UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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MEETING WITH ACMUI AND

NRC STAFF

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Nuclear Regulatory Commission

One White Flint North

Rockville, Maryland

Tuesday,

March 2, 2004

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

COMMISSIONERS PRESENT:

NILS J. DIAZ, Chairman of the Commission

EDWARD MCGAFFIGAN, JR., Member of the Commission

JEFFREY MERRIFIELD, Member of the Commission

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

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

Secretary

General Counsel

DR. CARL PAPERIELLO

DR. CHARLES MILLER, NMSS

PAMELA HENDERSON

THOMAS ESSIG

DR. MANUEL CERQUEIRA, Chairman, ACMUI

MR. RALPH LIETO

DR. LEON S. MALMUD, Subcommittee Chairman

DR. JEFF WILLIAMSON

P R O C E E D I N G S

CHAIRMAN DIAZ: Today we are meeting to hear from the Staff and from ACMUI regarding their programs. We are obviously very pleased to have this meeting and learn all the things, good things that are going on.

We will hear from the Staff first, I understand, and then from ACMUI. This is one of the annual briefings the Commission holds. We try to become fully and currently informed with all of the details.

And I think there are issues that keep coming up. Some of them are old issues that have a life of their own and others are new issues. We look forward to hearing from the staff and ACMUI on these issues.

With that, Mr. Paperiello, unless my fellow Commissioners have a comment, please go ahead.

MR. PAPERIELLO: Good morning, Chairman, Commissioners.

The Staff are pleased to have an opportunity to brief the Commission on aspects

relating to Revised Part 35, the medical use of byproduct material. And specifically, the Staff is going to be presenting the NRC's experience implementing this rule.

This medical regulation has evolved over the years and the latest revision that was completed in October of 2002 incorporates a risk-informed and performance-based philosophy.

The Commission is also going to be briefed on the status of follow-up actions related to dose reconstruction pertaining to an event which occurred at an NRC licensed medical facility involving an overexposure to a member of the public.

You are going to be briefed by both the staff as well as members of the Advisory Committee on the Medical Use of Isotopes on this subject.

And the advisory committee will also brief you on the revisions of Part 35 with respect to training and experience.

And with your permission, I would like to turn the presentation over to Dr. Miller.

DR. MILLER: Good morning, Chairman,

Commissioners McGaffigan and Merrifield.

I wanted to make a couple of opening remarks before I turned the microphone over to our presenters this morning.

Over the course of the one year that I have been the director of the Division for Industrial and Nuclear Medical Safety, I and my staff have taken on a challenge for continual improvement of our medical regulatory program. There are three near term goals that I have set for myself and my staff to work on.

The first is to enhance our working relationship and the utilization and effectiveness of the Advisory Committee for the Medical Use of Isotopes to advise the NRC.

The second is to complete the Part 35 training and experience rulemaking which we currently have undergoing.

And the third is to provide technical support to the regions on the implementation of the revised Part 35.

What we doing now, these next two days, is we are in our current meetings with the advisory

committee. We do that twice a year.

We have broken from those meetings to meet with the Commission this morning and will resume our meetings with the advisory committee this afternoon.

We had some fruitful discussions. And today we will focus on two subjects that Carl spoke about. And I would like to turn the microphone over to Pam Henderson from Region I to give the regional perspective on the implementation of Part 35 revised program to date.

Pam.

MS. HENDERSON: Good morning.

The NRC's approach to regulation of medical uses of byproduct material has undergone a profound change. It is less prescriptive. It is risk-informed and performance-based.

What we are seeing in the field. We no longer require submittal of detailed procedures for limited diagnostic programs. And licensees are still adjusting to this idea.

Licensees frequently have questions concerning interpretation of the regulations and the

expectations of the NRC. To that end, we have questions and answers on Part 35 on the NRC website. This has provided a wealth of information for licensees and for NRC license reviewers.

One of the most significant licensing challenges is to encourage licensees to use NUREG 1556, Volume 9, the "Program Specific Guidance About Medical Use Licenses."

This streamlines the licensing process both for licensee and the license reviewer. We are still seeing licensees submitting procedures from the old Regulatory Guide 10.8, Revision 2. But we are making a lot of progress because licensees are becoming aware of the ease of submitting an application under Volume 9.

COMMISSIONER MCGAFFIGAN: Mr. Chairman, could I ask a clarifying question?

This NUREG-1556, Volume 9, is that the NRC staff product? I also know we endorsed a Reg Guide that was submitted to us for diagnostic users. Is this your product or the other product?

MS. HENDERSON: That is the staff product.

COMMISSIONER MCGAFFIGAN: This is a staff product. But the other product is consistent with this staff product?

MS. HENDERSON: Yes.

COMMISSIONER MCGAFFIGAN: And we have found it as such.

Are people using that other product if they are diagnostic?

MS. HENDERSON: I don't know the answer to that question.

Inspectors are finding that most licensees express a preference for the earlier, more prescriptive approach to Part-35.

When we visit facilities, we find that radiation safety committee meetings are still being held quarterly.

Daily surveys are still being done in diagnostic use areas.

Dose calibrators are still being used to measure unit dosages prior to administration.

And licensees are still doing linearity, geometry and accuracy tests on their dose calibrator

at the same frequency and following the same procedures that were provided in Regulatory Guide 10.8, Revision 2.

Licensees continue to submit items that are no longer required. Quality management programs are still coming in but these are tapering off.

We are still getting detailed procedures for diagnostic use of byproduct material.

We need to improve licensee understanding of the details that need to be submitted for 35.600 technologies such as high dose rate after loaders and gamma knives, specifically for the safety procedures and spot checks that are required.

COMMISSIONER MERRIFIELD: Mr. Chairman, can I ask a clarifying question regarding the presentations on five, six and seven?

Why? Why are -- you said what the licensees are doing. Why are they doing that?

MS. HENDERSON: They feel comfortable. This is the reaction that we are getting. They feel safe doing it the old way because they know it meets the regulations and then some.

We need to improve licensee understanding of the 35.1000 emergent technology procedures. To that end, on the NRC website, we have posted guidance on the 35.1000 technologies. And this has been very helpful to licensees in understanding how they can meet the regulations and also to license reviewers who are reviewing license applications for these technologies.

The regions are updating medical licenses as the licensees come in for amendments and not waiting until renewal of the license, which can be up to ten-year renewal.

Updates include user authorizations. One example of this is under the new Part 35 regulations, 35-200 now deals with diagnostic procedures that do not require a written directive.

Under old Part 35, it included all diagnostic procedures whether or not they required a written directive.

We have had to go to the licenses and ensure that we are not taking away any authorizations for users.

We are also removing old license conditions that are now covered by the regulations such as HDR. Where we had five or more added conditions to licenses in order to allow them to use this equipment.

These conditions are now part of the regulations and are no longer necessary on the licenses.

COMMISSIONER MCGAFFIGAN: The licensee understands that?

MS. HENDERSON: Yes. Very well.

COMMISSIONER MCGAFFIGAN: You have given the lack of understanding about the new rule. I just want to be clear on that.

Thank you.

MS. HENDERSON: We have added new conditions to the licensees to permit them greater flexibility.

Inspectors agree that new Part 35 focuses inspections on more safety significant areas of medical programs.

We are ensuring that inspectors do a

performance-based inspection. That they do not do a record-keeping inspection. That they only look at a representative sample of the records.

The labor rates for inspection and management accompaniments of inspectors confirm that inspectors are implementing this new approach.

COMMISSIONER MERRIFIELD: In what way?

MS. HENDERSON: We are seeing that the labor rates are going down. And on management accompaniments, we are seeing that the inspectors are, in fact, doing risk-informed, performance-based inspections and not spending a lot of time reviewing records or looking at any prescriptive commitments the licensees may have made.

For most licensees, the first inspection under new Part 35 includes education about the details of the new regulation and guidance about program changes that may be needed.

Finally, the staff actions to address the challenges.

We are continuing dialogue with the licensee community. This is especially important

during licensing and inspection when we deal directly with the licensees.

There is close coordination of the regions and headquarters, specifically every other week the regions meet with the Part 35 working group to discuss various issues coming in from licensing and inspections.

These issues are able to be resolved very quickly and additional questions and answers are added to the website as we come up with these solutions.

The NRC public website has provided guidance to licensees with regard to 35.1000 procedures. This guidance can be updated whenever necessary.

And again, the questions and answers posted on the website provide a wealth of information for licensees.

Thank you.

DR. MILLER: Next I would like to have Tom Essig. He is going to brief the Commission on the status of the dose reconstruction effort in St.

Joseph Mercy Hospital that you had asked us to brief you on today.

Tom.

MR. ESSIG: If I could have the second slide, please.

First, in the way of background, St. Joseph Mercy Hospital is a 529-bed teaching hospital located in Ann Arbor, Michigan. On July 1st, 2002, a female patient was administered 285 millicuries of I-131 for treatment of thyroid cancer.

The patient's daughter was observed following the treatment to be frequently at her mother's bedside. The licensee did not allow anyone in the patient's room during the first 24 hours. However, no stay time restrictions were imposed after that.

The daughter was, as part of the reconstruction, noted to be present days two through four about 50 percent of the time. And days five and six, when her mother's condition worsened, was there essentially there all but four hours during the last two days. The patient died on July 7th.

With regard to the inspection activities, the inspection report documented the daughter may have received a total effective dose equivalent of 15 REM.

The licensee did not collect the bio-assays sample from the daughter. Thus, the TEDE explicitly assumes no internal exposure.

Approximately 20 other members of the public were exposed. Of these, ten individuals received an estimate dosage between 100 and 500 milligrams. The remaining ten received doses of less than 100 milligrams.

The inspection report also noted that the licensee did not take measures to ensure the doses were as low as reasonably achievable.

With regard to enforceable action, on May 7, 2003, a letter from Region III, regional administrator imposed a civil penalty in the amount of $6,000.

The civil penalty consisted of two parts, first for licensee activities which caused members of the public to receive doses in excess of the public limit of 100 milligram per year; and second, for the

failure of licensee to investigate and implement corrective action when it became known that a relative of the patient was not following the licensee's radiation safety practices.

If I could have the next slide, please. Slide three.

Regarding other actions taken to date. In December of 2003, the letter signed by the President of Society of Nuclear Medicine and the President of the American College of Nuclear Physicians forwarded a critique of the dose evaluation that was contained in the region's inspection report.

This critique, authored by Dr. Carol Marcus and Dr. Jeffrey Siegel, offered that the NRC's dose evaluation was as much as a factor of 17 higher than it should be, in their view. The NMSS's staff's preliminary evaluation addresses the five principal issues raised in the critique.

We will finalize our evaluation when we receive the ACMUI's views.

Further actions taken to date --

COMMISSIONER MCGAFFIGAN: Mr. Chairman,

could we get them to tell us what their preliminary views are? I know that they want to wait for ACMUI to finalize. But they could tell us -- there were five things where Carol Marcus and Dr. Siegel said you guys were conservative up to a factor of 17.

Do you agree or don't you?

CHAIRMAN DIAZ: If their preliminary evaluation is complete enough that they can stick their neck out?

COMMISSIONER MERRIFIELD: I do wonder, we did ask ACMUI to take a look at it. And any time you have a preliminary view out there, it starts to solidify themselves into a position. Whereas our purpose was to have ACMUI take a look at it and try to see if there was a basis for asking some questions.

I think the argument is it might weaken the value that we have placed on having ACMUI take a look at it if the staff solidifies its view too much.

MR. ESSIG: We have not shared that with the subcommittee.

COMMISSIONER MCGAFFIGAN: I am going to let

it go. This is not rocket science. It is stuff that you can calculate relatively quickly. So it is either true or it isn't.

COMMISSIONER MERRIFIELD: But keep in mind, the process that we going through right now is a reflection on the debate that has been engendered from the comments we received from outside stakeholders who have a very different view.

And I think, I leave it to Chairman Diaz, but I think that there is a utility if the staff has its view -- preliminary view that it has come to, it would be in an in-camera way without having access to that same information, ACMUI would come to its own conclusion and it would interesting to seeing how those two would conflict, if they do conflict.

They might come to the exact same conclusion despite not sharing that information.

COMMISSIONER MCGAFFIGAN: My personal view was that what Carol Marcus and Jeff Siegel laid out reflected that the Chairman's desire for realistic conservatism as opposed to ultra conservatism. But I

look forward to whatever happens in this process that we go through.

I mean, our doses models -- I mean, as a regulator, we should be realistically conservative but not ultraconservative.

CHAIRMAN DIAZ: I do agree. However, there is the fact that dose reconstruction is not as simple as it looks if you want to do it right. It is really a much more difficult process.

I think one time in my life I did try to teach dose assessments and I was having a real hard time with it. So it is not as straightforward. Simple calculations, yes. But a complete calculation requires a significant amount of detail and effort, considerations of everything from back scattering -- to all of those factors that actually come.

So why don't we let the process go.

COMMISSIONER MERRIFIELD: This distracts from the Staff's direction at this point. But I would like make additional comment.

I think -- and this is only my own view. But I think -- we suggested a notion of having ACMUI

taking a second look at this. What it does provide you is an opportunity for the potential to have three separate ways of looking at it.

Having done that, I think the next step in the process -- and I'm in agreement with you on the concern about over conservatism.

If they come up with three separate ways of looking at it, I think the next step would be a good rigorous dialogue between our staff, ACMUI and outside stakeholders to try to figure out how do you reconcile those differences of opinion to the extent that we can, so that we can come, perhaps, to some convergence in terms of agreeing on a principle for dose reconstruction as difficult as it may be.

CHAIRMAN DIAZ: We going to get three different answers.

COMMISSIONER MCGAFFIGAN: What struck me from the incoming letter was at one point and the response that Chairman Diaz had signed, we said that this was arithmetic. A person is here, so much time, you multiply a couple of numbers and it is finished. That was our assertion.

They came back and said, I don't think so and for the following reasons. It is more complicated than that. You are assuming -- that arithmetic -- the allegation that this is arithmetic is making a bunch of assumptions which we hereby challenge.

I'm just interested in -- I think it's right. We will have three different answers as to whether these simplifying assumptions were appropriate or not.

CHAIRMAN DIAZ: Like Commissioner Merrifield said, the idea is how do we achieve a certain amount of convergence in the methods to be followed so the answers will be reasonable.

COMMISSIONER MERRIFIELD: And a better understanding of everyone about the assumptions that we are making. So that we can be more a transparent regulator.

CHAIRMAN DIAZ: All right. Thank you.

MR. ESSIG: Could we return to slide four, please.

I believe I mentioned that in the January

12th letter from Chairman Diaz to the presidents of SNM and ACNP that ACMUI had been tasked to provide an independent analysis, as we have just discussed, and to provide us recommendations, if appropriate, regarding the ultimate dose reconstruction offered by the SNM.

We formed a subcommittee within the ACMUI on January 29th of this year to review the dose evaluation contained in the inspection report and the critique of it prepared by Drs. Marcus and Siegel.

The subcommittee was specifically requested to review each aspect of the dose evaluation and the critique offering the alternative methodology and to determine whether or not it agrees with the approaches, each approach and why.

COMMISSIONER MCGAFFIGAN: I would add, as Commissioner Merrifield just said, they can come up with an alternative approach.

MR. ESSIG: Yes.

COMMISSIONER MCGAFFIGAN: That should be within the scope of what they are doing.

MR. ESSIG: Yes.

On slide 5.

We are expecting ACMUI's report in about a month. We are sensitive to the committee's need for additional discussions at this time since the effort is just underway. That is our best estimate, about a month. We expect the subcommittee will deliver to the full committee in about that time frame. And then the full committee will have to deliberate and furnish a final product to us.

And we plan to use the Region III assessment, our own evaluations, the ACMUI report in forming conclusions regarding the merits of the SNM critique. And hopefully to use the results of this evaluation to inform future evaluations of this type.

And lastly, then, on slide six.

We will prepare a report which would be appended to the final response letter that is sent to the SNM and the American College of Nuclear Physicians.

That concludes my presentation.

DR. MILLER: Thank you.

Chairman, just to embellish a couple of

things that Tom said. One of the things we are trying to take this opportunity to do, both we and ACMUI, is to take a step back and look at what we got submitted by SNM, what the licensee did, what the staff calculations are, what ACMUI comes up and look for reasonable ways to proceed here. What can we learn from this?

And reasonable people can disagree. And I think in -- how should we be doing it in the future? Is there a better way to do it? I think we should always strive for that.

Also I would like to just note that regardless if you take Carol Marcus' calculations or the staff calculations or the licensee's calculations and whatever, in the case -- of this particular case, it would not have affected the outcome with regard to the action that the NRC took.

MR. PAPERIELLO: That concludes the Staff's presentation.

CHAIRMAN DIAZ: Thank you so very much. It's always interesting to look at the variability of results. And with this, Commissioner Merrifield?

COMMISSIONER MERRIFIELD: Going back to the point that Dr. Miller made at the end. It's good for you to bring us back to the point that it would not have changed the conclusion that we had.

But I'm also glad to hear you talk about the value of understanding how we got through that process.

Clearly, how we go about doing dose reconstruction is an item which does have a -- does engender a significant amount of debate among some of our external stakeholders.

And to the extent that we can use the St. Mercy case as a case study, to really in a transparent way explain to people how is it that we do these reconstructions and what are the assumptions that we would make in this case, similar to the ones we would make in other cases that we need to be more guarded about providing private information.

I think there is a utility matter. And I think part of my vision and I think others would agree that the hope is having gone through this exercise, hopefully, we can lower the tone and volume

of the debate so that when we are making our decisions, that these people even if they don't agree with us, they know what our operating assumptions are in going ahead and doing that.

Hopefully we can come to some convergence and deal with this in total.

Going back to the first presentation by Ms. Henderson. You talked about a significant education effort that your inspectors have been undertaking and folks in the region have been undertaking.

What is this -- has this driven an increase in the staff resources to conduct the inspections? I want to get some sense of that.

And also how long do you think this education effort is going to need to continue until we get to a point where people, although they may prefer the old way, will at least understand what we are doing with the new way?

MS. HENDERSON: I don't think it adds significantly to the amount of time spent on inspection because the inspectors do this as they are

going along as part of their inspection. They will explain the differences.

So I don't really think it adds a lot of time, nothing really significant.

As far as how long. Based on the last change to Part 35, I would say five years.

COMMISSIONER MERRIFIELD: Five years?

MS. HENDERSON: Yes. That would be my best estimate.

DR. MILLER: Commissioner, if I could also add, we have to remind ourselves that the Agreement States have three years to come to full compatibility on the revised regulations. So along with that, there is still the effort to work with the states as they come to compatibility on this so that we reach some consensus, not only in NRC-regulated facilities but in state-regulated facilities also.

COMMISSIONER MERRIFIELD: And presumably, they would require the five-year type of a cycle to educate the users and their licensees in their state as well.

DR. MILLER: Hopefully, you can learn from

what's happened in the ensuing period.

COMMISSIONER MERRIFIELD: We use currently in enforcement -- well, in taking a look at the issue of mis-administration, our old definition verses medical event, we now have our new definition in Part 35. We use a 20 percent number as the kickoff point. If you go outside of the 20 percent figure, that's where you fall into what is now our medical events.

How is it that we derived this number? I know this is one that we used for a very long time. How is it that we derived this number? And to the extent we have gone from a deterministic to a risk-informed framework, have we rigorously taken a look at that figure in a risk-informed way to see whether it still makes sense?

DR. MILLER: I can't speak to the ancient history of where the 20 percent came from. But it was revisited when the revised Part 35 was promulgated. And it was visited by both the Staff and ACMUI. And it was debated during the public comment period. We received public comments on it that were divergent.

The Staff finally -- the NRC finally decided to retain the 20 percent from the old rule, not necessarily because it indicated there was a deficiency in a licensee's program, but more because it might indicate -- well, let me correct that -- that it could indicate a deficiency in a licensee's program.

Not necessarily that in every specific case there was an absolute risk to the patient.

So there was a lot of debate on that. And it was included in the risk-informing of the revised Part 35.

I can't speak -- as I said, I don't know if Carl remembers where it initially came from. It was well before my time.

MR. PAPERIELLO: I'm going to speak on teletherapy and external beam. My understanding of external beam therapy, of course what you are trying to do is give the maximum amount of dose where you can generally for tumor suppression and not affect healthy tissue. Or at least affect healthy tissue to the point where it can recover.

When you start looking at the curves, a 20 percent increase in that dose would be significant. How you would translate that to all other modalities of therapy, I'm not sure.

I know we looked at it years ago when we selected the number.

But I want to make one point here. This is one of the reasons we changed the term from mis-administration to medical event. There is a number of things that happen, that occur because machinery that we licensed or an Agreement State licensed failed to perform as expected. On board micro processors failed. We licensed the machine.

So one way of -- one value in getting reported medical events is it gives us information to identify generic issues. And it seems like every time you get a new modality with a new type of device, unexpected failures show up. And then with time, they are eliminated.

In answering your question, 20 percent was looked at and was decided to be, with a lot of advice, reasonable when we adopted it. If you ask me

sitting here that every possible modality of therapy 20 percent means the same thing, I can't say that. And it probably does not.

COMMISSIONER MERRIFIELD: I know it is -- obviously, from a regulator standpoint, it is easier to use a single number. But given the range of modalities and the impact that that 20 percent may have, seems to be some variation.

So I think it is at least worth thinking about again.

I would say, Mr. Chairman, this is one of those examples. We dealt with Part 35, the meat of what the Commission was doing, a few years ago. Frankly, I know a little bit more about the topic now than I used to. In the main, we have made very, very positive changes as a result of Part 35. But I think it is good for the Commission to continue asking the questions and perhaps even taking a look back at a few of the things that we did then because there may be further -- I know Carl is wincing at the thought of that, but there may be further things we may want to think about or not.

MR. PAPERIELLO: Commissioner, actually, it is more complicated than that. This is the fastest changing technological changing area we regulate. This is moving faster than reactors are.

We think of reactors as being -- the fact is this is where the technology changes the most. I been with medical now, in one aspect or another, for over 20 years. What was done in 1978 when I first got involved to now has changed significantly.

So it is appropriate to have to change our regulations as modalities change. That's why we wrote 35.1000, because you can't put square pegs into round holes and then revisit what you done. It is the way it's going to be.

I have no problem with that. That is not a reflection on anybody. It is just a reflection that it is a very rapidly changing technology.

COMMISSIONER MERRIFIELD: Thank you, Mr. Chairman.

CHAIRMAN DIAZ: Thank you, Commissioner Merrifield.

That is a very good statement. I could

spend a lot of time on that but I will let it go.

Again, I think when we look at the issues with medical uses of radio isotopes, we have to come to grips with a realization that we do this thing to improve the health of patients in many different ways.

So there is always a little bit of risk and there is a little bit of that. But I think the overall sense that I always get is that these things are doing well and that there are errors, and those errors we learn from them.

But fundamentally, to me it is always a fact that people are really -- here in this agency are always concerned with how much radiation somebody gets because of the potential health effects of radiation. And this case we are using radiation for the purpose of healing or the purpose of determining what something is.

So those things always come back and say well, this is voluntary use and there is a difference in how we see it. And eventually, there is no doubt that things are going to be changed because the

technology change. And even we change, slowly but surely.

With that, let me just go back to this issue of the staff finding that continuation of items that are submitted that are no longer required. There already was discussion about it. This is not a new thing in this area. We see this in many of our licensees. They do want to have new things but when they come in, they say I don't want to change. I like what I had. I'm comfortable with it. I know how to do it.

And I think it gets into this issue of the concern with enforcement space.

Now, have we done enough as a matter of training when we go and train people on Part 35 which we do it during the first inspection, right? When the first inspection comes, we make sure there is some training.

To have people understand that enforcement, in many ways, has also changed as the way and that there is no real -- there is not that much significance in continuing to do items or where

prescribed because now we have them in a complete different plane of reference.

MS. HENDERSON: Absolutely. We point them towards 1556, Volume 9 which is much more streamlined. But it is just going to take a while for them to let go of their older procedures. And they are generally more prescriptive and they meet the regulations and then some.

CHAIRMAN DIAZ: And you know, this issue that you see, is this something that we should address more aggressively when we actually provide training and instruction, or you believe the level of which we are doing is sufficient to take them where we want go in a smooth path, not drastic steps?

MS. HENDERSON: I think that what we are doing in inspection and also when licensees come in for amendment or renewal of their licenses is enough. I think that they are slowly getting the message.

CHAIRMAN DIAZ: When you go from the Part 35 to the actual special application and the special licensee, do we make an effort to, again in this same vein, to understand whether particular issues or the

particular capabilities are to make sure that we get a good match between what they are actually required of the new Part 35 and what the capabilities are? Do we actually listen to make sure that we can communicate on what the requirements are in the manner that there is a good path forward?

MS. HENDERSON: I think so. I think we are doing that 35.1000 would be a very good example because this is new guidance for these modalities on the website. We work with the licensees. It is guidance so they may propose something as an alternative. And we go back to the regulations at that point to make sure that they are meeting them.

CHAIRMAN DIAZ: This five years, that's where you would think will get us to a place where significant fraction of them -- is there something that we could be doing extra that will help us get there?

Is the Staff looking at whether there are additional amount of training information, communications when we go on and especially during the inspections, or additional things we can put on

the website?

What is it that we can do to ease this transition forward?

I'm getting concerned that we got into this thing and now we are having to manage with a variability that maybe I was not really expecting in this area. I thought they were jump and 80 percent of them are going to say I love this issue. I'm not hearing that.

MS. HENDERSON: That's what we thought, too. But that is not case. Sure, there is additional effort that we could make to let licensees know that they do not have to follow the old procedures, that they can move in to use of the new regulations and not fear enforcement action. Sure.

CHAIRMAN DIAZ: But are we aggressively addressing those issues in a site-specific basis?

MS. HENDERSON: Yes, we are. Because it makes licensing easier for us and inspection easier for us, not only the licensee.

So we go in very aggressively. We will bring copies of Volume 9. We will sit down with

licensees and go through their program, if they like, or as we go through inspection will point out you are using unit doses. You are still assaying them before you use them. You don't have to do that unless you voluntarily wish to do that.

And they do. They are so used to the prescriptiveness of Part 35 that it makes them feel safe to continue using it.

CHAIRMAN DIAZ: All right. I think we discussed the St. Joseph Mercy Hospital case sufficiently. I believe I understand all I did not know about it.

So Commissioner McGaffigan.

COMMISSIONER MCGAFFIGAN: Could I ask something that was not on the agenda today but I know you are working on? The endorsement of the therapeutic guidance that has been submitted to us. How is that proceeding? When do you foresee being able to have a staff position as to whether you can endorse that guidance or endorse the guidance with modification?

MR. ESSIG: We have completed our initial

review of it and we have recommended some minor modifications to it. And it is now being reviewed at higher management levels within NMSS.

COMMISSIONER MCGAFFIGAN: Have you recommended those changes to the submitters or are these proposals --

MR. ESSIG: These are proposed changes that we want to make sure our management agrees with. And then we will recommend back.

COMMISSIONER MCGAFFIGAN: Again, I would urge that process go forward, especially if the Staff believes they are relatively minor. I hope that the management can take a look at them and get them back. And you can have the dialogue and we can get to conclusion.

There is a preface to the question. I know NUREG-1556, Volume 9 is our bible. But the criticism that we have gotten of our bible is that it was fairly complicated especially for diagnostic users.

Would it be appropriate when you are visiting somebody who is just doing diagnostics to say here is NUREG-1556, Volume 9, and by the way,

here is the thing that we have also endorsed that you may find it easier to use because it focuses just on diagnostic use? Do we do that?

MS. HENDERSON: We don't do that. But that is a good idea.

COMMISSIONER MCGAFFIGAN: It strikes me if we go through the trouble of endorsing these guidance documents and saying that they meet our needs, maybe it is the -- God knows if there were NEI in reactor space, they would be shouting it from the rooftops that afternoon and sending out E-mails and whatever. And maybe the communication with a much more diverse group of people from the Society of Nuclear Medicine, the American College of Radiology and all that is more complicated.

But I don't know that we should not also say, by the way, we have endorsed this and it is available on the website of blankety-blank organization or here's a copy. You may want to use it or once the therapeutic one is endorsed, use it.

There is nothing substantively different between them. They just put the stuff together in a

neater way.

MR. ESSIG: If I might add. When we did agree that the guidance prepared on diagnostic procedures was acceptable to us, we prepared and promulgated a regulatory issue summary announcing that. And it is actually on our website with a link to it.

COMMISSIONER MERRIFIELD: The guide is on our website. If it is on our website, then I think the inspectors should feel free to sort of say, hey, you can use this. If you find our stuff complicated, here is something that may be slightly plainer English. Not that ours is not plain English.

But I urge you to think about that.

It is just a question about how this community works. If it were NEI or a reactor's owners group, you mentioned it takes 10 years to get around to relicensing these facilities. But if it were NEI and there were flexibility involved, they probably would have a standard change package or maybe if it were appropriate to a particular reactor type maybe the owners group would do it.

Does anybody put together a standard license amendment that if you want to move to -- or maybe it is embedded in these guides -- if you want to move to the more flexible system that NRC currently allows, here is a standard license amendment you might be able to submit or here are options for a standard license amendment depending on what you do at your hospital that you can submit?

Does anybody do that?

MS. HENDERSON: Not specifically but in Volume 9 there are examples of what you can submit. And because it is done piecemeal, if they want to change a location of use, they can go to that area of the guide and it will tell them exactly what they need to submit. In the case of diagnostic, they don't need to submit anything.

COMMISSIONER MCGAFFIGAN: They don't have to submit anything?

MS. HENDERSON: Unless you are changing an address.

COMMISSIONER MCGAFFIGAN: Well, that is good information to have out there.

Let me ask one last question about the Mercy Hospital thing. I understand there was some good discussion yesterday with ACMUI. But one of the issues that came up -- and I'm just trying to understand our philosophy. If it were me and my mother at that hospital, and our current limit is 500 millirems for patient visitation, I will tell you if you are sitting out there with your calculator and telling me, Commissioner, you may be getting close to 500 so I don't think you should visit your mother tomorrow, I would probably tell you to go to some place south of here or something.

It would be -- I imagine this is in the medical community. I probably, as a result of having melanoma four and a half years ago, I probably have probably gotten 20, 30 REMS through PET scans and CT scans over the last four and a half years. And getting an extra couple of hundred millirems is not the end of the world.

So what is our regulatory philosophy if you have an ornery visitor of a patient and it is not Commissioner McGaffigan? You may have special rules

for me. I hope not. But what is the hospital supposed do with ornery Patient McGaffigan who says I don't give a damn what your calculations are saying, I'm going to visit my mother?

COMMISSIONER MERRIFIELD: Before you answer that, to put to rest any speculation, there is on the issues that are regulated before the Commission, there is no separate set of Commissioner standards.

That was tongue-in-cheek. I just want to make sure that the record is clear. No such separate standards exist.

COMMISSIONER MCGAFFIGAN: But it may be particularly difficult to deal with ornery McGaffigan. So take me as a typical patient --

COMMISSIONER MERRIFIELD: I can comment on that.

COMMISSIONER MCGAFFIGAN: What do you do with me?

MR. ESSIG: You are quite correct. We had a good lively discussion of this yesterday in the ACMUI committee meeting. One of the -- in the extreme case, we were -- we will not, for that case nor any

future cases, expect the licensee to take heroic action such as physically restraining the individual because we are talking about emotional issues here, as you noted. But in this case --

COMMISSIONER MCGAFFIGAN: Dying mother, pretty emotional.

MR. ESSIG: Yes.

In this case we looked at the licensee's actions to see if they were reasonable.

COMMISSIONER MCGAFFIGAN: But do you care about -- if the person is fully informed, the hospital did everything they could to try to keep me from visiting my mother on the fourth day because they calculated that I was going to exceed 500 millirems that day. And I said, sorry, I understand your rules. I understand NRC'S rules. Say it is not me. But I'm going to go visit my mother and I will wear whatever you want me to wear. But I'm going to visit my mother.

Is that person -- they have done everything reasonable -- would we take enforcement action in that case?

COMMISSIONER MERRIFIELD: There is an example that Dr. Miller can tell us about of a counter to what happened at Mercy Hospital.

DR. MILLER: Let me use that as an illustrative example.

There was a case, not exactly the same but similar kind of scenario at St. Joseph Mercy Hospital that we dealt with in Pennsylvania, University of Pennsylvania, a year or so ago, where the licensee did everything right.

They trained the individuals. They wrongly thought they could convert them to occupational status which would allow them to get higher limits. But they trained them. They followed their procedures.

They came back to the NRC ultimately once they recognized they could not be occupational status and asked for some higher limits for the parents. There was a case of a children's hospital.

In that case the region took enforcement discretion because the licensee did things as well as could be expected and did it right.

Now, with regard to ornery McGaffigan, the doctors and ACMUI can attest to this, it is the same as if you

are a patient in a hospital. The hospital cannot -- my understanding is a hospital cannot legally tell a patient you can't get up and walk out of here, even if your doctors are advising you, you better not leave your bed.

So it tugs at an ethical issue. And it is a very difficult issue to deal with. And we have had a lot of lively discussion about this, both the Staff and the staff in ACMUI.

Where do we draw the line? If someone -- if the licensee is doing everything that we the regulators expect the licensee to do, but yet you have someone who refuses to follow the guidelines --

COMMISSIONER MCGAFFIGAN: If you have your calculator out there and you are saying, gosh, you have done everything, Mr. McGaffigan, we have asked to you do, your mother has lived an extra few days beyond what we have expected and we really tell you, NRC rules would preclude you going in to see your mother today.

But I can't imagine they would tell me that very forcefully. I would hope they would not tell me

that very forcefully. If they did, I would say thank you very much. It is apparently within my rights. I would go visit my mother.

But it strikes me that this is an emotional issue whether it is visiting a mother or visiting a child. Those are about the two most emotional things you can do.

And we have to have reasonable use of enforcement discretion. And so describing how you would use enforcement discretion and what the hospitals has to do wrong in order to get into enforcement space where you would not use enforcement discretion -- I think the discussions you had yesterday with ACMUI, if they lead to some sort of clarification, it would be very useful.

CHAIRMAN DIAZ: Can they use time restrictions like or especially the patient is not sleeping or semiconscious, could they provide some type of guidance to provide --

DR. MILLER: Sure it could be in your procedures. As part of the training, you are going to want to educate them on the time, distance and shielding. And if the patient is

sleeping.

But as the Commissioner McGaffigan has correctly pointed out, if it gets to the 12th hour for a patient, it is very difficult to tell their loved ones, especially if they are in a distraught state, you can't be there. That gives us a very difficult situation to deal with as regulators so that we don't appear as if we are callous, which we not.

COMMISSIONER MCGAFFIGAN: Thank you.

COMMISSIONER MERRIFIELD: Just so the record is clear. I agree with Commissioner McGaffigan in the struggle on this. And if I were in that person's shoes, I would do the same thing. I don't really give a hoot about your regulations. I'm going to do what is appropriate.

And I think as a regulator, we do have to inject common sense and compassion into what we do in these kinds of circumstances.

If we have got a set of procedures that the hospital has followed, they done everything they could despite the person wanting to be in the room to

minimize the exposure, and there is some kind of informed consent or something of that nature, at some point I think that enforcement description is the right thing to do.

CHAIRMAN DIAZ: Of course, the Commission struggled with this when we did the patients rule. We actually had a significant amount of time looking at what is the approach that we should take when there is really a need for a visitor to be with a child or a mother to be with a child or vice versa, someone to be with their mother.

So, I think we all agree this requires a deeper look and a full understanding of the circumstances and a good approach from the licensees to try to match the needs of the patient and the family with some reasonable guidelines.

Thank you, my fellow Commissioners.

And with that, I believe I want to thank the Staff for their presentation. As always, it is good to see you, Dr. Miller and Ms. Henderson, Mr. Essig. And, Carl, I see you way too often, I think. Thank you. I just needed to say that.

And would the ACMUI committee please join us.

Well, welcome to the Commission. We are pleased to have you with us today. It is always a pleasure to see you again, Manny. I hope are you doing well. I hope the members of the committee are doing well.

We do realize, like Commissioner McGaffigan said, that the reactors get a lot of the attention, that this is one area where actually the people of our country and most other countries are actually receiving small, medium and sometimes large amounts of radiation because of health needs. And it is our purpose to make that as good as possible and your advice in this issue is very valuable to the Commission.

Thank you for your participation. And with that, Dr. Cerqueira.

DR. CERQUEIRA: Thank you very much, Chairman Diaz.

My name is Manuel Cerqueira. I am the Chairman of the ACMUI. On behalf of the committee, I would like to thank you and Commissioner Merrifield

and Commissioner McGaffigan to allow us to present two areas that we think are very important.

And the first area is the Part 35 revision on the proposed rulemaking. And this will be presented by Ralph Lieto who is a committee member.

Ralph.

MR. LIETO: Good morning. My name is Ralph Lieto. I'm the ACMUI member that is representing nuclear medicine physics. On behalf of the ACMUI I really appreciate the opportunity to speak to you on behalf of the proposed rulemaking on Part 35 revision.

The NRC published this rule on December 12th of last year seeking comments on the revision of the training and experience requirements. These training and experience requirements affect authorized users, authorized medical physicists, which is a new designation, authorized nuclear pharmacists and radiation safety officers.

The NRC proposed amendments to the training and experience affect the approval of these authorized individuals via both current mechanisms

which is board certification recognition and what is called the alternate pathway.

The proposed rules involve significant work by the ACMUI with NRC staff as well as NRC staff discussions with representatives of the affected boards and professional societies.

On behalf of the ACMUI, I would like to bring to the Commissioners' attention, three particular aspects that we feel need to be commented on that relate to this proposed published rule.

These have been raised in ACMUI meetings since the committee last met with the Commission, as well as were raised during the drafting of the proposed rule.

The three aspects involve board certification, the preceptor statement and transition issues in going from the current regulations to the proposed.

One of the questions, however, that was raised during the published proposed rule during the comment period was that should the word "attestation" be used to replace word the word "certification" in

preceptor statements.

The ACMUI would like to strongly reaffirm its recommendation to use the word "attest" or "attestation" in place of certification in the revised Part 35.

It should be noted that the comment period expired or ended last week on February 23rd. There may be some additional comments by ACMUI members on these issues after my presentation.

The criteria regarding board certification. The criteria for board certification to be recognized and listed in Part 35 is one that we feel is the crux of the proposed rulemaking. The importance of board certification cannot not be emphasized enough.

Board certification provides a means to assess and document the comprehension of a body of knowledge and/or basic skills of an individual. It does not determine the training program content nor its adequacy, nor does it determine the competence to supervise safety programs.

NRC expects that medical events can be related to board certification. We feel that this is

a misunderstanding of the board process.

Now, relating to the training and experience for a radiation safety officer which is found in Section 50 of Part 35, repeatedly during the rule revision process, the ACMUI stated that the training and experience revision should not exclude existing recognized boards that provide radiation safety officers.

Particularly in the new paragraph, which is Section 50(d)(2)(i) is a new paragraph that was added to allow medical physicists to serve as RSOs if they were certified in a board specialty whose certification process has been recognized by either the Commission or an Agreement State.

It appears that it was intended to authorize RSOs who were board certified medical physicists but were not AMP's. However, the proposed rule as currently written appears to disqualify certification categories in the American Board of Radiology and the American Board of Science and Nuclear Medicine from which many currently certified medical physicists serve as radiation safety officers.

Now, we feel this probably was not intentional. But we want to bring it to the attention of the Commission so that it is rectified before the final rulemaking process occurs. Otherwise, we are concerned that a shortage will be created of qualified radiation safety officers via this mechanism.

COMMISSIONER MERRIFIELD: Mr. Chairman, clarification. Would the change be so that the individuals who currently are, in effect, given a grandfather or would it also be inclusive of allowing those boards in the future to certify as well -- or to attest as well under your new proposal?

MR. LIETO: This would be for future. Because the grandfathering would take care of those currently. The way it is written is for future RSOs.

For example, in the American Board of Radiology, there is a certification speciality in medical nuclear physics which the way the tie-in currently, it appears it would preclude any future applicants from being recognized as radiation safety officers that were board certified via that

mechanism.

COMMISSIONER MERRIFIELD: One further clarification.

In the dialogue that you have had with our staff, was that an intended action, or do you believe that that was an oversight?

MR. LIETO: I believe it was oversight in the rewrite and the emerging of all the suggested changes that have occurred since the training and experience requirements have been discussed within, let's say, the last seven to eight months.

The advisory committee also would like to suggest that the process for a board to be recognized and listed on the NRC website is -- well, the suggestion is an entirely new concept and requirement. But the fact that this is occurring is going to to be a new requirement on the boards.

And we feel that while a formal application, regardless -- will be required regardless of the length of time that a board has existed that the current plan that NRC has to notify

boards via a letter or official notice needs to be supplemented.

The ACMUI would suggest that a notice go to the major societies whose diplomats comprise members of the various board such as the American College of Radiology, Society of Nuclear Medicine, American Society of Therapeutic Radiation Oncologists and the Health Physicists Society as well as the American Association of Physicists in Medicine also be notified about this.

In addition, we would like to suggest that a workshop be set up so that as this process goes forward, a workshop with the stakeholders which would include NRC as well as the boards, professional societies and maybe ACMUI members would occur.

The purpose is to address the specifics and finalization of the process for being listed in the boards -- for the boards being listed on the NRC website as well as creating a two-way dialogue to affect this listing process between the NRC and the affected groups.

COMMISSIONER MERRIFIELD: Mr. Chairman, one

further clarification.

The two items you have listed in slide 3, written notice and workshop with stakeholders, are those issues that you have raised with our staff yet?

MR. LIETO: Yes.

COMMISSIONER MERRIFIELD: Was there a response from the staff?

MR. LIETO: Well, I would say that there has not any opposition to it.

The formal letter process and formal notice process, I think, was always the accepted process from the get-go. There was concern raised by the ACMUI that just a letter going to a board may not be an adequate way to affect this process but include them in a two-way dialogue so that they understand what's going on.

But also trying to make the staff recognize maybe some of the difficulties in getting listing that might need to be overcome so that we are not setting out here maybe a year or so and everybody at the last minute is trying to get things done in terms of a listing on the NRC website for recognition.

One aspect of the revision to the training and experience rulemaking has been the NRC requirement for our preceptor statement. Based on input from the ACMUI the requirement for a preceptor statement was decoupled from board certification pathway to meet this NRC directive.

This is a new regulatory requirement for both board certified and alternate pathways for obtaining authorization from the Nuclear Regulatory Commission.

Now each new applicant bears the burden for obtaining this preceptor statement. The ACMUI believes that the definition of a preceptor will greatly impact the implementation of this requirement. The current definition listed in the slide is "an individual who provides or directs the training and experience required for an individual to become an authorized user, authorized medical physicist, authorized nuclear pharmacist or RSO."

We feel that the preceptor statement must be flexible, practical and minimize implementation burden, yet allow that a preceptor who is not the one

providing the direct training and experience, such as a program director who has knowledge of the training and experience as well as skills for that specific modality or use, to sign the preceptorship.

Also we feel and -- this has been addressed, as pointed out earlier today by staff, for accommodating multiple preceptor statements. The ACMUI feels that possibly there may need to be a change in the definition of the preceptor. A suggestion of modification might be, as indicated in the slide, would be an individual who provides or directs training and experience.

It would basically eliminate the article "the" between directs and training. This is just a suggestion for NRC consideration. We feel that it is important that the definition be flexible for its implementation.

Several questions have arisen and concerns raised in the ACMUI discussion on implementing this preceptor statement requirement. The ACMUI does not expect any answers at this meeting with the Commission but wishes to express these issues for

resolution during the final rulemaking process.

The question is: Who can be a preceptor? What documentation is required for an individual to be recognized by the NRC as a preceptor? And what information does that preceptor need or require to make an attestation of training and experience? What is his or her recordkeeping requirements to document this decision?

In grandfathering with respect to 35.57, for example, when changing from one licensee to another licensee, does a second preceptor statement need to be submitted? And must it be updated every seven years to address the recentness of training rule that is in Part 35?

How will it be handled if the preceptor is unwilling to provide, for personal reasons or perceived liability concerns, a preceptor statement?

What liability exists with a preceptor in making a statement? Especially if NRC is looking at relationships between medical events and training and experience, there may be these perceived liability concerns.

If the preceptor's unavailability is due to the fact that the preceptor died, the program terminated or there is some length between the program and a preceptor statement being obtained.

Ideally, a generic statement that would be acceptable, most acceptable and practical. However, can a single statement language exist that would be appropriate for an authorized user, RSO, nuclear pharmacist, medical physicist, as well as applicants who may not have achieved board certification yet.

There may arise situations where an individual may receive multiple modality training at different institutions or receive training at one licensee and complete that training at a second licensee.

Multiple preceptor statements would be most acceptable in this case because otherwise, it would be very problematic for a single individual to get a single preceptor statement that would cover the complete training and experience requirement.

Another issue is licensees whose radiation safety committees are authorized to approve

authorized users and authorized medical physicists such as broad scope licensees. They currently are capable of expedited approval process because of their committee authorizations, yet, may experience delays in this approval process because of the need to get -- for the delay incurred by getting this preceptor statement.

Obviously, we have raised many questions and concerns such as the preceptor statement itself sounds like it may create a bureaucracy of its own. Based on the past experience with Part 35 licensing, many problems arose when regulatory guidance became de facto regulations.

The preference at times -- with Part 35 has been that if it is a requirement, it should be in the rules. However, the ACMUI suggests that the implementation of the preceptor statement occur in guidance space and via the frequently asked questions on the NRC website to allow maximum flexibility in addressing the many issues raised regarding the preceptor statement implementation.

In the last slide, as the NRC goes forward

in transitioning to the revised Part 35, there have been few issues of concern that licensees and other members of the regulated community have raised. One has to do with individuals currently in training programs. They have not had the opportunity to document their training and experience because it was not a requirement.

The individuals in training need to be given this opportunity to document their training and experience. And possibly, a recommendation for consideration is that these training and experience requirements should be applied to individuals who are entering training programs after some time period in the year 2004 as opposed to trying to retroactively implement this with individuals in training who are nearing the end of that training phase.

The authorized medical physicist is a new definition which did not exist previously. Some Agreement States do not explicitly list approved physicists on their license.

In order to ensure that the current shortage of authorized medical physicists is not made

worse, a mechanism is needed to assure that not only is the initial pool of AMPs not compromised, but also to provide as a source of preceptor for future authorized medical physicists.

Lastly, the transition issue involves nuclear medicine authorized users.

Part 35 was revised -- before Part 35 was revised, I-131 use was based on therapy versus diagnostic applications, rather than the activity limits that are in the current regulations.

In other words, an authorized user who was authorized under Section 200 of Part 35 could use I-131 for diagnostic imaging and localization studies with more than 30 microcuries. This application is used to assess patients prior to thyroid cancer treatment and usually does not exceed a few millicuries.

Now it requires that that physician meet the training and experience requirements for therapy applications requiring a written directive in Section 392.

Some method needs to be found so that

authorized users currently providing this study for patients are permitted to continue providing this diagnostic application.

Because of the comment period that just closed, additional issues may be raised before the final rulemaking period occurs. The ACMUI can provide valuable assistance and will definitely make itself available to staff during the review and implementation of these changes.

So again, on behalf of the ACMUI, we appreciate the opportunity to comment and present our views on these changes.

DR. CERQUEIRA: Should we go on to the next presentation?

CHAIRMAN DIAZ: Yes.

DR. CERQUEIRA: The next presentation is going to be the ACMUI review of the NRC method of dose reconstruction. The presentation will made by Dr. Leon Malmud.

DR. MALMUD: Good morning, Chairman Diaz and members of the Commission.

I'm Leon Malmud, a board certified nuclear

physician and dean emeritus at Temple University School of Medicine serving as the representative of health care administration on the ACMUI.

The Chairman of the ACMUI, Dr. Cerqueira, appointed a subcommittee consisting of a patient advocate, a medical physicist, radio pharmacist, a therapy physicist and myself as chair to review material relating to the radiation dose estimates in the St. Joseph Mercy Hospital incident.

Briefly, a patient with metastatic thyroid cancer who was also in renal failure was treated on an in-patient basis with 285 millicuries of I-131. The renal failure is a relevant issue because in patients with impaired renal failure there is delayed excretion of the I-131. And therefore, a retained I-131 dose in the patient given to any visitors a prolonged exposure to the I-131 in the patient.

The patient succumbed to her illness six days following the I-131 therapy. During that six-day period, the patient's daughter, whom we are told was given radiation protection guidelines in order to minimize the radiation burden that she would

receive from her mother, chose to ignore the guidelines so that she could be physically close to her terminally-ill mother.

As a result of the daughter's noncompliance, she received a higher than allowed radiation burden to herself.

The NRC's methodology for calculating the radiation burden to the daughter is being called into question. Not the fact that in this instance that the radiation burden to the daughter was even in the best case scenario, exceeding the 100 millirem limit -- remember the public for the guidelines -- what was called into question was the methodology for calculating the radiation burden.

We are still in the process of collecting data and questioning the assumptions presented. For example, did the daughter actually sit by the patient's bed for 12 hours a day for 3 days with her arms physically on the bed and then, for 20 hours a day for the fifth and sixth days? What was the real half life of the I-131 in the patient. How was it measured?

It is the assumptions that are being questioned. The calculation, method of calculation is not that which is being brought into question.

In the absence of adequate contemporaneous records, and there were inadequate contemporaneous records, what assumption should be made before calculating the radiation burden to the daughter?

Also, how should a similar situation be addressed in the future? What guidelines would be helpful to RSOs and to licensees in addressing in a humane and compassionate manner noncompliance by people that we refer to as public visitors?

Would more timely notification of the regional office be appropriate? Would some other techniques for alerting the individuals who has refused to comply be effective?

We hope to have a final report for submission to the ACMUI within four weeks. At which point it will be reviewed by the total ACMUI and prepared for presentation to the NRC.

Thank you.

CHAIRMAN DIAZ: Thank you, Dr. Malmud. We

appreciate your very, very good summary of this situation.

Any other comments?

DR. CERQUEIRA: Those are the only two issues that we wanted to present to the Commissioners.

CHAIRMAN DIAZ: Okay. Thank you.

Commissioner Merrifield?

COMMISSIONER MERRIFIELD: Mr. Chairman, I guess, first, discussing the presentation that we first had by Mr. Lieto.

You have raised, I think, a lot of issues you got under consideration and then are, obviously, also being considered by our staff. I'm not really in a position to directly comment on my agreement or lack of agreement with the individual things you proposed. But certainly would hope that the staff in its dialogue can continue discussions with all of you and be able to explain to everyone where they are coming from and why they decided to make the recommendation they are going to be making to us.

On the issue of dose reconstruction, I

would agree with the Chairman, Dr. Malmud, that this is a very good presentation and I appreciate it. The issue of dose reconstruction we talked about, I think, quite well earlier on.

I do think it's going to be very helpful to get your independent views of how we went about conducting this effort. And certainly, as we go forward in the future, you talked about guidance documents, I think also having -- we ought to think about in the future having a very clear set of operating instructions for our own staff that everybody will be aware of as to how we go about making some of those judgment calls. To the extent we can.

Sometimes you have to make judgment calls on the spot. But to the extent we can be more transparent about our thinking on some of that, that's helpful. I certainly would recommend your continued dialogue on that issue as well.

In terms of additional questions, I guess I would -- I did raise an issue with our staff regarding the 20 percent number that we utilized

regarding medical events. I would be interested, if you did have any observations you want to make on that particular topic, given the dialogue that I had with Dr. Miller.

DR. CERQUEIRA: Dr. Williamson would like to make a comment.

DR. WILLIAMSON: Good morning, Chairman Diaz and Commissioners. I am Jeff Williamson, the therapy physics representative to the ACMUI.

Well, I think from the perspective of a working physicist in radiation therapy, to a great extent, our committee, the medical event criteria are not firstly criteria or harbingers necessarily of patient injury or risk. They were negotiated based on what our overall views were regarding the capability of the equipment now being used to deliver doses with a given precision, the kinds of QA guidelines we use which in radiation therapy we normally try to administer doses with a five percent accuracy.

So they, in essence, serve, I think, more as a harbinger of there is a problem with the

delivery or planning system that needs to be looked at. So it is kind of a performance end point that may be the ultimate goal of the new performance-based regulation to reduce.

And as our discussions evolved regarding the need for patient notification, the notification needs to be made because once one knows -- a federal agency knows of an infraction or avoidable error that was made and could possibly have consequences for the health of the patient, then there is an obligation to tell the patient.

But it is not firstly from our perspective a criterion that means harm or potential harm to the patient.

So it is set several -- you know a multiple of three to four above the normal operating procedure. It is certainly true that depending on the modality, the requirement may not always be easy to apply.

For example, permanent seed implants for prostate cancer is an area where -- or an application where the user, despite his or her best efforts and

the best quality control implanting, once the seeds are implanted, you really don't have control how much the prostate is going to reduce in volume as edema resolves.

Seeds may move. In some patients, the prostate may be more difficult to visualize on post implant imaging procedures than others.

So there is a whole range of things that could happen. You really have limited control. And 20 percent may not be completely reasonable.

So that is an issue we are now struggling with with the staff to give them guidance on how to apply the medical event criteria in a reasonable way to prostate implants that does not penalize well done procedures but helps identify the tails of the distribution of practice quality so that events that really are significant deviations from acceptable quality assurance practices are identified.

I guess that's in summary how we have tended to look at it as a committee and we thought that the 20 percent was reasonable on that basis.

CHAIRMAN DIAZ: I believe that one of your

colleagues wants to make a comment.

MR. NAG: I am Subir Nag. I'm a member of the ACMUI. I am also a clinician, a radiation oncologist practicing at Ohio State University. I would like to make additional comments. Dr. Williamson had given a physician perspective. I would in addition like to give a clinician perspective.

This would be on the definition of medical event. Also what the perception of the public becomes when you figure this medical event.

Where did this number, 20 percent, come from? I believe the number 20 percent came from the external beam, but there is a big difference between external beam and brachytherapy. An external beam, the volume that radiates is quite large. The volume that it radiates is outside the pocket is also very large. And therefore, I think 20 percent makes a significant difference in external beam because the colorings of the body is not only dose dependent but more importantly, is volume dependent.

And therefore, when you are radiating a big volume, 20 percent above what you wanted to give, you

can figure adverse consequences.

In brachytherapy, it is totally different. The volume within your target is much, much smaller.

Secondly, the volume radiates to the outside in extraneous mode. And therefore, the body would volume out probably a much more than a 20 percent difference.

I think this 20 percent that automatically permits an external beam needs to be examined. The reason is. When you label something as a medical event, you think of fear in the patient when there may be no abnormal consequences at all.

If I gave the target not 20 percent more but 100 percent more, I probably would not cause any damage because that is within the tumor area unless there was abnormal tissue within the area.

So what we need to figure out is what does the surrounding normal tissue get. Even that, it is not very easy because the volume, the dose mode that it may be only one CC and getting a much bigger dose and that may be a very minimal consequence.

The problem is once you have now labeled

something as a medical event, you have informed the patient. The patient perception is something went wrong. I am now overdosed. And even if they have minor side effects, this is because the doctor did something wrong and it may trigger adverse consequences, legal action -- when none of this should have happened.

So I think we need to either form a subcommittee or get the views of members of the American Bachytherapy Society, et cetera, and as to whether this 20 percent is set in stone or is ill-advised. Or it can be linked to what the normal tissue dosage are rather than what did the human get.

CHAIRMAN DIAZ: Thank you.

COMMISSIONER MERRIFIELD: If I could ask a follow-up question on that.

One of the issues that was raised by our staff -- Dr. Paperiello, I think, spoke to this issue, and that is: Using that trigger level as our identification of new modalities that may have some teething pains when they are first applied. Is the response that you have articulated different in that cases?

Does 20 percent make more sense?

MR. NAG: Probably not. I think it should be more risk based. I think you can use that 20 percent value to apply to the other information but not make enforcement based on 20 percent. Twenty percent may be a way to gather or let's check what is happening. But to use that 20 percent to enforce, make it a medical event, report it to everybody, may be a problem in my mind or in the clinician's mind.

COMMISSIONER MERRIFIELD: Chairman, I appreciate this dialogue. Obviously, like many of our boards, there are some differences of opinion and that's healthy. And I think it's good to see that as there are differences of opinion on this side of the table, too. And that's healthy.

But I think this is worthy of a further dialogue from my own part. I'm speaking for myself. It may be yet something else we may wish to consider having ACMUI either in the whole or as a subcommittee take a look at and see if we are doing this in the risk-informed way -- risk-informed not risk based -- risk-informed way that we like to do business around here.

Thank you, Mr. Chairman.

CHAIRMAN DIAZ: Thank you, Commissioner Merrifield.

That was a significant part of what I was going to do. So you guys have already preempted me which I resent. But that's okay. I'll live with that.

I do believe -- maybe you want to comment on it -- that there is a need now that we know more and we know some of this variations that exist and that we have to deal with it. Whether ACMUI could provide some additional recommendations to the Commission on what is a medical event that -- what are the issues that need to be dealt with? When does a medical event become an abnormal occurrence?

I think these are issues that you might want to look at because we deal with those issues all the time. And your expertise -- we normally tell the regions and the residents that you're where the rubber meets the road, that's where you are. We will value any recommendations or suggestions in how to go a little further, a path forward, and how we deal with

these issues.

I invite your comments, Dr. Cerqueira.

DR. CERQUEIRA: I think certainly, we can look that and then, in the area of therapeutics, it is certainly a very important issue. I think with diagnostics, again, if we sort of risk informed, it is certainly not as much of an issue.

But we certainly will be happy to look at that and come back to the Commissioners with further recommendations.

CHAIRMAN DIAZ: We report abnormal occurrences to the Congress. And we canvas all of these issues. And I think on certain occasions the difference between a non-medical event and a medical event, and an abnormal becomes important to us.

Any additional comments?

Okay. And I did hear very well the issue on the Part 35, especially the preceptor seems to require some additional pre-analysis before the final rule is made. And we value your comments on it.

I think that your comments, Dr. Lieto, on the transition. It is a very important issue.

Every time there is a transition there are issues. And those interfaces need to be addressed. And what I'm hearing is that we need to put a little more effort into those areas.

Any additional comments on that?

DR. CERQUEIRA: No. We appreciate the Commission's support on this. And obviously, the ACMUI will be available and make itself available to assist the staff in this manner.

CHAIRMAN DIAZ: I look forward to the completion of the report. With that, Commissioner McGaffigan.

COMMISSIONER MCGAFFIGAN: Thank you, Mr. Chairman.

On this issue of the 20 percent, I will just give you the perspective, may indicate some differences in this side of this table. I have no problem with you all looking at how we could communicate better about it.

Having just gone through a multi-year rulemaking where we ended up at 20 percent again the notion of launching a rulemaking to change the

definition of a medical event, given all the other rulemakings we have to do, given the budget stringency that we are facing, particularly in NMSS rulemaking space, that may not be the best use.

But in terms of trying to communicate better with the public, including the Congress, that a medical event does not mean an adverse effect on the patient. Rarely does it mean that. I think that was clear in the statements of consideration at the time we did the rule but maybe we fall back.

And I know there were reporting requirements that come with it. And they may have some baggage. And I understand the baggage. But I think it is more a communication issue than it is a rulemaking issue.

The number was chosen not because it is, as everybody have said, it is a point at which the patient is harmed. So we need to think about rulemaking versus communicating better and having...

The other issue I'm going to raise does not have to do with your presentation today. One clarification I was going to make.

On the Mercy Hospital case I was using 500 millirems for an ornery Commissioner that I hope is never in the position that that young lady was in. But at the time of the event, 100 millirems was the rule.

Because we first changed the patient release rule to 500 millirems several years ago. And then when we redid Part 35, we stayed with 500 millirems for patient release and adopted a proposed petition for rulemaking from one of the hospitals that we go to 500 millirems for patient visitation as well.

So there may be some confusion out there about the 100 versus 500. Five hundred is the rule today. And I'm very happy that 500 is the rule today. At the time of the Mercy Hospital event, the number was 100, the one that we are reconstructing the doses on.

The issue that I am going to bring up that was not on the agenda but was on your agenda yesterday is the issue that we brought you into security and got you a safeguard's briefing

yesterday. But what I am going to say at the moment, it is not safeguard information, it is national policy.

We have a commitment to -- our Ambassador to the IAEA has made a commitment to the IAEA code of conduct, the enhanced code of conduct on the safety and security of high risk sources.

One of the things we have to do under that commitment is have -- be able to have cradle to grave controls on high risk sources. And we have launched an effort with very strong support from the top of the Commission and strong support from elsewhere in the Executive Branch and the Congress that we get our initial inventory of who has high risk radioactive sources and get that in our hands, preferably yesterday.

We been at this now for a couple of months. We have told the Congress, I think in the Chairman's previous letter to Congress that we had launched this effort. And I just tell you that we want to get that data. Oak Ridge is our contractor. If Oak Ridge contacts you and says -- it is perfectly fair for to you call back to the NRC and say is this

person doing this on your behalf. And I don't have the name of the Oak Ridge contractor. But Oak Ridge is doing this.

Your Agreement States -- if your Agreement State is doing this, for the most part -- some of them asked us to do it. But for the most part, the Agreement State is doing it for us. But we want to have a pretty darn accurate inventory of who has what the IAEA has defined in the annex to the code of conduct to be high risk sources.

And that does not mean we are going to have reactor type security at your facilities. What it means is because these sources are largely self-protecting in your facilities, somebody isn't going to walk into a brachytherapy machine, take the source out and go off and do something with it probably without killing themselves fairly rapidly most days of the week.

We need to know where they are. And then we are going to separately figure out -- and you heard some of that probably yesterday as well -- where they stand, what additional security measures,

if any, are needed at various facilities.

We have decided that additional security measures are needed for large irradiators. We had decided that additional security measures are needed for manufacturers and distributors of high risk sources. That you have significant numbers of them. And the staff is working on additional categories, lower risk categories of folks and trying to decide whether we need additional things.

But the inventory is very important to us. I don't think you will be involved because I think it is your distributor that will be involved.

But we will also, I suspect, by the end of this year, certainly by some time next year, we are likely to have an export/import regime for these sources so that every high risk source that enters or exits the country requires a license.

And I think we are trying to lead the world in this effort. And I think we are leading the world in both of these areas in terms of getting an inventory and in terms of having an export and import regime that is implemented.

But I understand there was some concern. And it may show that we are not -- again communication is a lot of our problem around here. We may not have communicated well with people why we are doing this, why we are doing it and how we doing it. But it is terribly important that we get full cooperation from your community as we do this.

So if you have any comments, that's fine. Otherwise, everything I said is public information and is the sort of thing that's been in Chairman letters to the Congress.

CHAIRMAN DIAZ: I think it will be important that you see this information, that we receive the benefits of any guidance regarding the differences in this potential security requirements. That might be -- we are looking for simple things that people do to safeguard the sources.

COMMISSIONER MCGAFFIGAN: That latter stuff may be for their own deliberation. Not right in front of us.

DR. WILLIAMSON: Not on this topic. I wanted to before the close of the meeting make a couple of

comments on the dose reconstruction.

DR. CERQUEIRA: Do you have a comment related o this specific --

MR. LIETO: Is there something specifically that we can do to --

COMMISSIONER MCGAFFIGAN: You should have already, theoretically, we should have the data from all of you already. It was not an order that went out. It was an information request. But, if necessary, there's discussion among us as to whether orders will be issued to those who do not comply voluntarily.

DR. CERQUEIRA: It did come up during the discussion yesterday that perhaps there is a communication problem that some of the licensees were contacted without having any idea who was contacting them and what the information was going to be used for.

So I think the license community is not necessarily aware that this is ongoing or who was doing it. So I think that communication issue should be addressed.

COMMISSIONER MCGAFFIGAN: We are having to make an awful lot of follow-up phone calls. And I

appreciate -- one of the comments I understand was made yesterday was that you all are very reluctant to give somebody who calls you up your list of high risk sources.

I commend you for that. I absolutely and totally commend you for that.

So we have to make sure that you understand that the person contacting you is legitimate. But we also need the information.

And it is my understanding that the staff has been making hundreds of follow-up calls. And that may be because we didn't adequately communicate at the outset and give this person a bona fide that said this person is acting for NRC and this is a legitimate thing we are doing in response to a national commitment to the code of conduct.

Commissioner Merrifield usually makes speeches about communications being at the heart of all problem. And this may have been the case here.

CHAIRMAN DIAZ: Very good. Well, I think that this is an issue that concerns all of us and we want to find simple and good solutions to it. I

appreciate it.

COMMISSIONER MCGAFFIGAN: I think there was one comment.

CHAIRMAN DIAZ: I'm sorry. Go ahead.

DR. WILLIAMSON: Thank you very much.

I'm a member of the dose reconstruction subcommittee and two issues we were planning to follow-up on that may take longer than our month deadline would be to consider the general issue of to what extent do the rules allow compassionate dispensation to give a loved one or a caregiver a higher limit than would normally be accorded to the general public.

For example, NCRP has procedures and recommendations that will allow, in extraordinary circumstances, an individual to get up to a REM.

This is widely used for parents in managing pediatric patients who are getting x-ray examination. So we would like to make some recommendations on this and not sort of have the -- force hospitals to be in the position of actively discouraging always such patient visitation. Is that reasonable?

I think the second, the last comment I would like to make is also in the dose reconstruction subcommittee. We would maybe like to, if we possibly can, come up with some more general recommendations on how the scientific integrity of NRC dose reconstructions in general can be improved.

So we will use our examination of this incident to try to see if we can make some improvements along that line. It does in this case seem to be kind of a crisis of confidence of the regulated community. And these calculations may be more than it is any kind of a technical issue.

Finally, with regard to the Part 35 RSO certification, there is a lot of concern in the community. Many small licensees who do nuclear medicine, for example, the certified diagnostic x-ray physicist or nuclear medical physicist may be, by far and away, the most expert and qualified person to take on the RSO duties on behalf of a licensee, provided that the individual has work experience in those areas.

So it is not -- I don't think we are

trying to propose that the requirement for broad scope licensee RSOs be rewritten. But I think it is an issue of the smaller more limited scope licensees.

CHAIRMAN DIAZ: Well, thank you, Dr. Williamson. And I want to thank the staff and the committee for their presentation.

COMMISSIONER MERRIFIELD: I have one. This is a response to a comment made by Commissioner McGaffigan.

I share your concern about costs of rulemaking and things of that nature. I certainly would express a similar sentiment.

It would seem to me and I think my desire to have ACMUI take a look at the 20 percent figure, is reflective of what we went through on the reactor side relative to getting away from level four violations and going to non-cited violations.

We still are effectuating the right outcomes. We are getting our licensees to change their way of doing business.

But the degree of emotion involved in that, like going from a penalty to a non-penalty, was

reduced significantly. We are getting the kind of outcomes we want.

And I'm wondering even if we didn't change the 20 percent figure, if the issue of what do we enforce on and when do we enforce, might be looked at to see if in this area we may be able to turn the temperature down some as well. As long as we continue to get the same outcomes I think we would all agree on that.

CHAIRMAN DIAZ: Thank you. On the public health and safety basis that is certainly an issue.

Again, I want to thank you for joining us today as we being very valuable. We do appreciate and value your contributions to the Commission. We look forward to continuing our interactions.

And with that, we are adjourned.

(Thereupon, the briefing was adjourned.)