UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
***
MEETING WITH
ADVISORY COMMITTEE ON MEDICAL USES OF
ISOTOPES (ACMUI)
AND
BRIEFING ON PART 35 QM RULE
***
PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
11555 Rockville Pike
Rockville, Maryland
Wednesday, June 17, 1998

The Commission met in open session, pursuant to notice, at 2:06 p.m., the Honorable Shirley A. Jackson, Chairman, presiding.

COMMISSIONERS PRESENT:

SHIRLEY A. JACKSON, Chairman of the Commission
GRETA J. DICUS, Member of the Commission
NILS J. DIAZ, Member of the Commission
EDWARD McGAFFIGAN, JR., Member of the Commission

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

JOHN C. HOYLE, Secretary
KAREN D. CYR, General Counsel
L. JOSEPH CALLAN, NRC
CATHERINE HANEY, NRC
DONALD COOL, NRC
MAL KNAPP, NRC
JUDITH STITT, ACMUI
JOHN GRAHAM, ACMUI
NAOMI ALAZARKI, ACMUI
DENNIS SWANSON, ACMUI

P R O C E E D I N G S

[2:06 p.m.]

CHAIRMAN JACKSON: Good afternoon, ladies and gentlemen. Today the NRC staff and the NRC Advisory Committee on the Medical Uses of Isotopes, a.k.a. ACMUI, will provide the Commission with its annual briefing. The Advisory Committee last met with the Commission in April 1997 and a lot has happened in the ensuing year.

In June 1997, in a June 30th staff requirements memorandum, the Commission approved the staff's plan for

revision of both 10 CFR Part 35 and the Commission's Medical Use Policy Statement. The staff has proceeded in an expedited manner to develop the proposed draft rule language over the last year by establishing a working group and a steering group that included NRC headquarters and regional licensing and inspection staff, and representatives of the Organization of Agreement States and the Conference of Radiation Control Program Directors.

The program to revise Part 35 and the associated guidance document has provided more opportunity for input from potentially affected parties than is provided by the typical notice and comment rulemaking process. The staff has held multiple meetings with the public and professional societies and boards, have placed a straw man version of the rule on the Internet for comment, and met extensively with

the ACMUI and members of its subcommittees. I should say, parenthetically, that the Commission itself has had a number of visits from various groups with interests in our revision to the rule.

Today the staff will brief the Commission on the results of these activities, focusing on the more significant aspects of the proposed revision of 10 CFR Part 35 and the medical use policy statement. The ACMUI's presentation will follow the staff's, since their slides focus on points of agreement and disagreement with the staff's proposal.

Now, I understand that copies of the viewgraphs and copies of the two papers are available at the entrances to the meeting, and I welcome Ms. Haney, who we have not had the opportunity to hear from before. So, unless my colleagues have anything to add, Mr. Callan, please.

MR. CALLAN: Thank you, Chairman. Good afternoon. Good afternoon, Commissioners.

As you pointed out, Chairman, we are taking the unusual step of having the staff to go first to brief you for the reasons that you stated, and then we will be followed -- I am not going to rely on the acronym, I am going to say the Advisory Committee on Medical Uses of Isotopes.

[Laughter.]

MR. CALLAN: But we promise we will not leave after our presentation, we will stay and --

CHAIRMAN JACKSON: You didn't see the shackles that we --

[Laughter.]

MR. CALLAN: And we will be ready to come back to the table to respond to any questions you may have after the Advisory Committee's presentation.

Ms. Cathy Haney will be our principal presenter. Cathy.

CHAIRMAN JACKSON: Please, go ahead.

MS. HANEY: Basically, what I would like to do is to tell you -- go over what we will start with. We will discuss the process and the schedule, the approach, a discussion on the medical policy statement, the cross-cutting issues and the net impact on licensees from a burden standpoint.

For the process, as you said, we did use a working and steering group approach to develop the rule alternatives. We also used that same approach in developing alternatives for the medical policy statement. This group also developed what we call alternatives for the

cross-cutting issues. The cross-cutting issues being things that addressed all areas of the programs, whether we are talking diagnostic or therapy uses, things such as Radiation

Safety Committee Quality Management Program.

We held several facilitated public meetings to get input from the stakeholders. It was well attended by professional societies. And, as you said, we placed a straw man on the Internet in January. We received approximately 330 comments during this rulemaking process. The majority of them focused on training and experience. The remainder focused on the more technical areas of the rule.

With the approach -- as I said, we started out with identifying cross-cutting issues. These were primarily -- and the issues that were noted in the staff requirements memorandum. We have -- or we are proposing a change in licensing philosophy, as we have come to call it, which will reduce the amount of paper work that the licensees will bring to us at the time of amendment or license application. This being that we -- NRC would no longer review the procedures that the licensee has. They will still be required to have those procedures, but the licensing staff would not be reviewing. We estimate that this could impact -- reduce the amount of licensing, the time to review a license application by up to 50 percent, in that area.

CHAIRMAN JACKSON: What is a typical time frame for reviewing a license application?

MS. HANEY: It varies whether you are talking a broad scope, which is the larger. In that case, the average

may be as high as 70 to 100 hours. In the routine -- I say routine -- specific licensees, your smaller community hospital, maybe in the 10 hour range. Then license amendments, depending upon the complexity of the issue, would be slightly less.

We have developed a guidance document. It's following the same format that was used for the consolidated licensing guidance that we have put together before. We have been careful not to include any specific requirements in the guidance documents. This was one of items that the public mentioned that we should not do, if there were any requirements, they should appear in the rule.

The last thing that we did from an approach standpoint was to rely on requirements in other portions of Title 10. For example, if there was a requirement in Part 20, we did not -- we deleted the requirement from Part 35, figuring that the requirement in Part 20 was adequate.

To move right into the medical policy statement, this was an area where we received a large amount of comments from the public, and there were also a wide variety of viewpoints that were expressed by these individuals. The key elements that are the items that the working group felt were key elements in developing a proposed policy statement was that the policy statement should provide for the radiation safety of workers and the public, that we did not

want to intrude into medical judgments, that was at the discretion of the physician and, also, we wanted to focus our regulation on assuring that the use of radionuclides is in accordance with the physician's directions.

With those things in mind, the staff is proposing a revision to the medical policy statement. I won't go through line by line, but there are a few items that I want

to focus you to. In the first item -- bullet, basically, we are just doing a change in terminology there. There is no change in the scope or intent of the regulations. The current policy statement says medical use of radioisotopes, and we are just changing it to radionuclides to be more accurate.

In the second item, we are changing -- proposing a change from "minimize intrusion", which is what is in the current policy statement, to "will not intrude". We made this change at the advice of the ACMUI.

In the third item, this is where we bring in the focus that radionuclides are used in accordance with the physician's direction.

And in the last item, we have made a change there. The corollary statement in the present policy statement says that we will rely on industry standards. We are proposing that we use the term "will consider industry and professional standards" and we believe that this is more

consistent with identifying key objectives in the rule, putting the requirements for the objective in the rule that the licensee needs to meet and then putting the putting the more prescriptive requirement -- or more prescriptive requirements would fall to the industry standards for implementing the objective.

CHAIRMAN JACKSON: Let me ask you a question. I mean you have in this bullet 3, the phrase "where justified by risk" and that seems to indicate somehow perhaps a set point that would justify NRC's intervention or interceding on behalf of a patient. Do you have a qualitative, a quantitative idea of how you would arrive at that judgment?

MS. HANEY: What I would offer is that in the low -- the diagnostic uses of medicine are your low risk areas and your therapy area, therapeutic uses, for example, the teletherapy, the use of high dose rate remote after-loaders, those would be the high risk therapy areas, and that -- that's really where we would be looking at were justified by the risk.

CHAIRMAN JACKSON: And what do you -- do you define what you mean by radiation safety for a patient?

MS. HANEY: I think we do in the last statement where we are saying to assure the use of radionuclides is in accordance with the physician's directions. We would not question the physician's judgment. However, once the

physician makes a determination of how much radiation the patient should receive or the treatment, at that point NRC would pick up their regulatory authority and there we would be looking at instrument calibration, things such as that.

CHAIRMAN JACKSON: So exposures beyond what the physician would --

MS. HANEY: Correct. Or that differ from what the physician said.

CHAIRMAN JACKSON: Okay. Thanks.

COMMISSIONER McGAFFIGAN: Could I? I am having a little problem with the "will not intrude" into medical judgments as opposed to "minimize intrusion", which is what the 1979 policy statement says. I am a Commissioner who is going to be reluctant to give up patient notification, and I don't know whether the -- and I believe the medical community will say I am, therefore, intruding medical judgment affected patients. And so, can one be for patient notification and for "will" -- you know, the blanket "will not intrude", as opposed to "minimize intrusion"? The 1979

Commission was consistent. They minimized intrusion but they felt patient notification was important.

MS. HANEY: I believe you could support patient notification under Statement 3 of the proposed medical policy statement, provided we maintain the clause in the rule that says that if it is the -- at the discretion of the

physician, the patient should not be notified. I felt it could be justified under 3 because you are requiring notification following a medical event, and the medical event would be an example of where the physician's directions were not carried out and, therefore, that would give us the step into being able to notify the patient, justified under this statement. Even with the "not intrude" in Statement 2.

COMMISSIONER McGAFFIGAN: Okay. The 2 statement -- it may be more honest to say "minimize intrusion" rather than "do not intrude". Just, at first -- at first glance -- but we don't have to dwell on that. We will probably have a good discussion later.

CHAIRMAN JACKSON: And certainly in the Commission process. Thanks. Okay.

MS. HANEY: As I said, there were several cross-cutting issues that the group addressed, and I will go briefly through these. We do have some backup slides that go into greater depth if you would like us to go there, but I will just give you a two sentence version on each one.

On Radiation Safety Committee, in accordance with the performance-based approach to the rule, we are proposing that the Committee no longer be required. We have identified key elements that the Radiation Safety Committee currently perform and those items we have listed in the rule

and made them the responsibility of the licensee management.

COMMISSIONER McGAFFIGAN: Are your two sentences finished on that?

CHAIRMAN JACKSON: Let her finish. Let her finish.

[Laughter.]

MS. HANEY: Well, my two sentences are finished. That's two sentences. I'm okay.

COMMISSIONER McGAFFIGAN: On that item, I just want to make a -- the Radiation -- the basic rationale for giving up the Radiation Safety Committee is that there are other committees at hospitals that might be able to carry out this function, is that the thought?

MS. HANEY: That is one of the reasons. Another reason is that we want the licensee to have flexibility in how they manage their program and, in that, if there are other committees in a hospital forum that would allow them to address this problem. But we are also extending this particular proposed section to cover all licensees, just, again, to make it more explicit that there are some basic things in the Radiation Protection Program that we expect the licensees to do.

COMMISSIONER McGAFFIGAN: But is there a chance that radiation safety gets lost, if there isn't a Radiation Safety Committee, in a big hospital where people have lots

of other things to worry about besides radiation safety?

MS. HANEY: It's always a potential for that to happen. I think, given today's structure for the hospital setting with the Joint Commission on Accreditation of Health

Care Organizations, JCAHO, they require certain committees in a hospital now, one being a committee to review risk, and that would be an ideal location for radiation safety to fall under. So, yes, there is a potential, but I think in the hospital setting where the risk is the greatest, there are other committees that are in place, required by other organizations, that would address this item.

COMMISSIONER DIAZ: If I may follow on that question. I don't think it's the issue of the committee, are the functions that are required for the protection of health and safety that we envision should be carried out, are they going to be addressed by someone that will have accountability on those issues?

MS. HANEY: I believe the rule as proposed does that, in the Section 3524 where we --

CHAIRMAN JACKSON: Makes it clear that is a fundamental requirement.

MS. HANEY: I believe -- I believe so.

CHAIRMAN JACKSON: Okay. Why don't you do on.

MS. HANEY: Okay. Moving into quality management, again, we took a performance-based approach there. We have

deleted the current requirements as seen for the Quality Management Program. However, we have focused in on confirming patient identify, requiring written directives, and verifying dose. The licensees would still need to be required to have written directives and then they would need to develop procedures, develop, implement and maintain procedures for verifying patient identity and verifying that the correct dose is given to the correct patient.

COMMISSIONER DIAZ: Is this risk-informed on a certain way, or are you cutting across all procedures?

MS. HANEY: I believe it is risk-informed because the requirements for the written directive are in your therapy area and your high risk procedures. We really did not make any changes, or I should say significant changes to when a written directive is required and the procedures, the requirement for having procedures flow out of if you need a written directive.

The third issue is that of reportable events. There are two items that fall under this -- one, it being medical events, which we are proposing to change the term from misadministrtion to medical event, and then the second item being precursor events.

We have made some minor changes in the Medical Event Reporting to address two items that were brought to our attention by the public, one being patient intervention,

and the second being wrong treatment site.

In the area precursor events, we have included a requirement for reporting precursor events. We have, however, focused the definition for precursor events to events that would have implications beyond that specific licensee's facility.

In the case of notification following a medical event, the proposed rule contains the essential requirements as they appear in the current Part 35.

Then moving into training and experience, training and experience was one of the big issues of this rulemaking and if you would turn to the next slide, I do have a slide on this one.

CHAIRMAN JACKSON: Let me just ask you this question as a generalized comment. On all the cross-cutting issues, you know, obviously I think we are interested in

moving to a risk-informed and as appropriate performance-based approach question is the rule enforceable in your opinion?

MS. HANEY: Yes.

CHAIRMAN JACKSON: Okay.

MS. HANEY: Staff is proposing the requirements for training and experience be risk informed and focused on radiation safety. That was really our focus on going into making any proposed changes in the training and experience

criteria. We believe that individuals should complete a structured educational program and that educational programs should consist of a didactic training portion, which is your classroom training in physics and biology, things like that, and then practical experience, which would include experience in ordering, receiving packages and safety precautions, ways to prevent medical events and calibrating dose calibrators and eluting generators.

In some cases we have proposed some clinical experience where we believe that there is a greater risk posed by the procedure. An example of that would be in your use of unsealed radiopharmaceuticals for thyroid treatment, for example with your Iodine-131s.

We also believe that an exam should be given to assess clinical competency. The idea of an exam grew out of meetings with the professional societies, the facilitated public meetings, and also comment letters. The majority, vast majority of the individuals, did support an exam to assess clinical competency and because of that we are proposing that an item be included in the rule.

If you would like I can get into the specific hour requirements, but I think I will stop there.

CHAIRMAN JACKSON: Commissioner Diaz and then Commissioner McGaffigan.

COMMISSIONER DIAZ: On the issue of Iodine-131,

which is specifically separated -- it is a special category -- is the training then going to be Iodine-131 specific or are you still thinking of generic training plus? I mean there is a difference in how much you can provide generic training and how much you can go into a specific radionuclide use.

MS. HANEY: The proposed rule would require the didactic training and in that case I think it would be very general and really with the didactic training that is adequate, because you are learning decay formula. You are learning the radiobiological implications, things like that, so that would be very general.

In the practical that we are proposing, and in this case we are talking 40 hours of practical experience, we are also looking at five cases and we believe that this practical experience would be more tailored to what that individual is using.

For example, if an endocrinologist was coming in -- was wishing to become an authorized user, and for hyperthyroidism treatments or thyroid cancer, there would be a requirement for five cases. Some of that practical experience could be obtained while they were doing those five cases. They would still need to receive a package. They would need to order the material. They would need to assay it -- things like that -- so there is some overlap

there.

To answer your question, some would be very general, but I could see some of it being specific to the type of use the individual is doing because we are focusing in on radiation safety.

COMMISSIONER DIAZ: Yes. It would seem that as an equity issue that in some specific areas like Iodine-131 you really want to become very specific, not broad.

CHAIRMAN JACKSON: Let me make sure -- this is a piggyback to his question -- so then is the point that the didactic part is some baseline knowledge level --

MS. HANEY: Right.

CHAIRMAN JACKSON: -- that you would expect everyone working with radionuclides to have, and then where the specificity comes is in what you would call the practical training that is tailored to the particular radionuclide or set of radionuclides that are being used or tailored to the risks involved.

MS. HANEY: It would be tailored to the risks. I would like to say a flat yes to that, but in the case of the endocrinologist their five cases would be very specific, but if you are looking at a physician that is doing general nuclear medicine, that practical would be a little bit broader.

CHAIRMAN JACKSON: Right.

MS. HANEY: So I just wanted to give the full story.

CHAIRMAN JACKSON: I appreciate that. Commissioner?

COMMISSIONER McGAFFIGAN: I am going to follow on the same line of questioning. There basically are two categories of specialist who are adversely affected by the rule in that there hours of training is going to have to go up, and one of them, I understand, the Strontium-90 eye applicator folks -- we have had all sorts of problems in that area -- and misadministrations and damage to eyes and whatever.

The endocrinologists argue that you are trying to fit them in a one-size-fits-all box, that they have had zero problem, that this is straightforward. These are smart people and the 80 hours that are required at the moment is all they need for dealing with basically one radionuclide and one organ. If there were a backfit rule, which there isn't, for materials licensees, this would never pass a backfit test because there is no health and safety benefit that is going to accrue from upping -- in fact, they would argue and have argued that there will be an adverse health and safety benefit because it is a larger entry barrier and people will not bother to get -- to get certified and they will send people off to other specialists and the patient

has to now deal with a more complex medical system and all that.

But what is the rationale for increasing the time for the endocrinologists?

MS. HANEY: Staff's approach to the rulemaking in the training and experience area was to focus in on the radiation safety and from the comments that we received, the input that we received across the board from diagnostic therapy users, a certain amount of practical experience was needed as part of a training program.

To use the example of the endocrinologist, right now they are required to have three cases if they are in the hyperthyroidism area and 10 cases if they are treating the

cancer, so there is some practical that they are getting there right now inherent in the fact that they are in the clinic, that they are handling the pharmaceuticals, and treating the patients, and our pulling it out as an hour of a 40-hour practical -- well, it looks like an increase -- in the rule it is an increase.

I believe that you could get the clinical -- the practical training and the clinical at the same time, so it may not be as great as an actual net 40 hours that they must be in the clinic.

COMMISSIONER McGAFFIGAN: Why fix something that isn't broken is the question that they will ask, surely, in

the process that you are about to enter?

MS. HANEY: All I can offer to that is that we have attempted to focus on radiation safety and this is what we were -- the comments that we received across the board, that this was needed.

COMMISSIONER McGAFFIGAN: Okay.

CHAIRMAN JACKSON: Actually, this is probably more directed at Dr. Cool or Dr. Knapp, because it actually lifts it out of, strictly speaking, Part 35 rulemaking.

You know, since these training and experience requirements that you are focusing on have to do with radiation safety, do you anticipate any effort to require similar training and examination requirements for, experience requirements for other licensed individuals using the same types of licensed materials and faced with the same radiation safety risks but from a non-strictly medical point of view, industrial or research applications, possibly veterinary, which some people call medical, some say not, but you know -- what can you say about that from a consistency perspective?

MR. COOL: That is an extremely good question and one that we have done at least a little bit of thinking about.

In fact, the case in Part 35 here is not the first place where we have gone with an examination type of

approach. The radiography arena and the certification of radiographers by independent testing organizations for which there is one test plus several states are doing it, was a stalking horse, if you will, a similar kind of approach.

What we learned from this in terms of working in the unsealed arenas and how this scales out I think we ought to use to then look to see whether there are other arenas and other uses as we go back and look at it, to see whether or not it also makes sense.

There is an advantage in this arena, I would note -- that we have a number of professional societies and organizations who are in the business of testing and certifying people in terms of these particular fields, so we have that baseline which is not present to varying degrees in some of the other areas.

MR. KNAPP: And I would say that obviously we have a diverse set of licensees. In some cases in ways that perhaps we hear from the auto industry, it's better to have an automated breaking system than to train each driver to pump their breaks. In some cases there are other fixes which literally if we have some classes of licensees we can solve a problem with an engineered fix, but the fundament questions you asked, Chairman, I agree entirely with Don.

This is something we should consider across the

board and to the extent that we have similar risks and

similar needs I think we should take some more steps.

CHAIRMAN JACKSON: Okay.

MS. HANEY: Now I would like to move into some areas where there is a reduction in the regulatory burden on licensees.

In the slide that you see, the deletion of the Radiation Safety Committee and a requirement for the Quality Management Program, this would represent a significant reduction in the burden on licensees.

If we look at the diagnostic and the therapy areas as separate areas, some minor changes that we are proposing to the rule and more the technical orientation would also decrease burden. In the diagnostic area and the therapy area we are also proposing that the medical physicist -- change in the medical physicist, no longer requiring amendment to the license. This is a similar consistency with how we are doing it with other users in the rule.

There are some areas where there is an increase in the regulatory burden on licensees because of the proposed rule change, the first being that the rule now specifies that the licensee develop, maintain, and implement procedures.

The vast majority of the procedures that the rule is proposing to be included are already developed by the licensee and this is part of their license application.

There are however a few procedures that they currently do not have that they would need to develop if they were going to be in compliance with the rule.

We have also added the two reporting requirements, one for reporting unintended dose to the embryo fetus, or nursing child, and also for precursor events. While we do believe that there is a small impact here, there is however an impact.

Finally we would be requiring an output measurement for all brachytherapy sources, and this would be just to make our regulations more consistent. Right now we require it in the teletherapy area and the high dose rate remote afterloader area, but we are not requiring it in the manual brachytherapy, so here we are looking for consistency.

CHAIRMAN JACKSON: Did you get many comments in these three areas?

MS. HANEY: Where did we get the most? I'll start at the bottom first again.

The medical physics community was very supportive of requiring output measurements on the sources. We did not receive comment on the reporting requirements for the unintended dose to the embryo fetus because the version of the rule that went up on the Internet really had totally different language than what we are proposing now, so we

were talking apples and oranges and therefore I can't say that they -- the public has seen this.

I would expect that we will receive a lot of comment in both the area of the embryo fetus and the precursor events.

In the area of the procedures, the big comment there was don't put requirements for procedures in the license or in your reg guides. If you want us to have procedures, put it in the rule and state it upfront, which is what we have done.

CHAIRMAN JACKSON: Okay. Commissioner?

COMMISSIONER McGAFFIGAN: Can you give an example of a procedure that is not currently part of the license application that would be required by the new rule?

MS. HANEY: Right. An example would be that we have deleted the prescriptive requirements for labelling of vials and syringe shields and have gone to what we think and believe to be more performance-oriented, which is that the licensee should develop procedures for how they will label and under what conditions they will label.

The only other requirement would be falling back to the requirements in the Radiation Safety Committee. How we have resolved that area, we have asked for procedures for the interdepartmental, interdisciplinary communication between departments, and that was one of the things to

offset the fact that we would no longer require a Radiation Safety Committee.

COMMISSIONER McGAFFIGAN: Can I --

CHAIRMAN JACKSON: Please.

COMMISSIONER McGAFFIGAN: On the Radiation Safety Committee, which wasn't -- isn't it true that most of the written comments that we received from Radiation Safety Officers and the health physics community were against giving up the Committee for fear that it would get lost and other reasons, that the main impetus for doing it came from the hospital administrators.

I am not arguing for retaining all the prescriptive elements of the current rule, but that the notion of having a Radiation Safety Committee that doesn't get lost in the hospital infrastructure is something that the people who are in the field working in these hospitals are arguing for. Maybe they are all about to get fired by their hospital administrators, I don't know, but I am a little troubled by the disconnect there.

MS. HANEY: It is true that the comments from the Health Physics Society and the American Association of Physicists in Medicine supported retention of the Radiation Safety Committee.

We do have a lot of other comments from other organizations, however, that do support the deletion of the

Committee.

Again, I believe the proposed rule would still address the concerns of the Radiation Safety Officer. The authority for the day-to-day running of the program is delegated from licensee management to the Radiation Safety Officer. We are looking for that delegation in writing, so there is a clear path between the licensee, Chief Executive Officer, and the Radiation Safety Officer and because of that I don't think it would get lost.

COMMISSIONER DIAZ: If I understand the proposal, it's not to delete the Radiation Safety Officer --

MS. HANEY: No.

COMMISSIONER DIAZ: -- but the Radiation Safety Committee.

MS. HANEY: That's correct, yes. We would still maintain the Radiation Safety Officer.

COMMISSIONER DIAZ: For functions and communications that are important to safety should be maintained through the Radiation Safety Officer.

MS. HANEY: Yes.

CHAIRMAN JACKSON: And to have that specific

delegation in writing of which you spoke.
MS. HANEY: Right.
CHAIRMAN JACKSON: Okay.
MS. HANEY: And with that, this concludes our

formal presentation.
CHAIRMAN JACKSON: Any comments?
I do have one. This is on one of your backup slides having to do with resolution of reportable events. You almost got away.
It talks about the situation that meets the above criteria would not be reportable if it was the result of patient intervention in the treatment that could not have been reasonably prevented by the licensee.
Now will the final determination of what is reasonable be left to our licensees to make, or will that determination be left to the NRC Office of the General Counsel to judge on a case by case basis? Is this the General Counsel Full Employment Act?
[Laughter.]
MS. HANEY: There will be some events that the licensee will rule out automatically and say that it was the result of patient intervention, and we would never hear about them unless for example we were out doing an inspection and an inspector identified it by reviewing a dose log and then questioned why wasn't this reported.
In that particular case we would -- the inspector would bring it back through the regional office through NMSS and into OGC for determination of whether this falls into that category or not.

There also will be some cases where a licensee wanting to be on the safe side would call NRC and say in my opinion it was caused by the patient, but I just want to make sure.
I would expect too that in these cases where it did come to NRC's attention and that there was some question about what was reasonably prevented that we would also rely heavily on the use of our medical consultants and the ACMUI for whether they believed that it should have been a reportable event.
CHAIRMAN JACKSON: Are inspectors going to be directed to review logs from time to time?
MS. HANEY: No more so than what they are doing now, as far as going in and looking at doing a sampling of records to make sure that the program is functioning properly.
CHAIRMAN JACKSON: All right. Commissioner?
COMMISSIONER DIAZ: Yes. Since you were going away too easy --
[Laughter.]
COMMISSIONER DIAZ: -- I decided there's just a little bit of a problem in here. In the process of developing the new rule, have you come into some additional knowledge of how our particular procedures and regulations, or the absence of, in the area that we do not regulate --

say, accelerators and isotopes made by accelerators -- you know, is there a compatibility or are we so far apart that we don't even want to look at it right now?
MS. HANEY: I would say that it was mentioned at some of the meetings about whether NRC would be going into other areas of medicine, but we did not spend a lot of time in that particular area. The Working Group had

representatives from an agreement state and from a state that is trying to become an agreement state on the committee, so there were times during the process where they brought to our attention, well, this is the way it's done in x-ray, this is the way that it is done in nuclear medicine.

There was nothing that came to our attention that was a gross problem.

COMMISSIONER DIAZ: Yes, because I am not concerned whether we do it or not. I am concerned with the compatibility and consistence between processes that are used in this large, growing area, compared to what we do, and I think you have just kind of said that it came in bits and pieces but we really didn't look at it.

MS. HANEY: Correct. We didn't focus on that.

CHAIRMAN JACKSON: Yes, Commissioner?

COMMISSIONER McGAFFIGAN: Not to let them off too easily --

CHAIRMAN JACKSON: I'm sorry, Ms. Haney --

[Laughter.]

COMMISSIONER McGAFFIGAN: -- the cardiologists whom we may hear about from the next panel, one of the issues that they have raised, aside from training and experience, where they obviously support the proposed -- what the Staff is proposing -- is the issue of these treatments for restenosis I think is the right medical term get routinized?

At the moment I guess you are going to treat them under 35.900, and there is a requirement that there be a team including a radiation oncologist who participates in the various and sundry experiments underway with various treatment modalities, but when that gets routinized, and they are respectfully suggesting that the radiation oncologist doesn't need to be there and indeed in a real medical setting where it is now a routine practice, getting the cardiologist, the radiation specialist at the hospital, et cetera there, that that is enough and in getting an oncologist who at the moment, when it is an experimental thing, they can all come together and schedule it, but that is not how cardiology is practiced, so how will that, whatever treatment modality wins the horse race and gets the approval of the community and becomes the routine treatment for restenosis or maybe there will be several, how does that then transfer from 900 in your rules to some other place and

do you see a need at that point for a radiation oncologist to be part of the team administering the health care?

I know we are in an impossible position as a bunch of nondoctors to basically settle the scrap between the cardiologists and the radiation oncologists, but we probably are going to have to at some point.

MS. HANEY: Right now, the current rule is structured with the 35.900 -- what we refer to as "emerging technology" section, that you could license the intervascular use under that and in fact we have had conversations with the oncologists that this would be the ideal place for the intervascular use to come into play.

There is a lot of discussion though that the intervascular use that they are proposing does not differ significantly from that of what is being done currently with high dose rate remote afterloaders, so shouldn't it in fact fall under the medical device use.

Right now the current framework, as you said, is

to have a group with an oncologist involved. As they become more familiar in whichever treatment is going to end up being their preferred route and as Part 35 is finalized next year, I could see us having to make some tough decisions next year about whether it does in fact fall under this emerging technology where we would be looking at some possibly different training requirements for these

individuals or in fact is the use that of a medical device in an HDR unit and therefore it should just be treated as a medical therapy device and the cardiologist should be expected to have the same amount of training as a radiation oncologist if they wanted to become an authorized user.

So I think this is an evolving process that we will have to --

COMMISSIONER McGAFFIGAN: I am not sure we are going to have to make the decision in the next year given the rate at which the technology is emerging, but I think it is an issue that we are going to have to deal with at some point and the cardiologists obviously do not believe that it is likely that they are going to need the full training of radiation oncologists to administer whatever, whichever technology wins the day.

CHAIRMAN JACKSON: Commissioner?

COMMISSIONER DIAZ: Yes. Looking at the detail that we are going to require on precursor events, as you know, root cause analysis is deeply rooted in this Commission and I am not sure if it's the Commission or the entire Staff but I just want to make sure that when we go into this precursor event issue that we have constrained it to things that actually are licensable and can be of use rather than getting into a habit of saying this has a precursor.

What is the, from your viewpoint, what is the dividing line on how you actually get into trying to determine precursors?

MS. HANEY: What we are proposing as the dividing line would be an event that would have implications outside that licensee's facility.

Let me give you an example. That might be the best way to say it.

You have a manufacturer that gives you a procedure for calibrating -- let's use the high dose rate remote afterloader where there is risk involved with use of this procedure. The physicist takes and tries to implement that procedure and realizes that if he does exactly what that procedure says that significant exposure could occur.

In that case one would like to think that the physicist would go back to the manufacturer and the manufacturer would correct these procedures, but we also believe that it would be important for NRC to hear about these events so that we could consider generic applicability, possibly issue an information notice, or given the nature of the error, issue an NRC bulletin that would require further action than just an information notice.

COMMISSIONER DIAZ: Okay. I don't want to be a broken record, but again this would be a process that would

be fully risk-informed in the sense that you are not going to start looking for --

MS. HANEY: Correct. Right.

COMMISSIONER DIAZ: Thank you.

CHAIRMAN JACKSON: Okay. Well, I think before they ask any more questions, or I, thank you very much.

We will now hear from the Advisory Committee on the Medical Uses of Isotopes.

Good afternoon.

DR. STITT: Good afternoon. Good to be here, I think.

My colleagues and I are here today representing the Advisory Committee on Medical Uses. We would like to start with our first viewgraph, the process. We would like to say the NRC staff has been very responsive and forthright in dealing with these issues with the ACMUI, both in areas of agreement, as well as disagreement.

The regulated community has had significant opportunities for input and for participation, and Cathy Haney defined the myriad way we have been involved.

The web site has been an efficient use of technology to facilitate our communication. This has certainly been a very intensive time and labor process with a lot of demands on the NRC staff, but we appreciate the benefits that it should provide to the community.

In our presentation today, all of my colleagues get the opportunity to speak and we will speak when spoken to by you. John Graham is going to discuss the recommendation for medical policy statement.

DR. GRAHAM: Good afternoon. I hope it was serendipity that my name tag was placed at this seat since it seems to be the hot one so far.

In its staff requirement memorandum, COM-SECY-96-057, dated March 20, 1997, the Commission stated that it supported continuation of the ongoing medical use regulatory program with improvements, decreased oversight of low risk activities, and continued emphasis on high risk activities. This SRM directed staff to revise 10 CFR Part 35 and, if necessary, the Commission's 1979 medical policy statement.

This policy statement has been the subject of considerable review and discussion by the ACMUI since it represents the guiding policy for our review and recommendation on proposed regulation governing the medical use of isotopes.

As stated in the draft proposed policy statement on the medical use of byproduct material, dated June 4th, 1998, certain themes have emerged in ACMUI meetings, public-facilitated work shops and written and electronic comments that have convinced the staff that some revisions

of the medical policy statement are warranted.

These themes include insuring that the Nuclear Regulatory Commission will regulate the medical use of byproduct material, as necessary, to provide for the radiation safety of workers and the general public, but it will not intrude in the practice of medicine or with medical judgments affecting patients. It limits its role in regulating the radiation safety of patients to requiring that the physician's directions are followed and that it regulate the radiation safety of patients only where the voluntary standards or compliance with these standards are inadequate.

The ACMUI concurs with the staff-proposed revision of the medical policy statement which essentially retains Statement No. 1, that NRC will continue to regulate the use

of radionuclides in medicine, as necessary, to provide for the radiation safety of workers and the general public.

The ACMUI is gratified by the proposed Revision Statement No. 2 that NRC will not intrude into medical judgments affecting patients except as necessary to provide for the radiation safety of workers and the general public.

The ACMUI continues to advocate an alternative to the staff-proposed Statement No. 3, that the NRC will, where justified by risk to patients, regulate the radiation safety of patients primarily to insure -- to assure the use of

radionuclides is in accordance with the physician's directions.

The ACMUI recommends that NRC will regulate the radiation safety of patients only where justified by the risk to the patients and only where voluntary standards or compliance with these standards are inadequate. Assessment of the risks justifying such regulations will reference comparable risks and comparable voluntary standards and modes of regulation for other types of medical practice.

CHAIRMAN JACKSON: Let me stop you for a second there. You have referenced the Atomic Energy Act in coming up with this statement, because -- this is the lawyer's question. You could have such a statement, is that consistent with what the law requires? As opposed to saying that the NRC will regulate the radiation safety of patients in a manner justified by the risk to patients?

MS. CYR: I think -- I don't know that the Atomic Energy Act requires that you -- only where justified by the risk to patients. I mean I did not view this as a jurisdictional statement, I viewed this as sort of a judgment statement about where it was appropriate to --

CHAIRMAN JACKSON: Give attention.

MS. CYR: Right. To give attention.

CHAIRMAN JACKSON: Okay. And then my question to you, Mr. Graham, is there a compendium of risk from medical

treatments that would provide this reference that you are talking about here?

DR. GRAHAM: There is certainly not, to my knowledge, having sat on the Advisory Committee for three and a half years now, I believe, any simple document that we could go to that would, in clear black and white, draw those lines of risk. And I think what we are suggesting in the next part of our recommendation gets to the issue of having an ongoing process over the review of those risks and separating them into low risk versus high risk categories. And we speak specifically to the concerns that were raised by General Counsel and some of the background documentation that we received. So maybe it will become clearer in a couple of minutes.

COMMISSIONER DIAZ: Okay. Because I have got a little problem with assessment of risk, comparable. It seems like in certain cases when the assessment methodology is sharply defined or it is better defined, that that should be taken not as an additional imposition but as a definition, that when you do risk analysis or you actually establish risk inside a regulation as a goal or as a guidance, we might have better information that are available from voluntary methods or comparable voluntary standards in medicine, and we should not forsake those.

Am I making myself clear? In other words, I have

got a problem with this phrase "assessment of the risk

justifying" -- "will reference comparable risks and comparable voluntary standards" and you just say that, you know, there is really not a medical compendium, like the Chairman said, that actually will reference risk. Shouldn't we serve better by, in the cases which we have a risk assessment, that it is well defined even it is not comparable to other practice of medicine.

My impression is that medicine has so many variations that are based in the practice of medicines, the different biological responses of individuals, et cetera, et cetera, that we might be able to focus more on the use of radioisotopes or radionuclides in medicine and address that, you know, specifically, rather than trying to compare it always to other areas of medicine. I think some comparisons might be valid. I am concerned that you are trying to put this is a context that is very, very broad and I am not sure that that breadth is justified.

DR. GRAHAM: Well, I think it was a concern, and I will request clarification from other committee members, as appropriate. But I think it was a concern of the ACMUI that, in particular, it was the threshold of risk and the definition of threshold that needed to be evaluated in the broader context of risk assessment as it would occur in the other practice of medicine.

DR. STITT: I can add to that. If you understand, and you do understand the composition of the committee, basically, clinicians who are working in various parts of medicine, and so radiation medicine and radiation risk is a part of what we do. And so there are some philosophic differences. A patient who is having an anaesthetic to have radioactive isotopes used, a clinician would view several parts of that risk, in addition to, potentially, the antibiotic that might be used.

But when you strictly extract out, as you are probably more likely to do, looking at the radiation risk only, I think this helps to explain, at least to you, where we are using this in a broader context than you might be willing to do.

CHAIRMAN JACKSON: Okay. Commissioner.

COMMISSIONER McGAFFIGAN: I'll ask the question I asked earlier. If a majority of the Commission decides that it wants to retain patient notification, would it be more honest to say, in 2, which is essentially the same -- or at least start's the same as the staff -- or is the same, "will not intrude" go to -- back to the "will minimize intrusion"? I mean every letter that I have seen on patient notification starts off by saying that this is an intrusion into medical judgment.

DR. GRAHAM: If I could, I would like to

specifically discuss patient notification as an example of this.

COMMISSIONER McGAFFIGAN: We'll get to that.

DR. GRAHAM: It's about two paragraphs. I think it will sharpen or focus the discussion. It would help me in answering that question.

COMMISSIONER McGAFFIGAN: Okay.

DR. GRAHAM: So let me put it in that context.

COMMISSIONER McGAFFIGAN: We can come back --

DR. GRAHAM: And I will pursue it more specifically after about a minute from now.

COMMISSIONER McGAFFIGAN: Okay. The second

question, my sense is that the whole medical policy statement stuff, that we told the staff to go do Part 35, and we said, as appropriate, you know, argue about this stuff, because this isn't rules. This is a policy statement. Policy statements don't amount to all that much, to be honest with you, in regulatory space.

But I regard -- I look at this and I say, oh, my gosh, this is Institute of Medicine and all that regurgitated. We are back to arguing about whether there is a function for the NRC in this area, and the purpose of your policy statement, as opposed to the staff's policy statement, is to constrain us down into the smallest box you think we can tolerate for what the NRC role is. I mean is

that an honest -- it that a factual assessment?

DR. STITT: Commissioner Jackson, I think that as we have worked and worked this, we feel that the medical policy statement is the centerpiece from which regulation emanates. And I think that when you look at our conversations and our minutes and compare them to the proposal, they actually have many areas of inter-digitation and are very close, and I don't feel that the sense of our work has been a reflection of the Institute of Medicine report. We took our direction from you, as well as from the staff, after we had that Institute of Medicine discussion, I believe two years ago. And I really believe that we are looking at some fine points here, and probably different interpretations based on whether you are coming form the regulated community or the regulator community.

John, do you want to continue?

DR. GRAHAM: In the proposed rule revision of 10 CFR Part 35, Medical Use of Byproduct Material, which is dated June 4th, 1998, the Commission directed the restructuring of Part 35 into a risk-informed, more performance-based regulation. The ACMUI recognizes the challenge of defining comparable risk and we look forward to working with the staff of the NRC to achieve the Commissioners' goal of developing risk-informed, more performance-based regulation.

The regulation of patient notification following a medical event, which is slide No. 7 in your packet, represents a concrete example of regulation where there is no clear data documenting risk which justifies such regulation due to risk to the patient. Patient notification is fundamental to the practice of the medicine and there is widespread agreement regarding the need to notify the patient and the patient's attending physician, but the requirement by federal regulation to present the patient with an official written notification which will be sent to the Nuclear Regulatory Commission distorts these lines of communication and can create unwarranted fear and concern on the part of the patient.

The ACMUI has a fundamental concern that these medical events, at the threshold defined in the regulation, may not constitute a serious risk to the patient's health. The ACMUI advocates continued discussion with NRC staff to protect the patient's safety and promote the practice of medicine.

CHAIRMAN JACKSON: Now, let me make sure, you said something. Is the fundamental issue what the threshold is, or having a requirement at all?

DR. GRAHAM: Speaking as one member of the Advisory Committee on the Medical Use of Isotopes, I have

sat through hours and hours of meetings discussing how to

define the threshold and how to balance out the public safety, the safety of workers, the legitimate protection of the safety of patients and yet retain the practice of medicine. So, yes, I think it is an issue of the threshold.

CHAIRMAN JACKSON: So it is the issue of the threshold.

Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: There are a couple of other issues. You mentioned sending the same notification -- the current rule requires that we pretty much -- the report you submit to us has to be potentially made available to the patient, and, indeed, that probably is the practice out there, you just give them the report you send to us. The report you send to us is written in, presumably, bureaucratic gobbledygook that we are good at receiving, and the patient may not be. So what if you distinguished the -- or you weren't required any longer to provide the report that you give to us, but something that was more patient-friendly in the way of describing what the impact of this medical event might be on the patient? Would that relieve some of the concern?

DR. STITT: John is looking at me. John is a hospital administrator so he is not notifying patients.

There are some very specific time periods in the rule as to who is notified when and some if it is

notification. Other parts is sending a copy of the report and I think that is one of the issues. It's one thing to send a notice to an individual and it is another thing to send a copy of a report that may engender a lot of anxiety because they simply don't understand what is in it.

COMMISSIONER McGAFFIGAN: Right.

COMMISSIONER DIAZ: I'm sorry -- no, go ahead.

COMMISSIONER McGAFFIGAN: This issue of risk levels, I mean I suspect the medical community is not wild about this either, but there's currently passed by the Senate and under consideration in the House a Mammography Standards Act that will authorize the FDA to have patient notification to individuals who receive bad mammograms, and my recollection is mammogram -- you know, I'll refer it to the doctors -- but if we are talking about thresholds, if Congress were to pass that law, what is the judgment they are making about rems to a woman which may have been misapplied, that they now want the patient to be notified on? Is it of comparable magnitude to the numbers that we have in our rule, the 5 rem and 50 rem to an organ and all that?

DR. STITT: No. The mammogram quality standards refer to deficiencies in the mammography program so it is a systematic program approach.

COMMISSIONER McGAFFIGAN: You are talking about

the laws that exist today but I am talking about the law that the Senate has passed, the House is considering which goes to individuals.

DR. STITT: Are you talking about a particular dose from a mammogram or are you talking -- the mammogram quality standards have several issues.

One is the quality of the program, the units that are being used, and also reflect the potential for serious harm from the mammograms.

The reporting that we have been talking about in patient notification really is any particular patient, a specific event involving that patient, and my understanding of what we discuss in our Part 35 is quite different from mammography standard requirements.

COMMISSIONER McGAFFIGAN: As they exist today but not as the Senate and the Congress may -- I think Congresswoman Morella and various Senators, Snowe and others, are advocating an amendment to that law that would require something very similar to what we require today, so my question was just laying that aside, if Congress were to pass a law that requires patient notification for -- individual patient notification in the case of mammography, would they be essentially endorsing a threshold similar to the threshold that we have today in our rules, if you try to convert it to personrem?

DR. STITT: Mammography is diagnostic. It's a screening. It's a diagnostic test. This is entirely different from the therapeutic, so you are not measuring doses. In a woman's having a mammogram there is no dose that is being measured at that point in time so I think the two are very difficult to compare.

Now there is a notification requirement in the mammography standards and that is a notification as to the report -- that is, the report that is generated from that study, and that is one level of reporting and the other level is the program and how that program is carried out in an institution.

If there are programs that are poorly monitored with poor equipment, screens, films, et cetera, my understanding is that is where the reporting to the health care provider or the referring physician and the patient comes in.

CHAIRMAN JACKSON: Commissioner?

COMMISSIONER DIAZ: Yes. Let me go back to something you say -- just trying to refocus on the risk and if I might quote, it says, you know, the medical event might not constitute a serious risk to the patient health, and that may not constitute it becomes an issue.

How about if a physician determines that it does constitute a serious risk to the patient health? What will

be your recommendation regarding a patient notification? Just assume you make the determination it is a serious risk. Then what should be done regarding patient notification?

DR. STITT: It would be in keeping with what we would do in that circumstance or any other. You talk to the patient about what has transpired, be it a surgical event, a medication event --

COMMISSIONER DIAZ: But I mean in relationship to our obligations.

DR. STITT: I guess off the top of my head my response would be this is something that needs give and take with the NRC Commissioners and the Staff and the ACMUI.

If we are looking at specific thresholds, that would open up an area of discussion for the future.

CHAIRMAN JACKSON: Would you go on?

DR. STITT: We are going to look at a viewgraph entitled Radiation Protection Program. This brings up some issues that have already been discussed.

The entire section has become less prescriptive and the ACMUI concurs with the proposed rule. In particular, we agree that the elimination of the

prescriptive requirement for Radiation Safety Committee is one that can be workable throughout the programs in the country.

The proposed regulation permits the licensee to be

flexible and to maintain a Radiation Safety Committee consistent with the scope of their operations or to unfold that within the other requirements for the hospital operation.

CHAIRMAN JACKSON: Go on.

DR. STITT: Viewgraph on Written Directives. Dennis Swanson.

MR. SWANSON: Written Directives in COMSECY 96-057, the Commission directed NRC Staff to re-evaluate and revise the Quality Management Program requirements to focus on those requirements that are essential for patient safety. For example, requiring written directives confirming patient identity and verifying the correct dose.

The proposed rule addresses these concerns of the Commission, minimizes prescriptive requirements, provides for a performance-based approach to the Quality Management Program, and ensures patient safety. Thus, the ACMUI concurs with the proposed ruling which I think it's probably to emphasize however that when you go to a performance-based rule where you are going to have individual institutions developing their own procedures, that is going to definitely a change in how your inspection people take a review of that program.

Your inspections can't be as prescriptive either. Your inspectors are not going to have prescriptive guidance,

prescriptive NRC approved procedures by which to evaluate those programs so it's going to require certain changes in how the inspections work. That's important to point out.

CHAIRMAN JACKSON: Yes.

COMMISSIONER McGAFFIGAN: How do you violate this rule? Given how it is written, the Chairman asked earlier, is it enforceable, of the Staff, but it is how hard you have to work to violate the rule as it is drafted at the moment.

MR. SWANSON: Well, it is a performance-based rule so obviously if you have problems with misadministrations or medical events -- then those problems can derive from different mechanisms.

Number one, you may not as an institution have the appropriate set of procedures in place to appropriately provide those protections, okay, so that could be a violation in itself, that you do not have the appropriate procedures in place to address verification of identity, verification of the proper dose, et cetera.

Then a second way that medical events could occur is you could have the appropriate procedures in place and the individuals aren't properly following those procedures. In that case, then you have violated the training requirements for the people working at institutions with regard to them following the appropriate procedures and what those procedures are.

CHAIRMAN JACKSON: Go ahead.

DR. STITT: Written Directors and Procedures -- Dennis?

MR. SWANSON: I think we just did that.

DR. STITT: I'm sorry, Reportable --

MR. SWANSON: Unless you would like me to repeat

it?

[Laughter.]

DR. STITT: I think we got it the first time. Reportable Events.

MR. SWANSON: With regard to medical events, the ACMUI concurs in general with the proposed rule as it relates to the definition of medical events and the reporting of medical events to the NRC.

It is recognized that medical events associated with patient interventions or exposure of the wrong treatment site are difficult issues to define.

The ACMUI has noted that the background section to the proposed rule addresses specifically these gray areas and requests respective public comment. The ACMUI will continue to address these two problem areas in particular.

With regard to the proposed regulations addressing the unattended dose to the embryo fetus and nursing child, the ACMUI recognizes the Congressional mandate for the NRC to capture and report abnormal occurrences and that the NRC

has defined the unintentional radiation exposure of an embryo fetus or nursing child to be an abnormal occurrence.

The proposed rule appropriate relies on industry standards for the prevention of such exposures. ACMUI recommends a final regulation that avoids a real or de facto requirement for the mandated pregnancy testing of women of childbearing potential.

And with regard to precursor events, ACMUI does not feel that it is necessary to have a Part 35 rule addressing the reporting of precursor events, that the reporting of precursor events as defined in the proposed rule is adequately addressed through existing NRC and FDA regulations and voluntary reporting programs.

However, should the reporting of precursor events be retained within the Part 35 rule it's imperative that the responsibility of determining what needs to be reported be defined. In other words, the clause "in the opinion of the Radiation Safety Officer" or "authorized user" or a clause which states "in the opinion of the licensee" must be retained in order to prevent second-guessing on the part of NRC inspectors.

DR. STITT: Training and experience will be discussed by Dr. Alazarki.

COMMISSIONER McGAFFIGAN: Could I just stop on that one for a second. That is in there at the moment, this

"in the opinion of the Radiation Safety Officer" or "authorized user" -- the precursor events, if they are precursors of the sort that were discussed earlier, is the one day no later than the next calendar day overly burdensome? These are things that were -- that when we get them we are going to do things like put out an information notice or watch, just monitor the process as the manufacturer modifies the device or whatever, but it is not of the urgency that perhaps would require a one-day notice.

Is that something you all talked about, the one day in the precursor?

MR. SWANSON: No, I don't think we have specifically discussed that specific reporting requirement. My personal opinion on that is if you are going to leave it in the opinion of the Radiation Safety Officer or the opinion of the licensee is it one day from their determination that it is a precursor event? In that case, it is probably not a major burden.

If it was within one day of when the event occurred, that would be a burden because it does take some time to evaluate that event.

DR. STITT: Go ahead, Dr. Alazarki.

DR. ALAZARKI: In formulating ACMUI's recommendations for training and experience requirements and in keeping with Chairman Jackson's opening remarks, ACMUI

did attempt to heed stakeholder input but this has not been easy and in fact it's quite problematic because there are so many diverse views among the stakeholders.

Nonetheless, for 35.100 and .200 recognizing low risk of diagnostic procedures, ACMUI supports the proposed significant decreases in training and experience requirements to reflect only competence in radiation safety. ACMUI chose not to define criteria to determine clinical competence, which is in contrast to ACMUI's recommendation about 35.400 and .600 where high risk of the procedures mandated linkage to clinical competence.

ACMUI did strongly recommend that the decreased training and experience requirements for 35.100 and .200 be conditioned on physician candidates passing an NRC-administered examination designed to assure competence in radiation sciences and practices.

Further, central to its recommendation is that the currently recognized appropriate certifying bodies for radiation medical practice competence continue to be relied upon for assurance of clinical competence of individual physicians. We recommend a clear statement as part of the regulatory language from NRC that licensure does not constitute credentialing for radiation medical practice.

ACMUI was split in its voting on the recommendation of training and experience for 35.300 --

35.300 provides training and experience requirements for unsealed source radiation therapies, often using very high doses of Iodine-131, which are certainly high risk procedures to patients and personnel and require special consideration for protecting the general public.

As such, there is a definite similarity to 35.400 and .600 which ACMUI agreed required linkage to clinical competence upholding the current 500 plus 200 hours, as part of a three year ACGME approved residency program in Radiation Oncology as training and experience requirements.

Part of the committee would have favored comparable requirements for unsealed source byproduct radionuclide therapy procedures. As written however, the proposal is not to distinguish between the high dose usage and low dose, low risk diagnostic training and experience requirements.

We anticipate that there will be an abundance of spirited comments, hopefully, polite, in response to the Federal Register request for comments. The ACMUI advocates continued involvement with staff in reviewing these comments and formulating modifications, as deemed warranted.

As we understand it, the comment period planned is 75 days, starting in July, but because of the importance of these issues to so many diverse groups of practitioners and institutions, we urge the comment period to be extended

beyond the summer, when so many people are away on vacation, for 120 days. Thank you.

CHAIRMAN JACKSON: Okay.

DR. STITT: Shall we go ahead?
CHAIRMAN JACKSON: Any further questions?
COMMISSIONER McGAFFIGAN: Well, why don't I try the questions I asked earlier. The endocrinologists, and you just discussed it some degree, but they basically take the point of view that their 80 hours which are in the rules at the moment are adequate and there isn't a risk basis for extending the 80 to 120 and making the other conforming changes, and they are arguing that the staff took a cookie cutter approach to that area.
What is your opinion on that?
DR. ALAZARKI: Let me first call attention to a few other things and then bring it together on the endocrinologists. There are about, probably in the neighborhood of 15,000 board certified radiologists who use radiation material, radioactive byproduct material in their practices. There are about -- the Society of Nuclear Medicine and the American College of Nuclear Physicians jointly have a membership of about 12- to 14,000, but, of those, probably about 4,000 actively practicing physicians use these materials.
As I understand the numbers, there are about 300

NRC licensed endocrinologists using these materials, and --out of about 7,000. So less than half a percent of all of endocrinology, but a very small number compared to the other users. And, further, I believe that most of the endocrinologists who are using radioactive materials are using it to treat hyperthyroidism, not thyroid cancers, although there may be some.
The high risk in radionuclide therapy with I-131 is the cancer therapies, not the hyperthyroidism. So there may be some compromise that might be -- that might work very well for all concerned in terms of taking out the hyperthyroids and putting them perhaps closer to the diagnostic groups, which would not alter their requirements significantly, I don't think.
CHAIRMAN JACKSON: But it would introduce the need to have a restriction.
DR. ALAZARKI: Yes. It would change the way in which --
CHAIRMAN JACKSON: Right.
DR. ALAZARKI: Right. It would.
CHAIRMAN JACKSON: And so it would create a bimodal distribution --
DR. ALAZARKI: Alternatively --
CHAIRMAN JACKSON: -- of endocrinology.
DR. ALAZARKI: Alternatively, they are such a

small number participating that, you know, if you don't want to start making exceptions like that, which I think is totally understandable, then that is it, these are the requirements.
COMMISSIONER McGAFFIGAN: But for the physician who is just treating hyperthyroidism, it is an increase and it is an additional entry barrier for somebody who is --
DR. ALAZARKI: Only 300 though out of multiple thousands who we are talking about.
CHAIRMAN JACKSON: Are there endocrinologists that do both treatments, for hyperthyroidism --
DR. ALAZARKI: There may be. Very, very few.
CHAIRMAN JACKSON: Very few.
DR. ALAZARKI: Very, very few.
CHAIRMAN JACKSON: Okay.

COMMISSIONER McGAFFIGAN: Then the brachytherapy -- not the brachytherapy. The Strontium-90 applicators, you would agree that the increase there is warranted given the history --

DR. ALAZARKI: Absolutely.

COMMISSIONER McGAFFIGAN: -- that we have had with that?

DR. ALAZARKI: Right.

COMMISSIONER McGAFFIGAN: Okay.

DR. ALAZARKI: Right.

CHAIRMAN JACKSON: Commissioner? You wanted to make a comment, Mr. Swanson?

MR. SWANSON: Yes. With regard to that, from my perspective, probably why the ACMUI was split on the vote on Part 300 deals with, if you are truly taking a risk-informed approach to these regulations, and if you look at the risk of brachytherapy, for example, versus the risk of giving four millicuries or 100 millicuries of I-131, it is hard to argue that, you know, the internal administration of a radioactive drug, I-131, is just as risky, if not more risky than brachytherapy. So how can you justify having 700 hours and three years of training here and 80 hours over here? Okay.

So one of the problems with the training and experience requirements, as I see it, is we are going to have to look at uniformity across these sets of requirements. And that's, in fact, what I think led to some of the split vote in looking at the Part 300.

Let me also remind you that 40 hours is only week of training, okay. It's not like we are talking a lifetime on behalf of the endocrinologist.

CHAIRMAN JACKSON: Thank you. Well, I would like to thank each member of the staff and each of the members of the Advisory Committee on Medical Uses of Isotopes for today's briefing.

COMMISSIONER McGAFFIGAN: Did they get finished?

CHAIRMAN JACKSON: Were you done?

COMMISSIONER McGAFFIGAN: There is one more viewgraph.

CHAIRMAN JACKSON: I'm sorry.

DR. STITT: One more viewgraph. There is one viewgraph. We had very little to say. I would be glad to -- I'll let you continue.

COMMISSIONER McGAFFIGAN: Well, that's an interesting viewgraph because the word "enforcement" --

CHAIRMAN JACKSON: Why don't we talk about that viewgraph.

COMMISSIONER McGAFFIGAN: So I don't want to let them off the hook that easily.

CHAIRMAN JACKSON: Thank you.

DR. STITT: No, we would like to -- in fact, I was pushed to leave this in. We were thinking about putting this one aside. The ACMUI recognizes the performance-based approach taken by the NRC staff in the development of guidance documents and license submission requirements. The ACMUI looks forward to continuing our work with the NRC staff in these areas. That's pretty simple.

COMMISSIONER McGAFFIGAN: That covers this last viewgraph?

DR. STITT: That covers that slide.

COMMISSIONER McGAFFIGAN: Sorry.

COMMISSIONER DIAZ: The last bullet on that --

[Laughter.]

DR. STITT: No, it's easy to address, because as we were having our pre-sessions, we didn't get into that, so there is -- that is a non-entity right now.

CHAIRMAN JACKSON: So you put it on the slide for purposes of stimulation.

Well, the Commission, as always, will give serious consideration to the views expressed today as it reviews the staff's proposal for the revision of 10 CFR Part 35, the Medical Policy Statement.

It is clear that in many areas the staff and the Advisory Committee are in agreement as to the revisions that are necessary, but as in many things, the areas of disagreement will obviously require more attention by the Commission in its review of the two papers.

So let me thank again the staff and the Committee, and I would not that the Commission recognizes that the staff's development of the draft proposed rule, the associated draft guidance and the recommendations for revision of the medical policy statement in the time period provided was no small feat. However, it is now the performance standard.

[Laughter.]

CHAIRMAN JACKSON: Therefore, I would like to thank the staff for their diligence over the last year on this expedited rulemaking and let those in the reactor world understand the standard.

And if there is nothing more, we are adjourned.

[Whereupon, at 3:32 p.m., the meeting was concluded.]