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PUBLIC MEETING

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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OFFICE OF THE SECRETARY

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BRIEFING ON PART 35 RULEMAKING

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PUBLIC MEETING

One White Flint North
Room 1F-16
11555 Rockville Pike
Rockville, Maryland
Thursday, March 25, 1999

The Commission met, pursuant to notice, at 1:36 p.m., the Honorable SHIRLEY A. JACKSON, Chairman of the Commission, presiding.

COMMISSIONER'S PRESENT:

SHIRLEY A. JACKSON, Chairman of the Commission
NILS J. DIAZ, Commissioner
GRETA J. DICUS, Commissioner
EDWARD McGAFFIGAN, JR., Commissioner
JEFFREY S. MERRIFIELD, Commissioner

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

MAL KNAPP, EDO

CARL PAPERIELLO, NMSS

DONALD COOL, NMSS

CATHERINE HANEY, NMSS

JUDITH ANNE STITT, M.D.

DENNIS SWANSON, MS., B.C.N.P.

MANUEL D. CERQUEIRA, M.D.

RUTH MCBURNEY

LOUIS K. WAGNER, PH.D.

P R O C E E D I N G S

[1:36 p.m.]

CHAIRMAN JACKSON: Today, the NRC staff and the NRC Advisory Committee on the Medical Uses of Isotopes will provide the Commission with a briefing on radiation protection issues associated with medical uses of radioactive materials. The ACMUI, as the advisory committee is called, last met with the Commission in June, 1998. Much has happened in the last year.

In June 30, 1997, staff requirements, the Commission approved the staff's plan for revision of both 10 CFR Part 35 and the Commission's medical use policy statement. The staff has proceeded in an expedited manner to develop the proposed rule over the last two years. The process to revise Part 35 and the associated guidance documents have provided additional opportunities for input from interested parties on the Commission's rulemaking. The staff has held multiple meetings with the public and professional societies and boards, and met extensively with ACMUI and members of its subcommittees.

Today, the staff will brief the Commission on the status of these activities, focusing on the most significant issues associated with the proposed revision of 10 CFR Part 35 and what it's going to require to come to closure on that and the medical policy statements. The ACMUI presentation

will follow that of the staff.

And I'll ask my colleagues if they have anything to add. Dr. Knapp, would you please proceed.

DR. KNAPP: Thank you, Chairman. As you said this afternoon, we will be briefing you on the work that's been done on Part 35. You have at the table to my right, Dr. Donald Cool; to my left, Dr. Carl Paperiello; and to his left, Catherine Haney. Dr. Paperiello and Catherine Haney will be doing the principle part of the briefing for the staff. Afterwards, you will be briefed, as you said, by the ACMUI, who are seated behind us. To my far right, we have Dennis Swanson; to his left, Dr. Judith Stitt; to her left, Dr. Louis Wagner; to his left, Ruth McBurney, representing the State of Texas; and to her left, Dr. Manuel Cerqueira.

And with that, I would like to turn it over to Carl for the initial part of the briefing.

DR. PAPERIELLO: Good afternoon. This is in response to a Commission request that the staff brief the Commission on the status of the Part 35 rulemaking, and I would note that the staff has not provided the Commission with the paper to support this briefing.

We did want to discuss -- can I have the first slide? Next slide. We did want to discuss a handful of issues associated with the rulemaking for which the Commission may wish to provide further guidance to the

staff, and also describe where the staff stands in bringing a final rule to the Commission.

Next slide. I would note that the -- we have as a primary objective of the rulemaking to have a risk informed performance-based rule focused on the management component of the existing rule on its essential requirements. Now, I think the proposed rule represents a significant decrease in the requirements in the quality management rule, and even a larger decrease in its prescriptiveness, and to have a rule that explicitly provides for new modalities.

Could I have the next slide?

CHAIRMAN JACKSON: When you say patient safety, what do you mean?

DR. PAPERIELLO: I mean ensure that the patient receive the dose that the doctor prescribed or directed, as the case may be.

Secondarily, we wanted to add certain new modalities, such as remote Brachytherapy, after loaders, and gamma stereotactic radio surgery. The latter is commonly known under the brand name of Gammanyte, which is the most widely known brand. We would allow inpatient visitors to receive up to 500 millirem. And this is increased, so that a 100 millirem public dose limit is in accordance with international standards, which consider this type of exposure a medical exposure. Licensees will also have to

determine Brachytherapy's output activity prior use. We could rely on vendor or manufacturer measurements. And we believe we've also reduced significantly the record-keeping burden in the proposed Part 35.

Next slide.

CHAIRMAN JACKSON: Let me ask you a question here. Is the 500 millirem dose related to grandfathering old facilities? Or is related to having family and friends provide additional --

DR. PAPERIELLO: It's family and friends. In the international standard arena, the dose to care givers, including people who provide emotional support to patients, is considered medical exposure. And for those individuals, the recommendation is a 500 millirem, because it's generally understood this is not a year in and year out occurrence. This is probably occur once or twice in a lifetime.

MR. MCGAFFIGAN: Madam Chairman?

CHAIRMAN JACKSON: Yes.

MR. MCGAFFIGAN: My recollection is that this -- the University of Cincinnati had given us a petition in this area that we just folded into this rulemaking.

DR. PAPERIELLO: Yes. Can I have slide four? Although we believed the staff in the stakeholder's group generally converged on this rule, some individuals continue to assert that we should abolish Part 35 and stop regulating

the use of atomic energy act material by medical users or to limit the regulations solely to Part 20 and training and experience requirements. Some stakeholders want a formal quantitative risk assessment for the rule and want the NRC to grant a general license for diagnostic nuclear medicine.

MS. DICUS: Madam Chairman?

CHAIRMAN JACKSON: Please.

MS. DICUS: Question. The distinction between risk informed versus a risk-based rule, do you think that among wide range of stakeholders, there's a clear understanding of the difference between those two?

DR. PAPERIELLO: Cathy, could you --

MS. DICUS: I love being greeted with silence.

[Laughter.]

MR. MCGAFFIGAN: Pass the buck to the lowest level.

CHAIRMAN JACKSON: I don't know if Cathy wants to be called the lowest level.

[Laughter.]

MS. HANEY: I would say that there is some misunderstanding in the community. I know it's been a topic at several of the public meetings, and we have explained it very often. But to give you an example, it wasn't until the last meeting, which would have been about the eight of a series of meetings, that someone came up to me and said,

well, you know, now for the first time, I understand what the difference is. So, I think to answer your question, yes.

CHAIRMAN JACKSON: So, you've iterated to these people to explain --

MS. HANEY: Yes.

CHAIRMAN JACKSON: -- the difference?

MS. HANEY: We have tried very hard.

MS. DICUS: One other thing, if we could, just real quick: this lack of a formal risk assessment that is bandied about so much, does the staff -- how does the staff propose to respond to the ACNP and the Nuclear Medicine Association on that issue, or do you plan to respond?

CHAIRMAN JACKSON: How do you come with these questions?

DR. PAPERIELLO: I would like to respond to it, and it's -- the question right now is a question of time. I have convinced my -- in my own mind, I -- in fact, I've done my own informal risk assessment. And as I would get to -- in fact, if I could have the next slide. Let me -- if you look at the empirical occupational basis of nuclear medicine, the workers, if you look at the potential public doses, and if you take a look at the need to ensure that medical doses are directed by a knowledgeable physician, and I think you could justify the fact that you need a specific

license. General -- you would now allow general licensees to have exposures in the order of a rem or two a year, and some nuclear medicine technicians get exposures this high. It's above the point where you need badging. You need to give people Part 19 training.

If the material used would consistently go astray, then you could have public doses in excess of the public dose limit. An occasional error, either in misadministration or an occasional unit dose going astray, will not create a societal risk that is unacceptable. I'm defining that as 10^{-6} to the exposed -- you know, to the potentially exposed population. You need systematic -- you need systemic breakdown to have a problem. And that is the basis, I believe, of risk informed performance-based regulation. There needs to be a program, but an occasional lapse will not create an unacceptable risk.

So, I think that kind of analysis bounds this. You need a specific license. But, we have got to, and we have -- I believe when you look at the rule and what actually is required in diagnostic medicine, there are very -- relatively few requirements and most of them deal with Part 20, with the exception that the people, who use the material, have -- and this is an area where we're not going to get any argument, with proper training and experience, and you need to know that you're giving a patient a dose,

and it just doesn't happen inadvertently.

But other than that, there are no -- then there's a handful of requirements, which relate to Part 20. You have to have survey instruments. You have to keep record of doses. You have to have a radiation safety officer. You know, if you have to have a program, we're not going to tie the program down on a license. They are going to be able to make changes that you want to make. I mean, I think that we've done a good job in abolishing unneeded requirements and having a truly performance-based program.

MS. DICUS: Thank you.

DR. PAPERIELLO: Cathy, I'll turn the rest of the presentation over to you.

[Laughter.]

MS. HANEY: Okay, thank you, Carl. Good afternoon. I would start with slide six. And, basically, just to recap briefly the actions that the staff has taken since the June briefing, the key notes to note -- the key things to note on this particular slide is that we did hold four facilitated public meetings during the comment period. Three of them are meetings that we convened. The fourth one was during the all agreement state meeting, where we held a workshop with the agreement states. So, there was some focus on that meeting with regards to the agreement state issues.

The comment period for the rule closed on December 16th. We received approximately 225 comments on the rule of medical policy statement and the guidance. When you take these particular documents and put them all together, it comes up with about 900 pages of text that the staff has to respond to, as a result of the rule being published.

MR. MCGAFFIGAN: Could I ask a clarifying -- what do you consider -- I sat in on parts of the Rockville meeting in October, and lots of people were making comments in the course of the meeting. And I recall some; I'll come back to them later. But, are those comments on the rule, if they're spoken at a facilitated public meeting --

MS. HANEY: Yes.

MR. MCGAFFIGAN: -- that you have to analyze?

MS. HANEY: Yes, they are.

MR. MCGAFFIGAN: Gosh, I could have counted more than a handful at Rockville alone. So, I'm surprised it says a few. Nine-hundred pages doesn't surprise me. The 200 comments, you must have done some amalgamated --

MS. HANEY: Well, the 200 comments were actually letters. So within those letters, there were --

MR. MCGAFFIGAN: Oh, okay.

MS. HANEY: -- they could have been, you know, 10-15 page letters. In the case of transcripts, we were looking at probably about four or five inches of paper for

each transcript. And that's really what was handed up --

MR. MCGAFFIGAN: That's the 900 pages?

MS. HANEY: -- as being the 900 pages.

MR. MCGAFFIGAN: Okay. And there's one question I want to ask, if I could, at this point. Prior to the time period here, we had tried to do some extraordinary things to make this rulemaking go smoothly, once the proposed rule went out. I think it was June of 1997, we had a briefing here with ACMUI and the staff, and we made some final decisions then about how the structure of the rule might look like, etc., following that meeting. And then since nobody else was drafting, you guys put something out on the Web page, my recollection is probably September, October of '97.

But the complaint we have gotten is that it was a one-way communication during that period between, if I'm right, October, '97 and June, '98, that people -- it was out there, people were commenting on it, that we weren't commenting back. And it's -- in proximity, we're a learning organization. In proximity, at the moment, in the pre-proposed rule period, you're having very active communications. If you had this to do over, and we don't, would you have used that period between October of '98 and June of -- October, '97 and June of '98, differently? Would there have been more active meeting and communicating back

to the commenters, as to what our views were on the comments and all that?

DR. PAPERIELLO: I could say, yes, which would probably be a popular answer. I would say we could have probably done some more. But the time constraints on all this are a problem. You know, you just -- there's so much you can do within the time you have. And if you have more public interactions, you're, obviously, listening and you're not writing. So, I mean, there's been -- this is a big rule and it's just so many things -- you have so much time -- when you have a time constraint, there's just so much you can do.

We probably could have done more. On the other hand, you know, this is the first time we actually tried to write a rule on the Web. And we were trying -- we expected a lot more feedback than maybe we got. We've got to learn how to use that interaction.

CHAIRMAN JACKSON: So, you're arguing that, in fact -- I mean, I remember when the whole construct was laid out and the idea of doing this expedited rulemaking. And that by doing it on the Web, it would allow you to cut down on the time, and that had something to do with the proposed time frame. And so, the question is, in terms of lessons learned, what happened? Because, it was presented to the Commission as an expedited rulemaking and that we could

expedite it by doing this way.

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

DR. COOL: Two observations, I think. The first is that you always have the conundrum of getting something that people can react to and then feeling like they're already behind the curve. In this particular situation, there was already word on the street, there was already a lot of background information. And I'm not sure to what extent we may have been -- or would have been guilty of that, irrespective.

The second, to get to the question which you asked, was in writing this on the Web this first time, particularly with the proposed rule, the staff erred, if you will, in the direction of version control and not having too many iterations going up too close together, to allow people -- or allow, of course, to give people an opportunity to react to it.

In retrospect, we could have put additional versions up and been more interactive. But, it was one of those learning exercises of attempting to -- how often do you change something, when they just get around to getting it in? They start to comment and suddenly another version pops up.

MR. MCGAFFIGAN: Madam Chairman, I'm not -- I think we have a lot to learn. The thing that strikes me

about the staff on medical is we have a relatively modest staff. And on things like 5059, we can afford --

CHAIRMAN JACKSON: You have an army.

MR. MCGAFFIGAN: We have an army, right. We have an army to send out. So, I'm not -- I recognize here it's a limited number of folks.

The other point I'd make, one of the troubles in dealing with a rulemaking that's this comprehensive is some things that will not -- we will not talk about today, because they're not major; in a small rulemaking would be major. And, you know, it's -- there may well be a lot of these 900 pages of comments that, if they had been off by themselves, these fairly profound issues that we would struggle with, if we were bite size rulemaking. So, it's -- but, we don't -- I know these folks are doing the best they can in a very complex area with very limited resources, compared to those we throw at reactive rulemakings.

MS. HANEY: Okay. Slide number seven, I would just like to tell you a little bit about the continued interactions that we've had with the stakeholders, since the public comment period closed. In February -- early February, we had a facilitated public meeting with the medical specialty boards and the purpose of that meeting was to discuss some of the implementation issues associated with the training and experience requirements, if we were to

pursue what we had proposed -- what appeared in a proposed rule.

We, also, had two meetings in February with the subcommittees of ACMUI. The purpose for that was to prepare for the meeting we've just concluded of the full committee and to get some early input from the ACMUI about the staff's proposed response to the comments.

Another interaction we had was last week, I attended the conference of Radiation Controlled Program Directors SR-6 committee meeting. This is a group that is preparing equivalent medical rules for the suggested state regulations. And we are attempting to do a sort of parallel rulemaking with the agreed -- with the CRCPD on this. So, I sat in on that meeting and we looked at the suggested state regs, in light of where we were on March 15th with the proposed rule, which is kind of a moving target for us.

And as I said, we just completed a full ACMUI meeting at noon today. And then, we've also continued to have ongoing meetings with -- public meetings with the public, with Part 35 working group and steering group. And, again, I'd just like to note here that on the working group and steering group, we did have members of the agreement states and Organization of Agreement State and CRCPD representation. So, we have been trying to work very closely with the states on development of this rule.

The next view graph, please. There are a couple of captions that I would like to bring to the Commission's attention: the training and experience, the reporting requirements. There are two reporting requirements that we'll discuss in a few minutes. Also, staff's proposed response and dealing with comments on radiation safety committee and then the calibration of Brachytherapy sources.

For the purpose of the presentation, what I'd like to do is to briefly tell you what was in the proposed rule, what the major comments were in this area, and then staff's proposed response and how we would proceed into the final rulemaking.

CHAIRMAN JACKSON: Now, are these key issues key because of risk significance or because they represent the departures from the proposed rule?

MS. HANEY: They're key because of the risk. Actually, this answer is yes to both of them. They are risk-based and, in some cases, they are departures from the current Part 35. But, I would like to point out they are not the only issues that we're dealing with that are high risk for this rulemaking. As Commissioner McGaffigan said, there are some that I just have not chosen to bring to your attention, at this point.

With regard to training and experience, on view graph number nine, with the proposed rule, the staff did

depart from the current Part 35, in that we wanted to focus the requirements on radiation safety. And I'll focus specifically on the alternative path -- training pathways, that being the ones that individuals that are not coming to us being Board certified. In the case of diagnostic users, we made a significant reduction in the training hours. Currently, to become an authorized user for someone that would be doing imaging and localization studies, they'd have to have 1,200 hours of training. The proposed rule would have only required 1,200 -- I mean, I'm sorry, 120 hours. In the case of the therapeutic users, and this specifically the device users, such as the teletherapy, the remote after loaders, or the gamma seratactic reduced surgery units, we maintained a status quo, and that being three years worth of training.

With the significant reduction in the training hours, we believe that it was necessary to have an exam that would focus in on radiation safety. It would be used to assess the individual's knowledge of radiation safety. We, also --

MR. MERRIFELD: Madam Chairman?

CHAIRMAN JACKSON: Yes.

MR. MERRIFELD: I'm sorry, I have a question for purposes of clarification. On slide nine, you say training requirements for diagnostic users is significantly reduced.

Yet, when you turn forward, you have diagnostic uses -- I'm sorry, slide 11, under the staff response, you have diagnostic users -- uses increase from proposed rule. So, I'm just wondering --

MS. HANEY: Sure.

MR. MERRIFELD: -- you're reducing from what we had before, but you're increasing it from the original proposal? It's unclear to me where we're going on that.

MS. HANEY: Okay. The current Part 35 requires 1,200 hours; the proposed rule would require -- stated 120 hours; and we're going to propose that the hours go back up in the final rule to 700 hours.

MR. MCGAFFIGAN: Madam Chairman, can I --

CHAIRMAN JACKSON: Please.

MR. MCGAFFIGAN: I can hear the endocrinologist at the moment. The training requirements were not reduced significantly for endocrinologist using one isotope iodine and they complain that the 120 was a significant ratcheting upward on them, when there was no evidence of any problem. And I hope you're not going to be proposing you ratchet them up to 700, because --

MR. HANEY: No.

MR. MCGAFFIGAN: Okay.

MR. MERRIFELD: As a follow-up question, one of the things that we have said is, you know, we recognize that

the risks from diagnostic medicine are less, and that's certainly clearly the message from the users, that they've been telling us. I'm just wondering -- I'm wondering why you decided to increase, having been at 1,200, you were proposing 120, and now we're back up to 700? Why the differentiation in the area, which we have recognized as a low risk?

MS. HANEY: I can explain that. In light of the public comments that we received -- if we move to slide 10 and then I can answer your question.

CHAIRMAN JACKSON: Before you go forward, I have a question. We'd like to fit in two questions.

MS. HANEY: I can answer --

MR. MERRIFELD: I'd like to get that question answered. I'm willing to defer to use her presentation.

CHAIRMAN JACKSON: Yeah, I just -- which slide were you going to?

MS. HANEY: Well, I can go to 11, but I can answer it without moving ahead. And then, I'll skip -- when I get to page 11, I'll skip over it.

The short answer is that we received a significant number of public comments that we had reduced it too low. The 1,200 hours was an insufficient length of training --

MR. MERRIFELD: One-hundred-and-twenty hours?

MS. HANEY: One-hundred-and-twenty hours was

insufficient. And a lot of the commenters said that we should maybe go as high as a four-month training program. And we even had commenters that said we should stay at 1,200; we should not have touched it at all. And although it's low risk, what they were saying is that it's low risk because individuals that are handling the material have an extensive amount of training. It's not just a 40-hour week training program. The current users receive 1,200 hours, and that's one reason why the track record is so good in the diagnostic area. And the concern is that if the hours were reduced, that might impact on safety.

So, we're proposing to do up to the 700 hour, based on public comment. And, not just that the hours was insufficient, but that you can't learn radiation safety in 120 hours sitting in a classroom. You really need to be in a department, seeing how it operates everyday. Because, during that 120 hours, there may not be that spill on the floor. But, if you're in the department for four months, at least one day, you're going to see a spill and you're going to see how you respond to it in a clinical environment. So, it's really that training needs to be over a long period, as compared to just sitting in a classroom for 40 hours or 120 hours.

MR. MERRIFELD: Could you -- you received a number of comments saying that we had overshot the mark with 120

hours.

MS. HANEY: Right.

MR. MERRIFELD: Obviously, it must have been people, who were the other direction. Can you give us some nature of the sort of gross numbers of folks? Maybe you can't, but if you can --

MS. HANEY: I would say predominantly the nuclear cardiology community endorsed the 120 hours that we proposed in the proposed rule. They were really endorsing, saying that the 1,200 hours is not right; so, therefore, as long as we were coming down, this was a good approach.

We had a large population, American College of Radiology, which is a very large group of professionals, saying that we had gone too low and that we really should stay status quo. Then, there was another very large group of stakeholders, the Society of Nuclear Medicine, that was proposing that we should not even specify hours, that we should just assess competency. Put in the rule the objectives, what you want people to learn, and then focus in on the exam and require the exam to test competency. So, we really had a wide, wide range, and it was split along professional society lines.

Maybe I could comment on the endocrinologist for a second. In the proposed rule, we would have increased the training for an endocrinology by 40 hours. The

endocrinologist were very concerned about the impact that this would have on their profession, because of the increase, and they believed that they were the right individuals to be involved with treating hypothyroidism and thyroid carcinoma. We did consider their comments and we would propose going into the final rule that there would be no changes in the training and experience requirements for an endocrinologist over that what is in the current rule. So, in other words, we would maintain status quo.

MR. MCGAFFIGAN: Madam Chairman? Is there a danger, especially in light of what you said on the endocrinologist, and as you know, that's where I was in the proposed rule, but the truth in any number that fits -- one size fits all, that there may be other professionals -- the cardiologists, I know, did feel that they deal, again, with the relatively finite set of procedures and they might not need as much training as -- they're making arguments very similar to the endocrinologist. If somebody needs a full scope exposure to using literally any isotope in any medical procedure, then, obviously, that person needs lots of training. And are we -- by choosing a number, are we being overly prescriptive or -- that's, I guess, the question I'd be interested in.

MR. MERRIFELD: The way I would phrase the question is: how did you come about with the 700 hours and,

you know, what kind of comfort level can we have that that's the right number?

MS. HANEY: Well, I can tell you how we arrived at the 700 hours. I'll answer that question first; it's easier. For the -- 700 is comprised of two components: one is 120 hours of classroom work, and the other 580 is in the clinical environment. The 120 came about by looking at residency programs, looking at their class syllabus, and seeing what component -- how many hours were devoted to physics, how many were devoted to radiation protection, how many were devoted to chemistry. And using -- looking at these programs, we allotted the 120 hours. The 580 was arrived at based upon the comments that we received from the stakeholders, that they believed a four-month training program was needed to be able to handle material safely. And I'm focusing in only diagnostic use right now.

So, we were relying on the comments that we received and from individuals that are in training programs that are involved with this work day-to-day. And that's -- and we're really relying on what the commenters -- information that they gave us.

As far as the one size fits all approach, in the diagnostic area, it was very easy to focus in on radiation safety, as compared to the therapeutic uses of medical devices. If you remember last year, we spoke to you, saying

that we maintain the status quo with the teletherapy and its remote after loaders, because it was very difficult to separate radiation safety knowledge from clinical competency. We believed it was a little bit easier to do on the diagnostic area and whether you're using one radial nuclide to image one organ or you're using multiple radial nuclides for multiple organs, there is a core knowledge of basic radiation safety you should have, and we believe right now that that is the 700 hours.

MR. MCGAFFIGAN: But, then, you have the endocrinologists, who have long been grandfathered at 80, and you're not -- and you're telling us you're going to -- it doesn't all add up perfectly. I'm certainly not arguing to go above 80. But, you have said that for one group of people, dealing with one organ, 80 is enough; but for everyone else, who might also be, you know, in the category of dealing with a single organ and a single radio isotope, you're saying 80 -- you need 700. There's a little bit of a --

CHAIRMAN JACKSON: Is there a need to prescribe to pass the Board or is there some methodology for providing it on a professional techniques basis or something?

MS. HANEY: I believe if we do not specify hours in the rule, we would need some way of assessing the individual's competency. And the one route that was offered

to us was the exam -- requiring an exam. And whether NRC would have that exam -- would offer the exam, it would be contracted, or NRC would approve it, those were big issues. They were very resource intensive for NRC, whether you took route one, two, or three. And there was a lot of controversy about the exam, about what sort of things we would be looking for, a lot of complicating factors. And this is what came about from our February meeting with the medical specialty boards.

So, just to put into the rule the objectives for the training, like you must know a, b, and c, I don't believe it would give us added assurance that the individuals were properly trained or properly qualified.

MS. DICUS: One last question about the exam. The exam is on radiation safety?

MS. HANEY: The exam that we proposed in the proposed rule was focused on radiation safety. But, our proposal right now is not to go forward using the exam and, instead, NRC would be involved with approving training programs -- I'm sorry, not approving, recognizing training programs.

MR. MERRIFELD: Based on that question, what kind of staff resources would be required for us to be involved in approving those training programs?

MS. HANEY: Involved with the training programs,

I'm estimating approximately 1.2 FTE involved with the training programs. Now, that assumes that we would not spend an excessive amount of time reviewing training programs that were already approved by what's referred to as ACGME, the Accreditation Counsel on Graduate Medical Education. So, if -- so the 1.2 number assumes that we would give some credit to a program that was already ACGME approved. And the majority of our authorized users are coming to us through approved ACGME programs. There are a small number of individuals -- applicants that are coming through what we called alternative pathways, meaning private industry training courses.

MR. MERRIFELD: Would that number -- I guess this is directed towards Carl, would that require us to reprogram or do we need to add additional staff to meet those requirements?

DR. COOL: We are in the process right now of developing the budget for next year under the planning, budgeting, and performance measures. And, in fact, what I intend to propose to Carl next week will have some reallocations to cover this proposal, and it will be within the resources which I had available.

DR. PAPERIELLO: Please -- I'm sorry, but there is an alternative way, is what we used to do, which is deal with it through licensing. In other words, we did not have

anything in the regulations prior to 1986. Between 1975 and about 1986, what we did is we handled everything on a case-by-case basis, which, in my view, would be very labor intensive. Now, granted, we put some guidance out, which actually was what was written into the Part 35 in 1986. One of my concerns in this whole thing is this whole issue of training was never really re-looked at in almost 20 years, because what we did the last time was merely took what was in a licensing guidance.

Now, I would point out right today, we now do, at times, review training programs, to see whether they're qualified. We have done that. So, I'm not sure exactly how much we have done up to now, versus what this rule would require brand new. I don't -- it really depends on whether or not entrepreneurs, people that are outside of the current system would design and setup, you know, separate training programs. I'm not quite sure we've made a guess about what would happen, what's likely to happen.

CHAIRMAN JACKSON: I think we'd better move on.

MS. HANEY: Okay. I would move to slide 12, to medical events. One way or another, we've addressed the issues that are on the two pages.

CHAIRMAN JACKSON: She wants to ask a --

MS. HANEY: Okay.

CHAIRMAN JACKSON: -- question on slide 11.

MS. DICUS: Slide 11, this focus the NRC of approval of a training program. With regard to the agreement states, are they prepared to do this?

MS. HANEY: I spoke with the agreement states last week at the SR-6 committee meeting, so realize that it's a group of five people that were -- that I was focused in on. There were some that were willing to approve or recognize the training programs. There were some that said they would just rely on NRC. The issue of reciprocity, obviously, came up about this. And, again, you know, there is a wide variation of views.

CHAIRMAN JACKSON: Will ACMUI be involved in approving these programs?

MS. HANEY: Yes. What we anticipate happening is that someone would come to us with an application. NRC staff would do a baseline review, looking at the instructor qualifications, the environment that the training would be given in. We would form an opinion about whether the training program should be recognized or not. Subsequent to that, we would take it to the ACMUI. We would ask their opinion. Based on what their opinion was, we could go back and ask additional questions of the applicant or we would approve it and, at least at this point, we would notice it -- we would anticipate noticing our recognization in the Federal Register and then putting it up on the Website, so

there would be wide dissemination of the information that we had approved the program.

MR. MCGAFFIGAN: I just want to clarify this. The institutions -- I assume most graduate medical schools are accredited by ACGME. Is this a nanosecond process to say that Harvard Medical or Columbia Medical or whatever is -- the program is up to snuff? Or are we talking about you guys actually having to churn paper on something like that?

MS. HANEY: Well, what I -- again, realize, you know, this is a months worth of thinking here, because this is a very quickly moving process here. What we anticipate is that we would give approval to the ACGME programs. There are three ACGME programs in this area: radiology, nuclear medicine, and the therapeutic uses. And once we gave that approval, that would knock out probably about 90 percent of the programs. So, for example, the program that is at Harvard is already accredited under the ACGME nuclear medicine program. So, we would not look specifically at Harvard's program, as well as the University of Maryland's. So, that would take out the bulk of staff's work. And I'm estimating, I believe 10-20 hours of NRC time on these sorts of programs, where they already have had an extensive review by ACGME.

In the case where it's a non-ACGME approved program -- and I should also add in those American

Osteopathic Association, AOA, that is -- does an equivalency to ACGME. In the cases where they do not have the ACGME or AOA approval, that would take additional staff effort. It may even take an on-site visit, and I would estimate around 100 hours would be devoted to review that application. Also, you know, you say what number of programs would be -- we would be reviewing under that approach, and we're looking at, say, to 10-20, a small number of programs that would not fall under either the ACGME or AOA approval.

MR. MCGAFFIGAN: So, 10 to 20 hours for all of the 90 percent, or is it -- you're still spending 10 to 20 hours looking at Harvard Medical?

MS. HANEY: No.

MR. MCGAFFIGAN: No.

MS. HANEY: It would be the 10-20 hours on --

MR. MCGAFFIGAN: It takes care of 90 percent of your problem --

MS. HANEY: With the information that I have right now, that's a true statement. We're continuing to get information, as we're holding these public meetings, as we've had the public at the ACMUI meeting, where we attended it. So, people are constantly saying -- giving me extra information. So, if I come back to you in two months, it may be different, but it's because I've gotten additional information.

And the next subject area that I would like to discuss with you is that of medical event on page 12. Medical event -- the term "medical event" has taken the place of the term "misadministrations." In the proposed rule, we did make some changes with regards to what needs to be reported to us. As far as the threshold goes, we did not make significant change, and by the threshold, I'm talking about the 20 percent deviation between the prescribed dose and the administered dosage.

We added a definition -- we added a dose threshold as a means of dealing with the wrong treatment site, and we added rule text to exclude cases of direct patient intervention. We did go forward keeping a requirement in the rule for notifying the referring physician and the patient and responsible relative, if an event did occur.

The next slide gives you a --

MR. DIAZ: Excuse me.

CHAIRMAN JACKSON: Sure.

MR. DIAZ: On your page -- slide 28, when you're talking about these medical events, you know, part A, either A or B, are those -- are the "ands" in A, are those "ands" or "ands and or?"

MS. HANEY: In 28, you would -- between A and B, they're either, either condition. Okay, within --

MR. DIAZ: In A, those that differs and --

MS. HANEY: And either one of those.

MR. DIAZ: So, it's or?

MS. HANEY: Yes.

MR. DIAZ: Okay.

MS. HANEY: We received a significant number of public comments in this particular area. Many of the commenters believe that the threshold should be raised. They went as high as saying that we should allow a deviation up to 100 percent between the prescribed dose and the delivered dose. Also, they believed that our criteria for the wrong treatment site was too restrictive. And they believed that any cases involving patient intervention should be deleted from the rule. They particularly focused in on the rule language and said that it was a little bit too vague. And, again, we received the comments that the rule should not require notification in the case of an event.

On page 14, you see staff's proposed response. We are continuing to evaluate where the threshold should be. That was the focus of the meeting yesterday afternoon. So, we'll need to go back and evaluate the comments that we received from the ACMUI. Generally, we believe we'll keep it very close, if not identical, to the proposed rule. We will, however, propose a change in the issue of patient intervention, and we've corrected, at least hopefully

corrected the rule language to make it a little bit less vague or to make it clearly understandable.

But, we do want to hear about patient intervention cases, when the event has resulted in an unintended permanent functional damage to an organ or a physiological system, as it would be determined by the physician. This is picking up rule language that appears in our abnormal occurrence policy. So, in other words, the key here is that a lot of the cases that we've been hearing about since the rule -- the misadministration rule went into effect that involved patient intervention, we would not hear about, because they would not trip this threshold. And, again, we would propose that we continue to require reporting to the referring physician and the patient or responsible relative.

MR. MERRIFELD: Chairman?

CHAIRMAN JACKSON: Yes.

MR. MERRIFELD: On that slide, you first initially said that the direction that you appear to be going is that there would not be a change in reporting threshold from where we are right now. Now, I know -- I've had my -- I had asked my staff previously to review some of those reports, and some of them do seem to be relatively, at first blush, insignificant. Are we comfortable -- are you comfortable that we are, indeed, risk informed, in our determination that we need not change those thresholds?

MS. HANEY: Yes, and it's based on information that I have received in comment letters, as well as reviewing the misadministration reports to date and in consultation with our advisory committee.

MR. MERRIFELD: Okay. Because, some of the comment letters that I know we've received have been somewhat caustic on this matter, from the standpoint of thinking that we really should raise this. So, maybe you could share just a flavor of some of the other letters that you received that think that we ought to stay with the thresholds that we have now.

MS. HANEY: The commenters that we received that were in support of this felt that we had an adequate threshold, because it was the point where something significant went wrong in the treatment, and by significant, I mean whether it was procedural wise, something didn't work right in the radiation protection program. And we had put in a threshold into the rule that was a dose-based -- was a risk-based threshold and by crossing that, it's at the point where NRC should hear about it.

MR. MERRIFELD: Madam Chairman, if you'll bear with me for a second, I have a general question. We are talking about the comments that you've received. And I've had opportunities to read some of them. As I mentioned, some of them are, you know, complementary of the things that

we're doing and some of them are, as I said before, quite caustic, you know, people have some strong feelings about these issues. Many of the comments seem to be various groups of medical professionals, who have different opinions, and so that's -- I know where those folks are coming from.

But, what I'd like to get is some sense of the nature of non-medical professional comments that we've received. Do we receive comments from the general public about these matters? You know, patients rights groups, any of those individuals?

MS. HANEY: No.

MR. MERRIFELD: Have we sought out those groups to try to get some flavor for where they're coming from? Sitting from where I'm sitting right now, it seems like we're in the middle of different health professionals trying to tell us which way to go. And I haven't heard a flavor for what the patients think about all this, the people who are affected by these rules.

MS. HANEY: You're correct in stating that we really did not get any comment letters from the general public. I would say 99.9 percent of the comment letters were either from physicians or from medical physicists or from health physicist. We did seek out the patient rights advocates at the facilitated public meetings. We invited

patient rights. We invited hospital administration to come sit at the table. We invited nursing.

We did have a member of a patient rights advocate at all of the meetings. We, also, have a member on our advisory committee. And their prime focus was that NRC should not, by any way, limit medical care to patients; that patients should be able to choose where they go, whose going to do the treatment. We should not have regulations such that we would keep modality from coming into general use, because we over regulated it and, therefore, we killed it.

The other thing that was very interesting is that all of the patient rights advocates indicated that they were not in favor of having a requirement in the rule for notifying the referring physician or the patient in the case of a misadministration or medical event. They believed that the physicians would tell them. It was -- they were very much in favor of the -- we should not interfere between the patient and the physician's relationship.

It was actually kind of surprising. It wasn't what I expected, to be honest with you. But, again, back to your statement, we did not have comments on the rule from a member -- general member of the public, and we did try to get them.

MR. MERRIFELD: Thank you.

MR. MCGAFFIGAN: I think there's a huge silent

majority out there, a silent group. I'm not sure what it is, but it's a huge silent group that just doesn't get heard from and that's what the Commission --

Could I just -- on the threshold, I had a conversation with one of these folks, who was somewhat caustic, and they were particularly caustic about the 20 percent, and I didn't have it in from of me at the time, and that we somehow slipped this in and this was going to affect diagnostic nuclear medicine.

And as I read it, you have to -- the place where the 20 percent comes up, a dose to the skin or an organ or tissue, other than the treatment site, that exceeds by 50 rem to an organ or tissue and 20 percent of the dose expected. It has to be more than 50 rem off to an organ or tissue and 20 percent. What did they have him do there? I mean, the 50 rems doesn't matter to an organ?

MS. HANEY: No. I think the particular commenter that you had the conversation with is focusing in more on a requirement for another section of the rule, in 3563, that indicates that an individual -- a technologist or whatever could not administer a dose, if it differs from 20 percent of what the authorized user prescribed. And that's the 20 percent that I think they're focusing more on, on that.

And that actually is a good thing that's in the rule, because it gives the licensee some flexibility,

because, as we all know, the material is decaying away. If the patient is 15 minutes late, you're still within that 20 percent, so the tech can go ahead and administer it without going back to the authorized user and asking him if it's okay to administer it. The easiest -- the example would be, if the physician says I want 10 millicuries administered for a bone scan and the tech were to administer 10.1, which is a no never mind from a risk standpoint, if that particular phrase was not in the rule language, theoretically, that would be a violation.

MR. MCGAFFIGAN: Okay.

MS. HANEY: So that's really the 20 percent that they focused more in on. We did get comments on the 20 percent that was in the section on medical event reporting, and that's -- and in that case, the thought was that's too restrictive than diagnostic. But, I believe that some of the people didn't realize that you needed to trip that initial dose threshold first. They weren't seeing it together. And a lot of times once I had conversations with people and said, no, you've got to exceed this dose threshold before you look at the 20 percent, then they were like, okay, Cathy, it's okay.

MR. MCGAFFIGAN: Okay.

MS. HANEY: Okay. Moving from medical event, I'd like to take you to another reporting requirement, and

that's for the unintentional exposure to the embryo fetus and a nursing child. This requirement came about as a result, again, of the abnormal occurrence criteria that would require that an event such as this be reported to Congress. In the proposed rule, we included a statement that a facility would need to report to us and we used a dose threshold of five milliceberts or 500 millirem. We patterned the text of the proposed rule against that of the medical event text.

We received a significant number of comments on this section of the rule and, again, you could say that we were hearing from a select population of individuals. But, they were generally opposed to the requirement and they went so far as to say that either the criteria and the abnormal occurrence should be raised or else the abnormal occurrence policy should be revised to delete this requirement. They believed very strongly that the threshold would impact medical care, because, at this level, there are some diagnostic procedures that could be in effect. We were quoted as this is a defacto pregnancy rule. NRC, why don't you just call it a pregnancy rule. And, again, well, it's not appropriate to require notification.

I know the ACMUI will be spending -- want to talk with you about the particular thresholds and the implications in the medical care -- the medical practice, so

I'm not going to try to speak for them in that particular area. But, I would like to offer to the Commission two proposals for a resolution in dealing with this. The first one, which is staff's preferred approach, would be rather than placing this requirement in Part 35, place it in Part 20. The reason for that is that the requirement, as it appears in the AEO policy -- I shouldn't say requirement -- but the criteria for reporting, as it appears in AEO applies to all licensees, not just medical. Now, most of the cases, if we were to hear about them, would probably come out of medical. But, it's really more a general requirement.

And then if we put it into Part 20, we would be allowed to maintain some consistency with all of our programs, and not just focusing on our medical. If we did do it in Part 20, we would have to do a tie between 35 and 20, because Part 20 does kick out any medical exposure. So, there would be a little thing we'd need to do in 35.

However, the other option, should we decided to proceed with it, in this particular rulemaking, staff would propose that we raise the threshold to five rem. Now, this would be putting the threshold at the point where we would have to report anything that we heard to Congress. We would not be -- as the case with the medical event, we are well below the AEO criteria. In this case, I would put it right there. And, again, I would recommend that we maintain

consistency with the medical event reporting, as far as any other requirements.

CHAIRMAN JACKSON: So, I mean, is the embryo child considered an extension of the patient or a member of the public?

MS. HANEY: That's a very good question and I'm not sure that we've ever explicitly answered that question. There are those that would argue on both sides and I've heard both arguments.

CHAIRMAN JACKSON: What do you feel this comports with, your staff preferred approach?

MS. HANEY: With going to the five rem, I believe it doesn't really go with either side, but it's looking at the effects of the radiation on the embryo fetus and looking at NCRP documents, ICRP documents, and feeling comfortable with this value and, at the same time, it would allow us to meet our responsibility of notifying Congress and we would not be negatively impacting medical care.

MR. MCGAFFIGAN: Madam Chairman? Is option one also five rems or is it 500 millirems?

MS. HANEY: Well, if you want option one, I would like it to be five rem. However, the benefit of option one, it gives us additional time to investigate the implications of this --

MR. MCGAFFIGAN: The thing that strikes me, Madam

Chairman, is that we have -- I think it was a year or so ago, the National Institutes of Health put out the report about what radiation my generation got from the atomic test, as we were growing up and drinking --

CHAIRMAN JACKSON: Which is my generation.

[Laughter.]

MR. MCGAFFICAN: But, how we managed to -- how much dose we got to our thyroids, as a result of the atomic test and whether we should all be going off getting our thyroids examined. And, you know, they predicted many thousands of cancers, as a result of -- I think Massachusetts, where I grew up, I probably got a couple of rems, and, you know, this is New York Times. And here, we're saying five rems -- we're not even -- we're not going to worry about it. So, there isn't a reporting requirement, at least, until you hit five rems. I don't know; I don't know. It's -- we don't deal with -- we may well go with the Chairman's question: is this embryo a member of the public or is it an extension of the mother, and society, as a whole, doesn't deal with that question very well.

MS. HANEY: That's really a key to what we're saying. This is a reporting requirement and not a dose limit. And that's been very difficult to argue over the last year with the proposed rule being out, because people are seeing it as a dose limit and I'm saying, no, this is

merely a reporting requirement, making no further statements.

CHAIRMAN JACKSON: Okay.

MS. HANEY: Okay. The next topic I'd like to discuss is the radiation safety committee. In the proposed rule, we deleted the requirements for a radiation safety committee. The comments that we received from the radiation protection professionals, the health physicists, as well as medical physicists, generally, were opposed to the deletion of the requirement for the radiation safety committee. They thought it was very key to the performance of their job. It gave them a direct connection with the management of the facility. However, we received a large number of comments in the diagnostic nuclear medicine area, particularly from physicians that were generally opposed to retention of the requirement.

Looking at these two considerations and thinking that we need to have our justification based on a risk informed decision, the staff is proposing that we require radiation safety committee only on the higher risk modalities, and also where a facility has more than one high risk modality. So, for example, if a facility had a teletherapy unit and also performed iodine 131, thyroid cancer operations, then they would have to have a radiation safety committee. The purpose being here is that once you

get into these higher risk modalities, usually, you're getting outside of the nuclear medicine department or outside of the therapy department. You're involving housekeeping. You're involving the nursing staff, management, and the radiation safety committee provides a mechanism for bringing these groups of individuals together.

While we did put it back in the rule, we did not put all the prescriptiveness back in the rule that the current Part 35 has. Right now, the rule text only reads that the radiation safety committee would have responsibility for program oversight.

CHAIRMAN JACKSON: Why is it that the issue of involving housekeeping and the other things that come into play, when you have a high risk modality, not be true, if you had one such, as opposed to two?

MS. HANEY: It does come into play. And I guess what we're trying to be sensitive to the commenters, to the stakeholders that are saying that if we have a small program, we only have a remote after loader. There's only a small number of people that are interfacing with us from the housekeeping staff or from the nursing staff, and they have appropriate mechanisms in place to deal with this.

But when you start getting out of the one use, into multiple use, there's a whole other group of nursing, a whole other group of housekeeping people that deal with

individuals that are getting unsealed therapies. So, we were trying to not get a burden on the licensees. But, yet, you know, there is some truth in the fact that, you know, as soon as you have one of these departments, you bring in nursing or housekeeping, why wouldn't you? But, again, it's just listening to the public comments.

CHAIRMAN JACKSON: I mean, are you trying to make an argument that having more than one modality, that somehow the risk of accounts of some mishap goes up --

MS. RANEY: Yes.

CHAIRMAN JACKSON: -- you know, in some numerical or algebraic way?

MS. RANEY: Yes.

CHAIRMAN JACKSON: Yes; I see. Where's the formula?

MS. RANEY: Where's the formula? There's not a formula that I can give you. It's -- again, it's just listening to the comments that we've heard, being in these facilities, talking with our inspectors, licenser viewers, looking at what goes wrong. And the more people that you involve in these modalities, the greater the chance of something going wrong. And if something goes wrong in these particular areas, you're dealing with something that could increase the dose to a member of the public or to the patient or to the occupationally exposed individuals.

CHAIRMAN JACKSON: Do we have data in some kind of events database that tracks with number of modalities in the high risk modalities, that shows some progression in terms of numbers or severity of events, according to whether you go from one to N?

MS. RANEY: Not that I could tie to a radiation safety committee.

MR. MCGAFFIGAN: Madam Chairman?

CHAIRMAN JACKSON: Please.

MR. MCGAFFIGAN: The radiation protection professionals, who are generally opposed to the deletion of the requirement, how are they reacting to this cut the baby in half approach?

MS. RANEY: They were -- in any of the meetings where we have discussed this approach, they indicated that they were happy with the approach, that they believe that it was real spaced and that this was a much better way of going than deleting the committee requirement completely.

Okay. The last key issue that I'd like to bring to your attention is that of calibration of Brachytherapy sources, and this would -- this is outside of the area of the devices. These would be just the sources that would be used outside of, like a teletherapy and a remote after loader. The proposed rule contained a requirement to determine the output or activity. We, also, allowed in the

rule for the licensee to be able to rely on the manufacturer's calibrations, assuming the calibration was done in accordance with our rule.

The comments that we received, there was support and opposition for allowing the reliance on the manufacturer's calibration and there was a limited opposition to the requirement. But, again, the majority of the professional organizations, as in American Association of Physicists and Medicine and the Health Physics Society, were in support of the requirement.

Our proposed response to this is, is that we would continue to require the licensees to determine the output or activity. In other words, we would not make a change to the requirement in the proposed rule and that we would not grandfather sources. So, licensees would need to look at their sources that they currently have and assure that they have an output or an activity for the source.

MS. DICUS: Madam --

CHAIRMAN JACKSON: But, this is -- please.

MR. MERRIFELD: When you're done, I've got a question.

[Laughter.]

MS. DICUS: All right. Which ones would you not grandfather? For example, what if a source had been -- the manufacturer's calibration is done according to the rule,

why wouldn't you grandfather it?

MS. HANEY: Well, in that case, the licensee would have a certificate that said -- so, those -- well, we don't see that as grandfathering. We'd see them as complying with the rule. And it's those that would not have that certificate --

MS. DICUS: You would not grandfather?

MS. HANEY: Correct.

MS. DICUS: Any of them?

MS. HANEY: Correct.

CHAIRMAN JACKSON: Commissioner?

MR. MERRIFELD: I'm just trying to get some sense of what we're talking about. What's the impact of not grandfathering from a cost basis? How many -- what percentage or amount of devices are we talking about and how expensive is this additional calibration?

MS. HANEY: If I can remember back a year ago, I think we said that for those licensees that would have to go out and do this, it would cost them around $1,000 per facility, not per source, because once they got the equipment in, they could do -- use it on any number of sources. And based on data we received from the medical physics community, that there is only a limited number of individuals that would not be in compliance that would actually have to go out and get compliance. And in our

regulatory analysis, I think we used a number of around $760,000, as far as the impact of this requirement.

We solicited comment in the proposed rule on whether our estimates were correct or not. We did not get any comments that said that we were wrong. We didn't get any that said that we were right, but we didn't get any that said that we were wrong.

[Laughter.]

MS. HANEY: So, we -- and --

MR. MCGAFFIGAN: Before you put up big rule.

[Laughter.]

MS. HANEY: And based on the input that we received from the professional society, saying this was a thing -- a really good thing to do and that we should do it, we would proceed with it.

CHAIRMAN JACKSON: Suppose you had a commission, who used a Brachytherapy source and had a treatment modality, based on a nominal -- a treatment protocol, based on some nominal source activity, what does this do? Remember the Strontium 90-I source?

MS. HANEY: Yes. This is -- you have the sources where the physicians are treating to effect. And it really doesn't matter to them whether the source output is 10, 100, or 200, they're still treating to effect. This would cause them to go back, get the calibration, get the output of the

particular source. It more than likely would not get them to change the fact that, you know, now that they know that the half put is -- that the output is half what they thought it was, they're not going to double the treatment time. They would just adjust any of their calculations and their written directive based on the new value.

Okay. The last thing that I would like to bring to your attention are the agreement state issues, and these are the issues that the SR-6 Committee discussed with me last week, when I was in Alabama with them. And I bring them to the attention of the Commission, just so you are aware of some of the issues that we're dealing with under -- trying to attempt to move toward parallel rulemaking.

NRC is proposing that we not review -- pre-review licensee procedures prior to issuing the license, especially in the diagnostic area. The agreement states, most of them will continue to review the procedures prior to issuing the license. They believe that this is very needed to provide assurance that the licensee has adequate knowledge to operate safely.

There's also a difference in the goal of the authorized user. Again, most of the agreement states believe that the authorized user should be responsible for patient selection, prescribing the dose, and interpreting the study. NRC believes more that the role of the

authorized user is in prescribing the dose and then supervising the use of the material.

In the case of training and experience, the states were generally in agreement with the approach that NRC was taking. The one exception that they had is they believe that the endocrinologist should have more training than what we are proposing. In fact, they would bring the endocrinologist up from their 80 hours, up to the 700 hours that we're proposing. So, they would propose a significant increase. They, also, believe that it's important to have training and experience requirements for the technologists, since it's the techs that are actually handling the material.

There's a lot of discussion on the patient release criteria. This is in the requirement in 3575 and has to do with at what point you can release a patient from the hospital after they've been administered radioactive material. As you can remember a few years ago, we changed the rule to go to a dose-based rule, previously had said you could release if the body had less than 30 millicuries. And the agreement states -- some of the agreement states liked the way the rule is right now, dose-based

But, there is also a large number of states that do not like it. The concern has to do with radioactive material getting into landfills. If the patient -- if the

physician does a patient-specific calculation, allows the patient to go home, whether material leaves the hospital, goes to the landfill, sets off the alarm, it's the states that have to respond. So, they're concerned about that.

MR. MCGAFFIGAN: Could I ask --

CHAIRMAN JACKSON: Please.

MR. MCGAFFIGAN: Doesn't the same material go to the landfill, whether the person is at the hospital or they're at home?

MS. HANEY: In the case if they stay at the hospital, they hold the material for decay. So it would become -- it would sit in the hospital until it was indistinguishable from background.

MR. MCGAFFIGAN: I see.

MS. HANEY: In the case of the --

CHAIRMAN JACKSON: You hold the patient until the patient is indistinguishable?

MS. HANEY: Yeah, basically.

[Laughter.]

MS. HANEY: No, until you're less than 30 millicuries.

In the case of the embryo fetus in nursing child reporting, the states agreed -- or preferred that we take the Part 20 approach and spend a little bit more time looking at it. But, if we do not take that approach, they

believe the threshold should stay at the 500 millirem level.

There are also some concerns about the sections of the rule where we had assigned an H&S, health and safety designation. And they noted that this was really the first time that we had used the NRC's new policy on adequacy and capability for agreement states to look at an entire rule during the development -- during the rulemaking process. So, therefore, they were concerned about some of the sections that had been designated H&S designations, because of the implication it would have on the adequacy of their program. And we talked a little bit about the adequacy of the program versus the adequacy of their regulations. But, this was a very sensitive area to them and I just thought that it should be brought to your attention.

MS. DICUS: Before you leave the slide, how would these issues be resolved? Are you going to try to resolve them?

MS. HANEY: Well, some of them we are trying to resolve and some of them we've agreed to differ. Of course, where we agree to differ becomes important is on what the level of adequacy and compatibility is assigned to the particular requirement. We went through -- they used a process of using the suggested state reg as the basis and then feeding our rule into that. And I don't believe there were any problems on any issues where they were C or above.

So, we're okay in agreeing to disagree with them.

MR. MCGAFFIGAN: Could I ask a follow-up really on that? This is the plan made at the outset. There are lots of issues in this thing and you've highlighted some. I, honestly, would like to understand a little better why, for instance, on the pre-review of procedures, the agreement states do it one way, we do it the other. And I'm not sure it saves the day, because we have other people, or there's different rules, the authorized user, or whatever. But, it sounds like they're fairly profound differences, where you guys are used to agreeing to disagree; perhaps you have for decades. But, you know, we're sort of blessing the disagreement when we approve the final rule. And I just want to make sure why I'm on your side and I'm not on their side, at some point.

MS. DICUS: And another -- the issue of consistency, which we have in a lot of other areas besides here. But, you have a particular case where many of the hospitals across the nation are part of health provided corporations and they may have one set -- in one state, they do things a certain way and, yet, that same corporation in another state, that hospital may do things differently, and to what extent, at some point in time, that becomes a problem.

CHAIRMAN JACKSON: Okay.

MS. HANEY: All right. And then I would just like to summarize by saying that I hope I've clearly described our efforts to date, since we have issued the proposed rule, and hope we have summarized the comments that we've received from the stakeholders for you and given you a clear view on where the staff is on resolving some of these issues right now. And I would request any guidance from the Commission on whether we're taking the appropriate response to the comments and on the right path.

CHAIRMAN JACKSON: Thank you. Let me ask you this question? How long it do you think it would take you -- when you really come to resolution? I guess it depends on the degree of guidance you get from the Commission.

MS. HANEY: It does. And, I mean, obviously, the more time, the better, but it comes a point where you have to say enough is enough. We -- we're working very hard to meet the due date to the Commission, with the goal of the original date being the end of May and then with the second SRM that we got that would allow us to go into June. That will -- if we had an additional three months, I feel that we could do a better job of responding to the comments. And pretty much I've focused my staff's efforts on hitting the big areas first, knowing that, you know, the more time that we get, we'll go further down. And, obviously, because of the Administrative Procedures Act, we'll have to address all

comments. But, the degree to which we will address is clearly related to the amount of time that we have to do the rule.

Once we finish the rule, we still have the guidance document and the guidance document was -- did receive a lot of comments. And the key thing is that stakeholders are very concerned about us putting defacto requirements in the guidance documents, and we're being very careful not to do that. We're making sure that we have a direct tie to a regulation. And then, we still have the medical policy statement that sits out there that needs to be finalized.

CHAIRMAN JACKSON: Okay.

MR. MCGAFFIGAN: When would the guidance documents be ready?

MS. HANEY: It depends on what my due date is. If we had to stick with the May, June time frame, the guidance document would not be ready. I think if we had an additional three months, you know, maybe four months max, at the same time that we gave you the rule, we could give you the guidance document, and then that would allow you to look at them together, because of the importance of the stakeholders comments on the guidance documents.

MR. MCGAFFIGAN: Madam Chairman, one other clarification. This rule does require OMB review, right?

MS. HANEY: Yes.

MR. MCGAFFICAN: Not just in OMB concurrence, really, unless we -- don't we need that guidance document for the OMB concurrence process, given some of the stakeholders that we know who will intervene in the OMB process of I don't like where you are? Isn't past history that they ask the sort of questions that only the guidance document can answer in the review process?

MS. HANEY: Right. It is, and I think the preferred route is to have it available when we do go to OMB. However, we're not putting any requirements in the guidance document that aren't in the rule and we've pulled some things into the rule that previously had been in the guidance document, like submit the form and submit the procedures. So, we have everything. So, I would feel, if I had to, I could go to OMB and say all the record keeping requirements are in the rule. But the idea would be to have them together.

MR. MCGAFFICAN: Okay.

CHAIRMAN JACKSON: You know, the Commission actually is considering the time line and looking to see what needs to be done to allow you to have a good rule. And so, you're going to be getting that guidance shortly.

MS. HANEY: Okay, thank you.

CHAIRMAN JACKSON: Any other comments?

MR. MERRIFELD: Yes. I was going to make a comment, but the Chairman beat me to it.

CHAIRMAN JACKSON: I know all these -- that's all right, I won't make a comment. Thank you, very much. Let us hear from the advisory committee on the medical uses of isotopes. Good afternoon.

[Pause.]

CHAIRMAN JACKSON: You can proceed.

DR. STITT: We've been introduced. We have our name tags finally correctly placed in front of us.

CHAIRMAN JACKSON: Thank you.

DR. STITT: I'm going to adopt the process we've used before. You've seen us here in the past. And because this is an interactive group process, rather than doing all the talking, we have chopped up our comments to be made by different members of the group.

This has been a long process for the Committee, even longer for the staff, and probably the Commissioners. Don Cool, when we started our meeting yesterday, used a roller coaster analogy, as to some of the ups and downs. There are three of us, who are jumping off of the cart. So, we're going to be leaving it to the rest of you. But, it has been an interesting process; in general, very educational. And we have worked with the NRC staff to address the Commission's direction towards what we feel is a

rule that is risk informed and more performance-based.

I'll have slide number one, the ACMUI. And they feel that the occupational public and safety issues have been maintained in the revisions of Part 35. We have worked with a very interactive NRC staff. They've been responsive. They've given us statements. We've had a lot of give and takes, some knock down, drag outs.

The function of the subcommittee has been very useful, particularly when it came to the comments. We were presented on many occasions with the diagnostic and therapeutic subcommittees, with detailed, detailed comments from the public, and have been asked to address these. Probably one concern, or just to bring up one issue, if there's any shortcoming is that there were probably many other comments that we could have addressed, but time constraints literally just -- I would have to cut off the discussion, at some point. Some of those comments have come from the regular community, the users, and the public meetings.

We'll move on to specific points that we wanted to bring up with you.

MR. MCGAFFIGAN: Madam Chairman?

CHAIRMAN JACKSON: Yes.

MR. MCGAFFIGAN: I think Dr. Stitt just made a fairly profound point, and Cathy Haney said earlier, you

know, we can deal with these secondary comments as we have more time. Some of the comments that probably regard to the secondary that I witnessed at the Rockville meeting, there -- you know, probably having some advice from you all would help. So, I hope -- and under the Administrative Procedures Act, Cathy is going to deal with the recumbent. So, if we give the staff a little more time, I hope you guys use it to delve down into these so called minor comments, which, as I said earlier, in a bite size rulemaking, they're probably major comments.

DR. STITT: Well, my response to that is that I think we take that part very seriously, because we know where those comments came from and when reading them, we recognize some of the names and faces that are in the comment section. And probably the most time consuming part of many of our meetings have been some polarized views, some very strong opinions. But, if you're really trying to be interactive, we have -- I think we have done a good job, as a committee, and not necessarily come up with a consensus, but it's been a very effective part of how we functioned.

View graph number three for the ACMUI, Dr. Cerqueira.

DR. CERQUEIRA: Thank you, very much, Dr. Stitt and Commissioners. In terms of the training and experience, this, obviously, is one of the more controversial areas.

But the Committee really made an attempt to focus on the issue of radiation safety and not the practice of medicine. We intentionally tried to look at what were the essential features to go into radiation safety. And --

MR. MERRIFELD: I'm sorry, excuse me, do you have the right slide up there? Is that what you intended?

DR. CERQUEIRA: No. It's the previous slide, on page three.

DR. STITT: The label is training and experience. It would be in our package --

DR. CERQUEIRA: I apologize. I didn't look up in time.

And as a result of that, we went through all the meetings that Cathy clearly outlined. And the efforts that the committee really tried to focus on was to try to identify the specialty boards where radiation safety was being tested, and use that as a means to identify competency in that area. We, also, felt to try and identify specific training programs, where both the didactic classroom, laboratory training would be a team. This is essential to be reviewed by the committee and we've recommended that mechanisms be established for review of the content, as well as the people that would be involved in these programs, to be certain that they met the standards that were established by the NRC.

We felt that there were still a lot of people, who would not be able to either take boards or receive their training. We needed to, basically, provide alternative pathways for training experience that would apply to authorized users, to medical physicists, the nuclear pharmacists, as well as the radiation safety officers. We've attempted to clearly outline what we felt would be essential for reviewing this alternative pathway and give people an opportunity to enter through that mechanism.

As part of this, it recognizes a fair amount of people that have come into -- become authorized users through alternative pathways. We really felt it would be important to try to get a uniform national policy on training and experience requirements. I've had the opportunity to attend the meeting of the SR-6 group and if you really look at the agreement states, there's a fair amount of variability that's introduced, in terms of the training requirements. And somebody who meets all the standards in one state, relocates, has to reapply, and they find themselves without being able to practice, even though they were allowed to practice in another state. And we felt that it would have be prudent if now that this training and experience is going major review and revision, that the agreement states try to adopt a uniform policy, similar to what the NRC. A category C would be an appropriate level of

compliance between agreement states and the NRC; that this would provide a more uniform policy and make it a lot easier for people involved in training programs and especially for people coming in through alternative pathways.

These were the major recommendations that we made.

MR. MERRIFELD: Before we lave this slide, we spent some time talking with Cathy about diagnostic medicine and going from 1,200 hours to 120 and resulting on 700, which is still a significant decrease over the original requirements. Do you agree with that number?

DR. CERQUEIRA: Well, this is a controversial subject. Even up to two hours ago, it was discussed in one of the discussions. Since I'm perhaps a minority, I really feel that if I'm going to comment, perhaps the other committee members could comment, as well.

I think there are some issues related to -- well, again, looking at your risk-based training, they need to make it appropriate. We had some question in terms of determining where the training was gotten. And, again, I'm a nuclear medicine physician, but also a cardiologist. And we felt it was important to look at the risks, in terms of what was being done, and to try to guarantee that the training was obtained at a good quality program.

And I think in terms of the 700 hours, we felt that if you looked at, again, some of the things that Cathy

said about making sure that the person's environment, that that clinical experience was a part of regulation safety. And in some ways, it actually improves the quality of the people that are going to be doing studies, in terms of both the radiation safety aspects and someone who trains people that are going to be out doing this work. I think there's some good quality clinicians, as well. So, I think, in general, the committee felt that the 700 hours did provide some assurance, but I think that there were other things in this, as well.

CHAIRMAN JACKSON: Well, let's hear them.

DR. STITT: One of the considerations you have is when you take a look at -- with various areas in training requirements, you're going to have to be able to justify if there's differences in hours from a risk basis, okay. I think that's an example -- for example, the endocrinology people come in with a therapy procedure, basically, on cell byproduct material and with 80 hours of training. Well, how do you justify that vis-a-vis a group of people that are using unsealed byproduct materials, which include iodine 131, where we're saying 700 hours of procedure. So, you know, that's something you can't -- you can't just look at it solely from the perspective of the regulating rules and what their standard training is, but it also has to make sense from a justification standpoint. So when you're

taking a look at these, you need to keep that in your mind.

Well, I'm just going to take the back road, only in the sense that my experience in those we've represented would be in the therapy at the high dose levels. And when you look where the controversies are and where the concerns are, the status quo is basically being maintained at the four and six. And so, we're sitting around a little more passively in these parts of the discussions. I think this tends to be more the diagnostic and some of the therapeutic unsealed sources.

MR. WAGNER: Well, I think that on face value, there's always going to be questions raised. But, I think what we have to consider and understand is that we'll never have complete agreement on these issues. The recommendations that have come down are really a very measured decision, based upon looking at each of the individual practices, trying to look at the risks and benefits, and trying to make a very level assessment. If you just look at them on face value, sometimes you'll say, oh, that doesn't make any sense. But, if you look really deep and behind the arguments and the issues that individuals have placed in the committee and elsewhere, you'll see that there are subtleties in there that really enter into the question. And how you go one way or the other, based upon those individual subtleties, is always a

difficult issue.

For example, if you only do high dose therapy by the one modality, etc., how does that differ from a person, who uses diagnostic levels all the time? Well, the facts are the person, who is doing diagnostic levels all the time, that person is treating people, who you don't want to have high doses. So, you want to make sure that they have really good training across the board in multi-modalities; whereas one person is giving high doses all the time, is giving them to sick people, it's very, very well delivered, and it's a very systematic -- and I'm thinking of the treatment of the thyroid, for instance -- very systematic and it's very direct and it doesn't involve a lot of variation. So, there, you've got another issue. So, in all these issues, there's more to it than just the matter of say, oh, this doesn't make any sense on face value.

CHAIRMAN JACKSON: Thank you.

MS. MCBURNEY: I came into this advisory committee with some basic concerns, especially about the use of radionuclide, and my being an endocrinologist didn't help. That differed from other unsealed uses for therapy. But, some of the other members of the committee, as we expressed, you know, studied it -- you know, this is the reason for that discrepancy. I do agree that going to the 700 hours total for diagnostic is appropriate, because, as Cathy

mentioned, you do need some time in that clinical setting, in order to see all the different types of things that you would need to address, as a diagnostic authorized user.

CHAIRMAN JACKSON: Thank you.

DR. CERQUEIRA: I'd like to make one last comment. Some of the questions that the cardiology community has relates to where this training is gotten, in terms of the clinical experience. We pretty much support the 80 hours of adapted classroom and 40 hours of supervised experience. But, we're talking about 580 hours of clinical exposure to procedures. And as the rule is written, in terms of the ACGME requirements, the cardiology programs currently don't necessarily stipulate all of the hourly requirements, neither do the endocrinology boards or the ACGME, the endocrinologist. And this would somehow model some people, who are authorized users, but training people within the cardiology program to some preceptor statement for the people. Well, that would introduce a certain amount of difficulty. And it's true that these programs could be reviewed by the NRC and the ACMUI, but that would add quite a bit of work to the process.

MR. MCGAFFIGAN: Madam Chairman? I'm just wondering, classroom counting a number of hours, that's straightforward, probably counting the 40 hours is straightforward. What do we mean when we say you have to

have 580 hours of clinical experience? Does that mean if I'm a cardiologist -- a future cardiologist, that I sort of have to be in the hospital setting, where somebody might be using radionuclide down the hall during those four months, and if there's a spill there, somebody will pull me in and say, see, this is a spill and this is how we handle it, or -- and so, you'll just -- I mean, you'll just count four months worth of -- you cook up the 580 hours? Or is it real, you know, for 580 hours of your cardiology -- I'm not sure, your internship, whatever it is, four months you'll focus entirely on the use of radionuclides in treatment of heart disease?

DR. CERQUEIRA: As the current guidelines for cardiology training, they recommend that people that do this -- they have four to six months. And that 580 hours should consist of performing the stress portion of the studies, interpreting the studies, being there when the patient gets subjected with a radioisotope, being involved in some of the quality control with the department. But, I think the committee, in general, felt that it was important to have people in the clinical environment to see the problems that can occur: the spill that occurs on the treadmill, the -- and some of the other issues that arise. We felt strongly that to allow people to do as you say, which is basically just to be at a facility, to be in a classroom someplace,

would not meet the broad exposure, the time element, which is essential to see a variety of cases and a variety of problems that may arise.

MR. MCGAFFIGAN: If we pass this rule, people will be able to count those hours honestly and there won't be disputes as to whether the hour was devoted to this or whether the hour was devoted to watching open heart surgery down the hall or whatever?

DR. CERQUEIRA: Well, I think we can establish the rule -- and sort of the professional medical societies are encouraging this, and I think people will be compliant. But, obviously, there will be, you know, breaks in trust. But, in general, I don't -- I don't see it as going to be as much of an issue.

CHAIRMAN JACKSON: Dr. Stitt.

DR. STITT: One comment that addresses that. We felt there's an important role of the preceptor, who will be signing off on this particular training. The precepter is commonly the residency program director, who has a broad view of what that individual trainee has been involved in and is going to be less likely that, you know, an hour here or an hour there can be doctored; whereas, you're going to be looking at a broadened program.

CHAIRMAN JACKSON: Dr. Wagner?

DR. WAGNER: Yeah. I think also the other fall

back is the fact that these programs have to be approved -- the training programs have to be approved by the NRC. And if they're, say, an ACGME approved program, they're specifics from that agency to specify what an individual must do in the training program. The whole idea here is to keep it out of the rule -- keep the prescriptiveness out of the rule space, depend clearly on the professionalism of the training programs to decide what that is. And you have some control through your assessment of the programs, the approval of the programs. There's a preceptorship that has to be approved. So, there is guidelines here to make sure that that is maintained at the proper level.

CHAIRMAN JACKSON: Okay. Can we go on?

DR. STITT: Okay. We're on view graph four, medical event. The ACMUI agrees that the -- those thresholds currently capture events of concern and that proposed dose thresholds will provide regulatory relief from some of the lower risk events that have been numerous, and kind of confounding those of us who do consultations, and one of the probably strongest examples of that is wrong treatment site.

A large segment of consultation time concerns this third point, that is patient intervention. And we feel that events occurring as a result of patient intervention should not be reported to the NRC. There's one big caveat, and we

don't have all the language in front of us, but that, I think, was put in front of you by one of Cathy Haney's view graphs, such that a dose that would provide permanent injury to an organ or tissue wouldn't be captured. So, one of the examples, in spite of the best that you can do, an individual that's got a source treating the bronchus for lung cancer, they're bed rest, they have drugs written to suppress cough, but the patient can cough and the catheters can change position. That's a relatively common example.

We wanted to, in case you had any question, reaffirm that we don't support regulation that requires notification of the referring physician or patient, as we feel that this continues to be redundant in the existing standards of care.

MR. MERRIFELD: I'd like to -- speaking about redundant, you, also, have that same statement on the bottom of the next slide.

DR. STITT: Right.

MR. MERRIFELD: Explain to me the redundancy? And I know -- I think at the end of your statement, I'd like to hear and see whether our staff agrees with you or not.

DR. STITT: Patient care is what I do all day, every day, unless I'm in Washington. And if there is some modification of a treatment plan, whether -- no matter what created that, the patient and I discuss what's going on.

So, the redundancy relates to federal regulation; that is taking care of patients in the standards that I hold myself to and ethical standards require that I discuss this matter with the patient.

We have had two members of the public, who actually have been committee members of ACMUI, who very expressly stated that they found the reporting requirement frightening to them, as individuals; that they feel it's disruptive to their communication with the physician, who is managing them, and realize that the members of public, who are usually working with us, have been through some intense medical system. So, they are speaking from their firsthand knowledge, and they find that the requirement for reporting, the federal requirement, is interfering with their relationship with their physician. So, that's our personal experience, as a committee with members of the public.

MR. MERRIFELD: Starting with the Chairman, I'd like to get the staff's view of why we are where we are. Cathy or Carl?

MR. DIAZ: Excuse me, when you say "federal requirement," you mean NRC requirement?

DR. STITT: That's right, through Part 35 rules.

MR. DIAZ: Through Part 35.

MS. HANEY: This has been an issue that the staff has looked at for several years. It really came about first

with the medical -- the misadministration reporting in the early '80s, and it has elicited a lot of conversation among staff. By going back and referencing some of the old documents, the Federal Register notices, we are where we are today because of Commission decisions that have said that if -- I guess, basically, we don't want to be in a position where the NRC has information that the patient does not have. And without this requirement, we can't be assured that the patient would not have that information.

We, also, believe that by assuring that this information gets to the patient, that we are putting in position where the physician and the patient together can make an informed decision about their care. And these are items that have been issued in Federal Register notices and for why -- you know, basically, stating where we are today. But, it has caused a lot of discussion.

MR. MERRIFELD: Yeah. Did we -- just to reiterate my question, did we receive any comments from the public, outside of the medical community, asking us to repeal, you know, our regulations, as it relates to this particular element?

MS. HANEY: No. Other than the patients rights advocate that Dr. Stitt said that we have on the committee and the ones that attended the facilitated public meetings and, as she said, they indicated that the requirement was

not needed. Now, if you go back to the ACMUI of probably about two years ago, we did have a patient rights advocate that felt very strongly that this should be in the rule.

MS. MERRIFELD: This should be in the rule?

MS. HANEY: That it should be in the rule. But other than, you know, those particular points, we did not receive any comments on it.

CHAIRMAN JACKSON: Okay; thank you.

MR. DIAZ: Excuse me. Dr. Stitt, the redundancy comes from the fact that you feel that there is an intrinsic obligation for the administering physician to discuss with the patient any mutual misadministration that is beyond what you would call, you know, variations that exist in clinical settings?

DR. STITT: Right, that is talking to a patient about some event that happened. Another example, because that's probably easiest for me to talk in a fashion of patient care: a patient has been treated for cervical carcinoma and the source strength might have been used incorrectly. You have to talk to the patient to say the dose that we wanted to give you didn't achieve; we didn't use the right source; amongst five, we had one that wasn't the correct strength. So when we do your second insertion of the plan that we had for two insertions, we're going to make some adjustments. And part of the discussion would be

this means that we're able to give the dose that we wanted to give. So, it would most commonly come up in the course of discussing the patient's care.

MR. DIAZ: For example, in -- and I hate to bring those up, but, you know, we reported last year abnormal events on some major misadministrations, you know, to the Congress of the United States. And they're, obviously -- you know, they're all related practically to the thyroid, but not coming from endocrinologist office. And how would you deal with those, you know, real, large single issues that still are out there? How would you deal with it?

DR. STITT: Well, I don't deal with any thyroid --

MR. DIAZ: I know.

DR. STITT: Dennis, you want to take a --

MR. SWANSON: Well, I think what we're talking about, those are still being reported to the NRC. The concern deals with the patient notification aspects of this. And you're making the assumption that that physician is not notifying that patient.

MR. DIAZ: No, I didn't make that assumption. In fact, I wanted to be reassured of how you would actually deal with the situation.

DR. CERQUEIRA: And I think you said yourself, that instead of the reporting the misadministrations, the reality, in terms of for diagnostic uses, that does tend to

create a certain amount of distress in the mind of the patient, because he doesn't -- he or she doesn't fully understand the risk that's involved, which is relatively low. And if you look at all other areas of medicine, when I do cardiac catheterization, I can potentially do lot more harm by making mistakes, but I don't have to report it to a federal agency. It's basically controlled by committees and hospital rules, other areas within the hospital, the professional medical societies that control this. If I give the patient the wrong dose of an antibiotic, I don't have to report to anybody, again, because the risk is relatively low. And according to the committee, I can give a tremendous dose, which could have lethal effects, and there's no reporting requirements.

MR. MCGAFFIGAN: Even to the patient? You need not tell the patient I just gave you a high dose or something?

DR. CERQUEIRA: No. Again, but that's -- it's regulated at the local level and I don't have to report it to an agency. So, yeah, I think it's important to be able to do it within the hospital structure, the procedures in place currently that deal with these kind of issues. And I'd have to notify the patient.

We're saying here, notify the NRC. The risks are relatively low to these patients. In terms of the

doctor-patient relationship, it does create a distrust, which doesn't need to be there.

MR. MCGAFFIGAN: Could I ask --

CHAIRMAN JACKSON: Yes.

MR. MCGAFFIGAN: The patient notification is actually the referring physician notification. The referring physician decides whether to tell the patient, I guess, it's generally done. As you say, the practice of medicine would usually do. So why is it, if it's going to be done anyways, why can't -- and I think we made an adjustment in the rule, so that we don't have to -- whatever bureaucratic report you send in to us doesn't have to be the mechanism you use to talk to the patient, notify the patient. If you're going to do it anyways, what -- I guess you're saying why have a rule. But if we give the public some comfort, that if they're dealing with radioactive materials, if a mistake is made, they're going to know about it, at least there's a rule that they're suppose to know about it, in addition to whatever the practice in the community is. What's the matter with that?

DR. STITT: I think one of the issues is a disagreement about requiring notification and you use the -- it's your feeling that it would be comforting to the patient to have a copy of this letter. And we --

MR. MCGAFFIGAN: Not the -- I think we even waived

the copy of the letter, at least we talked about it.

DR. STITT: But, you can write it in your own words. But, there's a difference as to whether that's comforting or not comforting, depending on who you're talking to.

MR. MERRIFELD: I want to make a comment. I come from -- I'm a new commissioner. I came from the Senate Environmental Committee and one of the issues that we had with the Jurisdiction Subcommittee that I was staff director for was the Community Right To Know Act, which requires corporations that emit toxic substances to notify the community surrounding them -- notification of materials that were released to the public. There are similar reporting requirements under the Safe Drinking Water Act, and other federal laws that require notification of these materials.

The analogous situation is there were some efforts by someone in Congress some years ago of rolling that back, take away some of the reporting requirements. And the human cry, when the average member of the public found out, was exceedingly high. And while I recognize and appreciate the concern that you're raising about the fact that you already have a doctor-patient relationship, you already feel you have an obligation to provide this information to your patients, the problem is we have a requirement on the books now. And for us to repeal that and take away notification

for your patients that they currently have, in effect, somehow is denying them information that is currently available, is something, I think, although we haven't received a lot of comments on it yet, is something, at least, we certainly potentially could.

Now, I don't know whether the staff has explored with you all perhaps another option of doing this. It seems to me one of the other ways one might explore this is if you had a certification, the doctor could say I certify that I have provided this information to my patient. You say you informed your patient of this. If you're willing to certify to that and send us a letter with your certification, signing on the dotted line, that may be -- there may be no need for us to inform the patient, if you're willing to certify that you've already done it. I raise that as a suggestion. I don't know what your reaction is to that.

MR. SWANSON: In fact, if you look at the rule as proposed, one of the requirements is that as part of the reporting this to the NRC, as part of that reporting requirement, the physician must tell the NRC if they have reported this to the patient; and if not, why not, which would seem to address your issue. What becomes particularly disconcerting is the requirement that you have to provide any other written information back to the patient, as part of the patient notification. So, what happens is you have a

relatively minor event from a risk standpoint, you've explained it to the patient, the other things outside of it, you're going down your merry way in your care, and then all of a sudden they get this piece of paper, okay, that describes it on paper. And then it takes a new level of significance for them.

MR. MCGAFFIGAN: Honestly, I thought we had tried to deal with this issue of different types of notification. And Cathy could remind us, I thought we had tried to deal with it in the proposed rule and allow for there to be one method of communication with the patient and another method potentially far more bureaucratic with us, and I'm trying to search for that in the rule language.

MS. HANEY: That's correct, it's in there. I don't have the rule with me. It should be near the end of -- it should be 35.3 or 4 or 5(a)(1).

MR. MCGAFFIGAN: It says, assuming either a copy --

MS. HANEY: Right.

MR. MCGAFFIGAN: -- of the report that was submitted to the NRC or a brief description of both the event and consequences as they effect the individual. I'd assume -- when we put that flexibility in, I assumed most of you guys were going to opt for the brief description of both the event and consequences, as they may affect the

individual, in your own words and not give them -- if the reporting requirement fills everything from A through D, it's probably a pretty bureaucratic report that you send in to the rest of us. And I can see -- so, we were sensitive to this notion of trying to allow you to communicate with the patient in plain language and possibly putting the risks into context and have that separate from the report that you send to us for all these other things.

CHAIRMAN JACKSON: I think we've about exhausted this question. I think we need to move on.

DR. STITT: We have slide number five. Lou Wagner.

DR. WAGNER: This deals with the unintentional exposure to the embryo fetus and the nursing child. The ACMUI endorses the proposal to address the reporting in Part 20 rulemaking. But, in our discussions, it was quite clear that if that happens, the ACMUI feels that special consideration must be given to the pregnant patient.

I'd like to address why we feel that that's the case. In Part 20, you're dealing mostly with protection of the public, trying to prevent unnecessary exposures to the public. But, in medicine, we intentionally expose people to radiation. That's our job. That's what we do. And we may end up intentionally exposing a conceptus that we didn't know existed, okay.

We cannot, in medicine, ever separate a fetus or embryo of a woman from the woman we're treating, herself. And in medicine, we always have been involved with this risk informed type of procedure, in this situation. We always have to take into account what are the consequences of our action, not only on the health of the mother, but on that of the baby. We do it in our practice. So, it's an entirely different situation in just treating that embryo fetus as a member of the public. It's not that separate. It's not that clear. So, we strongly feel that if this is moved into Part 20, that some special consideration must be given to the pregnant patient.

We endorse the 50 milliceberts per five rem, as an appropriate reporting level, because that would have minimum impact on the patient-physician relationship and will have minimal impact on the current standard of care and the cost. We feel that the current proposal level of 500 millirem -- or that a proposal of 500 millirem gets into a lot more difficulty with regard to intrusion into the patient-physician relationship, and there's a lot more subtle issues that are involved with women who are pregnant, but can't be detected as pregnant. And those issues, which we've already addressed in the medical community and in medical care, but cannot be addressed within this kind of rule space.

We feel that the statements of consideration do emphasize this is a reporting level and not a dose limit. One of the biggest problems we run into across the field, and it's outside of your recognition, because you don't experience this, but we experience it a lot, and that is when we -- when people look at levels, they look at these levels of -- for occupational levels or other levels. And in the medical community, they translate them as to being the threshold for these levels. Or the area -- well, gee, it's really dangerous if we get above this level, whatever. Well, in medicine, we don't look at it that way. You have to look at the benefit risk issues. And so, in the statements of consideration, we need to emphasize that this is a reporting level and not a dose limit.

ACMUI does not support any regulation that requires notification. Again, we've discussed that. I guess we don't wish to venture into that issue again.

CHAIRMAN JACKSON: Okay.

MR. MERRIFELD: I have a question about this. It's just not clear to me, and it wasn't when we had our staff discussion, what is -- I understand the difficulty of determining whether a patient is pregnant or not, in cases where you don't know. But what is the right level to be concerned about where there is some knowledge that the patient is pregnant?

DR. WAGNER: You're asking for a threshold and in medicine, I can't give you that threshold, because everything we do is a benefit risk relationship. In some cases, it's higher; in some cases, it's lower. You can't define a threshold in medical care and saying that's it. You have to look at it, in terms of perspective.

These people are sick people. They are people, who need medical care. And the judgments and the rules of certain medical practice already establish protocols, by which we would manage the protection of these patients. Some of the diagnostic examinations that are given would be given on occasion to an individual, who cannot be detected at being pregnant and the dose would exceed the 500 millirem level. That would affect that kind of procedure and this kind of reporting, because it now puts a regulatory impact on that kind of procedure. And that tends to interfere with the patient care.

There could be individuals, in order to avoid the reporting, who would instead opt out for an examination that's not regulated. They could even deliver a higher dose. So, there's many facets where this can impact what we're doing when we set that level that low. So, we -- when you analyze this whole data, we did it for the risk benefit. We tried to look at the levels that would be considered to be definitely things that we want to know and we selected

the five rem level as being that based upon the risks and looking at the benefit risk, in terms of managing the patient, as a patient.

MR. MERRIFELD: Just my edification, to what extent -- you said the benefit -- to what extent does the determination regarding the fetus figure into it?

DR. WAGNER: Well, in diagnostic examinations, there are rules laid down as to what you do to try to screen out patients, who might be pregnant, for instance, okay. And so, you implement those rules, as your first line. Now, if the doses are going to be higher, in some cases, such as the iodine 131, whatever, in those situations, it actually is required that a pregnancy test be performed, okay. So, there is a discrimination that goes on.

What I'm trying to point out is that there are diagnostic examinations, which we presently do today, wherein the fetus would receive more than the 500 millirem. She might be in an early stage of pregnancy, but it's still with the standards of medical practice to go ahead with the study, in light of the fact you don't know about the pregnancy, okay. So, that's the reason this 500 millirem level really gets to be a controversial and tough level for us.

MR. MCGAFFIGAN: Could I follow up? Are you saying that what the 500 millirem level would do is drive

you in more procedures to do what you do in iodine 131, and basically by our reporting requirement, we would change the practice and a pregnancy test would probably be required among modalities?

DR. WAGNER: Yes, that could happen. And not only that, it might have another adverse effect, which might be that in some cases, in order to avoid the potential for the reporting, those particular studies, instead of being done in nuclear medicine, might be referred to an x-ray study, where the reporting isn't required, in order to avoid reporting, which we would like to not -- think not happen. But, it could require some physicians to order a different kind of examination, that might even deliver a higher dose, such as a CT examination or something of that nature.

MR. MCGAFFIGAN: CT exams typically would -- people get rems?

DR. WAGNER: Two rem.

MR. MCGAFFIGAN: Two rems?

DR. WAGNER: Two or four rem.

MR. MCGAFFIGAN: What does the fetus get, if --

DR. WAGNER: If it's an examination of the pelvis, two to four rem.

MR. MCGAFFIGAN: One of the problems that we have, as I said earlier, is the public is adverse, particularly when it comes to children, to apparently something in the

order of two rems to the thyroid, as a result of nuclear testing or -- and the National Cancer Institute says there will be 10- or 20,000 extra doses of thyroid cancers, as a result of the nuclear testing program, in getting into our milk and all that. So, you know, we deal with these -- you know, how do we --

DR. WAGNER: Well, I think the issue is, again, you have to look at this issue, in terms of whether or not you're talking about members of the public, where you're basing risks on something that -- you know, everybody knows that risks exist.

MR. MCGAFFICAN: Right.

DR. WAGNER: All those risk estimates that are made for those low doses are made upon extrapolated numbers, not on numbers that are really known or well defined, okay. Now, you're going to start applying those to patients and to fetuses. This is a different story. You can't do that. We're dealing with sick people. We're dealing with people that need medical care and we are going to intentionally expose these people to this radiation. That's our job, okay.

MR. MCGAFFICAN: Right.

DR. WAGNER: So, you can't separate the fetus from that. And medicine has recognized that for quite some time and has drawn up its rules and its guidelines, that are

based upon a risk informed decision, in terms of medical care for patients, separating out diagnostic examinations from other particular type of examinations that may deliver higher and higher doses.

MR. MCGAFFICAN: Can we just -- I'm sorry -- would you -- if one of these modalities, say, would result in three rems to the fetus, that you don't currently require a medical -- a pregnancy test before you administer, and after the fact, if I note that the fetus did get three rems, what is standard medical practice, with regard to watching that child after it's born and see whether any damage was done to whatever organ it was --

DR. WAGNER: Well, I have done, personally -- standard medical practice does not systematically follow all these patients, and it depends upon the situation. For example, if the patient was exposed prior to two weeks past conception, that falls within the realm of medical guidance. Many organizations, RCRP, for instance, the guidance is quite clear that the risks in this range, if anything happened, assuming the risk compared to the benefit, that there is no need to pursue any follow up or anything of that nature. I have personally followed them up, to find out what the heck happens. And I've looked at these records later on and done studies myself. But, it's not a matter of medical -- of standard medical practice.

Now, if the exposure occurred later and you didn't -- you did all your screening and everything is right, but it turns out, unfortunately, the patient was pregnant and at a later stage and whatever, then we have to assess the situation for the patient, look at the risks, benefits, and counsel the patient appropriately, with regard to what may have occurred, okay. That patient slips through our screening processes, etc., okay. So, that's the way we handle it medically, and it's a matter of a one-to-one basis with the patient, at the time.

Quite frequently, we'll get calls from an obstetrician, who will say, look, last month, it turned out that she was pregnant, at that time. I'll go back and look at the records and find out that based upon all the records, she could have not been more than one week past conception, at that time. That falls within the standard of practice. I informed the obstetrician, at that time, this is what occurred. There's no conceivable risks that anyone knows about this dose level, at this time. No action is recommended.

CHAIRMAN JACKSON: Okay. I think we've exhausted this one.

DR. STITT: All right. Let's go on to Ruth McBurney, who is going to discuss our view graph number six, radiation safety committee.

MS. MCBURNEY: Thank you. On this issue, the ACMUI does endorse the staff recommendations on the draft final rule, to require the radiation safety committee for licensees that have multiple types of uses under the high risk categories, those being unsealed radioactive material that require a medical directive, annual Brachytherapy, and then Subpart H, which is the teletherapy, remote after loaders, and gamma stereotactic units.

We, also, added a comment that if there were multiple units used under Subpart H, for example, if you had a teletherapy unit and remote after loading and Brachytherapy, that that also would kick in the need for a radiation safety committee. We feel that this recommendation, after seeing all the comments, is consistent with the risk-based approach that the Commission is taking toward these. These are the types of facilities that would be more likely to involve multiple areas of the licensed facilities, such as the nursing and housekeeping and so forth.

But, in setting up the -- also setting up the radiation safety committee and not putting in all the positions that would be needed on that committee, but just limiting those positions in the rule to those that must be included allows the licensee more flexibility in determining what other types of positions would be needed on that

committee. So, we feel that the rule does provide that flexibility.

DR. STITT: View graph number seven, Louis is going to talk about calibration of Brachytherapy sources.

MR. WAGNER: Okay. This one can be kept relatively short. One of the important points that the ACMUI -- we had promised that licensees can rely on manufacturers' calibrations, as long as that calibration is a current calibration. And we did not support the use of sources that lacked an appropriate calibration, and that is grandfathering those types of sources in. And I think that the intent here is that all sources have an appropriate calibration that's either traceable to NIST or traceable to a secondary standard from NIST.

We did not that there were multiple commenters in the APM, who supported verification of the manufacturer's calibrations, but the ACMUI did not feel that it is necessary to place this into rule space, although it does not inhibit any of the members to satisfy for themselves the verification on their own.

CHAIRMAN JACKSON: Okay.

DR. STITT: All right. We're going into our final topic. Dennis Swanson, who is also rotating off the committee, has been given the task of pulling this all together.

MR. SWANSON: I'm not sure about pulling it together. Actually, the committee sees a finalization of the risk informed performance-based rulemaking process, as a requirement for several additional considerations and changes that the NRC must take, in order for the rule to function as intended.

For example, with the licensing program, Cathy mentioned earlier that one of the areas where the agreement states are not in total agreement with the proposed rule deals with, for example, the agreement states want to have the licensee's procedures submitted and reviewed, which implies approval of those procedures, as part of the licensing function. The ACMUI does not endorse the practice of requiring pre-review -- NRC pre-review and approval of the licensee's procedures. The reason being is because what you basically do there is you require the licensee to submit a very specific set of procedures. The NRC reviews and approves or makes changes in those specific procedures, ties the licensees to those procedures, and what you have fundamentally done is taken a performance-based rule and now made it very descriptive again. So, it really goes against the philosophy of performance-based rulemaking.

MR. MCGAFFIGAN: Madam Chairman? So, you all support the staff in wanting to deregulate in this area, compared to past practice, but you're worried about the

agreement states continuing the past practice of reviewing procedures?

MR. SWANSON: Well, we have a concern there, yes. We definitely do support the staff in not requiring the submission of procedures and review of procedures, as part of the licensing condition. Now, it doesn't mean -- to address your concern, is when the inspectors go out, I mean, obviously, they're going to have access to people's procedures to review. So, it's just not -- what we're not doing is tying the people to a specific. It gives the flexibility to the licensee, again. It's very important.

With regard to the inspection program, I believe I said at the last ACMUI meeting, you're going to a very different approach here. You're going to a performance-based set of regulations that mandates that your inspection process also has to be performance-based, which is very different from the way inspections are done now, where you have a very prescriptive set of regulations and an inspector goes in to see if you're following or not following those regulations. Now, when an inspector has to go in and make an evaluation of the overall performance of the protocol, I think Dr. Paperiello hit it in his discussion, you go in and you find one of two things. The inspector needs to be able to judge is this still a well-performing program, even though there may be these

noise level of problems.

CHAIRMAN JACKSON: I have another appointment. Commissioner Dicus is going to take over for me. I would like to thank the two of you for your services.

MR. SWANSON: Lastly, an interesting issue, I'm not quite -- I'm not sure the committee is quite sure how to address this or the staff, but it deals with the issue of guidance documents and model procedures. I think it's important -- I think even the regulated community would welcome and needs guidance documents and model procedures. Where the problem comes in is, as we've seen in the past, you have a -- NRC publishes a guidance document or a model procedure and then that becomes a defacto regulation. This is the way -- this is our guidance document; this is our model procedures; this should be the way you should be doing this, which then turns into this must be the way you're doing this. And then all of a sudden, you take the performance-based approach and made it very prescriptive again. And that's difficult. And probably the best advice we can give is for the NRC not to even get into guidance documents or model procedures, because you want to stay out of that pitfall.

On the other side of the coin, again, on the other side, I think the regulated community probably needs some guidance and model procedures, and where are those going to

come from. So, it's a problem.

MR. MCGAFFIGAN: Madam Chairman?

MS. DICUS: Go ahead.

MR. MCGAFFICAN: The problem I see, there are probably some very sophisticated folks out that there don't need this and there's probably the smaller folks, who actually benefit -- they would just assume not have to invent procedures on their own and they'd like to go to the cookbook, although we shouldn't turn the cookbook into handcuffs.

MR. SWANSON: Yeah, exactly the point. The community is actually cheering for performance-base regulations. I think what we're going to hear, and I hear from the community already is, yeah, but they don't give me enough information, okay. So, that's the problem you're facing here, in going to this approach.

I'll just conclude by saying I think there is some -- ready to assist in all of these future dilemmas that you're going to have. It's easy for me to say it, because I'm going off the committee.

[Laughter.]

MR. MCGAFFICAN: When do you all rotate off? End of June?

MR. SWANSON: I believe in September.

MS. DICUS: Who is the -- I thought you said there

was a third person rotating off?

DR. STITT: Dr. Mel Pools, represents the research community.

MR. MCGAFFIGAN: But if you don't get off until September, you're going to get to work on this for a few more months.

DR. SWANSON: I'm going on vacation from now until September.

[Laughter.]

DR. WAGNER: May I excuse myself? I have to -- I have an appointment back home.

MS. DICUS: Okay; certainly. Thank you, very much. Commissioner Diaz, did you --

MR. DIAZ: Yes. A couple of questions. I think we all realize that, you know, this is not the end of the process; that, you know, just started really trying to use risk information in this area, in a better and more efficient matter. The first question is: these rules are, in itself, I want to call them batch processes. You know, you start them, you go, and then you got to stop sometime. Does the committee feels that at the present time, with this batch set, that the Part 35 is sufficiently risk informed to serve this nation for the next five years? Is that --

DR. STITT: Well, certainly, in my practice side, I've been living with the current standard for 20 years and

I like it a lot what we've been coming up with. I think it's very exciting.

MR. DIAZ: Okay. So, you think that it will happen in a certain lifetime. It won't decay very quickly.

MR. SWANSON: Which is, in fact, one of the advantages, I think, of going to a more performance-based set of regulations, in that you start getting very specific in the regulations. Then, as new technologies evolve, you're always butting up against your regulations. And if you can come up with a performance-based regulations, it really allows again more flexibility at the licensee's level, to start introducing and taking a look at these new types of things or new approaches or better ways to do things.

MW. MCBURNEY: I'd like to add that as the representative of the state regulatory agency on this committee, that we've been looking forward to this rule coming out, so that we can institute similar regulations in our state.

MR. DIAZ: Good. That's a very satisfactory answer. And then, a very simple question after that -- brace yourself.

MS. MCBURNEY: Brace yourself?

[Laughter.]

MR. DIAZ: Having gone through the process, and

I'd like your answer very much, and I think this is a good effort that it gets us someplace in a certain life time, in all of these areas that we look at, is there a particular area that needs additional research or really, you know, a deeper look, so that it can become more risk informed and serve this nation better, for the next batch, when -- you know, the next five years or six years, is there any particular area that you believe that requires a deeper look for the next go round?

[Pause.]

DR. STITT: I think right now we're all sitting here thinking in our own little worlds that we work most deeply in. My response to that would be it depends on how we find that this actually works. But, my impression is it's going to be more further than what we've been with before.

MS. MCBURNEY: I think some of the emerging technologies are going to be real challenging to how we address the radiation safety aspects of those, such as the intervascular Brachytherapy.

MR. DIAZ: Will the committee take note for maybe not in the next few months that you're going to be so busy dealing with this, but, you know, in the future, this is a particular area that I think looks -- a further look, as you go beyond. Thank you.

MS. DICUS: Commissioner McGaffigan?

[No response.]

MS. DICUS: Commissioner Merrifeld?

MR. MERRIFELD: I don't have any questions, but I have some comments I'd like to make. Is this the right time?

MS. DICUS: This is your last chance.

[Laughter.]

MR. MERRIFELD: This is my last shot; okay, today, at least.

I guess a couple of things I'd like to say. You know, I'm not a doctor and I'm not a physicist, but I'm a lawyer, which is a profession. And I know the difficulties that lawyers have when we sit around and try to self-regulate ourselves and decide how many hours of continuing legal education that we want and how much we want to require of ourselves. And it's always a difficult issue. And as we work through Part 35, it reminds me of that. We, as a commission, are doing things that have a significant impact on doctors and how they interreact with their patients. And we want need to be sensitive. Obviously, you have great concerns for your patients and we have obligations of the law that we're supposed to do, as well.

I guess, as it relates to the person notification area, I know that the community felt very strongly that this

is not an areas you feel needs involvement by us. But, it is an area, in which we have been involved with. As was related by Catherine, 99 percent of the comments received was from medical professionals, not from the public. And it troubles me a bit, that we don't have a better understanding about where the patients really are on this. And I think that's something we're going to need to continue to work through. Because, it's easy for us to look at all the comments on our plate. But, ultimately, from our standpoint as the NRC, we've got to be concerned about the health and safety of the public, and that's something we need to continue to wrestle with.

A final comment I would make is -- and the Chairman alluded to it, no, I've been very concerned that we provide our staff with additional time to make sure that we wrestle through all of what were some excellent comments, and making sure that we come up with a rule that makes sense. And though we have nothing to share today, I think there is -- we are grappling with timing issues and making sure we deal with those comments appropriately. And I just want to put on the record that -- I felt that was very important for us to do.

MS. DICUS: Thank you, very much. Well, I'd like to thank the staff, of course, and then very much thank each of the members of the advisory committee on medical uses of

isotope for our briefing today. I know it will take -- it takes time for you to come in. It takes time to review the large number of papers that you have to review. And it's truly appreciated that you're willing to give this time to us, because it's very helpful, as we go forward. And particularly, we would like to thank the three members, who are rotating off the committee for their service.

As Commission Mayfield and the Chairman indicated, the Commission is currently considering the time line in process for the development of the rule, and I suspect that we should have a decision on that very shortly.

The Commission members always give serious consideration to the views expressed here today and providing guidance to the staff, in resolving these very key issues that remain to the revision of 10 CFR Part 35.

If there's nothing more from fellow commissioners, then this meeting is adjourned.

[Whereupon, at 3:56 p.m., the briefing was concluded.]

CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING ON PART 35 RULEMAKING
PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Thursday, March 25, 1999

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Natalie Renner

Reporter: Doug Swift

ACMUI ANNUAL COMMISSION BRIEFING

Judith Stitt, M.D., Chair
Manuel D. Cerqueira, M.D.
Dennis Swanson, M.S., BCNP
Ruth McBurney, M.S., CHP
Louis Wagner, Ph.D.

March 25, 1999

General Comments

Part 35 Revision

- Rule is risk-informed, more performance based
  - Occupational, public, and patient safety maintained
- NRC staff interactive and responsive
  - ACMUI, subcommittees
  - Regulated community
  - Public meetings

Training and Experience

Part 35 Revision

- NRC focus is on radiation safety
  - Training should be obtained in a clinical environment
- NRC recognizes training programs and speciality boards
- ACMUI endorses alternative pathway for training and experience requirements for AU, AMP, ANP, and RSO
  - Encourages uniform national standards for training and experience

Medical Event (§30.3045)

Part 35 Revision

- Proposed dose thresholds adequately capture events of concern
- Proposed dose thresholds will provide regulatory relief for low-risk events
  - Example: wrong treatment site
- Events occurring as result of patient intervention should not be reported to NRC
- ACMUI does not support any regulation requiring notification of physicians and patients as this is redundant to existing standards of care

Unintentional Exposure to Embryo/Fetus and Nursing Child (§35.3047)

Part 35 Revision

- Endorse staff proposal to address reporting in Part 20 rulemaking
  - Special consideration must be given to the pregnant patient
- Endorse 50 mSv (5 rem) as an appropriate reporting level
  - Will have minimal impact on the patient/physician relationship
  - Will have minimal impact on current standard of care and cost
- Statements of Consideration need to emphasize this is a reporting level, NOT dose limit
- ACMUI does not support any regulation requiring notification of physicians and patients as this is redundant to existing standards of care

Radiation Safety Committee (§35.24)

Part 35 Revision

- ACMUI endorses the proposed regulation to require RSC for licensees who have multiple types of uses under subparts E, F, and H
  - Consistent with risk-based approach
  - Provides the licensee flexibility in program management

Calibration of All Brachytherapy Sources (§35.432)

Part 35 Revision

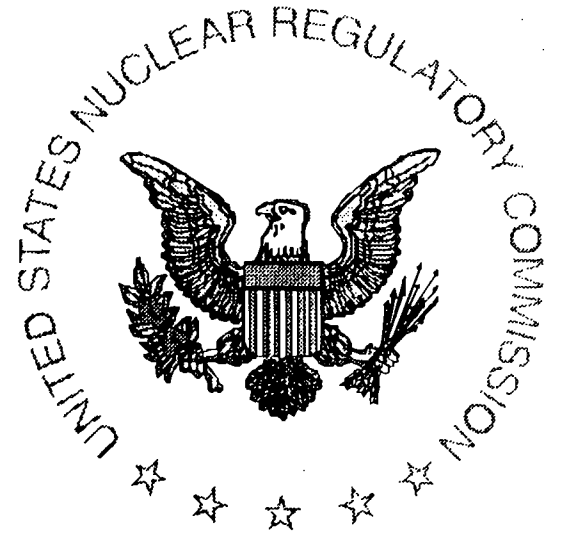
- ACMUI agrees that the licensee can rely on manufacturers' calibrations
  - AAPM and multiple commenters supported verification of manufacturers' calibrations
- ACMUI does not support using sources that lack appropriate calibrations (grandfathering)

Implementation Challenges

Part 35 Revision

- NRC's licensing program
  - NRC's review and approval of procedures
  - Training of license reviewers
- NRC's inspection program
  - Training of inspectors for performance-based inspections
- Role of guidance documents (model procedures)

Revision of 10 CFR Part 35
"Medical Use of Byproduct Material"



March 25, 1999

Carl J. Paperiello
Cathy Haney

Briefing Outline

Purpose of rulemaking

Global issues as identified by stakeholders

Staff efforts since June 1998 briefing

Key issues as identified by Commission and staff

Agreement State issues

Purpose of Rulemaking

Primary Objectives:

Risk-informed, more performance based

Focus Quality Management on requirements that are essential for patient safety

Allow for timely incorporation of new modalities

Purpose of Rulemaking

Continued

Secondary Objectives:

Codify requirements for gamma stereotactic radiosurgery units and remote afterloader units (updated requirements)

Allow inpatient visitors to receive 5 mSv (500 mrem) on case-by-case basis

Require licensee to determine brachytherapy source output or activity prior to use

Reduce recordkeeping burden

Global Issues as Highlighted by Stakeholders

Role of NRC in Regulation of Medical Use of Byproduct Material:

- Adoption of recommendations in NAS/IOM Report
- Regulation of medical use of byproduct material limited to Part 20 and T&E requirements

Risk-Informed vs. Risk-Based Rule:

- Lack of formal risk assessment
- General license for diagnostic nuclear medicine

Global Issues as Highlighted by Stakeholders

Continued

Licensing, Inspection, Enforcement Philosophy:

- Performance-based vs. Prescriptive-regulation
- Use of guidance document (model procedures)
- Submittal and review of procedures
- Use of third party accreditation programs

Actions Since June 1998 Commission Briefing

July 21, 1998	SRM issued to approve publication of proposed rule, medical policy statement, and guidance document
August 13, 1998	Proposed MPS, rule, and associated guidance published for 90-day comment period

Facilitated Public Meetings:

August	San Francisco, CA
September	Kansas City, MO
October	Rockville, MD
October	Bedford, NH

November 13, 1998	SRM issued to approve extension of public comment period to 120 days
December 16, 1998	Comment period closed

Continued Interactions with Stakeholders and Advisory Committees

February 17-18, 1999	Facilitated public meeting with specialty boards
February 23-24, 1999	ACMUI -Diagnostic Subcommittee Meeting (§§35.100, 35.200, 35.300, and 35.500 uses)
February 25-26, 1999	ACMUI Therapeutic Subcommittee Meeting (§§35.400 and 35.600 uses)
March 15-18, 1999	CRCPD SR-6 Committee Meeting
March 24-25, 1999	Full ACMUI Meeting
Ongoing	Part 35 WG & SG Public Meetings

Key Issues

Training and experience

Reporting requirements

- Medical events
- Embryo/fetus and nursing child

Radiation Safety Committee

Calibration of brachytherapy sources

Training and Experience

Proposed Rule:

- Focus on radiation safety
  - Training requirements for diagnostic users significantly reduced
  - Training requirements for therapeutic users maintained status quo
- NRC approved examination required to assess knowledge of radiation safety
- Preceptor required to affirm individual's competency

Training and Experience

Continued

Comments:

- Agree that NRC focus should be on radiation safety and not clinical proficiency
- Radiation safety training must be obtained in a clinical environment
- Variation in duration of training for authorized users in the diagnostic area
- Training duration should be maintained status quo for therapeutic users (sealed source) and for endocrinologists
- Support and opposition for the requirement for an NRC approved exam
- Training requirements should be consistent between NRC and Agreement States
- Authorized users should not automatically be allowed to be RSO

Training and Experience

Continued

Staff Proposed Response:

- Maintain focus on radiation safety

  --Diagnostic uses - increased from proposed rule

  --Therapeutic uses - status quo

- Focus NRC or Agreement State approval of training program

- Practical radiation safety training should be obtained in a clinical environment

Medical Event (§30.3045)

Proposed Rule:

- No significant changes in reporting threshold from current rule
- Added a dose threshold for wrong treatment site
- Rule text added to exclude cases of direct patient intervention
- No changes in time period for written report
- No changes in notification requirements for referring physician and patient/responsible relative

Medical Event (§35.3045)

(Continued)

Comments:

- Threshold should be raised
- Criteria for reporting wrong treatment site too restrictive
- Patient intervention should be excluded from reporting; however, proposed rule language was too vague
- Reporting period (written) should be consistent with Part 20 (30 days)
- Rule should not require notification of referring physician and patient/responsible relative

Medical Event (§35.3045)

Continued

Staff Proposed Response:

- Staff continues to evaluate reporting threshold
- Reporting of events involving patient intervention required only when the event results in unintended permanent functional damage to an organ or physiological system (as determined by a physician)
- Revise reporting period to match Part 20
- Continue to require notification of referring physician and patient/responsible relative

Unintentional Exposure to Embryo/Fetus and Nursing Child (§35.3047)

Proposed Rule:

- Report unintentional dose to embryo/fetus that exceeds 5 mSv (500 mrem) absorbed dose
- Report any dose to nursing child that exceeds 5 mSv (500 mrem) TEDE that is result of an administration of byproduct material to breast feeding individual
- Notify referring physician, pregnant individual or mother

Unintentional Exposure to Embryo/Fetus and Nursing Child (§35.3047)

Continued

Comments:

- Generally opposed to requirement
- 5 mSv (500 mrem) threshold will impact medical care
- Recognize standard of practice (reference MPS)
- Not appropriate to require notification of referring physician, patient/responsible relative

Unintentional Exposure to Embryo/Fetus and Nursing Child (§35.3047)

Continued

Staff Proposed Response:

Option 1: Staff preferred approach

- Revise Part 20 to include requirement for reporting and modify Part 35 to include a requirement for licensees to comply with the Part 20 reporting requirement
- Maintain consistency within all NRC program areas

Option 2:

- Establish 50 mSv(5 rem) threshold for reporting--clarify that requirement is not a dose limit
- Maintain consistency with notification requirements in §35.3045

Radiation Safety Committee (§35.24)

Proposed Rule:

Deleted requirement for RSC

Comments:

- Radiation protection professionals generally opposed to deletion of requirement for an RSC
- Diagnostic nuclear medicine physicians opposed to retention of requirement for RSC

Staff Proposed Response:

- Retain RSC for medical institution where material is used for more than one therapeutic type of use

Calibration of All Brachytherapy Sources (§35.432)

Proposed Rule:

- Require licensee to determine output or activity and source positioning accuracy within applicators
- Calibration measurements made by manufacturer acceptable if performed in accordance with rule

Comments:

- Support and opposition for the requirement as well as reliance on manufacturer calibration

Staff Proposed Response:

- No change to proposed rule
- Do not grandfather all sources currently in use

Agreement State Issues

Pre-review of procedures

Role of authorized user

Training and experience (AU, technologist)

Patient release

Embryo/fetus and nursing child reporting

H&S Designations

Summary

- Summarized staff's efforts since proposed rule was issued for comment
- Summarized comments provided by stakeholders on key issues
- Provided staff proposed position concerning the resolution of key issues
- Request Commission guidance on staff proposals

Backup

Training and Experience

Proposed Rule:

	Structured Educational Program		Other
	Didactic (hrs)	Practical (hrs)	
35.100, Unsealed - uptake, dilution, excretion	40	20	Physician, preceptor, exam
35.200, Unsealed - imaging and localization	80	40	Physician, preceptor, exam
35.300, Unsealed - written directive required	80	40	Physician, preceptor, exam, 5 cases
35.400, Manual brachytherapy	200	500	Physician, preceptor, exam, 1yr ACGME program, 2 yrs clinical experience
35.500, Sealed sources for diagnosis	8		Physician, Dentist, Podiatrist
35.600, Therapeutic medical devices	200	500	Physician, preceptor, exam, 1 yr ACGME program, 2 yrs clinical experience
RSO	200		Preceptor, exam, 1 yr or AU
AMP			Preceptor, exam, MS, 2 yrs
ANP	700		Preceptor, exam

Stakeholder Comments on T&E For Authorized User

Society of Nuclear Medicine	Hours not specified, exam only
American College of Nuclear Physicians	6 months/1200 hours, ACGME, no exam
American Board of Radiology	4 months, ACGME, no exam
American College of Cardiology/ American Society of Nuclear Cardiology	120 hours, exam
American Association of Clinical Endocrinology	80 hours, clinical, exam

TRAINING AND EXPERIENCE REQUIREMENTS - Alternative Pathway

	Requirements*
§ 35.290 - Training for uptake, dilution, and excretion studies *(Written Directive is not required - § 35.100)*	- 40 hours classroom and laboratory - 20 hours supervised practical
§ 35.292 - Training for imaging and localization studies *(Written Directive is not required - § 35.200)*	- 80 hours classroom and laboratory - 40 hours supervised practical - 580 hours supervised experience in a clinical environment
§ 35.390 - Training for use of unsealed byproduct material *(Written directive is required - § 35.300)*	- 80 hours classroom and laboratory - 40 hours supervised practical - 580 hours supervised experience in a clinical environment - 3 cases each use category requested
§ 35.392 - Training for use of sodium iodide I-131 for which a written directive is required	- 80 hours classroom, laboratory and supervised practical - 3 cases each use category requested
§ 35.490 - Training for use of manual brachytherapy sources (§ 35.400)	- 200 hours didactic - 500 hours practical - 3 years ACGME program
§ 35.590 - Training for use of sealed sources for diagnosis (§ 35.500)	- 8 hours classroom and laboratory
§ 35.690 - Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units (§ 35.600)	- 200 hours didactic - 500 hours practical - 3 years ACGME program
§ 35.50 - Radiation Safety Officer	- OPTION 1 - 200 hours didactic - 1 year supervised experience - OPTION 2 - Authorized user for type of use
§ 35.51 - Authorized Medical Physicist	- MS - 2 years experience
§ 35.55 - Authorized Nuclear Pharmacist	- 700 hours structured educational program

*Training must be in NRC or A/S approved program. An AU under §§ 35.290, 35.292, 35.390, 35.392, 35.490, 35.690 must be a physician. An AU under § 35.590 may be a physician, dentist, or podiatrist. An AU, AMP, and ANP must also have a preceptor statement.

Training Program and Board Approval

- Application submitted
- NRC baseline review
  - --Training Program
    - --- instructor qualification
    - --- program content
    - --- skills mastered
  - --Board
    - --- training program
    - --- required casework
    - --- preceptor statement
- ACMUI review of staff recommendation
- Approval noticed in Federal Register and listed on NRC Website

Resource Implications of Staff Proposal

Initial Review: Four Tier Approach

ABMS/AOA Board Approval - Office review		
10 Boards x 20 hrs		200 hrs
Non ABMS/AOA Board Approval -office review		
10 Boards x 20 hrs		200
Component of ACGME/AOA Approved		
Programs - office review		
10 Programs x 20 hrs		200
Non-ACGME/AOA Approved Program		
- office & onsite		
10 Programs x 100 hrs		1000
	Total	1600 hrs = 1.2 FTE
3 yr follow up		
20 Boards x 10 hrs		200
20 Training Programs x 10 hrs		200
		400 hrs = 0.3 FTE

Medical Event (§35.3045)

Proposed Rule: Either A or B

A. Dose that differs from prescribed dose by more than 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to skin

AND

- Dose or dosage differs from prescribed dose by more than 20%
- Fractioned dose differs from prescribed dose by more than 50%

B. Dose that exceeds 0.05 Sv (5 rem) EDE, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) SDE to skin

FROM

Administration of wrong radiopharmaceutical, wrong route of administration, wrong individual or human research subject, wrong treatment mode or leaking source

Part 35 requirements that impose a burden on licensee

Written Directive Not Required - Unsealed

Basis		Part 35 Requirement
Medical	35.6	Provisions for research involving human subjects
Part 30	35.12	Application for license, amendment, or renewal
Part 20	35.24	Authority and responsibilities for the radiation protection program
Parts 19/20	35.27	Supervision
Part 20	35.50	Training for Radiation Safety Officer
Medical	35.55	Training for authorized nuclear pharmacist
Part 20	**35.60**	**Possession, use, calibration, and check of instruments to measure the activity of unsealed byproduct material**
Part 20	35.61	Calibration of survey instruments
Medical	35.63	Determination of dosages of unsealed byproduct material for medical use
Medical	**35.69**	**Labeling**
Part 20	35.92	Decay-in-storage
Medical	**25.204**	**Permissible molybdenum-99 concentrations**
Medical	35.290	Training for uptake, dilution, and excretion studies
Medical	35.390	Training for imaging and localization studies

***Bold items DO NOT apply to licensees using unit dosages only**

Part 35 Requirements that Reduce Regulatory Burden

Written Directive Not Required -Unsealed

Basis		Part 35 Requirement
Part 30	35.14	Notifications
Part 20	35.26	Radiation protection program changes
Medical	35.63	Determination of dosages of unsealed byproduct material for medical use
Part 30	35.65	Authorization for calibration and reference sources
Part 20	35.75	Release of individuals containing radiopharmaceuticals or implants
Part 20	35.92	Decay-in-storage

Part 35 Sections Where Requirements Have Been Reduced

Written Directive Not Required -Unsealed

Current	Proposed	Requirement
35.13	35.13	*Amendment not required for change in areas of use
35.22	35.24	RSC deleted
35.27	35.27	Periodic reviews not required
35.50	35.60	Detailed calibration requirements deleted
35.51	35.61	Daily check of survey meter deleted
35.63	35.63	Unit dosage not required to be reassayed
35.67	35.67	Inventory sealed source semi-annual rather than quarterly
35.204	35.204	Moly breakthrough first elution rather than every elution
35.910	35.290	Training hours reduced
35.920	35.292	Training hours reduced
General recordkeeping		Recordkeeping requirements reduced

Information Required for NRC License

Unsealed Byproduct Material - Written Directive Not Required

- NRC Form 313
- RSO name and qualifications
- Description of facility and equipment
- Letter from management appointing RSO where RSO has agreed to appointment