UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

Title: BRIEFING BY ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

Location: ROCKVILLE, MARYLAND

Date: FEBRUARY 22, 1993

Pages: 86 PAGES

SECRETARIAT RECORD COPY

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING BY ADVISORY COMMITTEE ON MEDICAL USE OF ISOTOPES

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PUBLIC MEETING

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Nuclear Regulatory Commission

One White Flint North

Rockville, Maryland

Monday

February 22, 1993

The Commission met in open session, pursuant to notice, at 9:00 a.m., the Honorable IVAN SELIN, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

IVAN SELIN, Chairman of the Commission

KENNETH C. ROGERS, Member of the Commission

JAMES R. CURTISS, Member of the Commission

FORREST J. REMICK, Member of the Commission

E. GAIL de PLANQUE, Member of the Commission

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

WILLIAM C. PARLER, General Counsel

BARRY A. SIEGEL, M.D., Chairman, Nuclear Medicine

PETER R. ALMOND, Ph.D., Medical Physicist

JUDITH I. BROWN, Patient's Rights and Care Advocate

STEVEN C. COLLINS, States Representative

DANIEL F. FLYNN, M.D., Radiation Therapy

MELVIN L. GRIEM, M.D., Radiation Oncology

CAROL S. MARCUS, Ph.D., M.D., Nuclear Medicine

P R O C E E D I N G S

(9:00 a.m.)

CHAIRMAN SELIN: Good morning, ladies and gentlemen. The Commission is meeting at this time to receive a briefing from the NRC staff's Advisory Committee on the Medical Use of Isotopes. This briefing is fourth in a series of briefings in which the Commission is seeking to obtain the broadest range of input and advice on the NRC's regulatory system for medical uses of byproduct material.

The Commission's already keen interest in this area was intensified with the publication of the troubling series of articles in the Cleveland Plain Dealer and, more specifically, the recent tragic therapy misadministration patient death in Indiana, Pennsylvania. The Committee chairman, Dr. Barry Siegel, and several other members of the Advisory Committee are here with us today to shed some further light on these matters.

The Commission believes it is very important to ascertain the facts underlying all the incidents known to us in determining how best to achieve our regulatory mission.

Our mission is to identify and implement whatever improvements may be needed in our regulatory program. To the extent that the Advisory Committee can

help us accomplish the goal, the Commission will be quite grateful.

The role of the Committee can be simply stated, but it is enormously difficult in practice. That role is to provide technical support and related policy advice, to assist the NRC in making sound regulatory decisions.

The issues that arise in regulating the medical use of byproduct material not only are numerous and highly complex, they are often controversial.

The objective of our program is not to decide which procedure is appropriate in a specific situation but, first, to assure that the physician selected treatment is carried out properly with respect for the health and safety both of the patients and of the health care workers and, second, in case of misadministrations, to be sure that information is transmitted and that lessons are learned.

The issues involve sensitive and important questions concerning the proper balance between safety, health care costs and, to some degree, avoiding unnecessary intrusions into the practice of medicine.

We appreciate the efforts the Committee members have made to be here today to help us find the right answers to the difficult questions that we face.

Commissioners, do you have any opening remarks?

(No response.)

Dr. Siegel?

DR. SIEGEL: Good morning. Thank you very much, Mr. Chairman and Commissioners. I would like, on behalf of the ACMUI, to thank the Commission for this opportunity to address you and to discuss these important problems.

Let me quickly just introduce the members of the ACMUI who are here. Starting on my far left, Dr. Peter Almond, medical physicist from University of Louisville; next to him, Judith Brown, Patient's Rights and Consumer Advocate, from Silver Spring, Maryland; Steve Collins, state regulator from Illinois; to my right, Dr. Daniel Flynn, a radiation oncologist from Massachusetts General Hospital; next to him, Dr. Mel Griem, radiation oncologist from the University of Chicago; and to his right, Dr. Carol Marcus, a nuclear medicine physician from UCLA. Behind me are two of the FDA representatives, Mr. Donald Hamilton, from CDRH, and Dr. Eric Jones, from CDER.

CHAIRMAN SELIN: Good morning.

DR. SIEGEL: The Committee, in arriving here this morning, was provided with a great deal of information, as I know you all also have been. We have had the transcripts from all three previous briefings, as well as videotapes of those briefings; all of the staff papers that you had, or a good fraction of the staff

papers that you had, and we've studied them and looked at them carefully. Despite the snow, we all got here yesterday and met for about four hours yesterday afternoon, and had, I think, a very useful discussions of the issues that I'm going to address today, and I would encourage you to look at the transcript in addition to what I will try my best to articulate effectively today, but the transcript discussion yesterday, I think, had some very worthwhile debate on some of these issues.

Our task was to respond to a series of questions posed by the Commission and modulated to some extent by staff, or amplified by staff. There was a larger number of questions than I think we have time to deal with and, consequently, we are going to focus on those that are probably most medically germane and therefore most within our expertise to answer.

If I could have the first slide, please. (Slide)

These are the issues we want to talk about this morning. The NRC's response to the Plain Dealer series, what it was and what it should have been, issues relating to patient notification, issues relating to the NRC's role in patient follow-up, underreporting of misadministrations and other events, NRC's regulatory purview, and then, finally, Dr. Flynn is going to say a few words about

brachytherapy regulation, given his unique perspective as a member or consultant to the IIT in Indiana, Pennsylvania.

Next slide, please. (Slide)

The Cleveland Plain Dealer series unequivocally raised a number of very important questions suitable for both technical and public policy analysis. Although I think that the medical community's response in general, and a majority of the Advisory Committee's response, is that the Plain Dealer series was unnecessarily sensationalistic, nonetheless the issues are worthy of analysis. And the ACMUI stands ready to help the NRC by way of its senior staff management review of the medical program, and in any way we can assist the Institute of Medicine if that contract ultimately is let, we are ready to do so.

CHAIRMAN SELIN: Thank you.

DR. SIEGEL: We also fully recognize that we can't function as the primary advisors insofar as we know we are inherently conflicted in some ways because many of us are, in fact, licensees, and we fully recognize that. Nonetheless, it is just because of that that we bring the expertise we have to the table.

We also agree that the Plain Dealer series warrants a careful, scientific, dispassionate analysis of

the problems raised by the newspaper, and applaud the NRC for undertaking that analysis, but despite those kudos, I think there are things that in the series, the NRC input in interviews leading to the series and the subsequent quick responses of the NRC, there are things that could have been emphasized better, that we wish were had.

Number one, we wish the denominator had been emphasized better, and I know that in subsequent briefings that has been brought out, but we stand on our belief that the frequency of events and particularly serious events in radiation medicine is indeed quite low, and that was just not adequately emphasized by the Plain Dealer.

Additionally, the relative risks of radiation medicine by comparison with the rest of medicine needed to be emphasized and it was not -- and I'll make this point several times today -- but I want to emphasize that there is nothing uniquely hazardous about byproduct radioactive material by comparison with other things in medicine.

Every time you encounter a physician in our modern, high technology society, you run a risk that something will go wrong as a complication of a well-done procedure, and that the procedure may not be done properly. That's just part of the territory, and we can't go back to the days of all physicians could do was listen carefully and try to comfort patients. We are beyond

that, and if we want to have that kind of medicine, we have to understand those risks. We who practice radiation medicine do not believe that the risks that we encumber on our patients is any greater than the risks associated with the rest of medicine. And as I pointed out in the July briefing, actually an encounter with a nuclear medicine physician is among the safest things you can do in the medical environment.

The Committee was also troubled by the apparent level of NRC unawareness of some of these problems and, in particular, I was troubled by the notion that the NRC didn't know that patients could experience pain and suffering as a result of medical malpractice or malfeasance. I think that's a given, and a substantial portion of what happens in the tort resolution of malpractice events is related to pain and suffering.

Additionally, some clearer explanation to the Plain Dealer of the limits of NRC statutory authority would have been useful. The Plain Dealer repeatedly emphasized that the NRC had refused to take on responsibility for other forms of ionizing radiation, and although we are aware that there was one request by CIRRPC to consider taking on discrete sources of NARM, we are not aware that you'd ever received an invitation from Congress by way of a statute, to take on the other sources of

ionizing radiation, and certainly you wouldn't have refused that invitation.

I should point out just as a matter of dissent, that Judith Brown wants to congratulate the Plain Dealer for focusing attention on this problem, and heightening both government and patient awareness of the potential hazards. And I think the rest of the Committee doesn't disagree with her sentiment, it may be just a matter of her thoughts about the style of the way it was done. And certainly I hope that you will recognize that all of us, as professionals involved with medical care, find no solace in hearing about these tragic medical accidents. We share your great concern that these are things that we don't want to see happen to patients.

If I could have the next slide. (Slide)

This slide raises an issue not so much directed at the Plain Dealer. I reread carefully the article the other night, and really could only find one place where this was confused, but I wish to emphasize this to the Commission. What Carol Marcus and I do for a living is called "nuclear medicine". What Mel Griem and Dan Flynn do for a living is called "radiation oncology". We are both proud of our distinct specialties. Mel and Dan acknowledge that what they do is more dangerous, for the most part, than what Carol and I do, and we just wish the

NRC would try to keep its terminology straight in distinguishing between these two discrete specialties that you regulate, and we proposed yesterday that you might want to adopt the generic term "radiation medicine", if you are looking for a generic to describe the whole program. It does create some confusion in patients' minds.

Next slide. (Slide)

One of the important --

CHAIRMAN SELIN: I'd like to stop you for a second, Dr. Siegel --

DR. SIEGEL: Please. Yes.

CHAIRMAN SELIN: -- because, clearly, you are going on to some of the substantive issues. I don't want to get into a long discussion of NRC's response to the Plain Dealer. We're not the press police or anything like that, but I would like to just say, number one, it's not the function of the NRC, it's a function of the medical industry, if they don't believe that they've been adequately characterized, to make their own responses.

If there's an article in the newspaper that says American power plants are unsafe, we don't come out with an answer that says no, they really are safe. If asked, we'll put the facts up.

Our job is to analyze our own activities, and

certainly there are weaknesses in our regulatory activities that are pointed out in the press, and our main emphasis has been in this area. You're just expecting something from the NRC that the NRC is not going to do, which is to come out with an overall discussion about whether medicine is well practiced or poorly practiced, et cetera. That's the function of the medical communities to do.

I'm not going to go into a specific discussion of whether we should have said this or we should have said that, but I just think your criticism, or at least the main part of the criticism, which is that the general public will get a misleading impression and therefore it's our responsibility to correct that, is not appropriately taken. If we contribute to a misimpression, that's something that we shouldn't do, but our job is to look at the way we regulate what we'll call -- what did you say -- "radiation medicine" --

DR. SIEGEL: Radiation medicine.

CHAIRMAN SELIN: -- and to try to concentrate on that and, insofar as we haven't done a good job of that, I think we're subject to criticism, but not to the more general point of trying to set the record straight on the overall practice of radiation medicine. I mean, we have to know a little bit of that in trying to make sure that

the appropriate statistics get out, but that's really not our job. That's subject to legitimate criticism as being a support for, or promotion of, nuclear materials, this case, in medicine.

DR. SIEGEL: I do think that some of the comments made by the NRC as they were quoted in the Plain Dealer series did, in fact, contribute to some of the public misunderstanding --

CHAIRMAN SELIN: That certainly did.

DR. SIEGEL: -- and that's "newsprint under the bridge", if you will, and I think we won't gain much by going through the specifics.

CHAIRMAN SELIN: As a matter of principle -- I mean, we shouldn't say things are misleading/wrong, but it's not our job, conversely, to correct misleading/wrong or -- headlines or stuff in the press about this topic. And I don't really have anything else to say about that particular topic.

DR. SIEGEL: Okay. Next slide then, please. (Slide)

I'd like to go on to the issue of patient notification, what the current standards are in the medical community, and where the NRC regulations interdigitate with that.

CHAIRMAN SELIN: What was that?

(Laughter.)

DR. SIEGEL: Interdigitate, where NRC regulations interdigitate --

CHAIRMAN SELIN: We're wrapping fingers around it?

DR. SIEGEL: That's correct.

(Laughter.)

DR. SIEGEL: I think none of us on the Committee would disagree with the fact that the standard of care with respect to medical misadventures, or mistakes, or errors, with or without negligence, is truth-telling. There is no role for fraudulent concealment under circumstances where injury has occurred.

Whose responsibility is it to take truth-telling forward? It's a physician's responsibility to his patient both as part of the physician's ethical imperative and also as part of the physician's contract with the patient. It also, in the case where an institution is involved, is part of an institutional responsibility. And I think there's ample legal basis in our society for understanding that that's where the responsibility lies.

NRC regulations already exceed, in many ways, the usual extent of government intervention in what is predominantly a physician/patient and patient/institutional relationship. I would just point out that

Judith Brown thinks that that's just fine, and that the NRC should perhaps try to get its ideas spread around to the other government agencies that regulate medicine, and that this concept should become a more uniform one in our society. The rest of the ACMUI does not necessarily agree with that viewpoint.

COMMISSIONER de PLANQUE: Can I stop you on that point?

DR. SIEGEL: Please.

COMMISSIONER de PLANQUE: Do you, in your practice of medicine, know of any other area where misadministrations, shall we call them, do have to be reported to a patient? Is there any other practice?

DR. SIEGEL: To my knowledge, there is no other federal -- and I can't speak for all 50 states, but at least in the State of Missouri -- there is no other state or local requirement that would require that the physician notify a patient of an error. There are clearly legal duties to do so as part of the contract, but not as part of government regulation.

Now, did I do a thorough legal analysis of every law and regulation on the books? No. But I spoke with a number of malpractice lawyers, and I spoke with hospital counsel, and cannot find anything in Medicare regulations or other regulations that would require such notification.

So, I think -- I mean, General Counsel may want to take a look and see what else they can find, but this does exceed the current requirements under other government regulations.

Now, nonetheless, it's a fact of life. It is part of NRC regulations, and the question then is, how can NRC be assured that patient notification is occurring and is occurring properly? The Advisory Committee thinks that you've already got the mechanism in place to do that. The licensee is required to report to you within 15 days, in writing, regarding the misadministration, and is required to give the patient a written copy of either that report or an alternative summary and, in the case where an alternative summary is given, that is required to be sent to the NRC. And we believe that that licensee's report is the logical focus for NRC intervention, to ensure that notification occurred, and to ensure that notification was adequate -- and I'll go through more of those issues in a moment.

We also believe that now that misadministration reporting focuses on those events that are more likely to have deleterious effects, that medical consultants can, and should, be in the loop, and should help you evaluate misadministration reports at many different levels, as I will talk about in the succeeding slides.

CHAIRMAN SELIN: Could I stop you for a minute, Doctor.

DR. SIEGEL: Please.

CHAIRMAN SELIN: Are you going to talk at some greater length about proposed roles for medical consultants? As you know, that's one of the weaknesses in our management. We don't have a clear statement of what we believe a medical consultant can do.

DR. SIEGEL: Only briefly in passing, and we can deal with it more in questions.

Next slide, please. (Slide)

One important question is the rules allow for not informing the patient, and the specific language for not informing the patient says that if in the judgment of the referring physician informing the patient or informing the patient's family, would be harmful to the patient, then so informing the patient is not necessary.

I would point out that from the point of view of a legal standard of care, there is no legal compulsion to inform a patient if there is no actual injury or no likelihood of injury but, at the same time, I would also point out that the ethical imperative is to inform, nonetheless, unless there is a probability of either emotional harm or interference with necessary medical care.

So, the NRC rules, by requiring that the patient be informed even if there's no injury, unless doing so would explicitly, in some physician's judgment, harm the patient, goes a little bit further than the standard informal legal approach, and that may not necessarily be a bad thing, but I think you should be aware of it.

The Committee also believes that analysis of this potential circumstance is that we think there are very few circumstances that would justify not notifying a patient, under current NRC regulations or under the legal duties of the physician.

Dr. Flynn, at yesterday's meeting, raised the situation, for example, of a suicidal patient undergoing palliative radiation therapy for metastatic cancer to the brain, who is expected to have a life expectancy of less than 30 days, and an overdose in a patient such as that, you might well judge that that would, indeed, harm that suicidal patient, and that patient is better off not being informed.

Again, we think that the licensee's report is the focal point for NRC intervention in this process, with advice from medical consultants. And the report needs to quite clearly indicate when it occurs, the reasons why the patient was not informed. Judith Brown again thinks that it should be emphasized that simply a statement in there

that the referring physician thought it would do the patient more harm than good not to be informed, probably shouldn't be accepted as adequate evidence for why the patient was not informed, and that there should be more explicit medical information provided that then could be evaluated by the medical consultant.

With respect to how the consultants might intervene, two issues came up. One is a set of guidelines could, indeed, be developed for medical consultants as to reasonable sets of circumstances under which justification for not informing might be laid on the table. Judith also raises the question whether a regulatory guide for licensees to explain what sort of circumstances would justify not informing might be reasonable.

There is one important point, and that is that the referring physician is not an NRC licensee, and so the reach of the NRC may not extend to that referring physician and his or her interaction with the patient.

Next slide. (Slide)

COMMISSIONER de PLANQUE: Before you go on --

DR. SIEGEL: Please.

COMMISSIONER de PLANQUE: -- let's look at the general practice of medicine. While there may not be a legal requirement to inform the patient, you allude to legal or ethical considerations that would lead you to do

that. If, in general, in the physician's best judgment, it is not advisable to tell the patient, what is generally done? Is there some documentation made in the patient's file? Is there some documentation made to the hospital as to why the patient wasn't informed, in a general sense?

DR. SIEGEL: I can't speak for all physicians but, if you're aware of an error and you are reasonably certain it was due to negligence and you choose not to inform the patient, you are best to document that in your records.

Then you've got an interesting problem that you need to deal with in that patients now have access to their records as much or as often as they want, in most circumstances. So, it's a fine balance that one has to strike.

I, frankly, personally feel that the justifications for not informing are very few, and my own personal approach would be to inform. I think that truth-telling really works better, in the final analysis, in the practice of medicine, and the doctors who try to cover up their mistakes are usually not very good at it, and they invariably get in trouble as a result of doing it. And it's just not a practice that I certainly would encourage. My approach is to inform, but I do think that there are circumstances, such as the unique ones we pointed out,

where you might, in fact, determine that it's just not better to tell the patient.

But there's other kinds of harm that have to be considered. There's the harm of making a patient so distrustful of the environment in which they are receiving their care of a high strung patient, that all of a sudden they are no longer really capable of getting effective care, of making a patient so obsessed with the concern of injury that they become litigious to the point of not really wanting to be involved in their medical care.

And, so, the patient/physician relationship varies, as we characterized it yesterday, from being very casual in some circumstances where the patient and physician barely have any contact with each other, to one of a very long-standing close bond between a patient and family and it's particularly in the latter ideal type of patient/physician relationship where a physician's judgment will be of greatest value.

CHAIRMAN SELIN: Could I just follow up a little bit on this?

DR. SIEGEL: Please.

CHAIRMAN SELIN: Let's set aside the conditions under which notification would not be called for, just for the present. Is it your impression that in most practices of -- I'll use your phrase just for today, until I have a

chance to think about it -- in most practices of radiation medicine, that if there were misadministration, whether it was diagnostic or therapeutic, whether it would be one that we would feel is important enough to follow up with the Congress or not, that the physician normally would tell the patient, or normally should tell the patient, that they got 15 millirems instead of 10 millirems -- I mean, even not major ones with likelihood of not major health impact?

DR. SIEGEL: It's my impression that that is, in fact, what is done, and we really have no better data than you do. And it's our understanding that your informal analysis by staff up to this point of misadministration reports, suggests that referring physicians are informed, as they are supposed to be, nearly all of the time, and that patients are --

CHAIRMAN SELIN: I meant to go a step further. Let's take linear accelerators, you know, things that we don't regulate, but is it generally medical practice --

DR. SIEGEL: Yes.

CHAIRMAN SELIN: -- not just because the NRC requires it, but because it's good practice to tell people that they are --

DR. SIEGEL: Yes. And the first slide, I think, made that point. The standard of care is truth-telling,

and under circumstances where there is negligence and injury, not truth-telling is fraudulent concealment, and that gets you into even greater legal difficulties down the road.

CHAIRMAN SELIN: My impression is there really are two issues. One is not so much whether it ought to be done, but whether the NRC ought to require that it be done. And then the second is, what are the conditions under which -- are our conditions too tight for accepting it?

DR. SIEGEL: Yes. In some ways -- this didn't come out yesterday, but I think it's a relevant point -- in some ways, having the NRC in the loop sort of raises the anxiety level of the whole process, so that what could have been a physician talking to a patient saying, "Listen, we did the following thing, and these are the consequences. We are sorry it happened. It shouldn't have happened, but it did".

Now, the physician, on doing that, puts him or herself in a position of potential liability for malpractice. But by having that reporting to the federal government in the loop, that official document in the loop, it kind of raises everybody's awareness -- "Gee, what's going on here? This must be -- the doctor said nothing bad's going to happen, but then why all of a

sudden do you have to make this report to the NRC?"

So, I think that that is an important issue, and I frankly think that some of the failures to report in the past have been consequences of the fear factor induced by having the NRC in the loop. Some of the misadministrations that have been covered up in the past were inconsequential events. They were diagnostic misadministrations that would have resulted in no harm to the patient and, frankly, no bad reputation for the physicians or staff that were involved, and yet they were covered up because something compelled those individuals to want to stay out of this circle that involves the NRC.

So, I think that is an important issue, and one issue might be that maybe the NRC is on the right track as opposed to the wrong track, but then maybe we ought to do the same thing for the rest of medicine, and not just have it limited to byproduct material activities.

CHAIRMAN SELIN: Dr. Flynn, did you want to add something?

DR. FLYNN: No, I didn't, but in radiation oncology, even with linear accelerators, if a wedge is left out for one field, even though it may not qualify for a misadministration, even if the NRC did regulate the linear accelerator, the patient is told. And, so, that's my experience. Even if it were NRC regulated, even if it

would not have been a high enough of a dose differential to cause a misadministration report, the patient is still told. And usually that ends up being a very positive experience because I think the patient wants to be able to trust that you would tell them and communicate with them even when things don't go precisely as planned.

CHAIRMAN SELIN: Especially if it's a trivial difference, it's an easy way to build up confidence without scaring people.

DR. SIEGEL: Okay. Next slide, please. (Slide)

The next question that we were posed with was what should be the content of patient notification? The Committee believes that patient notification should include a full description of all reasonably probable medical consequences of the misadministration. And, thus, we all certainly agree that the patient needs to be informed about all deterministic effects. That includes both deterministic effects that can be expected to be immediate as well as those that may not appear for some period of time.

One gets into a much more difficult question, however, when you get into the realm of stochastic effects, and the Committee was not prepared nor do I think one could logically, in four hours yesterday, tell you where to set the threshold on proper reporting for

stochastic effects.

There are two issues that one might be concerned with with respect to stochastic effect reporting. First of all, is it medicolegally relevant to the patient? And in the vast majority of circumstances, it will not be medicolegally relevant, first, for one to claim damages, there has to be some injury, and a stochastic effect will not occur for some period of time. Even when the injury, the radiation-induced cancer, finally does occur, it still is an indeterminate cancer with respect to its radiation-induction, and the more-likely-than-not test means we're starting to talk about relatively high doses where we can feel reasonably certain that the cancer was induced by radiation. So, medicolegally it doesn't gain you very much.

Number two, what does it gain you in terms of the impact on what you tell the patient about what their continuing medical care and follow-up needs to be. And for the vast majority of stochastic effects, you wouldn't tell the patient to do anything different. If you have a 10 rem whole-body exposure and based on verified data have a 1-in-1,000 chance of radiation-induced cancer -- 1-in-100 chance of radiation-induced cancer -- you add that to a 22 percent lifetime probability of cancer -- with a 23 percent probability, you don't do anything different. You

don't start mammographic screening at an earlier age. You don't start PSA testing for prostate cancer at an earlier age. You continue to get medical care the way you would have routinely.

Now, there are certain circumstances with relatively high doses, particularly that involve very radiation-sensitive organs -- the thyroid might be a good example, with a misdirected dose to the head and neck in a very young patient, where you might do something like put the patient on thyroid hormone immediately because of the belief, the putative evidence, that suggests suppression of endogenous thyroid stimulating hormone slows the induction of thyroid carcinoma, and that there might be medical justification for doing so. But in most cases, you wouldn't change what you do. And certainly for doses less than 10 rem where Bier-5 says -- you know, our database falls apart -- it's very difficult to know how to advise the patient.

CHAIRMAN SELIN: A little bit like the "look out for falling rocks" sign.

DR. SIEGEL: Look out for falling rocks. And the trade-off is incapacitating a patient because of lifelong cancerophobia, and it does occur.

CHAIRMAN SELIN: Did you have the chance -- and by the way, it's not just the patient who is concerned.

I would like to emphasize that you have health care workers, you have neighbors, you have a lot of different people who in some cases come up. Did you happen to see the letter that the Commission sent to the people in the Indiana, Pennsylvania event?

DR. SIEGEL: We did not see that letter.

CHAIRMAN SELIN: I'd like to get that letter to you and see what your collective opinion was on it. You were asked about that, weren't you, Doctor?

DR. FLYNN: I was told that a letter was sent out after the fact, but I never have seen it.

CHAIRMAN SELIN: You, in fact, were never shown a copy?

DR. FLYNN: I have never seen the letter, no.

CHAIRMAN SELIN: Oh, is that right? That's different from what I understood. We'll make sure you get a copy of the letter, and invite your opinion.

DR. FLYNN: Thank you.

CHAIRMAN SELIN: I mean, it really does concentrate on the deterministic, but it does make some reference to the stochastic. You have a specific case in which you could take a look and see what your opinion may be.

DR. SIEGEL: Yes. A starting point that also would be helpful if you decide to get into this issue, is

to look at the kinds of informed consent documents that are used, first of all, in radiation oncology, but also the informed consent documents that are used in the research setting where ionizing radiation is involved. And people have worked reasonably hard on trying to strike a balance in adequately informing and yet not scaring people so much that they will choose not to participate in the research, and that's a difficult balance to strike.

CHAIRMAN SELIN: That's important because there you have a future action which you will or will not approve, as opposed to it just happened and what do you do about it.

DR. SIEGEL: Correct.

CHAIRMAN SELIN: A second question I wanted to ask you about on this point, forgetting for the moment the stochastic side, in some cases, even the deterministic impact isn't immediately observable, that people get certain doses of radiation, you'd want to watch them for a while to see if there were going to be a deterministic response. You could almost say that response was almost certainly due to the radiation.

DR. SIEGEL: Correct.

CHAIRMAN SELIN: Would you consider that to be part of patient notification?

DR. SIEGEL: Absolutely, and in fact the next

slide addresses that directly. If we could, please. (Slide)

That gets into the issue of patient follow-up is a component of patient notification. Once again, I think medical consultants can, and should, help to evaluate misadministrations with respect to the elements of patient follow-up, and the Committee thinks that a follow-up plan should be a necessary part of the notification to the patient either when injury has actually occurred or is likely to occur, and likely to occur includes those kinds of deterministic effects where even though they haven't happened yet, it's a reasonable probability that they will occur. So, pulmonary fibrosis, cataracts, at later times, and patients can be told, "This is what you need to do to keep ahead of those problems". Once again, the stochastic threshold is a policy issue that we weren't prepared to debate today.

CHAIRMAN SELIN: It's interesting. There are two aspects of this. One is the probability that something that will happen, but the second is a posteriori probably that if it happens, you're pretty sure it came from radiation. And with these cancers, you have a negative answer on both. In other words, you're not sure what will happen and, if it does happen, you're not sure it came from radiation.

DR. SIEGEL: Correct. But with pulmonary fibrosis to the same region that corresponds to the incorrectly placed radiation port, the evidence is pretty compelling that it was radiation-induced.

We think that the evaluation of patient notification by the NRC -- in other words, evaluation of the written report -- and with the aid of medical consultants should unequivocally include a consideration of whether the licensee has laid out an adequate follow-up plan for the patient. But then we think that NRC intervention should stop, that the NRC need not get into the business of actually following up patients. An NRC clinic doesn't somehow sound like a useful way to use your resources. Unless we have some fundamental change in the way all of government chooses to deal with all medical misadventures, the NRC would, in fact, already be going further than government does in this respect.

And the next slide --

COMMISSIONER REMICK: Excuse me, Dr. Siegel, before you do that --

DR. SIEGEL: Yes?

COMMISSIONER REMICK: Should I read anything in particularly on your use of medical consultants in contrast to NRC staff members who are medical doctors presumably with experience in radiation medicine, or would

you say consultants are --

DR. SIEGEL: If you had full-time staff who were physicians, then that would be okay, but I don't think you have any full-time staff who are physicians currently.

Next slide, please. (Slide)

I forgot one thing on the previous slide, and that is, Judith Brown thinks that the follow-up plan that you lay out to the patient should include not only what the patient needs to do medically, what kind of follow-up is appropriate, but also should give some estimate of the economic consequences of that medical follow-up to the patient.

I think the sense of the Committee otherwise was that at day 15 it might be pretty difficult to make an estimate of what those economic consequences would be, but the point is noted for the record. So that if the patient is going to need lifelong thyroid hormone therapy, some estimate of what that's going to cost and what annual follow-up visits are going to cost should be included in the licensee's report to the patient.

COMMISSIONER REMICK: Dr. Siegel, you said the medical plan that "you" lay out. Are you referring to NRC, or to the licensee?

DR. SIEGEL: The licensee should inform the patient that "this is the bad thing I did, this is what's

likely to happen, and this is what we think, based on what we currently know, you're going to need to do to stay ahead of this", recognizing that it's just as important to get that information into the hands of the patient's referring physician because the patient may run, not walk, to some other medical facility, rather than continue to receive their care in the hands of the licensee who supposedly -- or who just injured them.

COMMISSIONER REMICK: I wasn't sure if you were saying whether the NRC should develop the plan.

DR. SIEGEL: No, but if the licensee's report comes in and the patient had 600 rems or 1,000 rems exposure to the lung on top of what should have been there, and the medical consultant and the NRC staff conclude that there's an almost certain probability of a serious pulmonary fibrosis developing and the licensee's report says nothing about follow-up for that, the intervention by way of the enforcement conference, with the help of the medical consultant, should say, "Listen, you've got to clean up what you reported to the patient because it wasn't adequate". So, again, that report, with medical consultant help with the staff, is a way to intervene in the process.

The Committee knows that there was some question about whether NRC might want to get into the business of

long-term follow-up of patients, contracting with Oak Ridge, for example, to set up a patient registry, and the Committee thinks that if there were clearly defined unanswered scientific questions about some radiation effect that you wanted to have an answer to, that setting up a registry or a follow-up mechanism might be sensible. On the other hand, we couldn't think of what the question was. We think we know more about radiation-induced injuries and effects than most other noxious things that we encounter in our society, and we weren't sure what things you'd want to address. We also don't think you'd gain much from the point of view of framing regulatory questions by having an NRC clinic somewhere where these patients could go for follow-up.

We also feel reasonably strongly that the NRC's role should not extend to that of plaintiff's attorney. Our society has pretty ample mechanisms for people who have been injured in medical encounters, to find their way to an attorney who would be happy to undertake their case and claim compensation for damages from the physician and anyone else who was within 100 yards of the event at the time that it occurred.

CHAIRMAN SELIN: We'd be realistic --

COMMISSIONER CURTISS: You're not libeling us, are you, there?

(Laughter.)

DR. SIEGEL: No, not at all.

CHAIRMAN SELIN: A couple of these alternatives you're discussing aren't serious NRC alternatives. There is a legitimate question about when is the follow-up useful and when does it stop. There is a question about obligations to a patient as opposed to the regulatory process, not so much a long-term stochastic registry, but do we have an obligation, which I think you said we do and we clearly think we do, that each individual patient get a full report, not just enough information to find weaknesses in the regulatory or the administrative process. It's not our job to do the basic underlying biology insofar as the federal government has a responsibility, that's HHS' and not ours, and I don't think we're seriously thinking of opening a clinic -- a day care center maybe, but not a clinic. So, I'd just like to put to rest some of the -- not all, but some of the points that you raised.

DR. SIEGEL: Next slide.

CHAIRMAN SELIN: I'm sorry --

DR. SIEGEL: Please.

CHAIRMAN SELIN: The last point, as far as the tort question, our position is that medically important information should not be suppressed just because it could

have a very deleterious effect on the physician, from a tort point of view. It's not the other way around. We're not trying to -- I mean, basically, we're trying to take the position that the tort considerations are irrelevant to our health and safety. We're neither pro nor con toward tort law, but the medicine has to be taken care of and let the tort questions fall where they may. Commissioner de Planque?

COMMISSIONER de PLANQUE: I have one comment on this issue. It seems to me there's one fundamental piece of information we do need to know, and that is whether or not harm is caused, and I'm not talking about the long-term problem where obviously we know there are great difficulties. But it seems to me we need to know that, and not just for scientific purposes, but to know how successful or unsuccessful our regulation is.

We may be over-regulating to the extent that if you knew how much harm there really was caused -- or how little harm there was caused out there, you may want to address your regulations in one direction. If there's more harm than you think, you may want to address them in the other direction.

So, it seems to me that knowing when, and if, there is harm is critical for determining the regulatory direction.

DR. SIEGEL: It's difficult to disagree with that viewpoint but, by the same token, it's not easy for me to conceive of a very simple mechanism that won't involve an awful lot of paperwork without much benefit to achieve that. Would you consider sending annual questionnaires to patients to say "Where do you stand?"

COMMISSIONER de PLANQUE: No, I'm talking about the effects that are obvious within the first two months of the incident, let's say, where you know that there is a radiation-related effect or not.

DR. SIEGEL: Well, you have an opportunity to capture that kind of information because you're likely to still be in contact with the licensee --

COMMISSIONER de PLANQUE: Right.

DR. SIEGEL: -- as follow-up to the event at that point of view --

COMMISSIONER de PLANQUE: But there has been --

DR. SIEGEL: -- but the patient may no longer be logically within the licensee's grasp at that point because the patient may well have fled to another physician and, as I pointed out earlier, the referring physician now delivering the care, if not a licensee, may not really come under NRC's regulatory control. That physician might well be very eager, though, to cooperate with the NRC in trying to understand the events, so long

as issues of patient confidentiality were not being violated, and patient sensitivities were not being violated.

Dr. Marcus?

DR. MARCUS: I would like to make a comment in answer to your question in terms of nuclear medicine. The act we take when a patient gets an overdose of I-131 will preclude you knowing the answer to your question because, by keeping patients on Synthroid, you don't know if their thyroid works or not. The deleterious effect that you're worried about happening, you don't know unless you take the patient off the therapy.

Now, there may be a reason to do that because you may want to wipe out any remaining tissue because of fear that there will be a long-term cancer in 30 years or something. But to take them off Synthroid for the purpose of statistics I don't think is morally appropriate.

So, although the concept you have is good, I think you have to just take nuclear medicine and throw it away because the main thing we do precludes you getting the information that you're interested in because, really, I-131, to a good first, and almost second, approximation, is the only real problem we have.

COMMISSIONER de PLANQUE: But that's just looking at one aspect of the whole radiation medicine

field. I think ultimately you need to ask the question, is there harm being done or not? And your regulation should somehow be based on whether or not there's real harm out there.

DR. FLYNN: In radiation oncology, based on the dose, where the dose is delivered, what organs got that dose, a medical consultant, if the licensee does not provide an accurate statement as to what is the reasonableness of either possible or probable harm, certainly a medical consultant can provide advice as what is the chances of probable harm to that patient. And if you also have a visiting fellow program intact, that person here on NRC staff, would be a buffer between the reports that are coming in to you from the licensees and the medical consultant, and you can get a good feeling for the probability of harm. And, therefore, if you know that, you know what sort of follow-up tests specifically might be advisable to the patient, based on what organs were involved, what doses were obtained in that accident.

CHAIRMAN SELIN: By the way, nobody was suggesting that the treatment be modified in order to produce statistics. I don't think we would suggest that.

DR. MARCUS: No.

DR. GRIEM: There are a lot of voluntary efforts going on at present. In the children's cancer study

group, there's a long-term follow-up on any child treated with drugs and radiation. In the case of the neutron group, there are about 5,000 patients who have been treated with vast neutrons, and there is a total registry of those patients. Now, with the proton group, and PETCOG, and even working with the Russians and so forth, there are about 5,000 patients who have been treated. Those are all being followed up. So, we are developing a database of what to expect, and not just at one month or two months, but five years and ten years later.

I think there is data being developed -- in our own case, we're following up 4,000 patients treated 35 years ago for peptic ulcer, and what the outcome is. We've been able to follow up 70 percent of those people.

COMMISSIONER de PLANQUE: I think my bottom line is not so much that I have a specific idea as to how you should do this, but that's the ultimate question, and that's the question that the press will ask when incidents like this come out -- "Well, is there harm out there", and "do you know", and "how do you know?" So, it's a question of how do you best develop some technique for answering that, be it for regulatory purposes or otherwise?

DR. SIEGEL: And I don't have a clear answer, although I think that if the Advisory Committee sat and looked at a sampling of events, we might well be able to

give you a clear picture that there was, in fact, a very small percentage where additional follow-up data beyond what you already knew would even be warranted because the database about radiation effects is already so strong that making predictions is so logically easy to do.

COMMISSIONER de PLANQUE: Is good enough.

DR. SIEGEL: Right. Next slide. (Slide)

One of the questions you raised was is there underreporting of misadministrations. This slide is blank other than the title because we don't have any better data than you do. It is our sense that underreporting of misadministrations is not a major problem. It is not a pervasive problem. It occurs in a small number of circumstances, indeed, because of bad apples who want to cover up their mistakes. It occurs in some circumstances, as I pointed out earlier, because of the fear factor that drives people's behavior in the wrong direction, and that's unfortunate when that occurs, but we think you've got a plan in place to find out. Despite all the kicking and screaming about the quality management rule, it now provides a logical focus for you to find out whether there's any significant island of underreporting.

The states need to be in compliance by 1995. The Agreement States, you will have individual program audits, and you will have inspectability of those audits,

and you will have a chance to find out whether people are missing that they've had misadministrations simply because they weren't smart enough to recognize it, and you'll have some opportunity to see whether they are being covered up.

Next. (Slide)

An important question and one raised by the Plain Dealer was the issue of NRC's regulatory purview, and the Committee has some guidance for you on this one.

I think, as we've said before, it's important to recognize that byproduct material is not uniquely hazardous. It's certainly not uniquely hazardous by comparison with other forms of ionizing radiation used in medicine, and it's by no means uniquely hazardous by comparison with the other high technology things that are used in medicine -- patients undergoing cancer therapy sometimes get the wrong chemotherapeutic drug or get the wrong dose, and there are errors that occur as a result of those. The USP now has a medication error reporting mechanism, and recently has reported some deaths due to mix-ups during cancer chemotherapy. So, what radiation medicine doctors do isn't necessarily better or worse than what happens in the rest of medicine.

I think it's very important -- and I'm sure you understand this -- that you do understand that your purview includes a very small fraction of ionizing

radiation use in medicine.

Based on the 1991 Medicare data -- which admittedly applies only to the Medicare population -- the following statistics are of interest. There are about 87 million radiology procedures in that 1991 Medicare database. Of those, if you take all of the nuclear medicine procedures -- and that's, by the way, excluding ultrasound as not involving ionizing radiation, the 87 million -- if you take all of the nuclear medicine procedures -- which automatically is an overestimate because it's including the non-byproduct material nuclear medicine procedures -- all of the brachytherapy procedures, and 20 percent of the teletherapy procedures -- which is now probably an overestimate, but was right on-target for '91 because 80 percent are done with linear accelerators -- you come up with the percentage of those procedures as 5.95 percent of the total. If you now allow that one-third of the licensees are yours in two-thirds of the Agreement States, your direct purview is perhaps 2 percent of the procedures that involve ionizing radiation.

Now, admittedly, some of the things that you have purview over are the most hazardous things that involve radiation -- the brachytherapy procedures, the teletherapy procedures, some of the radiopharmaceutical therapy procedures -- but, nonetheless, it is a very small

fraction. And, consequently, that has to be kept in mind.

The Committee thinks that there is indeed a need for a set of uniform national standards -- didn't say regulations just yet -- standards that would relate to diagnostic and therapeutic uses of ionizing radiation in medicine --

CHAIRMAN SELIN: Regardless of the source.

DR. SIEGEL: -- across-the-board, regardless of the source -- but we raise the question -- and you won't like this -- whether the Atomic Energy Act provides the appropriate forum for resolving this problem.

CHAIRMAN SELIN: We're not looking for more business. I mean, we haven't so much enjoyed the medical regulatory function so far that we'd care to --

DR. SIEGEL: We're quite aware of that.

CHAIRMAN SELIN: -- but a question has arisen, and that has to do with linear accelerators. I mean, getting us into the business of x-ray machines is something that no one has suggested.

DR. SIEGEL: But there is potentially a role for the government to be in the business of regulating x-ray machines more thoroughly than may now be being done by the states. The recent problems in New York's Long Island relating to mammography, the fact that cardiac catheterization procedures sometimes involve doses that

get well into the therapeutic range and result in deterministic effects, are things that people need to pay attention to. And in a way, I think what would make the profession see this all as more sensible is that if it was applied across-the-board, it would make it more logical to physicians as a whole to be regulated with respect to the way they use ionizing radiations, rather than have one very small focus get all the attention.

I think that part of the problem that NRC may have with respect to the medical community viewing its regulations as credible, is the fact that so much of the ionizing radiation use does not come under the purview.

CHAIRMAN SELIN: Is outside the regulation. Dr. Marcus?

DR. MARCUS: Back in 1981, the Department of Health and Human Services got the legal mandate to put together guidelines for the states to decrease unnecessary radiation to patients in radiation therapy, nuclear medicine, and diagnostic radiology. It was part of a law that also encouraged them to get states to make sure their technologists were licensed.

They have not really done too much with this mandate. I think we see it in the mammography efforts now, and I think they're good. I think we may see it more. But just realize that the enabling legislation is

already in place to HHS, and it's simply been their determination so far as to where they are going to use their resources.

CHAIRMAN SELIN: Well, as a general principle, NRC does not set standards, be they radiation standards, air quality standards, et cetera. The general focus for radiation medical standards is HHS. Our job is to set up regulations and either supervise or charter inspections to be consistent but, as a practical matter, those standards often don't exist, and we end up pushing them.

But the specific question I wanted to ask you about was whether you see -- your Committee sees any benefit in our seeking support to extend our practice to cover linear accelerators, because that was suggested to us by some other people.

DR. SIEGEL: Well, I think the way I would answer that question is that I see benefit in Congress re-examining where it should be regulated. And I think an important point of that is that medicine is about to undergo a major upheaval in the United States. Things are going to change in the next few years. It's clear, the handwriting is unequivocally on the wall.

In the process of regulating this aspect of medicine, that regulation has to be done with a view to the national priorities with respect to all medical

funding and all medical regulation.

And, consequently, I think a global ionizing radiation act that deals with medicine, incorporated somewhere where it has the total medical picture being looked at, would be of ultimate benefit to this country, so that for lack of something else, yes, there might be benefit for the NRC going after this particular additional regulatory purview but, frankly, I would argue that if the country is going to do it, now is the time to do it and let's do it right. Let's take the whole shooting match and bring it all together.

Okay. At this point, what I'd like to do is briefly turn things over to Dr. Flynn, who is going to provide a few words about brachytherapy regulation and -- given his unique perspective as a consultant to the IIT.

DR. FLYNN: First of all, HDR brachytherapy -- it's a developing technology, and after the Indiana, Pennsylvania accident -- slide, please. (Slide)

After the Indiana, Pennsylvania accident, I had a chance to talk to senior officials in some of the medical professional societies that we're involved with as radiation oncologists, both the American College of Radiology, American Society of Therapeutic Radiology Oncology, and the American Endocuratherapy Society, which is the society of brachytherapists.

In talking to senior representatives in these societies, elected officers, it was the unanimous opinion, agreeing with myself, that HDR brachytherapy is not essential in any patient. So, therefore, the focus must be that before any HDR is approved to licensees, that you should reasonably expect that the HDR will be performed safely.

If we now look back at the Indiana, Pennsylvania accident, an accident that was discovered on December 1st that happened on November 16th, and a second incident on December 7th, led to the NRC Bulletin 92-03, which was, I felt, extremely timely. And I'd just take a moment to read the three key factors that were sent out on December 8th, to all the Omnitron 2,000 users, because it's extremely important.

Number one: In accordance with 10 CFR 35, the licensee shall make a radiation survey of the patient with appropriate radiation detection survey instrument, to confirm that all sources have been removed. This survey is in addition to any indication of the radiation levels provided by the area monitor. The survey shall be done immediately after completion of the therapy, but prior to removal of the patient from the shielded room. That's number one.

Number two: The licensee shall not conduct any

procedure for which a decoupled source cannot be removed expeditiously from the patient and placed in a shielded condition. The licensee shall have written emergency procedures describing actions to be taken, including surgical intervention. Should the source not return to the shielded container at the conclusion of treatment, the licensee shall assure that appropriate staff and equipment are available immediately at the location the HDR procedure is performed, to implement the written emergency procedures, and it goes on to describe what equipment.

Number three: The licensee shall ensure that personnel are trained both in the routine use of the device and emergency procedures to return the source to a safe condition. Training shall be provided immediately for new personnel and retraining provided semiannually for all personnel.

Now, all of this sounded very familiar to me because at least the voluntary standards by the American College of Radiology put out two years prior to that involving -- and it's only a document that's only eight pages long. It's double-spaced. You can read this in five minutes.

This was provided to all people in radiation oncology and to all brachytherapists. Clinical use -- this is by the American College of Radiology now. Source

removal requires source counting, final patient survey, et cetera. Emergency procedures must be established for handling source breakage, loss of sources, and contamination from unsealed sources.

So, these voluntary standards are going out to those of us who practice radiation oncology and, as far as the membership in the professional societies, basically, we're all members of these professional societies, either one or more of them. The Society of Brachytherapists -- that is, the Endocuratherapy Society -- has 450 members. So, we're a very small subset of radiation oncologists. ASTRO has a membership of 2500 active members. American College of Radiology, about 30,000, to include nuclear medicine and diagnostic people, which dominate that organization.

So, I think it's important when we look to this accident in Pennsylvania, that we take this NRC Bulletin 92-03, which was put out in a matter of hours after the second event, and look to this as being a document which could be applied to all HDR brachytherapy because, as I emphasized in the beginning -- and I got the support of senior elected officers of all the organizations involved -- that HDR brachytherapy is not essential in any patient, and it's a very promising technology which is going to develop and go forward, however, it must be done safely.

And I think that as far as what specific HDR regulations are needed, certainly in terms of regulations you have time to develop regulations, but you have a mechanism, the NRC bulletin mechanism, to reach the other users in HDR brachytherapy because, after all, when one opens the room to retrieve the patient from the room where the procedure was performed, one merely has to just turn on a geiger counter which would immediately go off-scale if there's a source that's been left open -- that takes a matter of a few seconds, it is not a long, involved procedure.

And if these catheters are sutured to the patient, the physician has to be there because, if the physician is not there and a device breaks off inside a catheter which is sutured and sewed to the patient, certainly a 19-year-old technologist is not equipped surgically to remove catheters surgically from a patient nor to retrieve the source, neither would the physicist, because you'll remember the second incident on December 7th was a catheter that was for endobronchial treatment or esophageal treatment, was taped to the nose. Now, that can be removed by a physicist, but if it was a catheter sutured to those patients, such as in the Indiana case, a physician would have to be there and would have to have the instruments to remove the catheters.

So, I think I would only modify 92-03, which I participated in writing with the NRC staff, in looking back to see where there could be any other loopholes that should be closed -- and I think the term in paragraph 2, "appropriate staff", should be replaced by "the responsible physician, and the physicist, and other appropriate staff as necessary", because those of my colleagues in brachytherapy have -- the initial reports that I have had is that the IIT report is nothing but superior. It's a superior report, something the NRC should be proud of, and that I've had no one offer a counteropinion that the physician and the physicist shouldn't be there at the console when the patient is being treated. I haven't had a single dissenting opinion to that effect.

So, I think it's important for you to proceed to cover the other HDR instruments, of which there are only two other manufacturers, Nucleotron and Gamma-Med.

Next slide. (Slide)

CHAIRMAN SELIN: Before you go on, you had adequacy of training there.

DR. FLYNN: As far as training -- I'm sorry -- there are certain subcommittees in the American College of Radiology who are working both on the physics and physician criteria for using HDR. These are ongoing. And

I understand at our next ACMUI meeting in May, we'll be addressing training specifically because certainly the training is necessary for handling the device for which they are licensed, and also for emergency procedures, but as far as the more broad global training that's necessary, this is something that's very complicated and under discussion right now by our Committee and by the professional associations.

CHAIRMAN SELIN: When you look at that, I hope you also look at the question of recertification, not just initial training to keep people just up-to-date.

DR. FLYNN: Yes.

CHAIRMAN SELIN: Thank you for the kind words, we haven't gotten an awful lot of those in this area. Appreciate the IIT comments.

DR. FLYNN: Next slide. (Slide)

I think having a medical consultant be a member for any IIT involving any medical misadministrations is very important that I'm sure that NRC would select the medical consultant from the area in which the misadministration occurs -- if it's nuclear medicine, a nuclear medicine physician; if it's in radiation oncology, a radiation oncologist; if it involves physics, a medical radiation physicist; if it involves brachytherapy, a physicist who is doing brachytherapy all the time -- and

I think that's important.

I think also in terms of ACMUI membership, it was always my opinion that our committee itself should be balanced, to make sure that you have the input you need both in nuclear medicine and radiation oncology, and that the tilt in membership right now is a little bit more towards nuclear medicine areas, so that I would encourage you to keep looking at that to see where your needs are and change the membership if you think it needs any change, depending on the types of issues that are coming up.

But I'd also like to point that the visiting fellow program is a very successful program, and I hope that you recognize that also, but that if you have a certain number of visiting fellows, that it should be equal membership from both nuclear medicine and radiation oncology because you can utilize this person as a physician since you have no physicians on your staff, to act as a buffer, a buffer between, let's say, Office of General Counsel, between the medical consultant who is putting information to you, and to the licensee whose medical people are feeding you information. And if they are feeding you information which you find is not complete, then you can use this visiting fellow and use the ACMUI membership to help you decide what needs to be

done further, including follow-up instructions that are given to the patient. Written follow-up instructions that are recommended in terms of what he can bring in his hand back to the referring physician who understandably is not an expert on radiation effects and may not know what to look for, let's say, six months later for radiation fibrosis in the lung, or a year later if there is damage to the bowel. And that concludes my comments.

CHAIRMAN SELIN: On the question of ACMUI membership, do you have any general comments not just on the balance between the medical membership, but the nonmedical membership? I can't find exactly the right word -- I'm trying to include physicists with the medical membership, but state members, or the patient's rights, or other groups?

DR. SIEGEL: We discussed this yesterday, and I think that given the Committee's increasingly expanded role in helping to advise you on policy issues, that the expanded membership makes sense. It may be, though, that from an operational point of view, we might need some consultants to the Committee, and might need to break into subcommittees for certain analysis of technical issues, so that we don't have to have 20 people sitting around the table arguing the fine details of a new set of brachytherapy proposed regulations. And that's something

we can operationally try to work out with the staff.

CHAIRMAN SELIN: Mr. Collins, Ms. Brown, anything you'd care to add?

(No response.)

Commissioner -- did you have some closing comments?

DR. SIEGEL: No, just that we once again thank you for the opportunity to comment, and stand ready to help you.

CHAIRMAN SELIN: We have some questions.

DR. SIEGEL: I know we do.

CHAIRMAN SELIN: Commissioner Rogers?

COMMISSIONER ROGERS: It occurs to me, and I may be wrong on this, but I somewhat have the impression, in just looking over the events that we've had to focus on, that at least a large number, maybe most, and I'm not sure whether it's most or not, of the errors that took place, were actually committed by technical rather than medical M.D.s. I'm not sure if that's correct or not, and I wonder if you have any supportive data to be able to separate out just actually where the error was committed and to what extent there was an M.D. involved, and to what extent there were not M.D.s but technical people. And along that line, I'd like to have your thoughts of just where do the M.D.'s responsibilities begin and end as part

of this total process of radiation medicine.

Also, I'd like to hear what your thoughts are with respect to the role of the radiation safety officer, and to what extent the radiation safety officer has adequate responsibility and authority, and to what extent that's a problem, as a member of a team.

DR. SIEGEL: Okay. I can speak to some of those, and I think other members of the Committee may want to address them as well. We have not done a thorough analysis of all misadministrations, and did not yesterday even attempt to do a thorough analysis of the 85-some-odd abnormal occurrence reports that were involved.

My sense is that most of the nuclear medicine events involve predominantly ancillary personnel errors rather than physician errors, but to the extent that they involve failure of procedures, then they are physician errors because that gets to the heart of physician responsibility. The physician is responsible for what goes on in his or her nuclear medicine department, and that extends right down from making sure that radioactive materials are secured against theft, up to and including the point of making sure that the right stuff gets in the right patient.

And I think that diffusing that responsibility down to a lower level in the process would not make sense.

It needs to rest with the medical professional who ultimately has the responsibility for the care of that patient.

In the case of radiation oncology accidents, those problems have, in some cases involved physicians, in some cases involved medical physicists, in some cases involved technologists. Dan and Mel may want to speak to whether they think there's a preponderance of one group or another, but I think the fairest answer is we really haven't evaluated them in detail. Peter?

DR. ALMOND: Well, my experience is that the misadministrations or errors, it's not one single one, but it's a series of mistakes or errors that are made. For example, a computer may not function correctly, but then someone later on doesn't notice an adverse skin reaction on the patient. That was clearly the case in the Maryland situation. So, it's a series of errors and, you know, various people involved in those.

DR. FLYNN: I would say that there's a -- I see it in my specialty, as Mel can comment, two different kinds of types of errors that are occurring -- those errors which occur extremely rarely with licensees that have a good QA program and follow the QA program, and those errors or problems that occur in licensees that need a lot more help, that are a lot more isolated, they don't

have redundancy in terms of the chart-checking.

I'll give you an example. If you had a patient who was the wrong patient treated -- it happens extremely rarely. Go up to the waiting room, Mrs. Smith's name is called out, it's her turn to be treated, and let's say Mrs. Jones is confused, gets up and comes to the room and is treated instead of Mrs. Smith. That's happened a few times in the last ten years.

If the NRC inspection shows that the licensee had a QM program whereby two means of identification of the patient were required -- one being calling out the patient's name, the second being that there was a photograph in the patient's chart. Okay. Now, you discover that the licensee, in reviewing all the charts, that several hundred charts they all have the photograph in, except in this case, an act of God, whatever, the photograph had fallen out, and a new technologist didn't recognize Mrs. Smith and instead she treated Mrs. Jones.

Now, you go to another licensee where the exact same thing happened, and when you look at the charts you find that the licensee had a QM program, their QM -- not the NRC's, but their own QA program -- but you looked at the charts and only half the charts had photographs in them. "Why aren't the photographs in here, it's in your own program?" "Well, it's time-consuming, we don't have

the time to do it." That indicates that there may be some underlying problems that the licensee isn't even following their own QA program, let alone the NRC's QA program. And I think that those types of errors can be reduced, and that's why I think the effort has to be focused on the minority of practitioners and licensees, whether it's 1 percent, whether it's 5 percent, that are problem licensees, and I think that's where I would put my emphasis. I don't know if you have any comment, Mel?

DR. GRIEM: We looked at this question of is there a systematic error in treatment, and thanks to one of the film manufacturers, they made a film for us that we could record by placing the film under the patient, could record the dose and where the treatment was delivered, and do that daily for a year, and we singled out a disease -- two residents worked on this -- and we identified certain errors or misadventures -- one, that the patient moved; second, that the technician didn't set the patient up on Tuesday as it was designed on Monday; and, finally, that the physician didn't aim the beam at the right part of the tumor -- and we scored all this and we singled out various physicians A, B, C, and D, and I don't know that I was B or C at the time.

But at any rate, we looked at this and published all of this. This kind of work is going on today, and

we're looking at specific diseases like cancer of the prostate where the dose is key to the ability to cure that patient, and two Ph.D.s are working on this question -- what equipment is needed, what systems are involved, and where are the errors occurring? So, I think it's an ongoing question that larger centers are looking at.

Now, what can be learned from the accident? I think there are some system design things that might be done. Likewise, there's some engineering that has to be involved, and this is human engineering. Why did the nurse look at the monitor and not respond? Why wasn't the second detector used? And we know from a linear accelerator accident in England, one detector isn't enough, you need two, and they need to be separate. It seems to me there are lots of things we can learn from an analysis of what you people have seen and what the Agreement States have seen. And have you taken a look at the Agreement States and your program, and are there differences, and can we learn from that?

And then I think, finally, some innovative things could be done in educating people. Should we be using more videotapes? Should the instructions be in plain English rather than in deterministic and mechanistic and stochastic effects, and some of the other things? Should the reg guide be put in, say, high school English,

for people who need to use it? I think there's a lot more that could be done that would be very constructive to prevent some of the future things that may happen.

DR. SIEGEL: I don't think we specifically addressed your question about radiation safety officers, and if I understand the intent of the question, it's the fact that the radiation safety officer sometimes gets left out of the loop.

COMMISSIONER ROGERS: To what extent do they have authority, and to what extent is that authority recognized, and how big a problem is that?

DR. SIEGEL: I think we believe, as a Committee, that radiation safety officers need to be in the loop. They need to know what's going on in their institutions. They need to understand the safety concerns of all of the activities in the institution, and they need to have authority granted by the institution to regulate those activities. And it is clear that in certain circumstances, because of a lack of management commitment to radiation safety, the radiation safety officer is emasculated, and the net effect is that the radiation safety program falls down.

It would seem to me that your inspection process has an opportunity to uncover that that is the operational mode in that institution, and there is a likely focus for

intervention. We believe that radiation safety officers need to do their job. And as we discussed yesterday, being an RSO is not just a matter of being a good medical physicist, or being a good health physicist, or being a nuclear medicine doctor or a radiation oncologist.

First of all, what you know needs to be matched to the license. I wouldn't be a very good radiation safety officer for an HDR license. I don't know anything about it. Frankly, I don't want to learn anything about it either. But -- because I don't want to practice that -- but the radiation safety officer needs to have the kind of experience that matches and is well tailored to the license, and the radiation safety officer needs to completely be in the loop, and I think you really should carefully look at that. He needs to be a bit of a policeman. He needs to be someone who pays attention to detail. He needs to be a good manager of a staff in a large organization where he's going to have a bunch of people working for him. And paying attention to that issue, I think, is an important concern for the future.

CHAIRMAN SELIN: Dr. Almond?

DR. ALMOND: Yes, I'd like to add to that that the radiation safety committee can play a very important role in this, and I don't think one should ignore that because the RSO very often does not have the necessary

broad training in all these areas, but certainly on the radiation safety committee you should have those people who are experts in the different areas, and can interact with the RSO and make sure the job is being done, and on that committee should be administration, as you know, where the authority lies to carry out what the decisions are made.

DR. SIEGEL: But that requires a level of radiation safety committee commitment that also needs to be raised to the forefront. When we think we're having a problem at my institution, or we may have an investigator who is not quite doing things the way we'd like him to, we don't hesitate to, as the radiation safety committee, to write a letter to the investigator and say "Your privileges to possess radioactive materials are in danger of disappearing if you don't clean up your act", and if that doesn't work, we write to the dean as a committee, and things do change.

And, so, in order to have a well run radiation safety program and really do it effectively, you need to have an officer and a committee that chooses to function a little bit like a policeman to make it work reasonably effectively, given the kind of academic freedom issues that you come up against in the university setting, in particular, where people feel that any governmental

involvement in anything that they do is an imposition on their rights as university professors. That's a real problem that you have to deal with in a university setting, as many of us know.

CHAIRMAN SELIN: We're going to move on to Commissioner Remick and then -- I'm sorry.

DR. MARCUS: Just one comment. I thought that in the Cleveland Plain Dealer series, there was a rather sloppy confusion between a misadministration in the NRC sense, and medical malpractice. Medical malpractice that is not a misadministration in the NRC sense, does not go right to the radiation safety officer or the radiation safety committee, it goes to the risk management committee because there's going to be a malpractice suit.

A lot of the criticisms expressed in the articles, and I think expressed by NRC and some of the Agreement States people who were involved, I think missed this point. If you look, for example, at the Alta Bates situation in California, you had a physicist who made a mistake in his calculations, handed the calculations to the physician, the physicians went over them, made the same mistake or didn't check it, whatever, but ordered it as written. Their interpretation, when they found out later that it was a mistake, was that it was a malpractice case, but it wasn't a radiation safety problem. They

didn't have a generic problem with their radiation safety program. They goofed. And they went right to their risk management committee, which is a committee that management sets up to handle these.

It's very bad if you then turn around and say, "Ha, you're hiding a misadministration". They weren't. It's a mistake in how you're looking at the definition of the terms. And I think it's a mistake if NRC uses the definition of "misadministration" to mean any malpractice event, which is not what your definition was intended to do.

If the physician orders something stupid, and it's carried out exactly according to his decree, that's not an NRC problem usually, unless he does it a lot of times and someone wants to take his license away, but that's a malpractice issue. And I think it's really important for you to decide in your mind where the line is here.

CHAIRMAN SELIN: Wait a minute. Are you saying that if the standard procedure were some 10 units of radiation and the physician makes a miscalculation, not knowingly takes a chance and his peers say that was a wrong procedure, but he makes a miscalculation, you're saying that's not a misadministration?

DR. MARCUS: The misadministration rule reads

that the dose was given according to the order of the physician. If the physician makes a mistake, whether it was a stupid mathematical error, or it was a stupid clinical judgment, or it was not even stupid but just a risky judgment, whatever the reason, that was not meant, as I recall, to be in the misadministration rule. What you're talking about is carrying out the orders of the physician.

DR. SIEGEL: Carol, I'm not sure I agree with you, but in the interest of time, we might want to debate this at another time. I think what you may be getting at if, let's say, the standard of care for a particular cancer is to prescribe 4,000 rads, and the physician specifically prescribes 6,000 rads because he believes that that's the dose he wants to give, and that results in an injury, that's not a misadministration. But on the other hand, if the physician meant to give 4,000 rads and makes a mistake --

CHAIRMAN SELIN: And orders 40,000.

DR. SIEGEL: -- and orders 40,000, that's a misadministration.

CHAIRMAN SELIN: Even if it's the physician's order.

DR. FLYNN: Can I make one comment?

CHAIRMAN SELIN: Yes.

DR. FLYNN: That I think the key word missing here for the QM rule is the "calculated" administered dose differs by a certain percentage. So, I think Barry and Carol are both wrong, in one sense, that -- (laughter) -- that supposing the physician discovers now that the cobalt source was miscalibrated for decay the previous year, but he did deliver the dose as based on the calculated administered dose, based on, let's say, faulty decay criteria, was given properly, it wasn't the physician who committed the misadministration at that point, it becomes a gray area because you have to go back to see that, well, if the source wasn't calibrated right, that becomes another type of problem.

DR. SIEGEL: But, ultimately, we're missing the key point, which is that we share your genuine desire to make sure that the right things happen, and that things get calculated right, and that the sources are calibrated properly, and that physicians ultimately write the correct prescription, and that it's carried out properly. And we can argue a lot about whether a particular event is or is not a reportable event or a misadministration, but that really doesn't cut to the chase appropriately.

CHAIRMAN SELIN: Right.

DR. SIEGEL: I'd hope we could move on, but Judith has a comment.

MS. BROWN: I wanted to go back to the RSO situation for a moment. I think my concerns have been really heightened, seeing the videos of the meetings you've had, increasing the already concern situation I had with what's really happening out there. And although this Committee can tell you what should happen and how things happen in their very good institutions, I think it leads to disturbing questions about what is happening when that process breaks down and when the RSO is bypassed or ignored and, in the case of the Oncology Services Corporation where one RSO hadn't visited one of the facilities he was responsible for, for six or seven months.

I remember that Commissioner Curtiss said in one of the meetings that you had, that although the staff is preparing something to address this situation, that could take up to two years, and that we really need to do something now. That's a long to have possibly a great level of breakdowns in these systems.

CHAIRMAN SELIN: Mr. Collins?

MR. COLLINS: Yes. With regard to the roles of various persons involved in this process, the medical physicist role is not clearly defined anywhere in anyone's regulations, I think. The RSO much better so, but there needs to be some improvement, but we need to start looking

more seriously at the medical physicist's role. Maybe there's not much of a place for the states in the NRC with the Agreement States' program, but there is a place somewhere where they need to be looked at with regard to training, qualifications, functions, duties, responsibilities.

DR. SIEGEL: And I think we would certainly believe that when next given the chance to explore it, that looking at medical physicist licensure is one of the things we would very much want to consider.

CHAIRMAN SELIN: We can go a little out of order. Commissioner Remick?

COMMISSIONER REMICK: I'd just like to add to what Dr. Almond said about the importance of the radiation safety committee, and I would also add the importance of management in backing up the authority of the RSO. My own experience, I've seen it particularly in the university environment when you have some prima dona investigators who don't want to comply with the regulations or the procedures, but the radiation safety committee and management can play a very important role in backing up the RSO.

I'd just like to say -- I apologize, I must slip out -- but I found the meeting very informative, constructive, and highly professional. In my own

background, I have had the actual experience of using, handling, byproduct material as well as special nuclear and source material, but I have no experience in the medical use area. And one thing I find at the NRC, and this is not intended to be critical because I find it of myself, is a lack of a good overall picture of the whole medical area and where we fit in. So, I think the Committee serves a very useful purpose. In fact, I find that meetings of this type reinforce the importance of us having such a committee of professional practitioners, to inform us based on your actual experience and not in the abstract. And I just want to compliment you for the job you've done. It's been very helpful to me, and I greatly appreciate it.

DR. SIEGEL: We hope that means that this is not one of the advisory committees you are planning on cutting, given the directive from the White House.

(Laughter.)

COMMISSIONER REMICK: You must have read one of the trade journals. Thank you very much.

CHAIRMAN SELIN: Commissioner Rogers? Thank you.

COMMISSIONER ROGERS: I'd just like to come back to your point, Dr. Siegel, which I think is correct, that the physician has a responsibility, that you don't want to

diffuse this responsibility and place it in several different individuals and, therefore, nobody has the overall responsibility.

My question is, to what extent is that really taking place, though? It touches upon Judith Brown's concerns of what's really -- what we hear from you folks who represent the best in the institutions, and what may actually be happening on the average out in the field.

We all know that physicians are very busy. They are pressed hard, and some of the problems that occur here really are problems of a managerial sort. You might include them -- and human engineering, in a certain sense, you might call them that -- but there really is somebody looking at the entire system of the procedures that are being carried out and who's going to do what, every little bit of it, including the person, the nurse and somebody reading a meter who is not a physician or a medical physicist, and trying to see that possible errors that can creep in are dealt with beforehand, anticipated and dealt with. I know that everybody tries to do that, but it's always a constant, ongoing battle to eliminate those things.

We see errors -- I know you don't like us to think in terms of a nuclear power plant reference, but I think we can all learn from the 40 years of experience in

nuclear power plants with respect to nuclear safety. And we know that it is a constant battle to improve the systems to eliminate those small errors that always creep in. And I'm just really concerned to what extent busy M.D.s are taking the time to -- if they have the responsibility you say they should have and do have, that's fine -- to what extent they really can take the time to look at every single part of what's going on in the care of their patient where an error could occur, and how often do they do that. I'm sure they're concerned about it just as we're all concerned, but it's a question of to what extent is that responsibility really being thoroughly discharged?

DR. SIEGEL: Well, that's a very difficult question to answer. In part, I'm not sure how, if you will, NRC empowerment of people further down the chain really takes the physician out of the loop in any way, or makes the physician any less responsible for the event. I mean, ultimately, the physician has to have that responsibility, and has to have control. I mean, does a physician know every single setting on a gamma camera going on while patients are being scanned in a busy nuclear medicine department? No. But a physician does and should know that the technologists that work for him, or work in his institution, have been properly trained to

use the equipment so that they get good quality images out every day. Does the physician stand and watch the dose calibrater reading for every diagnostic radiopharmaceutical dose that is put into a patient? No. And doesn't watch the injection or perform the injection. And yet it's not clear to me how putting the responsibility more directly on the nuclear medicine technologist, or on the radiopharmacist, or on the medical physicist, ultimately will solve the problem.

COMMISSIONER ROGERS: Well, you keep coming back to that point. I haven't suggested that personally, so I don't know whether somebody else has suggested it, but I'm just saying that if the physician has the responsibility, then that physician has the responsibility for seeing that the systems are in place --

DR. SIEGEL: Correct.

COMMISSIONER ROGERS: -- that have to deal with these things, and for seeing that there's some checks on those systems, not that they are just initially in place and then forgotten, that there has to be a constant review from time to time, to see that, yes, indeed, the procedures that everybody says that they are to follow, that they actually follow them.

DR. SIEGEL: You won't find any disagreement from this Advisory Committee on that point. We all agree,

and your own rules require it. Your rules pertaining to supervision require that the licensee shall periodically review the activities of the supervised individuals, to make sure that they are in compliance with the licensee's instructions regarding safe use.

The rules are in place. Are there occasional places that don't follow the rules? Sure, you know that. I mean, it happens in everything you regulate. Is the medical environment unique in that respect? I really don't think so. And I think the overriding link between the physician and the patient puts on the physician an additional level of ethical responsibility that you may not encounter in many of the other kinds of activities that you regulate.

So, I think that the focus is on getting the physician and the institution to be committed to radiation safety, to be committed to doing a good job, and then having those systems in place, and you have the mechanism to inspect for those things and to look see if it's really happening.

Do any of you want to disagree with that, or answer that?

DR. MARCUS: I'd just like to add one thing. The quality of person you get as an RSO, if it's in a larger institution and you're not using the physician,

depends in large part upon the kind of job he has. With your regulations, and especially the new Part 20, being an RSO is becoming secretarial physics, not health physics, and it's getting harder to interest really well trained people into going into a field where they are doing a lot of clerical work. They sometimes do so much clerical work that they don't either take the time to look at overall safety or they are not the type of person who thinks that way, because the type of person who thinks that way is not going to be a secretary.

And I think it might help if you kind of looked out for what you are asking the RSO to do. On the one hand, you want him to be very smart and very perceptive but, on the other hand, you make him do a lot of things that might not really be that important from a safety point of view.

DR. FLYNN: Can I make a comment?

CHAIRMAN SELIN: Sure.

DR. FLYNN: I think going back to the so-called "problem" licensees, I want to give an example of that. I think if you find serious problems with a licensee, if you look a little further you're going to find serious additional problems, that there's going to be problems maybe with the RSO, problems with the teletherapy quality control program, whether they follow they follow the NRC

quality management program or not, problems with the brachytherapy program. You are going to find clusters of problems with problem licensees. That's why I think you should focus your attention on them.

It's sort of like if you were not the Nuclear Regulatory Commission, but supposing you were Department of Transportation, and you come up with regulations. You want to reduce all fatalities in auto accidents in 1994 to zero. You probably won't succeed but, let's say, if you focus your attention on the device, the automobile, a safe automobile with mandatory restraints, with good highway systems, with speed limits enforced, but get the drunk drivers off the road and get the people off the road who are on drugs, then you're going to reduce the fatalities by aiming your efforts towards the problem driver, just like you would toward the problem licensee.

COMMISSIONER ROGERS: Yeah, well, I know what you're saying. You're telling us that 80 percent of the problems come from 20 percent of the people. It's the old Pareto principle that we all know about, and it's certainly correct, but it's not the entire story. There's still something left over. And one of the problems that we see here -- I certainly have seen it since I've been on the Commission -- that even -- let's just look at nuclear power plants and forget about the area in which you are

working, that some of the best operators, the best performers, go sour. We cannot, just because they have been good at one time, assume that they're always going to be good, because they slip. And some of our most serious problem plants have been some of our best performers ten or 15 years ago.

So, if you say, "Well, we have a problem, and we have to get at changing that problem", then the Pareto principle is the best way to approach it. Try to look at where the most problems are occurring and go to work at those first, but we can't stop there. That's not going to be good enough.

DR. FLYNN: I didn't say you should stop there, but maybe the good licensees, until they become bad licensees, are surveyed every two or three years, but the problem licensees, every six months, every three months, if necessary.

DR. SIEGEL: And that really is why you don't inspect a licensee just once at the initial licensing, you inspect periodically. To amplify that, medicine is changing in that respect, and recertification is becoming a reality. The American Board of Nuclear Medicine is issuing time-limited certificates as of 1992. The American Board of Radiology is now issuing time-limited certificates in radiation oncology as of this year. That

has not yet occurred for diagnostic radiology. So, your board certificate is not good forever anymore, and that's becoming the increasing trend in medicine.

COMMISSIONER ROGERS: I'm finished.

CHAIRMAN SELIN: Commissioner Curtiss?

COMMISSIONER CURTISS: I don't have any further questions that haven't already been raised or addressed, but I would like to thank you all for slogging through the weather here and coming on short notice to address a wide range of things, some of which we didn't discuss here, that are extremely timely on our and your agenda.

I found the presentation here this morning to be stimulating. It covered a number of things that you're recommending, I think, that we consider either in terms of things we ought to do or, in some cases, things we ought not to do, and that input, I think, is appropriate coming from you. I thought this was a balanced presentation. I'll look forward over the next several months, as I'm sure the Commission does as a whole, in dealing with you on trying to come up with a balance, a timely and effective resolution of the issues that we've discussed here.

CHAIRMAN SELIN: Commissioner de Planque?

COMMISSIONER de PLANQUE: Yes. In the interest of time, I have about four issues I'd like to touch on,

and you may not want to comment on them right here, but it may be something that you can help us with later on.

First of all, personally, I find the issue of relative risk one that I would like to know more about. It's used all the time, and it's hard to get your arms around it. Dr. Pollack was kind enough to prepare some data for us, and looking over this data, I can see that the statistics on mortality and morbidity with respect to anesthesia are probably the best comparison. Some of the others, as best I can tell, consider mortality and morbidity as a result of the lack of success of the treatment and, therefore, you've got an apples and oranges comparison.

So, I, for one, if you have more data like the anesthesia one, which I see as a more direct cause-and-effect and not related to the disease effect, I think that would be useful for us to see and to at least know about.

For one, I will also be interested in following what's happening with the mammography event in New York. At least according to the press, New York State, for one, has been considering -- and I don't know where they are on this yet -- patient notification requirements. This is a particularly interesting one that you find in routine diagnostic procedures because harm may not be an excessive dose, but may be the absence of finding a problem that

would have been found had the mammography been done successfully. So, that's another twist on a major issue.

I would be concerned -- and we don't have time to do this now -- in your advice on where you see the FDA/NRC interface, whether you see gaps that need to be filled, or whether you see overlaps that are leading to duplication or more effort than is necessary.

And the fourth one is -- and you indicated you are going to be looking at this -- the credentialing programs, how we should or should not use those in a regulatory framework -- and this ties in with Commissioner Rogers' comments on roles of technicians and RSOs and medical physicists -- how should we look at these programs and especially in terms of what's happening in the Agreement States as well as the ones that we regulate directly?

If we have time and you'd like to comment on any of these now, that's fine; later is also okay as far as I'm concerned. I would like to thank you for this briefing and for your advice. As you indicate, the medical area is probably going to be changing rapidly. More and more things are coming out, like the mammography incident. So, I think, as Commissioner Curtiss says, it's going to be extremely important that we continue to get your advice on these matters, and that we can do as much

as quickly as possible, if there is a need to act. So, I would thank you.

DR. SIEGEL: Thank you. I agree with your analysis of your questions, namely, that we're not prepared to answer them all this morning because they are pretty weighty questions, particularly the issue of whether diagnostic accuracy should be regulated is one that really cuts to the heart of the whole issue of what's the appropriate level of government regulation of all of medical practice. And as I said earlier, there may well be an appropriate level, whether it's within the confines of the Atomic Energy Act or in some other forum, is a matter for national policy debate. Thank you.

CHAIRMAN SELIN: Mr. Collins, you had a remark?

MR. COLLINS: Yes. You made an opportunity available earlier, and I didn't take advantage of it. I'd like to request another.

CHAIRMAN SELIN: Of course.

MR. COLLINS: Thank you, sir. With regard to this FDA/NRC interface, one of the problems I'd like to caution against there, whoever ends up looking at that, is there's not much of a lack of statutory coverage of areas right now, but when you look at what's really being done, there's an extreme shortage in the amount of resources that HHS or FDA is able to put into their area in

particular. Not that there is not in yours maybe, but certainly there is a shortage. It's been brought up with regard to accelerators, whether or not maybe a global agency should be in charge of all ionizing radiation, and a particular question about accelerators.

The states already have authority in this area. Some of them are exercising it, some of them are not. In my opinion, in many states, this is a huge accident waiting to happen. And since it's at least 5-to-1 accelerators to teletherapy units -- in Illinois, 7-to-1, and rapidly increasing that ratio -- there needs to be more done in this area.

When you approach, or if you approach, looking at this, I'm sure you're going to get an initial resistance from the states with regard to whether or not any federal agency should look into this further. On the other hand, if it's decided that a uniform national standard is set and there is a federal agency that's going to be put in charge of administering it, right now the knowledge I have from the various states is that NRC would be the agency of choice.

One other item as a result of all these meetings, I understand that the NRC staff is currently initiating a process to develop some specific regulations on high-dose-rate remote afterloaders; if there's not,

there should be, and the states are anxious to participate early in the process.

CHAIRMAN SELIN: I would like to emphasize, we're not talking about regulating the devices, we're talking about -- the question is to what extent, if any, we should be involved in regulating the use of the devices.

MR. COLLINS: Exactly.

CHAIRMAN SELIN: The question isn't do we change our basic role with respect to FDA, but does our substantive coverage get slightly extended, or somewhat extended, to involve the different source of similar radiation to the type we already work with. It's not work we're looking for, but it was recommended to us at one of the other three meetings.

We'd like to thank you very much. Your Committee is very important. Clearly, there has been significant improvement in the value that we get of your work. You are in a peculiar situation in that most of our advisory committees we are able to get expert advice without having the intrinsic conflict of having to rely in large part on our licensees to provide that advice. It's not generally available in this area, and I'm not talking about narrow conflict in the sense of something that's good for the NRC and not being good for one of your

institutions, but the broader advice as to, you know, not wanting to have your freedoms even more tightly constrained than they are. For instance, our Act is different from other acts. We are called to do things in the case of ionizing radiation that comes from byproducts that is not called for in other cases of radiation, and we're going to follow our law obviously, and you are going to help us od it.

Similarly, this question of patient notification is not entirely of our concept. We happen to think it's good policy and good politics, but people who use services that we license, whether it's nuclear power or nuclear medicine, have a feeling that everything is quite open but, nevertheless, whether it's our idea or not, that's just the way it is, and your help in doing it, we appreciate.

I was listening to Ms. Brown. Maybe we should have some mediocre institutions represented on the board also, so you have a broader range of experience on what can happen in bad places, but probably we won't follow up.

DR. SIEGEL: How would you elect them?

(Laughter.)

CHAIRMAN SELIN: Well, there's no shortage of candidates.

DR. MARCUS: I represent both extremes, the

county hospital and UCLA, so you've got it all, if you just take what we offer.

CHAIRMAN SELIN: Thank you very much. We'll have quite a few considerable questions to go in.

(Whereupon, at 10:50 a.m., the meeting was adjourned.)

CERTIFICATE OF TRANSCRIBER

This is to certify that the attached events of a meeting of the United States Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFINB BY ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: FEBRUARY 22, 1993

were transcribed by me. I further certify that said transcription is accurate and complete, to the best of my ability, and that the transcript is a true and accurate record of the foregoing events.

Phyllis Young

Reporter's name: PHYLLIS YOUNG

ISSUES

- NRC response to Plain Dealer series
- Patient notification
- Patient follow-up
- Under-reporting of events
- NRC regulatory purview
- Brachytherapy regulation

NRC RESPONSE TO PLAIN DEALER SERIES

- Dispassionate analysis of problem appropriate
- Denominator could have been emphasized
- Relative risks could have been emphasized (Byproduct RAM is not uniquely hazardous)
- Apparent level of NRC awareness troubling (That pain and suffering can be due to medical malpractice should not be a revelation)
- Clearer explanation of limits of NRC statutory authority

$$NM \neq RO$$

$$RO \neq NM$$

PATIENT NOTIFICATION

- The *"standard of care"* is truth-telling, NOT fraudulent concealment
- Physician and institutional responsibility
- NRC regulations already exceed the usual extent of government intervention
- The licensee's report to NRC is the logical focus of intervention to insure notification occurred and was adequate
- Medical consultants can and should help to evaluate reports of misadministrations

JUSTIFICATION FOR NOT INFORMING PATIENT

- Standard of care: no compulsion to inform if no actual injury or likelihood of injury
- Exceeded by NRC regulatory requirement to inform unless doing so would harm patient
- Very few circumstances would justify not notifying patient under current regulations

CONTENT OF PATIENT NOTIFICATION

- Should include full description of all reasonably probable medical consequences
- Where to set threshold on stochastic effects?

  Medicolegally relevant?

  Impact on follow-up recommendations?
- Should include clear instructions regarding need for follow-up and continuing care

PATIENT FOLLOW-UP

- Medical consultants can and should help to evaluate reports of misadministrations
- Follow-up plan necessary when injury has occurred or is likely to occur (? stochastic threshold)
- Evaluation of patient notification should include consideration of the follow-up plan
- NRC follow-up intervention should go no further (unless there is a fundamental change in overall governmental oversight of medical misadventures)

PATIENT FOLLOW-UP

- NRC-sponsored follow-up patient registry or other data gathering mechanism is potentially appropriate to address unanswered scientific questions, but is not needed to address regulatory issues
- NRC's role need not extend to that of plaintiff's attorney

UNDER-REPORTING OF MISADMINISTRATIONS

NRC REGULATORY PURVIEW

- Byproduct RAM is not uniquely hazardous
- NRC's purview currently only includes a small fraction of ionizing radiation use in medicine
- Whether there is a need for uniform national *standards* relating to all diagnostic and therapeutic medical uses of ionizing radiations is an important *policy* issue

BRACHYTHERAPY REGULATION

- Need for specific HDR regulations
- Need for direct physician and physicist supervision of brachytherapy
- Adequacy of training

ADDITIONAL ISSUES

- Medical consultant should be member of IIT for serious misadministrations
- ACMUI membership