apply, but later on do, then we will have the possibility of opening that examination to cure these issues in the eyes of either the Agreement States or the NRC by allowing them to come by and come back to the ABR and to take this examination and pass it.

So it really is mechanistic in our point of view to be able to offer it in that form. It has nothing to do with requiring a second examination because no one ever brought that up to us. It was our idea to do that so that we would have a free standing examination that we could offer to people who needed to cure an issue with their AU status.

DR. NAG: I agree with you completely. You have offered a solution for the diagnostic component of the ABR. But what you are writing here, just ABR and not writing diagnostic ABR, and that may create problems later on. That's all I'm trying to say.

DR. EGGLI: That is not in the proposal; that is in the question. Let me specifically read the proposal that is put forward in response to that question.

The proposal says, all trainees would be required to acquire the necessary training and experience, and to pass the required examinations to

become an authorized user. There is no reference to any specific number of examinations.

So this proposal does not, in response to NRC's question, does not propose necessarily any additional examination. So this subcommittee's proposal is that they - that the candidates get the training, they get the experience, and they pass whatever the required examinations are. The required examinations are - NRC will determine whether or not the proposal the board makes meets the requirements.

If - I would again ask if you could try to address the question - if NRC is satisfied that the examinations as they exist meet the requirements, I can't see that NRC would necessarily require a separate exam.

Could you specifically address that issue, Cindy? If NRC is satisfied that the exam as it currently exists meets all the requirements, would the NRC require a separate or additional exam?

MS. FLANNERY: Okay, I think just to clarify a little bit. I guess a couple of things. One is, NRC does not recognize a board; we recognize a certification process, okay. And if that certification process meets NRC's requirements then it will be recognized.

And just to kind of break it down, there are three sections really. There is a classroom laboratory training section; there is a supervise experience section; and then there is the exams section.

And in each of those sections there are required topics that need to be included.

If a board can demonstrate that all of those requirements are met, NRC will recognize that certification process, okay.

So I think that kind of hopefully addresses Dr. Nag's concern in that we are not recognizing the ABR as a whole; we are recognizing the different certification processes.

As far as the question on the exam itself, NRC does not review or evaluate exams. But the board does need to demonstrate that the exam does improve the listed topic the NRC has in its regulations. And if a board can do that with just one exam, then that is fine. Another exam is not required later if that was your question.

DR. NAG: Thank you.

DR. EGGLI: I think that was - does that satisfy your question, Subir?

CHAIRMAN MALMUD: The other point I would

make is that we have been sitting on this committee for a number of years together. And the only instance in which there was a challenge to someone's status as an AU was supported by the NRC, but voted against by the members of this board - of this committee. So the NRC has been reasonable and has shown flexibility not with regard to its standards but with regard to interpretation of the standards.

Dr. Vetter.

VICE CHAIRMAN VETTER: I move that the advisory committee endorse the subcommittee report of the board certification pathway for AU status.

CHAIRMAN MALMUD: Is there a second?

MR. LIETO: Second.

CHAIRMAN MALMUD: Any further discussion?

All in favor - oh, Dr. Welsh.

DR. WELSH: In relationship to Cindy's comment that NRC recognizes certification or processes but not boards. So the solution proposed is that there would be certificates that say AU eligible. Will that carry any weight given that it is outside the formal board certification pathway that is issued by the American Board of Radiology?

CHAIRMAN MALMUD: that's a question to you, Cindy.

MS. FLANNERY: I'm not certain I understand the question. The way ABR when they submitted the documentation for our review, it was explained that the certificates that have AU eligible on them would be issued to the diplomates who meet NRC's criteria. If it does not have AU eligible on it, those diplomates for some reason did not meet NRC's criteria, and there are various reasons for that.

And that is identified on our website that way. Basically saying that anybody who got certified after the identified year with the words, AU eligible on the certificate, would be able to apply for AU status under the board certification pathway.

I don't know if that clarifies it.

DR. WELSH: The certificate comes 18 months after finishing residency program. So the problem at hand is that there is an interval, 12 to 18 months, in which somebody could complete their residency training and not have that certificate whether it says AU eligible or not. They won't have it for 18 months. There is a proposed solution, but I'm questioning whether or not this proposed solution would have any merit or weight with NRC given what we just said.

DR. EGGLI: One of the direct statements of the proposal is that NRC will accept that verification by the board that the candidate has completed all of these requirements. And what I thought I had previously heard is that NRC is open to considering that as a solution dealing with resolving any residual legal questions.

DR. WELSH: And that is my question, given the wording I just heard about recognizing the board's certification process versus recognizing the American Board of Radiology.

DR. EGGLI: I know, but this would be part of that process now.

MS. FLANNERY: And it was our understanding of the proposal is that this would be a new certification process, different than what is currently recognized.

CHAIRMAN MALMUD: The question has been called.

All in favor?

(Show of hands.)

CHAIRMAN MALMUD: Any opposed?

(Show of hands.)

CHAIRMAN MALMUD: One opposed. Any abstentions?

(Show of hands.)

CHAIRMAN MALMUD: One opposition, one abstention.

MS. GILLEY: May I make a comment on my opposition?

CHAIRMAN MALMUD: Please do.

MS. GILLEY: Okay. Without the assurance of rulemaking this would have an impact on the Agreement States because of the opportunity to evaluate this change would not be brought before 36 Agreement States as to the change in the certification process. Thank you.

CHAIRMAN MALMUD: Thank you.

I'm sorry, I heard a comment? Oh, please.

MS. CHIDAKL: My name is Susan Chidakl. I am a senior attorney in the Office of General Counsel that assists and advises the staff with regard to rulemaking. And with regard to whether regulations need to be officially - go through a rulemaking process in order to accomplish what it is that you or the staff is trying to do.

I've been sitting in this meeting, and I apologize, because obviously I was not familiar with this issue before I heard about it being on the agenda today.

I really don't understand what the issue is. So I think that is why the staff is having a hard time answering the question as to whether a rule change is going to be necessary or not. And of course I'm going to have a lot of input as to whether we have to go through a rulemaking or not. Could somebody please explain to me why there is this gap now? Why is there this problem?

In order for me to understand what it is you are proposing to resolve the problem.

CHAIRMAN MALMUD: I think Dr. Eggli can handle that.

DR. EGGLI: The American Board of Radiology was one of the few certifying boards that gave its certification immediately on completion of training. The vast majority of certification boards in the American - that are under the American Board of Medical Specialties have a - either an advanced training or a clinical period of time after the completion of training before they issue a final board certificate.

The people when they complete their training go out and actually work, and this is true of all the specialties, they go out and work as sub-specialists in this area. If the use of materials is

unique in that it requires some form of authorized status to be able to handle those materials.

The diplomates in the time gap between completion of training and all testing have - what?

MS. GILLEY: Completion of testing.

DR. EGGLI: A completion of training and completion of testing relevant to the authorized user status, because they won't be tested on that again as they complete this additional year; will not be able to work as radiation workers in that gap, which will basically create an employment problem and possibly an access problem for patients as they complete that final critical phase of training that gets them their final board certification.

MS. CHIDAKL: May I ask a question? When you are talking about this clinical aspect, is that what is the same thing as in our regulation that says work experience?

DR. EGGLI: No, they will have completed that work experience in the core portion of their training. This is purely clinical experience.

MS. CHIDAKL: It is not required by NRC?

DR. EGGLI: That is not required by NRC. So the American Board of Radiology diagnostic radiology is modifying its program to come in line

with what the rest of the boards do. The only option then for these diplomates in the gap is to be certified by the alternate pathway.

The way I personally see the alternate pathway is, it is for folks who are training and meet all the training and education requirements, but are not training in a program where the training process has been recognized by NRC.

Now what we are doing, if these people would have to go down the alternate pathway, that would completely abrogate board certification as a pathway to user status for the 1,500 annual diplomates of the American Board of Radiology. So part of this is to maintain board certification as a relevant process to achieve user status and to allow these people in the gap between completion of all training relevant to authorized user status to become an authorized user prior to getting that final tag that says board certified.

MS. CHIDAKL: In other words if I understand you correctly the final bit as you - or whatever you want to call it, the final segment, is something above and beyond the NRC's requirements.

DR. EGGLI: Above and beyond.

MS. CHIDAKL: Thank you for that, I

appreciate that.

CHAIRMAN MALMUD: Thank you.

That completes the discussion of that item, and we will move on to the next item on the agenda, which is Mr. Lieto.

MR. LIETO: Thank you, Mr. Chairman.

This is the annual report of the ACMUI subcommittee on medical radioactive material events. This will now be an annual report in the future, not a partial report in the fall.

And the subcommittee membership listed there, everybody had a piece of the pie and contributed, so you are looking at the sum of all those contributions.

The report is based on the NMED database for fiscal year 2008. It is based on the events that had been reported during that time. Again in this report I will talk about that a little further and its importance.

The medical events were reported by category of use in Part 35 as well as a section that includes other reportable material events related to the medical use.

This is the second annual if you will report, so obviously it's still undergoing some

iterations of improvement, and three features in this report that we have attempted to include to better describe the impact of these reports is to indicate the number of patients involved in each event. We are trending over the last couple of reports, the number of patients involved as well as the number of events for each category of use of medical events, as well as the other reportable events, to give us some type of trending information, and have made an attempt to estimate on the frequency of occurrence of these medical events. And I will describe the information that was used for that.

The first category of use, or two categories of use, for Parts 35/200, there were three events involving diagnostic prescriptions of radionuclides in which patients got I-131. There were four events involving therapeutic radiopharmaceuticals requiring a written directive, involving four patients for I-131, and one event involving eight patients with Samarium-153.

The table here indicates three of the events for I-131; each are singular events in terms of patients being affected. The type of error that was described in the NMED report, as well as the actions that affected the - as a result of the event being

discovered. All three types of errors reported here are human errors, and the actions were - ranged from additional training to a policy procedure modification, as both technicians and all those involved with a written directive.

The next table here related to these events, again, all human errors related to following either written directive, the written directive or written instructions - excuse me, policies and procedures. In one case follow up action involved disciplinary action. Modification of procedures and retraining. The one event related to the Samarium was discovered after a patient assay of the therapeutic dose, it was determined that the wrong setting was used for the dose calibrator; it was a syringe setting instead of a vial setting - or excuse me, a vial setting instead of a syringe setting. And then they looked back at previous Samarium administrations there were the same type of error that had been included.

The one event down at the bottom of the table there involved sodium iodide 131, two patients were in the department; both scheduled to receive iodine therapies. And the dosages were switched as to - regarding the therapies that they were supposed to receive.

To compare a number of patients to last year's report and the radionuclide involved, not much of a change in the number of I-131 patients. There were no Y-90 patients involved, but we did see a big jump in Samarium. But I think again this was a singular event that occurred. So you can see that the - comparing the number of patients involved from `07 to `08 it almost doubles due to one singular event.

In providing an estimate of frequency of occurrence of the medical event, the committee used three sources of data in - to use as a denominator for the treatments involved. The principal source was the IMD medical information data. This source of information was the same that was used in NCRP 106 that we talked about earlier. Another source of information was data provided by the American College of Radiology of CMS procedure data for the year 2006.

As probably members of this advisory committee can probably better describe, one of the limitations of CMS data is that the data are Medicare-Medicaid patients, and that it does not include private payers, and those types of sources of information. But it does provide us with a lower bound of number of individuals that received the treatment. So as a result any estimates of frequency

would maybe provide us with an upper bound on the frequency of occurrence.

For the 35-1000 uses, we contacted the vendors themselves, principally Dr. Thomadsen and myself, and got 2008 data in terms of number of treatment dosages that were provided by the vendor. And this reflects the Y-90 microspheres and the I-125 gliasite administrations for 2008.

So if you look at frequency of occurrence, there were 15 patients involved. Our estimated number of treatments were 26,000, dividing a frequency of occurrence of roughly 6 X 10^-4th.

And this compares favorably with the number estimated in last year's report.

For 35-400 manual brachytherapy events, there were nine events, and you need to note in your handout, there is a change in this data regarding 35-400. After the presentation was sent out for inclusion in your packet it was discovered that one of the I-125 seed events was determined on follow up investigation to not be a medical event. And that was an event that involved three VA patients. So this - the slides are intended to reflect that update, and you may want to make changes in your packet accordingly.

There were nine events involving 111 patients. The radionuclide distribution on these events were seven events involving I-125 seeds. The one involving palladium 103 seeds and one involving cesium-137 low dose brachytherapy.

Looking at the distribution events, I want to point out here, this should in this second to last row here, that should say two hospitals in the VA systemic error category.

But as you can see the type of errors that were identified, there are three events involving misidentification of the prostate on trans-rectal ultrasound; faulty weld after implantation resulting in seed leakage; a Mike applicator jam resulting in leaked seed - a leaking seed during implant; a wrong dose being entered into the treatment planning system and resulting calculating error; a wrong magnification entered inn to the treatment planning for - I believe that was a gamma knife - or excuse me, I'm trying to remember which one it was - but any how it was a wrong magnification factor in the treatment planning system which resulted in two patients being referred as a medical event.

And again the two VA situations currently being reported, one involving 92 patients, and the

other involving 10 patients for a total of 102 patients in that VA system events.

So a total of nine events for a total of 111 - involving 111 patients.

A common issue, observations regarding these events, a common error found was with the prostate implants an improper identification of the gland boundaries; Mick applicator errors which were user failure errors, not the device itself. And then the bulk of these involving the VA situation which has been more than adequately described in previous presentations.

In attempting to provide an estimate on the frequency of occurrence, the number of treatments were based on the IMD data for 2006. So 111 patients over 50,000 treatments for the year resulting in an estimate on the frequency of occurrence of about 2 X 10^-3rd.

Recommendations submitted by the subcommittee were, calculations and data entry need to be checked by a second person; that a use of a nomogram as a secondary check for these types of treatments; better user training and practice with Mick applicators are needed. And I believe this is a repeat recommendation from last year was adequate

training on trans-rectal ultrasound and fluoroscopy use for confirmation of the boundaries.

Going to medical events for remote after loaders in teletherapy, devices in comparing 2007 through 2008, the - there were 17 events in 2000, ten in this year. There were 14 events last year in HDR, eight this year, and you see the distribution, based on descriptions in the NMED that did provide descriptions, we did break these out as to how many involved MammoSite versus vaginal cylinder applications for the HDR treatment.

There were no events involving a low dose remote after-loaders. There was one event involving Gamma knife, and one event involving a cobalt-60 teletherapy.

Regarding the HDR there were four events with a nucletron device. Three of these events involved wrong catheter link being entered into the treatment planning, and one event involving wrong step size entered into the treatment planning.

For the variant HDR there was - there were two events, one involving wrong length, and the other in which the MammoSite balloon deflated during treatment and resulted in an event causing wrong - or not wrong, but unintended dose distribution.

There was one event involving a variant HDR gamma med involving MammoSite application - or a therapy, and this was wrong dose entered into the plan.

There was one event involving Gamma knife in which the image descriptions were reversed, so the wrong side of the brain was treated. And in the cobalt-60 teletherapy unit event, the therapist misread the written directive, and a wrong dose was - the patient was treated with the wrong dose.

If we look at the HDR errors, there were two things that stood out: wrong length being entered into the treatment planning system; and wrong dose.

Compared with the number of - comparing the number of procedures by HDR, Gamma med and teletherapy, in terms of number, coming up with frequency of occurrence, for HDR there were eight failures - and again this was based on the IMV as well as the ACR data. HDR, there were eight failures over 62,000 procedures for a 1 X 10^-4 frequency of occurrence. Gamma knife, much less, 8^-5th frequency of occurrence. And for teletherapy which is the least - shall we say the least number of procedures that are performed - was one event over the roughly 2,000 procedures, and a frequency of occurrence of 5 X 10^-

4.

And all these events involving the HDR errors were attributed to human error, as opposed to any type of mechanical.

Regarding radioactive materials - this should actually be broken out with the 35-1000 separated out, but Part 35 events that are not medical - that are other events under 35-1000 there were four events, medical errors. There were two events involving pregnant patients who were administered therapeutic amounts of radioactive materials, actually 131, sodium iodide 131. And then the other reportable errors, the categories were broken into lost sources, leaking sources that were not implanted in patients, contaminated licensing packaging, and basically a catch all group called miscellaneous.

Regarding medical events in 35-1000 uses, these all were Y-90 microspheres. The two involved TheraSpheres. The other two were not described in the NMED documentation as to what form they were.

There was one patient involved with each event. And estimating the frequency of occurrence, there were four patients, and based on the vendor data provided for the number of dosages supplied, which was roughly around 3,500 - 3,600 treatments, resulting in

an error of 1 X 10^-3rd.

There were two pregnant patients. What is notable about this is that both patients had timely serum HCG pregnancy tests prior to administration. Both tests were negative. I don't see any errors here provided - shall we say on the part of the medical licensees. They did everything that I think can be expected; yet two of these events occurred.

And the doses, the embryo doses, were estimated, and these were both in the range of between 30 and 40 rads.

Regarding other reportable medical occurrences, regarding lost sources either sealed or unsealed, there were 13 events. The events are described here, ranging from I-131 capsules, iridium-192 seeds. There were six events involving I-125 seeds being lost, either after implant or during autoclaving process, source being inadvertently disposed into scrap recyclers.

One event involved a shipment of 114 palladium seeds that were in storage prior to implant - I don't know if they were prior to implant or after receipt - it was determined to not do the implant. But these became lost in a storage area undergoing renovation prior to return to the vendor.

There were two events that were reported after our last - I guess our preliminary report in the fall. A patient after implant was with - for I-25C prostate treatment, was cremated; there was quite a lengthy description in the NMED report on follow up and decontamination of the crematorium. But there were no excessive exposures to members of the public that resulted from this event.

One was loss and recovery of a plutonium cardiac pacemaker. I guess there are still some of those out there that have not been returned yet. And obviously that speaks to their reliability, but I don't go there.

But anyhow evidently upon death of a patient the funeral director removed the pacemaker; didn't realize the type of pacemaker he had, and just kind of threw it into the box. The other pacemakers are removed, and then when the licensee found out that the patient had passed away conducted an investigation to try to find the pacemaker. And actually there was sort of a back and forth, no it's not here. Then the funeral director realized that he actually did have it, and it did get recovered and returned to Los Alamos for proper disposal.

Regarding leaking sources there were seven

events; all involved iodine-125. These were reported in the fall. Also three of these events were found from white testing, surveying, visual inspection of storage containers and prepackaged cartridges which were found to be contaminated.

Two events were found on seeds which were unused after implant, and another was done after autoclaving and cartridge loading.

Vendor analysis found that one seed was likely damaged during use in the applicator. One had surface contamination but no defects in terms of the weld or encapsulation. And one event was determined to be excessive force with the seeds being stacked in the shipping container, and the excessive force on the package resulted in the seeds becoming compromised and leakage occurring.

Regarding leaking sources again here are description specifics of events that occurred. One was a jammed applicator, and a technician improperly unloading the seed cartridge with bare hands found both the cartridge and the hands contaminated. There were two events discovered by the vendor during seed assembly. In one case seeds were shipped out before the event was discovered, and then another example was the crimping work tool was found to be contaminated

before any seeds were sent out.

And the last event did involve a patient post-implant for seeds coming back for follow up treatment regarding their condition. The patient was being addressed and treated with a cauterization tool, and the cauterization tool nicked one of the seeds resulting in leakage of the seed and I-125 uptake by both the patient's thyroid and contamination of the equipment.

Regarding packaging this was a little - there were four events. Three events involved technetium contamination exceeding reportable limits. And again emphasizing the importance of doing obviously leak tests - excuse me, wipe surveys on packages that are coming in. I think a lot of nuke techs think this is sort of one of those things that you need to just go through for formality purposes. I think this exemplifies the need for this obviously. Packages involved in the events that resulted in this are described in the slide.

One package involved the I-125 seed shipment for implant. It came open but the package itself was not compromised; so the sources were all contained in the package but they were not in their lead shipping container.

There were four events involving machine malfunctions. One was a Gamma knife. The shielding doors failed to close after treatment resulting in staff having to manually close the door, a negligible dose was reported. I don't know what negligible means, but I'm assuming that we are talking something that is probably less than background levels, or background limits.

There was no deviation from the written directive, so the net result in any increased dosage to the patient from the treatment outside the expected directive.

There were two events involving HDR machines in source failures. The sources failed to retract. Both of these occurred during field engineering servicing events, and in one case the source became disconnected, and the top of the source capsule was clipped off in the vault, and the second event involved the during a source exchange the old source failed to enter the container. The cause of both the dummy and active sources were extended at the same pathway and became stuck. In both cases the vendors sent out teams to recover the sources, and take care of the devices and put them back into service.

Another event again did not result in any exposure to personnel. It was a Gadalinium-153 attenuation sources that are part of a Gamma camera system, do attenuation correction. These were timed to do attenuation corrections when sort of in a pre-program mode when staff was not present. And basically late in the evening - or excuse me, early mornings. And the shielding failed to retract. The cause was that during cleaning the cleaning personnel entangled the cables in such a condition that the - after the shields opened the signal to retract failed to occur.

But the reconstructions determined that no inadvertent exposures occurred because staff was not present.

There were - there was a singular event involving overexposure to the extremities. These are radio-pharmacy techs manufacturing sodium iodine 131 capsules in a radiopharmacy. Extremity doses ranged from 50 to 100 rem for the extremities, and the lack of written procedures and proper handling tools were cited.

So I tried to trend some of these events. If we look at the events over the last three years that have been reported by the subcommittee, for 200

events, 300 events, the number of events has not changed much although you could say that the number of patients involved almost doubled.

For 400 events, again, principally due to the VA event, the number of events has not really changed, but the number of patients affected increased by over a factor of 10.

For over 600 events, again, number of events actually have decreased, and the number of patients involved is almost half.

Regarding 35-1000 uses really can't say there is any trend there at all; goes up in `07 and has dropped down dramatically in `08.

This to compare this report in the - from the subcommittee, when you look at the NMED annual report which was published in March, this looks at the medical events determined by the NMED annual report. Now as you can see here, the medical events are fairly constant, or maybe slightly trending downwards. The abnormal occurrence reports are events which are determined by NRC staff and reported annually to Congress appear to be increasing, but it's a variance that really - we're looking at such a small number of events it's really hard to say whether this is - has any trend associated with it. And not knowing the

denominator we can't really say that there is an increasing trend for this, because most of these tend to be therapeutic events, therapeutic administrations, and there is increasing use over this five-year time period of therapeutic applications.

Now one of the things that I think needs to be noted is that the numbers on the medical advance in this - from the NMED annual report doesn't jibe with what this subcommittee has been reporting. We've been within plus or minus three events overall, and so I was trying to figure out what the discrepancy in this was. And the major factor is that the NMED annual report is based on the date of occurrence. So if an event let's say occurred in fiscal year 2007 but was reported in fiscal year 2008, it would go into our report, but those numbers would go into the previous year's report, and that report would then be adjusted.

The big contributor to this issue appears to be that some Agreement States do not report their events in a timely manner. Because if there was timely reporting the reports from this subcommittee should match the NMED report and that I think is one of the biggest causes for the discrepancy.

The subcommittee's opinion - or I should say the subcommittee chair's opinion is that it's

process is the better of the two, because otherwise you are constantly going back and having to adjust for or provide amendment reports, because of events that were not reported in the year that they occurred have to be adjusted for those events.

And so at this time I want to express my appreciation for Duane Wright who is in the back here, and Tom Smith from Idaho National Lab, who maintained the NMED database for their assistance in answering my many emails and phone calls in this - on this report. And anytime I had an NMED question on an event or a query, results or whatever, they got back to me very very promptly, and were quite patient in some of my questions to them. So I want to express a great deal of appreciation to Duane and Tom.

Regarding trending the other medical events, you see what appears to be an increase in the number of lost sources. The subcommittee consensus at this time is not to make any recommendations regarding this. We felt that we needed to maybe see if this changes over time a little bit, or the trend continues.

Leaking sources were up and down over this three-year period. Fetal embryo dose is the same. Landfill alarms which we reported in the past, I

didn't talk about it previously, but just from the fact that we did report it in past reports, I did include that, and it's fairly low.

And then miscellaneous events. Again, you can't really make assessment or comments about trends. It's been way down, and it goes back up.

Regarding recommendations, there was an event that involved a lot of discussion by the subcommittee involving a 90 eye-applicator event involving three patients which was initially reported as a medical event, and because it was originally reported as having a wrong calibration resulting in a 50 percent overdose. This was later retracted, because it was determined that at the time the prescribed dose was administered, and it wasn't until a recalibration of the eye applicator was done that it was determined that the calibration was off based on the current NIST calibration procedure.

But it did I think bring up a point that the subcommittee wanted to emphasize, which is that strontium eye applicators must have a calibration by the current NIST traceable standard.

So basically it's a reaffirmation of the NRC information notice that went out in May of 2002. I think the reason this came to event is that the

Agreement States had three years to implement that recalibration requirement, and I think that is the reason why this came to light.

But the - and again I want to thank both Duane and Dan and Beth for their assistance on that issue.

Finally our recommendations: events reporting needs to be improved. The subcommittee said very often it's devoid of causes. The remedial action information needed to analyze events for areas of improvement. I think establishing a consistent requirement. And I think also timely reporting is very important.

Recognizing events that were reported - or excuse me, events are underreported, this was in the OIG audit of the NRC Agreement State program, I think emphasize the importance of gaining value from these reported events, both medical events and other material events.

And again, NMED improvements, I think being able to do some queries by more than a single word so that we are not missing these events would be a very beneficial improvement. And also just being able to do queries by license type. This is not something currently available but maybe something that

NMED may look at in improving our queries and reporting and being able to identify events that relate to medical use.

So I think there is a lot of information that are not medical events that are valuable to licensees.

And with that, Mr. Chairman, that concludes the subcommittee's report, and the subcommittee as a whole would be glad to entertain any questions, comments.

CHAIRMAN MALMUD: Thank you, Mr. Lieto, for an extraordinarily thorough job. And we appreciate all the effort.

Are there any questions or comments for Mr. Lieto? Dr. Vetter.

VICE CHAIRMAN VETTER: Was there any attempt, or do you think it's feasible to find - on your third from the last slide you have leaking sources, lost source and so forth. Is it feasible, or do you have denominators, have you tried to find denominators for those?

MR. LIETO: For the other medical events it was really difficult to come up with denominators. For leaking sources, do you look at the number of individual seeds shipped? Or do you look at the

number of treatments for seeds? And for some of these events in - I'm sorry, for leaking seal sources -

VICE CHAIRMAN VETTER: There must be half a million sealed sources out there.

MR. LIETO: I would not be surprised. I mean if we look just at the I-125 I suppose we might be able to go to vendors and determine how many seeds were shipped in the U.S. for treatment use and use that; that might be a possibility. Because all these events - at least in this case I believe all the leaking sources involved I-125 sealed seeds. But if it involved other sources, it might become problematic. But that's something I think maybe the subcommittee might consider for that.

For a lot of the other ones, we really just could not come up with anything that would be logical to use as a denominator, so we just stayed away from that.

CHAIRMAN MALMUD: Thank you. Any other comments?

DR. THOMADSEN: Just as a rough number -

CHAIRMAN MALMUD: Dr. Thomadsen.

DR. THOMADSEN: Just as a rough number, apparently rough, on the slide, a number of manual brachytherapy procedures, there were 50,000. Roughly

you have around 100 seeds per procedure; that would give you about 5 million seeds out there.

CHAIRMAN MALMUD: Thank you.

If there are no other comments, I want to thank you for your report - oh, Mr. Lieto.

MR. LIETO: Just one other thing: it doesn't require any action by the committee at this time. But at the end of the packet in your booklet is a brief set of slides on a topic described as 6-Sigma. This is being presented for the committee's edification. It's not anything we need to address at this time, but it's a concept that might be considered for future reports as a means of describing these events, the medical events especially.

Dr. Thomadsen is probably the subcommittee expert on this, and is probably the most versed. But we would welcome your feedback if this type of analysis would provide added value for these reports in the future, or is just the frequency of occurrence, percentage of occurrence, adequate?

But it was a new shall we say method of analysis that the subcommittee had kicked around, but we thought it might be a little overwhelming to present in this report, and also time considerations.

CHAIRMAN MALMUD: Thank you. Is this the

system that the airline industry uses?

DR. THOMADSEN: Right, developed mostly by Motorola and the automobiles. It is used in the airlines and many other industries at the moment.

CHAIRMAN MALMUD: Thank you. It's a goal. Our problem remains one of knowing what the denominators are, doesn't it?

MR. LIETO: Yes.

CHAIRMAN MALMUD: Doctor?

DR. VAN DECKER: I was wondering if I could ask a question out of curiosity. Going back to yesterday's discussion on the international INES scale, what percentage of these several hundred odd little pieces here and there do you think would have been reported under this, especially under lost sealed sources and a few other things under level one, and whether you think any of this stuff would have reached more than level one in the reporting scheme.

MR. LIETO: The loss sources, no, because I think these are all category four sources. Regarding the medical events, I think the majority of them might - based on the discussions from yesterday, might be rooted in that. I mean like the 600, there was one event with gammonite that we got -

PARTICIPANT: Pull that mike closer.

MR. LIETO: Oh, I'm sorry. Because the one event under 600 for gammonite would probably definitely have been on that scale, and I think the 400s, or the manual brachytherapy. I guess another one, that are not medical events that might be of interest, or a question as to whether they would be reported, would be the fetal dose events to pregnant patients.

CHAIRMAN MALMUD: Dr. Welsh.

DR. WELSH: I have a question just out of curiosity regarding the fetal embryo dose cases. Both followed a negative pregnancy test. One of them said that the patient failed to follow directions. Do you know what that meant?

MR. LIETO: Well, the patient had been instructed after administration of the therapy, and I guess threw caution to the wind after the therapy and - well, let your imagination do the rest.

(Laughter.)

CHAIRMAN MALMUD: Dr. Eggli.

DR. EGGLI: On the Part 200 events, on the first one where failure to write an adequate written directive was taken, the action was training for scheduling staff? And how is failure to write a written directive a scheduling problem? Just out of

curiosity. This sounds like a physician error, not a schedule error.

MS. GILLEY: You have as much information as we do, which is one of the - excuse me, Debbie Gilley. You have as much information as we have. As many of these are very cryptic explanations of what happened. So that's - made them out of the NMED report.

DR. EGGLI: It sounds like some poor scheduler is taking the rap for a physician error.

MR. LIETO: I think that was an event where the patient was intended to get an I-123 diagnostic uptake study, and instead got an I-131 dosage.

DR. EGGLI: And he got - the person who writes the written directive doesn't bother to verify that before running the written directive?

MR. LIETO: Well, it wouldn't have required a written directive, because the intent was to give a 123 diagnostic study. So there wouldn't have been a written directive.

DR. EGGLI: Well, if they actually administer a dose greater than what is it 30 microcuries of I-131, to administer that does would have required a written directive, regardless of what

the patient was scheduled for.

CHAIRMAN MALMUD: Thank you. May we move on?

Thank you very much, Mr. Lieto.

We will move on to the next item on the agenda. And Cindy Flannery is on for infiltration, infiltrations of therapeutic radiopharmaceuticals as medical events.

MS. FLANNERY: Well, this presentation is really just a continuation of a discussion we had at the December 18th, 2008 teleconference. And I will just briefly summarize that discussion and where we left off.

I have provided a description of an event involving infiltration of F-18 FDG, and it was reported to the NRC as a possible medical event because the dose to the tissue potentially exceeded the medical event criteria of 50 rem to the surrounding tissue.

I explain how the event was later retracted, because it is and has been NRC's position that infiltrations do not need to be reported to the NRC as medical events. And that is really based on supplementary information to a previous equivalent regulation which is 35.33. And that states, quote:

Extravazation is the infiltration of injected fluid into tissues surrounding a vein or artery. Extravazation frequently occurs in otherwise normal intravenous or intra-arterial injections. It is virtually impossible to avoid. Therefore the commission does not consider extravazation to be a mis-administration, unquote.

So this supplementary information doesn't provide a distinction between diagnostic and therapeutic administrations. This language is also almost 30 years old. I think IV administrations of therapeutic radiopharmaceuticals are more common now than they were back then, and also now NRC has regulatory authority over NARM, which with its higher energies if infiltrated, it will result in a higher dose to the surrounding tissues than, say, something like technetium 99m.

So I think with all these things being taken into consideration, NRC staff felt that it was prudent to seek ACMUI input on whether we should reevaluate our current position on infiltrations.

CHAIRMAN MALMUD: Thank you for bringing that before us. Does anyone have any comments on the issue of therapeutic infiltrations? Dr. Eggli?

DR. EGGLI: As a person that does some of

these things, I have mixed feelings about how it ought to be handled. We certainly - the vascular access we obtain for a therapeutic administration gets a whole different level of scrutiny than the vascular access we obtain for a diagnostic administration.

I will not push a radioactive treatment dose forward if I cannot draw blood back from the line. Now, that doesn't give you 100 percent assurance depending on how you catheterize the vein. A stainless steel needle can give you a blood return, but you have to tip the needle out. But however we almost never used butterflies anymore for treatment, and we use plastic catheters which are far less likely to produce a blood return with a partial extravazation.

So our efforts at making sure we really have a good line before we push a therapeutic agent into a vein is a whole different level of assurance when we administer a diagnostic pharmaceutical for the very reason that you mention here, that the potential tissue consequences are very different.

CHAIRMAN MALMUD: Anyone else wish to comment? Debbie?

MS. GILLEY: Cindy, your example was for fluorine 18. You were able to give tissue dose enough

to meet the requirements of a medical of 50 Rem?

MS. FLANNERY: Yes, there was an evaluation done by a licensee, and we also did the evaluation internally, and that potential was there, that the 50 Rad limit could be exceeded.

MS. GILLEY: However you are really requesting for therapeutic application, because fluorine-18 is a diagnostic -

MS. FLANNERY: Right. And as far as the December 18th, discussion, ACMUI did give a recommendation for NRC to keep its current position and to not require reporting of infiltrations of diagnostic administrations as medical events even if that 50 rad was exceeded.

We think the question that is really on the table right now for ACMUI is applicability to therapeutic administrations. So if ACMUI had a recommendation on whether that should be considered for infiltrations of therapeutics.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: We have had in injection of therapeutic, liquid radioisotope, for many many years, even when I started my residency, even in the `70s we were injecting things. So injection of therapeutic is not new. My feeling is that that we need to restate

our previous position in the December 18th 2008 meeting that accepted that it would not be considered a medical event. We always take the best precaution we can, as Dr. Eggli had stated. But the 50 centigrade really it is very difficult to apply, because it depends on the volume that you are considering. If you take a very small segment of the stint. That portion will get 50 centigrade even if you exhibit a very small amount of radioactivity. The 50 centigrade, in almost every circumstance, it will be exceeded depending on what volume you are considering at 50 centigrade.

CHAIRMAN MALMUD: Dr. Vetter.

VICE CHAIRMAN VETTER: Yes, that gets to something I was thinking too: how would you define infiltration in this sense, and how would a technologist recognize that infiltration had occurred?

CHAIRMAN MALMUD: That's part of the question we are being asked. Dr. Eggli?

DR. EGGLI: I think there is a partial position that might be reasonable, which is, if a therapeutic extravazation results in clinically obvious tissue damage, then maybe it becomes a medical event, that first of all if there was no extravazation there wouldn't have been local tissue damage. And if

there wasn't tissue damage it's probably not of real interest. So whether the possibilities would be to consider the criteria of tissue damage resulting.

This is one of the things that we actually worry about very often in diagnostic radiology but we extravagate nonradioactive iodinated contrast materials there is actually probably a greater risk of tissue damage in that arena than anything we are going to do therapeutically, certainly by volume of cases.

But if you wanted to track something I certainly would track anything that fell short of actually producing tissue injury.

CHAIRMAN MALMUD: I have a question. Has the - has anyone reported to the NRC an incident of tissue damage from a therapeutic injection of a radiopharmaceutical?

MS. FLANNERY: Not that I am aware of. However there was a very recent report that was made of an infiltration of iodine-125 monoclone antibodies. The patient support was not located properly, and so that is an example of I think an infusion that still an infiltration had occurred.

In this case there was an estimated skin dose of 360 to 710 rads, but there were no adverse effects seen at the injection site.

CHAIRMAN MALMUD: No visual evidence of tissue damage was reported. Thank you.

Someone? Steve?

MR. MATTMULLER: I guess I would like to add on to Dr. Eggli's remark. I guess the first question that comes to mind, how would you know? Because after most therapeutic infusions, we don't scan. So unless there is obvious tissue damage afterwards we would never know.

CHAIRMAN MALMUD: It may become an issue in the future. I'm old enough to remember the earliest days of chemotherapy when the infiltration of a chemotherapeutic agent intravenously, nonradioactive, would result in tissue damage. And at that time the hospital that I was training in hired a nurse whose sole responsibility was the injection - preparation and injection of the chemotherapeutic agents so that they wouldn't be in the hands of everyone else who was doing IVs. But I'm not aware of anything that has occurred as yet with a radiopharmaceutical.

Dr. Howe?

DR. HOWE: I don't have an example of that, but just to answer an earlier question, and that would be, if we were to go in this direction, what

kind of criteria would we use? We don't use the word, diagnostic, and therapeutic, very often. And so I would think we would make the distinction between written directive and non-written directive.

That would eliminate the 30 microcuries of I-131, because that is oral. And we are talking about something that is being injected.

So you would be in essentially for all practical purposes your therapeutic administrations. And then if as Dr. Eggli said you wanted to go to obvious tissue damage then that limits the number further to effects. And to answer your question about the future, as we get into more beta pharmaceuticals we have a higher potential.

CHAIRMAN MALMUD: Yes. Dr. Welsh.

DR. WELSH: So I would say I like Dr. Eggli's comment because if we need to do anything at all. Because if we want to say that we are going to go with the dose, more than 50 centigrade and 50 rem, first of all how do you verify the dose? And secondly, as Dr. Nag pointed out, there are area and volume concerns here, so that a small microscopic area might get 50 Rem. Other square centimeters might get less than that.

So it becomes a very tricky analysis.

Therefore if we are going to do anything at all I would favor what Dr. Eggli said, that the important point is if there is any tissue damage, that's the important criteria.

CHAIRMAN MALMUD: Dr. Nag.

DR. NAG: If you go by tissue damage, the tissue damage can be called both by the extravazation of the radioactive material or by the saline or whatever material that you are giving before or afterwards. And it becomes difficult to say that this was - number one it becomes difficult to say what caused the damage; and number two, the damage sometimes is caused way later, so you have to come back and find it late in the day.

CHAIRMAN MALMUD: Dr. Eggli.

DR. EGGLI: I'm not aware of any case of saline extravazation causing tissue damage. As a matter of fact, when you can't get an IV administration of saline to a vastly dehydrated patient interstitially is an accepted practice. So again I'm not aware of the vehicle for a radioactive treatment having the capability of being responsible for tissue damage.

CHAIRMAN MALMUD: I think you are correct with regard to the saline. You perhaps, Dr. Nag,

meant the pharmaceutical itself rather than the radioactive component of it causing the irritation and the tissue damage.

Dr. Howe pointed out an interesting element, and that is that the way we might describe this is with a written directive rather than therapeutic dose. The question is, should this be just reported as a non-event but at least reported for recordkeeping. Or is this something that really is already handled with regard to the individual institution or lab or office that injected the pharmaceutical, radiopharmaceutical, having to deal with sequellae of a local reaction? Which is what can happen on a regular basis in other situations. These things occur without radioactivity in the hospital, and the patients are certainly quite eloquent in pointing out the pain or the irritation that has occurred, and the hospital does have to deal with these issues directly. I'm not sure I have an answer.

Ralph.

MR. LIETO: If we have then reported, then what are you going to do with the data? I mean are you going to - I mean in terms of like a remedial action or a root cause, I mean I'm really at a loss as to you are reporting this data, but what are you going

to do with it if you have them report this? And I think you are looking at such an extremely unusual occurrence. If this was happening more often, I would have thought we would hear about this as occurring with licensees. Which I have a question, the report that you have with the monoclonal antibodies, was this something that was in the literature? Was this something just reported to a region? Or -

MS. FLANNERY: It happened in an Agreement State, like it was just reported two weeks ago.

MR. LIETO: Okay, so this was like an event report?

CHAIRMAN MALMUD: It may be that we should - oh, go ahead.

MR. LIETO: Because you know a question regarding the dose, which I think either Dr. Vetter or someone talked about, is the methodology that they are using to calculate these doses I think needs to be reviewed, because looking at the - with the fluorine-18 I mean it's kind of like, okay, you pick the size, and then this is the dose that you will get. And then they range from above reporting to below reporting.

So I think if we are going to do some type of dose assessment on this, I think there needs to be

standardization on the dosimetry and how we are going to calculate this.

CHAIRMAN MALMUD: And certainly part of the issue will be separating the reaction to the radioactivity versus the reaction to the pharmaceutical. And we don't have any database or expertise for handling that. Also, the issue hasn't occurred yet, so we are talking about a theoretical issue at the moment.

Dr. Suleiman and then Dr. Nag I think.

DR. SULEIMAN: Something like this should be reported to FDA under their adverse event or severe adverse event reporting system. If it's a pharmaceutical that causes some severe problems, it would get - it should get reported. It could be that there is misinformation on the labeling in terms of how it's used. It could be the medical device through which it is being administered.

So there are also - the nonradioactive risk components of the whole process. So there are mechanisms to get this reported. So if we see a trend with a specific drug, or if we see a trend with a specific medical device we will take action.

CHAIRMAN MALMUD: Then we will hope that Dr. Suleiman's agency will inform us at the

appropriate time if necessary.

Dr. Nag.

DR. NAG: I would highly support Dr. Suleiman's suggestion that this is already being reported as an adverse event. However the first thing before us is, should NRC consider it as a medical event. Now if we consider this as a medical event, if we go through all the procedures and identify whatever-3 or 4 or 5-- the patient will have to be informed; the physician have to be informed, blah blah blah, and the - you have to go into all the reporting mechanisms. And therefore I am thoroughly against this being reported as a medical event.

CHAIRMAN MALMUD: Would you make a motion that this not be reported as a medical event at the current time?

DR. NAG: Yes.

CHAIRMAN MALMUD: Second to your motion? Dr. Welsh seconds the motion.

Is there any further discussion of this motion? Dr. Eggli?

DR. EGGLI: Just one residual comment. If I were to use residual damage, I would put permanent in front of it. And I'll tell you what, the patient already knows. So there are no reporting

issues.

But that doesn't mean I disagree with the motion that Subir is making.

CHAIRMAN MALMUD: You wish to amend the motion to have the word, permanent -

DR. EGGLI: Well, no, right now Subir's motion is that therapeutic infiltrations not be considered medical events. But regardless if there is permanent tissue damage, the patient knows; the referring doctor knows; and everybody knows.

CHAIRMAN MALMUD: And it would go through the FDA probably.

So the motion is not amended. It has been seconded. Any further discussion of the motion? Yes.

DR. FISHER: Just a quick question. It may not be a medical event. Is it still a misadministration in your view?

DR. NAG: The word, medical event, has replaced mis-administration. So mis-administration and medical event are now synonymous. We don't use the word, mis-administration, anymore.

DR. FISHER: That's why I asked the question, because does the intended radiopharmaceutical provide any benefit to the patient? Was there enough material that - I mean

maybe you had skin damage at the point of injection. Did the patient still receive the intended benefit of the infusion? Or was it a mis-administration that resulted in the patient not receiving the desired treatment?

DR. NAG: There is a technical definition of medical event, and it is very specific. For example in a permanent implant you administer the required number of millicuries. It went to the proper place, but then migrated to other areas. That is not called a medical event. It is not what we intended, but that is not a medical event.

I think this is something very similar.

CHAIRMAN MALMUD: Excuse me, Dr. Nag, what Dr. Fisher is saying, if I may interpret it, is that if you intended - if the intention was to administer 10 millicuries, but 8 millicuries infiltrated at the injection site, and the patient only was able to get two millicuries intravenously to the target organ, since he only got 20 percent of the administered dose was that - isn't that a medical event? That's what Dr. Fisher meant by his question if I interpreted his question correctly. Then Dr. Eggli, you had a comment.

DR. EGGLI: I think in response to

Darrell on this, the answer is by the definition of medical event, yes, it's a medical event. However this particular medical event is specifically exempted from being defined as a medical event. If that sounds circular, but this occurrence would meet the medical event criteria, but it is specifically exempted from consideration as a medical event.

CHAIRMAN MALMUD: What exempts if from consideration?

DR. EGGLI: Infiltration. It is specifically exempted from being defined - by definition the medical event, the infiltration is exempted from being classified as a medical event.

MS. FLANNERY: That is correct. Based on the statement and the supplementary information.

CHAIRMAN MALMUD: Thank you.

Mr. Lieto?

MR. LIETO: I'm going to be maybe on thin ice by disagreeing with Dr. Eggli, but I would not consider it a medical event. Because not based on the exemption; it's because the written directive was to administer 10 millicuries. They administered 10 millicuries. The written directive isn't a 10 millicuries - that so many millicuries goes to a certain organ, so forth and so on. So if they

administer 10 millicuries -

DR. EGGLI: I have to disagree -

CHAIRMAN MALMUD: You are both agreeing though that it is not a medical event.

DR. EGGLI: But I have to disagree with Ralph because part of the written directive specifies route of administration.

CHAIRMAN MALMUD: And Flannery has explained the reg, and the reg speaks for itself; so we will live with the reg as it is. And it still is in line with the motion on the floor.

Have we voted on the motion?

DR. NAG: Not yet.

CHAIRMAN MALMUD: No. May we vote on the motion? Want to call the motion?

All in favor?

(Show of hands.)

CHAIRMAN MALMUD: Any opposed?

(Show of hands.)

CHAIRMAN MALMUD: Any abstentions?

(Show of hands.)

CHAIRMAN MALMUD: One abstention - oh excuse me, two abstentions. So the motion passes. Thank you.

MS. FLANNERY: All right, thank you very

much.

CHAIRMAN MALMUD: Thank you.

We will now move ahead, and the next item is the summary of the enforcement process and enforcement actions against medical licensees.

MS. COCKERHAM: Dr. Malmud, can I suggest that we take a break, and then we will resume with the outgoing member presentations?

CHAIRMAN MALMUD: Yes, we will. We will follow your suggestion. Thank you.

(Whereupon, the above-entitled matter went off the record at 2:36 p.m. and resumed at 2:49 p.m.)

CHAIRMAN MALMUD: Ashley.

MS. COCKERHAM: We can go straight into outgoing member presentations, if Dr. Nag wants to start, and then Mr. Lieto, followed by Dr. Vetter.

CHAIRMAN MALMUD: All right, thank you. We now invite our outgoing members to give a presentation, if they wish, beginning with Dr. Nag.

DR. NAG: I am not going to make any formal presentations. I know everybody is waiting to -- would like to finish this off very quickly. But I would really like to thank and appreciate all the NRC officials, all the current as well as the past ACMUI

members whom I have had the honor and privilege of working with.

I don't know how much I have contributed to the ACMUI or NRC, but I can tell you that I have learned a lot from my experience in the last nine years. I have learned how the process works, how the government works. I have learned how to say my contribution and also learned when to shut up and not talk.

I have seen over the last nine years that there has been quite a bit of change in the NRC over these years. Specifically, what I have seen is that the NRC has become more willing to listen to the ACMUI, and that that has been increased or heightened by having recommendations that have been made into formal motions and that have been written into formal motions, into action items and not only into action items but there has been a close follow-up in the subsequent meeting to make sure that the action items have been worked upon.

That, I think, has been a major change in the NRC from the time that I first started.

Another point I might want to make comment is that in the Federal Register there was a notification for a radiation oncologist physician to

fill up my position, and specifically it stated that person must have gamma knife experience.

I heartily agree that the person who is going to fill my position should have both gamma knife and brachytherapy experience. It is highly imperative that this new person have brachytherapy experience as well.

So the ideal situation would be someone with both brachytherapy and gamma knife. However, if you do not find someone with both brachytherapy and gamma knife experience, I would highly recommend that the person have at least a broad brachytherapy experience, the reason being as follows.

Brachytherapy is not a narrow subject. It is a very broad subject, including HTR, including low dose removable brachytherapy, low dose rate permanent brachytherapy and many of the new emerging modalities, and this cannot always be fulfilled by one person. So you would need a second person to help along with that.

Secondly, a gamma knife usually -- not always, but usually is done by someone with basically external beam experience and someone who is specialized in brain tumors.

So it is very difficult to find someone

with that kind of specialized experience to have also a brachytherapy -- a broad brachytherapy experience.

Looking at the number of medical events and the number of concerns that have been brought before the ACMUI over the last nine years, a vast majority of that has been problems or incidents with the brachytherapy component, very small number with the gamma knife component and, if it does come up, I submit you can very easily get a consultant to advise you on that specific problem or that specific issue.

So I think this would sum up my observation over the years, and again I wish to conclude by thanking all the members of the ACMUI and the members of NRC, obviously, who are here for the very great learning experience that I have had in my tenure in the ACMUI.

CHAIRMAN MALMUD: Thank you, Dr. Nag. I can assure you, having been a member of the Committee for the last number of years, that you have contributed considerably to the Committee, both in the subcommittee work that you have done and, very importantly as well, in looking over the fine details of some of the motions that have been made and making recommendations for refining them in order to avoid unintended consequences.

So the entire Committee and, certainly, the NRC is equally appreciative of your efforts. You have not been here without contributing. I can assure you of that.

The next individual is Mr. Lieto.

MR. LIETO: I guess it is me. As I thought about attempting to put my experiences on the ACMUI into some thoughtful and unbiased perspective, I figured that such an attempt probably requires a wisdom I don't possess and is better possessed by my learned ACMUI colleagues, both past and present.

As I was preparing this presentation, I was reflecting on my past years in the ACMUI and some of the accomplishments which far exceed any disappointments, as well as some of the compromises that have occurred. But I figured, since Ashley insisted that this be brief, these things probably are better addressed by a reflection of the minutes and summaries that already exist.

Being a fan of old movies, I remember when I first started on the ACMUI the first year at least was somewhat -- I was really, I have to say, naive, and I think a lot of members might have the same impression, and I was totally in a reactive state to what was going on.

There was no advance preparation for coming into this, and I think the current process has been so far improved for incoming members from when I first started that you are kind of almost like a deer in the headlights for your first year or so. But I would not -- I would be remiss in not expressing my appreciation to those that assisted me, both past NRC staff and past colleagues, on the NRC workings at the time.

I would also like to express my appreciation to my outgoing colleagues who also assisted me, but especially Tom Essig from NRC staff, but also past members like Nicky Hobson, especially Sally Schwartz and Jeff Williamson who was a very, very quiet influence on all of us.

I guess I would also be foolish to expect that anyone who comes into this role possesses all the information and expertise to adequately support what they need to do.

I think one of the things that I have learned in representing the nuclear medicine/physics area of expertise in my role is that I have always been a firm believer in the words that Woodrow Wilson quoted -- in this Woodrow Wilson quote, which is "I not only use all the brains I have, but all that I can

borrow."

I think we need to gain that expertise from other parties, but we need to be careful not to develop a partisan perspective in this role, and I think we need to maintain a process that what is in the best interest of the patients and what is also in the best interest of the practice of radiation medicine.

I guess I was asked to provide some words of wisdom. Again, you guys are going to look out, because they really don't exist. But I thought there might be some areas that are opportunities for improvement, which are in areas that, I think -- there is a term that management likes to use, but maybe this might better be expressed as challenges for the present or future.

One of the things, I think, that we all recognize is that medical technology is developing far faster than the regulations can stay abreast. Licensees and, I think, especially the NRC, want to avoid major rulemaking, which takes years to do.

Now whether these opportunities or suggestions that I am going to briefly describe occur in rulemaking or guidance based, I think that will be determined by what are the best by applying sound

scientific principles and performance based approach to problems and using a team approach.

I think the first thing that I wanted to mention was the training and experience or board certification. This Part 35 revision has been in some phase of development or revision for almost 15 years, from what I can tell, and it still has problems.

This has, I think, been maybe a major disappointment during my stay on the ACMUI. I think it went from a straightforward, workable process and has just been an ongoing quagmire that has expended a tremendous amount of not just only NRC staff resources but also the affected parties involved, and we still have the board certification process somewhat marginalized.

So I think it is an area that we still need to address and, hopefully, can resolve and improve. Maybe what we need to do is look at a whole different paradigm as to the training and experience and what that needs to be established in the regulations.

I also wanted to say a comment about NRC support for the ACMUI. The agenda, the ongoing items, the subcommittee activities far exceed anything that existed when I started, and I want to say that I know

that NRC employment, looking at some of your staffs, has increased over about 20 percent in the last three years, but there really has not been anything to address the increased needs for the medical use activities supporting this committee.

I think when I was looking at the NRC website, I think there is about 20-plus FTEs that support the Advisory Committee for the Reactor Waste Group, but there is about .6 assigned to the ACMUI, and I think this inequity needs to be addressed.

I would like to personally recognize those two ladies over there, Ashley and Cindy, for all they have done. There have been some improvements since my arrival here, but what these guys have achieved has been super, and I think that there are some times, especially with all the phone calls I make to Ashley and e-mails and so forth, there's got to be three people there that are answering all that stuff. I think she does a tremendous amount in supporting and what she accomplishes for the ACMUI, and for the assistance I want to say thank you.

The one thing, I think -- Another thing that we need to be aware of in the future is the patient release rule. This is still under attack. The Part 35 patient release -- or excuse me, the

Section 3575 that provides this -- I don't know if many of you know this or realize this, but recently Mr. Peter Crane filed an appeal in Federal Appeals Court, a move to rescind this patient release rule again.

Maybe he thinks what is going on is well intentioned, but I most definitely think it is wrong-headed, and I think that I would like to emphasize that it is critical for the ACMUI to continue its support of NRC staff in the denial of this petition, because I think it is not in the best interest of patients, and I think the ACMUI, if needed, should also encourage the medical community to provide assistance to the NRC, if that is what is needed.

The other area that -- items or, I guess, opportunities or challenges to be, I think, addressed in the future is the National Source Tracking System.

Currently, this only affects Category 3 and Category 4 sources. While I can understand the need for it in that range, I think its implementation to date has been very expensive. It is still fraught with some problems in its implementation, and still, I think, it needs added input from affected licensees. But my concern is mostly of this is extended into the category 3 and 4 sources which will affect a large

number of medical shipments.

I think it has the potential of being extremely burdensome in requiring resources that far exceed any benefits for tracking into that range.

The other item I wanted to bring up was ICRP-2005 recommendations. But I think we have already seen, as discussed earlier in our presentation, and I think we know where those areas of concern may be problematic. I will kind of leave that there.

The last item was something that, I think, is going to be of increasing concern and needs to be brought up before this committee, is that as health care is rapidly moving into an electronic records situation where, in fact, some medical centers already have announced that they are paperless, there is a current need to establish, I think, acceptable guidance for electronic signatures for required NRC documents.

I would suggest that this be done initially in guidance base, because it is going to involve, I think, rapidly evolving technologies, but having an electronic signature standard is going to be critical to NRC inspection and enforcement teams as they go out in doing their activities with licensees,

and I think there needs to be a standard to determine what is acceptable as they perform these licensee inspections.

Leaving the ACMUI is bittersweet. This is a group photo of ACMUI when I started, and I want to say that I have enjoyed participating with every single person on this committee, both past and present.

I think the interactions have been professional and collegial and productive. Even though NRC staff may also find this hard to believe, I have enjoyed working with all of these people, and -- I was trying to say this with a straight face, but I really do. There's been differences and disagreements, but I think it was all done in the best interests of the patients and trying to minimize any burdensome nature of regulations.

I firmly believe in the value and necessity of the Committee, and to both the NRC and licensees, and have the best wishes to all present and future members in achieving success over past disappointments as well as future challenges to be addressed.

So with that, I want to say thank you, and arrivederci.

CHAIRMAN MALMUD: Thank you, Ralph. I will tell you that the feelings are mutual. We have all enjoyed working with you, and your accomplishments are also numerous in terms of the subcommittees that you have served on.

You know, it is easy to be Chairman. It is very difficult to be a chief of a subcommittee, because the subcommittees really do the work. So I am very appreciative of the work that each of you has done in your subcommittee work.

We have enjoyed working with you very much, and you have been a major contributor as well.

Now we will move on to Dick Vetter. Dr. Vetter.

VICE CHAIRMAN VETTER: Thank you very much. I would like to add my thanks to my colleagues' for the opportunity to work with this committee.

One of the things that I have been most impressed with is the intelligence seated around this table, from all walks of medicine and from the leadership at NRC. It has really been a pleasure to work with all of you and, like Ralph said, I think most times it has been collegial, but there have been some challenges for us now and then.

If we can measure success as Booker T.

Washington suggested, it is to be measured not so much by the position that one has reached in life but by the obstacles which he has overcome while trying to succeed, we have been a very successful committee in the past nine years while I have been working on the Committee.

We have faced many, many issues which are obstacles, and we have worked through them. The NRC has had its perspective. We have had ours, but we have, in fact, overcome them.

The obstacles that surprised me the most when I became a member of this Committee were those of personalities and how some people expressed themselves, some behavior and parochialism. In fact, that really surprised me, how some people acted out, and I think really were rather vocal on how they addressed members of the NRC. I was a little bit embarrassed at times by that.

On the other hand, we did work through it. I certainly don't question their motives, their values, etcetera, but there times when I was a little bit surprised how certain members of this Committee conducted themselves when interacting with the NRC staff.

Perhaps some of that is driven by --

conflicting may be too strong a word, but values that aren't exactly always the same or are perhaps directionally a little bit different, and that is the NRC's primary value here is to protect people and the environment. And as we sit around the table listening to all of us present our positions, our value, obviously, is the needs of the patient come first. In fact, if it weren't for patients, we wouldn't even be here.

So the needs of the patient come first. It is a strong value for all of us. And I know -- I don't mean to imply it is not a value for the NRC, but they come from a little bit different perspective. So of course, the challenge then is for us to work together in that regard.

In recent years, it is my experience that this Committee has become extremely collegial. I think we are working very well together. We are working very well with the NRC staff. I think part of that may have something to do with leadership on the part of the NRC and this committee.

Some of it has to do with the make-up of the membership of the Committee, but I personally think that we are now all looking at the same elephant, to where when I first joined the Committee,

I am not sure that was the case, but we certainly are now. So I would credit that to the excellent leadership and to the intelligence and collegiality associated with the membership.

So as we struggled together, as you struggle together going forward with these different values, I would say that the way we work through that is to focus on quality. Here is a quote from John Ruskin who says, "Quality is never an accident; it is always the result of intelligent effort."

So I would appeal to all of you to recognize that, in terms of trying to resolve any conflicts in values, recognize that the needs of the patient come first within a regulatory system that protects people and the environment.

I think we can work together. I don't -- Well, and we have been. I think it is just a matter of recognizing that.

New challenges, just briefly: From the medical side, for most of us sitting around the table, this is obvious. For some members of the public and for some NRC staff, it may not be so obvious.

Medicine is under a great deal of pressure to both increase quality and reduce costs. The cost reduction pressures are tremendous and, in fact, there

has to be a transition in medicine over the next several years as more and more people retire, become qualified for Medicare, and as reimbursements consequently go down for hospitals.

It is going to be a very, very significant issue. So we have to be -- While we want to improve quality, and we want to use our regulations appropriately to help drive quality, we have to be very careful about any unfunded mandates that increase the cost of medicine. It is simply going to be very difficult in this country to accommodate that.

I am not trying to make excuses, not trying to say we shouldn't do what is necessary to increase quality. We need to recognize that the cost is a very significant issue.

Then for all of us, of course, we want to do what we can to improve the health care safety culture, in spite of these cost reductions, the need to reduce costs.

So we are leaving. You will be -- You are left to continue on. We have had a few things to say, and we appreciate the opportunity to contribute; and as T.S. Eliot says, "For last year's words belong to last year's language, next year's words await another voice, and to make an end is to make a beginning."

So we are making an end, but it is also a beginning, as you know. A transition always has two sides to it. There will be some times when I will be your patient, and I hope, when I am your patient, that the needs of the patient come first. But I am also going to step out of this role as time goes on a little bit more, and I hope that the NRC does what it can to protect the environment, because I am going to be out there sampling that environment and spending as much time as I can.

Thank you once again for the tremendous opportunity to work with you.

CHAIRMAN MALMUD: Thank you, Dr. Vetter, and a personal thanks from me as well for being so supportive in serving as the Vice Chairman of this Committee, in addition to all the other roles that you have played.

Your voice has been one that I have always relied upon for your judgment and your knowledge. You also come from an institution which is able to provide health care in a most efficient way in terms of its costs per discharge compared to other hospitals of less fame but greater expense.

So having you with us has been an advantage, even in such issues as the cost of

fingerprinting, which you were able to provide to us in a way that no one else was in terms of the actual expenditure on behalf of an institution to meet a requirement for -- not so much for the NRC, but for the Homeland Security Department.

We will miss all three of you. It has been a wonderful experience for all of us to work with you. I agree -- Oh, there is a photo of you holding a fish. I didn't see that before.

VICE CHAIRMAN VETTER: That is why I want that environment protected.

CHAIRMAN MALMUD: You are going to make some of us jealous.

I think we agree that the number one reason that we are here is on behalf of the patient, and the NRC is driven by rules and regulations which govern it, sometimes without a full awareness of the impact on patient care. That is the reason that this Committee exists.

It is at the request of the NRC so that we may assist the NRC in being responsive to patient care issues as well as its major mission, and I appreciate that role on behalf of all of us to society via the NRC.

My father was an immigrant, and he said to

me that no one born in the United States could understand how wonderful it is here compared to elsewhere. Now he didn't come from Canada or another nation such as our own. He came from an oppressive environment in Europe.

As I have gotten older, I understand fully what he meant. I have served on more than one government committee, and it is astonishing how responsive our government is to the desires of its citizenry.

For that reason, it is a very inefficient government. Democracy is extraordinarily inefficient. It has to represent every opinion. It has to respond to every opinion, and we see that here.

We see all of us, everyone on this Committee, everyone in the NRC, having the same desire, which is to serve the public, and the bottom line for us is the patient, but we come at it with different viewpoints and sometimes different parochial interests, as you point out, and yet the overriding interest is always the welfare of the patient, the welfare of the individual.

We live in an extraordinary society. We are very fortunate to live at this time in this nation, and this is another example of it, and the NRC

is another example of a Federal agency that is reflective of the government that we enjoy.

So on behalf of the members of the Committee, and I know I speak for each one of us, we will miss you. We will miss the input from the three of you, and your legacy will not be buried with your departure. Your legacy goes on in all of the deliberations that have occurred, and will continue to occur as we continue to deal with some of the challenges before us.

So thank you very much.

Did you wish to say something?

MR. LEWIS: If I may.

CHAIRMAN MALMUD: By all means, Rob.

MR. LEWIS: Thank you very much, Mr. Chairman. The meeting started with Charlie Miller thanking you personally and also passing on Chairman Klein's thank you for a job well done and appreciation of your work, Mr. Leito and Dr. Vetter and Dr. Nag.

Anything I can add to that would kind of be silly at this point, but I can only add my personal thank you, and also I would like to associate myself with Dr. Malmud's comments that you show a lot of humility in your contributions, but they really are great through the work of the Committee.

Personally, it is very inspiring to me to work with people that put the welfare of others high on their list of things to do, and the ACMUI participation is just another form of that.

So in that regard, as I said, it is very inspiring to me and also to all my staff, and we have so many new people that it is very important that we have people that provide that inspiration for people on the NRC staff that are just entering their careers in this field. So thank you for that.

Also your contributions are directly relevant to the NRC's mission protecting health and safety. This I can't stress enough, because it is not an exaggeration. We cannot do our job without the advice we get from this Committee and the advice we got from the three of you over the years. So thank you for that.

You won't be replaced. I think it is -- There will be three new people, but I don't think that it is realistic for us to believe that the contributions that the three of you have made will be replaced by the next three. We hope it will, but we have to be realistic.

We ideally would have liked to bring on your replacements to this meeting, but we are a little

bit behind on that front. We are working on that. The one area that we immediately have to replace is the Vice Chair position. So I will say something about that in a moment.

Anyway, on behalf of the NRC staff, thank you very much, and we wish you the best, and congratulations.

(Applause.)

MR. LEWIS: Also, that was the only farewell speech in history that used the word lymphoscintigraphy. So we will remember that.

The Vice Chair position is a very important position, as you all know, and as this meeting closes, I would like to ask, and he has graciously accepted, Dr. Bruce Thomadsen to assume the duties of Vice Chair for the ACMUI. So thank you.

(Applause.)

DR. THOMADSEN: All I can say is I am going to not be able to fill Dr. Vetter's shoes or hip waders, as the case may be.

MR. LEWIS: Thank you very much. I let us continue with the agenda.

CHAIRMAN MALMUD: Ashley?

MS. COCKERHAM: I was just going to go to the next topic, if you are ready.

CHAIRMAN MALMUD: Please do, yes.

MS. COCKERHAM: We are just going to do the administrative closing. For members of the public that are ready to leave, if you will just grab a feedback form, fill it out, on your way out the door, I would appreciate it.

We are going to go over the seven, eight motions that were made during this meeting. Then we will choose the next meeting date.

Alright. We will start with Item Number 1: NRC staff should allow interventional radiologists to become authorized users for yttrium-90 microspheres with (1) 80 hours of training, which was summarized on Slide 4, and then I just read the title for Slide 4. So I will copy/paste that into the actual recommendation.

For number (2), training that includes the eight items on Slide 5. Again, I will copy/paste that into the recommendation -- and the operation of a quality management -- that is probably not worded correctly -- quality management for dose calibrators.

Obviously, we will have to work on the wording here, but I think we have the gist of what we want. Does anyone disagree or have questions about that? I know that one is written poorly right now.

Alright. For the last piece: Have completed three years of supervised clinical experience in diagnostic radiology and one year in interventional radiology.

Alright. We will move on to Item Number 2: NRC staff should revise 35.39-B(1)(ii)(g)(3) to read: "Parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its beta emission or low energy photon emission or AJE electron and/or -- and then I guess the regulation skips to 35390-B(1)(ii)(g)(4). That will be revised to read, "Parenteral administration requiring a written directive for any radionuclide that is being used primarily because of its alpha particle emission."

Go to Item 3: NRC staff should revise 10 CFR 35.490 and .690 as proposed, with one exception. Delete the words "private practice." So the regulation should read: "Five hundred hours of work experience under the supervision of an authorized user who meets the requirements in 35.490 or .690 or equivalent Agreement State requirements at a medical institution or clinic."

VICE CHAIRMAN VETTER: Excuse me. Didn't we -- I thought we had changed "private practice" to

"solo practice" or something of that sort. Did we just eliminate it?

DR. NAG: We just replaced with "clinic."

MS. COCKERHAM: Okay. That was discussed, but I don't think it made it into the formal recommendation. Okay?

Item Number 4: To prevent recurrence of events like those at the V.A., ACMUI recommends: (1) Every brachytherapy quality assurance program should include peer review as published by the American Brachytherapy Society; and (2) authorized users should perform post-implant dosimetry.

That item was tabled. So I am guessing we will get back to that at a teleconference.

Item 5: ACMUI will create a subcommittee that includes three members, and get back to Dr. Don Cool.

This is in response to the ICRP report. So you guys will get a subcommittee together.

CHAIRMAN MALMUD: I recommended a subcommittee.

MS. COCKERHAM: You have?

CHAIRMAN MALMUD: Yes. Dr. Thomadsen has agreed to chair it, and the other two members are Debbie Gilley and Dr. Van Decker.

MS. COCKERHAM: Okay. I will add that to this chart. And is Dr. Cool aware of that?

CHAIRMAN MALMUD: No, because the committee was drawn together after Dr. Cool left.

MS. COCKERHAM: Okay. So make sure he gets the memo.

Item Number 6: This is in regard to NCRP Report 160. For Part A: ACMUI came to a consensus on NCRP Report 160, which is believed to be scientifically sound and well written.

(b) ACMUI believes NRC and Agreement States should co-act and maintain dose records and keep ACMUI aware of the issues, but should continue a policy of not intervening with medical practice.

(c) ACMUI supports the medical principle of, first, do no harm, and expressed continued concern about exposure to children.

(4) or, I guess this should be (d): ACMUI's current believe is that the benefit of medical procedures involving radiation outweighs the risk.

Did we get the idea of what we wanted here? Okay.

Item Number 7: ACMUI endorsed the subcommittee report for candidates who may experience a delay between the completion of their training and

experience and receipt of their board certificate.

For Item 8: NRC staff should not require licensees to report therapeutic infiltrations as medical events.

Any questions? Okay.

The next thing I have are calendars for potential dates for the next meeting. I have gone ahead and crossed out all of the dates that the ACRS room is not available. So we will be back in the other meeting room.

I have also tried to look at society meetings, professional organizations, things like that that would be going on.

So do we want to go back to the Monday-Tuesday meeting schedule? I know those on the west coast prefer to travel on Sundays. Would we want to go with the 26th and 27th of October? Okay? The 19th and 20th?

DR. WELSH: I can't speak for everybody. So I encourage people to voice their opinion, but Thursday-Friday seems to work out far better for me as a practicing clinician.

MS. COCKERHAM: Okay. Is anyone opposed to Thursday-Friday? This is your committee meeting. So everyone please speak up. You are the ones that

have to fly to D.C.

Okay. So it looks like we have two Thursday-Fridays on the schedule. How about October 29th and 30th? Is there any preference to keep it at the end of October or in the middle? The 15th and 16th or the 29th and 30th?

DR. EGGLI: I will be away on the 15th and 16th.

MS. COCKERHAM: Okay. So 29th and 30th, do we have any conflicts? Wide open?

DR. WELSH: Astro might begin on November 1st.

MS. COCKERHAM: November 1st through 5th.

DR. WELSH: But there are committee meetings.

DR. NAG: A committee meeting for Astro starts on 21st of October. So it means that for people who go to Astro, they will have to fly from here straight to Chicago.

MS. COCKERHAM: I guess that affects you, Dr. Welsh. Oh, yes, that does affect travel for NRC. The way it does work, though, is that you purchase your own flight anyway. So you would be fine. Would anyone else be attending the Astro meetings? Dr. Thomadsen?

MS. FLANNERY: Ashley, maybe the new oncologist coming on.

MS. COCKERHAM: So we have two days in November, and they are a Monday-Tuesday preceded by a Federal holiday. I don't know if you can see November from here, but it has X all over it.

Debbie was suggesting November, and I had November originally on here, and by the time I got done with my X's, I had two dates left, and they are Monday and Tuesday, which are the 9th and 10th, which is followed by the 11th, which is Veterans Day.

DR. THOMADSEN: This year?

MS. COCKERHAM: This year.

CHAIRMAN MALMUD: The point was made that this year the 9th and 10th are followed by the 11th.

MS. COCKERHAM: Yes. My point was the 11th is a Federal holiday. I don't know who that impacts, but just so you are aware, and we are going back to Monday-Tuesday, if we do that.

CHAIRMAN MALMUD: Is there any objection to the 29th and 30th?

DR. THOMADSEN: No objection.

DR. FISHER: If that is a problem for anyone, the 26th and 27th are also --

MS. GILLEY: I can't be here.

MR. LEWIS: We can look into if there any options for traveling from here to Chicago. We can't guaranty anything, but we can look at the question.

MS. COCKERHAM: I know in Dr. Welsh's case it is possible, because the airport that he flies out of is very small and is very expensive. So he is able to purchase his own flights, which he already does. So he could easily purchase the flight that goes from home to D.C. to Chicago, back home for well under the government rate. But I don't know for the new radiation oncologist who comes on and for Dr. Thomadsen if that would be the same case.

DR. THOMADSEN: Actually, what I would probably do would be to take the bus to Chicago and then fly Chicago-D.C. back to Chicago and then take the bus home from there.

MS. COCKERHAM: It's going to get complicated.

DR. NAG: It is only one and a half hours. How long does it take, one and a half hours, two hours?

DR. THOMADSEN: About four hours.

MS. COCKERHAM: I don't think we can guaranty anything on travel. I think that may get complicated. The 15th and 16th does not work.

DR. WELSH: What about the 19th and 20th?

MS. COCKERHAM: Those dates are open, and those are fine.

CHAIRMAN MALMUD: Nineteenth and 20th? Anyone have a conflict?

MS. COCKERHAM: It is a Monday-Tuesday.

CHAIRMAN MALMUD: October.

MS. COCKERHAM: No conflicts? Alright. I am going to go with the 19th and 20th as our first dates. If we have to have back-up dates, we always choose those as well. I guess would they be the 29th and 30th? We don't want to get into a Tuesday-Wednesday or a Wednesday-Thursday meeting, do we? I am seeing noes. Okay, and the 15th-16th, which is a Thursday-Friday doesn't work.

CHAIRMAN MALMUD: So first preference is the 19th and 20th. Second preference is the 29th and 30th.

MS. COCKERHAM: Yes. Alright. That's all I have.

Closed session.

CHAIRMAN MALMUD: We will now go into a closed session.

(Whereupon, the foregoing matter continued in Closed Session at 3:37 p.m.)