UNITED STATES
NUCLEAR REGULATORY COMMISSION
***
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

U.S. Nuclear Regulatory Commission
Two White Flint North
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The above-entitiled committee meeting commenced, pursuant to notice, at 8:30 a.m.

P R O C E E D I N G S

[8:30 a.m.]

DR. CERQUEIRA: Good morning. I would like to welcome everybody to this morning's session. Everyone should have gotten the forms for reimbursement and, obviously, there will be questions about filling them out. I still don't quite know how to fill them out after a couple of years.

So if they have questions, Cathy, who should they contact?

MS. HANEY: Either contact me or Betty Ann Torres. But the forms that Robin talked about yesterday, all of those forms go to Personnel. The only forms that come in to Betty Ann or to me are the ones for your reimbursement for your consulting services and then the travel forms.

DR. McBURNEY: So we mail these to Betty Ann?

MS. HANEY: The travel, yeah, the travel and the hourly reimbursement, those can go to Betty Ann.

DR. CERQUEIRA: Has everyone met Betty Ann Torres? She sort of helps to coordinate all the activities, so she is the one who sends the e-mails and all the other correspondence. So if you have any questions, you really should go to her.

We have half a day's agenda. Are people leaving early? Do people have early --

DR. WILLIAMSON: I leave at noon.
DR. CERQUEIRA: Okay. At noon. So we definitely will end on time. Cathy brought up the point, there is open discussion about the next meeting dates and some of those other items. So I think we will be able to get to those in the proper order.
MS. HANEY: I will do this later, too.
DR. CERQUEIRA: Do you want to make comments?
MS. HANEY: Well, I would like to add one thing. At break time, I will put it around on the desk. Don Cool got copies from the International Commission on Radiological Protection on a task group report that has to do with managing patient dose and commuted tomography, and they are asking NRC for any comments. Now, that is not something that we regulate, obviously, but I will put the document around at people's seats, and if you wish to comment on it, you are more than welcome to, and you can just respond back directly to the information on this letter. It would be nice if you cc'd us just so that we know what we were looking at. But this is strictly an optional information sort of thing, so don't feel you have to, but if you want to, it is fine.
DR. CERQUEIRA: Well, the first item on the agenda is the NRC Lessons Learned Mallinckrodt exposure events and Cindy Pederson will be making the presentation.

MS. PEDERSON: Good morning. Let me know if you can't hear me, I have got a little bit of a cold, so I will try to do my best.

I am Cindy Pederson, I am the Director of the Division of Nuclear Materials Safety in NRC Region III. And I will spend a little time this morning telling you about a special initiative we took based on a couple of exposure events at two facilities, that we basically decided to examine our own regulatory processes to see if there were enhancements that we should make.

Mallinckrodt Lessons Learned is only one of several initiatives that the Nuclear Materials Safety Program is undergoing this fiscal year.

Handouts I believe were passed out in the small size, so if you want to follow along there, it might help a little bit.

Today's agenda, I think in order to talk about the Mallinckrodt Lessons Learned, I need to give you a little context on what the actual events were. They were in two locations, Maryland Heights, Missouri, which is a suburb of St. Louis, which is their manufacturing facility. Here in April of this year there were some discoveries that led to us doing a number of inspection activities, and at Mallinckrodt manufacturing facility, there were actually three areas that overexposures to extremities occurred, and

I will talk about those more later.

Then, also, Harrisburg, Pennsylvania pharmacy also had an extremity overexposure to one of their pharmacists.

Then I will talk about the charter for the Lessons Learned Team, and I am happy to say a number of the team members are here today, and so any hard questions at the end of today's session, or at any time during the session, will be diverted to some of the folks of the audience. And let me just tell you who they are. Joe DeCicco from NMSS was with us on the team. James Cameron from Region III was on the team. Marjorie Rothschild from the Office of General Counsel, and Agi Seaton was our facilitator, who is also here with us.

I will briefly touch then upon the process that we used as a team to examine our regulatory programs. Then I will talk about our major findings. And, lastly, I will talk about a few of -- some of the higher priority recommendations we came up with. And I need to tell you this is a work in progress still. The report has not yet been issued, so these are still under evaluation at this point. And then I believe there will be some time left as well for questions at the end.

So let me start first with the manufacturing facility. I am going to talk a little bit about the sequence of our involvement and things that went on. Then I

will spend time talking about the overexposures in more detail.

Our involvement started in April of this year, and we were notified of an extremity overexposure potential in the neighborhood of 250 rem or greater. This occurred from an event where an individual handled a Molytech generator column with his gloved hand. Actually, early indications from this event were it could be on the order of 2,500, so we were talking about a very significant radiation exposure to the extremity. We started our inspection the next day.

As we were doing our inspection, the licensee, obviously, was doing their own investigation, and as they looked harder into the exposure event on the Molytech generator column, they learned a number of things which led them to look into other areas of their facility. And they identified two other areas of their facility where significant exposures were occurring to their workers.

The two other areas were indium-111, hand-labeling vials, and indium-111 is a state regulated material, which complicates things as we go forward, and I will explain that a little bit further. The other area at Mallinckrodt Manufacturing was their Sterility Laboratory. That is a quality control function and they were taking aliquots of various materials and testing them from a QC standpoint. That was another area where they were handling unshielded

material.

During this time they were making a significant discovery that monitoring of their film badges, ring badges was not showing them truly the highest dose that individuals were receiving on basically their fingertips as people were handling the vials and the syringes and so forth. We then, based on this new information, upgraded our special inspection to become an augmented inspection effort.

The NRC has got a number of types of inspection you probably are aware of, what kind we consider a routine level of inspection. Then we have a reactive or special inspections which are more significant. Then if it even becomes a bigger issue, we have two further kinds of teams, Augmented Inspection Teams and then the highest level is the Incident Investigation Team. This was that next to highest level of inspection effort.

Because of the issue with indium-111, we included a State of Missouri Representative on our Augmented Inspection Team. This proved to be highly successful. It allowed us as a team to evaluate all aspects in all areas where these overexposures occurred, which included NRC licensed material and state regulated material.

In June we issued a confirmatory order. We obviously had significant concerns with performance of Mallinckrodt. They developed a number of corrective

actions. We wanted to insure these were acceptable and legally enforceable, so we issued what is called a confirmatory order, which basically means the licensee agrees to the conditions. We discussed them with them and they were in agreement with taking those corrective actions, and they also waived their hearing right by entering this agreement with us.

Since an Augmented Inspection Team does not evaluate for potential enforcement, we then had a follow-up inspection in July where we evaluated whether or not violations had occurred, and we concluded there were five apparent violations. Certainly, exposures over 50 rem, a shaladose equivalent, exceeded our regulations. Secondly, failure to use procedures and engineering controls to assure doses were ALARA.

Thirdly, failure to assign the highest dose to the extremities. Remember, they were using doses based on film badges, versus the actual dose the fingertips received, which, in some cases, were many times higher.

Fourth, their manufacturing line for the Molytech generators, they did a modification to that and they did not have their Radiation Safety Committee review that new process line. That was also an apparent violation.

And then unrelated to the specific overexposures that I have mentioned already, there was a subsequent event

that we also found an apparent violation with.

And just bringing you through the final piece here, we did have a predecisional enforcement conference with them in September. The enforcement action is still pending on that.

DR. NAG: One question. Do you require or does NRC require monitoring in the fingertips in any situation? Because I am not really aware. I have done many procedures, I don't remember wearing a fingertip badge, I always wear the ring badge.

MS. PEDERSON: Right. What our expectation here would be is that they would be able to calculate or estimate what that higher doses on the fingertips would be, versus simply relying on what the ring badge read. They need to see if that is truly representative of what the dose is to the maximally exposed area. This case it wasn't. Our expectation was, and they have since done calculations. They did TLD studies and various things to get a relationship between the ring badge dose and what the fingertip dose would be.

This was a very difficult process to go through. I am jumping ahead a little bit, that is okay. Because they had a number of different people who had different techniques. Some people would handle material this way, some may have done it this way. So they have to go back

through interviews and production records to try to identify doses individuals received.

Speaking of doses, if you flip to your next page, there is a table. Now, before we get to the table, let me just briefly talk about Item Number 1 a little bit more and that is the Molytech generator that had a dose. Dose refinements have been going on, we think probably now in the area of 500 rem or so.

But this was a contract employee who was working on the generator line where they actually produce the generators. 19 curie molybdenum, 8 curie tech 99 M, and he was doing rework. The generator wasn't performing as expected and so the individuals began some manipulations of the column, did not do it in accordance with procedure. Actually, the procedures told him he should have never been doing that.

This individual misunderstood the difference between radiation and contamination, obviously, a significant failure in understanding. He thought his glove protected him from the radiation source. Now, our inspection has found that that was an isolated individual who lacked this knowledge, but, clearly, for this individual it was significant.

A lot of variability on the dose that the individual received. Based on reconstructions, based on

people's lack of memory or whatever, differences in which hand he held it in and so forth. So it became very difficult, and, obviously, when it was a contact dose rate, time of contact was critical to the estimation of the dose. So there is a high degree of variability, but based on the subsequent reviews that were done, we are believing it is on the order of 500 or so rem.

Yes?

DR. WAGNER: Have you seen any biological fallout with regard to reaction, skin reactions, et cetera?

MS. PEDERSON: The individual was seen, I believe it was about two weeks after the exposure, and there were no signs of erythema or any physical effects. And so that also makes us believe that in the assessment, it was in that range.

Yes?

DR. CERQUEIRA: Just a procedural question, you mentioned, you know, a contract worker. Now, at medical facilities, when you allow somebody to handle radiation, there is a lot of procedures that you go through to make certain. In this sort of a situation, was there some procedure in place? Obviously, this individual lacked knowledge.

MS. PEDERSON: The individual, be it contract or not, at Mallinckrodt would go through the training program.

Here, basically, the workers on the generator line were contractor workers at the time. Now, they no longer are, they are now employees of Mallinckrodt. But there was a unique aspect on a contract individual versus an employee regarding access to procedures. That was a problem and an issue, it wasn't a direct relation to the overexposure itself though.

DR. CERQUEIRA: But in terms of the NRC regulations, I mean we have talked about sort of training and experience requirements for physicians, technologists and everything else. In industry, do you have those similar requirements?

MS. PEDERSON: We would expect them to be trained to the level necessary to do the job, be it an employee or a contractor. We wouldn't treat them differently because they were a contractor. They would still be required to meet the same types of training and experience in order to do the job

DR. CERQUEIRA: But are those specified? I mean, you know, Part 35 doesn't have those individuals, does it?

MS. PEDERSON: For the Mallinckrodt manufacturing facility, they have a unique license or a unique facility, and we have some level of requirements as part of their license itself. The specifics on the training, I am not familiar with exactly. I don't believe we made any differentiation between contract and regular workers,

however.

Yes?

DR. VETTER: Just to comment on that, in my experience, most employees write into the contract what the expectations of the contractor are relative to training. So in this case, I don't know if they did, but they could write into the contract that the contractor was responsible for training their employees relative to basic radiation safety. And then the employer, in this case Mallinckrodt, would be responsible site-specific training. And so I don't know if they did.

MS. PEDERSON: No.

DR. VETTER: But they could require their contractors to provide them with employees who had some basic radiation safety, but it wouldn't be site-specific.

MS. PEDERSON: In this case, Mallinckrodt was responsible for both parts.

DR. VETTER: For everything.

MS. PEDERSON: Yes.

DR. CERQUEIRA: There is a little bit of a disconnect if you look at the risk that is involved, you know, with a 30 millicurie dose of technetium in a hospital setting versus the potential at one of these manufacturing facilities. And, you know, we are so heavily regulated in a hospital setting, but within industry, maybe I don't fully

understand it, but there seems to be a lot more leeway. Basic radiation training could be a four hour course, is that right?

MS. PEDERSON: The -- I'm sorry.

DR. VETTER: I guess I don't see a difference. The employer still is required to protect to the extent of the regulations or beyond. I don't see a disconnect in the regulations.

DR. CERQUEIRA: Well, what are the hourly training requirements for a contract worker who is going to come in and handle these, you know, potentially high doses?

DR. VETTER: That is not specified, and it isn't specified for hospitals either.

DR. CERQUEIRA: Well, say, for nuclear medicine technologists, I mean, you know, we have dealt with that in and there are requirements.

DR. VETTER: No, there is no hourly.

DR. WILLIAMSON: No, it is not dealt with. There is no hourly expectation.

DR. CERQUEIRA: That's true. That's true. There is a background.

DR. WILLIAMSON: It is only for authorized user and a few others.

DR. McBURNEY: Well, for manufacturing and for other large industrial type operations, we require a certain

amount of training as part of the licensing process. You can't write into the rules for each type of facility, how much training that would entail, but it has got to be sufficient to cover the type of material that they are handling.

DR. CERQUEIRA: Give me a ballpark figure. I mean --

MS. PEDERSON: I am getting technical advice from James back here, and it was three days for these workers.

DR. CERQUEIRA: Three days, 24 hours. Okay.

MS. PEDERSON: Anything else? Okay. Let me briefly touch on the indium-111. This is the table. Oops, I am sorry, it is not the table. The problem with sitting with your back to the screen. There we go. Sorry.

Now, these numbers were at the time of our inspection report. They have since been refined, and the highest dose that is there, 591, is no longer the highest dose. They have revised doses, the highest now is 319 rem. However, there still remain five individuals, or five boxes, if you will, that were over 250.

Now, the indium-111, they were hand-labeling vials of the product. And even though it is a state regulated material, since Part 20 talks about controlling of NRC licensed material to ensure your total dose from licensed and unlicensed doesn't exceed our regulations. So Part 21

applies because these workers also handled byproduct material at the facility.

Now, the vast majority of the activity they utilized was state regulated, but our Part 20 does still apply because they had combined doses.

This was repetitive handling, individuals handling from 100 to several thousand vials a year, nominally 20 millicuries or so per vial.

In this case, again, they had to go back and interview people, some no longer at the facility, trying to determine how people -- what people's technique was, what the production runs had been, and so forth. So, a complicated process in order to try to determine the doses to these individuals.

Of interest here, they did have an automatic labeler. They had it attached to another production line that they were trying to get up and operational, but they had a lot of engineering problems with it. You know, basically, it was right behind them in the room. After this all came to light, they were able to make the automatic labeler portion of that production line functional, so that was one of the corrective actions they took.

DR. NAG: One question. Indium-111, does anyone know what energy and is that placed in a glass vial or in a shielded vial? Does anyone know?

MS. PEDERSON: Can I get help from the back?
MR. CAMERON: It was a glass vial.
DR. NAG: Indium-111 is the gamma or what energy?
MR. CAMERON: It is a gamma emitter.
DR. NAG: Energy?
MS. PEDERSON: It was a glass vial, gamma emitter.
MR. CAMERON: We don't know what the energy was.
MS. PEDERSON: We don't know what the energy is.
MS. SCHWARZ: The range of energies is low level X-rays as well up to 300 KEB.
DR. NAG: Do you have it in high?
MS. SCHWARZ: Both sides above 40 is at the bulk, I mean it is 143 -- 20, I think.
DR. NAG: Energy makes a big difference how you are handling it.
MS. PEDERSON: Yes. The third area, which had over 50 rem, however, not quite as high as the previous two areas, was their Sterility Laboratory, so it was a quality control function. They were handling both NRC regulated and non-NRC regulated materials.
In this case they were very concerned about maintaining sterile conditions, and they were concerned about introducing potential sources of contamination, non-radiological, but contamination of the product. So they weren't always using appropriate shielding, vial shields or

syringe shields.
Again, this was a case of repetition and, basically, small amounts each time, but over many, many times, the accumulated doses added up significantly.
DR. WILLIAMSON: What exactly were they doing?
MS. PEDERSON: They were taking samples of basically a lot of pharmaceuticals to test it to ensure, I believe through FDA process, that they had sterile or aseptic conditions such that they ensured the injectable product was safe for human use.
DR. WILLIAMSON: So that they were handling the small aliquot that was removed as a sample?
MS. PEDERSON: Yes.
DR. WILLIAMSON: Not the large vat or whatever.
MS. PEDERSON: Correct. No, they were -- I'm sorry, they were drawing the aliquots from the larger batch.
DR. WILLIAMSON: Okay.
MS. PEDERSON: And then doing the testing on the aliquot.
Yes?
DR. WAGNER: Could you clarify, first of all, how this was initially discovered? Obviously, it precipitated an inspection, but how was it initially discovered?
MS. PEDERSON: If you go back to what I called Number 1, the Molytech generator event, where an individual

had a high ring badge and, during investigation, they determined the individual was handling the material in close proximity to the radioactive material. Their investigation from that event broadened and they looked into other areas of their manufacturing to determine were other people handling, in near proximity, radioactive material that was unshielded?

And as they started to look, they found more and more areas where people were doing this. And so they basically, you know, went out and asked people, are you doing this? How are you doing this? How are you handling the material? And as they did they, they identified that people were basically handling material unshielded.

DR. WAGNER: Who is they?

MS. PEDERSON: Mallinckrodt.

DR. WAGNER: Mallinckrodt. So the finding of this all was precipitated by actions within their protocols to investigate things and it wasn't brought on by necessarily an overexposed reading initially?

MS. PEDERSON: Correct. Correct.

DR. WAGNER: It was brought on by just a high reading.

MS. PEDERSON: Correct.

DR. WAGNER: And then an initiative on the part of Mallinckrodt to self-investigate themselves as to what was

going on, is that correct?
MS. PEDERSON: It was their investigation that discovered these things. The self-initiation part, it is a little hard to state exactly --
DR. WAGNER: Well, that is what I am trying to figure out.
MS. PEDERSON: -- because the NRC was there as well, asking questions. And so you never are able to fully understand the separation.
DR. WAGNER: Before the NRC was ever notified, before they were notified, --
MS. PEDERSON: Yes.
DR. WAGNER: -- what was the event, what were the events that caused them to do this investigation, prior to notification of the NRC?
MS. PEDERSON: It was the Molytech generator column event. They received a high badge reading. They began their investigation of the Molytech generator event. We then arrived the next day, and then, at that point, with questions and so forth, all of it expanded into looking. But the licensee was the one who did identify the issues.
MR. DIAMOND: A question.
MS. PEDERSON: Yes.
MR. DIAMOND: So in hindsight, once this investigation by Mallinckrodt commenced, a number of high

exposures were identified going back in the prior years?
MS. PEDERSON: Correct.
MR. DIAMOND: Why do you think there was no success in identifying these high exposures in prior years? What policies were not in place, or were in place but not effectively used?
MS. PEDERSON: There were a number of opportunities where we believe Mallinckrodt should have identified these earlier. They had other high badge readings that we don't believe they fully examined the possibilities of why that was and what the techniques were.
There also was a significant failing on Mallinckrodt's part to recognize the difference in their badge readings and the dose rates the fingertips were receiving. Mallinckrodt knew people were handling material this way, both supervisory staff and HP staff, and they did not recognize the difference. They were relying on the ring badge.
Also, and we will get into that later, but there were --
MR. DIAMOND: This is the real problem.
MS. PEDERSON: A clear problem, a huge problem, yes, on this disconnect between recorded dose and actual dose and the failure to recognize that difference.
DR. CERQUEIRA: But a problem that generalizes to

everything that we do, and perhaps, you know, a corrective action in the regs that would not so much, you know, require that people do a translation from the dose at the ring badge versus the tips.

MS. SCHWARZ: Can I ask a question? What were the actual identified hand doses? Are these the hand doses of the projected fingertips?

MS. PEDERSON: These are the projected fingertip doses.

MS. SCHWARZ: Were the hand doses themselves in excess of state and federal limits?

MS. PEDERSON: The ring badge doses were not in exceedance.

DR. WAGNER: I think the issue then, if we are defining this, and it is really important, I guess, to get to the issue, as I understand it, there was training of these individuals, correct, who were handling it?

MS. PEDERSON: Yes.

DR. WAGNER: So they were supposedly trained?

MS. PEDERSON: Yes.

DR. WAGNER: However, upper management and staff were not recognizing that handling of these things were causing high doses to the fingertips versus what was being read on the badges, and they weren't investigating that initially or taking the initiative to look into that issue,

is that correct?
MS. PEDERSON: Yes.
DR. WAGNER: So the lesson that is learned is that even with supposed training, if you don't specify these little subtleties and emphasize the need with regard to these kinds of little caveats in our training, and the fact that the ring badge is not going to pick up the fingertip dose, which we all know, I mean that is something that is terribly obvious, then the fact is that training breaks down, and then the training breaks down when the staff and those in charge don't take initiative when you get a high badge to the fingers. So that is basically the Lessons Learned here.
MS. PEDERSON: On the licensee's part.
DR. WAGNER: On the licensee's part.
MS. PEDERSON: There are some things that, and when we examined our Lessons Learned, we were focused on our regulatory programs, and we think there are enhancements to our regulatory programs from an oversight standpoint that we should take as well.
MS. SCHWARZ: What were the actual reported finger badges, the hand doses?
MS. PEDERSON: James, do you recall?
MS. SCHWARZ: Range, I mean were they of a stature such that --

MR. CAMERON: Do you mean in previous years?
MS. SCHWARZ: No. Since these are fingertip calculated doses, what were the actual hand doses that were coming back that were essentially not calculated to project fingertip?
MR. CAMERON: The actual recorded doses of the badges in previous years was in the neighborhood of -- Sterility Lab, I think the highest dose was 17 rem a year.
MS. SCHWARZ: Seventeen to the hands.
MR. CAMERON: Right. For the staff that were involved in the labeling of the indium vials, from that activity, doses were typically in the range of 300 to 400 millirem a week. So on the same order of magnitude, about 15 rem a year.
MS. SCHWARZ: Okay.
MR. CAMERON: The difference, because of the handling of the indium, the true dose rate to their fingertips was about a hundred times what the badge would say.
MS. PEDERSON: I think I need to pick up the pace a little bit. Let me try to keep you guys on schedule for today. I hate to start you off late on your first one, and, you know, everybody else gets compressed.
Harrisburg was a very different event. It was one pharmacist who accumulated dose over the first half of the

year, so we are talking about a more isolated kind of issue. But it brings up some very interesting things. Let me first talk about the actual doses, and the way this is, I have got it laid out, I think you have to go back to page 1, because we had the chart in between. I think it is on the bottom, is that right, down there in the corner? Okay.

If you look at the doses, a new pharmacist began in November, got a little over 2 rem in December. He was in training in January, so at that time they didn't -- off the Mallinckrodt dosimetry records, it didn't have anything. They later got something from the training program. February dose was a little over 8, March dose was over 26, so a cumulative would have been 34. April, another 13, and May put him over the 50 rem.

But what you will notice is Mallinckrodt didn't recognize that real time. So now let me take you to the column on the left. There was about a two month delay between the actual receipt of the exposure and when they got the dose records back and evaluated from the vendor. So this two month delay was very significant in this case as far as their failure to recognize this person was going to exceed the 50 rem.

Now, there were reasons that the individual was picking up more exposure that expected. He was new, his technique was not very good, he was not very proficient, and

they weren't overseeing him to the point where they recognized these things. Early on, in the first couple of months, he was doing second and third run production, which is lower production quantities and volumes, but in May he began to be the only radiopharmacist on first run, which is the highest production run, and the highest production pressure.

A couple of times during the first several months, the RSO did talk to the individual about his technique, but it wasn't enough to get the individual to not exceed the requirements. This individual was also not using the prescribed shielding. He wasn't using -- he was using a bullet type shield versus the flange shield, which they required by procedure, or their expectation, and the guy was not using forceps either. He felt he could draw doses more quickly without using that.

He was focused on production. And, as I said before, sometimes he would have to draw a dose two or three times to get the right dosage, so proficiency, production, lack of adequate oversight, all of those things led to him having the high exposures. And then the lack of demanding good vendor performance prevented -- or basically didn't give them real time information. And so by the time they put it all together, it was too late, he had already exceeded the 50 rem exposure.

DR. NAG: Cindy?
MS. PEDERSON: Yes.
DR. NAG: What is the usual turnaround time from the end of the month till you get the film badge reading back? Is that on the order of a few days, a few weeks?
MS. PEDERSON: Anybody who can help me on that one?
DR. WAGNER: I can help you from experience.
MS. PEDERSON: Yes.
DR. WAGNER: If you don't have a special agreement with your supplier, it is about two months, okay. That is very consistent with that. But, usually, you make an agreement with your vendor and say, if a badge reading exceeds this level, call us and let us know so we can look into that. And that is apparently not what happened here, because in June you got this 27 rem badge reading that is just not apparently getting called to the RSO to say, hey, we got this high reading, thought you ought to know about it.
MS. PEDERSON: Actually, in May they did get a call.
DR. WAGNER: They did?
MS. PEDERSON: Yes. But the problem being is there was a confusion on whether the actual dose that they were talking about the 26 rem dose for March, confusion, the

licensee believed that was the cumulative year-to-date exposure, and it wasn't, it was the monthly exposure.

So there were -- and, also, after that point, they also had confusing information provided to Mallinckrodt regarding what the cumulative dose was for the year.

DR. WILLIAMSON: What was their action level for investigating a potential overexposure? It must be substantially less than 50 rem.

MS. PEDERSON: They did, and I don't recall. Joe or Jim, do either of you recall? I remember they had ALARA levels, but one of the failings at this pharmacy was, even though they exceeded their action level, they didn't take adequate corrective actions in order to deal with it.

DR. WILLIAMSON: Because even if they had mixed up and thought 26 was the cumulative, I would have assumed that would be over an reasonable action level for investigating.

MS. PEDERSON: It is. The prior year's radiopharmacist's doses were in the range of 20 to 29 rem for the entire year. So, clearly, even if it was a cumulative exposure, you are correct, it exceeded what you would expect.

DR. WAGNER: Not only that, he was working the third shift up to that time basically.

DR. NAG: Another question. These are actual film badge readings and not calculated readings?

MS. PEDERSON: Yes.
DR. NAG: Okay. Thank you.
MS. SCHWARZ: What isotopes are they working with?
MS. PEDERSON: I'm sorry?
MS. SCHWARZ: What isotopes are they working with?
MS. PEDERSON: The majority are tech 99 M, but they also had thallium and other radiopharmaceuticals as well.

Now, I will try to break into actually the Lessons Learned initiative, now that I have given you the background of why we had one. We put together a team of NRC and also a state representative to do our work at looking at our regulatory programs. And, again, this was focused on lessons to be learned by the regulator, not lessons to be learned by the licensee.

Because of the numbers, duration, two facilities, same corporate oversight of Mallinckrodt, the Office Director, Bill Kane of NMSS, determined we should have an agency-wide Lessons Learned initiative. I was asked to lead that. We had regional representation from the other regions. We had two individuals, Joe was one, from NMSS. Marjorie, we had OGC counsel. We had a representative of the Office of State and Tribal Programs, Research, Human Factors persons, and, also, we went through CRCPD to get a state person, and we had an individual from the Commonwealth

of Pennsylvania.

We began in September, finished up the bulk of our work in October and we are in the very final stages of putting our report together. We were asked to look at a number of areas, requirements, particularly the issue of total dose. This is, I mentioned earlier, the summation of NRC regulated and non-regulated materials.

We also looked at our licensing program and guidance, our inspection program for reactive, generic, if you will, or broad, and also reactive inspections. We also looked at our interactions with other regulators, predominantly the state, but we also considered others. And we also looked at how well we had implemented our existing procedures and guidance.

Since our strategic plan has overexposure measures, we wanted to look at that and see if there was any implication there. And, of course, product would be recommendations, and, of course, you have to document your recommendations, so those are the last two steps.

And when we looked at recommendations, we put them in context of the four agency performance goals, those being maintaining safety, enhancing public confidence, increasing our effectiveness, efficiency and realism, and reducing unnecessary stakeholder burden.

Just a minute on the process. We basically looked

at the weaknesses or problems on the licensee's performance. We looked at possibilities where NRC could have had an impact or identified something earlier. When we looked at all of those and tried to sort them, they predominantly fell into licensing and inspection, with a little bit of legal and a little bit of interaction with other agencies.

We then developed our recommendations, of which we came up with quite a few. And then we basically came to a consensus as a team on what those findings were. Also, the team did prepare two draft inspection procedures to try to get a quick start on implementation of some of the recommendations.

One of our mission items was to determine whether the NRC did have an impact on these overexposures. And what we concluded was nothing we did had an impact or contributed to the overexposures occurring. Those were all within the licensee's control and the licensee being responsible for their own performance.

What we did identify, however, in the case of the Sterility Lab at Maryland Heights, was we missed an opportunity to have observed those activities which could have led to earlier identification of the issue. That was based on a couple of factors, one being perceived low risk in this area. We understood they were handling small quantities of material and we, too, we looked at the dose

records that they had which showed doses well within regulatory requirements.

The second piece of that is entry into this laboratory is quite difficult from a sterility standpoint, as you would expect. You have to ensure anything that comes in, people included, have the appropriate type of dress and so forth. And those two factors in combination dissuaded us from looking at that lab, yet, there were many other areas that we looked at, real time observations, including middle of the night kind of things, and we just hadn't gotten to this yet.

DR. CERQUEIRA: A question from Jeffrey.

DR. WILLIAMSON: But there wasn't -- would there have been any opportunity to observe the hand-labeling?

MS. PEDERSON: Interesting. I was going to mention that. For us, no. That was the state regulated material and we didn't have jurisdiction to observe that one.

DR. NAG: One question. In hindsight, you are calculating the fingertip dose and you found many of these because this is calculated rather than ring badge dose.

MS. PEDERSON: Yes.

DR. NAG: Did you already have in force any regulation that requires the licensee to take radiation exposures at different parts of the body other than the ring

badge?

MS. PEDERSON: We don't prescribe how they do, but we do have -- our regulations would require that they do record the maximally exposed dose, or maximally exposed area dose. Therefore, they would be obligated to determine, by whatever means necessary, to make that kind of dose assignment.

DR. NAG: Are you aware of any other manufacturers that are giving you doses at areas other than the ring?

MS. PEDERSON: Well, we are going to start looking into this area, and that is -- I will just jump to that now. We have a temporary instruction which is an inspection tool we utilize as an agency to go out and look at potential licensees that have the possibility of basically direct handling of material.

In addition, soon after these things came to light, we put out an Information Notice to our licensees, I hope you folks have seen that, talking about these kinds of problems, to make licensees aware that this possibility exists and we have seen it.

So, twofold, we have communicated with licensees. We are going to be doing a temporary instruction inspection in the near term, and then a number of our recommendations enhance that area as well.

MS. SCHWARZ: And your recommendations are now

including calculating fingertip doses, if that is deemed --

MS. PEDERSON: We are going to -- one of our recommendations is to enhance our guidance documents that have a discussion more about extremity monitoring.

I see I am getting really close here. So let me jump to -- again, these recommendations are not final. The report is not final yet. NMSS and the regions will examine the recommendations the team came up with to determine what we are going to actually implement. Along with everybody else, we have limited resources. You know, we came up with several dozen recommendations, some of more value than others, obviously.

But let me just give you a flavor of some of the ones that we think are more helpful. In the inspection area, these are basically enhancements to our existing program. We think in many areas they will make us more efficient, effective, and we also think they will have a positive impact on safety.

One thing, since the one area where we missed our opportunity to observe earlier was the Sterility Lab, we are suggesting we ensure our inspectors meet the entry requirements into areas where -- or all areas where licensed material is used, even if that is an onerous process.

We also want to encourage greater joint inspections between the NRC and the states. In the past we

have always notified states that we are coming. This time we want to make it a little bit more proactive and saying we would like to go out within the next quarter. When can we do this together? Because we really found benefits in going out with the State of Missouri on our Augmented Inspection Team, because it gave us the ability to look at all the rad material including -- you know, radiation is radiation, you know, why this is NRC's or this is the state's? So we are trying to encourage joint inspections.

Also, we want to put in our guidance documents the expectation to do off shift inspection. Many of our people have been doing it, it is the right thing to do, to go see first runs at pharmacies. Unfortunately, our guidance is a little behind the times, saying we should occasionally do that. Well, that should be the norm. So we are looking at trying to change our guidance documents to our inspection staff.

We also want to ensure that our workers -- excuse me, we evaluate workers' knowledge of risk, getting to this issue about radiation versus contamination. Do they realize truly what the contact dose rates are of the material that they are manipulating and so forth?

Also, as we touched on earlier, evaluating the extremity dosimetry. Is it truly reflective of the maximum dose?

And my last slide, again, licensing. Again, we want to enhance some of our guidance documents to ensure our license reviewers and our licensees are cognizant of these types of issues. And, also, we want to have more site visits for our license reviewers for significant licensing actions.

And then just the last kind of cats and dogs area, the National Materials Program, and I am sure many of you are familiar with that agency and state initiative that is being looked at from a very broad perspective on, you know, how should we, the nation, regulate our radioactive materials? And we think there are some insights from the Mallinckrodt Lessons Learned experience that we can share with the National Materials Program Working Group and Steering Committee.

Corrective Action Programs, we touched on briefly. Mallinckrodt, as a part of their order, will have a required Corrective Action Program at the Maryland Heights facility. We are looking at a recommendation to look at other high risk, complicated, large facilities that also should have a Corrective Action Program. We are also wanting to ensure we disseminate risk information to our staff in an appropriate fashion and for appropriate use.

And the last one is more of an administrative type issue, but it is something that, to facilitate our

expectation of inspectors going out in the middle of the night to look at manufacturing or a pharmacy, or radiography, for that matter, that we have the backup administrative system to support them from a time and attendance standpoint.

Hopefully, my goal is in November we will have the report to Bill Kane. And then, as I said before, NMSS, with input from the regions, will evaluate our recommendations and determine what should be implemented. And I am about a minute behind. Sorry.

DR. CERQUEIRA: Excellent job. Ruth?

DR. McBURNEY: From an Agreement State standpoint, I certainly agree that the licensing program, the site visits are really important for the licensing staff to go out prelicensure. Over the past few years we have licensed several production facilities, primarily cyclotrons and accelerators for production of radiopharmaceuticals. And just to see the process and look at, you know, potential areas where exposures might be obtained and address those in the licensing process is real important, so that you are not just sitting at a desk looking at a picture, you are actually going out there and seeing how the process is going to work.

MS. PEDERSON: We agree, and currently we do some of that. Our recommendation is do some more.

DR. CERQUEIRA: Dr. Nag.
DR. NAG: I would like to know how does the license now read measuring the maximum dose to the part of the body? I mean is it something like very unambiguous or is it something that can be set where the ring badge is all we need?
MS. PEDERSON: We have not come up with a specific language to go in the licensing guidance or the inspection guidance in most cases. We have our list of several dozen, and the likely process that will be used is that will be turned over to the working group working on that particular licensing document. They will then determine what the correct words are.
DR. NAG: One of the things, you know, you are trying to identify what things NRC would have done. Would you not have had the language more appropriately written or more explanatory so that people would not say, well, the maximum reading of the ring badge and that is all we need? Isn't that a lesson that you could have learned?
MS. PEDERSON: Yes, it is, and that is why one of our recommendations is to improve the language. If you saw the document, the way we have got is a lot of things we have identified as needing enhancement or improvement, and then we have suggested that it be incorporated into this document or that document.

DR. CERQUEIRA: Good.
MS. HANEY: I was just going to comment on what Dr. Nag said. I think the question has a little bit to do with the wording in Part 20 for the occupational dose limit. And I don't have Part 20 in front of me, unfortunately, but I think it basically just says that the licensee has to limit the dose, as Cindy said, the maximally area to whatever, depending upon whether it is the whole body or the extremity.
You run into a Catch-22 if you get very specific here about the fingertips. You know, you are also going -- Part 20 is probably our best performance-based rule that we have for the materials licensees. So I mean you are almost, to get to the point of you must assess it in this case to the fingertip or whatever, you go against what we are trying to do and taking away some of the flexibility for the licensee. But the tradeoff there is that the licensee needs to, you know, is to be able to think ahead and actually decide what is the maximally exposed area.
DR. CERQUEIRA: Sally.
MS. SCHWARZ: I would make the comment that I would doubt any licensee actually calculates fingertip exposures, that they have assumed to this point in time certainly that the actual ring badge is reflective of what they are looking at and are required to look at, and that

this calculation, certainly, was discussed in our institution. It is not something that routinely is done by licensees.

DR. CERQUEIRA: So you are recommending that perhaps more regulation in this case would be --

MS. SCHWARZ: No, I don't think more regulation at all is required. I think that that would be counterproductive.

DR. CERQUEIRA: Okay. Jeff.

DR. WILLIAMSON: I think you may have mentioned it, but I think maybe the most useful thing would be to write an Information Notice and send it to all Part 35 licensees.

MS. PEDERSON: I am surprised at the response.

MR. CAMERON: It has been done.

MS. PEDERSON: We have. We can certainly get you another copy, though. And I don't have one with me, but I am sure we can get you one. Would it be helpful if we brought a number of copies down before you adjourn today?

MS. SCHWARZ: Yes.

MS. PEDERSON: Okay.

DR. CERQUEIRA: Richard.

MS. PEDERSON: Also, I am sorry, I think James had a response for some clarifying information.

DR. CERQUEIRA: James and then Richard.

MR. CAMERON: The issue of calculation really doesn't come into play for most licensees. In the case when shielding is used, I think the Society for Nuclear Medicine published a study several years ago where they did dosimetry studies on technologists' hands, and found that there was very little variability if you were handling shielded containers.

What is important is when you are handling unshielded containers, the dose gradient near the surface of the container is so much higher than in a shielded container that that is the only time when it would really be necessary to do that kind of calculation. For most licensees it wouldn't be an issue.

DR. CERQUEIRA: Richard.

DR. VETTER: I wanted to make that same point. Number one, that for most licensees, if they are using syringe shields, it should not be a problem. I think it is good for them to check, though.

The second point I wanted to make is I wanted to compliment the NRC and this task group on putting together what I perceive to be a very forward looking interdisciplinary project that is directed toward giving licensees some good technical guidance rather than looking for screwing down -- making the regulations tighter.

MS. PEDERSON: Thank you.

DR. WAGNER: That is very good.
DR. CERQUEIRA: One last comment from Lou and then we will move on.
DR. WAGNER: Just one question, if the licensee, and the people handling these isotopes, had followed procedure, then would the ring badge have correctly reflected what their hand dose was? I think that is the critical issue with regard to this particular situation.
MS. PEDERSON: No, I don't believe so.
DR. WAGNER: And the reason is?
MS. PEDERSON: I need to break it down into the various areas. The Molytech generator, had they followed procedures, that exposure would not have occurred because the individual would not have been doing that manipulation. However, in the indium lab, this was the expected approach was hand-labeling.
DR. WAGNER: Oh.
MS. PEDERSON: Now, there was variability clearly in how people handled the material.
DR. WAGNER: Right.
MS. PEDERSON: But, as I mentioned, they had an automatic labeler, it wasn't operational, so they fully expected they were doing the hand-labeling.
DR. WAGNER: So the real correction in this issue is to change the way they are supposed to be doing things,

and then to make sure that their employees actually do it the way it is supposed to be done.

MS. PEDERSON: Yes.

DR. WAGNER: That is the real correction.

MS. PEDERSON: Using engineering controls, procedures, appropriate oversight, many things.

If anybody is interested, we can make copies if anybody would like to read the inspection reports, for example. I have got a single copy with me, but if anybody would like them, I can leave those copies with Betty and maybe we can have more copies made if you are interested.

Thank you.

DR. CERQUEIRA: Thank you very much, Cindy, an excellent presentation.

The next item is NRC Agreement State Working Group on Event Reporting, and Kevin Ramsey.

There is a handout that is coming.

DR. WAGNER: We have to make sure your luggage passes the weight test.

DR. CERQUEIRA: You know, Cathy and I were chatting that it is amazing that this group seems to actually be going through the book before coming to the meeting, so in terms of the NRC personnel, if you can -- I know lots of times these presentations get put together at the last moment, but if you do have materials ahead of time,

it probably would save time because it looks like the committee will read them the material, and I think that would be useful to get it out before the meeting if at all possible.

DR. WAGNER: I also think this way is much better. This is a much better way to hand it out, because we can take notes on it if we have to, and it is certainly readable.

DR. CERQUEIRA: Okay. You know, Lou is going off the committee, so he has got to get his jollies in.

MR. RAMSEY: I am glad we are getting off on the right food here.

DR. CERQUEIRA: Kevin.

MR. RAMSEY: This presentation is just for information only. Our Working Group is doing a general review of Event Reporting, which, of course, touches on just about everything the agency does. So we just wanted to inform you what we were up to, just so you are aware of it. It is not particularly focused on any one particular type of event.

Back towards the beginning of the year, Don Cool, the Director of the Division of Industrial Medical Nuclear Safety, sent out a memo suggesting that this Working Group be formed. The goal was to improve the effectiveness, efficiency and realism of the event reporting area. And,

basically, it was just to assimilate what we have learned over the last few years. There has been a lot of changes in the programs and what we have been doing in the last few years.

We have established a Nuclear Materials Events Database and we have been working with that for several years now, so we feel like we are in a position to step back and take a look at it and see if that is -- how well that is working and where we can make improvements.

There has been a large effort to increase the sharing of the event reports from the Agreement States, getting them into this overall system so we can look at events nationwide.

And there is an NMSS Generic Issues Program which was completely overhauled a few years ago, and so that was another reason to take another look at it.

Now, the membership, it was decided that it would be a joint NRC/Agreement State Working Group. And the membership is pretty broad. For NRC, Mark Sitek and myself are representing NMSS. Kevin Hsueh is from the Office of State and Travel Programs. Harriet Karagiannis is a representative from the Office of Research. Steve Sandin is from our Incident Response organization. We have a regional representative, Linda McLean, from Region IV, and a facilitator, Agi Seaton, is a contractor.

From the Organization of Agreement States, Bob Danserau is from the New York State Department of Health. And from the Conference of Radiation Control Program Directors, we have Helen Watkins from the Texas Bureau of Radiation Control. So we have a pretty broad assortment of people on the Working Group.

This slide is just to let you know that we have pretty much been meeting either physically or by conference call once a month since April. The one thing you might note is that we did not brief a Steering Committee until September. That is because we didn't have a Steering Committee until September.

We struggled a good bit trying to get the charter approved. From about April through September, we were going through constant changes and revisions with the charter. And when we started off, the intent was that it was kind of a local, just take a look at this and give your findings to NRC management. It was kind of an internal thing. And the effort broadened a good bit over those months, and the decision was made that, well, we should have a Steering Committee, but rather than form a new Steering Committee, the National Materials Program Working Group already had a Steering Committee, so they just suggested that we report to them also.

So when the charter was finally approved, they

said use that same Steering Committee. And so we briefed that Steering Committee at the end of September, and we have had one conference call since then.

But just to run through where we are at now in terms of the charter, it was finally approved in September, and there is two primary areas. We want to review the information that is collected, and we want to review what we do with it after we get it. You know, just basic questions of, are we collecting the right information, and are we using it appropriately or effectively?

So the first task is to review the NRC's Strategic Plan, which is kind of our Bible right now, and identify what information, specifically, what event information we need to satisfy the Strategic Plan. And that plan is broken up into several chapters. What we are looking at specifically is the Materials Safety Chapter and the Waste Safety Chapter.

Then, once we have done that, we are to review the NRC regulations and identify what information we actually collect. Then compare the two, identify any discrepancies between what we need and what we actually collect, and recommend how those discrepancies should be resolved. And that is the biggest task, I think, and that is the one I think management has the most interest in.

Task two was to look at the guidance that is

provided to licensees and to consider whether improvements are needed to improve the reports that we get from licensees.

Now, I am not sure exactly how much discussion we have had, or you have had already, but --

MS. HANEY: Kevin, Don went over the Strategic Plan and the goals.

MR. RAMSEY: Okay. I just took a quick blurb out of some stuff in the report, if that is of any use to you. But, basically, in 1993, the Government Performance and Results Act was passed, and that basically requires all federal agencies to have these Strategic Plans which explain how they are going to accomplish their mission, and it sets out goals and measures. And then, of course, an annual report is required to Congress each year telling Congress how we did.

Now, just to give you an idea, we are currently drafting our report, but I will give you an idea of what we plan to do in terms of the comparison. We are going to have a Strategic Plan Table that will basically lay out what is the goal, how are we measuring it, specifically, what is the event measured. If it is not event related, we just won't address it any further. But if it is related to an event, what is the measure? And, of course, then what event data do we need to measure it? What regulation obtains it, if

any? In some cases, we don't have any regulations for some of these measures. And then, of course, what is missing or what is needed?

Now, under the regulations, of course, we will go through and list the citation, describe what the reporting requirement is, list the Strategic Plan link, and the link would be back to that column on the data that is needed. Which need does that reporting requirement satisfy?

We are going to list the level of Agreement State compatibility. We are going to take a shot at Safety Significance, and this will kind of be our own personal opinion, because it is not really clearly defined anywhere as to how to rank Safety Significance. And then, of course, any recommendations we have on any changes to the regulations.

So that is basically what we plan to do so far as the information that we collect. Now, what we do with the information after we get it, there is a task to review the information that is in the Nuclear Materials Events Database. There are some concerns that certain types of events may be under-reported, so they want us to take a look at it and assess if we think we are missing stuff, and, of course, recommend any improvements.

There is also a task to review the NMSS Generic Issues Program and identify opportunities for improvement.

Step back and take a very broad look at what analysis should be done, who should be doing them, when should they be done, and, of course, how should the results be utilized.

Specifically, we are looking at internal stakeholders and internal is like NRC regions and Agreement States. It isn't so much the general public, but we are looking at how the various regulatory agencies should be sharing this information and how we should be using it. One of the complaints that we have gotten from the regions and the Agreement States is they spend an inordinate amount of time trying to feed this database, they don't feel like they are getting very much back from it. So we want to look at that and try to make recommendations.

DR. CERQUEIRA: We have a question from Dr. Wagner.

DR. WAGNER: Have you any idea how you are going to assess whether information is under-reported?

MR. RAMSEY: Well, --

DR. WILLIAMSON: And under-reported by whom?

MR. RAMSEY: During the IMPEP, there is a program where the regions and the Agreement State programs are reviewed, it is referred to as the IMPEP program, Integrated Materials -- something -- Evaluation Program. I forget what the initials stand for. But each year the program, each of the programs -- a few of the programs are assessed, and that

has been done.

I think all the Agreement States and the regions have been reviewed within the last four or five years, and some of those reviews have found that there are programs where some of the events weren't getting recorded or shared, or whatever, in a timely manner.

DR. WAGNER: Is this internally amongst you?

MR. RAMSEY: Yes.

DR. WAGNER: So it is an internal information assessment, not a matter of trying to assess whether or not licensees are under-reporting, is that correct?

MR. RAMSEY: Right. I mean there is internally, but also we can go back to some of the inspection findings and look at how often licensees were cited for not reporting events. If the inspection came in, reviewed the records, found the reportable event, the licensee failed to call in. So there is enforcement information out there that is an indication of whether licensees are just not recognizing that they have something that needs to be called in.

DR. WAGNER: And you are basically taking information that is internally existing, going back looking at your records?

MR. RAMSEY: Yes.

DR. WAGNER: And trying to pull them together to say --

MR. RAMSEY: It is not an easy thing to get a handle on. They just wanted us to take a look at it and see if we had any reason to believe that we were missing certain types of information. There is a lot of anecdotal evidence floating around that give people reason to believe that maybe we don't have a handle on everything.

The last task was to look at the computer systems that are used. There are several computer systems that are used to both create the reports and track the reports, and archive the information.

So just examine, do an overview of the systems that are out there, and specifically address several questions that came out of some previous reviews.

The first one is a concern that's been raised by the Agreement States, that NRC should delay posting event reports on their website. A lot of times -- well, not a lot of times, but there are some occasions in the past where Agreement States have called us right away and said, hey, we just learned of this.

And the way our system is set up, we basically turn around and post that on the Internet the next day. And a few states got in situations where they hadn't even gotten an inspector out to the site yet, and the media was already calling up saying, hey, what is this?

And some states suggested that some of these

events should be held until the states had it, you know, a day or two to follow up, get the inspector out there, find out what's going on, before everything is released to the public.

So were asked to take a look at that to see if the posting of the information should be delayed a day or two, which isn't really unheard of, because we do that routinely with releasing reports, anyhow.

Another question was, should NRC have one agency-wide tracking system? During some of these program reviews of the Regions, it was discovered that we're all -- we all have different ways of tracking our followup actions.

Is that a bad thing, or should we all be doing it the same way? So we were asked to take a look at that. We were asked --

DR. CERQUEIRA: Kevin, if I could just -- you know, perhaps -- we've got the Committee here. Part of this is an information for us, but is there any kind of input that you want from us on, say, appropriateness of some of these things or other items that might be important to look at?

MR. RAMSEY: Quite honestly, given the point that we're at, we're writing the report right now. I mean, I would welcome any comments you have, but I don't know that I'm in a position to go back and do any more research than

we've already done.

DR. CERQUEIRA: Okay, so, are you going to go over the results of some of the findings then, right?

MR. RAMSEY: Well, I don't have a lot for you at this point, because like I said, we're trying to figure out what the results and findings are.

I will note that we issued a questionnaire to the Regions and Agreement States, asking for input. That was issued in July, and we got responses from 21 of the Agreement States, about two-thirds of the Agreement State Agencies responded, and, of course, all four NRC Regions responded.

The results of that, just in general, from a guidance standpoint, when we asked them about what guidance they provide the licensees, basically everybody provides licensees with copies of the regulations.

There's not -- some people provide a little more, but not much. And it was noted that if tools could be developed to help licensees maintain an awareness of the reporting requirements, that would help, because right after they go through the licensing process, and, of course, right after they have an event, they are very much aware of the reporting requirements.

In between, a lot of licensees lose track of what it is they're supposed to be reporting.

DR. CERQUEIRA: Dr. Wagner?

DR. WAGNER: Reporting is an extremely difficult issue. We recently had several circumstances that occurred at our facility where we knew what to do, logically, but then the question came down to do we have to report it?

And I admit that I went to the regulations and I said, holy cow. I mean, how am I going to find that in here?

They had just changed the regulations in some parts. We had just got new stuff in. It's not collated yet, and it's impossible to find it.

I don't know if it exists, but it really would be nice to have a search engine or something available on the Web, or some easy-to-find thing where you can go in and you can say, okay, these are the key words to what happened.

Now, do I have to report it? Let's see whether there are rules on reporting things like this? That would be very helpful to users, to know what it is has to be reported, what are the regulations with regard to reporting?

Do I have to report this in 24 hours? Do I have to report this in 30 days? What's the whole issue here?

And with us, obviously, our answer is simply, okay, we can't figure it out, so we're going to call the state and ask them what the heck the rules say. Then, of course, they say, we'll get back to you.

Okay, so those are the situations, and I think it is difficult to know, and regulations are not written in a way, at least from the state of Texas, because that's what I'm familiar with, that I know exactly what to do when something occurs under my license.

And a real clean way of knowing what to do would help the users real well with regard to reporting.

DR. CERQUEIRA: So you're recommending sort of a Web-based system with a user-friendly interface and a good search engine to be able to search specifically for things within the regs? Is that something that's doable or in the works?

MR. RAMSEY: Oh, yes. I mean, it's easy for us -- for our working group to sit here and say we recommend somebody to do this, somebody else go out that actually has the responsibility to go do it.

DR. CERQUEIRA: I guess, Ruth, from the States -- does Texas have a user-friendly Web --

DR. McBURNEY: We have all our regulations on a website. One of the things that we're going to be doing in the future is trying to improve that website so that people can look up various items.

MR. RAMSEY: But I know that one of the common complaints, especially on the NRC regulations -- and this is just the way our regulations are set up -- that the

reporting requirements are applicable to any single licensee, are scattered.

DR. WAGNER: Yes.

DR. CERQUEIRA: Or, as license amendments in some cases with modifications.

DR. VETTER: Just to follow up on Lou's recommendation about being able to search, is it possible to put together a NUREG or a guidance document that simply pulls them altogether so that if I don't know that I have to report, I just pull that NUREG off the shelf and it will lead me through the reporting process, or whether it -- or the information on determining whether or what I have to report?

MR. RAMSEY: Well, there was one large NUREG that the NRC put out a few years ago. I don't know that it was very helpful, but it pulled all the requirements. It was just a big list of all the reporting requirements and all the recordkeeping requirements in the regulations.

But, again, since it was all requirements for all types of licensees, you still had to go through and pick out which ones applied to you.

DR. VETTER: It didn't have a decision tree in it?

MR. RAMSEY: No. I mean, it was just a laundry list of what all was in the regulations.

What we've looked at is -- we've recently gone

through a guidance consolidation effort on the licensing guidance, and we've put out a series of NUREG reports which basically replace the standard review plans that we had, saying, here's the guidance for portable gauge, and here's the guidance for fixed gauge, and here's the guidance for medical, and on and on and on.

And in those, it's a little bit -- it's addressed a little better as these are the reporting requirements that are applicable to you for this particular type of licensee.

And we took at a look at that and said, we've got that for licensing, and that's pretty good; why don't we just take that, maybe improve upon it a little bit, and make that -- use that same tool for both the inspectors and the licensees, so the inspectors can have one list of the requirements that are applicable to that particular type of licensee, and use that when they go out on inspections to remind them that this is what's reportable.

DR. CERQUEIRA: I think this sort of approach would be helpful, and that again would simplify it.

Dr. Nag, and then John.

DR. NAG: Particularly what Lou suggested, is really doable, I mean, having a search engine and so forth. But therefore, it does require resources in -- and it requires quite a lot of technical resources to develop the webpage and put the search into that.

Now, is this the function of the ACMUI to suggest or recommend that some of the resources of the NRC be used to develop such a search engine?

I mean, NRC is spending a huge number of manhours developing all these regulations, and if people cannot find the regulation, it's not that helpful.

So, can we make that recommendation?

DR. CERQUEIRA: I think that they look to us as the end user. We provide them feedback with what we or our professional societies that we represent are finding as problems.

I certainly think we can make that recommendation. Whether it's going to be acted upon is sort of one of a budgeting item, but I think people are getting the flavor of it, you know.

Web-based applications reduce costs, make a lot of things possible that aren't possible in paper copies, and it's definitely the way to go.

And if we look at all other applications that most of the things we do, banking and everything, it's all being done in that format. This would be useful.

John?

MR. GRAHAM: Well, I think I'm raising the same point, but from a different perspective. Going back to the goal that was set for the group, it was to improve

effectiveness, efficiency, and realism.

Has your group discussed trying to identify the outcome, the information, the knowledge that's gained out of all of this reporting, in quantifying the potential benefit that comes from it, so that you can get into a cost/benefit analysis. I would start from 40,000 to ask the question of maybe it's not under-reporting, but maybe there's over-reporting going on.

Maybe the benefit from all this reporting is so negligible in terms of the behavior modification in the field, that instead of investing in web-based sites with search engines, a cheaper solution would simply be to quit doing it.

[Laughter.]

DR. CERQUEIRA: Do you have a motion?

MR. RAMSEY: If you go back to the tables, I think we're going to touch on that. It's going to be up to management on how to proceed with it.

But those tables that I showed you for the strategic plan and the reporting requirements, going through all reporting requirements we have on our regulations, and saying does this even fill any need under the strategic plan? And I suspect that the answer for a lot of reporting requirements is no.

Well, we don't even need it for --

MR. GRAHAM: That was my last comment.
MR. RAMSEY: So the obvious question is going to be, well, should we get rid of that reporting requirement?
MR. GRAHAM: At least in management in the year 2000, one of the tools we're developing now is that people not only need to do lists, they need to start generating what not to do lists. It's like what did you did, what have you done, and with the 40 things we're asking you to do today, you cannot continue to do the other 50 things you did in the past, and you've got to prioritize.
We probably aren't as effective at identifying what not to do as we are creating these huge to-do lists that never get completed.
I'd strongly encourage the group, that, yes, there's an opportunity here, potentially, to say, you know, there's very little incremental information of benefit that comes out of this, and potentially the recommendation is just to quit reporting it at all.
MR. RAMSEY: Yes, I think we're going to come out -- I entirely expect to come out with recommendations to change things in the regulations, and I expect to make recommendations to change things in the strategic plan.
Because when some of those things were worded, it sounded great from maybe a policy standpoint, but I don't know that anybody stepped back and said, is anybody going to

be able to make sense out of this, because we're bumping into things where the strategic plan talks about releases to public domain.

Public domain isn't defined anywhere. In the regulations, we don't deal with public domain, we deal with restricted areas and unrestricted areas, which isn't the same thing.

So we're in a situation where we're trying to gauge these measures and we're taking the event reports and we're having to interpret them to figure out if we should count it under the measure or not.

And we're getting into trouble with those interpretations, because half the time, it never gets interpreted the same way twice.

DR. CERQUEIRA: Jeff?

DR. WILLIAMSON: Yes, to bring this back to radiation medicine, I notice that in Part 35 there is a subsection or Subpart M and L that have the reports and recordkeeping. Are those complete? Is there anything in Part 35 that's not listed as a reportable event in Subpart M?

MS. HANEY: No, everything is in those two subparts, and we patterned 35 against Part 20, because it's a similar thing in Part 20. There's a recordkeeping and a reporting section, and that's the only place that you have

to go to look.

DR. WILLIAMSON: That helps a lot.

MR. RAMSEY: Just to go on, insofar as reporting Agreement State events to the NRC, when we asked the Agreement states how they felt about that, the general response was that we should allow more time for them to submit their reports to NRC.

They raised the concern that the priority should be on them conducting their investigation, not them dropping everything and filing the reports with NRC. And quite honestly, some of the NRC Regions felt that way about NRC headquarters also.

[Laughter.]

MR. RAMSEY: Insofar as the Nuclear Materials Events Database, we asked them how they felt about using the database and the data entry, and generally everybody felt that it was okay. Some agencies expressed a desire to have some more options in terms of how they enter the data, as to whether they do it themselves, or whether they can just simply pass the paper copies on to a contractor and let him, you know, do all the coding into the computer.

I mean, obviously, some state programs are bigger than others, so some states would rather do it themselves; other states would rather just pass it off and let a contractor do it.

So we may make recommendations of providing more options to the programs, depending on what their capabilities are.

Under the computer systems, generally they felt that NMED was useful, but it was noted that it can be difficult if you don't use it very much. Of course, the tracking systems vary. Many agencies still just keep track of things on paper, which isn't necessarily a bad thing, but, you know, we're going to take a look at that and see if there is any recommendations we can make there.

Insofar as the products that come out of all of this, pretty much everybody felt that the information notices that NRC publishes are very useful.

There is also a quarterly newsletter that NMSS puts out to its licensees. Most people felt that that was good, but it wasn't very timely, and so sometimes it's not the best way to get the word out.

There is also a quarterly report that's put out from the Nuclear Materials Events Database. Not everybody was aware of it, and even the ones that were noted that it could be improved.

In defense of that report, I would note that it's only -- the contractor has only been being putting that report out for a year or two, so, obviously, there's room for improvement there as we learn what information is most

useful to the licensee -- or to the Regions and the Agreement States.

When we asked them about various national and international activities, people were pretty much aware of what was going on with our interactions internationally. I didn't really have too many concerns insofar as sharing information internationally.

So, basically, where we are now is that we're in the process of preparing a rough draft of the report. We hope to have that done by the end of the month and to get that to the Steering Committee.

After they have had a chance to look at it, we're going to brief them again in early December and see what they thought, if they think we're going in the right direction.

We'll have another meeting shortly after that. Then we'll go back and draft up the final report, and hope to have that done by the end of January.

One last round with the Steering Committee, and we look to have a final report out by the end of March. That's where we are.

DR. CERQUEIRA: That's great, that's a very useful oversight. I guess we'll look forward to the report, and perhaps at the next meeting we could actually get a draft of where it stands.

I guess that one of the things that did come up is, you know, how can this Committee try to implement or make suggestions to do this. And probably one of the things is rather than just a discussion, try to get it as a motion to the NRC that would -- you know, voted upon by the Committee, relative to the use of sort of electronic media for availability of the regs for event recording, and to sort of tie that back into the strategic plan, how that's a direction that would provide satisfaction to the users, as well as to the public in terms of the confidence in the system that's being there.

So, does anybody have an idea for a motion? Comments? Yes?

DR. WAGNER: The issue with reporting is, I think it's -- as far as I can see, it's pretty risk-based. I mean, from what I know of within what I have to report, it's really based on risk.

So I don't think there's a difficulty from the standpoint of the license personnel or the licensees having to report things. It is a matter of knowing what the report is.

But I also would like to point out that at least in the state of Texas, I know, our university carried on an investigation of information that was available to the public, that was being stored at our regulatory agency, but

apparently wasn't being used at the time.

And we put together a lot of that information, and then went back to the state and said, okay, here are a lot of things that we found out about violations and citations and things of this nature, and here's what's going on, and here's a big report on all of this, and here's the top categories of where citations are, et cetera.

And all that data was then turned around and used for a recommendation that said, okay, now, based upon this information, how can we streamline an inspection process? How can we make it easier, both on the state and on the licensee with regard to inspection?

And how can we change these things? I think they have developed a new format of doing inspections and carrying this out, and it's been effective. So, data is valuable, but it shouldn't be collected unless it's going to be used, and I think that's the big lesson there.

DR. CERQUEIRA: Ruth?

DR. McBURNEY: Just following up on that, that report was shared with all the Agreement States at the last Agreement States meeting so it will give the other states an opportunity to use that kind of data.

DR. CERQUEIRA: So what kind of recommendations are we going to make to help Kevin move this forward?

MR. RAMSEY: Well, the one -- let me note just one

thing for you to keep in mind.

Part of the dilemma that we have with all these reporting requirements is our working group is primarily focused on the NRC's version of the regulations, but as we get more and more Agreement States, what you are really up against, depending on where your facility is is you have got the NRC's version of the regulations and you have got 30-plus state versions of regulations, and so if you suggest we'll put it up on the Internet with a website, well, you are talking 30-plus websites and 30 different agencies that have to somehow allocate the resources to maintain those websites, so trying to --

DR. CERQUEIRA: I'm sure states would allow the NRC to maintain it.

MR. RAMSEY: It's hard to get a handle on it sometimes.

DR. NAG: I'd like to make a motion.

DR. CERQUEIRA: Yes.

DR. NAG: I'd like to make a motion that the ACMUI recommends that the NRC develop the NRC website to include a search engine to be able to find the relevant sections including reporting requirements.

DR. CERQUEIRA: Okay, perhaps with links to states which would help with some of those issues, to what exists at the states at least. No?

[Laughter.]
MS. HANEY: That's a lot.
DR. WAGNER: I must admit I am not from an NRC state. I am from the State of Texas and I know what we have got there, but maybe the NRC really has something like that. I don't know. I guess we ought to ask that question first.
MR. RAMSEY: Do you mean the links?
DR. WAGNER: I mean --
MR. RAMSEY: Search engines for like saying, here, you know, I've got this problem -- do I have to report it?
I mean there are search engines there but personally I haven't tried to do any key word searches or anything.
MS. HANEY: I don't think it would get you where you want to go.
[Laughter.]
MS. HANEY: The regulations are there and you can do searches but really what you are looking for is "I had a medical event. What is the criteria for reporting it" and, boom, it comes up with the criteria, and that doesn't exist.
DR. NAG: And not just the reporting criteria. If you are going to set up a webpage, you need to have, you know, all the other things as well.
I mean if I want to today set up a program I want to know, you know, what are the requirements and other

things.

MS. HANEY: Well, some of that is taken care of through the NUREG-1556 series, which are the guidance documents and those are on the web, that if you go to it and you say I want a license for a nuclear medicine facility you get everything in that document that you need to know to apply for a license and the reporting requirements are going to be in that, so that is what I mean.

The information is there but it is not easily accessible and really what you are looking for is something that is easily accessible for the reporting and recordkeeping requirements.

Now for the licensing requirements and everything that would apply to a facility that does x, y, z, that is there and that is searchable so I mean you are kind of talking two different things here.

DR. CERQUEIRA: Richard?

DR. VETTER: Well, I gathered earlier that one of the things you were trying to sort out was whether under-reporting might be related -- well, whether or not there was under-reporting, and I perceived that if there is under-reporting it would be due to two primary reasons.

One is people don't know they have to report so they can't find the information. That is what this motion perhaps addresses.

The other is that the licensee has made a determination that they don't have to report when in fact the NRC would disagree with that determination, and I don't know that you are even addressing that issue, but relative to both of them I think the licensee would find it helpful, at least I do, if the regulations are arranged similar to the way the new Part 35 is that simply pulls out all of the reporting requirements and puts them in one section.

It makes it very easy. That is easier than going to a website, in fact -- pull it off the shelf, or you can go to the website and pull up the regulations and look for "reports" and there they all are.

In previous issues of regulations you have had to read through the whole thing, trying to figure out whether or not you have to report.

The new format, I think, is really very helpful.

MR. RAMSEY: But even within the various parts you are still going to have a situation of -- I can't recall if there's any reporting requirements in Part 19 but there's reporting requirements in Part 20 that are applied to all licensees and there's Part 21 and then there's Part 30.

DR. CERQUEIRA: That is why you would like a search engine.

MR. RAMSEY: And there's Part 35, and even if you consolidate everything within one part, you know, you have

got all these other parts scattered throughout.
Some people have even suggested let's get all those reporting requirements and put them all in one part.
DR. CERQUEIRA: Well, if you guys can't do it on a website, how do we do it without having all the documentation?
John, you had a comment?
MR. GRAHAM: I think it's a suggested friendly amendment to your motion, just as a preamble, that the ACMUI recommends that the Working Group on Event Reporting consider the benefit of information obtained from reporting compared to the cost of the required reporting.
I think the other point was "and the ACMUI recommends consolidation of reporting requirements to facilitate compliance by licensees" and then the last component about the website.
DR. NAG: Well, you are the master in drafting motions and I leave that to you.
DR. CERQUEIRA: We need an heir to John's legacy so --
[Laughter.]
DR. CERQUEIRA: -- so basically we could add that -- Ruth, one last comment and then we should probably get to the break..
DR. McBURNEY: I think probably what would be -- I

mean having the search engine would be good but having some sort of guidance on event reporting, you mentioned that you at one time had one that listed all of them, but to have that and then organized by topic of licensee like all materials licensees and then medical, industrial, and so forth, would be helpful.

DR. CERQUEIRA: Okay. Well, we have a motion with an amendment.

DR. WAGNER: Second.

DR. CERQUEIRA: Second. Any further discussion?

[No response.]

DR. CERQUEIRA: Let's take a vote. All those in favor?

[Chorus of ayes.]

DR. CERQUEIRA: Opposed?

[No response.]

DR. CERQUEIRA: Anyone abstain?

[No response.]

DR. CERQUEIRA: So everyone is in favor, all the voting members, yes. Good.

Kevin, thank you very much. We look forward to hearing about the progress and we will take a break and reconvene at 10:15.

[Recess.]

DR. CERQUEIRA: We need to get a quorum here. I

think people want to be done by noon, so we need to get back on track.

It's been pointed out that in the forms that you were distributed, you know, claim for reimbursement for expenditures on official business, there's also a form for you time as a consultant. And we're going to try to get a copy of that and make it available to people.

It took me two years to figure out how to fill it out.

MS. HANEY: Just send it to Betty Ann's name, the Washington, DC 20055.

DR. McBURNEY: Okay.

[Pause.]

DR. CERQUEIRA: The first item on the agenda is update on other rulemaking activities from Cathy Haney.

MS. HANEY: All right, actually, I have three things to talk about or three things to cover under this session. I'll cover two and Torre Taylor will cover the third one.

I'm going to talk about the revision to Part 71, which is our transportation regulations, and then a revision to Part 35, that I mentioned yesterday, a reference to 35.75, and the Torre is working on a rulemaking plan that would deal with, again, a reporting issue.

Most of these are fairly -- at different stages,

so what we'll be looking for from the Committee on each one of these, is a little bit different.

The Part 71 rulemaking is an effort that's underway now to revise the transportation regulations, and it's to make it consistent, where appropriate, with the International Atomic Energy Agency's Transportation Safety Series, which is referred to as ST-1.

The majority of this rulemaking is probably not going to affect the medical and academic licensees. There will be some changes that do.

But most of it is really the larger spent fuel transports and the higher-level waste. But I really felt it was necessary to bring it to the Committee, in case someone happens to say, well, what's NRC doing with Part 71? At least you'll be able to give them an answer now.

The actual plan: We're working with the Department of Transportation because in this area, DOT comes into play, as well as NRC. DOT published an Advance Notice of Proposed Rulemaking back in December of 1999, on that, and there was an opportunity for public comment on that through DOT.

NRC published an issues paper in July of this year, where they raised about 18 different issues that they asked the public to comment on. That was a similar or same approach that we used back with Part 35, where we put the

issues out and got some early input before we moved into a proposed rule stage.

Then NRC held three public meetings in August, September -- two during September -- to cover the Part 71 rulemaking.

Where staff is right now is preparing a draft proposed rule. Our goal is to provide that document to the Agreement States in the December timeframe for their review and comment.

Those comments would come back to us; we would incorporate their comments into the document, and the in March, 2001, we would go to the Commission with a rule for them to review. Again, this is a proposed rule.

The Commission would bless that proposed rule and then it would go into the Federal Register. So, if -- this is almost for information for your professional societies.

In around probably the May timeframe, I'd be checking the Federal Register Notices to see if the rule is out, and if you want an opportunity to comment on it.

Again, it's a very small issue that pertains to the use of medicine, but on your generator shipments back and forth, the label requirements, the survey requirements, the contamination requirements, some of those things are the ones that you're going to need to be looking for.

And the goal is to have a final rule by 2002. So

that's it on Part 71, unless you have any questions on that one.

DR. CERQUEIRA: Can you give us a flavor, perhaps of whether it's going to decrease the amount of radiation reporting and regulation, or will it stay the same?

MS. HANEY: I think, relatively, it will probably stay the same. It's really right now for the organizations that are doing international shipments.

There's inconsistency between the international regulations and NRC regulations. And because of that, we want to move -- obviously, consistency is better. The only place that you're getting into maybe some performance-based areas, possibly, or moving away from the prescriptive, might be in some waste areas, if you're shipping low-level waste.

But again, that doesn't -- it's not the sort of low-level waste that the medical facilities are shipping back and forth; it's the wastes that are going to like the Barnwells and the Envirocare and things like that.

DR. CERQUEIRA: I think it would be important to go on record that sometimes when you're regulating these really high-risk levels, some of the regulations filter down inappropriately to the low-risk uses such as medical.

I think the Committee, in general, would be against anything that, you know, would add further regulation to something which is already relatively safe.

Is that the feeling of the Committee?

MS. HANEY: And that's why I would say that when you do see the proposed rule next Spring, it's possible, depending on where it comes out and if there are issues that would definitely filter down to the medical community, I might ask Staff to do a presentation only on those issues for the Committee.

But at the same time, you, as being out in the industry, might want to keep your eyes open, because most of this is going to apply to the non-medical, and, therefore, the medical and the health physics community are going to just choose not to comment on it.

And I want to just heighten awareness with this.

DR. CERQUEIRA: Richard, did you have a comment?

DR. VETTER: Just to the extent that it makes the regulations in this country more compatible with international, I think it's a good idea.

MS. HANEY: Yes.

DR. CERQUEIRA: Right. Any other comments?

[No response.]

MS. HANEY: All right, I'm going to move on. But before I hit the really controversial one that will send everybody out with raised blood pressure -- that's what I told Lou as he was reading what I left in front of his desk at the break time. I could see his blood pressure going up.

We did provide you with a copy of the Federal Register Notice that was going to solicit additional nominees for hospital administrators, so put a yellow sticky on it and drop it on your hospital administrator's desk so that we can have some additional applicants to look over.

The other thing is that we've provided you with a copy of the ICRP book that I talked about, and then the strategic plan that some of you had asked for.

Okay, so now I think I've put off the inevitable discussion here. All right, this has to do with Part 35. This would be a proposed rule that would go out after the rule we've been working on and have been discussing is published.

So we're looking at a proposed rule sometime next year. And the history to this, as I said yesterday, was that when we were preparing the package that -- the Commission paper that would go to the Commission, transmitting to them, the final Part 35, an issue was raised regarding notification if a member of the public was exposed to a patient that had been released under Part 35.75.

And the Part 35.75 requirements would be that you could release up to the 500 millirems standpoint.

In the Commission paper, we just highlighted it to the Commission and said it's an issue that came up at the last minute, and we can't deal with it right now, but one

possible way of dealing with it is for staff to develop a rulemaking plan.

The purpose of developing a rulemaking plan is, we lay out all of the options for the Commission that they could consider. When the Commission was evaluating this, they made the decision that they really did want to receive a report in this case.

And since they wanted to receive a report, there was really no use going through the rulemaking stage. So the Commission directed us to develop a proposed rule that would come up to them seven months of the date of the SRM, so seven months from October, we have to have a proposed rule to the Commission.

And the Commission's directive was very specific, and that's the document that I handed out to you.

So we don't have a whole lot of leeway with what goes into the rule, however, one of the things that the Commission did say is that the statements of consideration should clearly indicate the Commission is not modifying its previous position; that the NRC does not intend to enforce a patient's compliance with the licensee's instructions, nor is it the licensee's responsibility to ensure compliance by patients, once they leave the licensee's facility.

So, today, and maybe for just a couple of minutes before we turn it over to Torre, I think it would be

interesting to hear from you, what sorts of things you think I should put in the statements of consideration to highlight this particular item. What would be most meaningful to you as an end user to see in the statements of consideration?

I have attached a document that has Commissioner Dicus's views on this particular item. This is taken from the voting record on Part 35 and it is on our website, the entire voting record of it.

But this particular one had to do specifically with this issue. As you can read through it, Commissioner Dicus did not support the development of the proposed rule, however, you need to realize from the Commission's standpoint, it's the -- if the majority of the Commission is in favor of a particular action, we do go forward with it.

So with that in mind, the question on the table is, you know, I can't not do a proposed rule, so that's not an option. But the issue is, what sorts of things would you like to see in the statements of consideration?

And recognize that to the extent possible, this -- we've tried to do a risk-based rule here, a risk-informed rule, making the reporting limit at five rem, rather than 500.

And one last thing before I turn it over to Jeff and Lou, who are going to go crazy --

[Laughter.]

MS. HANEY: Is that this is not a dose limit. This is a reporting threshold, and that's the biggest thing that we have to keep in mind. We are not trying to set up dose limits in Part 35 for this particular issue.

Okay, now, you can deal with --

DR. CERQUEIRA: Jeff is turning red already.

DR. WAGNER: Jeff, breathe in and out, in and out.

[Laughter.]

DR. NAG: Before we have or make comments, I want -- since I'm new to the Committee, I want to understand a little bit more about what, exactly, this means. I would like to understand the implications of that before I make any comments.

MS. HANEY: All right, the best thing would be an example. I could give you an example where a patient comes to the hospital for iodine treatment greater than 30 millicuries, and the licensee is making a decision on whether to release the patient or not, the normal sort of routine. They decide not to use the default tables because they're going to go case-specific, because the patient has assured the licensee that they are going to go to their mountain retreat and not see anyone.

So, in good faith, the licensee releases the patient, documents, does everything right. And that's it.

Two weeks later, three weeks later, the patient

comes back for a checkup, and in just casual conversation with the licensee, happens to say, oh, you know, I told you I was going to my mountain retreat; I didn't. I got on an airplane, I flew to Hawaii to see my daughter.

And then we would envision happening is a little light going off in the licensee's head saying, uh-oh, you know, that's not what I based the release on. Let me go back and look at what the release was based on, recalculate, and the recalculation shows that the individual on the airplane sitting next to this patient could have received 5,001 millirem.

If they received 501, I don't want to hear about it, because we're going to put this threshold up at the five rem limit. But if the other, the passenger next to him got greater than five rem, that the licensee would have to notify us.

This would not require the licensee to ask the patient when they come back for their followup, oh, by the way, did you do what I told you to do? That's not what this -- that's not what we want to do.

This is if the licensee learns --

DR. NAG: And what would be the consequence of learning that? Would they be penalized? Would they be fined? Would they be shot? Would they be killed?

[Laughter.]

DR. NAG: What would be the penalty?
DR. WILLIAMSON: All of the above.
MS. HANEY: Well, it depends upon what was the cause. In all honesty, it probably would trigger and inspection of some type, because you are now at the five rem limit, which as some implications for possible risk procedure problems. I'm not getting into the biological problems, but there are some higher consequences at a five-rem limit rather than a 500 millirem limit.
So more than likely, the licensee -- the NRC would go out. If NRC goes out and they find that it was exactly the case that I just described to you, I mean, unless you violated a procedure somehow, there would not be a violation, there would not be a civil penalty, and we wouldn't shoot you for that.
We might find something else, but the -- so in that case -- but now, in the case where we got out and we start looking, and find out that the original release -- let's say, the tech used a patient-specific calculation for another patient and said, hey, this applies to that, didn't clear it through the authorized user, did no checking, there was no authorized user oversight in it, and all of a sudden, everything starts to unravel, then, yes, there could be a possible problem there.
The other thing would be that you're looking at it

from a citation standpoint, is the situation where we go out and do a routine inspection, and in our routine inspection, we happen to look at these records, and we find out that a record was not done properly, the release was not done properly.

Let's say you failed to give instructions, and when we calculate what could have happened, if the patient didn't follow the normal standard of care, standard practice, if we could get over the five rem limit, then we would cite you -- we could possibly cite you for not reporting, number one, and then again, now you're into the citation space.

So those are the extremes. The intent is not a "gotcha" here; the intent is information gathering.

There is also -- the reason that the Commission went this way and wanted a proposed rule is back to our abnormal occurrence reporting requirements. It says we need to report to Congress, when a member of the public gets these higher exposures.

How can we make those reports if we don't have a reporting requirement for the licensee to tell us?

DR. CERQUEIRA: Dr. Nag?

DR. NAG: Can you make a reporting requirement that you report but if it is not your fault you are not penalized because --

[Laughter.]

DR. CERQUEIRA: I think part of the problem again is the vagueness of this, and I concur with Commissioner Dicus's report on this. It is very vague that you would detect it, you know, through voluntary means. Jeff?

DR. WILLIAMSON: Well, would the augmented inspection team go after the patient and get a warrant to enter their house and totally ruin the relationship between the health care provider and this patient? Is that a possible consequence of this? I mean who would investigate it? I guess it would have to be the patient.

MS. HANEY: Well, I think, Jeff, I don't see the augmented inspection team going after the patient on this.

I think what we see it as, you know, first we have got the mandatory reporting to Congress, that aside.

What we would see it is going in to look to see what happened and then if we started to see patterns developing we would go out with information notices, newsletter articles saying licensees, you know, we have seen four or five cases where the patient hasn't done what they told us to do and the licensee used a case-specific calculation of 5 percent occupancy and this resulted in a situation where the public was exposed.

Dear Licensee, maybe next time you use a case-specific calculation, maybe you might want to think two

or three times about using the 5 percent occupancy.

That is what the information is going to be used for.

DR. WILLIAMSON: Well, okay, but I guess the question is, the problem, practical problem I see is I don't think the licensee and probably neither the license nor NRC has the legal authority to make an investigation of what the patient did to determine whether this overexposure occurred. How is that to be done?

MS. HANEY: See, that is the voluntary aspect, Jeff, of it.

This is what I really think needs to come across clearly in the Statements of Consideration and that's the points that I am looking for you guys to provide.

The intent is not for the licensee to go out and investigate the patient, nor is it for NRC to go out and investigate the patient. This is just if somehow a tidbit of information filters to the licensee and then maybe they ask a question about it. Oh, you know, I heard you did this or that, and then you back off.

DR. CERQUEIRA: That's such a vague way of finding it out. How -- you know, do we feel that for diagnostic doses if you give somebody a bone scan, if it's all therapeutics, we are talking about a very small number of patients and public alarm, the way this would generalize to

the public is they don't understand the difference between diagnostic and therapeutic, so every patient who gets a bone scan, the public concern that, you know, maybe they are going to a bathroom where somebody has urinated and you pee into the urinal or they are sitting on a bus next to somebody who just got a diagnostic dose, I think that the fear to the public, the concern of patients themselves, is disproportionate to the amount of risks that's involved.

I think Commissioner Dicus says she is unaware of any data to support that this has occurred or that there ever has been a problem. Ruth?

DR. McBURNEY: Well, we just adopted the change in the release criteria and the whole basis, 35.75 going from a dosage based rule, not being able to release them higher than 30 millicuries to a more performance based rule is with the understanding that the procedures, that the instructions are given to the patient and that they understand and that they are willing to follow those instructions.

That is just based on good faith effort. Beyond that, I don't know what more -- and if those procedures are being followed the licensee should not be penalized -- or at least that they make sure that the patient understands.

Now whether you've got a renegade patient that is going to go off --

[Laughter.]

DR. McBURNEY: -- and do something different, that is beyond the scope of regulatory aspects, but where you have got a licensee totally ignoring and leaving out the step of instructing the patient and making sure that they understand, then it does get back to -- because that was the whole basis of that performance-based rule.

DR. WILLIAMSON: But I think that is adequately covered by 3575, which requires -- it's very detailed in outlining the possible bases for releasing a patient with therapeutic amounts of --

DR. CERQUEIRA: You both are agreeing. You are not disagreeing?

DR. McBURNEY: That's right.

DR. WILLIAMSON: Yes, and I'm sure my reading of 35.75 implies that the instructions that have to be given to the patient are consistent with the occupancy and other factors used in the calculation and so you would have the ability to probably review those I should think for consistency.

MS. HANEY: Well, Jeff, what about the situation where you have got a licensee that doesn't give the instructions, plain doesn't give them, and goes ahead and sends the patient home. The licensee's consultant comes in, does an audit, identifies this to the licensee, that they have not been providing instructions they need to do so, and

they start looking at what could have happened and they come up with a patient could have exposed a member of the public to greater than 5 rem.

That is what we want to hear about. I mean you are talking about the good licensees and theoretically we should never get a report like this, so there should not be a problem, but also realize the situation -- and I hate to say this -- but remember 35.75 covers breast feeding.

If, similar to the Tripler incident, where the physician advises the mother to stop breastfeeding, and she comes back a couple weeks later and says I didn't stop breastfeeding, now, you know, that is not -- the licensee can only do so much, but that is the report we want to hear.

That is where if it is high enough that is what we are required to go down to Congress, so realize this is almost -- we should never get a report but there are some licensees out there that don't do a good job.

DR. WILLIAMSON: Well, maybe a more reasonable thing if you insisted on a reporting requirement would be to report all instances of failure to give instructions to the patient where consequences of said omission would exceed this reporting, this exposure threshold.

That is something within the realm of possibility of the --

DR. CERQUEIRA: That's one, not two.

DR. WAGNER: That is one. It would just eliminate two. That is where the big problem comes because what they are really asking here is that you somehow make a determination about unlicensed material as to what it might have exposed a member of the public because this patient did not follow your instructions and so you have to go -- and then I believe also this rule would require, and correct me if I'm wrong, that you find the person who may have gotten the 5 rem and you tell them, okay? -- and you don't really know if they did or not because you can't reconstruct the situation.

To me this is really, this is a witch-hunt. I think this is a problem.

DR. WILLIAMSON: Yes, I think it places the presumptive burden on the licensee to do this investigation of an individual that they have no legal, basically no leverage to do, no resources to do.

MS. HANEY: Well, suppose, Jeff, in the Statements of Consideration we made it clear that we did not expect the licensee to do anything more than what they are doing right now and that was very clear in the Statements of Consideration.

Would that -- that would help, I'm sure, but it is not where you want to be, right?

DR. McBURNEY: Except for the reporting.

MS. HANEY: Except for the reporting, yes.
MS. SCHWARTZ: It seems like, Cathy, that eliminating two would be reasonable and then essentially the person who had been exposed is the problem and a person that you really won't track down most likely.
I mean that would be the real problem is the person that's exposed, but that won't happen.
What is going to happen is the report that is sent by a good licensee -- a good licensee would send you the report and say this patient came back and told us this, and I think in reality what you are looking for are those licensees not giving adequate instructions.
That doesn't help either because probably the ones that aren't giving instructions aren't going to tell you that this patient came back and exposed the public, so the person who is exposed is not going to be notified. I mean that is really the person who -- the public -- and they shouldn't be, but you are essentially penalizing the good licensees by this additional reporting requirement and there is really no purpose for it -- I mean it seems to me.
DR. CERQUEIRA: Do we have some input from Legal on this in terms of the vagueness of this, you know, learn through voluntary means. What kind of requirement does that place on somebody?
Then the requirement for the licensee to provide

and identify exposed individuals with a copy of the report -- I mean how do you identify those, as we have said? I mean what about the liability issues to the individual, to the facility?

I mean if somebody gets on a plane, can everyone on that plane bring a suit against the physician for exposure?

Marjorie?

MS. ROTHSCHILD: First of all --

DR. CERQUEIRA: Get on the mike, please.

Good legal counsel doesn't want to get on the record, you know?

[Laughter.]

DR. CERQUEIRA: She wasn't listening to me.

SPEAKER: Do you want a moment to look at it or do you want to talk now?

MS. ROTHSCHILD: You know, I really can't provide an on-the-spot opinion but probably the reasoning for number two is to avoid actions which possibly might be considered to raise privacy issues.

Cathy, would you agree with that, what voluntary means?

MS. HANEY: Yes, I think the issue, the reason number two is there is if NRC has to report to Congress exposures to members of the public. It doesn't say -- you

know, it doesn't differentiate between members of the public, whether you got it through voluntary or whether because the licensee didn't follow their procedures.

When you look at you have got a member of the public that has got an exposure we want to know about it, so that is why two is in there.

MS. ROTHSCHILD: Wait a minute. We were focusing though on the licensee learning through voluntary means.

MS. HANEY: Right, so the licensee -- right, so, you know, we are going so far as to say, Licensee, you don't need to follow up on every patient, but it is only if you learn about it.

DR. WILLIAMSON: Marjorie, does this mean that if the patient agreed to submit him or herself to a full investigation that would be, NRC would consider the licensee responsible for performing this investigation of these actions that occurred outside their facility?

MS. ROTHSCHILD: I can't get into, really, you know, enforcement and --

MS. HANEY: Also realize that this is -- our first priority is to get the rule out and then the next one is to start the revision of the rule.

[Laughter.]

MS. HANEY: So --

DR. CERQUEIRA: It's job security.

MS. HANEY: Yes, it is job security for sure, so Marjorie is right. Some of these issues have not been thought out. The main this is we know we have to go back to the Commission with a proposed rule that says "Do this."

MS. ROTHSCHILD: I would just add that we do have very broad statutory authority when it comes to requesting or requiring that individuals provide us with information but we also are aware of other issues, such as in Part 20, occupational exposures to a pregnant woman, we are talking about a declared pregnant woman to avoid a situation where, you know, we are requiring a licensee to ask questions that may raise privacy issues.

DR. CERQUEIRA: I believe Jeff.

DR. WILLIAMSON: Oh, I think the real issue is can the -- is it really possible for the NRC to require the physicians or whoever, the licensee, to do an investigation and to report something about a material that is no longer licensed? It is no longer a regulated material.

Can they require us to report something that is not even regulated?

DR. NAG: What do you mean by that?

DR. WILLIAMSON: It is no longer regulated because the patient has been released and once that patient is released it is no longer on your license. That material has been dispensed in a proper way.

It is outside your facility. It is not under your control. It certainly isn't under a patient's license unless the NRC wants to give the patient a license, you know, I don't see how this can possibly even be valid.

DR. CERQUEIRA: Yes. Dr. Nag?

DR. NAG: I read Commissioner Dicus's views. I fully agree with his or her views. That's one.

Secondly, I think if you have to write up a report I think you need to differentiate between a correctly given instruction that is not followed by the patient versus an incorrect instruction that's been given to the patient. I think the two are quite separate.

I mean you cannot do witch-hunting on a case where all the right instructions were given and not followed by the patient. It's like saying I told the patient to take the drug twice a day but the patient took all the drug in one day and died, and I get penalized.

DR. CERQUEIRA: That is a very good point and a very good analogy because patients are given instructions on taking medicines and all kinds of things that have nothing to do with radiation. There's other situations.

There is no precedent for this. This is unbelievable.

I mean I can see the issue if the patient isn't instructed properly, and then I would contend that that

material is still licensed because you didn't do it right. You didn't get rid of it correctly, and it is your responsibility.

That is one thing, but if you did everything right and then something still happens, that is not your responsibility and we shouldn't be getting into this. This is silly. Jeff?

DR. WILLIAMSON: Well, I wonder maybe if we shouldn't make a motion that the ACMUI recommend to the Commission that this new reporting requirement be limited to the reporting of errors made in the release procedure or the delivery of instructions to the patient that could possibly cause exposure to another individual to exceed the threshold of 5 rem.

DR. CERQUEIRA: Any further discussion? I'm sorry, Bill?

MR. UFFELMAN: I think you all are getting to a very good conclusion here. I am Bill Uffelman. I am a Director of Public Affairs and General Counsel for the Society of Nuclear Medicine and this proposal is -- well, my e-mail is probably burned out by now based on some early responses from some folks whom Cathy I'm sure knows who I am talking about.

[Laughter.]

MR. UFFELMAN: I was going to suggest to you as an

attorney this is kind of the don't ask, don't tell policy with strict liability to the licensee for actions, unwitting actions, by third parties, so I was going to suggest that there in fact be an affirmative defense, if you will, that the licensee, having in fact issued proper release instructions and whether not includes the extra step of the individual signs that they have been so instructed, and that in fact the instructions perhaps include something to the effect that your failure to follow these instructions could result in exposures to other individuals -- in other words, get at the exposure requirement -- that in fact that creates an affirmative defense that the practitioner/ authorized user can say -- "Here is my file."

Now god help them if they don't keep that kind of stuff in the file, but it puts a positive action. There is something they can do to in fact show that they are doing the right thing and then also I would suggest that I will tell my members don't ever ask and don't listen to responses, but I mean that is another issue.

[Laughter.]

DR. NAG: Yes. I mean quite simply if someone is about to tell me, do I have listen to this? No, I don't want to listen to this. I am going out. You can tell whoever else you want -- don't tell me.

I mean that is my best defense if you are going to

have an unwise law.
DR. CERQUEIRA: That's true. John?
MR. GRAHAM: That was my only observation I think the ACMUI should recommend as part of the Statement of Considerations that it is our recommendation to licensees that they have to follow a don't ask, don't tell policy.
This is just as absurd as the other arena in which this has been going on for about eight years now, and that is the best legal advice I think that they could receive.
DR. CERQUEIRA: So we have a motion. Is there any further discussion or amendments to Jeffrey's motion?
DR. NAG: I think we have some legal people here. Is that legally enough or is there --
DR. CERQUEIRA: I don't think our focus has to take in legal considerations.
I think it is pretty much the feeling of the committee that it's appropriate.
No further discussion?
I call for a vote. All in favor?
[Chorus of ayes.]
DR. CERQUEIRA: Opposed?
[No response.]
DR. CERQUEIRA: Abstention?
MR. LEEDHAM: One abstention.
DR. CERQUEIRA: Okay.

MS. HANEY: Okay, next topic. All right, the other is -- I'll have Torre do this one.

We are -- as Torre comes up front -- we are in the process of developing a rulemaking plan.

The package at this point is at the stage where it is ready to go forward so -- we hope it is ready to go forward, so this is more just an information standpoint of what we are -- we just want you to be aware of it.

If the Commission decides to go forward with a rulemaking in this particular area, we will bring it back to the Commission, and with that I think I'll just turn it over to Torre.

MS. TAYLOR: For the record, I am Torre Taylor with the Rulemaking and Guidance Branch. I think Cathy pretty much said it in a nutshell there.

MS. HANEY: Sorry.

MS. TAYLOR: This is the official topic, Event Reporting, Unintended Non-Medical Exposure to an Embryo/ Fetus or a Nursing Child.

I am going to start just giving some background as to why we are even looking at this, and then just give you kind of a status.

We are in the process of finalizing the paper and getting it ready to go out.

Way back when, in 1996, the Commission issued a

final staff requirements memorandum on the AO, Abnormal Occurrence, reporting criteria in our final policy statement, and the Commission directed the Staff to report to the Commission on how we are going to identify unintended medical radiation exposures to an embryo/fetus, or to a nursing child, and also talk about the experience with voluntary reporting, and they also asked us to look to see whether or not the policy should be revised to omit reference to these types of incidents if the Staff doesn't recommend a mechanism to get these kind of reports.

The Staff reported back that this would be evaluating during the revision of Part 35, which was Cathy's wonderful project for last how many years?

So with that Part 35 revision, the final analysis came out to be that they would put a reporting requirement in Part 35 itself rather than Part 20 or other parts because most cases this would occur under medical situations, so the final rule, as you know, did contain a requirement for licensees to report to NRC of any unintended exposure to an embryo/fetus or a nursing child that exceeds 5 rem, and there again that is the reporting threshold. That is not a dose limit.

The Commission came back with a finalized SRM on February 16th, 2000, with the final SRM on that report. And they agreed with the Staff's recommendation, but they told

us to look at rulemaking plan to revise Part 20 or other Parts of the regulations to require this same notification for non-medical and intimate exposures.

And they gave us the option to include a no-action option if the Staff believes rulemaking is not necessary.

Now, what we did is, we formed a working group composed of Staff and NMSS, NRR, Office of State and Tribal Programs, Office of Enforcement, and Office of General Counsel.

And we reviewed the current regulations, the issues, and looked at developing options for a rulemaking plan. Essentially we looked at the current reporting requirements to see what was already there, what situations were already covered, and to see if there was any need to revise the regulations.

And as Cathy indicated, at this point, we're developing the rulemaking plan and it's a draft, and the Commission paper, and we're finalizing it and getting it ready to send up to the Commission.

Now, at this point, due to the nature of the topic, we have not submitted it to the Agreements States for comment. And if the Commission tells us to go forward with rulemaking, we will at that point, finalize the draft rulemaking plan and we will submit it to the Agreement States with their normal 45-day comment period, in

accordance with our NMSS Office Policy and Procedures Letter on the rulemaking process.

And that's pretty much it.

DR. VETTER: What does five rem mean? I mean, what does five rem to the embryo/fetus mean? How do you -- is this an effective dose? There are all kinds of ways you could interpret that.

MS. TAYLOR: Well, I think it would be a total effective dose, yes. And we'd have to get into -- if we had to go forward with the rulemaking, we would have to evaluate the specifics.

DR. VETTER: You'd have to evaluate how we arrive at that estimate.

MS. HANEY: Yes, Dick, that would be one of the things we kind of struggled with Part 35, how to refer to the dose, and when we talked about embryo/fetus, whether it was absorbed, total effective, and we went -- did a lot of research back through and talked a lot with some of the reps from HPS about what was the best way to refer to it.

MS. TAYLOR: More than likely, we would just, if we went forward with the regulation, use the same approach that we used in Part 35. But that is one of the issues from a technical standpoint that we're going to have to be very careful about how we refer to it in the regs, if they tell us to go forward.

MS. HANEY: I mean, all this is contingent on whether they say go ahead and do it. There are a lot of things -- I mean, the things we're considering, revised Part 20, so you cover all licensees. Do you revise Part 30, which covers all materials licensees, Part 40, which is source material; Part 50, which is special nuclear material?

And you go into some parts that you guys probably don't even know exist, because it doesn't touch any of your areas.

So there are a lot of different ways we could do this, and then as Torre says, one of the options is not to do it at all, recognizing that there is only -- if there is going to be an exposure to the embryo/fetus, 99.9 percent of the time it's going to happen in a medical environment, and that's covered by the revision to Part 35.

And, is a rulemaking needed to cover these other areas? I mean, that's really the question that we're going to put before the Commission.

DR. CERQUEIRA: Lou?

DR. WAGNER: I guess I don't understand the idea of putting it in the Part 20. Is for the consideration, perhaps for an occupational employee?

MS. TAYLOR: No, this will be non-occupational.

DR. WAGNER: It's non-occupational, so it's a matter of the same basic rule just being stuffed into 20?

MS. TAYLOR: Well, Part 20 is the standards for radiation protection, and within that Part, you have to limit -- you have to -- how do I want to word it?

You have to operate your facility in such a way so that members of the public, in addition to the occupational dose limits, don't exceed the dose limits also.

DR. WAGNER: So the point is that you if you have a pregnant worker in your building who is not designated as a radiation worker, and you have designed your situation so that there could be basically some higher exposure areas in some departments where they might have access, and they happen to be pregnant and had access to those on a continuous basis, then perhaps the baby received 500 rem over the working course or something like this?

MS. TAYLOR: You're talking about at a licensee's facility?

DR. WAGNER: Yes.

MS. HANEY: I think the answer is yes. I think the answer is yes. I mean, it applies to --

DR. WAGNER: Is that what they're looking for?

MS. HANEY: Well, I mean, they're looking to capture the whole world of anytime the embryo/fetus would get exposed to greater than five rems. So they're looking for the entire population.

We got most of it in the -- with Part 35. I mean,

you're right, and I think the example you used is a good one. It's the woman that chooses not to declare her pregnancy, but you know darn well she's pregnant.

MS. TAYLOR: Well, you're referring to a non-radiation worker.

MS. HANEY: Yes, a non-radiation worker.

DR. WAGNER: Yes.

MS. HANEY: I mean, where a member of the public wouldn't have to declare their pregnancy. One of the issues that we've put -- you know, that we're going to put forward to the Commission is, you know, how do you -- you can't force a member of the public to declare their pregnancy.

DR. WILLIAMSON: I don't think you can force a worker to do that, either.

MS. HANEY: You can't. And the precedent has already been set.

DR. WAGNER: But it is at a five-rem level. I mean, if they're not a radiation worker, and they're going to be exposed to those kinds of doses, that's kind of really out of line.

DR. WILLIAMSON: A radiation worker --

DR. WAGNER: They're not talking about a radiation worker.

MS. TAYLOR: In part of our analysis, we did look at that, and determined that that situation is already

covered because they would still be protected within the occupational dose limits.

DR. WAGNER: So we're not trying to cover that?

MS. TAYLOR: Right.

DR. McBURNEY: Is the reporting level for members of the public already at the five?

MS. TAYLOR: No, it's 100 millirem.

MS. HANEY: Actually, it's a hundred.

MS. TAYLOR: Now, for the AO reporting criteria, it's to the adult, the minor, embryo/fetus, and at the adult level, it's five rem.

DR. McBURNEY: So isn't a nursing child a member of the public?

MS. TAYLOR: That's what we're saying. That's what we've determined.

DR. McBURNEY: And wouldn't the mother of the embryo/fetus also be a member of the public?

MS. HANEY: Exactly.

DR. McBURNEY: And fall under those reporting requirements?

MS. HANEY: Exactly.

DR. WAGNER: So the conclusion is that it's really not needed? It's covered under all other rules and reporting requirements, and I think that's the option. We recommend that's the option you take.

I think we ought to say that, because it seems to be a redundant and silly rule.

DR. McBURNEY: And in some cases, conflicting.

DR. WILLIAMSON: Point of clarification: Does Part 20 already contain a reporting requirement that if anybody gets more than five rem, it has to be reported?

MS. TAYLOR: Well, it has the occupation dose limits for your workers, and it has the dose limits for a member of public, which is at 100. It's got the ten percent of the adult worker for the minor occupational worker.

So essentially the only provision that is not covered is a member of the public who might be pregnant, the exposure to that embryo/fetus, and we're obviously not going to go into a separate dose limit or dose threshold reporting requirement for that.

DR. WAGNER: But where the mother goes, the fetus goes.

MS. TAYLOR: Exactly.

DR. WAGNER: And so I guess the only issue then is, is that when you report it, you have to report it as both an exposure to the mother and her baby.

MS. TAYLOR: Well, that's part of the issue, that we may not know that person is pregnant.

DR. WAGNER: Right.

MS. TAYLOR: And we believe, in our analysis, that

-- and we also believe that it's going to be more in major incidents that this happens; that it's not going to be through normal use.

That if a licensee informs a member of the public they happen to know was exposed, that woman at that point would say, I'm pregnant, is there any concern here? And we feel that in the very few cases that this might even happen, if it even would, that we would probably get this information anyway.

DR. WILLIAMSON: So has it been determined that a fetus is not a member of the general public, and that, therefore, a special regulation is needed for the fetus?

DR. WAGNER: There are rules on the fetus. I mean, there are dose limits on fetus and stuff. I think it's been -- a precedent has been set that recognizes that a fetus is a member of the public, at least is a considered person. It's a considered person, and therefore under the Part 20, it would be definitely a member of the public.

DR. WILLIAMSON: I guess then I'm questioning, and agreeing with you, I guess, that why is a separate regulation needed if already, Part 20 addresses overexposure of members of the general public which would by definition, include --

MS. TAYLOR: In our analysis, we did not separate out the embryo/fetus as a separate entity from the mother,

because we believe it is a joint entity, and the mother is protected at the 100 millirem limit and that we would find out about those exposures.

DR. CERQUEIRA: So all of the comments have really been against this. Is there anybody who is in favor of such a rule or regulation in any form or way?

MS. HANEY: As I said, this is really the first stages where we are right now. I mean, again, the timing of the Committee meeting -- and I just didn't want you to be surprised in six months if we're talking about a proposed rule, if the Commission decides to do it.

So, the Committee will have another opportunity on this particular issue, if the Commission tells us to go forward.

DR. WILLIAMSON: But shouldn't we make a motion.

DR. NAG: Before the Committee asks you to go forward, if the Committee already learns that the ACMUI had made a strong recommendation against it, I'm sure that they can overrule it, but I think they will think twice if we have a strong recommendation.

MS. TAYLOR: We will put in the paper that we discussed this briefly with the ACMUI and what your motion was.

DR. CERQUEIRA: Briefly, it was 30 minutes.

[Laughter.]

MS. HANEY: It's all relative.
DR. CERQUEIRA: Richard?
DR. VETTER: Can I ask a question? What happens to -- what do the regulations require today? If a member of the public receives more than 100 millirem as a result of a licensee's activities?
MS. TAYLOR: If that licensee is aware of that, which we hope they would be, but I guess there are some situations where they may not be, but they have to report that to NRC. If they have also identified that member of the public, they also have to notify that member of the public about same exposure.
DR. VETTER: Therefore, this proposed regulation, expanding it to Part 20, actually conflicts with an already-existing regulation.
MS. HANEY: Well, Torre, let me ask you a question: Wasn't there one population that we said that there was no reporting requirement for?
MS. TAYLOR: General licensees are not tied to that specific report to a member of the public. They have to report thefts, incidents, losses of materials, if certain dose limits or doses could occur.
MS. HANEY: But even with specific licensees, I thought there was one small -- I mean, unfortunately, I'm trying to remember back two months ago to the last time I

was involved with this.

Wasn't there a small population of whether it was a member of the public or a worker that was not covered by Part 20?

MS. TAYLOR: That's not ringing a bell at all.

MS. ROTHSCHILD: Would that be the undeclared pregnant occupational worker?

MS. TAYLOR: Are you thinking about that?

MS. HANEY: I don't know.

MS. TAYLOR: Generally, you have the occupational workers who are pregnant and have declared their pregnancy, workers who are pregnant and have chosen not to declare their pregnancy, but they are already covered under the occupational dose limits, and then you have the member of the public that are pregnant.

And then you have general licensees who only have to comply with two parts of Part 20 which require them to report theft or loss of material or incidents of certain dose limits.

DR. CERQUEIRA: The Chair recognizes Professor Williamson.

DR. WILLIAMSON: Well, I suggest the following motion: Whereas Part 20, as currently written, already contains the requirement for all material licensees to report exposures to the general public exceeding 100 mr,

including any exposed fetuses, the Committee, ACMUI, recommends to the Commission, that no further rulemaking activity regarding a fetus reporting requirement be undertaken.

DR. CERQUEIRA: Second?

MS. SCHWARTZ: Second.

DR. CERQUEIRA: John, is that good?

DR. NAG: We may have to add about the workers, the limit --

DR. CERQUEIRA: So you're proposing an amendment?

DR. NAG: Well, I mean, I haven't thought about wording it, but Dr. Williamson mentioned about the general public of 100 millirem, but the possible pregnant worker, but even then, the limit is up to five rem.

So I would like to add the pregnant worker as well.

DR. WILLIAMSON: Well, I think the fetus of a pregnant worker would be considered a member of the public. They're not --

MS. HANEY: They're at 500, if they declare their pregnancy. Their reporting requirement would be a 500 millirem of an occupational worker.

DR. WILLIAMSON: Okay, well, then we could amend my motion so that the last phrase --

DR. CERQUEIRA: Why don't you just remake it?

DR. WILLIAMSON: All right. Let's see, so the intent of my remaking it will be to limit this simply to member of the general public. I think that was because that's what the rulemaking activity was aimed at.
They had already excluded the need.
MS. HANEY: Go with what you said first, Jeff. I mean, your -- did you by any chance get close enough?
MS. SEATON: All I got was, whereas Part 20, as already written -- already contains coverage for all exposures of 100 millirem --
COURT REPORTER: Could you use the mike so that we can have it in the transcript?
DR. WILLIAMSON: I can try to restate it.
DR. WAGNER: Maybe you might want to say annual.
MS. SEATON: And I'll try to get it. Go ahead.
DR. WILLIAMSON: Okay, so I haven't written it down, but I'll try to do it extemporaneously again.
Whereas, Part 20, as currently written, already contains a reporting requirement for all material licensees to report exposures, annual exposures of the general public exceeding 100 mr, as a result of their activities, including any fetuses, the ACMUI believes that no further reporting requirement for exposure of fetuses is necessary.
MS. HANEY: Now, the only question is that Part 20 doesn't specifically say including fetuses. It just says

members of the public. It's kind of implied that the fetus is part of the mother, who is a member of the public.

DR. WAGNER: But usually they travel with the mom.

MS. HANEY: Yes.

DR. WILLIAMSON: They are already members of the general public. You've just said they are.

MS. HANEY: Jeff, a friendly modification there, since the issue here is to cover all NRC licensees. Your specific recommendation said materials licensees. You ought to just make it apply to all licensees.

DR. WILLIAMSON: All licensees.

DR. CERQUEIRA: All licensees.

Okay, do we have a second on the motion?

DR. VETTER: Second.

DR. CERQUEIRA: Further discussion?

DR. WILLIAMSON: One more friendly amendment to my own motion.

DR. CERQUEIRA: John has a rule about amendments, doesn't he? When you get beyond a certain number, you have to remake -- no, go ahead.

MS. HANEY: The recommendation, as Jeff indicated with my modification, is caught by the transcriptionist. She's just doing notes, quick notes.

MR. GRAHAM: I understand, but have we picked up the issue of the pregnant worker?

MS. HANEY: Yes.
MR. GRAHAM: Is that covered?
MS. HANEY: That's covered under Part 20, if they declare their pregnancy.
DR. NAG: Right, but that's not covered by what Jeff said. I would like to add the pregnant worker into Jeff's motion so that it's more inclusive, and it is still below the five rems, so --
DR. WAGNER: Torre, didn't you say that --
MS. TAYLOR: We have addressed that in the rulemaking plan itself, and then with the Commission, saying that we don't need to even look at that because it's already covered in the regulations.
DR. CERQUEIRA: Good.
DR. WILLIAMSON: The only thing we might consider adding to the motion is another whereas: Whereas, fetuses are considered to be members of the general public.
DR. WAGNER: Let's not get into that.
DR. CERQUEIRA: All right. Call for a vote.
All in favor?
[Show of hands.]
DR. CERQUEIRA: Opposed?
[No response.]
DR. CERQUEIRA: Anyone abstaining?
[Show of hands.]

MS. HANEY: Okay, one abstention and everyone else is in favor.

[Ten yeas, no nays, one abstention.]

DR. CERQUEIRA: Thank you. Excellent. Do we have any more items?

MS. HANEY: Betty Ann is going to talk to us real briefly about where we stand on the self-evaluation criteria, and then we'll just talk about when we're going to meet next time.

DR. CERQUEIRA: Okay, and we can talk perhaps a little bit about the agenda in the future, some recommendations, and formats and things.

MS. TORRES: I think it is winding down.

I am not going to say much about the ACMUI self-evaluation. I will save that till the end because I do have some other comments regarding other documents.

First, I have to say when I came to the NRC less than a year ago and I was told that I would be working with this committee I was thinking, oh, my gosh.

I have to give my thanks to Cathy Haney. She has been very, very helpful, in my being able to my job and also Torre Taylor and Diane Flack and Trish Holahan, but I especially thank you committee members because every time I have contacted you by phone or e-mail you have been right there, responding all the time, and that really makes my job

much easier, and thank you so much.

Also, Theron Brown is not in the room but I have to say he is the expert with this equipment and I'll have to say this meeting has run really well --

DR. CERQUEIRA: Very smoothly.

MS. TORRES: No failures at all, so I give my thanks to him.

Now several of you asked about getting a copy of the strategic plan. I managed to scrounge up six copies, so --

MS. HANEY: We've got more.

MS. TORRES: You're got more? Good.

Okay, so Melissa had more and she passed them out. Great. So I have six extra copies.

[Laughter.]

MS. HANEY: We can give extras.

MS. TORRES: Okay. Dr. Cerqueira mentioned travel forms. I have passed out some travel forms for you. If you have questions you can contact me, e-mail me or contact me by phone.

There's also professional service vouchers that I will be passing out and that is to account for your time, your professional services, and if you have questions about those forms, filling them out, then you can contact me.

Someone said they wanted some of the inspection

reports regarding the Mallinckrodt incident and the information notice that went out. I do have copies over there, so when you are ready you can just pick up one.

This happens to be inspection reports here.

This is the information report, which is much smaller, but they are over there.

Now ACMUI Self-Evaluation -- that is something that is done annually by this committee, by "self" and is provided to the Commission and we just did one, the committee did one last year, and that was forwarded to the Commission.

This one we will be doing, you will be doing, excuse me -- we, the Staff, will also evaluate this committee but the evaluation I am talking about now is self-evaluation and this is where you have input into how you meet the certain criteria that are in your book. There are criteria in your book. We will be doing that at the spring meeting.

If you have any questions regarding that you can contact me. Cathy Haney is very good at a lot of answers for a lot of things because she has been working with this committee for quite awhile.

That is all I have to say about the ACMUI self-evaluation. Ruth?

DR. McBURNEY: In preparation for that meeting, I

think it was real beneficial last time to have a draft or maybe get e-mails from the committee on each of those questions and sort of bring those together so we get a draft document that we can just go down the list.

MS. HANEY: So what we could do, Ruth, is maybe when we decide when the meeting is going to be, about six weeks before the meeting we will send this out with a reminder, "Please take a look at these" -- give you your feedback and then I'll integrate it into one document, and that will be what you work from at the next meeting.

MS. TORRES: Yes.

MS. HANEY: Okay.

MS. TAYLOR: That would be helpful.

MS. TORRES: Any more questions or comments?

DR. WILLIAMSON: It might be helpful to send the self-evaluation of last year.

MS. HANEY: That's in the book, Jeff. You've got it.

DR. CERQUEIRA: The very last page.

MS. TORRES: Okay. Any other questions or comments?

DR. NAG: Has anyone ever given themselves a negative evaluation? Or yes-yes-yes-yes --

MS. HANEY: Well, we have only actually done this, this is the first time that the committee has evaluated.

This was an effort that started about two or three years ago for the advisory committees -- NRC has three of them -- to develop self-evaluation criteria, and then for Staff to evaluate them, so the one that you have in the book is the one and only one that's been done, so certainly if you don't feel that you're doing a good job in one particular area we can -- you can always put down "no."

DR. CERQUEIRA: John?

MR. GRAHAM: And I think I'd observe for the record, having been here for the better part of six years now, that we have continuously advocated at time different parts of the committee that the NRC could potentially pull out of most of the activities related to the medical use of isotopes and that this committee would then become moot.

Yes, we have had that discussion -- many times.

DR. CERQUEIRA: Okay, well, thank you very much.

I think the use of the e-mail, I think everybody on this committee has an e-mail address and uses it and certainly getting the material out -- it's a burden bringing all these heavy papers and things so whatever can be done by e-mail would be I think the best way to do it.

All right, then we go on to the next --

DR. WILLIAMSON: I just want to make a suggestion about that.

I am the Chair of a committee in the AAPM called

the Radiation Therapy Committee and at our three meetings we typically have hundreds of pages that we need to review, so we have put everything online electronically as PDF documents with a secure access and members of the committee can download and print what they feel they need to if they want to mark up something or just keep it on their laptops, and that has eliminated the need for briefing books in our organization.

DR. CERQUEIRA: All right. Well, I think we have to discuss the next meeting dates and agenda topics.

Perhaps we can start with the agenda topics a little bit. Pretty much the Staff proposes the topics of issues that they feel they need input from the committee or they want to inform the committee of ongoing actions.

I think it would sometimes be -- the types of things that we go over are usually information to us or decision-making. For the information it would be useful, as we said yesterday, if the material is sent out ahead of time, certainly e-mail access would be the best webpage access.

It should really be brief I think in terms of the overall presentations at the beginning of these sessions.

Most of us, if we have the material, do take the time to go through it, so I think the presentations here could be somewhat focused. We don't always need an

extensive review, background material.

Again, we have got a varied committee and I think if people have specific questions or issues we would sort of be able to supply that during the meeting.

For the information I think there should be a specific focus on the relevance for this committee in any of the decision making relative to regulations for medical use.

The other thing that we're asked to comment on is actually decision-making where basically the Staff has been asked to create a document or make decisions for the Commissioners and we should have these questions that you would like input from the committee on clearly identified and perhaps at the beginning of the presentation show the question so we know exactly what to focus on and then bring them back towards the end so we can address each question specifically and again the presentations would be useful if they just focus on the relevant background for the committee members.

There's a lot of things that go on behind the scene that are important but I am not sure that they really contribute very much to the decision-making of the committee.

Jeff?

DR. WILLIAMSON: I think the word "decision-making" is a little misleading.

DR. CERQUEIRA: Yes.
DR. WILLIAMSON: I think we make recommendations and give opinions. We have no decision-making authority in this organization.
DR. CERQUEIRA: I stand corrected.
DR. WILLIAMSON: Except perhaps as regards making rulings on training and experience.
DR. CERQUEIRA: It's advisory. Okay. What else under agenda topics do we --
MS. HANEY: I think the focus of the next meeting is probably going to be some more of these board issues, letters that we have gotten and questions that have come up from people that are starting to read Part 35 and coming in with implementation questions, so I think the big focus of that meeting will be implementing Part 35 depending where we are on the rulemaking that I talked about, the proposed rule as well as what the Commission decides to do on the one that Torre talked about.
There may be some fine points, some input that we are looking for you on that particular item.
Cindy Pederson's talk this morning is going to move into Phase 2, which is going to really start implementing some of the recommendations that's going to come out of that group, and with that we are going to start revising inspection procedures and a lot of our inspection

procedures touch the medical, so there may be a presentation on that particular area.

The other thing, too, that we didn't talk about today, because we are right in the middle of it, is the implementation of the Medical Pilot Inspection Program that went out for a year, so by the next meeting we should have lessons learned on that, and that took a much more performance-based approach with inspecting for licensees of using unsealed materials, and the question will be whether we move into the sealed sources with that sort of use too, so at least from what I know now, trying to project out six months, that is the sort of topics, almost a continuation of this meeting.

DR. McBURNEY: Where will we be with IBB?

MS. HANEY: Well, I think we will have hopefully gained a little bit of experience with getting some license amendments out and what some of the requirements are.

We could maybe have a little more formal discussion on what the training requirements should be for use of IBB under the new Part 35 and focus more on our requirements as compared to whether it is done by what specialty -- you know, maybe we'll be moving closer to having some type of is it 700 hours in one year or 700 hours in two or 700 in three or do we even go there.

It may be more than just a two-hour discussion

that we would have at the next meeting on that and we would focus on the future as compared to right now.

This one was a little bit hard because we were trying to deal with right now and set the stage for the future.

DR. CERQUEIRA: Jeff?

DR. WILLIAMSON: Yes. With regard to intravascular brachy, Bob Ayres presented what I thought were preliminary criteria for writing license amendments. You know, I think there was considerable disagreement with those criteria within the committee, so what is going to be the resolution of that?

Are you simply going to go ahead with the criteria as he stated them or are you going modify them and give us another opportunity to look at them?

MS. HANEY: Well, I'm kind of guessing here, Jeff, but I think what is going to happen is we are going to have to deal with this issue right now that we are dealing with it.

I think it's enough for management here to know, NRC management, that is in the decision-making for what goes into these license amendments to know that the committee has some issues with the level of prescriptiveness in these requirements, on some of them like for example an easy one is whether a film badge needs to be stipulated or not, so I

think -- I mean you certainly have the opportunity to look at them again and it could be one of those issues that the committee chooses to put on the agenda.

If you look at one of the self-evaluation criteria, it is, you know, do you bring issues to Staff? I mean this could be one that you want to revisit where Staff is.

DR. WILLIAMSON: One of the complaints that has been made in the past, since we don't get a follow-up on the resolution of some of the things we give opinions on, especially those where there's sort of, you know, obviously disagreements between the Staff and what the committee recommends, so I definitely think this one should be revisited and at least the resolution of what you decided to do be presented to the committee.

MS. HANEY: We can do that.

DR. CERQUEIRA: It might be worthwhile again -- I agree that lots of times we have four hours of discussion and then we never really see what the conclusions are, and perhaps we could -- we generate the minutes and there are specific recommendations that are made, especially where we take a vote.

Maybe at the beginning of the meeting we could review sort of an update on the specific issues that we made recommendations on.

DR. WILLIAMSON: That actually was proceduralized briefly under Larry Camper.

MS. HANEY: Yes, and we did it for the first -- and we have been so focused on 35, and so this really was the first meeting where we are almost starting with a clean slate to a certain extent on some of these issues about like the inspection and the new rulemakings that I have brought to you, but certainly at the next meeting we can start out with what we have been doing and what we did with your recommendations.

DR. WILLIAMSON: That would be good.

DR. NAG: I did not bring this up while we were discussing the SRM -- although we did mention about it, I did not make a motion because we were running out of time.

Is it appropriate to make a motion now and if it is I would like to make a motion that the ACMUI does not support the Commission decision about the SRM to instruct the Staff to propose the level of support of revision to Part 35, especially the words similar to what Commissioner Dicus had said, but I would like to make a motion and read it out very similar to this.

Is it appropriate to make that motion? Can we do it?

I think that will reinforce the ACMUI's position that, you know, we are really -- I said that we are

supporting Commissioner Dicus' additional view. I would like to make that as a motion.

DR. CERQUEIRA: I don't know if there is a precedent for this. I think it's probably a bad precedent to sort of, you know, to read one Commissioner's sort of minority vote perhaps --

DR. NAG: When we were discussing we basically all supported what her position was, so what I want to say I support that position and make a motion that the ACMUI feels this way and the Commissioners can do whatever they want.

DR. CERQUEIRA: I don't have -- Ruth?

DR. McBURNEY: I think it would probably be more appropriate during the rulemaking process.

I mean they have already decided to go forward --

DR. NAG: But we can still --

DR. McBURNEY: -- with this rulemaking and we can still make that statement, but it would be more appropriate during the rulemaking process, I think.

DR. CERQUEIRA: Richard?

DR. VETTER: I thought the sense of our earlier motion actually captured that.

DR. McBURNEY: That's right.

DR. VETTER: Without actually mentioning her words, we took that position.

DR. NAG: We didn't make any --

DR. VETTER: We did. We --
DR. McBURNEY: We did.
DR. VETTER: We proposed an alternative rule --
DR. McBURNEY: Right.
DR. VETTER: -- which eliminated the putative responsibility to actually determine by questioning a patient or listening to a patient.
MS. TORRES: Excuse me, may I say something?
The Commission does get a copy of the minutes, so all your discussions are brought to the attention of the Commission.
DR. CERQUEIRA: Do they read them?
MS. HANEY: Oh, yes. The minutes are read. That I know. They are also provided copies of the transcripts and on occasion when there are key issues such as this one, the Commissioners will go back and read it.
DR. CERQUEIRA: So I guess the feeling was it's been incorporated.
Dr. Diamond, do you have any further comments or suggestions?
DR. DIAMOND: I believe it's been incorporated into the motion that Dr. Williamson has already put forward and voted on.
DR. CERQUEIRA: Okay. Jeff?
DR. WILLIAMSON: I would just suggest to Mr.

Chairman, when you prepare the minutes, which I think you have to do, you could indicate that the sense of the discussion was that this was not a very practical or necessary rule but that if a rulemaking had to be made and there was concern over this, here is the opinion of the ACMUI, in terms of a proposed replacement rule.

DR. CERQUEIRA: Okay, so I guess then the feeling of the committee is that it has been incorporated. Okay.

There is one item that did come up that Cathy and I talked about briefly and that really sort of goes back to what I see as probably the big agenda for this committee for the next several years both in terms of the expanding technology and sort of the turf wars that have traditionally been fought in this arena, and that is related to IVB.

I guess the cardiology -- I am not an interventional cardiologist and I guess I am the only representative on the committee who is, even though I am a nuclear medicine physician I am also a cardiologist.

And I really don't feel comfortable speaking for the interventional cardiology community. I guess a letter had been sent, requesting an appointment to the Committee of an interventional cardiologist who could pretty much give their viewpoint.

I guess it's perhaps gone into the wrong channels and will probably have to be resubmitted, but I -- well, I

do think it would be appropriate to get their input. I think, by my not being an interventional cardiologist, I can't speak for them.

And also, by being Chairman of the Committee, I've tried to keep sort of a neutral position as much as possible, and to some extent, that doesn't allow me, I think, to be as strong an advocate, perhaps.

But I think it would be appropriate to have input from an interventional cardiologist to this Committee.

Dr. Nag?

DR. NAG: How about having an input from an gynecologist/oncologist who does implants in the population, input form the urologists who do the prostate implants, and the number of prostate implants are much larger than the cardiologists.

How about having input from the endocrinologists? I mean, I think you are setting a precedent that would sort of -- is not really required, because the brachytherapy is being done by so many different people.

The neurosurgeons do all the gamma radiation with that, so each of those subspecialties will then require a representative.

MR. LEEDHAM: This is an administrative point: I don't know how you have your Committee set up, but at FDA, we have advisory committees, and we have a list of

consultants that can be brought in when we have special topics to be discussed.

If we have an application that's going to be affected by a certain specialty like oncology or neurology or cardiology, we will then have special government employees who are consultants to the FDA, who will come in for those meetings. Do you have that capability here?

MS. HANEY: We have the capabilities. What we just do is invite individuals to come. And we can do it by subspecialty or by specialty. The issue comes about whether they're a voting member of not.

I mean, if they are an invited guest, they're not a voting member; if we seat them on the Committee, then they do have a vote.

But in all honesty, the Commission does consider all views, whether you're voting or not voting. The actual membership of the Committee is approved by the Commission, so, I mean, in order to seat another specialist on the Committee, we need to get Commission approval.

So we're kind of in between with what FDA does, but we can have someone at least come.

MR. LEEDHAM: I think that might solve the problem you were talking about with the interventional cardiologist and so forth.

DR. DIAMOND: My suggestion would be to go and

formalize to some extent, how we select our invited guests. Everything that is said does make it to the public record, does become a part of the transcript.

And perhaps it would be best that in the future, when we invite people, that we ensure, number one, that they were actual experts in that particular field and not just representing the particular financial interests or other interests of a group, number one.

And, number two, when we have these discussions, that they be more focused to specifics that this Committee would be interested in.

So, for example, two of our speakers, our invited guests yesterday, I think, were very effective, and one was not, and perhaps if we had ensured that every individual who had been invited actually was an experienced practitioner in the field, that would have been helpful.

And if we had provided them with a series of questions, or lists of concerns or topics, that we could have been a lot more focused and not just talking past each other, and that would have provided us the information, the guidance that we would like to see.

DR. CERQUEIRA: Although, again, we don't ask people to come and speak. I mean, people request. Well, we could ask people, but --

DR. DIAMOND: That's what I'd like to see. In

something like this, instead of asking someone at the last minute to come --

DR. WILLIAMSON: But they weren't asked.

MS. HANEY: Well, what Dr. Diamond is referring to is when we issue a Federal Register Notice to make the meeting announcement known, we say that if you would like to submit information for the record or if you want to make a presentation, contact us.

So that was done in one case. And it was, in my situation, you know, knowing that we had had a request for time to speak from one specialty, I made a decision, and I did talk to Dr. Cerqueira -- I'll drag you in on this, too.

DR. CERQUEIRA: Sure.

MS. HANEY: About whether it would be worthwhile or not to give the other professional organizations an opportunity to talk for a couple of minutes. I mean, in hindsight, it might not have been the best decision to do that, but what we're looking for is, you know, everyone having the opportunity.

Now, looking ahead to next meeting, we might want to formalize that, and if there are specific members, individuals from the public that you would like to have as invited guests, rather than relying on them to notify us, we ask them, we can do that.

DR. CERQUEIRA: In this situation, we got a

request from the cardiologists to make a presentation, and Cathy and I discussed it and we felt it appropriate to get sort of the other perspective.

DR. DIAMOND: Exactly, so this circumstance, this special circumstance of individuals were asked in an effort to maintain fairness, if you will, but I think that in the future, it would be useful to invite specific experts with instructions that we'd like to cover specific areas of concern, focused, and not start talking past each other again.

DR. WILLIAMSON: The idea would be to invite somebody to come because of their professional expertise and represent their opinion and not come as a member of an organization.

DR. CERQUEIRA: It's kind of hard to separate that out.

DR. WILLIAMSON: It is, but you can certainly invite them as individual practitioners versus inviting them as a representative of an organization. There is a big difference. You pay their expenses to come here and participate.

DR. CERQUEIRA: Well, no, we --

DR. WILLIAMSON: Yes, you can. We can invite a consultant.

MS. HANEY: But that's different than what was

done yesterday.

DR. WILLIAMSON: That's correct, and that's what I'm point out. I'm suggesting that I think that's really what David means.

MS. HANEY: And we can do that, but we also have to recognize that the Commission will be contacted by professional organizations, wishing to make a statement on behalf of their professional organization.

DR. WILLIAMSON: I'm not suggesting that we exclude that.

MS. HANEY: Okay.

DR. WILLIAMSON: But that if we want somebody that can participate in a less partisan way with this group of people, we should invite them with that expectation, and, of course, they'll have their connections with their own community, as all of us do, too.

DR. CERQUEIRA: But, Jeff, part of the problem with that is to ask individual people, if you look within any professional medical society, you're going to have a variety of opinions on certain things.

And part of the reason to try to get to societies is to see them as the spokespeople for the field. Because, you know, I know that even within the interventional cardiology community, there is a lot of disagreement as to what will eventually work and not work.

DR. DIAMOND: So perhaps the way to get around that is if we're going to have a focused discussion like this, perhaps the way that we approach it is, we contact the appropriate professional organization or organizations and say we would like to have a discussion of this issue and would you please nominate from your society, someone who has extensive personal experience, and that we would like to address topics A, B, and C.

DR. CERQUEIRA: Yes, I think that would be more appropriate, rather than inviting individual people. And we've always, you know, relied on that method, and the societies pay for their people to come and everything. So it's -- John?

MR. GRAHAM: Well, I think it has to be a spokesperson representing the group, because it's the group that has to collectively develop recommendations that -- the only thing I'd add is that I think we ought to request of those specialty groups, that if they are proposing a different set of training criteria to substitute for what we've documented in the new Part 35, that that should be formalized with a vote of recommendation from their group to be presented to this Committee.

The missing link yesterday was, I don't specifically -- that's fine if you want to come here and say I don't agree with what you've written up as the proposed

training criteria, but then if you don't give us a very specific alternative that we can evaluate to determine whether it achieves the same level of safety, then it does just become a circular discussion about, well, we don't think it ought to be this elaborate, it shouldn't be this specialty; it ought to be some other way.

So, I guess I'd recommend that as you are contacted by specialty groups that have an interest in these developing modalities, that that would be a staff request to them, that they understand the expectation is that they're bringing forward specific alternative recommendations that achieve the radiation safety requirements that are outlined in the revised Part 35.

DR. CERQUEIRA: Yes. I think it's appropriate now. I think that a year ago when we had these discussions, it was evolving technology with no available equipment out there.

Now, as we heard from Bob Ayres, it is going to be out there, and it is more of a decisionmaking.

You know, Neki, from a patient's perspective, you know, these are sort of turf wars to some extent, and I guess that sort of sitting in the audience, the best approach is to stay out of the way.

But how could we resolve this, or at least make some recommendations to the NRC from a patient's

perspective? She doesn't want to get near the microphone.

MS. HOBSON: No, I really don't know. I kind of expressed my views yesterday on the issue that was on the table.

DR. CERQUEIRA: Right.

MS. HOBSON: But it was obvious that there was some turf war going on, and I guess our Committee needs to stay clear of those as much as we can.

DR. CERQUEIRA: Yes, Lou?

DR. WAGNER: I mean, I think the point is that the Committee has to stick to what our criteria are for making any rule decision, any decisions. We have to say what is required to meet these standards of safety, period.

That's all we've got to focus on. And the turf wars go away. You focus only on that, and you listen to everybody, and give everybody their fair say.

I do think it would be helpful if we limited the people who want to speak to a certain amount of time, and tell them ahead of time, you have a certain amount of time, and you will be cut off after five minutes or ten minutes or something, to make your statement.

Discussion is open, but to make your statement, you have a limited amount of time. That we do. There gets to be some -- some things get to be disproportionate, and when speakers jump in and interrupt other speakers who are

trying to make their statement, that is totally inappropriate, and that should be stopped immediately.

Speakers should not interrupt other speakers and jump in and say, well, you're lying or you're not telling the truth. That's just inappropriate, and that should be stopped immediately.

DR. CERQUEIRA: Yes.

DR. WILLIAMSON: I really think I disagree with your solution, Manny. I think that from the perspective of the cardiologist, it would be much better to have NRC pay the expenses for someone to come here and participate fully in the discussion with this Committee as a non-voting member, instead of having to bear the burden of a partisan -- being the partisan representative of some group and stand up and give some little five-minutes speech.

I think, you know, the way to not get involved in turf wars is exactly what Lou said. We need some -- you said we need somebody with the clinical expertise to have a complete discussion. We should get somebody with the clinical expertise and instruct them that's the reason for them being here.

I initially, you know, began to interact with this Committee, more or less on that basis. As you know, I was invited here and my expenses paid because the Committee at that time lacked resources in a certain area or expertise in

a certain area.

DR. CERQUEIRA: I guess the one thing is that if you look at the people around the table, most of us were nominated by professional medical societies as sort of a nominee. That didn't mean that the NRC had to be appoint those people, but certainly that was the mechanism by which people are currently here.

DR. WILLIAMSON: I think it would be appropriate for Cathy to contact a couple of these groups and ask for recommendations for a couple of people, and then you could choose somebody.

MS. HANEY: But that's the issue of then they're here as an invited guest.

DR. WILLIAMSON: That's correct, an invited guest.

MS. HANEY: So the issue that I think that Dr. Cerqueira is bringing up is invited guest versus a seated member. And there are different rights with being a seated member.

DR. WILLIAMSON: I understand, but it's not possible to have a seated member in six months.

MS. HANEY: No, definitely not in six months, but I think the issue is whether we would peruse that long-term. No, for the next meeting, if the Committee believes that it's appropriate. You don't need to answer now. We can wait till we see the agenda or get closer to the meeting.

Or I can act on it now. It's just -- go and ask -- you know, say we will be having a Spring meeting and we would like to invite some one from your organizations to represent whatever at this meeting.

And I can do that right now, but then the question is whether I pursue trying with the Commission to get a cardiologist with intravascular experience seated.

DR. CERQUEIRA: Richard?

DR. VETTER: I would favor inviting subject experts for the next meeting, not pursuing long-term appointment at this time. There were some in the cardiology community who feel that this is going to go away; that there are medical -- that there are medicines that will replace the radioactive therapy.

DR. NAG: I think I support Jeff's position that instead of -- I mean, we invite, rather than having the societies send someone, we invite people. We can ask for suggestions from the societies, but we don't have to take them.

We know who the experts are, who are the ones who are giving international courses, who are -- and have the society input, and the ACMUI can give some names, and you know, Cathy or the Staff can select one person and invite them at the NRC expense.

It will, I think, serve a couple of purposes:

One, that person would not be bound to be representing only a society position, but will be giving an expert opinion. You know, I think that would be a much better way.

DR. CERQUEIRA: So there is some thought to have a consultant type person, not necessarily represented by the professional medical societies, although I think that from the cardiology perspective, they still would like to have somebody here who could sort of espouse the overall views.

DR. WILLIAMSON: They can always request a time slot for five minutes to speak.

DR. CERQUEIRA: Or we would have somebody sit on the Committee, basically, as a non-voting member till that gets decided.

DR. DIAMOND: I'd like to echo a point that Lou made, which is, let's say we have one or two or three invited guests here; that instead of having them come up and make PowerPoint presentations, I think it's much better for them to be seated at the table so we can have a focused discussion of issues, and not just a presentation after a presentation. We need to really cut to the chase and be able to have an interactive discussion. So I would suggest that type of format as well.

DR. CERQUEIRA: I think this time, we were dealing with two issues: One was obviously the NRC's need to have some immediate recommendations on how to do the licensing.

And the other one was sort of this ongoing issue about who is going to be doing the procedures. A lot of people are pulling out their date books, so I think we have to select a date.

Now we will have a spring meeting, is that correct?

MS. HANEY: We will have a spring meeting and I would say we can go ahead and pick the date. Recognize we might have to change the date because typically the ACMUI briefs the Commission once a year, and in that case we are somewhat at the mercy of the Commission's schedule, which might cause a change, but to be honest, given where we are right now, unless the committee sees a need to brief the Commission I am not sure that we need to, but I also don't want to tell you whether you need to brief them or not.

That is something that we can change, you know. We can revisit back in the January timeframe, so with that as a caveat I would look for a meeting date some time around the end of April, beginning of May, and I am not sure when Easter or any of the holiday, the spring holidays would be but if you want to -- and I know Dr. Alazraki gave me her schedule so I have that one.

DR. CERQUEIRA: Now if we do meet with the Commissioners, is this rule that all five of them have to be present?

MS. HANEY: Yes, so you are really -- but I think unless I hear a reason that you guys feel strongly that you need to meet with the Commission about the status of the medical program, I would probably recommend to the Commission that it really be put off until you have got some experience with implementing Part 35, and then it gives you something to talk about to them.

I don't believe that they have any issues right now that they want to discuss with you guys, so I think we are probably clear of a Commission briefing but just know that I might be calling you and saying remember that Commission briefing that I said wasn't going to take place? Now it is going to take place.

End of April -- draw up a date.

DR. WILLIAMSON: The last week of April looks good.

DR. NAG: The last week of April looks good. The last week of May we have the ACRO meeting.

DR. WILLIAMSON: I would certainly like to omit May, since I have a grant application due.

DR. CERQUEIRA: So we are really talking about April. The last week of April is for me a little bit difficult because of preparation.

DR. DIAMOND: Does anybody know when Passover is next year?

MR. UFFELMAN: Passover begins on Saturday, April 7th. Palm Sunday is the 8th. Easter Sunday is the 15th.

DR. DIAMOND: So the very end of April will be fine.

DR. CERQUEIRA: Yes. Would the 18th and 19th of April work? That is a Wednesday-Thursday combination similar to what we have done today.

DR. WILLIAMSON: That works for me.

DR. CERQUEIRA: Okay, so 18th and 19th of April.

I guess by that time we will have hopefully published Part 35 and --

MS. HANEY: I would hope so.

[Laughter.]

DR. CERQUEIRA: Now will you be continuing with the committee?

MS. HANEY: My continuance with the committee is not for sure yet. There are some discussions about taking the responsibilities for this committee and moving it to another branch within our organization. John Hickey is the Branch Chief for that.

If that takes place, then I mean I won't be sitting here. I will be sitting in the back, you know, doing -- turning red in the face I guess when you talk about things and I want a microphone.

[Laughter.]

MS. HANEY: At the same time, it is very possible that I will be here, but there is some talk about me changing.

DR. WILLIAMSON: What is the other branch?

MS. HANEY: The other branch is called the Materials Safety and Inspection Branch.

Bob, Roberto and Diane are all in that branch. For those that have been around for awhile, it is Larry Camper's old branch. Now Larry has moved on to work in another area but John Hickey is the Branch Chief and he would be sitting here, but I won't be far away.

If I am not sitting here, I will be close by.

DR. McBURNEY: We certainly appreciate you.

DR. CERQUEIRA: Yes, I think Cathy basically has all the stored wisdom of the Part 35.

I would like to -- John?

MR. GRAHAM: One last item on training, just to get it into the official record of the meeting.

There was some discussion regarding how to deal with individuals that didn't have the specialty training that we had identified in the rules that were under development, so I would move that the ACMUI recommends exemptions to the designated specialties listed in 35.961 based on a case by case review by the Chairman of the ACMUI with input from other members of the committee as requested

by the Chairman.
DR. McBURNEY: Second.
DR. VETTER: I don't know -- I am not sure I --
DR. CERQUEIRA: I think this was related --
DR. VETTER: There are a couple physicists --
DR. CERQUEIRA: -- to the physical chemists yesterday who --
DR. VETTER: I understand that.
MR. GRAHAM: We were in closed session at the time we reviewed those.
DR. CERQUEIRA: Okay. I thought we were re-opening the issue.
MR. GRAHAM: No, we just didn't officially get it in.
DR. CERQUEIRA: So we have a proposal and a second.
Any discussion?
[No response.]
DR. CERQUEIRA: Call for vote.
All in favor?
[Chorus of ayes.]
DR. CERQUEIRA: Opposed?
[No response.]
DR. CERQUEIRA: Anyone abstaining?
[No response.]

MS. HANEY: Everyone in favor then? No abstentions?
DR. CERQUEIRA: Yes.
MS. HANEY: All right. Declare the meeting closed.
DR. CERQUEIRA: I declare the meeting closed. I would like to thank all the members and the Staff for their support, and we ended on time.
[Whereupon, at 12:00 p.m., the meeting was concluded.]