UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

***

1998 ALL AGREEMENT STATES MEETING

The Wayfarer Inn

121 South River Road

Bedford, NH 03110

Saturday, October 31, 1998

The above-entitled meeting commenced, pursuant to notice, at 8:30 a.m.

P R O C E E D I N G S

[8:30 a.m.]

MR. CAMERON: If we could have everybody in, we have a few announcements, business-keeping things, before we get started with the presentation we have all been waiting for.

Roland has an announcement.

MR. FLETCHER: Good morning.

This is not a pleasant announcement. A former member of my staff, Charles Flynn, I was just informed yesterday, passed away.

He retired about three years ago. I think some of you know Charlie or knew Charlie and I just wanted to pass that on.

I'll put whatever information I have when I get back on E-mail, if any of you would like to give condolences to the family.

MR. CAMERON: Thank you very much, Ron.

Okay. Another business announcement or another announcement -- for those of you who are taking the shuttle from the hotel to the airport this afternoon, they would like you to be there about an hour or an hour and 15 minutes before your flight so that they can get you there in time for check-in.

I just promised Aaron I would mention a propos of our discussion yesterday about registration fees and paying the hotel and that that there are tax issues that should be considered also in this whole deal in terms of nonprofit corporations or not being a nonprofit corporation, so that is just another planning item and Roland had put

something on the agenda yesterday that was facilitator critique and I didn't know about that.

This is one of Roland's many surprises but I conscientiously tried to figure out what that meant and I had just about one minute on that before we go to Ed for his presentation.

As I said yesterday, it's always a real pleasure for me to facilitate this meeting because you are just such a great group of people to work with and I and others have been impressed by how smoothly this meeting has gone and I think that this partly reflects the progress that has been made in the agreement state program generally a propos of Dick Bangart's comments yesterday afternoon, but it also reflects the hard work that Roland and the others on the OAS Executive Committee have done and also great planning work that Diane and her staff have done on this meeting, and I would just like to publicly thank her staff for all the logistical support.

It's been terrific and also of course the NRC people who helped plan the meeting.

I do have one suggestion, and it all ties into starting the planning for the meetings as early as possible.

My suggestion is in terms of agenda we -- as you noticed yesterday, we were here till, I don't know, it seemed one o'clock in the morning --

[Laughter.]

MR. CAMERON: -- but we ran over and we might think about having fewer topics on the agenda so that we could have more time for

discussion, because I don't think that the question and answer and discussion parts of the meeting got us over time. I think it was just a question of the sheer number of presenters, but it is always tough to figure out who are you going to cut out, because all of the presentations are interesting, and ask yourself, would you really have wanted to miss the comment that NRC is not a member of the intelligence community?

[Laughter.]

MR. CAMERON: So that sort of puts things in stark relief, this issue.

I don't think John will ever live that one down.

In line with fewer topics, we might want to think about whether we want to have more sort of problem-solving sessions where we can get a lot of people involved in a discussion and this may not be a good example, but I was sort of thinking when Aaron did the Moses Cone presentation that there were a whole lot of things that may be how do you prepare to deal with these types of incidents from a whole bunch of different viewpoints.

You could do something like that, but that is just one suggestion, and going back to Roland's comment when we were talking about formally licensed sites and about it would have been useful to have had a dialogue, a problem-solving dialogue on that issue before the agreement states were hit with it, we might want to think at this meeting to make sure that we identify any future issues that might be coming up like that that we will want to address, and as I said

yesterday in response to Dick's comment, the General Counsel believes that these meetings are very important and would always be ready to offer my services, if that is helpful and not just to facilitate the meeting but if I can help in terms of meeting planning, I would be available to do that.

Yes, Roland?

MR. FLETCHER: We didn't formally make arrangements for this, but I would like for everyone, as soon as you get back, to maybe jot down some critique comments and E-mail them or fax them or whatever to me or to Stan -- it's for Stan's benefit as next year's Chair, so anything that you might want to suggest as a modification to what we did here, or, you know, as Chip said, maybe fewer topics -- and also if you know now dates that you could not attend a meeting. We usually in October -- if we know now that there are certain dates you would not be able to attend, that information would be helpful also for Richard.

MR. CAMERON: Good suggestion. Well, just a preview of the agenda. We are going to start off with Ed Bailey to talk about life cycle studies of sealed sources, an accident waiting to happen that did, and I know Ed was polishing this up till the late hours of the morning.

[Laughter.]

MR. CAMERON: So why don't we go to Ed and then we'll get into the other parts of the agenda. Ed?

MR. BAILEY: Well, I have the feeling that there is a conspiracy going on here. If you all noticed yesterday I had on a coat and tie. I was supposed to give a talk and I was going to look

professional, sort of. So what do you do? You move it to 8:15, and by the way, I am rally hacked. I could have slept in fifteen more minutes if I had known we were going to carry on --

[Laughter.]

MR. BAILEY: And my uniform for today, since I am going to get on an airplane is not a coat and tie, so I am just going to be up here talking.

Don Bunn -- I have put him down as a co-author -- so if there are any questions that I didn't know the answers to that you asked, that would be his part of the paper.

Some people said what is life cycle? They thought it was a dog food or something -- but anyway, if you haven't done any sealed source and device evaluations recently or if you have not been IMPEP'd -- and I have been real nice. I have not said anything about what I feel about sealed source and divide IMPEPting, you will be encouraged to include a working life on your write-up of the source or the device and on this page is all the guidance, and half of it is my E-mail, asking for where is, what is the guidance.

There is no ANSI standard. There is no test. It's sort of give me what you think the lifetime is and the reviewer is supposed -- should evaluate the product's estimated working lifetime to determine whether it is justified based on the information submitted.

I would like to see this go away and this little project that we had here emphasizes one of the reasons I would like for it to go away. Next slide, please.

The company that had this little accident was a company called NDC. Two years ago they moved from one building to another and in the process they came upon several Americium sources that the father of the current president had purchased some time in the '60s somewhere and they decided it's time to get rid of them. They'd been in storage for years. They were not on the license. So in the process of leak testing them, they found that they were leaking a lot of Americium, so the company went through an Americium contamination event.

At that time one of the things that we said was if you are going to be working with Americium, even if it is just gauges, only sealed source is authorized, you should have alpha survey meter, we decided, because they couldn't detect it.

The company was founded in 1966 and employs about 145 people. They manufacture gauges for on-line process, measurement and process control utilizing a variety of radioactive materials. They distribute them both specifically and generally licensed. There were 4,000 devices installed worldwide of their devices. Next slide.

So the background of the accident was they were working with Amersham to determine the actual working life of the source capsule, and Amersham had requested them to return some old sources for analysis. Now I haven't contacted Amersham to see what they were going to do. I know when I was working at Texas Nuclear we had some processes that we went through. We took some sources when they came back in in gauges we would run them through a sizing device to see if they would still slide

through. We would measure the lengths and all this kind of stuff, and we would look at them and see if they were corroded.

Usually the thing that made us not use a source was not that it was out of round or any of this other stuff. It just looked nasty and so we were saying, well, we don't know if it's going to work.

Anyway -- we'll find out what Amersham is going to do. Amersham also wanted them removed from the source holder. Now in true fashion, gauges should have the sources put in them so that it is difficult to get them out. You don't want the sources to come out easy, so NDC -- Amersham said, well, we want you to do it before you ship them to us, so they undertook to remove three sources from their holders. Next slide.

The source -- information on the source: it is 100 millicurie Americium 241. Single encapsulation, which I found interesting, but then it dawned on me, doofus, that in order to use the Americium x-ray, the low energy x-ray, you have to have a thin window, and this is essentially a back-scatter device. The window thickness, .2 to .25 millimeters -- that is not real thick. We don't know the date that the source was manufactured but the company had originally received it in 1978 so the device or the source was at least 20 years old.

It reportedly was either a glass bead or a cindered glass pellet, and for those of you who do sealed source and device evaluations, that is the ANSI rating for the source.

The source removal process was that they put a jig for holding the source-holder and they put it in a fume hood and then they

took a pipe and put it in front of it to direct this thing, then they took a hand-held butane torch, propane torch that you can use to pick up tile or whatever, and they started to heat or burn away the epoxy which was holding the source in a source-holder, and I will show you a drawing later on of this arrangement. Next slide.

The theory behind it was that -- and those quotes are actually out of their report. I didn't think up these nice words. "No mechanical means of removing the source capsule from the holder. The object was to heat the entire capsule" -- heat the entire thing -- "to first burn away the epoxy, then the out-gassing of the epoxy or the expansion of the air trapped behind the capsule will push the capsule out of the holder, the source-holder. The source-holder is placed such that if the capsule comes out at expected speed, it will be captured in the can" --

[Laughter.]

MR. BAILEY: So here, and this is eligible for one of my slides award, but this is a drawing that they sent in to show us the thing.

Here you have the alpha survey meter that they have got set up -- okay. Here is the block. Here is the source-holder.

This is that piece of pipe I mentioned to you. That is the can to catch it, and inside that can, this part is styrofoam, okay? It's a great design. Okay, go ahead.

It was done inside a hood. Now as you will see later in one of the things that we need to check on, we don't believe this hood had

any filtration at all. It was just a hood. It was to vent stuff out. Next slide.

The sequence of events -- January 21st they successfully removed two source capsules. The next day they were doing the third one and as reported in the report there was a loud bang -- and according to the man who was doing it, who was the RSO for the company, heat was immediately removed.

The alpha survey meter did not indicate any reading during this thing but the guy from the previous thing, they'd gotten smarter. He took the alpha survey meter and brought it nearer the source or the area and found out, yes, we have got contamination and, as it says there, the alpha meter registered a high reading.

He did a second thing. In order to locate the source capsule itself, because it had flown off and around, he got the gamma meter so that he could locate it in the presence of the alpha contamination. I mean this guy is not a dummy and he found the source. He closed off the room. He was doing it in the fume hood and he had -- on that hood -- and he apparently only had like six inches. He'd pulled down the thing so that his clothing and stuff was about all that got contaminated. Next one.

Then they did a survey for contamination, continued it. They shut off the hood blower. They covered up the hood. They called the consultant that they had used before and then they went to the roof and sealed off the vent with plastic and measured on the roof for the alpha contamination and plastic over it to keep it in place.

They notified us the following day and we sent an inspector to the site and a few days later the consultant was able to work it into his schedule to start doing the work.

Actually, in two weeks we issued our notice of violation, which was not bad, I didn't think, or actually it was three weeks. We had an enforcement conference with them and we do not have what I would call administrative penalties. I cannot say you messed, you've got to pay us $40,000 or whatever. We have to go to court, as several states do, to actually get a monetary penalty but that doesn't mean that we can't meet with them and get them to agree to pay a penalty.

So we met with them and it went back and forth between the lawyers, and really it happened pretty quickly considering it was a legal document, and we finally on May 12th got the signed stipulated agreement back from them with two checks, which I will show you later. Go on to the contaminated areas.

This was just a single sealed source. The fume hood and equipment was contaminated. The worker and his clothing were contaminated. The source loading room, which is the room where the fume hood was located, the whole assembly of the piping for the vent was contaminated. The roof of the building was contaminated as was the parking lot. Okay, next.

This is the actual source holder. This is the catch-can. Those are bagged up. Okay.

Here are the people surveying. Go ahead. Next, please.

And here is the area on the roof that was contaminated and marked off, cleaned up.

And here is one of the things that we're a little confused on. I had this data in my file on what the urinalysis showed for this person. Now remember this was supposedly a glass or cindered source matrix, and yet we do see uptake and we do see excretion through the urine.

We need to go back now and relook at this data. In fact, this was the data I had obviously when I prepared the slide and I talked to Don and I said Don, did we ever get a final report? Well, we got the final report. I got it after I got up here, and the estimate now is CEDE .137 rem and the CEDE bone is 2.3 rem for this individual, but I think we are going to have to go back and look at the form and some other stuff to see if these are really good numbers. Next slide.

Cost of the cleanup -- everybody is looking for actual data on how much it costs to clean up. The health physicists and cleanup crew was at least $50,000. The waste disposal was $12,000. We don't have a figure for the equipment replacement nor for the lost time in production that resulted, but still it was, for a small little silly accident, to me that was large dollars. Next.

I thought you all might be interested in the terms of the agreement. What they agreed to was to pay us $1500 for our time spent on the project. They agreed to an outside audit at six months and one year. They paid a $10,000 penalty and they are on probation for 12 months, and the probation basically says if they do anything bad,

violate any regulations, their license will be terminated without a hearing, so we feel that it was an effective way to deal with this situation.

When they sent back the signed agreement they had two checks, one for $1500 and a second check for $10,000, and we took them to the bank and cashed them and they were good.

[Laughter.]

MR. BAILEY: Okay -- next?

Unresolved issues. We don't know the source failure mechanism. I don't know if the source broke at the weld and leaked. I don't know if the thin window was punctured. I just don't know. The source is still at the location. Amersham is supposedly going to be sending a shipping container to get the source, to get it evaluated, but it may be one that we need to send to Oak Ridge or someplace to get some independent evaluation of why it failed.

I still question the value of the working life on these sealed source device evaluations, because they don't mean anything. There's not a standardized test.

Having worked for a company that made gauges and so forth, you replace gauges because of the electronics. Very rarely was a source the reason why you replaced a gauge.

I think we need to look at the appropriateness of using epoxy to hold sources in place. If this had been mounted on a -- and this was used in a gauge that does some paperwork -- if there had been a

fire in a paper manufacturing place, would we have seen the same reaction? would the source have shot out there? I don't know.

The gauge -- and then we did the evaluation -- is, you know, rated and said it can be used in these conditions. It was not likely to fail under the accident conditions and so forth, but I think we are really going to have to look at that.

Another issue is the actual dose to this individual and we are going to have to look at that again.

The last one I have on here is the solubility of Americium when it is glass or ceramic matrix.

The third thing, sort of an issue we learned, was when we went to get this incident file, we didn't have a complete incident file. There were still unresolved issues, so one of the things hopefully we will do out of this is get some review mechanism so that all incidents are reviewed at the end and signed off, yes, we have got all the information we need to do this.

I think that is the last slide -- yes. Any questions, comments?

[No response.]

MR. BAILEY: Thank you very much.

[Applause.]

MR. CAMERON: Okay. Thank you.

We are going to move into the next presentation and we will be out by Noon. I just wanted to assure everybody of that, because you do have travel plans.

Before we get into the Part 35 final rule, Cathy Haney from the NRC is going to give us the status of consolidated guidance, and a propos of Halloween I am glad to see that the witches are here, so -- sort of a term of endearment that we have developed -- so Diane and Cathy.

But Cathy, are you ready for -- to start off on the guidance?

All right.

MS. HANEY: Copies of these viewgraphs are being handed out hopefully, and I'm going to go through them real quickly, because -- just to keep us -- to have more time for Part 35. But if you need more detail, please feel free to ask me for it.

Basically I'm here today with my section leader hat on, at least for this 15 minutes, and then I'll turn to the chair of the Part 35 working group. But I want to talk about the license guidance consolidation project. This was a three-year project that we were looking at. It came about, oh, out of our efforts in the business process reengineering program when we were looking at the licensing materials licensing. And one of the things that came out is that the guidance for licensing and byproduct material area was in numerous documents. It was not always available electronically. Some of it was outdated. And that we needed to do a little bit of consolidation with it.

So we came up with this project, and our goal is to develop approximately 22 NUREG documents, and they -- the first part of the

first, oh, couple documents deal specifically with a specific modality. Then as you get into some of the latter documents you're dealing more with some generic issues like Part 20, which is just a document that would be geared strictly to Part 20 compliance. Each NUREG is going to contain the information that you see on the slide on the viewgraph. It would tell the licensee what they need to send in to apply for the license. They would give some sample procedures that the licensee could use, and they give a checklist, sample license, and they even go so far as to give an inspection and an audit checklist.

The process that we've been using for this project has involved the use of self-managed teams. On these teams typically they have headquarters staff from our office, from Nuclear Material Safety and Safeguards. They also have representatives from our regional offices. When we are identifying people for these teams we look for the different individuals that have a specialty in the particular area that we will be preparing the document for. Some of the teams also have representatives from the agreement States, and in that case we work with OAS to identify the appropriate individuals to participate on these teams.

The team comes to Washington, develops an outline, then goes back to their offices, work for a couple weeks on developing the document, and then they come back to headquarters and we prepare a draft document. The draft document is then first reviewed by a pink team. The pink teams focus more as on the regulations: Does the document capture and describe the regulations properly?

Typically you're seeing middle managers on this, and in some cases we have used senior technical staff that are very experienced in this area to review at the pink-team level. The document typically undergoes a change and then after that we have a read team review, which is your upper-level managers, typically Don Cool is on these teams. We do have our Office of General Counsel is involved and this review is focused more on policy as compared to just focusing in more on, you know, are the regulations properly cited.

We have had organization of agreement State participation in these docs. It started back in August of 1997 when we described the program and gave a little bit about the number of resources that we would be looking for. Also during the monthly status report -- we give monthly status reports on the NRC-OAS conference call. And at that time we usually say what teams we're starting up, whether we'll need agreement-State participation on these teams, and, you know, where we are with specific documents if we have State people working on them at that time.

We also, you know, either at that time or, you know, if something comes up, you know, when it's not appropriate, the timing's not right to do the OAS conference call, we also would ask for participation just going directly through the Office of State Programs to OAS.

And then the last couple slides that you have there are where we stand on all the documents, and again for the sake of time I'm not going to go through all of them. It shows you which documents are

published in final. There are three of them that are in final. Then documents that have been issued in draft. The key there, that note is the volume 4 says September. It's actually going to be an October date. So it's a little bit different than what you have in your handouts. And then we have the soon to be published in final documents, and there are approximately I think six that we have not started working on yet at all.

And with that I'll just take any questions that you have.

MR. DUNDULIS: Cathy, a question. Are the documents or will the documents be available electronically? The reason I ask is a lot of States, you know, don't use the same codification system as NRC, and if they could, you know, if we want to put them in our procedures manual, you know, instead of 10 CFR 20-point-whatever, if we could have them electronically, then we could edit our own appropriate, you know, equivalent regulation. It's probably would be something that would perhaps ensure that they might be used.

MS. HANEY: Yes, they are available on the NRC web site, and we put them out there when they are issued in draft, and then when they're issued in final. It's just those two spots. But we also, you know, have other versions available that, you know, if you would need to, we can talk, you know, about making it easier for you to incorporate your regs. But they are up on the web site now.

MR. CAMERON: Okay. Good. Are there other -- Kirk?

MR. WHATLEY: Cathy, how are comments handled by groups that are writing NUREG documents? Are the comments basically determined to

be appropriate or inappropriate by the group that's only by the group that's writing the document, or how is that handled?

MS. HANEY: Okay. What happens is we have received comments on some of the documents. When we receive the comments, the team reviews them first and attempts to resolve them, and they'll either incorporate the comment into the document or they won't, but then when you hit the pink-team and red-team review, there's a managerial review of how the comments are handled. So it's -- you've almost -- you've got a second and a third-tier review of the comments to make sure that the working team -- the writing team incorporated them appropriately.

MR. CAMERON: Okay, does that answer your question, Kirk?

Anybody else? Steve.

MR. COLLINS: Steve Collins from Illinois. Would you identify which one of the working groups you've actually got agreement-State participation on and which ones not?

MS. HANEY: I was afraid you were going to ask me that. I can't. I will be happy to, you know, follow up with it, but I didn't have that documentation with me when I left Washington yesterday, so I apologize.

MR. COLLINS: Is it accurate to say that on most of the working groups you have had that agreement-State participation, or not?

MS. HANEY: I think it's -- no, I don't think that's accurate. I think their agreement-State participation has been probably less than 50 percent.

MR. COLLINS: We asked for, begged for, and demanded early and substantive participation rights. We got it, and we're not using it.

MR. CAMERON: Okay. That's a good point for people to think about.

Anybody else on consolidated guidance?

Okay. We're going to move into Part 35 now, and Ray Karras had a suggestion for us that if we do have a few minutes before 12 left that we might want to discuss the dates for the next meeting, since everybody is here. So be thinking about that.

There is a separate agenda for this part of the meeting, and I hope everybody has a copy of that, and we are going to deviate a little bit from our standard practice over the last couple days. After each discussion topic after all of you are done discussing it, we're going to see if there's any comments from the public. We do have several representatives from the medical community with us who might want to comment on some of these issues.

Cathy will go into a little bit of the history of this, but there have been three public meetings on -- workshops on the proposed rule and to just give you a brief overview of some of the agenda and issues from these meetings, we have spent time discussing the whole issue of risk at these meetings. In other words, is the proposed rule risk-informed, what does risk-informed mean in the context of patient treatment. Has risk been incorporated appropriately into the rule? Do

we need something more? And what is that something if there is a need for that.

The whole issue of risk was related to professional standards in the medical community. Those of you who have looked at the draft medical policy statement can see that there is a provision in there about the NRC considering what's called I think industry consensus standards in regulating, and there is a Federal statute that requires all Federal agencies to consider these voluntary consensus standards in setting up their framework.

And consideration of industry standards can take two forms. One is, as Cathy and the working group have done, they have incorporated some industry standards, standards of practice, into the regulation or into the licensing guidance. But there's also another element to this, which is deferral to industry standards, and that's where you go back to the risk issue. In other words, if you look at an area and it's low risk and in addition there are standards of practice in the medical community for that particular area of making sure you have the right patient, things like this, then that may dictate the NRC not regulating in this particular area.

Then there's the whole cost issue. Are the costs of compliance, the costs on the regulators, the cost on the industry is -- how does that fit into the risk equation?

And then there's also the individual issues, which I think are flagged on your agenda, training and experience, reportable events,

things like that, and most importantly perhaps for this group the compatibility issue.

So Cathy is going to begin with sort of a history of the rules, the regulatory philosophy. We will go to you for questions after that, but I think we should keep questions on that to clarifying questions.

Yes, Joe?

MR. KLINGER: Yes, Chip. You're referring to an agenda and some items and we don't seem to have that over here.

MR. CAMERON: Okay. I thought -- I'm sorry, I thought that was passed out. Okay. They are out on the desk. Diane Flack is going to go and bring some in. And this is just another Halloween trick of the staff. I found out about the agenda late last night.

MS. HANEY: It wasn't that late. It wasn't midnight yet.

MR. CAMERON: But, Diane, I think that the people on that side are the ones who need it.

MS. HANEY: The other thing is the agenda does not allow an open time for comments on other areas other than these cross-cutting issues, and there was no ulterior motive by doing it that way, it was just a matter of after I got the agenda done and started on the trip, I realized, you know, I'd forgot a time slot for general discussion. So it wasn't done on purpose.

MR. CAMERON: We know that the staff on this rule is not disingenuous. We appreciate that. But there may be someone who offers comments on that. But, Cathy, why don't you go ahead, and then when

you're done with the first segment, if it's okay with you, we'll see if anybody has any clarifying questions about the rule itself, and then we'll keep moving on.

MS. HANEY: Sure. Okay.

What I want to do is just take maybe about five or ten minutes and go through some of the background to the rulemaking and what got us where we are today. Back last year, in March of last year, the Commission issued direction in a staff requirements memorandum, the SRM that you see up on the screen, to go forth with the rulemaking to revise part 35 into a more risk-informed, more performance-based regulation.

There were a couple of specific things that they directed us to do, and that was really to focus on procedures that pose the highest risk, to look at alternative ways for regulating in the diagnostic area. They talked to us about capturing relative safety issues and precursors, and for those of you that were at the workshop last year, we spent a lot of time talking about precursors, and if you've gotten a chance to look at the new rule or the proposed rule you'll see that we did not include precursors. And I'll give you a little bit more background on that when we get to the section on reportable events.

They also gave us the option of changing "misadministration," the term "misadministration," to "medical event." The term "misadministration" in the past has had some negative connotation, and we've heard that from the different stakeholders with this rulemaking, and we felt that if we changed the term, that might make things a little bit better. It does not have to be medical event,

and again over the year if you thought of a good term, we can still change it.

They also asked us to redesign Part 35 to allow for timely incorporation of new modalities. The reason for this, the best example I can give in this case is several years ago when high dose rate remote afterloaders came into use, there was no real section in Part 35 that we could tag them to -- or I shouldn't say no real -- there was not an easy section that we could go to for licensing. The closest thing we had was teletherapy. And what happened was is we started issuing the first licenses with reference to the teletherapy sections, but we would say do A and B but don't do C and D. And it's a confusing way of regulating. So we wanted to set up the rule that would hopefully allow for us to incorporate these new modalities a little bit easier. And we'll spend a few minutes on that I a few minutes.

Also they asked that we revise the quality management program to focus on radiation safety. In this area they did say we could use a mix of prescriptive and performance-based regulation. And some of the things they noted was that we should include was making sure the patient's identity was verified and making sure that the patient -- correct patient got the correct dose.

The last thing is, as Chip made reference to earlier, is that we could us available industry guidance and standards when possible. Basically what we did is we looked at what was the industry standards that were available, guidance documents. We went through

them, picked out what we thought was very key, and if these particular standards we thought were key, we incorporated them into the rulemaking.

Next slide.

Our approach. And it was fun, the early days. The first thing that we did was we identified what we refer to as cross-cutting issues, and these were issues that pertain whether you were using radioactive material in a diagnostic setting or in a therapy use. Some of these cross-cutting issues were something like the requirement for a radiation safety committee, your training and experience requirements, the thresholds for reportable events, requirements like that that we needed to look at for do we still need them in diagnostic, do we still need them in therapy, can we make any differentiation between these particular requirements.

We also were looking at what we refer to as a change in our licensing philosophy. I'm sure most everyone in the room is familiar with the current licensing approach, that being when a licensee submits a request for a licensing action to us, they also submit their procedures. NRC would review those procedures and then issue the license, and the licensee would be tied to these procedures in most cases.

Under the approach that we're looking at right now, the licensee would no longer submit procedures to NRC at the time of license application. All that they would do is commit to us that they will develop procedures that would put them in compliance with Part 35. So in other words there's no prereview by NRC in this approach.

This has brought up the issue of -- well, Cathy, aren't you just shifting the burden from licensing to the enforcement, because when the inspectors go out, they will have to spend the time reviewing the procedure. And we believe that we are not shifting the burden to enforcement in this case because we are still going to continue to do performance-based inspection, and our inspectors will not be looking into the procedures -- the majority of the procedures unless for some reason they have cause to, they see noncompliances at the facility doing followup in response to a medical event and feel that further review is necessary.

And with that in mind, we have developed a guidance document. It's one of the NUREG documents that I just spoke about a few minutes ago. It's volume 9. We do have extra copies of the document outside the room, so feel free to take them so we don't have to carry them back, and take two or three if you'd like. And this particular document provides the guidance for someone that is interested in applying for a license. It also provides any needed information that a license reviewer would be using. So in other words an applicant on the outside is going to be using the same criteria that someone from NRC will be using. There will be no hidden documents, standard review plans, things like that, that have not been reviewed by the public.

There are model procedures, and these are procedures that are that, they are simply models. We will not be evaluating a licensee's, you know, going out and saying well, your procedure is inadequate because it doesn't do exactly as the model procedure in NUREG

volume 9 says. If there were key things that we thought important to radiation safety that were appearing in these model procedures, we took them from the procedure -- well, we left them in the procedure, but we also put a corresponding requirement in the rule.

Our goal was not to have any hidden requirements. Now since it's gone out for comments, people have told us well, you know, you put this is a should or this -- you know, you put this as a shall, but yet there's no corresponding regulatory requirement. So what I'm going to admit now is we didn't do a perfect job on the NUREG, an that's one of the things that we're looking to the public to help us with to identify any of these hidden requirements that they see in the NUREG but there's not a corresponding tie in the regulation.

And then the last thing from an approach standpoint was we relied on the requirements in other parts of 10 CFR. For example, if there was a requirement in the current Part 35 that also appears in Part 20, we took it out of 35 and let Part 20 be the overriding requirement.

Next slide, please.

And some of the examples that we took out of Part 35 were the requirements for an ALARA program, and as you can just read down the list. The only thing with the second bullet is there is one small requirement in Part 35 for surveys, and that has to do if you're using material, unsealed material for a written directive.

The thing here that's important, as I've been talking to people, is to say even though the requirement no longer exists in 35, it does not mean that you don't need to be concerned with this. The

biggest one is the ALARA requirement. I've had people come to me, mostly the physicists, saying how could you delete ALARA? It's so important. And I said I haven't deleted it. You've got Part 20 that says develop an ALARA program. You don't need a corresponding prescriptive program in Part 35.

Next slide.

Just from a standpoint of, you know, how did we do this, we used a working group steering group approach. I am chair of the working group. Don Cool is chair of the steering group. When we set up these groups, we tried to get representatives from all the appropriate offices at NRC. We have a representative from the Office of General Counsel, from the Office of Enforcement, we have a regional licensing person, an inspector. We also asked for participation from the States, and it's been wonderful. We have two State representatives on the working group. One is Dave Walter from Alabama. It's been very nice because he's been chair of the SR6 committee. And so we've been able to discuss mutual concerns. The other thing is -- person we have is Marcia Howard from Ohio has been on the group, and they've provided wonderful support to us. And I know it's taken up a lot of their time from their other duties, but I have appreciated it.

On the steering group, Tom Hill has represented the States, and again has just been wonderful to work with. And what we've done in the working group would basically come up, develop as much of the rulemaking as we could. If we hit a point where we needed a policy call, we'd call the steering group together and say help, and we'd get

some advice from them, and then we'd go forward and implement what they asked us to do.

All meetings of the working group and steering group have been public meetings, and we have had public attendance at these meetings.

It's been a small enough group that typically we've allowed time for interaction, and again, that's been very beneficial to the rulemaking process.

Last year we held three meetings. I think when we spoke last year we had just finished the Philadelphia and Chicago meeting. At those two meetings we were discussing rule alternatives where we had some ways of addressing these cross-cutting issues and going from there what are your recommendations on which approach to go to. So far this year we've had, as Chip said, we've had a couple of facilitated public meetings already. There are three of them we've already conducted. This is the last one, so maybe the last time I do this presentation. But again we've received a lot of comments on the rulemaking. The big concerns are, as Chip said, are risk assessment, the comment period, radiation safety committee deletion.

And then we did place a strawman rule on the Internet. We have had a lot of public participation. All the comments that we received on the strawman prior to March 1 were taken into account in developing the proposed rule. Any comments received after March 1 we'll take into account on developing the final rule.

Next slide.

How is Part 35 set up? Just real quickly here, we still use an appendix approach to the regulation. The big changes have been that there are separate sections for records and a separate section for report. There is a specific question in the Federal Register asking, soliciting comment on whether you like this approach or not. We patterned it after Part 35. We did retain subpart J, which is your training and experience requirements. The reason we retained it was because we're proposing a new approach to the training and experience requirements, but until that one gets fully implemented, we need a fallback, and that's why J is there.

And K is the emerging technology section that I just spoke about.

Next slide.

Proposed implementation schedule. We're proposing six months from the date it's published in the Federal Register for it to become final, and then we have allowed an additional two years for the training and experience requirements. When we get into the T&E then I'll give you more in-depth information on why that two years is appropriate.

I will say at this point the Commission has been requested to extend the comment period on the rule beyond the November 12 date, and we will be going back up to the Commission and asking for direction on whether we extend that comment period date or not.

MR. CAMERON: Thanks, Cathy. Let's take some clarifying questions and since this looks like it is the only portion where we

might be able to talk about general approach and other general issues, we can get into that, too.

Questions, comments, clarifying questions, comments on approach from anybody around the table? Kirk?

MR. WHATLEY: I guess we wouldn't be an agreement state, maybe, if I didn't say something about this. I guess we've come at it every year since 1983 or so, when the NRC, in the Federal Register, proposed a general license for nuclear medicine, both diagnostic and therapeutic, if you remember that.

That's literally what he wants, with absolutely no review of physician qualifications, no review of procedures or anything, and the justification for that at that time was that the inspectors would review the procedures. It's just reincarnated itself here all together.

It didn't accomplish what it -- NRC did not accomplish at that time -- when I say NRC, I really don't know who I'm talking about and I don't include everyone from NRC in that. Someone from NRC did not get what they wanted to accomplish and I think it was literally to get out of regulation of nuclear medicine, both diagnostic and therapeutic, and I think this is another step towards that.

The justification then was that the inspectors wouldn't have to review procedures or anything at that time and that's what I'm hearing again here today.

There was a little rumble by a few agreement states at that time that were in opposition to that, but it received very little attention from the review group. The reason I asked the question I did

earlier, comments were submitted, never responded to, never knew whether NRC got the comments or whatever, and it certainly had very little impact, and that attention was not gotten by NRC until Region 2 and Region 3 of NRC opposed this proposal back around 1983.

I don't remember the exact dates. In fact, the medical licensing staff of NRC took leave, Pat Black and Joe DelMedico, specifically, took leave to go before the Nuclear Regulatory Commission in opposition to what was proposed then, which is virtually -- there are a lot of similarities today.

It got the attention then and I remember, I believe it was Commissioner Asseltine at that time, commenting, some public record, that -- Bill Spell and myself went representing the agreement states at that hearing, and Commissioner Asseltine chastised the review group, at that time, for not presenting the entire picture to the Commission of what was going on; only their views.

As a result of that, the Part 35 revisions were changed, procedures were put -- review of procedures was put back in, review of physician qualifications and so on were reinstated.

I think if this group would go back and look at the comments that were submitted to that proposal in 1983-84 time-frame, that those comments are still appropriate today. They haven't changed. The reason that Part 35 was proposed to be changed in '83 or when it was eventually changed in '86 was that nuclear medicine had become such a common practice that anybody could do it.

That was in the Federal Register by NRC and I think a lot of us would disagree with that and I think there are -- I think it's a double standard here. There are other industries out there that you could apply the same things to, but will never do it because it's not medicine, and I just think we have double standards.

I think this is something that deals with patients, deals with people, and we are trying to get out of the business. I just have a whole lot of problems with it, I still do.

MR. CAMERON: Thanks for that fundamental piece of history, Kirk. I guess that Cathy and perhaps Don should address whether the issue of the NRC is getting out of the business again. I'm glad you carved that last statement, that you disagree with getting out of the business, right, Kirk? Just to summarize what you said, the business being regulating the practice of nuclear medicine.

MR. WHATLEY: I think we're all obligated to make sure that before we issue a license, if someone is capable of handling radioactive material in a safe manner, I do not think that these -- the way it's being proposed now will ensure that.

I guess my bottom line is if NRC -- the whole issue to me is compatibility. If you want to do it that way, you do it that way, but don't tell me we've got to do it that way.

I mean, if you say it's a low compatibility issue, I'll be quiet. I guess that's the bottom line. Let us do it the way we feel is appropriate and is needed.

MR. CAMERON: Okay. Thanks, Kirk. Let's go to Cathy and then see if there are any other comments around the table on Kirk's comment. Cathy?

MS. HANEY: A couple of things. One is that I believe the rule does give you the flexibility of doing things the way you want to. If you want to continue to review procedures prior to issuing the license, you do have that flexibility, the way the rule is set up. So that addresses one of your concerns.

We do want to make sure that individuals using the material are qualified before we issue the license; hence, the retention of the training and experience requirements. We have changed the focus on the training and experience to radiation safety rather than clinical proficiency and with that, hence, the significant reduction in the diagnostic area.

At the time of licensing, we would still be looking to make sure that either the individual has had the proper number of training hours or else they're certified by an organization that NRC has approved and under part of this certification, we would be looking to make sure that prior to sitting for this certification of board, whatever, that they had to have taken the required numbers of hours in training in radiation safety.

So I believe that we are still living up to the checking to make sure someone is competent before they handle the material.

As far as the emphasis to not review procedures up front, this is really the guidance that we have been getting from the current

Commission, to more performance-based, when we can; to rely more on the industry standards.

To a certain extent, the medical community is not the same as it was in 1980 or 1970. There are a lot more industry standards available now that they can rely on. They don't necessarily need to rely on NRC regulations.

So I guess what I'm saying there is we really have -- this is being done at Commission direction to go this approach, which is a little bit different than where we were in 1983.

Don, do you want to add anything?

MR. COOL: The issue of a performance-based regulation is something that I think maybe requires a lot of discussion and, Chip, I don't know that we have nearly the amount of time to talk about the philosophy that goes behind a performance-based regulation.

The Commission has been looking at this, as Cathy said, in a variety of forums and it boils down essentially to saying that there are a number of things out there that are important and the Commission would prefer, where it can, to state the requirement in terms of the intended objective; doses are within the Part 20 criteria; people are qualified; events are responded to.

Now, those are big picture items and there are all sorts of variations within that. And having written the requirement that way, allow the licensee the flexibility to craft their procedures and approach in a way that makes sense with them, with the particular environment in which they are in.

For some of the institutions, they have got a variety of other people also running around looking over their shoulders. You've got JCAHO. You may have various boards and other groups who are doing accreditations. You may have audits. Several of the professional societies, we have been told, now actually have auditors coming in and doing various accreditations on the institutions.

The approach that the Commission has been looking at is to say if those systems are in place, and that's the reason that the rule is written, you see, develop, maintain and implement procedures, and you're quite right, we wouldn't necessarily look at them ahead of time and that makes a number of people very uncomfortable.

We don't have that certitude, because we've looked over their shoulder and we've sort of dug around in the middle of it, and we're, in fact, then carrying some of the luggage for them because if we happen to miss something, and that has certainly happened, then we have, either implicitly or explicitly, some of the blame for missing a point.

Let them proceed in the inspection process. That doesn't mean that the inspector goes out and then sits at the desk in some licensee's corner of the room and spends all day looking over the procedures and said I don't like this, I don't like this one, I don't like this one, three violations.

That's not what is intended. What's intended is the rule says for you to develop and maintain procedures. Have you got the procedures? Okay. Are they written down? Are you implementing them?

Yeah. How? Tell me about it. Let's walk around a little bit. Let's see it in practice.

If the answers to those questions is yes, move on. If they screw up, then go back and look and say what was going on here, did you have the procedure, did you implement the procedure, was there something in there that was a fundamental part of that procedure which you weren't doing or which you didn't include, which you didn't address. That's when you would be in a violation.

MR. CAMERON: Thanks, Cathy and Don. I think that was a useful sort of juxtaposition with some of the concerns that Kirk had. I would ask all of you around the table to be thinking about these perhaps two different approaches and is there a way to allow the states the flexibility to sort of choose which approach they think is better. But let's go to Bill.

MR. WHATLEY: Just one quick comment.

MR. CAMERON: Okay. Go ahead, Kirk.

MR. WHATLEY: I think the answer to your last comment is just give us the same flexibility that -- give the agreement states the same flexibility as you give the nuclear medicine licensees.

MR. CAMERON: Okay. Thanks, Kirk. We're going to go to Bill, Aubrey and then to Jake, and then to Pierce. Bill?

MR. DUNDULIS: I'm going to preface my remarks with these are my personal opinions, since I haven't officially cleared them with my senior management, but based on a lot of experience dealing with nuclear medicine.

I think I kind of second Kirk's philosophy that it's giving away the store. In actual practice, you know, they say we'll catch it during inspection.

Well, if you have actually done inspection of nuclear medicine facilities, you're going to find out most of it's done in doctors' offices. A lot of them are radiologists. And under the current system, they are at least sort of putting something in place and there is some physician oversight, but in actuality, if you went through most of these places, the nuclear medicine tech is actually running the operation and the doctor kind of checks in periodically to read the films.

With the current system, they at least have to go through procedures and, quite honestly, with the old Reg Guide 10-8, other than very large institutional licenses with professional radiation safety staffs, most of them just use the 10-8 check-off; you know, Appendix 1, Appendix 2, Appendix 3, fill in the blank, and whether it's a check-off or not, the important thing is they are committed to it and it's an inspectable item.

From what I have seen of the current proposal, it just says, oh, well, let them develop their own procedures or do whatever.

I'm not sure that in a lot of cases, quite honestly, unless they're utilizing consultants, they're going to be able to come up with procedures.

So I think I would kind of second Kirk's bit. If NRC wants to regulate their slowly diminishing or rapidly diminishing number of

licenses that way. I think the last statistics I saw, far and away, the majority of the medical licenses were in agreement states and I think I would agree with Kirk that if they want to do their small fraction of the licensees that way, so be it, but make it a level of compatibility such that agreement states were probably a lot closer to their licensed community and kind of know whether, when you're applying some encouragement, if it's a pat on the back or, in some cases, a pat slightly lower on the anatomy is required.

Thank you.

MR. CAMERON: Okay. Thanks, Bill. Let's go to Aubrey.

MR. GODWIN: I'm a two microphone person this morning, I see. A couple of things. First of all, the business of not submitting procedures and letting the facility sort of develop procedures in accordance with its own interpretation of the regs is what I view as regulatory entrapment and a pretty good way of setting someone up for a violation.

They're really going to have to be writing a proposed -- a procedure, excuse me, such that they think that they've covered everything in the reg and then during inspection, even if you don't look at everything initially, but when you find something that looks like a violation, you go back and start reviewing, there is a fair probability that they're not going to write it exactly like they should.

If they have been in for a review and you have already approved them in advance, they'll wave it back at you showing where you approved it and you're trapped, to a degree. As it is, they are trapped

and they are just out collecting cites, because you let them hang out there where they can collect it.

I think it's to the advantage of the licensee or the applicant in this case to have his procedures reviewed in advance. Certainly, the major items in it ought to be reviewed. I think it's to their advantage. I think it's to the -- actually to the patient's advantage, and it's to your advantage.

You also have a chance to look at their qualifications and training. Even if you only look at radiation safety training alone, you at least have some feeling that this individual has some idea of what radiation is.

Perhaps even to the extent that we have a test for everyone that goes into it, not necessarily administered by the state, but may have a national testing program set up so we can get into it.

There's been a lot of comment about all these standards floating around, industry standards. That's well and good. They're all voluntary. You can drop out of them at any time and continue to practice medicine or, in many cases, if you're an engineer, you can quit following some of the engineering voluntary standards, keep on practicing engineering, if you've still got your state license.

The fact that there is a voluntary standard in existence is fine and great for reference in your regs, but you need to understand that in the practice, they are not bound to follow that voluntary standard and may not follow that voluntary standard and can drop it at

any time and continue to practice, unless you, by some legal means, have bound them where they cannot abandon that practice.

And if you do that, you're essentially back to having prescriptive regulations, because then you tie them specifically to some external rule, you just didn't write it, that will bind them just as tight.

MR. CAMERON: Thanks, Aubrey. In a few moments, we will go to see if any of the representatives of the medical community have a comment on this whole idea about the procedures we're takling about, about the difference in approach, about if, in fact, that these professional standards are just completely voluntary and whatever.

But let's keep going here and we're going to go to Jake now and then we'll come back to Pierce, and then up to Ed. Jake? And Cathy, do you want to clarify something? Go ahead.

MS. HANEY: I guess let me just take two seconds to clarify what Aubrey says. We would be looking at training and experience qualifications up front. So that is something that we would definitely evaluate prior to issuing the license.

The other thing, though, again, is just to echo what I have said earlier, is that I really do think that the rule does give the flexibility for the states to continue their current practice of reviewing procedure up front. There really isn't anything in the rule that would preclude you from doing that. It just may be whether you want to have the rule language that says develop, implement and maintain.

The philosophy of not reviewing the procedure up front really comes in the NUREG and that is not in the regulation.

The other thing, too, is that in the procedures, if there was something that we believed was essential for safety, whether it be for occupational or public safety, we did include that requirement in the rule. So in essence, the procedures are a nice way of following through on doing something, but the best example is in the case of the dose calibrator. We believe that it was important to do accuracy on a routine basis and, therefore, we left to the rule rather prescriptive in this area by saying you must do accuracy.

At one point, one version of the rule and probably around the January time-frame, said make sure your dose calibrator is calibrated, period, and that was all that was in the rule. And then in the model procedure, we found the more prescriptive requirements.

But on looking at that procedure, we realized that some of those items we believed were essential and we did not want to leave it up to the licensee to say, well, gosh, I don't think I should do accuracy, I don't think I should do linearity, whatever. We pulled that into the rule text. That was our method of assuring that there was some safety built into the rule.

MR. CAMERON: Thanks, Cathy. Let's keep moving on on the idea of general approach here and one other issue for the medical community perhaps later is to inform the agreement states and the NRC of what they feel about the issue of the flexibility that should be granted to the agreement states to implement the new NRC rule.

Jake?

MR. JACOBI: First of all, let me preface my comments that I am all for a performance-based regulation. I really think that's the way to go.

However, having said that, I try and look at some things and one of the things Bob Quillen always said, when you hear ideas, ask yourself does it pass the straight face test when you look at the principal.

So I've got to ask the question and maybe NRC doesn't want to answer it, but if it is true that you issue licenses without evaluating procedures because people have training and experience, then we can have California issue a mod, another license. We do not need to ask for procedures for industrial radiography. We don't need to ask for procedures for irradiators.

If the individual has had experience and training, just let him tell us what equipment he has and we'll issue the regulation.

Now, I've got a whole bunch of issues, but if your fundamental principal that training and experience and what's in the regulation is all that you need, then we can just do the same thing with other licenses and if that's true, then, NRC, if you believe it, start doing it.

The second issue, where you talk about do we need to have to review these or should we do them during inspections. I think experience has shown to us that when there are changes in regulations, especially a large change, like we did when we went to the new basic rad

health standards with Part 20, that even the consulting medical physicist firms didn't really know what was going on and had a hard time trying to implement that.

Now, if they who are professional organizations providing hospital support have that trouble, I don't need to tell you the trouble the individual doctors who are trying to be the RSO at small hospitals had, much less the cardiologist in a box on every street corner these days, what they had.

They're not going to understand necessarily what's required, and so then you have people operating with potentially harmful practices until such time as an inspector can go and help them out.

The third thing that I'd like to say is one thing that maybe the NRC could convince us they're right is to provide a report right now of compliance issues at different types of medical facilities; number of non-compliance broken out by categories, how many patients have been given the wrong dose, how many exposures to patients that shouldn't have been exposed, and do a report that itemizes what the major items of non-compliance have been and what the status of them is for new licenses and existing licenses, and come back in two years, after your regulation has been published, and provide the same data for both new and existing licenses under your new regulations.

That way, maybe you can -- if you do the proper inspections, I think you might be able to have some data that would say either you're right and a state should start considering this or you'll have data that say you made a mistake and you need to go back.

MR. CAMERON: Thanks, Jake. A lot of good issues there, I guess including the issue of is Part 35 broken, does it need to be fixed, from the perspective of agreement states and others.

How about the compliance, the baseline compliance data? I mean, that might be useful for other things than just having a baseline to compare a proposed rule.

Cathy, any comments on that point or Jake's point about the question? You might not want to answer about -- and I'm not saying that we have an answer, but do you want to say anything?

MS. HANEY: Just because you put me on the spot now, right?

MR. CAMERON: What's that?

MS. HANEY: Now that I'm on the spot, right?

MR. CAMERON: Yes.

MS. HANEY: No, I don't want to answer.

MR. CAMERON: Okay. That's fine.

MS. HANEY: No, I do, with a couple of things. I don't know if I will give you a full answer or not.

I think it's fair to say that this approach with Part 35 is the first step and that if this approach is successful, we would look into other areas of the materials, other materials areas, and put this same approach, take the same approach with the licensing and inspection.

It has been a hard process over the last year to start looking at this change in philosophy and how we would implement. We have had, as I said earlier, inspectors and license reviewers working with us and this is a total change for them.

So there has been a lot of give and take in how we're doing it. So I think if it would be successful with 35, you would see us going into the other areas and making corresponding changes.

The other item that I would say is that we have had the luxury of writing the rule and the guidance document at the same time, which we don't have right now with the other NUREGs that we're developing, the other guidance documents.

So if we find something that was in the guidance document that really needs to be in the rule, it's easy to put it into the rule and vice versa; if there was something in the rule that really didn't need to be there, we could put it into the guidance document.

And with something like radiography or irradiators, as they're developing the guidance documents, they don't have the luxury of saying, well, gosh, this really -- if we didn't have this in the model procedure, we wouldn't have to tie a licensee to the model procedure. We could just put it in the regulation, and that's been a benefit, of why it's worked on the 35 process.

As far as looking at compliance now versus compliance two years after the rule goes into effect, that's a great idea and it's something that we should consider.

MR. CAMERON: We're going to go to the rest of the -- this is important, this general discussion. Don, I don't mean to not have you say anything at this point. I just want to remind people that we are under sort of a time constraint. But I think this beginning overview on approaches is particularly important.

Pierce?

MR. O'KELLEY: I wanted to echo something Jake said, I do also agree with the principal of performance-based regulation, but I want to know if anybody has considered the enforcement implications.

I see major additional time on enforcement, arguing who's right, who's wrong, is it an enforcement issue, is it not. I mean, I understand there are many ways to skin a cat, but has anybody considered how we're going to deal with enforcement under these new performance-based regulations?

MR. CAMERON: Cathy?

MS. HANEY: Yes. We have considered enforcement and, again, that's been a subject of a lot of discussion. It's much easier to enforce a prescriptive rule than it is a performance-based rule.

Again, hence, while we were very careful to put key requirements in the rule as compared to the model procedure, the rule, the way it's written right now, we believe, is enforceable when we're following up on medical events, which would probably be the -- if we look at safety significance, it's probably the biggest thing that we would be looking at in this area.

There are specific requirements in the rule that we believe we could tie people, licensees to, rather than referencing the model procedures.

Again, experience will show whether I eat my words or not that it's enforceable, but we have been spending a lot of time on it and

I expect that we will continue to spend a lot of time on enforcement as we move into this next stage.

MR. CAMERON: And just for all of your information, okay, the transcripts from the three workshops that we did, they do have some rather lengthy discussions on this enforcement and inspection issue that may be helpful to you in formulating your comments on the proposed rule, and I think we're going to hear about whether there -- what the status of an extension of that comment period is.

Pierce, you have a follow-up.

MR. O'KELLEY: A follow-up. Maybe some guidance to the states on how you think enforcement will work and some training in these new areas might be beneficial somewhere down the road.

MS. HANEY: Okay.

MR. CAMERON: That's a good suggestion, rather than somehow build a record and do some training on that. Ed?

MR. BAILEY: I'm not sure I'm going to make any value judgments. I'm just going to toss out some things.

If the agreement states look at their X-ray programs, that's almost what you've got with a system of where you don't approve procedures up front.

Now, you may like your X-ray system right now and you may think it's doing a great big job, a wonderful job, but when we look at the relative risks from the radiation exposure from your materials program and your X-ray program, you know, if you sit back and just logically think of the dose consequences, why the heck aren't we asking

for detailed procedures from every X-ray facility before we let them use their X-ray machines?

Now, if you've got a terribly bad situation in your X-ray field, then you're going to have, I think, a negative attitude about the proposal that NRC has about not submitting procedures up front.

I think we probably could, if we had thought of it, given NRC quite a few examples from the X-ray area of difficulties we've had in really going into the facility and looking at the procedures or not looking at the procedures, just going in and taking machine measurements or whatever we do, and we could give them some real good examples of problems we have seen in that area.

And maybe we ought to go back and look at some of those if we strongly believe that we need to continue to get the procedures.

So I think that's where we're headed or where NRC is headed with their proposal and I'm not sure whether I agree with them or don't agree with them at this point.

MR. CAMERON: Thanks for that analogy, Ed. Let's go to Richard and then I want to go to the public. Richard?

RATLIFF: My fifth item I had was how many states review X-ray procedures prior to registration. I'm thinking the same thing. We have high dose rate fluero units. We have accelerators.

What we have seen and I think is going to be the wave of the future is that performance-based rules are going to be better for everybody. We have a sign in our associate commissioner's office that

says change is inevitable, agony is optional. And I think that's what we're going to see is that we have to do change.

I think risk is the main issue. We've got areas where we know that if they spill all the technetium or give it to the wrong patient, the risk is low, versus radiographer, where we see people missing fingers, missing hands, things that we know there's a direct effect.

And the inspection really it should be an exchange of information. I'm not sure how many of your acts changed after you became agreement states, but ours still had that we protect public health, safety and the environment, and we promote the peaceful use of sources of radiation.

If we're a hindrance, I think we're into the box and we can't think out of the box. I know even our own staff want detailed things on minimal risk areas.

One of the things that I think we need to look at is a new paradigm of the inspectors doing something, and I always liked what Oregon does, that we have been able to do, is have the inspector deliver the license, go over it with the people who are going to be the actual users, the technologists, because what I see now is many procedures are developed -- the comment was made that the licensees couldn't do their own procedures.

That's true, many of them don't. They are developed by somebody else and they don't follow them. I think if they're required to follow a procedure and then we go and it's a performance base, that

they really are performing adequately, we're much better off and we can devote our resources to areas of really high risk that we are not being able to now.

MR. CAMERON: Thanks, Richard. We're going to go to the public now and Steve Collins, who is at the mic, we'll let him go, and then I will ask Dr. Caretta to address that.

Steve?

MR. COLLINS: Steve Collins, from Illinois. Remembering back to what Kirk was referring to earlier, when he and Bill Spell went and testified, I drafted up most of Bill Spell's draft remarks that he took for that meeting and then I, in that time-frame, was a part of the working group that worked with NRC on the development of Part 35.

Kirk alluded to the fact that if the compatibility category is the right category, we don't have much concern. At that time, we specifically asked what would be a compatibility category and we were told and assured at that time that almost nothing in Part 35 would be a matter of compatibility. That's not the way it happened.

Some of us felt very much betrayed. So a lot of our concerns of the agreement states, if we really know we're going to have the flexibility, a lot of our concerns will go away and you're going to have the opportunity for a really good test case where you're going to have Alabama, which is going to keep its current system, almost without change, and you're going to have NRC, who is going to go totally -- almost totally performance-based, and you're going to have a lot of the rest of us, like Illinois, that are going to be right in between.

We know there are certain parts we are very much willing to back off on. There are other parts, like review of procedures in advance, but there are certain areas of the procedures we don't want to back off on.

So one of the real keys right here is going to be the compatibility issue and I hope, when we are finished with these remarks, maybe since that is cross-cutting, that we can go ahead and go to that out of order and make sure we can get some assurance of compatibility levels on the rule.

MR. CAMERON: I think that we're going to have to hit hard on -- because I think that's a good perspective, Steve. I think we're going to have to hit hard on these compatibility, proposed compatibility designations for the provisions of the rule.

I mean, we won't have time for in-depth discussions, but you guys, you people need to be assured of what the compatibility designation is and whether you agree or disagree with it. I'm going to have Dr. Caretta, from the Society of Nuclear Medicine, give us his comments and maybe he can address this general issue of agreement state flexibility, too, if you want. Go ahead.

CARETTA: That depends. Is Ed Bailey here?

[Laughter.]

CARETTA: I guess I will say something about California then, since I'm regulated by Ed's group.

I'd like to thank the agreement states for giving me a chance to make some public comments and these are comments that the

Society of Nuclear Medicine has presented that all of the other public hearings and in writing to the Commission. And listening to the discussion about the changes in Part 35, the one word that has come out of all the agreement states' discussions and all of the meetings that I have attended has been risk and risk-based and what is risk.

I think when you look at Cathy's first slide, it says focus Part 35 on the procedures that pose highest risk and oversight alternatives for diagnostic procedures consistent with risk. I think that's our major concern, that if you look at diagnostic nuclear medicine and then the therapeutic aspects of nuclear medicine, there is significant differences in risk.

One of the commenters talked about non-compliance issues and would the NRC go back and look at the issues of patients getting the wrong doses or things like this.

I would encourage that because the one thing that has been missing from all of the non-compliance issues has been the denominator of tests compared to, for non-compliance, with tens of millions of diagnostic nuclear medicine procedures being performed each year.

If you can show me that there is a significant health and safety problem with five to 500 patients getting the wrong dose, I think that's minuscule and within background noise and human error. If you can show me that there are hundreds of thousands of patients that are having problems over these multi-millions, then that's a significant risk that we should look at.

So we're only getting part of the story if you look at non-compliance. Tell me what the baseline is for the number of procedures that you're comparing the non-compliance issues with.

The other issue that was mentioned is this rule-making has been on a relatively fast track for a government agency. If the IRS moved this fast, maybe we wouldn't all be paying too much taxes by next April.

But we have been concerned about the issue of risk. We have been very concerned that there has been no risk assessment performed other than that that was involved in the National Academy of Science Institute of Medicine report, looking at the risk of diagnostic nuclear medicine procedures.

So we, yesterday, hand-delivered a letter to Chairman Jackson, asking that the Commission extend the comment period for the ongoing revision of Part 35 to allow for the development of the risk analysis and rule accordingly.

This letter was signed by most of the groups that are involved in diagnostic and therapeutic nuclear medicine, the Society of Nuclear Medicine, the American College of Radiology, the American College of Nuclear Physicians, the Health Physics Society, which is -- I better get the correct one of the Health Physics Society.

It was signed by the American Association of Physicists in Medicine, it was signed by NEMI, the Nuclear Energy Institute, the Council on Radionuclides and Radiopharmaceuticals, and we would ask that

the agreement states consider sending a similar letter to the Chairman asking for a risk assessment being performed.

So those are my comments officially as a representative of the Society of Nuclear Medicine.

My personal comments in terms of the agreement state compatibility is that I feel the agreement states should be given the most flexibility possible to tailor their programs to the needs of the medical community in their states.

We have a very workable program in California where we communicate with the regulators on a regular basis. Our input is sought. Our professional standards are sought. We had a dialogue with the regulators and we worked together to provide the highest quality of nuclear medicine procedures that involve the public health and safety as well as the clinical practice of nuclear medicine.

So, Chip, thank you for allowing me to address the agreement states group.

MR. CAMERON: Thank you very much, Bob. I think that was useful and I think that, unfortunately, this whole discussion could go on all day. You have the proposal basically that the medical community put in front of you; not just for an extension of comment, but to support the need for a risk assessment. I don't want to necessarily open up a big discussion about what you want to do about that suggestion or on risk, but I think it would be useful for the Commission to hear any comments that agreement states have about this issue of do we need to go back to the drawing boards, do a risk assessment, whatever that

is, because there is a lot of debate on the methodology for doing that, but do we need more risk information before we proceed with this rule.

What I would like to do is get any feelings, yes, no, whatever, it depends, from you on that issue, see if there are any other comments in the audience, and then go to training and experience.

Joe?

MR. KLINGER: As far as risk, is the byproduct material risk review group, is that -- will that help this situation with the medical rules or is that just kind of comparing it to the other industries?

MR. CAMERON: That's a good question. Don Cool is going to answer it.

MR. COOL: The really short answer is no, because that study has a much broader basis, looking at all the different types of byproduct systems and doesn't have the level of detail which would get you to the kind of individual procedures and activities, particularly within the subset of nuclear medicine, such as Dr. Caretta was talking about.

Its focus was originally intended to be the much bigger issue of where within an overall regulatory regime various kinds of uses, everything from the irradiators to the smoke detectors fall, to try and validate the overall system of regulation.

So while it's out there, while the principals and techniques may well be useful then to go and do something, that study itself was not designed to specifically address this particular subset issue.

MR. CAMERON: Thanks, Don. Go ahead, Joe.

MR. KLINGER: But having all those people in place and having their experience of this exercise, could they modify it easily to do some risk review specifically in the area of medical use?

MR. CAMERON: Don?

MR. COOL: That's certainly a possibility. The original contract and the original mandate did not get there. There is nothing that says that you couldn't amend, add to, or start a new one. The existing contract is completed and, in fact, we've had to add some additional money to the original estimates.

What they say about research and developing a risk assessment is a little bit like that, is really not research or risk assessment if you know what the answer is or how much it's going to cost or exactly how long it's going to take.

MR. CAMERON: One point of information for all of you and I have a suggestion for Roland, is that there was a lot of discussion on this risk issue that the methodology should be agreed on in advance and that the agreement states and the medical community and others be involved in the process of how that methodology is identified.

Roland, would you coordinate that? Just a suggestion. Would you coordinate the consideration of whether the agreement states want to indeed send anything in on it? Go ahead. Why don't you give us your view?

MR. FLETCHER: Well, I was going to request, when everyone has had the opportunity to review this correspondence, to get a feel here for the number of states that feel that we should write a letter to

get the comment period extended, and we can proceed from there, since everyone's representatives are here.

MR. CAMERON: Should we check back after the morning break?

MR. FLETCHER: Yes.

MR. CAMERON: Okay. We'll do that. We will come back to this issue.

Any other comments in the audience, from someone we haven't heard from so far?

[Laughter.]

MR. CAMERON: I mean, he has so many hats, though, I guess we'd probably -- he'll have a hat we haven't heard from. Before we go to Steve, is there anybody else out there who wants to say anything?

[No response.]

MR. CAMERON: Okay. We're going to Steve and then to Bob from Ohio, right? All right. Go ahead, Steve.

MR. COLLINS: Steve Collins, from Illinois. I really would like -- and maybe Dr. Caretta is the right one to do this -- to get a little bit better definition of what you're looking for in a risk assessment. I say that in the context of the medical policy statement for basically the medical community and a lot of the state regulators really do not think it is the right place to be in the decision-making process of how much radiation is administered to a patient.

If we're only talking about a risk assessment from the point of view of the Part 20 standards, I think there are plenty of data already available out there from film badge records and ring badge

exposure reports and stuff like that to probably fairly quickly do an assessment in diagnostic versus therapeutic environments and that sort of thing.

MR. CAMERON: Thanks, Steve. I think that's probably important enough to just get a quick read from Dr. Caretta on that issue, before we go to training and experience, because that might help you decide what you want to do with this thing.

Bob? And state your full name for the transcript.

OWENS: Bob Owens, State of Ohio. I'd like to address sort of a process issue, back to what Ed Bailey was talking about when he mentioned the X-ray facilities as far as lack of procedures.

That sort of tied in with -- well, another statement that was made goes to the nuclear medicine facilities, will there be proper procedures developed by the private clinics and so forth or the doctors' offices.

The State of Ohio does require standard operating procedures for all X-ray facilities, as well as instructions of workers, and historically we found that it has been most difficult for these facilities to develop appropriate procedures; not that they're trying to be difficult, not that we are trying to be difficult.

Finally, they would come back to us and say what is it that you want, we'll be glad to do whatever.

So it just points to the fact that if you leave this to a purely performance-based approach, where they develop whatever they

want, do whatever they want, and you inspect them based on their procedures, whatever that is, then I think we're missing the boat.

They would like to do the right thing, as much as we would like for them to do the right thing. If that gets you back more to a prescription, so be it. That's what the X-ray folks are asking for.

I just wanted to make that point.

MR. CAMERON: Thanks for that point, Bob, because it is a good one. I would just note, for information purposes, that a number of licensees at the workshops expressed the same notion of they don't want to be put in the bind of not knowing what's expected of them. They would like certainty in advance in that regard.

Dr. Caretta, can you just give us like a brief statement on what you think this risk analysis would be?

CARETTA: This is my own personal opinion, because the Society hasn't taken a definite policy. I know Carol Marcus, at the last meeting in Bethesda, gave the review of what we're looking at in terms of risk based analysis and performance.

But what I would look at is what in Part 35 is going to assure that there is, in diagnostic nuclear medicine, protection of public health and safety in terms of radiation exposure, and we're concerned, for example, there's a part -- there is a rule in the part that says if a diagnostic dose is greater than 20 percent of the intended dose, that this is a problem area, a medical event.

Is there any data that shows that 20 percent of a technetium dose, a 20 millicurie technetium cardiolyte dose for heart scanning,

that 20 percent difference is a significant health radiation safety problem for the patient or general public? I don't think it is.

I think this is the type of analysis we need to do because we're concerned that the risk of using diagnostic radiopharmaceuticals, and, in particular, the NRC regulates technetium, they don't regulate gallium, they don't regulate indium, they don't regulate valium, why are we looking at technetium without knowing what the true risk is to the patient or public.

I think that's our concern, that we look at exposure to patients and publics, and part of it is -- was mentioned under Part 20 is readily available. You can look at dosimetry records for the personnel for the hospital employees and things like this.

MR. CAMERON: Thanks, Bob. Jake, real quick, while Cathy is being out setting up for training and experience, because we really need to go there.

MR. JACOBI: I'll make this real quick.

MR. CAMERON: Great.

MR. JACOBI: On this risk study that we're talking about, I hear a fundamental shift on what some of the philosophies, at least maybe I've been in the business too long, but when I was started, the philosophy was no unnecessary exposure, no exposure without benefit.

I agree there is an economic impact and you've got to definitely say sometimes this is just not worth the effort -- I love the term below regulatory concern, but we can't use it. But I've got to be

careful, from what I see, even the non-Catholics are crossing themselves.

[Laughter.]

MR. JACOBI: But what I'm hearing -- I think I heard if it's -- you give an exposure to somebody and it's not going to hurt them, it doesn't matter, and if that's where we're going, unless I'm wrong, it's a total philosophical shift from where we all grew up.

MR. CAMERON: This may be a paradigm shift going in. Okay. Think about the letter. We'll revisit that after the break. Cathy is going to tell us about training and experience.

MS. HANEY: I have two viewgraphs on training and experience and then we can turn it over for discussion. First, I want to tell you the approach that the working group took and that was that we would focus the training and experience requirements on radiation safety.

And as I said earlier, we do not see NRC making an assessment of clinical competency or clinical proficiency, however you want to refer to it. It's only NRC's authority over the safe handling of the material.

The other thing that we believed was important is that individuals should complete a structured educational program and there would be two aspects to that. One, didactic training and the other practical.

We believed very strongly that authorized users, radiation safety officers, medical physicists, whatever role you're going to play being authorized by this rule, that you should have some hands-on

experience with handling the material or doing that work for which you are going to become authorized.

The didactic training would refer to training in physics, chemistry, again, all relative to radiation safety, but it's more your classroom sort of work. By structured, I don't mean it -- you know, we're not recognize -- we are recognizing that there are several modes and mechanisms available now for getting training that doesn't require you sitting in a classroom with 20 other people and a teacher sitting up front. But, again, it's more structured toward number of hours of training.

The other thing that we have incorporated into this rule is the requirement to take an exam. Based on what we heard from the public meetings last year, facilitated meetings as well as the all agreement state workshop, we believe that it was necessary to evaluate someone's competency and proficiency by having them take an exam. So we have incorporated a requirement for that into the rule.

This is basically what the requirements boil down to, so you don't need to review through the whole rule. The 100 and 200 would really be your diagnostic area. In 300 would be where a written directive was required. Then 400, manual brachytherapy; 500, your sealed sources; 600, your therapeutic medical devices.

Under the 35.600, you'd be looking at the requirements for users of remote afterloaders, for gamma knives, and for teletherapy units. Then we have the radiation safety officer, authorized medical physicist, and authorized nuclear pharmacist.

There are still two approaches to becoming an authorized user, and I'm going to use authorized user as an example, but this applies to whatever category you fall into up there on the viewgraph, and that is one that you either have the number of hours that you see on the screen and then this other category or else you're certified by a board.

The current rule lists the boards by actual name. The proposed rule does not. What it says is that you are certified by a board that NRC has approved.

Now, we'd be interested in seeing if the agreement states are interested in approving these boards. There is, again, no ulterior motive by excluding the agreement states or having them in there right now.

We're looking -- we're discussing more Commission approval of the boards. The approach that we see for NRC approving a board would be that an organization comes to us and says to the NRC we would like to become approved to give the exam -- I mean, approved as a certifying organization, and in doing that review, we would say, well, how many hours does it take to -- how many hours of radiation safety training would someone have before they can sit for your board, do they have any practical experience handling the material, is there any preceptorship involved, and if the answer is yes-yes-yes, theoretically, NRC would approve them.

There are some extra things they would need to tell us and those items are found in Appendix A of the proposed rule and for the

sake of time, I'm not going to go through all those requirements again. They boil down to some procedures and bylaws and resources devoted.

But the key here is the exam that we see under the certifying approach is that an exam focused on radiation safety, they would have to be willing to grade their exam separately.

In other words, we don't want someone to pass a certifying board, pass all the questions on clinical competency and fail all the ones on radiation safety principals, and then they say, well, we passed our boards, therefore, let me be an authorized user.

So we would keep looking at the exam for these certifying entities directly to radiation safety.

The reason we left that approach in the rule rather than going to strictly specifying the hours practical experience was because NRC rules allow a licensee to just not do a license amendment if they have someone coming in that's board certified. They just need to notify NRC within 30 days.

So we wanted to still leave that approach in there because it did allow the licensee a little bit of flexibility in bringing new people onto staff.

Now, if someone chooses not to go the certifying route, then they do have to fill in these hours that you see on the screen. The biggest difference to point out is the reduction in hours in the unsealed uses of pharmaceuticals. We have made very little changes in the therapy area.

That being that when we spoke with the ACMUI last March, they advised us very strongly about making changes in the 35.400 and 600. They recognized that we wanted to focus in on radiation safety, but they argued very strongly and effectively that radiation safety and clinical competency are so closely intertwined in the therapy area and because the risk associated with use of material in the therapy area is so great, that we needed to have the more significant training and experience requirements.

So we did leave it there, but we also added on a requirement for an exam.

Now, this exam is different from the certifying exam. Well, not in principal and actually the questions, but we're looking at NRC approving two different things; approving a certifying board or approving an exam organization.

Under this route, ACME Testing could come to us and say please approve our exam for evaluating radiation safety and if NRC would approve it, and here we would be looking at the level of difficulty, making sure that they're correctly assessing all areas that we believed were important for radiation safety, then we would, in fact, approve it.

So an individual could take just the exam under this approach and not be certified.

The training and experience area has received probably -- well, actually, I guess now it's a tie between which is the biggest issue, T&E or risk assessment. Prior to last week's meeting in

Rockville, I would have said T&E was winning, but I think risk assessment might be top on the list now.

The endocrinologists are significantly affected by this rule. We would no longer have a section specific to endocrinology. They would be falling under the 35.300 uses. We would be increasing their training by 40 hours, and that being 40 hours of practical. They have lobbied very hard that this could impact use of material by endocrinologists. There has been a lot of Congressional interest in this area, asking us, you know, "What are you doing, NRC, and why are you doing it."

The other significant area of interest in the T&E to note is cardiology. The cardiologists are definitely in favor of this approach in the diagnostic area because it has reduced the number of training and experience requirements. They are encouraging Congress to endorse what NRC is doing.

Then in the intravascular area, it's more just pointing out that the use of radioactive material in intravascular brachytherapy is being studied now. They have not decided on what the best radionuclide to use is, what is the best approach, and being very leery of where we would place them on this chart.

They're asking that we hold off on placing them on this T&E chart until they figure out what the best mode of treatment is. So those are the two big things that have come up at the public meetings relative to training and experience.

Then the last thing I'd like to just note is the level of compatibility associated with this, because I think that is key to this organization. The proposed -- the new T&E requirements are category C and by the new ones, I mean the T&E requirements that have been brought into the modality-specific sections.

I referenced in my introductory remarks that we did keep subpart J in the rule. Subpart J is a D. It currently is a D and it will stay a D.

The reason we left it as a D is that essentially in two years, subpart J will go away. Since you have three years to incorporate it, it's kind of silly to make you do something with it now and then in two years, in NRC states, it will go away and then you would have to do another rule-making.

So we left that alone. From this discussion, I hope you see why we needed to maintain D -- I mean, maintain J, and that being that organizations can't start coming to us to get our approval on the certifying exam or on the exam until the rule is final, and then if we had not maintained J, essentially, the day that the rule went into effect, no more authorized users could be -- or no more physicians could become authorized users until a board acted or an exam organization acted and we took action, and we didn't want to stop the practice of medicine until everybody got all the approvals in and the paperwork done.

So we assumed that two years would be a sufficient amount of time for that process to take place, hence we put the two years in the rule.

So what that, Chip, I'll give it back to you.

MR. CAMERON: A great summary, Cathy, and just to underline, I mean, let's talk about the compatibility levels with each of these issues as we go along.

Is everybody clear about what the compatibility levels are here and is everybody in agreement with what they are? Pierce? Then we'll go to Aubrey.

MR. O'KELLEY: I guess I don't know that I'm talking compatibility. I've just got some still general comments left over from last time.

I know we worked in the government and, you know, what's reason got to do with anything. But I'm a little concerned about consistency. We spend all this time chasing every millirem in the environment and regulating down to nothing. But then we hear comments like the 20 percent dose is no big deal, increase in dose.

Are we being consistent? Are we treating everything the same? And I don't think we are. Since most of the people -- most of the general public's radiation exposure is from medical procedures, are we not saying we don't care about it? And I don't think we need to get there.

And just another aside is when the cardiologists agree with it, I think you better look real close.

[Laughter.]

MR. CAMERON: That's like I don't feel comfortable calling the ops center. It's one of those things that's going to go unexplained.

Aubrey?

MR. GODWIN: In looking at this scheme that's being developed, I have a few questions. For example, who is going to approve the exams? Who is going to approve the training courses? Because not all of these look to be necessarily university or medical school oriented.

And is the intent that the regulatory agencies are going to approve it and does this mean we're going to have a sealed source catalog of schools for medical education along with a sealed source catalog of schools for industrial radiography? And while we're at it, why don't we have a sealed source catalog for just general radiation safety training?

Will there be one exam given in general radiation safety, say, for the diagnostic level and perhaps a more extensive one given for therapeutic levels and will these exams be preparatory maybe to taking a general exam for the certification by the physicians, and we don't really care whether they ever get certified?

But how is this going to work? There's a lot of little devil in the detail type issues I'd like to run some rabbits on if we've got time, but I'd like to hear some answers to that.

MR. CAMERON: Those are also, I think, good comments for the staff to consider, because there may not be answers yet, but, Cathy, could you address that?

MS. HANEY: I can answer a couple of them. One, as far as who would approve it, NRC would approve, at this point. The rule is set up so that the NRC would approve it, but that's not to preclude agreement states from approving it and that's something that we can discuss, whether you would prefer to see the wording in with NRC and an agreement state or you'd like to just see it NRC approval.

So either organization, but it would definitely be approval by a regulatory body.

Aubrey mentioned could there be one exam that would be given for everyone to take and there was a lot of discussion at the Rockville meeting on this. We convened a special board or special panel and we had representatives from maybe about ten different boards come in and talk to us.

And the concept of them getting together and developing one radiation safety exam was explored. They didn't say yes or no, but it was mostly left as that's an idea that's definitely worth considering.

So we would not have a problem if someone did that or if a group of people came together or a group of states came together or however. That really is an option.

Then the last comment that I would make is that at this point, we do not see NRC approving the training programs. We would only

be looking that the number of hours are met. In this case, we would be relying on the exam to show that the individual mastered the skill.

I think I got all your points, or at least addressed most of your points, Aubrey.

MR. CAMERON: Thanks a lot, Cathy. Let's go to Kirk.

MR. WHATLEY: Pierce, I'd just like to say my cardiologist is one of my favorite people in the world.

[Laughter.]

MR. WHATLEY: I'm glad he was there. Cathy, you've used a term today and it's been used for years, and I'm not sure, if we ask around these tables, that we'd get the same definition, and that is authorized user.

That term appears on every license that's written probably or most of them anyway. What is NRC's interpretation of authorized user on a radioactive material license? I'd like to come back with another question, too.

MR. CAMERON: Okay. Fine.

MR. WHATLEY: What does that mean and what are the responsibilities of an authorized user? I'll be specific. On a diagnostic, non-iodine-131 radioactive material license.

MS. HANEY: The authorized user would have the responsibility for assuring that the radioactive material was used safely.

MR. CAMERON: And the specific example?

MS. HANEY: And the same thing, whether it's in the diagnostic or therapy, I would give the same answer. I think a question that's been debated over the years, and I know it's different between states and also between states and NRC, and that is that in NRC eyes right now, the authorized user does not need to be the one that is reading the scan or interpreting the results of the test.

I know some of the states have different policies, just from discussions I've had with state representatives.

MR. CAMERON: Kirk?

MR. WHATLEY: If I were in Africa and chose to get a certified health physicist to do my radiation safety aspects and wanted to only do diagnostic non-iodine studies, why would my physicians need any training if they're not required to select patients, prescribe dose or interpret the results, or the responsibility for radiation safety was with somebody who really knew what it was about?

Why would they need to go through all this training? What's the purpose of it?

MS. HANEY: Well, again, I would just go back to that NRC has put the responsibility on the authorized user to assure that the material is handled safely. Now, in the degree to which the physician is involved in the procedure is licensee-specific, I recognize that, I know that in some cases physicians are administering the material in the very small operations, to the fact that the physician may actually never handle the material and it's actually the technologist that's handling the material.

But from an NRC standpoint, we're looking for the authorized user to have the responsibility for handling material safely, for supervising the use in the office.

MR. CAMERON: Okay.

MR. WHATLEY: Just one more.

MR. CAMERON: One more, go ahead, Kirk.

MR. WHATLEY: I just think we're training the wrong people perhaps or maybe not even training all of the appropriate people may be a better way of saying that.

It was NRC's definition. NRC defined what they meant by authorized user and they define that in a letter written to Dr. Acock in South Carolina. And in that letter, they said that on a radioactive material license issued by NRC, that that meant three things.

The authorized user was to select patients, prescribe the route of administration, dose to be administered and the isotope, and interpret the results. That was all of the definition of what an authorized user meant on an NRC license, until about 1983 when new ideas came from somewhere. That was taught in the medical licensing courses that NRC presented. I know that for a fact, because I taught several of them.

MR. CAMERON: Okay. Thank you, Kirk. Let's go to Ed, and then Jake, and then we're going to go to the audience and we'll take a break.

Ed?

MR. BAILEY: You all have all heard it probably repeatedly from me. We have in our regulations, for instance, on therapy, that the authorized user must be physically present when radiopharmaceutical therapy doses are administered. And to the best of my knowledge, we have not had any misadministrations when that regulation was met.

I would agree with you. I'm darn near as old as you are and I remember that those were three requirements and they were -- I mean, and when I talk to the physician people in California and in Texas, when I was there, they pretty much thought that's what they were supposed to do, too, was be involved in the nuclear medicine procedure.

But we do see some people who apparently don't feel that they need to be. I think if you went to Dr. Caretta's facility, you'd probably find that he was involved in nuclear medicine. I've been to Carol Marcus' facility. She has a different personality with her patients.

[Laughter.]

MR. CAMERON: That's a comforting thought, Ed. Thanks a lot. Are you still going, Ed?

MR. BAILEY: No.

MR. CAMERON: Or are you done?

MR. BAILEY: No, I'm done now.

MR. CAMERON: All right. Thank you. Let's go to Jake and then see if anybody in the audience has a comment on training and experience. Go ahead, Jake.

MR. JACOBI: I'd just like a little clarification. I heard you say the authorized user is the one responsible for safety.

Does that mean that maybe you could have a medical physicist as the authorized user and you do not need any physician listed on a nuclear medicine license?

MS. HANEY: No, that's not our intent.

MR. JACOBI: Where is the requirement that there be a physician involved as an authorized user?

MS. HANEY: That's a good question and it's something I think we have to address between now and June.

[Laughter.]

MR. JACOBI: I just wanted to let you know that, again, taking the analogy from the X-ray program, we have had a lot of X-ray techs who want to set up an operation on their own without a physician involved.

Strongly consider you figure that if you do want a physician, you figure out what the physician's role is and make that really clear, because the way I see it now, you don't require it and need a physician.

MS. HANEY: Okay.

MR. CAMERON: Okay. Thank you, Jake. Let's go out to the audience. Any questions out there?

[No response.]

MR. CAMERON: All right. We're going to give Kirk --

SNELLINGS: I have one question.

MR. CAMERON: Okay, Dave, go ahead.

SNELLINGS: I'm Dave Snellings, from Arkansas. You said that the NRC would approve this exam. Does that mean that there is also -- whenever this exam is challenged by someone who fails it and challenged legally in a court of law, does that mean that the NRC is also going to stand up and say, yes, this is a fair exam? You know, you go through all the process of exam building and determinations, like American Board of Health Physics, for example.

They put an extreme effort in making sure the exam is correct, fair, et cetera, et cetera. Is that -- does the NRC mean that that's what they're going to do in their approval process?

MS. HANEY: That's probably one of the big issues that we discussed last week with the different boards about what NRC's role would be and looking at the different requirements to do an exam from strictly the -- being an examining organization.

Some of your question, yes, we see NRC doing, some no, and I think, again, it's the details that we'll need to get at. We would expect the exam to meet all exam standards and levels of difficulty and things like that.

And I believe if it went into court, we would say, yes, this was an approved exam to evaluate someone's radiation safety and we made this approval on this basis.

But, again, some of those details we need to work out, but we know about them and we know that's something we need to look at.

MR. CAMERON: Okay. Go ahead, Ruth.

MS. McBURNEY: In your discussions with these certifying boards and so forth, is it likely that some of them may develop a modified exam to meet the requirements for the exams?

MS. HANEY: Yes. Right. Most of the boards said that they would take their current exam and split out the radiation safety questions and grade those separately, but they brought up -- then you get into some problems with the validity of the exam when you start splitting out questions and grading them separately over a smaller number. Again, those are the details that we need to work out.

MS. McBURNEY: I mean, something like the American Board of Health Physics developing an exam to meet the requirements for the radiation safety officer, other than their certification exam.

MS. HANEY: Yes, they talked about that. The question really came up, especially with the health physics, which is would just part one be sufficient or do you need part one and two. So those are questions that still need to be addressed.

MS. McBURNEY: Okay.

MR. CAMERON: Okay. Let's go, the last comment on this issue, to Kirk and the we're going to take a break.

MR. WHATLEY: I'll be quick. I think what's missing in the definition of authorized user as it's written, as it's written, it simply says an authorized user is an individual who meets certain criteria and is named on a radioactive material license.

I think what's missing is what are his responsibilities. It's sort of like saying a pitcher is someone named on a baseball roster

who has had so many years of experience. That in now way defines a pitcher on a baseball team. I think if that could be added to that, I think it would help clarify some of the problems here.

MS. HANEY: I think that's something we'll look into. I think it's a great point.

MR. CAMERON: Good. Thank you, Kirk. Let's take a break until -- let's come back a little bit after quarter to, okay? And there is a sign-up sheet going around for those of you in the audience, if you would please sign in. And think about this issue about the risk assessment, and we will address that when we get back.

[Recess.]

MR. CAMERON: Now that we have finished with the Part 35 discussion, we can -- thanks Don and Cathy.

MS. HANEY: You're welcome.

MR. CAMERON: Okay. I think Roland is going to want -- when Roland gets here, we're going to have him sort of lead the discussion on where you want to go with the risk assessment issue. We have radiation safety committee and I think that that's going to be fairly straightforward.

But what I want to remind everybody is that we're going to look at the compatibility designation for each of these important areas when we talk about that area. So that hopefully when we get to the compatibility part of this, we have already discussed most of the important provisions.

Roland, do you want to talk with your colleagues about the letter?

MR. FLETCHER: Yes. I was -- we have quite a few gaps here, but I think we have a majority. I would just like to know the preference from board members, from OAS members, as to whether or not OAS should send a similar letter requesting the extension of the comment period.

If you are in favor of that, just raise your hand.

[Show of hands.]

MR. CAMERON: One clarification. Are you doing this in pieces? Because I guess that the request was also on the need for a risk assessment.

Dr. Caretta, the request was to support the extension of the comment period and to support the need for a risk assessment?

CARETTA: Yes.

MR. CAMERON: Both. Okay. Two parts. All right.

CARETTA: But we'll settle for each.

[Laughter.]

MR. CAMERON: You know, the medical community, they've been beaten up. Cathy?

MS. HANEY: A couple of things you might want to consider in deciding how you're going to vote on this. Obviously, there's a question of extending the rule-making process to allow for a risk assessment to be done and that would require a change in the June '99 date.

Inherent in that also is a request to just extend the comment period from November 12 to something else, but realize right now the staff is operating under the Commission direction that the rule will be finalized by June of '99.

If you extend the comment period without extending the June '99 date, there are some ramifications to that, that being that I have less time to address all the comments, being one, and, again, that -- and this assumes that the June '99 date is not extended.

The other thing being is that right now the schedule calls for three opportunities for interaction with our advisory committee, one being a full committee in March, the other being subcommittee meetings in February, with a diagnostic subcommittee and with a therapeutic subcommittee.

If the comment period is extended and the June '99 date stays fixed, some of those interactions are going to go away and that has a certain amount of impact on the rule. How much I can't tell you, but it would be something that we would be losing.

So when you're deciding the approach to take with this, realize there are a couple of variables here; you know, one is extend the June '99 date or just extend the comment period, keep June '99 fixed, and then the issue of risk assessment.

Thank you.

MR. CAMERON: And, you know, you don't need to get -- that's good information, but you don't need to get real complicated about it,

because we can get sort of wound up and stuck in these permutations, I think. Go ahead.

MR. FLETCHER: I think the only adjustment I would make to what I said before is are you in favor of a letter to extend the comment period to permit or allow time for a risk assessment and consideration for extending the effective date of the regulations.

Those who would like to see that, please raise your hand.

[Show of hands.]

MR. FLETCHER: I think we better count. Raise your hands again.

[Show of hands.]

MR. FLETCHER: Eleven. Those who are not in favor of it?

[Show of hands.]

MR. FLETCHER: One. Those who don't care?

[Laughter.]

MR. FLETCHER: I think it's a majority of those who voted. So I guess we'll put something together. Rich, I'm going to have to depend on you and I to put together a letter. What we'll do -- it's going to have to be fast track because the comment period is two weeks away. So we'll put something together real quick and make sure that copies are circulated.

Yes?

MR. JACOBI: Just a question. You said a letter to include a delay for a risk assessment and I heard somebody mention what we

should pick up on real careful is what is a risk assessment going to constitute.

I think that's a real key thing to talk about.

MR. CAMERON: One point there, I guess, is that you could take a process approach to that, which is that the methodology should be decided in advance and the agreement states should participate, too. That's one approach. But you may take a long time to thrash out what it should be. I don't know.

MR. FLETCHER: Well, let's keep in mind that the first thing we have to do is get a delay for the end of the comment period. I mean, we can't -- I don't think we can put everything in place prior to that happening.

MR. CAMERON: Okay. Well, you have a decision, I guess, and a path forward on how you're going to address it.

MR. FLETCHER: I'm not comfortable with the number, but --

MR. CAMERON: You're not comfortable with what?

MR. FLETCHER: I'm not comfortable with the number of 30 agreement states and 11 voted for it, but that's what we'll go with.

MR. CAMERON: All right. Let's go to radiation safety committee.

MS. HANEY: The proposed rule does not contain a requirement for a radiation safety committee. It is deleted. In getting to this position, the working group looked through the current requirements for the radiation safety committee and identified what were the key components under the current rule, and kind of did a split.

If it's key, it belongs in the rule. If it's something that would be nice to do or just to highlight for the licensee to be aware of, we put it into the guidance document.

We created a new section called 35.24, and it has to do with the authority and responsibilities for the radiation protection program. The idea here was we wanted to allow licensees as much flexibility as possible for running their radiation protection program, but, again, keying back to that there are some key requirements, we felt it was necessary to put into the rule that licensee management had to approve requests for licensing actions.

The next item that we added to the rule was that there should be administrative procedures for interdepartmental interdisciplinary coordination. The reason this went into the rule is we felt that that was probably one of the best things about the radiation safety committee, is it forced, on a quarterly basis, the different areas in the hospital where radioactive material are used, to get together and to talk about radiation protection issues.

By going with this requirement, we felt that we were giving the flexibility for the licensee to decide what's the best way for their organization to communicate.

We recognized that these procedures would vary from licensee type to licensee type. For example, a very large hospital would have a very elaborate procedure. A smaller facility, just a single doctor's office, may have a procedure that's two lines long that says when I change the contractor for calibrating my survey meter, I'll make sure

that I tell the tech and the receptionist, and that might be it at that type of office.

But basically we're looking for the licensees to figure out a way of how they're going to get information and how they're going to coordinate their radiation protection program.

The other thing with this is that we do recognize that some licensees may choose to continue to have a radiation protection -- I mean, a radiation safety committee, because it works at their facility, but the key here is flexibility.

The last thing that we added under 35.24 is that the radiation safety officer would sign a statement indicating that he is aware that he is radiation safety officer. We have several enforcement cases that we can point to where, when you actually look into the root cause of the problem at the facility, the radiation safety officer says either, "Gosh, I didn't know I was supposed to be radiation safety officer, they never told me what my duties were, they never game me time," things like that. I'm sure you've all heard similar statements from some of your licensees.

But we thought it was important that we put that requirement into the rule.

As far as the level of compatibility, we have assigned a D to 35.24. We have given it an H&S designation, though, and this is something that we probably should talk -- spend a few minutes. I know we're pressed for schedule, but basically whether this should be an H&S designation or not.

Let me take a second and go back and address some of Tom's comments from yesterday on compatibility. The working group went through and assigned levels using the policy to the different sections of the rule.

What went out in the Federal Register Notice indicated what level was assigned to each particular item. After the rule was published, we had several conversations with working group members, with steering group members, and also with state programs and what came out of that is that it was important for NRC to identify what in that particular requirement has the H&S designation, is it all of these things or is it just one of them.

Then in the case where you have designated an H&S category, you need to tell us why you did that, because it's important for you to have that information when you're commenting on whether you agree with our designation or not.

So we have gone through. The working group has done a first cut at designating why items should be designated an H&S. It has not been reviewed by the entire working group nor by the steering group, nor by management. So what I would like to propose at this time is we spend maybe just a couple minutes talking about, at least for the key requirements, whether you agree with the designation of H&S or not and, if not, why not.

Then we'll use that information, I'll have the working group probably conference call over the next couple of weeks or so and talk

about these issues and then go back through the -- using the working group/steering group approach, get some type of blessing to this.

Once that information is available, use office of state programs to disseminate the reasons for why the H&S designation, to get it out into the states. I recognize that the June 12 date holds firm -- June 12 -- I've got June on my mind -- November 12 date for the end of the comment period holds firm, that you won't have that information when you're providing your comments, and I apologize for that, but I want to make sure you're getting the best sets of comments that you can bet.

So I would encourage you, when you do comment, to comment based on the designation that's in the Federal Register. So if we say H&S, come back and say we don't think it should be H&S, we think it should be C or whatever.

But what I'm trying to say here is that we recognize that we've fallen a little bit short on getting you information and if you give us a couple of weeks, the working group/steering group will get that information out to you.

MR. CAMERON: Okay. Cathy, could you just explain for everybody what the designation for this requirement of D and then the H&S, what that means in terms of agreement state flexibility?

MS. HANEY: With the D, it means that it's not required for compatibility, but with the H&S designation, it means that the state has to adopt the essential objective in order to maintain an adequate program.

MR. CAMERON: Thank you. Let's go for comment on the compatibility designation or the rule itself. Jake?

MR. JACOBI: Just a note that having people sign records is -- putting that as a requirement, it's not necessarily performance-based.

MS. HANEY: That is true and this is where there are -- I've already admitted there are parts where it is a more prescriptive rule and the Commission gave us the flexibility to have a more prescriptive rule in some areas, and because of the enforcement cases we could point to, we felt that it was important to cite that.

MR. CAMERON: Cathy, in terms of the H&S designation, in this context, the requirement to have a radiation safety committee is deleted.

What would it mean that the state would have to have to fulfill the basic objective of not having a radiation safety committee?

MS. HANEY: I believe that I will ask for help from members of OSP that were on the working group if they want to come to my rescue.

They would need to have these three items addressed some way in their rule.

MR. CAMERON: Okay.

MS. HANEY: If they still wanted to have a radiation safety committee required in the rule, as long as the committee would get involved in those three things. If the essential elements of those three things were adopted, then it would be acceptable.

MR. CAMERON: Okay. The basic explanation, though, is that they could -- if they thought that the licensees in their state should have -- there should be radiation safety committees, they could have that requirement.

MS. HANEY: Yes.

MR. CAMERON: All right. Let's see who we're going to first. Aubrey? Go ahead, then we'll go to Steve.

MR. GODWIN: I guess my comment is in the larger institutions, I think there is a need for a radiation safety committee and I think it serves a pretty valuable function. It assures some coordination across departmental lines and I think you're making a mistake by deleting it as a requirement in your program.

Now, for non-institutions, you don't need it, I agree. But where you have an institution situation, I think you do need your committee operation.

I'm not sure how you got the H&S on it, other -- I guess it's that coordinating function. Management is responsible for that anyway as part of the operation of their license and I'm not sure I could -- I would agree with the H&S part. The D part is probably appropriate, but I think that you really need a committee and ought to keep it in that, but still compatibility ought to be in D.

MR. CAMERON: Thanks, Aubrey. That's a view on the radiation safety committee. Steve?

MR. COLLINS: Steve Collins from Illinois. The NRC staff and, I believe, the MRB, in its bottom line question to determine

whether or not the essential objective is met, the test has been does the licensee have to do the same thing.

If you answer yes to that, it doesn't really matter how you phrased your rule to get to it, but that's the question they ask, is did the licensee have to do the same thing. If the answer is yes, then you've met that test.

MR. CAMERON: Any of the state programs people want to comment on that at all? Paul?

MR. LOHAUS: Paul Lohaus. A couple thoughts. One is in referring back to the process that the working group went through, I think one important aspect is to very clearly define the essential objectives or the intent of this section. I don't have the section in front of me, but in looking at that, what are we really trying to accomplish with that section.

I think as Steve pointed out, one of the criterion that we've tried to use to draw judgment which would indicate when a requirement, let's say, is outside of the bounds of meeting that essential objective is that if you looked at what actions a licensee would have to take to comply with NRC's requirement and the actions that would be taken to comply with the state's requirement.

And they're basically the same, but I think the essential objectives are, in fact, being met. If there's different actions that are required, then it may indicate that it's outside of the bounds of that requirement. So that's at least one criterion that could be applied in making a judgment.

But I think the first thing, and referring back to how the working group approached this was to really try and very clearly identify what's the purpose, essential objectives of that requirement that -- what's the intent.

Another thought, too. When I talked yesterday, I talked about applying the criteria and following the process. In this case, in looking at the health and safety criterion, one of the things, again, that the working group did is it looked at requirements that were significant from a public health and safety standpoint and those requirements that seemed to have a very, very high threshold, because really all of the requirements have a health and safety base.

But there were some that really seemed to rise above that and the working group did try and identify or define a criterion and the criterion is that if this requirement was not in place and at least one event occurred, at the most two, that the absence of that requirement in concert with those events could result in an exposure that would exceed the basic radiation protection standards in Part 20.

In a sense, it is, in some cases, a very difficult criterion to apply. In other cases, it's relatively easy. But I think if we look at the requirement and say if that requirement was not in place, are there certain situations that could occur or events that could occur because of the absence of that requirement that could result in the basic radiation protections standards that are set out in Part 20 being exceeded.

If the answer is no, then it remains as a category D, not required for compatibility, and although there's a health and safety significance to the requirement, it really doesn't rise to the level where it should be identified as one that a state should adopt in all cases.

That's what we're really trying to, I think, identify with the health and safety requirements. If the answer is yes, then it really ought to be identified as health and safety.

I might ask Roland or Aubrey if they'd like to comment here, too, because we spent a lot of time as a working group trying to define this and the idea was we didn't want to have a lot of requirements identified as H&S, but there are some that have a significance that really should be in that category.

So just for a process point of view for the group, is that if they disagree with the conclusion that these three requirements, with the dashes in front of them, might lead to such a result, they could say you don't really need this to be a health and safety designation.

MR. LOHAUS: That's correct. What Cathy was referring to is that when we looked at this, we said there's really not enough information about the rationale, what events could occur, why that really rises to the level of health and safety, and one of the things that we sort of tasked ourselves to do is to go back and go through that process, identify the rationale, and then set that out so everyone could have a chance to look at it, and it provides, I think, a much more

meaningful basis for comment and for reaching a collective decision, does that rise to that higher threshold.

MR. CAMERON: I suppose that would be one rationale for extending the comment period from the agreement states' point of view, is that they need more information on indeed what the rationale is for the compatibility designations in the proposed rule.

MR. LOHAUS: Sure.

MR. CAMERON: All right.

MR. LOHAUS: I don't know, Roland or Aubrey, if you want to maybe amplify or add to that, but try to capture that thought process we went through.

MR. CAMERON: Aubrey passes.

MR. FLETCHER: What I recall, and it has been a while ago, but I know that when we looked at the specific rules that we were trying -- we were trying to make every effort to get as many category C, if you will, to give states more options as possible.

But when we got to a situation where a rule specifically was a C, but if we asked ourselves a question, what if this isn't done, you know, what if there is no requirement for this, is there a health and safety implication, and that's really the test that we kept using.

Even though we tried to give maximum flexibility, we had to ask ourselves if this isn't done, is there a health and safety implication.

MR. CAMERON: So I guess that's the question for the group, too. If these three requirements in front of you aren't done, is there a health and safety implication. Let's go to Aaron and then to Ed.

MR. PADGETT: My comment isn't specifically on that. I just wanted to support Aubrey's comments earlier. I believe by taking out the requirement for a radiation safety committee, that we are making a mistake and one that will bite us as we go down the road.

I do think a lot of the specificity that we had associated with that could have been taken out, but I hate to see us lose the radiation safety committee.

MR. CAMERON: Thank you. Let's go to Ed and then to Marcia, so she doesn't have to stand up there long, and then we'll go over to Gene.

MR. BAILEY: I guess after hearing that explanation, Paul, I'm a little -- since we have to have Part 20 anyway, why would anything, any other requirements other than Part 20 be related to health and safety in such a way that the dose limits in Part 20 would be exceeded?

Interlocks on irradiators are not necessarily absolutely necessary to prevent -- or for someone to stay within those limits.

I'm saying you've already got the requirement that you will not expose them to that and how a licensee or registrar goes about doing that, it can be locked, it can be a lot of different things. So to make those a health and safety seems to me to be going beyond Part 20. You're going beyond what you need to meet the objectives of Part 20.

MR. CAMERON: I would ask that you apply that to looking at these specific requirements, too. Go ahead, and then we'll go back to the table.

HOWARD: Marcia Howard, Ohio. When I was looking at this, I looked not just at the radiation safety committee or lack thereof. I looked at the title of the section, which is the radiation safety program, which, in my eyes, would be a health and safety issue if it were lacking.

It's not just the radiation safety committee, but the title of that whole 35.24 section which is the radiation protection program.

MR. CAMERON: That's another interesting twist perhaps on this, what exactly is that designation being applied to, because if you look at it in light of the whole program, you might reach a different conclusion.

Gene?

MR. MISKIN: When we issue a broad license, we want to make sure that the credentials on the people on the radiation safety committee and if you eliminate that, what you're, in essence, saying is that management is responsible for those decisions.

So it seems to impact on the broad license.

MS. HANEY: This particular regulation wouldn't require to broad licenses in NRC space that are issued under Part 33. But if you get away from the broad licensees and just talk large medicals that are Part 35 licensees, you're right.

Essentially what we've done is shifted the burden from the radiation safety committee and put it with the licensee.

MR. CAMERON: Okay. So obviously I think you can see the implications of that. Let's -- Jake, do you have something to say on this? Then we'll go over to Bill.

MR. JACOBI: I guess today is my day for asking for clarifications. I've got another clarification. What is meant by management? Is it the CEO, the COO, is it the head of one department when you have multi departments? Is it the person in charge of all the departments?

If a hospital has clinics around town and something affects just one of the clinics, is it the person in charge of that particular clinic?

Could you clarify what management is?

MS. HANEY: We did define it and short of looking up the words here, it would be the chief executive officer, as defined in 35.2 right now.

MR. CAMERON: Okay. Thank you. You may need to -- the suggestion is maybe you need to take a closer look at that.

Let's go to Bill and then over to Ed.

MR. DUNDULIS: Getting back to Aubrey's comment. I agree that in the typical one doctor private practice, the radiation committee may be somewhat redundant. But I think I would concur with Aubrey that in the institutions, it's essential for radiation safety because in these days of consolidation and mergers and buyouts and budget cuts, if

you don't have a committee for something, then it kind of gets shuffled aside.

And if we have a committee, you know, where you're basically designating a relatively senior manager be part of it and you're telling them that they've got to meet quarterly, then at least four times a year, hopefully, that senior manager is going to realize how important a radiation safety program is and what funding is needed to make sure that any potential safety issues don't become real safety issues.

Whereas just dumping the ball in management's court and particularly in light of the fact that management is the CEO, I think it's going to be the squeaky wheel gets the grease. If there is not a vehicle to get word to senior management, they're going to assume everything is okey-dokey until the proverbial excrement hits the air circulating unit, and then everyone is going to go, well, why wasn't I told about this.

So I think I would opt maybe for a split track. I mean, I agree with the level of compatibility, but I think that if you're going to drop it, drop it for the sole practitioners, but keep it for the institutional non-broad medical licenses, because I think that if you eliminate it, it's going to come back to bite you.

MR. CAMERON: Thanks. Let's go to the final comment up here, to Ed.

MR. BAILEY: I guess I've lost how we do licenses, but I have always assumed, maybe incorrectly, that I was not licensing the

authorized user and I was not licensing the RSO and I was not licensing the radiation safety committee. I was licensing that institution.

As that being the person who is licensed, the management of that institution has always been responsible. I mean, our standard practice is when we do an exit interview, we want to talk to the administrator of the hospital or whatever.

So I don't understand that this apparent shift in philosophy, unless it's just sort of messed up in the stating of it.

MS. HANEY: It's probably messed up in the stating of it. We would still -- we're the same way, we hold the licensee responsible. The way 35 is set up right now, there are some functions that are the radiation safety committee's and this is just -- with the radiation safety committee requirement gone, these requirements needed to go somewhere and we felt that it was important enough to explicitly state that it was the licensee's responsibility, but we're not changing any of the licensing philosophy in this area.

MR. CAMERON: Any further comments from the audience?

[No response.]

MR. CAMERON: Cathy, can you go into the quality management issues?

MS. HANEY: Sure.

MR. CAMERON: And when we get to the end here of this last section, I'm hoping that maybe we don't need to do it, but I want to get your opinion on that. So whatever you guys want to do.

MS. HANEY: In the case of the quality management program, the working group and NRC deleted the requirement for a stand-alone quality management program. However, there were certain elements of the quality management program that we thought should be maintained.

These elements really go back to the Commission's direction in the March SRM that we could use a combination prescriptive-performance rule in this area, but we still needed to maintain a couple of key items, and it was only the key items that we maintained.

There are two new sections, 35.40 and 41. We still have the same requirements for written directives. We didn't make any changes in what would require a written directive. Then we have required that written procedures for administrations, requiring written directives be developed that would provide high confidence that the patient's identity is checked and that each administration is in accordance with the written directive.

We use the term high confidence there to get away from the absolute, where you could say that every medical event was a violation and hence the use of the term high confidence. We really just carried through in that case what was in the existing rule.

The other thing, I guess, is of interest here is the compatibility designation. The Federal Register notice indicates this at a C level for compatibility. So, again, we can spend some time discussing whether C is appropriate or not.

One last item, and then I will turn it back to Chip, is that in the rule, in 35.41, under this particular item, this last item, you will see that there are three or four tiers under that or not tiers, but additional requirements there, and those were items that, again, started out in the reg guide, in the NUREG, but we found that they were very key to what we believed is assuring that the administration is in accordance with the written directive, and hence we brought them back into the rule.

MR. CAMERON: Thanks, Cathy. And just to make sure everybody understands the compatibility level, C level, in this context, means?

MS. HANEY: It means that the essential objectives should be adopted to avoid conflicts, duplication or gaps and the manner in which the essential objectives are addressed may be different than that used by NRC.

MR. CAMERON: So it's not a verbatim adoption.

MS. HANEY: Correct.

MR. CAMERON: What do people think about what's been done in terms of quality management, including the compatibility designation here? Any concern?

[No response.]

MR. CAMERON: I guess that means it's acceptable. Perhaps not. Joe and then Aubrey.

MR. HILL: I see it as a big improvement. They finally realized that what they had done was a mistake and we avoided that

pitfall. But the couple of items that they had, I mean, it's hard to disagree with those. They're pretty essential. So it's good.

MR. CAMERON: Thank you. Aubrey?

MR. GODWIN: I think there needs to be understanding that the written directive part may not appear in the radiation regulations, and many states have written directive requirements in other parts of their medical practice act or somewhere else in their law.

So the state radiation program may not be the one actually adopting that and there needs to be credit given to that.

MR. CAMERON: That's a good point. Cathy, is there such a recognition, have we thought of that, that maybe the requirement may be incorporated outside of the state radiation protection program?

MS. HANEY: I guess I would maybe call for help. I would assume that that would be acceptable with a C designation, that the requirement for a written directive would appear outside of the rad protection program requirement, as long as there was a requirement somewhere.

MR. LOHAUS: That's correct. The C designation provides that as long as the essential objectives are met, they can be met in a different way, but as long as they're there and covered, that would meet the component C compatibility criteria.

MR. CAMERON: Okay.

MR. LOHAUS: Just one additional point. Steve mentioned the alternative legally binding requirement. This is another change that occurred with the new compatibility policy and it does provide greater

flexibility, that you can handle the requirement through a different means, provided it's generic and it accomplishes the objective, and it's legally binding.

MR. CAMERON: Thanks, Paul. Roland?

MR. FLETCHER: That's what I was going to point out. The terminology that we agreed on was that it be a legally binding requirement.

MR. CAMERON: All right. Ed, have you got a comment?

MR. BAILEY: Yes, and this, to me, will sort of be what our inspectors would be facing without written procedures.

Would our requirement that the physician be physically present when it's administered do away with the requirement for a written directive? Does the doctor need to write themselves a written directive to administer the material?

MS. HANEY: The way the rule is currently written, you would still have to do a written directive.

MR. CAMERON: Even though the requirement that the physician was present might satisfy the same objective that the written procedures. I guess that's the question.

MS. HANEY: That's the question, yes. I'm answering it that the proposed rule right now would not give -- would not acknowledge that, but that's not to say that obviously if you would like us to consider that, we can consider that in the final rule-making.

MR. CAMERON: Can you tell everybody what compatibility designation would allow the California procedure to satisfy this?

Cathy, I hate to make you walk through all this compatibility wonderland, but --

MS. HANEY: I feel like this is a test here.

MR. CAMERON: Cathy or Paul. I mean, essentially, what would allow that to do that, Paul?

MS. HANEY: Maybe a C would do it. Would a C do it, Paul? If I re-look at this definition.

MR. LOHAUS: I think part of the key here would be the enforceability and whether that would be applied generically, because part of the concept, as I understand it, of the legally binding requirement is that it has to be generic, has to be applied uniformly, and has to be enforceable.

If you were able to demonstrate that those three aspects were met, I believe that that would meet the spirit of the component C. But this may be an area that we need to take a look at and think more about, but that's an initial reaction. But I think the key point would be whether it really clearly can be identified as a legally binding requirement that provides an alternative to having it set out in a regulation.

MR. CAMERON: But, I think, isn't that -- I don't know if that really gets to the issue here. You could have the authorized user being present could be a legally binding requirement, but you still need to address the issue of whether we're requiring the state to have written procedures, and that's the only way to meet that requirement, or if they can show -- if you look at what objective the written procedures

are supposed to accomplish, if they can meet that through another mechanism, is that okay for them to use that.

I think that's the key question.

MR. BAILEY: Let me make it simpler. Let's say the physician administers the material directly themselves. It's my understanding that the purpose of the written directive was to prevent misadministrations, to prevent the doctor's prescribed dose that they wanted to give somehow getting confused in the process of going from the tech to the pharmacist to so forth.

And if the doctor is administering the material themselves, I don't see that -- I think you've met that objective.

MR. CAMERON: Let's get Don's take on this. Don?

MR. COOL: We're going to need to talk about this a little bit more, but I've been sitting here thinking about it and talking with Cathy and, in fact, you may be exactly right.

Given that the objective is to make sure that that which the physician wants to happen happens and that written directive that is, in certain circumstances, where we're dealing with fairly substantial quantities of material, we want to make sure that there is a trail.

If you have a legally binding requirement that puts that physician at the point, then I think perhaps you could argue that that objective has been met.

We'll have to talk about that a little bit more, but I think you may, in fact, have a process where you could say that that achieves the same objective. MR. CAMERON: Good, thank you.

MR. COOL: So perhaps this is exactly the kind of discussion of points about other ways to accomplish the same thing.

MR. CAMERON: Okay. Terrific. Anybody in the audience on quality management?

[No response.]

MR. CAMERON: Okay. Next up is reportable event. Cathy?

MS. HANEY: There are a couple of things that we addressed under the reportable event areas and that being precursor, reporting of medical events, and at what threshold, and then there is an additional new reporting requirement in the rule and that has to do with reporting doses to embryo, fetus and a nursing child.

We'll start out with the medical event definition. We made very little changes to the current requirement, but we did make some, and our reason for making changes in this area were we wanted to address two things.

One was patient intervention and then the second item we wanted to address was what's been coined, at least in NRC space, as the wrong treatment site, and the wrong treatment site being the case where, say, a source came out of a holder laid next to the person's leg for 15 minutes or an hour, the leg got a dose.

Maybe it was only 100 millirem, but if you look at the written directive, the leg wasn't supposed to get anything, hence, by a legal definition, it's a medical event, and that has caused us a lot of problems over the years.

So we restructured the rule to say, first, that you had to exceed the dose threshold, a dose threshold, and that being the five rem. So in cases where the source did lay next to the leg for two days before someone discovered it, then we do want to hear about it. But if it was just the five or 15 minutes and there were -- the licensee's internal procedures of checking these patients caught it, that's fine, we don't need to hear about that particular event.

So we also added a requirement, as I said, for patient intervention and we worded it such that it would not be a medical event, would not be reportable if it was a result of patient intervention that could not have been reasonably prevented by the licensee.

Now, I recognize that that's a little bit of gray wording there, because what the licensee may call patient intervention may not be what a regulatory body calls patient -- would call intervention, but this was our best attempt at fixing those two problems.

So at all the public meetings, this is one of those big areas. If you can think of a better way of addressing these two issues, please tell us, and I would be very interested in hearing about them.

Let me go on to the next slide. I referenced the precursor events. Just a little short history on that. The Commission did tell us to look at ways of identifying precursor events. We spent a lot of time last year defining what a precursor event was. We got it down to -- just came up with the objectives.

We wanted to capture events that could then -- circumstances that could lead to systematic errors or systematic problems. We

discussed this with different stakeholders. We went back to the Commission with a Commission paper giving the -- citing the pros and cons of including precursor events.

In the final rule, they directed us to remove any requirements to report precursor events. This was on the basis that the current reporting requirements in Part 20 and Part 30 of our regulations provide us with adequate information and we did not need a prescriptive requirement in Part 35.

They also told us to go issue an information notice just to heighten people's awareness of this particular requirement, the requirements in 20 and 30 as far as reporting.

I don't have a slide or a viewgraph on the third area of reporting that I mentioned, and that being the requirement that was added to the rule to report doses to a nursing child or to a embryo fetus. That's in 35.3047. To give you a little history of that, NRC needs to report certain events to Congress.

Everyone is probably familiar with what is referred to as abnormal occurrences. One of the AO criteria is that you report events such as this to the Commission and to Congress.

The Commission came back and said how can we report it if no one is telling us about them. So we said, okay, their point, so we included this requirement in Part 35. There are several questions in the Federal Register specific to this particular item and I would encourage you to look at the Federal Register notice and maybe focus

your comments on answering a couple of the questions that we ask in this particular area.

We put a dose threshold for reporting for those particular items in there because we didn't need to hear about it at every particular -- all the cases. So we wanted to -- considering the risk-informed nature, we wanted to throw that into the rule.

The other thing to note in this particular area is that this is unintended dose. If the authorized user knows that the woman is pregnant, knows that the woman is nursing and chooses to administer the material, that's fine, that's -- you know, we don't want to hear about that.

It's only the case where the authorized user did not know about it up front.

The other thing is this has been referred to as NRC's pregnancy rule. It is not -- we're not -- this is not a de facto way of getting people to assess -- you know, that you must assess pregnancy status.

We looked at the standards that were available and it was very clear that all the professional standards had a statement on when it was necessary to do pregnancy testing and we opted to rely on those and we took the approach of only when the standard didn't work and something went wrong, that's when we want to hear about it.

This is just a reporting to NRC. I apologize that I don't have a viewgraph on it, but you may want to focus some of your comments in that particular area.

As far as the level of compatibility, all these reporting requirements are assigned a C level.

MR. CAMERON: And C means it doesn't have to be there.

MS. HANEY: C is -- if I read this enough times, I'll know it by heart. And I'm not going to mess up, that's why I'm reading it. C is that the essential objectives should be adopted to avoid the conflicts, duplication or gaps. But back similar with written directives, there are various ways that would be recognized as acceptable for adopting the requirements.

MR. CAMERON: Anybody have concerns or support for the way this particular portion of the rule has been done, any comments on the compatibility designation? Any clarifications? Kirk?

MR. WHATLEY: Just one real quick one. Section 30.45 contains a statement that the Commission recognizes that the standard of practice for authorized users is to assess the pregnancy or nursing status of their patients.

I would point out, on NRC's current and proposed rules, the authorized user is not required to examine the patient, review the patient's chart, consult with referring physician prior to administration of diagnostic doses, not requiring a prescription.

If that statement is true, I think the Commission has been given some inadequate and inaccurate information.

MR. CAMERON: Cathy, a response to that?

MS. HANEY: I think this goes back to our earlier discussion, which was that it would probably be good for us to establish

the requirements for the authorized user and I think if we did, a lot of these concerns would be addressed.

MR. CAMERON: And, Kirk, do you think that would be satisfactory or do you think there's still a problem here?

MR. WHATLEY: There's a problem, to me.

MR. CAMERON: Kirk said there is still a problem to him. Aubrey, do you want to provide us a clarification on this?

MR. GODWIN: I don't know that I'd do that, but whenever you decide on your definition of authorized user, I'm going to be interested in how you can, under the law, have one place where the authorized user does one thing and does something else somewhere else in the same practice of medicine, which is apparently what we're trying to do at this point.

There appears to be a different definition of authorized user in practice for a diagnostic versus therapeutic.

MR. CAMERON: Thanks, Aubrey. Bill, a comment on that?

MR. DUNDULIS: Not this, but it's just kind of another related issue. This is something that's kind of been going on in the past dealing with the therapy area and I notice a lot of the same wording is carried over into some of the same confusion.

Particularly in therapy, not only is dose specified, but how many portals or two views, 180 or three, 120, and under the current one, I've never been able to get a good answer and since the wording is carried over.

If the prescription calls for the dose to be delivered in three segments of three portals and it's delivered one or two and they catch it, particularly with the amount of radiation that's being delivered during therapy, it may be of minor consequence, but, at the same time, it could technically trigger reporting and that's something I've never been to get a good answer on.

If the dose is right and it goes to the right organ, but for some reason it's supposed to be three or 180, is that the wrong site or wrong mode of administration, as is meant by the NRC. It gets to be a big issue for therapy and if it's intended, probably either in some supplementary guidance or something, or if that's not intended, but it is an issue that could come up in therapy just because of the magnitude of doses delivered even during a single treatment.

That's kind of a confusing question.

MR. CAMERON: Cathy, can you shed any light on that?

MS. HANEY: I guess, again, I'm not going to be able to answer it 100 percent. I'm aware that there are some problems in the event reporting criteria and obviously the American Association of Physicists in Medicine has been pointing that out to me, and I suspect their letter is going to really lay it out clearly.

So I'm kind of waiting to hear all those specific comments and to get some input from of the practicing physicists about the best way of dealing with this problem, because I do recognize that it is somewhat confusing and it may not work in all areas.

So I think you will see a better rule as a result of the comments coming in.

MR. CAMERON: Joe, do you have your card up? Okay, fine. Anybody from the audience have a comment on reporting?

[No response.]

MR. CAMERON: All right. The next issue is patient release. I think we heard some data yesterday that may be relevant to patient release from Ara Tahmassian. Cathy, go ahead.

MS. HANEY: I guess this is more just a general discussion, because over the last year I have heard a lot of comments from the agreement state perspective in this particular area.

The working group did not make any changes in the 35.75 requirement from that that went into effect a little over a year ago. So I think a lot of the comments are more directed to the previous rule-making, when we took this and made it a more performance -- not performance -- a dose-based rule.

The previous rule had the 30 millicuries, five MR per hour, at a meter, and we took it to a dose threshold of 500 millirem to the maximally exposed individual.

So this is more an opportunity for the states to go on record with their concerns with this rule-making and if they would like to see changes and what changes they would like to see in this particular area.

35.75 has been assigned a C level. Let me just verify that. Level of compatibility. It has a C and a D, paragraph A, which is where

the 500 millirem appears, is a C and then the remaining paragraphs are a D level.

MR. CAMERON: Are there states around the table who feel that 35.75 should be revised? Are there concerns with 35.75?

MR. FRAZEE: Terry Frazee, State of Washington. One concern and that is that it's 500 millirem basically to the general public. My initial read on the initial petition and everything was for -- the concern was for the family and care-givers, because otherwise they're restricted to 100 millirem for general public.

Up to basically yesterday when I looked at one of the proposals that was brought forward on how to do some of these things, the reference was, well, and we'll check it and if it's no more than 500 millirem to the co-workers, the guy could go back to work. And it's like wait a minute, the co-worker is not -- it didn't sit right with me.

Of course, then you go back, you look at it, well, the rule does say that it's 500 to basically a member of the public. And I think that went beyond what the original intent of the petition was.

MS. HANEY: NRC was responding to a petition when we did the rule-making several years ago. As we evaluated the response to the petition, we opted to go to the 500 millirem to the maximally exposed individual.

I think what you're saying is -- you could argue is, is the maximally exposed -- the dose to the maximally exposed individual equivalent to the dose to someone that's caring for the patient while

they're in the hospital for one or two days. I guess that's an area that we could discuss.

But from the standpoint of the rule-making, we really are talking maximally exposed and if that's going to be the spouse or going to be the child, then that's the individual that you should be concerned about and making your decision to release based on that person, maybe not necessarily based on the dose measurements that were taken in a sample case in a hospital.

But I think that that information is useful in trying to decide and evaluate whether the person -- the spouse at home is going to get greater than 500 millirem.

MR. CAMERON: Okay. There may be -- I don't know, you may need to have an additional conversation on that issue.

Let's go to Aaron, and then to Dr. Caretta, and then we'll go to Jim and to Steve. Aaron?

MR. PADGETT: First, I would like to ask how many states are releasing -- allowing the release of patients up to 500 millirem at this point in time?

[Show of hands.]

MR. PADGETT: Okay. We have been doing it now ever since the rule first came out. We've looked for a way to allow ourselves to do it while we were getting a rule in place, found a mechanism and put it in place. So we are gaining experience with it.

One of the little experiences that we have gained is this; everyone understands what's going on in the medical field and you have

lots of let's call them entrepreneurs out there who are looking for ways to make a buck any way they can, others looking for ways to cut costs any way they can.

So as you implement this, just watch out and be careful of some of the practices that will pop up. They have popped up in our state and we are trying to find them and as we do, strike them down as best we can.

One example of that is this. We had a hospital who decided that if you release a patient, he's released. So, therefore, they can bring him in and zap him, give him the full dose, and release him, as long as he meets the regulatory guide requirement.

But there's a catch here. We're not through with this guy or this patient. We still have some procedures we want t his patient to have performed. So we're going to -- to cut costs, we're going to release him from the hospital after we inject him to go over to this unlicensed place to have these procedures performed.

And we looked at that and looked at the numbers that they would -- the folks over there would be handling, the radioactive material they would be handling, the waste they would be handling, and said, no, not until the judge looks at us and tells us you have to allow that, we're not going to allow that, you will have to license yourselves to bring those patients in and perform these procedures.

So I just put that out as a kind of a warning. There are lots of little nuances that come up unintended, you don't think about up front, but watch out for them because they're sure nipping at our butts.

MR. CAMERON: Thanks, Aaron. I believe that's what you mentioned yesterday, too. Bob, you want to make a comment?

CARETTA: I appreciate your putting me on early. I've got to try to catch a flight at 12:45.

This is one of the issues where the Society agrees with the NRC. This may be a first, Cathy, that we're supporting you, but we think the 500 MR rule is a good rule, particularly because it still retains the physician control of the patient who is being treated, and, in our case, it's usually with high dose I-131, orally or intravenously, for either thyroid cancer or other cancers.

Because the physician has the ultimate responsibility as to whether the patient is going to comply with the instructions, even if they would fall within the 500 MR rule and if we've got a patient who, because of incontinence, because of social situations, because of level of education, can't comply with the instructions, then we are not going to release that patient until we feel very comfortable that there is not going to be a health and safety issue with the public or with the family members.

The other thing I'd like to mention is that there is an article that was just published in the October issue of the Health Physics Journal by Richard Sparks from Oak Ridge and Jeff Siegel and Rich Wall, looking at the need for better methods to determine release criteria for patients administered radioactive material, and their last sentence is the one that I want to leave as a take-home message and

would suggest that you all get a copy of this report and take a look at it.

It said based on their results, the current NRC dose-based methodology for the release of patients administered radioactive materials significantly over-estimates the dose equivalent to others from I-131 therapy patients.

So I think -- this is a peer review journal. It's an article that's been done with great care in dosimetry and I would recommend that you look at that.

The other issue that you need to be aware of is that unless the states and the NRC are going to imprison patients in hospitals, there is no legal way that we as physicians can require anyone to stay in a hospital bed. The patient always has the individual right to sign themselves out against medical advice.

So we can treat a patient with 100 millicuries or 200 millicuries of I-131, we can admit them because we feel medically that's the best way to treat this patient in terms of health and safety, and that patient can demand and will walk out of the hospital without any recourse from the medical community.

MR. CAMERON: Thank you, Dr. Caretta. There is some, I guess, new information for us to consider perhaps. Jim, let's go to you, and then Steve, and then Roger has something, and Jake, Aubrey, dozens of other people.

McNEES: This week I've been here, we've talked a lot about different releases, although sometimes we call them by different things under dose-based methodology.

We started off the week, we had a presenter talking about releasing objects, tools and things that might be contaminated. They kind of give it a key word of clearance and their slide had a dose, a cumulative dose of one MR, one MR per year to the maximum exposed individual.

A little while later in the week we talked about decommissioning rules and the dose-based there. So now we've gone from one up to 25 MR. So if the ground is contaminated with I-131, we can release the ground at 25.

You think about a licensee or a pharmaceutical company processing it, the nearest exposed individual to the place, he has to keep the general public below 100 MR.

Then for a while we discussed GL devices, which started off at the 500 and now it's going to be at the 100. And now we're talking about release of patients, which is the same thing as clearance of patients, as applying to the clearance rule, and we're up to 500.

The point being it seems that we have a tremendous spread in the allowable dose from one to the other and perhaps we ought to reconcile those differences.

MR. CAMERON: Thanks, Jim. That sort of relates to the point Pierce was making earlier about consistency and are there rationales for distinguishing between these situations.

Steve?

MR. COLLINS: Steve Collins, Illinois. Partly a follow-up on the same thing that Jim was talking about. Several years ago, a lot of us were arguing heavily that the standard did not need to be dropped from 500 millirem a year to 100 millirem a year.

I'm a little concerned now that we seem to be all of a sudden concerned about finally being able to get one part of it raised up to meet a need to where it used to be, particularly when ICRP and NCRP recommendations specify clearly that the 100 millirem is for long-term average, not for an occasional case where a patient or a family or even co-workers might get the 500 millirem on a year every now and then.

It does meet the guidance, it does meet the radiation protection guidance that we have, and I really don't think we should be that concerned about it. A lot of members of this group were even arguing that we wanted to keep 500 millirem for NARM, but NRC forced us, using its compatibility tool at the time, since we were supposed to control total dose from all sources to their licensees, to drop it to 100.

MR. CAMERON: Roger?

MR. SUPPES: Another aspect of the variability is the solid waste facilities that typically have alarms, we're seeing a significant increase in alarms in Ohio and investigation of those. We don't know when we get the report what the cause is, but in the last 12 to 18 months, the vast majority of those alarms in Ohio at licensed solid

waste land fills are from our medical radio isotopes, and that where patients have been released and the material ended up in a solid waste collection vehicle and the alarm went off.

And we end up spending a minimum of eight hours, by the time you count travel time, report time, getting out there doing the investigation and the write-up, and there's no way to manage that cost that's associated with those kinds of incidents.

We're seeing 50 to 75 of those kinds of incidents on an annual basis in Ohio.

MR. CAMERON: What's a solution to that?

MR. SUPPES: I don't know that the -- I don't know that we have a solution, per se. But I think it's just another aspect of where you have different kinds of release criteria and different kinds of things that are acceptable, quote-unquote, in different settings, that it's not acceptable in Ohio, by state law, for any radioactive material to be commingled with solid waste, any.

MR. CAMERON: Thanks, Roger. Steve, do you want to do a quick follow-up?

MR. COLLINS: I think I can answer part of your question.

MR. CAMERON: All right.

MR. COLLINS: Part of the solution to that would be in the instructions that the physician is required to give the patient orally and in writing, that those require that specific instructions on not using disposable things, except when you have to, and all of those disposable items that you do use that may be contaminated would have to

be collected, double-bagged and stored at the facility or at the home, wherever they're staying, for decay instead of putting them in that solid waste vehicle.

Illinois is up to almost two responses per week on the average now to land fill monitor trips as a result of --

MR. CAMERON: Do you have such a requirement that you're talking about to try to cut down on that?

MR. COLLINS: Not yet, but we are tracking the number of responses and the amount of time we spend so that next time we amend our fee rules, the category of medical licensees that uses these isotopes is going to be paying for these increased costs.

MR. CAMERON: So then they might have the incentive to do something about it. All right. Jake?

MR. JACOBI: A little bit related to the -- we haven't really discussed it, but somewhat related to the dose to release of patients, and Colorado has adopted NRC criteria for release of patients.

But in the rule here you're also changing Part 20, allowing individuals who visit patients in the hospital to receive up to a half a rem.

One of the bases that we used in approving release of patients with a higher dose was an economic benefit that was associated with that and we thought the risk was acceptable.

But if the patient is in the hospital, you don't have that economic benefit and looking in the rationale in what you have put out for this, you've merely said we believe it will be a benefit or an

emotional benefit and you really haven't met any standard for justifying an increased exposure to people visiting a hospitalized patient.

So before you can adopt that, you need to go back and get some more data and do a better cost-benefit analysis.

MS. HANEY: Okay.

MR. CAMERON: Okay. Thanks. Let's have two final comments up here. Aubrey and Aaron.

MR. GODWIN: I would call this a prime example of my ticket ticker regulation or, excuse me, site ticker regulation, in that when the inspector comes in and starts reviewing the physician's instructions and dose calculations and things, I can almost guarantee you he can come up with a different opinion of whether they were adequate and you'll be at loggerheads for a while deciding which one is right.

It will probably end up in a cite if you've got a real gung-ho inspector.

The other thing is I'm not sure that in developing this regulation that NRC really looked at all the cost-benefit and environmental impact assessments necessary for it, because I'm pretty sure, in fact, there isn't anything for state responses and cost to state taxpayers for us to go out and find out it's another bit of waste, it's because things are being released at a higher level, to go home.

When he goes to a hospital, the hospitals can isolate things and hold them for a little bit, but if he goes to a home and they're on Depends, it will go to the trash because they're not going to be able to hold it very long at the home.

MR. CAMERON: Aaron, you seem to be agreeing with that.

MR. PADGETT: Yes, I do agree with that. They're not going to hold that in the trash at the home very long. It's going to go in the solid waste.

One of the things we have done to try to cut down on the number of responses that we have to make is we tell the land fill, hey, we'll come out the first time, we'll go over it, we'll go down through and try to educate you as much as we can and so forth.

The second time around, though, we expect you to get a consultant to come out and assist with this. Now, we don't stick to that hard and fast, but that's generally something we're trying to follow. So now the land fill is having to pay for it through getting a consultant out there.

Hopefully they'll go back to the folks that sent it to them and send the costs back where they belong.

MR. CAMERON: There is another possible solution. Roland?

MR. FLETCHER: I wanted to comment on what Aaron just said, because we have adopted a very similar policy. It has gone so far that there are some of the collection agencies that actually go and identify if it's coming from a residence and gives further instructions to that residence that if they have to pay for the removal, then they may stop picking up that resident's trash.

We've also put in a strong recommendation to the hospitals because some of the collections, unfortunately, were coming from hospitals that were setting off the alarms, that they get the same type

of monitor that the land fill that they're shipping to has and make the same settings, so that hopefully they can ensure that they don't set off the alarms.

MR. CAMERON: Okay. Thank you. There are some approaches then to dealing with this problem.

What more needs to be said about compatibility other than the fact that it would be very useful for the document that Cathy mentioned for the -- it would be useful for the states to have that document in terms of commenting on the proposed rule.

I get the sense of that from around the table. Does anybody disagree with that or have anything else to say about compatibility? Cathy?

MS. HANEY: I would say I think the only problem is the timing issue, and that was the November 12 comment period. I think it's unrealistic for us to be able to get something out to you that would say the H&S by the November 12 date, only because I want to get you something that's good.

I mean, I can obviously give you what I have right now, but I don't think that's going to help you a lot.

So while I'm very happy and willing to give you something, I think it's just an issue of when you would get it, and we'll try as quickly as we can to get something out.

MR. CAMERON: Okay. Thank you, Cathy. Any other comments on compatibility and this rule before we go to the final point of

business, which is the date for the next year's meeting, if that's indeed what you want to do? Tom?

MR. HILL: I would just like to make one kind of comment, from having served on the steering committee for Part 35. There was a comment mentioned earlier about enforcement issues and I would just kind of like to relay at least one of those meetings that I participated in. There was -- I guess it would be fair to say -- passionate pleading for specificity so that you can write non-compliance items and that went on for a long time.

So just to let you know those issues were talked about and from both sides. I just wanted to make that clear. There are others that were talked about that same way, too, but in that one particular one and one particular meeting, although it occurred several times.

MR. CAMERON: Okay. Thanks, Tom. Roland, could I turn it over to you and Richard for annual meeting?

MR. FLETCHER: Thank you. First of all, I would like for all of us gathered here to extend our appreciation to Chip for facilitating the meeting.

[Applause.]

MR. CAMERON: Thank you. Thank you very much.

MR. FLETCHER: Now, I'm not sure what the best method is to go about this. I had asked earlier for dates when people knew they could not do it, and I guess I'll ask Richard what dates he's looking at for hosting.

MR. RATLIFF: It's really going to depend on what's going on in Austin and what hotel availability there is. You really can't speculate until I go back and check. But we were thinking sometime the first two weeks of October. That would avoid Halloween.

MR. FLETCHER: We're going to avoid Halloween next year.

MR. RATLIFF: And no weekend travel. So it would be like a Monday or Tuesday travel and have the meeting Wednesday, Thursday, Friday.

MR. FLETCHER: Let me just say, if that's the time-frame, please check your calendars for the first two weeks in October and if there is a conflict, if there is a conflict that you know of or anticipate, then you need to let either myself or Richard know, preferably Richard because he's making the schedule.

Are there any other items that this body needs to consider? Diane?

MS. TEFFT: Just a comment on the dates, and I just heard the tail end of it, but I always thought that the first two weeks in October were not good maybe for the NRC, because they may not have funding. Is that true?

MR. FLETCHER: They get a brand new budget on the first.

MS. TEFFT: Well, maybe.

MR. FLETCHER: We're still on the mics, so make sure your comments are on the mic. Is there any reason that you know of right now where the first two weeks in October would not be acceptable? Sometime

during those. And no one here needs a Saturday, and let me clarify that, too.

No one here needs to stay over a Saturday. We will work with that guidance. Is there anything else you need, Richard?

MR. RATLIFF: The only thing, I kept looking back in our past motion stuff we've had, at one time, we did say that we really, to have a resolution or something, we had to have a majority of the people present. When we took the vote on the risk, we didn't have a majority of the people present, and I'm not sure that works with what we've done.

There is nothing set in stone, though, is the only problem.

MR. FLETCHER: Let me ask again. Those who would like us to send a letter to the Chairman of the NRC requesting that the comment period date be changed in order to do a risk assessment and consideration to change the effective date, please raise your hands.

[Show of hands.]

MR. FLETCHER: Fifteen. That's 50 percent. For our vote, that's 16. So I feel more comfortable.

Anything else, Richard?

MR. RATLIFF: All finished.

MR. FLETCHER: Once again, let's recognize Diane's staff for the wonderful job that they have done in setting up this workshop.

[Applause.]

WALTER: David Walter, Alabama. We've gone through Part 35 very quickly today and I want to make an impassioned plea one more time to all of the staff members and all of the directors. It's very bare

out there on the internet. There is not a single state comment and that really makes us look bad, since we're supposed to be the ones that really want to have this early involvement. Let's make use of it, okay? Appreciate it.

MR. FLETCHER: Joe.

MR. KLINGER: Just one thing. Jake brought up a point the other day. He likes it when somebody has a good letter out there and they just make it available to him. I was thinking about this. Why don't we use the conference web site for that?

If you have a letter that you're really particularly proud of and you would like other people to adopt, get it to the conference, they'll put it out so you can download it, you can cut and paste and do whatever you want, and maybe more people would respond to some of these proposals.

Because I know when I face these things, I say I wonder what so-and-so is thinking about. If it's sitting out there on the web site, I know the conference would be happy to do it, I think it would be a good function.

MR. FLETCHER: That's an excellent point, because it's a lot better to start with something than start from scratch. So I agree with that.

I see no other standing at half masse, so I will adjourn this -- I'm sorry, Diane.

MS. TEFFT: No, that's it.

MR. FLETCHER: The meeting is adjourned.

[Whereupon, at 12:16 p.m., the meeting was concluded.]