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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.)

1     STAFF AND PRESENTERS:

2     DR. DOUGLAS EGGLI

3     DR. LEON MALMUD

4     DR. JEFFERY WILLIAMSON

5     DR. RICHARD VETTER

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

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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.

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

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

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

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

20                  DR. EGGLI: Mr. Chairman, Commissioners, thank you.  
21                  Can I have the next slide please? As part of the revision of Part 35, the  
22                  ACMUI was asked to review the training and experience requirements for  
23                  all classes of authorized individuals.

24                  Next slide please. The goal of ACMUI's  
25                  recommendations for training and experience requirements was to make

1 the requirements for training and education commensurate with the risk.

2 That is to develop a regulation --

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

5 DR. EGGLI: I am now on slide three.

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

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

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

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

18 Next slide please. The ACMUI recommended that  
19 training programs would be responsible for developing a curriculum that  
20 would satisfy the broad educational and experience objectives required  
21 by the regulation.

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

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

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

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

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

14                  Next slide. Subsequent to that the Organization of  
15 Agreement States expressed concern over authorized user training and  
16 experience requirements for Subparts 200 and Subpart 300 uses. The  
17 concern hinged on specific didactic educational requirements, not the  
18 total number of hours of training suggested by the rule and the rest of the  
19 discussion will hinge around these Subparts 200 and 300 training and  
20 education requirements.

21                  ACMUI felt that it was appropriate that the total number  
22 of hours of training be reduced from 1,000 hours to the recommended  
23 700 hours. However, the distribution of training hours represented a  
24 concern for ACMUI.

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

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

12                  Next slide. American Board of Radiology has indicated  
13 that it intends to require all diagnostic radiology residents to be trained to  
14 Subpart 300 use certification. This means that Subpart 390, Training and  
15 Education Requirements, have to be the basis for radiology training.  
16 Radiology residencies will be required to train residents to the alternate  
17 pathway requirements in large part because initially approximately 20  
18 percent of radiology residents are not board certified in their first year of  
19 practice and subsequently become board certified. If we do not train to  
20 the alternate pathway requirements, these people will be unable to  
21 become authorized users during that time prior to their board certification.

22                  Next slide. ACMUI felt that the 200 hours of didactic  
23 requirement was excessive and recommended 80 hours for Subpart 300  
24 sub-uses. The recommendation was based on the input of ACMUI

1 members who actually designed and delivered these educational training  
2 program.

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

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

14 Next slide. The components of the classroom and the  
15 laboratory training are not well defined. This was in keeping with the  
16 intent to make the rule performance-based rather than prescriptive.  
17 However, with a specific requirement for hours of classroom and didactic  
18 training, there is a relatively large requirement for training that training  
19 directors are now uncertain about what will be accepted as qualifying  
20 education.

21 Next slide. Training directors need to be certain that the  
22 programs they design will meet the intent of the regulation particularly  
23 because Agreement States although they have a high compliance  
24 requirement for the regulation itself can have significantly different  
25 implementations of the guidance and some of the explanation of what is



1 considered laboratory training will be defined in guidance space rather  
2 than regulatory space.

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

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

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

13 DR. WILLIAMSON: Okay. Well, thank you. May I have  
14 slide 2 of my presentation. Let me describe the subcommittee charge. It  
15 was charged with evaluating the appropriateness and justification for the  
16 20 percent threshold in the current medical event rule; secondly, how to  
17 best communicate risk associated with medical events; and thirdly,  
18 development of basically recommendations to make the rule workable in  
19 permanent interstitial brachytherapy with emphasis on prostate implants.

20 Why that is so important as you will see from our  
21 presentation, the difficulties with the current rule are exaggerated or  
22 appear with permanent implants and prostate brachytherapy with nearly  
23 50,000 procedures a year is by far and away the most common form of  
24 permanent seed implantation and now the most frequency practiced

1 indication for brachytherapy overall. So that is why so much of the talk  
2 focuses on that.

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

7 Slide 4. What I'd like to do is give you a little clinical  
8 background on the procedure to give you a feel for the complexity and  
9 difficulty of our task and why it is still in flux. I'll briefly sketch the main  
10 areas where we have achieved consensus and point out that many  
11 details yet are to be resolved, but I think we at least have the beginnings  
12 of an approach we all agree on. I'll touch briefly on a few of the issues  
13 that are still under discussion.

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

22 The probe can be adjusted to control the depth, the  
23 penetration into the patient. If you look at slide six, you can see an  
24 ultrasound image that is illustrated there showing in the little white box

1 how you can actually see a needle. Then the white dots on the image  
2 illustrate the different potential needle positions that exist.

3 Slide 7 please. This diagram illustrates the procedure  
4 flow for the most commonly used method for achieving prostate implant.  
5 So it consists of three parts. Two weeks before the procedure, the  
6 patient comes and a volume study is done. Basically a set of preliminary  
7 images with the ultrasound probe are taken. Then given the input from  
8 the physician, the contoured target organ, critical anatomy, the absorbed  
9 dose that the physician would like to give, preplanning is done and this is  
10 used then to determine the source strength, the number of needles they  
11 are loading and so on. The seeds are ordered.

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

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

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

4 Slide 9 please. So one problem that can occur is that  
5 during the procedure the patient anatomy can differ significantly from  
6 what was seen on preplan. Depending on the treatment of the patient,  
7 the prostate could have shrunk. The position may not be achieved  
8 exactly. As the physician inserts the needles, the prostate responds by  
9 becoming edimatiuous and swelling up, so it's of a different size. It also  
10 moves when you put the needles in. So the bottom line is the authorized  
11 user must be free to adapt the preplan to the anatomy as he or she sees  
12 it at the time of the procedure.

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

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

1 Slide 12 please. So is it justifiable? For temporary  
2 implants, the subcommittee felt that it was a reasonable regulatory action  
3 level so long as it is understood to be a surrogate for QA performance  
4 and not an indicator for patient harm. For patient harm occurring at this  
5 level would be highly dependent upon the dose, the proximity of critical  
6 structures, the type of disease and so forth. No general statement could  
7 be made that 20 percent will or will not cause injury. But it's nonetheless  
8 a good endpoint for is the operation well run.

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

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

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

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

24 Essentially the idea would be, slide 16, to define a  
25 medical event as being one in which the implanted activity in the target

1 volume differs by more than 20 percent. How exactly this would be  
2 worded is still under discussion and hasn't achieved consensus.

3 Slide 17. Another problem that we attempt to address is  
4 when the written directive is closed to revisions. As written now, basically  
5 the authorized user can revise the written directive at any point up to and  
6 following the final post implant dosimetry and this has caused some  
7 abuse by certain authorized users who have used this as a loophole to  
8 evade regulatory compliance with the medical event definition.

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

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

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

22 And Slide 21, try to make the enforcement of medical  
23 event more consistent with industry practice. I've listed some of the  
24 principles here in order to make sure compliance with the reporting  
25 requirement is followed and that the simple reporting of an event is not

1 seen as an invitation for punishment. Thank you, this concludes my  
2 presentation.

3 CHAIRMAN DIAZ: Thank you.

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

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

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

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

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

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

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

21 So we think the one millisievert constraint that ICRP  
22 uses is more appropriate for an ALARA program and may be a good goal  
23 for some programs but we do not feel that it's appropriate to use it as a  
24 constraint.



1 Slide 6 please. If we look at some typical doses to  
2 medical personnel, they typically are tens of millisieverts in the cardiac  
3 lab and PET lab. And in the cardiac lab, constraining the dose, if you  
4 would, they want to use the word constraint, constraining the dose to less  
5 than five millisieverts is rather easy because the average energy of x-rays  
6 in the cardiac lab are low enough that wearing a lead apron will attenuate  
7 97 percent of the scattered radiation from use of the x-ray in the cardiac  
8 lab.

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

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

22 Next slide please. Another use of constraint is in the  
23 public dose arena. ICRP does say that it is appropriate to allow  
24 exposures of a few millisievert to certain individual members of the public.  
25 In this case, the constraint is above the limit of one millisievert. But

1 they're saying a constraint of few millisievert is appropriate in certain  
2 cases. However, we should not be rigid in the application of that  
3 constraint and should even allow it to go higher in certain circumstances.  
4 An example they use is a constraint of as much as 20 millisieverts for a  
5 parent of a child who has received radio iodine and receives considerable  
6 care.

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

14 Next slide please. In a general sense, ICRP applies  
15 public dose constraints to or constrains them to less than one millisievert  
16 and suggests that an appropriate level is 0.3 millisievert. The committee  
17 consider that application of that constraint to be problematic and  
18 extremely costly in particular in designing and constructing medical  
19 facilities. The NCRP uses a general, they don't call it constraint, a  
20 general sublimit of 0.25 millisievert. However, they indicate that it's  
21 appropriate to design medical facilities so that the limit to a member of  
22 the public would be one millisievert, if it's designed per NCRP  
23 recommendations. Their methodology contains considerable  
24 conservatism.

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

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

15                  Next slide please. Relative to worker doses, ICRP, as I  
16 mentioned earlier, has recommended that the pregnant worker, the  
17 effective limit for that worker is one millisievert because the limit to the  
18 abdomen or the fetus would be one millisievert. That risk is very low as I  
19 mentioned earlier and that would be problematic for certain areas of  
20 medicine, in particular for the PET lab.

21                  For workers, ICRP has reiterated a previous  
22 recommendation of 20 millisieverts for radiation workers. Again, we  
23 consider that problematic for some areas of the hospital, again, the PET  
24 lab being perhaps the most problematic. Even though average  
25 exposures to medical workers is less than 5 millisievert or 500 millirem,

1 even though the average is less than that, there are individuals for  
2 instance in certain cardiac labs, certain PET labs, etc. whose exposures  
3 do push the limit and to drop that limit would be particularly problematic  
4 for those individuals. So we support the NRC's recommendations and  
5 the current NRC annual limit of 50 millisieverts.

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

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

15 DR. WILLIAMSON: Thank you. The second slide  
16 please. Now in contrast to the first presentation this is essentially a  
17 completed work and has been responded to by the NRC staff. The  
18 charge was to review Region III's dose reconstruction in this incident;  
19 secondly, to review an alternate dose reconstruction methodology  
20 proposed by Drs. Siegel and Marcus on behalf of the Society of Nuclear  
21 Medicine; and thirdly, to make general recommendations to NRC  
22 regarding dose reconstruction.

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

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

11 Slide 5 please. So what we did is we reviewed these  
12 calculations along with the Marcus-Siegel critique and performed our own  
13 reconstruction using Monte Carlo simulations to a limited extent. In  
14 addition, we interviewed the former RSO of the institution and interviewed  
15 the Region III inspectors as well as reviewed documentation supplied to  
16 us by the licensee.

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

1 versus 15, under the most conservative scenario, than NRC's. We  
2 thought that idea had merit.

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

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

22 On Slide 9, there is a summary of the specific  
23 differences regarding distance reconstruction, EDE versus DDE and so  
24 forth. You can see there that despite the fact we have sympathy with

1 their general position, the numbers we think were very different and within  
2 a factor of two of what the regions were.

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

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

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

1 be ignored in favor of the maximally conservation one that is barely  
2 plausible.

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

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

8 CHAIRMAN DIAZ: Thank you so very much, Drs.  
9 Malmud, Williamson, Vetter and Egli. We appreciate your presentations  
10 and the speed with which we just went all of those things. As you realize,  
11 the Commission always get these ahead of time. So we are prepared to  
12 the multi-speed and adapt as we can.

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

19 DR. MALMUD: The issue remains one of concern  
20 particularly today when most nuclear practitioners are trained as part of  
21 radiology training programs and the radiology residency now includes  
22 technologies that didn't exist 10 or 15 years ago, particularly MRI and CT.  
23 So that the board requirements for nuclear medicine training within a  
24 radiology residency are three months of the residency. Three months of



1 the residency obviously is about 600 hours, all totaled. That's inclusive of  
2 all the clinical experience in reading the films.

3 The term didactic had been used to describe the 200  
4 hour requirement of the 600 hours for the radiology residency and  
5 number 1, 200 hours of didactic classroom work is excessive and there  
6 isn't that much information to transmit of a classroom type. So the term  
7 didactic has been replaced with classroom and laboratory which does  
8 meet the feelings of most of the members of the committee but not all  
9 because there remains concern that the definition of laboratory is not  
10 specific enough.

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

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

22 If the Commission feels that our definition of classroom  
23 and laboratory is acceptable, we would like that to be, we would be very  
24 happy with that ruling provided if that's the understanding because the  
25 program directors do not want to have to be mealy-mouthed in their

1 definitions of words. They would rather be very straightforward and  
2 honest and say this is what our residents have all received.

3 Now why is this an important issue? Because as the  
4 presenter pointed out to you, most of our residents do achieve board  
5 certification but in the first year after finishing training, they are not yet  
6 board certified. Therefore, they must meet the standards for those who  
7 are not board certified.

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

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

23 You're saying that that really should be a major  
24 consideration. Up to what level? Up to the level of 50 millisieverts?  
25 Should there be a limit into how much an exemption is an exception? I

1 think the Commission will have a serious time -- I will have a serious  
2 problem with just a blanket exemption. There has to be some limits,  
3 some assurance that a reasonable limit will not exceeded. Anybody?

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

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

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

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

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

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

12                 I will tell folks, for any members of the public here that  
13                 this is a place where we're trying to help people and I have received a lot  
14                 of CT scans and a lot of PET scans and I even had 50 gray of radiation in  
15                 my left axial last year to help prevent melanoma from coming back. So  
16                 50 gray is 5,000 rads. You guys can do the calculations, it was right  
17                 here, as to what that is in rem but it's a lot and it's what we do to try to  
18                 help people.

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

24                 I hope we can make a decision with regard to the issue  
25                 that you raised as to what the words classroom and laboratory mean in a

1 way that's really going to be binding because I don't want a doctor who's  
2 in Virginia or the District unable to practice in Maryland or visa versa or  
3 somebody who's in New York City not being able to practice in  
4 Connecticut and New Jersey or visa versa. This is an area where we  
5 need to have national standards. So if you have indications that in  
6 guidance space this could unravel, I urge you to call it to the staff and the  
7 staff could call it to our attention.

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

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

21 I would urge you. I think you're fairly unique in the world  
22 in your existence. I'm not sure that the French regulator or the British  
23 regulator has any thing like the Advisory Committee on the Medical Use  
24 of Isotopes and this may be something you do individually, but I would  
25 urge that you be very aggressive in conveying the medical community's

1 points of view to the ICRP. I know there are doctors on ICRP but in that  
2 you make sure that people in other nations who practice medication as  
3 you do also are paying attention to ICRP because it will come up and  
4 potentially affect them.

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

15 So I urge you to pay attention. I'm on for a full and open  
16 debate here. I will also point out to you something that I know is going to  
17 happen at some point this year, or I think it's going to happen at some  
18 point this year, OSHA is going to put out a request for information with  
19 regard to occupational dose. Their occupational dose rules go back to  
20 ICRP 2 and the 1970s and have been amended to be consistent with  
21 Presidential guidance issued during President Reagan's Administration, I  
22 believe, in 1987. I think somewhere in the process this request for  
23 information going out, and again I would urge the medical community,  
24 I'm addressing the medical community through you, to pay attention to

1 that request for information and to provide your perspective because it  
2 will be very important.

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

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

15 DR. WILLIAMSON: If I could make a quick comment on  
16 that, it is really a difficult undertaking. You're asking for a simple  
17 decidable, well-defined rule that applies to a process or activity even  
18 when done by the best expert in the country has a certain amount of  
19 variability to it.

20 COMMISSIONER McGAFFIGAN: No, I understand.

21 DR. WILLIAMSON: That's the difficulty.

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

1 CHAIRMAN DIAZ: Commissioner Merrifield.

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

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

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

23 Relative to the dose reconstruction at St. Joseph's, I  
24 recognize this was a complicated and a diplomatic course that all of you  
25 had to go through. Related to the specific issue of patient care and the



1 caregiver, I agree with my fellow Commissioners. I would be open if  
2 there's some further thought on what the right number would be. I think  
3 when we agreed to try and increase that, I think it was with a shared  
4 concern about the need for the empathy of the individuals involved and I  
5 think we gave it our best shot recognizing our health and safety mission.  
6 But I for one certainly have a continuing open mind on that.

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

12 DR. WILLIAMSON: In some areas, they would increase  
13 because there was a series of potential medical events where large  
14 number of seeds were placed outside of the prostate and that was by  
15 evaded basically backdating or updating the revisions some time after the  
16 procedure. So in that area, I think it would be tightened up and might  
17 create a few more.

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

24 But it would be interesting if somebody reported a case  
25 to you and said to you, "I overdosed one voxel of tissue by 51 percent

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

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

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

24 DR. WILLIAMSON: I hesitate to speak for the  
25 subcommittee because we haven't actually considered what would be the

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

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

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

17 Secondly, the target organ, the prostate which is the  
18 example that we're using here, consider it to be a lemon, a lemon-sized  
19 organ, sitting within an orange around it in the pelvis measured by an  
20 ultrasound device which does not always differentiate the border of the  
21 lemon from the border of the orange. So what is the target? Is the target  
22 the prostate or is it the prostate and the soft tissue around it, ill-defined in  
23 some instances by the ultrasound. In some institutions the initial  
24 measurement is made with an ultrasound. In others it's made with a CT  
25 scan. In others it's made with a newer technology, MRI, which gives

1 much better resolution and therefore, can define the prostate better and  
2 define the target organ to a degree that was not possible only a few years  
3 ago but which is not yet the national standard. So to apply new criteria to  
4 a technique not yet universally available would be a mistake.

5 So now we have a variation in the definition of the dose,  
6 meaning a variation in the target organ is it the prostate or is it the  
7 prostate and the soft tissue around it, and then we have three different  
8 means of measuring it; ultrasound, CT, MRI and they are not identical  
9 imaging modalities. Furthermore, the actual measurement may be taken  
10 at three different times, certainly at the time of treatment, but also pre-  
11 treatment. If it's pre-treatment it's probably ultrasound measurement. If  
12 it's during treatment it may be the rectal ultrasound or the intra-rectal  
13 ultrasound or it may also be a CT that's obtained at that time.

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

24 Now, are there problems and Commissioner --  
25 Chairman, you point out very correctly that there are problems. What

1 happens if in instilling 100 seeds 50 of them happen to line up in the  
2 bladder, cause a radiation burn to the bladder and a fistula to the rectum?  
3 That's a problem and that's what we're trying to deal with without  
4 constricting the physician's ability to treat the patient, to find a system of  
5 reporting that's sensitive enough to catch the outliers and we're working  
6 on that.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

8 (Laughter)

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

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

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

19 DR. VETTER: Yes, the lower level would be one that  
20 would be generally applied and the higher level would be for very unique  
21 cases where the caregiver, the parent, for instance, of a child who was  
22 actually actively involved in the care of that patient, and in order to apply  
23 the higher limit, we would have to provide that parent with some training  
24 and with radiation monitoring.

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

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

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

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

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

23                  DR. WILLIAMSON: All right, I think that it's based on the  
24 widespread observation by the license community that the simple  
25 reporting of a medical event triggers a punitive response. Even though



1 there may be no citation of a violation, a reactive inspection is triggered.  
2 You know, from an institution's point of view, a big risk of liability and bad  
3 publicity. From the physician's point of view sometimes there's an  
4 intrusion into the patient/physician relationship occasioned by reporting  
5 requirements, so one of the recommendations that has been made by  
6 the subcommittee and not debated yet by the ACMUI, is that the  
7 reporting requirements as written in the Part 35 should be triggered only  
8 in the event where the medical event, in fact, has caused an injury or is of  
9 the severity level that it could cause an injury and that would be a clinical  
10 decision, perhaps made by a medical consultant.

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

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

17 DR. WILLIAMSON: No, that would be a medical event  
18 but the reporting requirements and the responsibility to the patient as  
19 codified in Part 35 would depend on a separate determination whether it  
20 was material to the patient's future medical decision-making, whether it  
21 necessarily would trigger all these requirements and you know, it would,  
22 for example, not put the physician in the bind of having to trade off patient  
23 confidentiality versus medical necessity, if in case, reporting a fairly trivial  
24 kind of administrative medical patient might undermine the relationship  
25 and actually hurt the treatment.

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

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

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

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

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

13 DR. EGGLI: Well, I think there is guidance published in  
14 the Federal Register and if the States would all adopt the guidance in the  
15 Federal -- that was published in the Federal Register, then there is no  
16 problem.

17 COMMISSIONER JACZKO: Okay, thank you.

18 CHAIRMAN DIAZ: Okay, Commissioner Lyons.

19 COMMISSIONER LYONS: This is also a very new area  
20 for me, so forgive me if these questions are a bit naive but returning to  
21 the point of the area that Commissioner Jaczko was just exploring maybe  
22 two questions ago on the medical event definition and you focused on  
23 Slide 19 and I'm looking more at Slide 16. But also the point that  
24 Commissioner Merrifield was making on what is meaningful to report, as  
25 you Dr. Malmud went through your discussion of lemons and oranges, I

1 was finding myself wondering whether the 20 percent which is suggested  
2 on that Slide 16 is at all meaningful to use Commissioner Merrifield's  
3 words. It's not at all obvious to me that it's even reasonable that the  
4 number should be anything approaching 20 percent, perhaps, much  
5 larger.

6 I also found myself wondering whether there is sufficient  
7 certainly in the dose that you wish to deliver to pretend that a 20 percent  
8 variation is a magical number. Maybe I'm way off base on that question  
9 and then my third question, again probably very naive, is -- can you  
10 perhaps handle some of these questions by the way a patient consent is  
11 worded? If a patient consent to a procedure is worded to forewarn the  
12 patient of the vast range of uncertainties, and variables which you went  
13 through for us, would that or could that fold into restricting the definitions  
14 of medical events?

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

25 COMMISSIONER LYONS: All of the above.

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

9 So the 20-percent rule is something that we're still  
10 struggling with and we need a rule that puts some limits on how far away  
11 from the intended dose the final dose should be. Perhaps, the members  
12 of the committee who are most knowledgeable on this have approached  
13 it by looking at how we calculate the dose to begin with, let's talk about  
14 the dose in terms of the activity in the seeds that are being administered  
15 rather than the ideal dose to the target organ which may be the prostate  
16 or the prostate and soft tissue around it.

17 Then if we know we're giving 100 seeds that contain X  
18 amount of activity, and we deliver the 100 seeds, we know we're okay. If  
19 20 percent of those seeds wander for one reason or another, we're still  
20 okay, but if 21 percent wanders, we've now crossed a threshold which  
21 would require some kind of documentation.

22 The question then arises, should the patient be advised  
23 that it's 21 percent rather than 20? Should we alert the patient  
24 unnecessarily and create anxiety on the part of a patient who already is  
25 being treated for cancer about a side effect which he may not

1 experience? And these are difficult questions which we are struggling  
2 with right now. But I believe what the tone on the committee, excluding  
3 myself, I'm not a radiotherapist, I think they can come to a resolution to  
4 make recommendations.

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

7 DR. MALMUD: The patient consent process, in general,  
8 includes every possible untoward event that could occur including death.  
9 So when one has consent forms that list all of the possible negative  
10 outcomes, then is the patient really informed any longer? And the  
11 answer is, we could go from one extreme to another. I recently had a  
12 procedure done myself and the surgeon said to me one of the  
13 complications is death. And we both laughed, we both laughed. I signed  
14 the form, of course. One of the complications is death. You know, one  
15 out of 10,000 patients or so may die of anesthesia in the course of a  
16 procedure.

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

1 NRC staff that we work with, it's been a wonderful year for us to work with  
2 them.

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

5 CHAIRMAN DIAZ: I'm sorry to hear that.

6 (Laughter)

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

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

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

20 DR. WILLIAMSON: Okay, one quick comment; I think  
21 your questions make a lot of sense. And what we have tried -- but it's  
22 very confusing. One thing that's helpful and we thought about in guiding  
23 our work is the medical policy statements which combines a boundary  
24 between medical practice issues which are not the concern of the  
25 Nuclear Regulatory Commission, and the patient safety which is. And so

1 the medical policy statement defines the patient safety component as  
2 being let the physician decide, it's the physician's decision, that's not  
3 regulated. The execution however, is fair game for regulations.

4 So when we say QA significance, we're trying to define a  
5 more workable set of criteria that will help the staff be able to determine  
6 when there are QA significant deviations from the delivery intended by  
7 the physician and not to make it depend on all these difficult issues which  
8 you raise which are different for all the different sites and really can't be  
9 resolved by a set of regulations.

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

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



1                   Therefore, we always come to the same point in the  
2                   medical application of radiations, that there are variations in the human  
3                   beings, there are variations of responses, how the tissue responds, there  
4                   are variations on the skills that I apply. What the Commission really is  
5                   looking for is for the assurance that the right skills are applied at the right  
6                   technique. That's really the bottom line. What we are looking for is for  
7                   avoiding the potential unique, you know, random, uncontrolled  
8                   misapplication of a technique that could result in patient harm.

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

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

1 throughout the United States and through the tumor conferences that are  
2 held in every hospital throughout the United States. So there are many  
3 peer reviews of performance by each of the specialities.

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

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

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

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

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

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

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

1       been bad actors in this particular community is important to keep in mind,  
2       too.

3                               Thank you, Mr. Chairman.

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

11                              (Whereupon, the above entitled matter concluded.)

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