NUCLEAR REGULATORY COMMISSION

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MEETING WITH THE

ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

(ACMUI)

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WEDNESDAY

APRIL 20, 2005

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The Commission met in open session, pursuant to notice, Commissioner Nils Diaz, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

NILS J. DIAZ	Chairman of the Commission
EDWARD McGAFFIGAN, JR.	Member of the Commission
JEFFREY S. MERRIFIELD	Member of the Commission
GREGORY B. JACZKO	Member of the Commission
PETER B. LYONS	Member of the Commission

(This transcript produced from electronic caption media and audio and video media provided by the Nuclear Regulatory Commission.)

STAFF AND PRESENTERS:

DR. DOUGLAS EGGLI

DR. LEON MALMUD

DR. JEFFERY WILLIAMSON

DR. RICHARD VETTER

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

CHAIRMAN DIAZ: Well, good afternoon, the Commission is very pleased to meet with ACMUI today. We do this I think once a year. So we're always looking forward to interacting with the Committee and being presented with your views about how our regulation of the medical isotope use by the community is ongoing.

We look forward to discussing the issues of the agenda. I'm sure that you realize that we have some schedule and that we're going to have to allow me and my fellow Commissioners time to question. So with that, I would ask my fellow Commissioners if there are any comments and if not, Dr. Malmud, proceed.

DR. MALMUD: Good afternoon, Chairman Diaz and Commissioners. I'm Dr. Leon Malmud, the current Chairperson of the NRC's Advisory Committee on the Medical Uses of Isotopes. We welcome this annual opportunity to meet with the Commission to inform you of some of the Committee's accomplishments.

Today we're going to highlight four areas where the Committee has provided or will provide training, will provide recommendations to the NRC staff. Three of these areas, the 10 CFR Part 35 Training and Experience Rule, the 20.05 ICRP recommendations and the dose reconstruction for the St. Joseph Mercy Hospital case represent efforts which were completed by the Committee during the last

year. The fourth area entails refining criteria for the definition of a medical event.

Most of what you will be hearing today on this fourth topic stems from the efforts of the Medical Events Subcommittee. We believe that although the efforts are not yet complete that sufficient progress has been made that such a briefing is in order.

Seated with me at the table today immediately to my left is Dr. Jeffrey Williamson, a therapy physicist and chairperson of the Medical Events Subcommittee and Dose Reconstruction Subcommittee. Dr. Williamson will lead the discussion on two topics, the medical events definition and the St. Joseph Mercy Hospital caregiver's exposure.

Dr. Douglas Eggli who is sitting immediately to my right is a nuclear medicine physician, a nuclear radiologist and will lead the discussion on Part 35 T&E Rule.

And two seats to my left is Dr. Richard Vetter, the Radiation Safety Officer, who will lead the discussion which summarizes the results of the review performed by ACMUI of the ICRP 20.05 recommendations. This review was completed at the request of the Advisory Committee on Nuclear Waste in order to support the one day topical meeting. If I may, therefore, I'll introduce our first speaker, Dr. Eggli.

DR. EGGLI: Mr. Chairman, Commissioners, thank you. Can I have the next slide please? As part of the revision of Part 35, the

ACMUI was asked to review the training and experience requirements for all classes of authorized individuals.

Next slide please. The goal of ACMUI's recommendations for training and experience requirements was to make the requirements for training and education commensurate with the risk. That is to develop a regulation --

COMMISSIONER MERRIFIELD: I think we need to go one more slide. You're now on slide three and goals.

DR. EGGLI: I am now on slide three.

COMMISSIONER MERRIFIELD: One more. The folks up in the booth, you need to go one more slide please.

DR. EGGLI: The regulation was to be risk-informed and performance-based rather than prescriptive.

Next slide please. The ACMUI established a Training and Education subcommittee. The initial discussions revolved around the elements of training to be included, who should provide the training and who could attest to the adequacy of that training.

Next slide please. The ACMUI felt that certifying boards should remain actively involved in the process. Additionally, an alternative pathway was recommended for individuals whose training experience did not lead to board certification.

Next slide please. The ACMUI recommended that training programs would be responsible for developing a curriculum that

would satisfy the broad educational and experience objectives required by the regulation.

Next slide please. ACMUI did not recommend a specific time allocation for individual curriculum components, instead recommended a content to be mastered as part of the concept of a performance-based regulation.

Next slide please. ACMUI felt that certifying boards would not be able to certify competence but would be able to attest to mastery of a requisite body of knowledge. Certification of confidence has medical legal ramifications that were unacceptable to most certification boards.

Next slide please. ACMUI recommended that the attestation be performed by the training director who is responsible for similar attestations of training experience to the certifying boards.

Next slide. However, NRC subsequently determined that the public interest would be best served by requiring that an authorized individual supply attestation from training experience.

Next slide. A proposed rule was published based on ACMUI recommendations for the performance-based regulation.

Next slide. Subsequent to that the Organization of Agreement States expressed concern over authorized user training and experience requirements for Subparts 200 and Subpart 300 uses. The concern hinged on specific didactic educational requirements, not the

total number of hours of training suggested by the rule and the rest of the discussion will hinge around these Subparts 200 and 300 training and education requirements.

ACMUI felt that it was appropriate that the total number of hours of training be reduced from 1,000 hours to the recommended 700 hours. However, the distribution of training hours represented a concern for ACMUI.

Next slide. The reason for that concern is the fact that most clinical nuclear medicine in the United States covered under Subparts 200 and 300 are performed by physicians trained and certified by the American Board of Radiology. That represents approximately 70 percent of the clinical volume within the United States.

Next slide. Because of competing demands for training time from new diagnostic modalities, radiology training programs are likely to tailor their training time to NRC requirements. Within diagnostic radiology, there are 11 content areas which must be mastered during the training program. Diagnostic radiology training program is already a five-year training program.

Next slide. American Board of Radiology has indicated that it intends to require all diagnostic radiology residents to be trained to Subpart 300 use certification. This means that Subpart 390, Training and Education Requirements, have to be the basis for radiology training. Radiology residencies will be required to train residents to the alternate

pathway requirements in large part because initially approximately 20 percent of radiology residents are not board certified in their first year of practice and subsequently become board certified. If we do not train to the alternate pathway requirements, these people will be unable to become authorized users during that time prior to their board certification.

Next slide. ACMUI felt that the 200 hours of didactic requirement was excessive and recommended 80 hours for Subpart 300 sub-uses. The recommendation was based on the input of ACMUI members who actually designed and delivered these educational training program.

Next slide. Since the total experience will be likely limited to 700 hours, practical and clinical experience time would be disproportionately reduced to accommodate for a 200 hour didactic training requirement and in the final regulation now, the term didactic is not used and it's substituted by classroom and laboratory training.

ACMUI was concerned about a potential adverse impact on the time allotment for clinical and practical training. Nuclear medicine training in diagnostic radiology is unique in that it emphasizes physiology rather than anatomy. None of the other anatomically-oriented content areas within diagnostic radiology reinforced this training. The other ten areas are anatomically rather than physiologically-oriented.

Next slide. The components of the classroom and the laboratory training are not well defined. This was in keeping with the

intent to make the rule performance-based rather than prescriptive. However, with a specific requirement for hours of classroom and didactic training, there is a relatively large requirement for training that training directors are now uncertain about what will be accepted as qualifying education.

Next slide. Training directors need to be certain that the programs they design will meet the intent of the regulation particularly because Agreement States although they have a high compliance requirement for the regulation itself can have significantly different implementations of the guidance and some of the explanation of what is considered laboratory training will be defined in guidance space rather than regulatory space.

Next slide. A discussion including NRC staff and involved stakeholders to better define acceptable classroom and laboratory components would be invaluable to program directors in their efforts to design training programs that will satisfy the intent of the regulation while yet providing adequate clinical experience. Thank you.

CHAIRMAN DIAZ: Thank you. We will continue and then we'll ask questions all at the end.

DR. MALMUD: Thank you, Mr. Chairman. The next presentation will be by Dr. Vetter. We changed the order. The medical event definition by Dr. Williamson.

DR. WILLIAMSON: Okay. Well, thank you. May I have slide 2 of my presentation. Let me describe the subcommittee charge. It was charged with evaluating the appropriateness and justification for the 20 percent threshold in the current medical event rule; secondly, how to best communicate risk associated with medical events; and thirdly, development of basically recommendations to make the rule workable in permanent interstitial brachytherapy with emphasis on prostate implants.

Why that is so important as you will see from our presentation, the difficulties with the current rule are exaggerated or appear with permanent implants and prostate brachytherapy with nearly 50,000 procedures a year is by far and away the most common form of permanent seed implantation and now the most frequency practiced indication for brachytherapy overall. So that is why so much of the talk focuses on that.

Slide 3 please. I'd like to acknowledge my fellow subcommittee members, Drs. Diamond and Nog, the radiation oncologists on ACMUI, Mr. Lieto and Dr. Zelac who has served as the staff liaison.

Slide 4. What I'd like to do is give you a little clinical background on the procedure to give you a feel for the complexity and difficulty of our task and why it is still in flux. I'll briefly sketch the main areas where we have achieved consensus and point out that many details yet are to be resolved, but I think we at least have the beginnings

of an approach we all agree on. I'll touch briefly on a few of the issues that are still under discussion.

Next slide, slide No. 5. Slide No. 5 is not a publicly available slide. What it is is showing you an artist's depiction and photograph of what image-guided source insertion looks like for prostate cancer. The basic idea is that a trans-rectal ultrasound probe is used to image the patient, dynamically image the prostate. Fixed rigidly to that probe is a large, thick template with a matrix, a rectangular matrix of holes that served to guide the needles bearing the seeds in a direction parallel to the probe.

The probe can be adjusted to control the depth, the penetration into the patient. If you look at slide six, you can see an ultrasound image that is illustrated there showing in the little white box how you can actually see a needle. Then the white dots on the image illustrate the different potential needle positions that exist.

Slide 7 please. This diagram illustrates the procedure flow for the most commonly used method for achieving prostate implant. So it consists of three parts. Two weeks before the procedure, the patient comes and a volume study is done. Basically a set of preliminary images with the ultrasound probe are taken. Then given the input from the physician, the contoured target organ, critical anatomy, the absorbed dose that the physician would like to give, preplanning is done and this is

used then to determine the source strength, the number of needles they are loading and so on. The seeds are ordered.

Then the patient comes. The same apparatus is used but this time for real and the arrows here indicate that it's an interactive procedure with the physician re-imaging and watching as the needles are inserted to make sure they can go into places as quickly as possible. So these are all based on ultrasounds.

The third stage is then post implant evaluation. In this setting which can be immediately after the procedure or as long as thirty days after, x-ray CT imaging is used to define the location where the seeds are and compute the final dose that the patient actually received. You might anticipate what the difficulty is here which is that it's basically doses from stage one have to be compared to post implant doses on stage three with very little control over how this is achieved.

Slide eight shows a preplan that is done based on volume imaging showing the very regular array of seeds in isodose curves.

Slide 9 please. So one problem that can occur is that during the procedure the patient anatomy can differ significantly from what was seen on preplan. Depending on the treatment of the patient, the prostate could have shrunk. The position may not be achieved exactly. As the physician inserts the needles, the prostate responds by becoming edimatious and swelling up, so it's of a different size. It also

moves when you put the needles in. So the bottom line is the authorized user must be free to adapt the preplan to the anatomy as he or she sees it at the time of the procedure.

Next slide please, number 10. This side is also not publicly available, but it shows a CT image and you can see that the seed positioning is much more irregular indicating that there is really somewhat limited control over exactly where you place the seeds. Based on this dose, post implant dose, this is considered to be the most definitive estimate of delivered dose and is the one that would be used as an endpoint in clinical trials. Published works by reputed practitioners in the field demonstrate that on average this dose can be eight to ten percent higher than the preplan dose with a standard deviation as high as 10 percent.

Slide 11 please. I won't go into the definition of current medical event except to note that it is generally applied in prostate brachytherapy to the preplan versus the post plan dose.

Slide 12 please. So is it justifiable? For temporary implants, the subcommittee felt that it was a reasonable regulatory action level so long as it is understood to be a surrogate for QA performance and not an indicator for patient harm. For patient harm occurring at this level would be highly dependent upon the dose, the proximity of critical structures, the type of disease and so forth. No general statement could

be made that 20 percent will or will not cause injury. But it's nonetheless a good endpoint for is the operation well run.

So generally, we felt for the reasons I have given that a dose-based medical event definition is not workable for permanent implants because of the limited control and the multi-stage nature of the procedure.

Slide 13 gives some of the reasons which I have already covered.

Another problem on Slide 14 is the wrong sight provision of the medical event definition. It basically says if more than 50 percent change in dose and 50 rem, that's a medical event. Because you cannot control the position of the seeds or the geometry of the target organ, it's probably almost in every prostate implant there is at least one voxel of tissue that may exceed those criteria.

So what is the essence of our proposals? Number 15 please. It's basically to define medical event in terms of where the sources are implanted rather than the dose delivered.

Essentially the idea would be, slide 16, to define a medical event as being one in which the implanted activity in the target volume differs by more than 20 percent. How exactly this would be worded is still under discussion and hasn't achieved consensus.

Slide 17. Another problem that we attempt to address is when the written directive is closed to revisions. As written now, basically

the authorized user can revise the written directive at any point up to and following the final post implant dosimetry and this has caused some abuse by certain authorized users who have used this as a loophole to evade regulatory compliance with the medical event definition.

So I think that there is full consensus that medical event written directive revisions should be allowed only for valid medical indications and there are several proposals we are entertaining how to do this, basically alternative definitions of written directive for prostate implants.

Slide 18, I won't go into that since I'm running out of time. I'll jump to Slide 19. We're still working on this as well, but our general consensus is that medical events should be treated as a QA performance surrogate and divorced as much as possible from patient harm.

Slide 20, the two implications that we have considered of this premise is that the medical event reporting criteria to the patient and relatives and so forth should be altered to make it less punitive.

And Slide 21, try to make the enforcement of medical event more consistent with industry practice. I've listed some of the principles here in order to make sure compliance with the reporting requirement is followed and that the simple reporting of an event is not seen as an invitation for punishment. Thank you, this concludes my presentation.

CHAIRMAN DIAZ: Thank you.

DR. MALMUD: Thank you, Dr. Williamson. The next presentation is by Dr. Vetter and it's on the review of the ICRP 2005 draft recommendations in support of the ACNW. Dr. Vetter.

DR. VETTER: Thank you. The International Commission on Radiological Protection makes recommendations on the safe use of radiation. These recommendations are considered in promulgating regulations in this country. Therefore, it's very important for us to keep up to data on what those recommendations are. We will just touch on a few of the issues that we have reviewed.

Slide 2 please. We will limit our comments to the items of greatest interest to the ACMUI and will not comment on others that have no bearing on our mission.

Next slide please. One of the elements of ICRP recommendations continues to be the use of the concept of justification. That is justification for radiation exposure. In the draft recommendations for 2005, ICRP indicates a justification of a practice lies more often with a profession than with government and justification for the application of procedures falls on practitioners. So for example, justification of a new modality falls primarily on the profession of medicine and justification of the application or use of the modality in the care of a patient would fall on the practitioner. The committee agrees with that discussion on justification.

Slide 4 please. ICRP has been using the concept of constraints for some time and in the 2005 recommendations, they go into some more detail on their use of constraints. Frankly, many of us find their discussion to be rather confusing. They apply constraints on both sides of the limit. That is below the limit and above the limit.

Basically, a constraint is a restriction on dose. ICRP considers that achieving constraints is obligatory for a -- it's an obligation of a radiation safety program and if constraints are exceeded, that the program has failed. Our committee considers the use of the word failure in this context to be a very negative message, in fact, could be counterproductive and think that we should be reserving the discussion of program failure to radiation limits not to constraints.

Slide 5 please. An example of a constraint is the use of a constraint or sublimit for a pregnant worker. ICRP recommends a constraint of one millisievert. In this country, we have a current limit of five millisieverts or 500 millirem for pregnant workers. That is to the abdomen of a pregnant worker and we consider that to be a safe level. In fact, that is a very small fraction of the threshold where we would see developmental effects and the risk of childhood cancer as a result of exposure to those levels during pregnancy would be negligible.

So we think the one millisievert constraint that ICRP uses is more appropriate for an ALARA program and may be a good goal for

some programs but we do not feel that it's appropriate to use it as a constraint.

Slide 6 please. If we look at some typical doses to medical personnel, they typically are tens of millisieverts in the cardiac lab and PET lab. And in the cardiac lab, constraining the dose, if you would, they want to use the word constraint, constraining the dose to less than five millisieverts is rather easy because the average energy of x-rays in the cardiac lab are low enough that wearing a lead apron will attenuate 97 percent of the scattered radiation from use of the x-ray in the cardiac lab.

When you move to PET however, we have much, much higher energies. It's 511 KEV annihilation radiation and personal protective equipment basically has no effect on attenuation of that radiation. So if we have tens of millisievert exposure to personnel in a PET lab, the abdominal exposure is also going to be approaching that and it would be very easy for exposures to the abdomen to exceed the five millisievert, that's the 500 millirem in this country. Steps have to be very deliberate in reducing those doses.

In general, nuclear medicine, it's not so much a problem because those exposures tend to be less than five millisieverts anyway. But we would emphasize that if the regulations were promulgated to reduce the limit to the abdomen in the PET lab, that would be very problematic.

Next slide please. Another use of constraint is in the public dose arena. ICRP does say that it is appropriate to allow exposures of a few millisievert to certain individual members of the public. In this case, the constraint is above the limit of one millisievert. But they're saying a constraint of few millisievert is appropriate in certain cases. However, we should not be rigid in the application of that constraint and should even allow it to go higher in certain circumstances. An example they use is a constraint of as much as 20 millisieverts for a parent of a child who has received radio iodine and receives considerable care.

The NRC limit of five millisievert to a member of the public from a radioactive patient has been working well. That is patients who have been released from hospitals has been working well and the NCRP in fact recommends five millisieverts for members of the public who are exposed to those patients and even recommends in some rare circumstances the limit should be as high as 50 millisievert if the caregiver has received appropriate training and is monitored.

Next slide please. In a general sense, ICRP applies public dose constraints to or constrains them to less than one millisievert and suggests that an appropriate level is 0.3 millisievert. The committee consider that application of that constraint to be problematic and extremely costly in particular in designing and constructing medical facilities. The NCRP uses a general, they don't call it constraint, a

general sublimit of 0.25 millisievert. However, they indicate that it's appropriate to design medical facilities so that the limit to a member of the public would be one millisievert, if it's designed per NCRP recommendations. Their methodology contains considerable conservatism.

The point the committee would like to make is that ALARA is working. The concept of ALARA is working in medical radiation safety programs and we think we should stick with that.

Next slide please. Just to underscore some more recommendations from the NCRP or these recommendations from the NCRP, they have recently published a physician statement in which they reiterate a limit of one millisievert to members of the public, indicate that that limit could be raised to five millisievert for caregivers of radiation therapy patients and they don't limit it to those released, it could be applied to those in the hospital as well. And in certain cases for care of a child or a very sick elderly parent or something that the limit should be raised to 50 millisieverts, once again, indicating that it would be appropriate to provide appropriate training for those individuals and to monitor those individuals.

Next slide please. Relative to worker doses, ICRP, as I mentioned earlier, has recommended that the pregnant worker, the effective limit for that worker is one millisievert because the limit to the abdomen or the fetus would be one millisievert. That risk is very low as I

mentioned earlier and that would be problematic for certain areas of medicine, in particular for the PET lab.

For workers, ICRP has reiterated a previous recommendation of 20 millisieverts for radiation workers. Again, we consider that problematic for some areas of the hospital, again, the PET lab being perhaps the most problematic. Even though average exposures to medical workers is less than 5 millisievert or 500 millirem, even though the average is less than that, there are individuals for instance in certain cardiac labs, certain PET labs, etc. whose exposures do push the limit and to drop that limit would be particularly problematic for those individuals. So we support the NRCP's recommendations and the current NRC annual limit of 50 millisieverts.

Final slide please. In conclusion, the ICRP has proposed use of constraints. We find those constraints to be very confusing and problematic and would lobby against the application of those in promulgating NRC regulations and we also find that the ICRP proposed occupational limits would be problematic for some modalities. Thank you very much.

DR. MALMUD: Thank you. Our next presentation is by Dr. Williamson again and this relates to the St. Joseph Mercy Hospital case as presented for historical purposes. Dr. Williamson.

DR. WILLIAMSON: Thank you. The second slide please. Now in contrast to the first presentation this is essentially a

completed work and has been responded to by the NRC staff. The charge was to review Region III's dose reconstruction in this incident; secondly, to review an alternate dose reconstruction methodology proposed by Drs. Siegel and Marcus on behalf of the Society of Nuclear Medicine; and thirdly, to make general recommendations to NRC regarding dose reconstruction.

Slide 3 please. I'd like to acknowledge the subcommittee members on this. This was again a technically complicated project.

Slide 4. I'll briefly review the chronology of the incident. Nearly 300 millicurie oral administration was given to a patient, I-131, who subsequently developed impaired kidney function. Despite the admonitions of the radiation safety licensee and warnings to use shielding and minimize time and so forth, the patient's daughter, a family member, allegedly spent six to 21 hours per day in close proximity to the patient for the course of the treatment. Region III's dose estimate was 15 rem. The Marcus-Siegel critique argued this was too conservative by factors ranging by anywhere from 1.6 to 17 depending on assumptions one made.

Slide 5 please. So what we did is we reviewed these calculations along with the Marcus-Siegel critique and performed our own reconstruction using Monte Carlo simulations to a limited extent. In addition, we interviewed the former RSO of the institution and interviewed

the Region III inspectors as well as reviewed documentation supplied to us by the licensee.

Slide 6. So our findings were that the 15 rem estimate was the most conservative estimate that seemed to us to be possible without being totally implausible. We did find that the general ideas and suggestions of the Marcus-Siegel critique had merit. For example, the idea of distance reconstruction when data is lacking regarding exactly where the patient was, using more sophisticated assumptions such as the patient is a volume source instead of a point source and trying to reconstruct overall decay times and distances seemed responsible. As a result, our reconstruction of the dose was somewhat smaller, 9 rem versus 15, under the most conservative scenario, than NRC's. We thought that idea had merit.

Slide 7. A major issue however turned out to be that actually the licensee disputed Region III's dwell time scenario basically claiming based on what seemed to us to be a fairly thorough and more contemporaneous investigation that actually 50 percent of the time the daughter was behind the shield. This would reduce the DDE further to, we estimate, four to six rem. One of our recommendations was that in future incidences the inspection report should acknowledge and reflect the alternative reconstruction of the licensee and give justification for dismissing it, which the report didn't do.

Slide 8. Siegel-Marcus critique, we agreed with many of their general suggestions about using more sophisticated tools in settings that I have mentioned. We also agreed with the concept of using the EDE rather than DDE, essentially average dose over the body core rather than maximum dose as a regulatory endpoint in such cases which in fact seems to be the NRC position as codified in its Regulatory Issue Summary 03-4. However, we found that Drs. Marcus's and Siegel's specific estimates were way off base numerically and that they used numerical approximations that were too simplistic such as inverse square law.

On Slide 9, there is a summary of the specific differences regarding distance reconstruction, EDE versus DDE and so forth. You can see there that despite the fact we have sympathy with their general position, the numbers we think were very different and within a factor of two of what the regions were.

Slide 10. So our general recommendations were that more sophisticated tools are indicated, first of all when doses are near the regulatory limit and some significant consequence hinges upon accuracy, which it didn't actually in this case, when the licensee disputes the dose reconstruction scenario by NRC or when the plausibility of the dose reconstruction assumptions are suspect and/or data is not available, both of which were the case here. Also when usual approximations are suspect.

Slide 11. So our recommendations were to the NRC staff, yes, encourage licensees in similar incidence to use the EDE which the ACMUI felt was much more likely to be correlated with both any injurious, non-stochastic injuries and epidemiological consequences of exposure than would DDE. For disputed dose reconstruction, use ranges and/or justify rejection of licensee scenario.

The third bullet is very important. The NRC should figure out some method of exempting caregivers from the 500 mR limit when warranted by humanistic and medical considerations and has great sympathy for the point of view expressed in Dr. Vetter's talk and also as I understand this has been acted upon. Our understanding from having read the response of the staff was is that they felt our position regarding dose reconstruction technically was not warranted and that there was so much uncertainty in this case that common sense reconstruction should be ignored in favor of the maximally conservation one that is barely plausible.

So we found that essentially we were in disagreement with the final staff determination on that point. Thank you. This concludes my presentation.

DR. MALMUD: Thank you. We're available for questions.

CHAIRMAN DIAZ: Thank you so very much, Drs. Malmud, Williamson, Vetter and Eggli. We appreciate your presentations

and the speed with which we just went all of those things. As you realize, the Commission always get these ahead of time. So we are prepared to the multi-speed and adapt as we can.

Let me just begin the questioning very quickly. On the area of Part 35, of course, we've been working on this for a long time. We just issued the rule. You made some additional comments on the potential for adjusting some of the training. Is this an issue that still needs to come back to the Commission or are your interactions with the staff clearing the issue? I just didn't know exactly where we were.

DR. MALMUD: The issue remains one of concern particularly today when most nuclear practitioners are trained as part of radiology training programs and the radiology residency now includes technologies that didn't exist 10 or 15 years ago, particularly MRI and CT. So that the board requirements for nuclear medicine training within a radiology residency are three months of the residency. Three months of the residency obviously is about 600 hours, all totaled. That's inclusive of all the clinical experience in reading the films.

The term didactic had been used to describe the 200 hour requirement of the 600 hours for the radiology residency and number 1, 200 hours of didactic classroom work is excessive and there isn't that much information to transmit of a classroom type. So the term didactic has been replaced with classroom and laboratory which does meet the feelings of most of the members of the committee but not all

because there remains concern that the definition of laboratory is not specific enough.

In our institution, I'm speaking now personally not as a member of the committee, laboratory means the clinical laboratory as well. When I say I'm in the clinical laboratory, I'm seeing patients either doing I-131 therapy or seeing patients we plan to treat with I-131 or doing scans including cardiac, nuclear medicine and general nuclear medicine.

If that is the definition that we will be held to, we have no problem. If the definition is a wet lab where we're doing experiments that are not directly related to patient care, then we feel, some of us feel, that we may be committing something intellectually dishonest if we affirm in a statement for residency training that the trainee has had 200 hours of classroom and laboratory work.

If the Commission feels that our definition of classroom and laboratory is acceptable, we would like that to be, we would be very happy with that ruling provided if that's the understanding because the program directors do not want to have to be mealy-mouthed in their definitions of words. They would rather be very straightforward and honest and say this is what our residents have all received.

Now why is this an important issue? Because as the presenter pointed out to you, most of our residents do achieve board certification but in the first year after finishing training, they are not yet

board certified. Therefore, they must meet the standards for those who are not board certified.

If that is the understanding and there's an agreement, everyone I think is reassured, minimum standards are met and we believe that the necessary information can be imparted, remembering also that all of our residency candidates in radiology have received many other hours of physics training which is all relevant to nuclear medicine because the physics of imaging is the physics of imaging.

CHAIRMAN DIAZ: Thank you. Let me go to the issue of events and the exemptions and so forth. I do happen to agree that ICRP sometimes gets a little bit confusing when they use the word "constraints" versus other type of more precise, I'll call it, either dose related or actually related to the effects that radiation has. Without getting into that because we could spend probably a day on that issue in here, let me just go to this issue of exempting caregivers which is an issue that we grappled with many years ago and Commissioner McGaffigan and I were at the forefront of changing the 100 millirem to 500 millirem.

You're saying that that really should be a major consideration. Up to what level? Up to the level of 50 millisieverts? Should there be a limit into how much an exemption is an exception? I think the Commission will have a serious time -- I will have a serious problem with just a blanket exemption. There has to be some limits, some assurance that a reasonable limit will not exceeded. Anybody?

DR. MALMUD: We agree with you and I would ask Dr. Vetter if he would apply to that. Do you feel comfortable with it?

DR. VETTER: Sure. We don't have a consensus. We haven't tried to receive a consensus on that, on a limit. But there is, I think it would be safe to say, a general feeling that among the committee members that we do need to do something beyond what we currently have. The current regulations do allow us to release patients based on the assumption and based on some calculations that a member of the public could receive up to five millisieverts.

For in certain cases and in particular a very medically ill patient who is hospitalized such as this case that Dr. Williamson just reviewed where, and in this case the patient died, family members want to spend time with that patient and in that particular case, the limit was one millisievert. We simply feel, the committee feels something has to be done about that. Now we have not tried to reach a consensus whether that should be 50 millisievert or exactly what that should be or how we should implement that.

CHAIRMAN DIAZ: Well, it certainly is an issue that we need to grapple with because of course, the occupational dose of 50 millisievert is very well established. The dose that we established of five millisievert was really almost a compromise saying there has to be something done so that caregivers can be close to their families.

But there is also a responsibility that the Commission has to make to ensure that licensees prevent, let's call it, almost unauthorized or not well supervised exposures that could result in significant health hazards. So I believe this is an issue that fundamentally we do care about and that we're very concerned with. With that, Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: Thank you, Mr. Chairman. I have commented over the years on that one subject that it God forbid, one of my children ever were in this circumstance you wouldn't keep me out of it. I would be like that lady that's in Mercy Hospital, but I hope I'm never in that circumstance.

I will tell folks, for any members of the public here that this is a place where we're trying to help people and I have received a lot of CT scans and a lot of PET scans and I even had 50 gray of radiation in my left axial last year to help prevent melanoma from coming back. So 50 gray is 5,000 rads. You guys can do the calculations, it was right here, as to what that is in rem but it's a lot and it's what we do to try to help people.

One thing that Dr. Eggli said was that he was concerned about different guidance on T&E and Dr. Malmud said the same thing. This is a Category B degree of compatibility. We have said that from the get-go, but you have said States might in the guidance level change that. I hope that doesn't occur.

I hope we can make a decision with regard to the issue that you raised as to what the words classroom and laboratory mean in a way that's really going to be binding because I don't want a doctor who's in Virginia or the District unable to practice in Maryland or visa versa or somebody who's in New York City not being able to practice in Connecticut and New Jersey or visa versa. This is an area where we need to have national standards. So if you have indications that in guidance space this could unravel, I urge you to call it to the staff and the staff could call it to our attention.

DR. EGGLI: If I might respond just briefly. I think the issue is that the Agreement States aren't required to adopt all of the guidance and that the definition of what's laboratory will be in guidance space rather than regulatory space. So there's a potential, sir. It's not to say that will it occur, but I worry about the same issue as you've just described.

COMMISSIONER McGAFFIGAN: Well, I call that to my fellow Commissioners' attention. I wish we had known enough to handle it. We did this massive rulemaking. We can't anticipate it. We can't anticipate everything. We really intended that there be, despite concerns from the Agreement States, that this be hard and fast and we didn't subject the doctor as I said earlier to those differences. How am I doing? Three minutes.

I would urge you. I think you're fairly unique in the world in your existence. I'm not sure that the French regulator or the British regulator has any thing like the Advisory Committee on the Medical Use of Isotopes and this may be something you do individually, but I would urge that you be very aggressive in conveying the medical community's points of view to the ICRP. I know there are doctors on ICRP but in that you make sure that people in other nations who practice medication as you do also are paying attention to ICRP because it will come up and potentially affect them.

That isn't really your job, but my fear is that although it's just a few doctors in the U.S. and actually it would be doctors everywhere and if it isn't doctors everywhere today, it will doctors everywhere ten years from now as some of these modalities get more broader use. So I hope, I have not memorized our comments to ICRP, they were quite voluminous, but I hope your perspective was reflected. I know the justification point was reflected, but I hope some of your points were reflected in the staff's comments to ICRP and it's an ongoing process. It is by no means over and whether we're going to adopt any of that stuff is an independent decision that we will make.

So I urge you to pay attention. I'm on for a full and open debate here. I will also point out to you something that I know is going to happen at some point this year, or I think it's going to happen at some point this year, OSHA is going to put out a request for information with

regard to occupational dose. Their occupational dose rules go back to ICRP 2 and the 1970s and have been amended to be consistent with Presidential guidance issued during President Reagan's Administration, I believe, in 1987. I think somewhere in the process this request for information going out, and again I would urge the medical community, I'm addressing the medical community through you, to pay attention to that request for information and to provide your perspective because it will be very important.

I will say that I'm sympathetic on the medical events, brachytherapy. Again, I wish we were -- we need to find a way to do some bite-sized rulemakings that aren't resource intensive because I warn you in the rulemaking area at the moment, security and all we have to do there is this tidal wave, a tsunami, and a magnitude 9 earthquake and having just done the medical rule to do the tweaks, it can't get complicated. It has to be bite-size and frankly, I'm not sure anything is bite-sized in medical especially because if it's meant to be binding, it involves consultation with the Agreement States in a process that typically lasts a long time. So I don't know whether I asked a question during that time period. I gave you some free advise.

CHAIRMAN DIAZ: No, but I did learn a lot.

DR. WILLIAMSON: If I could make a quick comment on that, it is really a difficult undertaking. You're asking for a simple decidable, well-defined rule that applies to a process or activity even

when done by the best expert in the country has a certain amount of variability to it.

COMMISSIONER McGAFFIGAN: No, I understand.

DR. WILLIAMSON: That's the difficulty.

COMMISSIONER McGAFFIGAN: And I wish -- up on Capitol Hill which four of us came from, if we heard this testimony, there would be a bite-size provision tucked in a bill somewhere and we would try to solve it. That doesn't seem to be our rulemaking process.

CHAIRMAN DIAZ: Commissioner Merrifield.

COMMISSIONER MERRIFIELD: Going through this relatively quickly on the issue of the T&E requirements and the concern about where the States are going, I think one always needs to be careful about anticipating what might happen when it hasn't already happened and I'd rather give the benefit of the doubt to the States. That having been said, I agree with Commissioner McGaffigan. I think the intent was to try to have a uniform set of requirements here which is why we went with the Option B. We'll just have to see how it plays out and respond if indeed it's necessary.

On the ICRP recommendations, I think I'd agree with fellow Commissioner that I appreciate the work you put into taking a look at that. I have some concerns about some of the wording and the methodology and I think you've raised some important questions and things for us to think about.

I reflect, last week, I was at the convention on Nuclear Safety which deals with principally reactor issues and we received questions from our counterparts internationally why we had not adopted various ICRP recommendations and the answer was we use ALARA and we get the same outcomes. We needn't change our regulations just for the sake of changing our regulations if from an outcome perspective we're where we ought to be.

Relative to the dose reconstruction at St. Joseph's, I recognize this was a complicated and a diplomatic course that all of you had to go through. Related to the specific issue of patient care and the caregiver, I agree with my fellow Commissioners. I would be open if there's some further thought on what the right number would be. I think when we agreed to try and increase that, I think it was with a shared concern about the need for the empathy of the individuals involved and I think we gave it our best shot recognizing our health and safety mission. But I for one certainly have a continuing open mind on that.

On the issue of brachytherapy, I will ask a couple of questions. I'm wondering given the recommendations you've laid out if we were to go down that road and I realize you're only part way down the road, but if we start going down that road, what kind of reduction would you anticipate in the number of medical events reported?

DR. WILLIAMSON: In some areas, they would increase because there was a series of potential medical events where large

number of seeds were placed outside of the prostate and that was by evaded basically backdating or updating the revisions some time after the procedure. So in that area, I think it would be tightened up and might create a few more.

I think in the area of wrong site medical events is kind of an unknown area. If you want my personal opinion, I think that it's perhaps because of the ambiguity and what's perceived to be the unenforceability of the rule that everybody's afraid to report marginal cases and the issue of how to, as I have been told by your staff, interpret that clause is not known.

But it would be interesting if somebody reported a case to you and said to you, "I overdosed one voxel of tissue by 51 percent because the seed was two millimeters off from the intended location." What would you do? The Office of General Counsel did come up with an interpretation of written directive revisions that is perceived as having created a loophole and the reason the loophole is there is because it's a dose-based criterion where there may be like a six to eight week period from beginning to end of the procedure before you have the final dosimetry and at the time you start planning it with a lot of variability. I know that's a hedging answer. I don't know how to quantify the level of event reporting, but I would hope that it would encourage people to report things more so you'd have a better profile of what's going on.

COMMISSIONER MERRIFIELD: Yes. I think that's a fair response. It may well be and I've been concerned before about whether we've got the game a little too high on some of these issues and where the right place ought to be. We have a requirement that we submit to Congress an annual report about abnormal occurrences. An element of that report clearly is the significant medical events based on dose.

Now part of your recommendation is that we perhaps move away from some of that and if we move away from using the dose criterion, ultimately what we have to figure out, and I think this is part of what you all are going to have to continue to focus on a little bit, is what are the criterion we're going to use to report to Congress that we have abnormal occurrences. I'd like to see a little bit more focus on that. I don't know if you have any preliminary comments.

DR. WILLIAMSON: I hesitate to speak for the subcommittee because we haven't actually considered what would be the impact on the abnormal event reporting criteria. We haven't really come to completely a final resolution on the concept of dose either or at least, I personally within the subcommittee, feel that dose is an important way physicians specify their clinical intent and there should be at least a limited role for that even in prostate implants though I completely agree with the subcommittee consensus that the way it's being interpreted now really does create, I think, some problems and confusion about what is a medical event and what is not.

CHAIRMAN DIAZ: The bottom line has to be some balance between the medical effectiveness of the procedure and the public health and safety considerations.

DR. MALMUD: You are, of course, absolutely correct. Perhaps we could summarize the problem so that you could understand what we're deliberating currently. One can define the dose as the amount of activity administered in the seeds or the dose calculated to the target organ. There are two different ways of doing that.

Secondly, the target organ, the prostate which is the example that we're using here, consider it to be a lemon, a lemon-sized organ, sitting within an orange around it in the pelvis measured by an ultrasound device which does not always differentiate the border of the lemon from the border of the orange. So what is the target? Is the target the prostate or is it the prostate and the soft tissue around it, ill-defined in some instances by the ultrasound. In some institutions the initial measurement is made with an ultrasound. In others it's made with a CT scan. In others it's made with a newer technology, MRI, which gives much better resolution and therefore, can define the prostate better and define the target organ to a degree that was not possible only a few years ago but which is not yet the national standard. So to apply new criteria to a technique not yet universally available would be a mistake.

So now we have a variation in the definition of the dose, meaning a variation in the target organ is it the prostate or is it the

prostate and the soft tissue around it, and then we have three different means of measuring it; ultrasound, CT, MRI and they are not identical imaging modalities. Furthermore, the actual measurement may be taken at three different times, certainly at the time of treatment, but also pre-treatment. If it's pre-treatment it's probably ultrasound measurement. If it's during treatment it may be the rectal ultrasound or the intra-rectal ultrasound or it may also be a CT that's obtained at that time.

And if it's after treatment, remember, the treatment itself alters the size of the organ, because there's swelling in response to the seeds being implanted. So now, the lemon itself is going to change size within the orange around it. Therefore, the delivery of the therapy depends upon the skill and experience of the therapist to a very large degree because this is a system of precise estimates. And therefore, to apply a 20 percent rule to it can get us into trouble and discourage the application of the therapy when it is absolutely clinically appropriate or to frighten a patient who has to be notified of a problem that wasn't a problem.

Now, are there problems and Commissioner -- Chairman, you point out very correctly that there are problems. What happens if in instilling 100 seeds 50 of them happen to line up in the bladder, cause a radiation burn to the bladder and a fistula to the rectum? That's a problem and that's what we're trying to deal with without constricting the physician's ability to treat the patient, to find a system of

reporting that's sensitive enough to catch the outliers and we're working on that.

CHAIRMAN DIAZ: And the bottom line is that same patient that you're trying to restrain the radiation to the prostate if the tumor is already encapsulated, you actually want to irradiate the orange.

COMMISSIONER McGAFFIGAN: The only point I was going to make that, you know, I'm always looking for bite-sized things and in nine years I haven't found one yet, but if this problem of interpretation which creates a loophole was propagated by OGC, then maybe it can be solved by OGC. And you may think it's a one-way sword and we're fixing the loophole and we're not fixing all this other stuff and I'd be happy if you guys could tell me how to draft that, but I would respectfully suggest if the staff is really in agreement that there's a problem with an OGC interpretive decision then maybe OGC can fix it.

DR. WILLIAMSON: I would like to clarify if I may, please, my point.

COMMISSIONER MERRIFIELD: I'm really glad that I asked this question by the way.

DR. WILLIAMSON: I don't think this is --

CHAIRMAN DIAZ: I am charging all of this to Commissioner Merrifield at the next Commission meeting.

DR. WILLIAMSON: I don't want this to be construed as a criticism of OGC I think there are some problems with the words –

COMMISSIONER McGAFFIGAN: That's all right, blame the lawyers.

DR. WILLIAMSON: -- that are there and one reason we have gotten -- you know, we were attempting, I think, to reconcile the decision criteria and what is a medical event with the written directive to essentially try to close the loophole, try to respect patient's -- you know, promote patient safety and detect those practitioners that are beyond the -- you know, in the tails of the standard distribution of practice skills without constraining or making it difficult --

CHAIRMAN DIAZ: Gentlemen, you have come to the right place.

COMMISSIONER MERRIFIELD: Mr. Chairman, since it's my question, I just want to finish up.

COMMISSIONER JACZKO: Commissioner Merrifield is working on his medial degree.

COMMISSIONER MERRIFIELD: No, no, no, no. I could respond to that but I won't.

CHAIRMAN DIAZ: It pay more, it really pays more.

COMMISSIONER MERRIFIELD: Well, I mean, at the end of the day, I think the search is for finding out what is truly meaningful in terms of reporting and I think the heart of that is clearly where I'm coming from, I think you're on the right track. Two final small things; I was going to tweak you a little bit as I always do various people on the slides

and the number of acronyms and some of the language and I do that because our audience is beyond just the folks here at the table and in the room. It's our general public as a whole. It's important to use plain English in order for them to understand it.

That having been said, I have to give you a compliment, Dr. Malmud. You provided the clearest plain English explanation that I think you could have. It was excellent. As an attorney --

(Laughter)

COMMISSIONER MERRIFIELD: -- and not an inside person, I would compliment you on that.

CHAIRMAN DIAZ: Thank you very much, Commissioner Merrifield. Commissioner Jaczko.

COMMISSIONER JACZKO: I want to follow up a little bit on some of the points raised earlier. On the issue of exemptions -- I'll turn on my microphone. Is your recommendation that there should be, I thought I was hearing almost two levels but there would be a higher level for exposure or whatever we determine the level to be for caregivers and then an even higher level if there's training and monitoring?

DR. VETTER: Yes, the lower level would be one that would be generally applied and the higher level would be for very unique cases where the caregiver, the parent, for instance, of a child who was actually actively involved in the care of that patient, and in order to apply

the higher limit, we would have to provide that parent with some training and with radiation monitoring.

COMMISSIONER JACZKO: Okay, so that would be a second level then, above the more general.

DR. VETTER: Yes, exactly but below a certain level as well, as the Chairman points out , as necessary.

COMMISSIONER JACZKO: Right, so there would still obviously be a limit there.

DR. VETTER: Yes. The example that we often use is the recommendation of the NCRP in which the general limit for a member of the public is one millisievert, that's you know, a wide application for release of a patient who contains radio-iodine or other radioactive materials for individual members who that person might come close to, 5 millisievert but then for a person who is actively involved in the care of that individual, the 50 millisievert.

COMMISSIONER JACZKO: Thank you. One of the -- and this kind of follows up on some of the discussions we've had with the concept of medical event and slide 19 of that presentation you talked about a recommendation here and I mostly just want perhaps a better understanding and this may have been subsumed by the discussion we had but there you have recommendations to treat medical events strictly as a QA performance surrogate divorced from patient harm. If you could

just explain to me a little bit more what you mean by that kind of a concept.

DR. WILLIAMSON: All right, I think that it's based on the widespread observation by the license community that the simple reporting of a medical event triggers a punitive response. Even though there may be no citation of a violation, a reactive inspection is triggered. You know, from an institution's point of view, a big risk of liability and bad publicity. From the physician's point of view sometimes there's an intrusion into the patient/physician relationship occasioned by reporting requirements, so one of the recommendations that has been made by the subcommittee and not debated yet by the ACMUI, is that the reporting requirements as written in the Part 35 should be triggered only in the event where the medical event, in fact, has caused an injury or is of the severity level that it could cause an injury and that would be a clinical decision, perhaps made by a medical consultant.

It would not be able to be encoded in the rule. You would not be able to say that 5 percent or 20 percent or even 50 percent is necessarily going to be a patient injury.

COMMISSIONER JACZKO: So would that -- and this is a very new issue for me, so would that be something other than a medical event? Is that what you're suggesting that that would be?

DR. WILLIAMSON: No, that would be a medical event but the reporting requirements and the responsibility to the patient as

codified in Part 35 would depend on a separate determination whether it was material to the patient's future medical decision-making, whether it necessarily would trigger all these requirements and you know, it would, for example, not put the physician in the bind of having to trade off patient confidentiality versus medical necessity, if in case, reporting a fairly trivial kind of administrative medical patient might undermine the relationship and actually hurt the treatment.

This has come up in my own experience as a practicing medical physicist and others have related it too. And I think the more vague and second point which we have yet to try to flesh out in more detailed recommendations is how can the discovery of a medical event and its reporting be made more sort of a constructive experience structured along the methodology that we use within our clinics. We all have active QA programs and risk management programs where events -- we encourage the reporting and documentation of events. We actively follow them up. We use them as tools for correcting and improving our programs, and it's not something that occasions -- triggers a legal kind of adversarial response and makes people hesitant to cooperate with the system unless it's crystal clear that it's a medical event and we have to accept all this punishment.

So how could enforcement policies be modified to, I think, have the effect you clearly intended to have.

COMMISSIONER JACZKO: I just want to ask one final question, changing directions a little bit and going back to the issue that you talked about with the definition of didactic training and it seems that the issue stems largely from the definition of laboratory. It's expected to be the most -- before you answer that, that one was more rhetorical, I think. The real question I have is, do you have any evidence right now that there is going to be a disparate definition of laboratory from one state to another or this is something that you see as a possibility or is there evidence to indicate that?

DR. EGGLI: I think there is no evidence but the concern comes from the issues of how the word laboratory is used. In some academic practices it is used to mean the entire clinical operation but yet, if you want to take a dictionary definition of laboratory, that's not the definition. So, the question is, how will the definition be applied and whose definition. Although yes, it's theoretical, it's a concept that in the medical community means something different than it means in lay terms and I think any time you have that kind of difference there's a significant potential for interpretation bias.

COMMISSIONER JACZKO: Are there other existing de -- I mean is that term use in other context where there would be some kind of guidance?

DR. EGGLI: Well, I think there is guidance published in the Federal Register and if the States would all adopt the guidance in the

Federal -- that was published in the Federal Register, then there is no problem.

COMMISSIONER JACZKO: Okay, thank you.

CHAIRMAN DIAZ: Okay, Commissioner Lyons.

COMMISSIONER LYONS: This is also a very new area for me, so forgive me if these questions are a bit naive but returning to the point of the area that Commissioner Jaczko was just exploring maybe two questions ago on the medical event definition and you focused on Slide 19 and I'm looking more at Slide 16. But also the point that Commissioner Merrifield was making on what is meaningful to report, as you Dr. Malmud went through your discussion of lemons and oranges, I was finding myself wondering whether the 20 percent which is suggested on that Slide 16 is at all meaningful to use Commissioner Merrifield's words. It's not at all obvious to me that it's even reasonable that the number should be anything approaching 20 percent, perhaps, much larger.

I also found myself wondering whether there is sufficient certainly in the dose that you wish to deliver to pretend that a 20 percent variation is a magical number. Maybe I'm way off base on that question and then my third question, again probably very naive, is -- can you perhaps handle some of these questions by the way a patient consent is worded? If a patient consent to a procedure is worded to forewarn the patient of the vast range of uncertainties, and variables which you went

through for us, would that or could that fold into restricting the definitions of medical events?

DR. MALMUD: The questions that you raise are not naive. They're actually quite insightful and right on target. What we're dealing with and I'm not a radiotherapist, I'm a nuclear physician by training, so the radiotherapist could address this directly without me being an intermediary but it's precisely the issues that I raised, the different ways of measuring, the question about the anatomy, the change that actually occurs in the anatomy during the course of therapy which alters the dose, once the dose has been delivered because of the swelling involved. And then the migration of some of the seeds, some of the seeds do migrate.

COMMISSIONER LYONS: All of the above.

DR. MALMUD: They're all issues. The 20-percent rule is a rule which can be applied retrospectively, which is what raised the antennae on some individuals, suspecting that the calculations done retrospectively were done to cover up a mistake rather than to give an accurate measure of the dosimetry when, in fact, an accurate measure of the dose can only be obtained after the therapy has been administered, after the swelling is down and after we see the prostate retrospectively and the seeds located in the prostate.

So the 20-percent rule is something that we're still struggling with and we need a rule that puts some limits on how far away

from the intended dose the final dose should be. Perhaps, the members of the committee who are most knowledgeable on this have approached it by looking at how we calculate the dose to begin with, let's talk about the dose in terms of the activity in the seeds that are being administered rather than the ideal dose to the target organ which may be the prostate or the prostate and soft tissue around it.

Then if we know we're giving 100 seeds that contain X amount of activity, and we deliver the 100 seeds, we know we're okay. If 20 percent of those seeds wander for one reason or another, we're still okay, but if 21 percent wanders, we've now crossed a threshold which would require some kind of documentation.

The question then arises, should the patient be advised that it's 21 percent rather than 20? Should we alert the patient unnecessarily and create anxiety on the part of a patient who already is being treated for cancer about a side effect which he may not experience? And these are difficult questions which we are struggling with right now. But I believe what the tone on the committee, excluding myself, I'm not a radiotherapist, I think they can come to a resolution to make recommendations.

COMMISSIONER LYONS: But could some of this be handled in the patient consent process?

DR. MALMUD: The patient consent process, in general, includes every possible untoward event that could occur including death.

So when one has consent forms that list all of the possible negative outcomes, then is the patient really informed any longer? And the answer is, we could go from one extreme to another. I recently had a procedure done myself and the surgeon said to me one of the complications is death. And we both laughed, we both laughed. I signed the form, of course. One of the complications is death. You know, one out of 10,000 patients or so may die of anesthesia in the course of a procedure.

But when we get to the point where the surgeon is so defensive in the Philadelphia area where malpractice is a major issue, negligence insurance is a major issue, then we see that we cross into another area which creates a new set of problems. So we're human. We walk this narrow road between too little and too much and we try and do the best that we can. I think with the talent that we have on the committee, excluding myself, and with the staff that has been extraordinarily supportive this year and I've watched the staff evolve, the NRC staff that we work with, it's been a wonderful year for us to work with them.

We've argued much more amongst ourselves than with the staff and the staff has been there and been supportive.

CHAIRMAN DIAZ: I'm sorry to hear that.

(Laughter)

CHAIRMAN DIAZ: He has one comment but we need to be quick and precise.

COMMISSIONER McGAFFIGAN: I just wanted to tell the Commissioners, you know, this is deja vu all over again in some sense. We tried -- you know, this was a major focus for the Part 35 rulemaking that we completed a few years ago and the patient notification issue was one that Commissioners thought about, and I thought because it's a long time ago now, my memory is fading, that we gave you some flexibility in the patient notification area. We can revisit but revisiting when you -- the Part 35 rulemaking for the two of you is about four or five inches thick and went through numerous changes.

Now, we're into bite sized stuff, but as I said, I haven't found that bite sized thing yet.

DR. WILLIAMSON: Okay, one quick comment; I think your questions make a lot of sense. And what we have tried -- but it's very confusing. One thing that's helpful and we thought about in guiding our work is the medical policy statements which combines a boundary between medical practice issues which are not the concern of the Nuclear Regulatory Commission, and the patient safety which is. And so the medical policy statement defines the patient safety component as being let the physician decide, it's the physician's decision, that's not regulated. The execution however, is fair game for regulations.

So when we say QA significance, we're trying to define a more workable set of criteria that will help the staff be able to determine when there are QA significant deviations from the delivery intended by the

physician and not to make it depend on all these difficult issues which you raise which are different for all the different sites and really can't be resolved by a set of regulations.

CHAIRMAN DIAZ: If I may take this opportunity to try to close this meeting up, let me just make a comment because Dr. Malmud keeps referring to himself as just a nuclear medical physician, a few years ago, I'm not even going to say how many years ago, I used to cross those bands. I used to spend you know, two half days in the Veterans Hospital doing nuclear medicine and two half days doing radiation therapy and two half days doing other things in the medical -- luckily for you, I have forgotten all about it. So you have nothing to worry about.

But I -- what we are seeing is really the fact that as technology and medicine advance, there are more precise measures that can be taken. A few years ago, there were no seeds and people used to be irradiated with electro-magnetic radiation which we can control a lot less and that used to go, you know, all over the place no matter how we advanced, but the fact of the matter is that we could not control the deposition of the energy, we could not control it geometrically as well as you can by implanting seeds.

Therefore, we always come to the same point in the medical application of radiations, that there are variations in the human beings, there are variations of responses, how the tissue responds, there are variations on the skills that I apply. What the Commission really is

looking for is for the assurance that the right skills are applied at the right technique. That's really the bottom line. What we are looking for is for avoiding the potential unique, you know, random, uncontrolled misapplication of a technique that could result in patient harm.

Within those bounds we have really worked for years trying to come up with a rule that will be more performance based, that will actually will be of more benefit to the nation and at the same time, insure that we're doing what our job is. And you heard it over and over, we are open, I believe, you know, if I reflect my fellow Commissioners, to revisit these things in a manner that this is better for the people in our country and that we don't unnecessarily alarm them but at the same way, we need to exercise our responsibilities under the law to provide protection of public health and safety. I'm trying to make that a summary.

DR. MALMUD: And we respect that. We know that we certify through the specialty boards in each of the specialties that treats patients, in radiology, radiation oncology, nuclear medicine and so on. We certify radiation physicists in medicine and then we -- once they're out in practice, we do look at performance based activity. We do that through the credentialing committees of our hospitals, through the quality assurance committees of our hospitals, through the morbidity and mortality conferences that are held in every community hospital throughout the United States and through the tumor conferences that are

held in every hospital throughout the United States. So there are many peer reviews of performance by each of the specialities.

The goal always is to first do no harm and secondly, to do good in the process of not doing harm. And what we're trying to do is walk that fine line and we appreciate the need to establish standards so that the public maintains its confidence in the health care system and that even more importantly than maintaining its confidence that we provide good medical care with as few complications as possible.

We recognize that that's a responsibility that also falls onto the NRC indirectly because of the fact that we're using radiation and we try and bring all these things together and that's why we struggle amongst ourselves to come up with the wording that will meet the need that will provide the patients with the safest, best care possible, not deny them care because of excessive rulemaking and yet, not allow them to be injured because of inadequate rulemaking.

CHAIRMAN DIAZ: I think that in many ways describes what we try to do in many other issues.

COMMISSIONER McGAFFIGAN: Mr. Chairman, this is perhaps my last meeting with the Advisory Committee on the Medical Uses of Isotopes. I do want to thank you. As I said earlier, I think your unique in the world in having this access to the regulator and providing enormous time commitments on your part to get into the details of all this stuff and I think is the advisory system at its best.

I've said this before to ACRS. If I have a chance, I'll say it to ACNW. I think that this is federal science advice at its best and we appreciate it or I appreciate it. I'm sure my colleagues do, too, but this may be one of my last times ever to have a chance to say that.

CHAIRMAN DIAZ: Thank you so very much, Commissioner McGaffigan. Any final comments?

COMMISSIONER MERRIFIELD: Mr. Chairman, I join Commissioner McGaffigan in appreciating the presentation and the quality of the work that we receive from ACMUI. I would, and again, maybe it's the lawyer in me, I think this has been a pretty good lovefest today and I think as we go down the road to thinking about medical events, I think you do need to keep one thing in mind and we do have reporting requirements to Congress and while there are many ways in which we may change the way that we report medical events, I think if you look back at the history of this particular area in which we have a relatively small window of regulation in the medical community, and you look at the statistics statistically, and this is most -- the vast majority of this is as a result of the particular modalities themselves, but the rates of malpractice are exceedingly low and I would like to think to some small degree that the rigor of our regulatory authority has some small impact. I don't know how we can quite measure that, but it has an impact on that. And I think it's important that while we may have a better way of doing this and be less intrusive, the backstop of having those reports and having us

as a regulator who can go after those few individuals who have been bad actors in this particular community is important to keep in mind, too.

Thank you, Mr. Chairman.

CHAIRMAN DIAZ: Thank you very much. Any final comments? If not, we really appreciate. It's been -- you know, I don't think it's been a lovefest. I thing it has been a goodfest and we have actually benefitted from it. I hope you also have seen from the Commission the interest that we have and we continue to be looking forward to interacting with you and to your work and you with the staff. With that, we're adjourned.

(Whereupon, the above entitled matter concluded.)