UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Use of Isotopes

Nuclear Regulatory Commission

One White Flint North

Conference Room 1F7-9

Rockville, Maryland

Sunday, February 21, 1993

The meeting convened, pursuant to notice, at 2:05 p.m., Barry Siegel, Chairman of the Committee, presiding.

PRESENT:

Barry Siegel, M.D.

Peter Almond, Ph.D.

Judith Brown

Steven Collins, State of Illinois

Daniel Flynn, M.D.

Melvin Griem, M.D.

Donald Hamilton, FDA

E. Eric Jones, M.D.

Robert Bernero, NRC

Larry Camper, NRC

Richard Cunningham, NRC

John E. Glenn, NRC

Carl Paperiello, NRC

P R O C E E D I N G S

MR. GLENN: Good afternoon, ladies and gentlemen. I'm pleased to welcome you to Rockville, Maryland, for a meeting of the Advisory Committee for Medical Use of Isotopes. My name is John Glenn. I'm chief of the Medical, Academic and Commercial Use Safety Branch of the Nuclear Regulatory Commission.

This is a meeting of the Advisory Committee on the Medical Use of Isotopes and it is being held in accordance with the rules and regulations of the General Services Administration and the Nuclear Regulatory Commission.

The meeting was announced in the Federal Register on February 9, 1993, and the Federal Register notice stated that the meeting would begin at 2:00 p.m.

The function of the Committee is to advise the NRC staff on issues and questions that arise from the medical use of byproduct materials. As such, it is an advisory committee. It does not direct the staff but provides counsel.

Today's meeting is a little different than normal meetings in that this a pre-meeting for the Committee to get together and share its thoughts with each other prior to having a briefing of the Commission tomorrow at 9:00 a.m.

Members of the Committee have been provided with

handouts and transcripts from three recent briefings of the Commission on the topic of the NRC's medical use program.

The first of these briefings was held by the staff on January 22.

The following week the Commission was briefed by representatives of several agreement states who described the implementation of the medical use program in their states.

Finally, on February 8, 1993, the Commission was briefed on the findings of its independent investigation team into the tragic circumstances of a recent misadministration in Indiana, Pennsylvania.

I would like to introduce some of the members of the Committee who are seated here today. Beginning on my left, we have Eric Jones from the Food and Drug Administration.

Melvin Griem, who is a physician involved in therapy.

Dr. Daniel Flynn, who is another physician involved in therapeutic treatments.

We have Larry Camper, who is the chief of the medical and academic section of the NRC.

We have the Chairman of the Advisory Committee, Dr. Barry Siegel.

To my right, we have Judith Brown, who represents the public and patient interests on the Committee.

We have Steve Collins, who is a member of the radiological staff of the State of Illinois, who is our state representative.

Finally, we have Don Hamilton, who is also representing the FDA.

I will just take a note of a few of the members of the Commission who are in the audience. If I miss anyone, I will apologize.

We have Robert Bernero, who is the office director in charge of the medical use program.

Dick Cunningham, who is the division director with oversight over the medical program.

We have Janet Kotra, who is representing Commissioner Curtiss.

Carl Paperiello is seated in the audience. He was the leader of the independent investigation team that looked into the Indiana, Pennsylvania, event.

We have Sally Merchant, who is a member of the medical and academic section.

We have Josie Picone, who is a member of the medical and academic section, and Janet Schlader, who is a member of the medical and academic section.

With that, Dr. Siegel, I will turn the meeting over

to you.

DR. SIEGEL: Although we maintain our sign-in sheet as a record of public attendance at the meeting, I would actually appreciate it if the individuals in the audience who have not already been introduced would please introduce themselves.

MR. FRANKLIN: Ben Franklin of the McGraw-Hill Nuclear Publications.

MR. BERICK: David Berick. I'm with the Environment and Energy Subcommittee of the House Government Operations Committee.

MR. MOSELY: Michael Mosely with Syncorp International.

MS. KENNY: I'm Shannon Kenny with the American College of Cardiology.

MR. DAVIS: Dave Davis with Plain Dealer.

MR. MARQUIST: Chris Marquist with Knight-Ridder.

DR. SIEGEL: Thank you.

Our job today is to prepare for tomorrow morning's 9:00 a.m. briefing. As all of you know, we have been given a large amount of information to digest and have been posed with a series of questions that we should try to grapple with for tomorrow's briefing.

To put this in perspective, it was about seven weeks ago when I first learned that there was a possibility that the Commissioners would like to hear our perspectives on both the Cleveland Plain Dealer series as well as the Indiana, Pennsylvania, event. It seemed to me that it would be reasonable for us to provide that input. So we put together a meeting and here we are today.

Several weeks thereafter, as a consequence of a meeting that occurred between Commissioners Curtiss, Remick and De Planque, we got a small list of questions that we should digest. That list was subsequently added to, and then with assistance of staff in NMSS, some of those questions were reframed and put into perspective. Those are the primary goals that we need to deal with.

Given all the information we have received, given the questions we have received, given the opportunity that I have had as Chairman to speak with nearly all of you individually but not in an officially convened meeting, I put together a series of slides that constitute the talking points for our briefing tomorrow. I sent those to all of you last Sunday, on Valentine's Day, forgetting that many of you would not be at work last Monday for Presidents' Day, and had a chance to talk with most of you later in the week.

I have since modified those slides slightly. The version of the document that has one per page and gives you lots of room at the bottom of the page to take notes is the document I would like to work from. You will see that the changes I have made are relatively minor.

Consequently, what I would propose we do is go through the issues as I plan to present them with Dan Flynn's assistance. Dan has specifically asked to address the brachytherapy questions that come out of the Indiana, Pennsylvania, event. We can determine whether others of you on the Committee have a specific desire to make specific statements as part of the briefing or wish to respond to whatever questions we get from the Commissioners.

As we did last time in the July briefing, although I might make the initial attempt to address a question, it is open to any of you either in dissent or to make a point more clearly than I was able to do and to add to. I don't see any other way we can do it. Unlike the staff, which at its briefings had had, if you will, weeks and weeks of intensive effort to develop a consensus staff position, it will be more difficult for us to have a clearly defined consensus, but I think nonetheless we can try our best to come up with some general principles.

The initial question list from the Commissioners was very broad. The purpose of focusing the list somewhat is so that this Advisory Committee can comment on the things that it has particular expertise to comment on.

The question list gets into issues of broad national policy. The Advisory Committee's input might be relevant to those questions, but perhaps at a point when those questions are framed more carefully or more completely than they are currently framed. That's why I have focused on issues that I consider to be predominantly medical issues, not necessarily big picture policy issues, although, as you will see, one towards the end is a big picture policy issue.

We can deviate from this if we choose to. Sally will be delighted to retype all these slides tonight if we have to and have the 100 copies prepared for the public for tomorrow morning. Hopefully the snow will stop so that there will be a public tomorrow morning.

With that, let's start, unless any of you have a comment as to process or approach. If we are good, we don't have to be here four hours either, as scheduled, which would be okay with all of us.

The issues I propose to discuss are shown on the introductory slide that says we want to address the NRC's

response to the series that occurred in the Plain Dealer briefly. As you will see on the next slide, I will be brief.

Then to talk about matters of patient notification and what are physician responsibilities, institutional responsibilities, and NRC responsibilities.

Then patient follow-up, with the same concerns.

Whether or not this Advisory Committee has any better data on under-reporting of events. As you will see, that slide currently doesn't have anything on it other than just "under-reporting of misadministrations."

The issue of NRC regulatory purview.

And some issues related to brachytherapy regulation and other radiation therapy issues as they relate to this Advisory Committee.

Just from first glance, did I leave out any major elements relating to the Commissioners' questions or the staff's analysis of those questions?

[No response.]

DR. SIEGEL: In terms of NRC response to the Plain Dealer series, I propose to say that we believe that the Plain Dealer series raised a number of very important questions and that we agree that an appropriate scientific dispassionate analysis of those problems is appropriate and are indeed glad

to see that the NRC staff is planning a senior management review and planning an outside review to be conducted by the Institute of Medicine, or at least preliminary thought it will be conducted by the Institute of Medicine of the National Academy of Sciences. I assume no contract has been let yet. And would stand ready as an advisory committee to assist senior management and the Institute of Medicine in its deliberations.

Recognizing full well that this Advisory Committee is composed largely, although not exclusively, of individuals who work for licensee institutions and therefore, recognizing, as we said in July, that this Advisory Committee is in some ways inherently conflicted, nonetheless it is precisely because of what we do for a living that we have the expertise that allows us to address some of the questions that are being considered by the Commission. In any way we can help the Commission we are ready to do so.

With that positive note in mind, a few negative notes relating to the Plain Dealer series and the NRC response to the Plain Dealer series.

It is my personal opinion, and correct me if I don't speak for you, that in many ways the Plain Dealer series, while it was loaded with facts and useful information, presented those facts in a way that was oft sensationalistic. Perhaps

that's the way newspapers have to do things to get the attention that they are eager to get.

But given some element of sensationalism in what was presented, the NRC in response to the Plain Dealer series had an opportunity early in the process and in fact even during the course of being interviewed for the Plain Dealer series to point out certain things that seemed not to have been adequately emphasized in the series.

One, the denominator which we as a Committee have talked about so much, although mentioned in the series, is really mentioned in passing rather than thoroughly emphasized.

Two, the relative risks of radiation uses in medicine could have been emphasized. Everything that happens when patients encounter physicians and the health care system is risky. Every single thing that happens. Modern technology is very risky.

In the old days when all you could do was hold a patient's hand, it was unlikely you could do much harm, but you also couldn't do much good. With the tools we currently have we can do a lot of good; we also can do a lot of harm. Sometimes it just goes with the territory. Radiation therapy is risky; chemotherapy is risky. Sometimes it gets multiplied because or medical malfeasance, malpractice, misadventure --

choose whatever term you like -- bad judgment, but it is part of medicine. There is nothing we are going to do that is going to change that. Medicine is always going to be associated with risks as long as we use those tools.

I think pointing out somewhere along the way that byproduct radioactive material is not uniquely hazardous as compared to the rest of medicine would have been something the NRC could have done early and something that the Plain Dealer could have figured out a way to incorporate in the series.

I personally found statements in the series and in follow-up relating to the level of NRC awareness of the problem to be troubling. To me it seemed hard to understand that the NRC was unaware that patients experienced pain and suffering as a result of medical malpractice. That shouldn't be a revelation. In fact, the jury awards related to medical malpractice are as oft due to pain and suffering as they are to actual damages. So I think getting that point across would have been important.

Finally, the issue of the limits of NRC statutory authority. The Plain Dealer repetitively made the point that the NRC refused to accept responsibility for things other than byproduct material, for linear accelerators, for naturally occurring radioactive materials, for non-byproduct accelerator

produced radionuclides for diagnostic x-rays.

I think the NRC response early could have included statements to the effect that if Congress had asked by way of a statute, the NRC would not have refused to accept the responsibility, but it's important to understand that what NRC currently regulates is limited by its statutory authority, not by the whim of staff.

That's what I want to say about the Plain Dealer series. I don't know if it will come out as clearly tomorrow as it just did now.

Any comments on that? Do you want to add to it, Steve?

MR. COLLINS: As representative of the states, based on my 20 years of experience with various states, except for byproduct source and special nuclear material, which is by federal statute the NRC's, the states don't want to give up the rest to any federal agency. Most of them do all the rest of those things and they don't want to give it up to a single federal oversight, although we would like to have uniform standards in place. The Conference of Radiation Control Program Directors has some model things out there but not all states have put those into practice as we have.

DR. SIEGEL: For the purposes of understanding this,

John, Larry, Dick, have there been official congressional overtures to take over other aspects of the medical use that you are aware of?

MR. CUNNINGHAM: Not that I'm aware of.

MR. GLENN: Not that I'm aware of.

DR. SIEGEL: There was some notion that you had been approached at sometime by perhaps CRCPD about taking this over.

MR. GLENN: There was a proposal a few years ago that accelerator produced isotopes might legitimately come under our purview. That was limited to that one particular area, not all sources of radiation.

DR. SIEGEL: You supposedly refused to do that. First of all, did that happen, and second of all, what was the basis for refusing to do that, if you can recount?

MR. GLENN: It was referred to the CIRRPIC, which is the federal group that exercises broad oversight over the use of radiation. The recommendation that came out of that was that there was no compelling reason for the NRC to seek such authority and we have not sought such authority.

DR. SIEGEL: For the record, what does CIRRPIC stand for?

MR. GLENN: I was afraid you were going to ask that.

MR. BERNERO: The Committee on Interagency Radiation

Research and Policy Coordination.

MS. BROWN: I have one thing.

DR. SIEGEL: Yes, Judy.

MS. BROWN: Just my opinion. I think the points you brought up are good but I also wanted to say that I thought the Cleveland Plain Dealer performed a public service in bringing all of these things together, doing the very tedious investigation. From what I heard, viewing the tapes of the Commission meetings, no one disputed any of the facts. The sensationalism -- I don't know what they have to do to sell papers in Cleveland. I would probably give them some of that. I just wanted to say I thought they did a great job in bringing it together.

DR. SIEGEL: Thank you.

DR. FLYNN: May I add something?

DR. SIEGEL: Yes.

DR. FLYNN: I think the denominator is very important, though. This year somewhere between 30,000 and 40,000 brachytherapy procedures will be done. In fact, tomorrow is Monday. We expect about 200 will be done in the country. Probably every one will go extremely well.

I think you have to understand the anxiety patients go through when preparing for a very complex technological

treatment that hopefully is going to either cure them of their cancer or at least have a prolonged remission from their cancer.

I projected from the College of Radiology patterns of care studies that for 1993 -- in Massachusetts some of them are being taken out of commission because they are replacing them slowly with linear accelerators that can do other things like electrons and high energy beams and everything -- that there are about 400 cobalt machines in actual operation. There are more than that licensed but not all the ones that are licensed are actually treating patients right now. There are about 2,000 linear accelerators. So there is about a 5 to 1 ratio of linear accelerators to cobalt machines. Most patients are being treated on linear accelerators now for their cancers by external beam.

I think you may find that in Illinois. I'm not sure what the ratio is in Illinois, but in Massachusetts we have 48 megavolt machines of which eight are cobalt, but three are basically not treating patients anymore. So the ratio between linear accelerators to cobalt is increasing.

I called up the Cancer Society. For 1992 the estimated number of patients with cancer newly diagnosed is 1,130,000. About half the patients with cancer got radiation

that year as part of their treatment for cancer. That's 550,000 people in 1992 who were treated with radiation for their cancer as part of their treatment or all of their treatment. Of that number, probably close to 100,000 patients were treated on cobalt machines which the NRC regulated.

My point is the denominator. The number of patients that were treated poorly in terms of major errors being made is small. How small? I don't know if we can come up with a number, but it's very small. So I think the denominator is very important.

Many of these patients have no alternate treatment. Many of these patients are sent to us to treat because either the results with radiation are better than surgery, there is no effective chemotherapy for the cell type of cancer they have, or radiation added to surgery will decrease the chances of recurrence and increase their survival rate. If these 550,000 patients were not treated, I'd hesitate to tell you how many of these patients would die because of not getting radiation.

MS. BROWN: I would hope that would not be the alternative. What I see as a public service is focusing attention on how dangerous an area this is and the practitioners in it, albeit very careful, could be more careful. If something like this makes them think the fourth

time as opposed to the first, second and third, and in that fourth they might catch it, I think that's a service. If they think there might be a chance that there is going to be a stronger look over their shoulder as a result of NRC action in response to this article, I think that is good too.

DR. FLYNN: Here is where the crucial debate comes. I think there are two kinds of errors out there. There are the errors that are going to be very rare, that the good programs with good quality assurance in place with people double checking charts, with different people checking charts every week, are going to discover a very rare error that was classified as a misadministration, many of which will not cause harm to the patient, but we have to know about them because we have to afford quality.

Then there are some other practitioners where they may not have as well developed a quality assurance program as might be expected and they might not have everything in place to catch the problems. That's probably a very small minority. You can argue if it's one percent of all the licensees or half of one percent, but I think that's where the attention should focus. I don't think it's possible to reduce the errors to zero, but I would like to see the attention being focused on those licensees who need help.

MS. BROWN: I think you are right, Dan. I think the ripple effect will do that. Because of the attention the Cleveland Plain Dealer brought to this, we are finding out all sorts of things, from what I saw at the Commission meetings, about how RSOs aren't even visiting the facilities, how they are being excluded from the process. We are finding out more about the people who aren't up to speed in terms of quality assurance. I don't think we would be having these discussions or we would be asking these agreement states such pointed questions if this series of articles weren't written.

DR. GRIEM: I just calculated that about 25 million procedures were done last year. In other words, a patient who is treated where the goal is a curative procedure will get 30 treatments in which two fractions are given. So it's 60 procedures. If you figure in the patient where you are attempting to relieve symptoms, the palliative procedure is generally about half that effort. You come up with about 25 million procedures being done. That's the denominator in this whole thing.

DR. FLYNN: Are you saying that each patient has 60?

DR. GRIEM: If you treat the patient for six weeks, 30 treatments, and you usually treat two fields a day, you come up with 25 million procedures.

DR. SIEGEL: I think it's safe to say that the dominator is large. You can make the denominator appear to be larger because the patient doesn't care if I come to this radiation therapy department, will I be mishandled on treatment 19. What the patient wants to know is what is the probability when I walk into this radiation oncology department that I'm going to have a good therapeutic experience. The fact that a therapy actually might consist of 30 or 40 individual procedures is a way to make the numbers look bigger, but actually it's ultimately probably not relevant, in all fairness.

MS. BROWN: I think that's right, Barry.

DR. SIEGEL: But the denominator is still very big.

MS. BROWN: True, but I think you put your finger on something that I felt as a consumer who is not in this field at all but jumping right up there on the learning curve. Even as informed as I am about this area, the first thing I asked Barry was, if anything happens to me or my immediate family, can we come to St. Louis? Because I have no idea, with Maryland being an agreement state, who is doing the dosimetry, who is doing anything. I can't look over anybody's shoulder with any knowledge. Even my husband, who has got a doctorate in pharmacy, can't do anything in this area. You guys have to be

so good, because we don't have any way to check.

DR. FLYNN: I think, though, if I were a cancer patient reading a series, I would be extremely frightened. I don't know if that would help me at all. I would have liked to have seen a comment -- which is accurate, by the way -- that if half a million people a year in the country are getting radiation as part or all of their treatment for their cancer -- right now there are 250 million people in this country -- several million are walking around, having been cured of their cancer where radiation was part of their treatment. I'm talking about people who were treated 10, 20 years ago. There are several million people walking around right now cured of their cancer. Several million. Some of them might be in this room right now.

MS. BROWN: I don't dispute that, Dan.

DR. FLYNN: I would have liked to have seen that balance.

MS. BROWN: You're right. But if I'm frightened by this article and I'm frightened into asking the doctor, who has already intimidated me in most cases -- even being who I am for the last 15 years and being a consumer advocate, I'm still intimidated by a doctor who seems rushed. Oh God! Can I ask him this question? To ask the question, Excuse me, is this the

dose that was prescribed? Is this millicuries or microcuries? Can you check for me? I know I need to ask that question. I'd be real nervous doing that. But if this article frightens me into helping me find the courage to do that, I think there is a service there.

DR. FLYNN: As long as it's not frightening people without the education that you have into denying the treatment and having people go out and get themselves killed because they were frightened beyond rational judgment about not accepting a treatment which was going to help them. We've had patients who have turned down treatment not because they have read an article, but usually because they are just frightened in general by the stories they've heard.

MS. BROWN: Since the series was in December, have we had any feedback from the community about any patients who have read this? I'm just curious whether anybody has had any problems.

DR. GRIEM: Not in Chicago.

DR. SIEGEL: We did not have any in St. Louis. There was some small amount reported in Cleveland and the Plain Dealer in a follow-up article a few days after the series indicated that their contact with the local hospitals indicated that it was a very minor problem. The medical community

concern was perhaps thrown of proportion.

MS. BROWN: I am even more interested that the effect of this series of articles may have been not to frighten individual patients but to focus national attention. That's the best outcome I can imagine.

DR. GRIEM: As far as the question of where you should go, there was a patterns of care study. In other words, how you treat certain benchmark cancers, breast cancer, prostate cancer, the two big ones. This was done by a voluntary group where they surveyed small hospitals, large hospitals, training programs. About five years later they came back and said, well, given what we know about this practice, what are the outcomes? So there is the patterns of care and the outcomes of this. They looked at these specific cancers to see the outcomes. It's a very monumental piece of work. So there is data.

MS. BROWN: Good.

DR. SIEGEL: Larry.

MR. CAMPER: We agree that the denominator is very important for all the reasons mentioned. We have been looking recently, somewhat frantically, I might add, to try to find sources for the denominator. We have simply not been able to find the rainbow with the pot at the end that has all the

answers. We can find bits and pieces from different sources.

A couple thoughts come to mind. If you are really going to consider the denominator and realize that a misadministration is a failure in the delivery system, I think both numbers are important, the number of patients, the number of procedures, and also the number of times radiation is in fact applied in total. Every time that application occurs the possibility for error occurs, and if you are going to look at delivery problems, then you ought to know how many times does that opportunity present itself.

There are ways to get a handle on the denominator, but they involve time, they involve expense, and they most likely would involve some approval from OMB. We have to wrestle with that and determine what we are going to do about it. We agree it's very important, but there is no simple, quick source, unfortunately.

Another point to be made is that when you talk about misadministrations right now in the agreement states the definition for a misadministration is different in most of the agreement states than it is currently with NRC. The agreement states have not yet been required to put in place the definitions that were set forth in the quality management rule. So in most cases they are still using the definitions that we

used to use.

Until such time as we are all working with the exact same definition for misadministration it will be difficult to get data that is all talking in the same terms and have a good handle on what the risk factor really is.

DR. FLYNN: Unless you take the number of misadministrations in the NRC states and multiply it times the fraction of licensees in agreement states versus NRC states.

DR. SIEGEL: I think there actually are a number of other issues that were raised in the Plain Dealer series and other points that one might have contention with. Many of those the NRC both in terms of its interviews that contributed to the series and in subsequent responses has dealt with quite effectively.

This list could be bigger. The things I picked are the things that I think are particularly important. But we could go on. I don't want to, because in fact one of the things I did last night was re-read all the articles and the letters to the editors and the editorials again with my pen out, looking for things that troubled me. I figured we could spend the entire four hours with Dave Davis out there just picking apart what he wrote and he'd have no opportunity to publicly comment. We are not going to do that, because that's

really not our job.

I will make one comment, though, and that is when the Plain Dealer speaks the forests of America weep. You have helped to kill a lot of trees. That's okay. We like reading.

Steve.

MR. COLLINS: I have one more thing. The bottom line on all of this from my perspective and from talking with several other states is that we have by this focused attention figured out a few ways where we can improve as regulators what we are doing and we are going to add a few more regulations to help in this area, and it's as a result of some of the increased focused attention on this.

One thing I didn't think was brought out. I would like to see if you all agree that this is a true and accurate statement. When you take the radiation treatment of cancer and compare that to any and all other treatments that could be used for this, even before this series of articles came out the radiation treatment would still be the safest mode of treatment as far as frequency of accidents or misadministration or whatever you want to call it. Is that an accurate statement?

DR. SIEGEL: I'm not sure we have clear information about accidental events associated with surgery or chemotherapy. One can certainly look at complication rates.

Dr. Polycove (phonetic) has in fact done that.

MR. COLLINS: The overall risk from radiation?

DR. SIEGEL: To look at the overall complication rates of risk related to radiation, chemotherapy and surgery, and the overall risks of radiation actually look like they are lower for more or less equivalent cure rates of particular cancers. But obviously that's on a cancer-by-cancer basis.

I think one of the things that the Chairman and the NRC have been very careful to point out is that the NRC's purview is to regulate the proper application of the radiation, not to regulate the prescription itself. Some of the things the Plain Dealer described were in fact properly applied bad prescriptions, and they in fact resulted in very bad result. No one is happy about that. But that's not something the NRC has considered to be within its statutory purview up to this point in time. I actually address that point a little bit later in the slides.

Judy.

MS. BROWN: It occurs to me that in no other form of treatment is misadministration or a mistake going to affect anybody's health but the patient. In your field the public can be unknowingly adversely affected.

DR. SIEGEL: Although exceedingly rarely. The kind

of event that occurred in Indiana, Pennsylvania, where not only was the patient badly injured -- killed -- but the general public was injured, is at least a couple of orders of magnitude below.

MS. BROWN: We've talked about early discharge with I-131.

DR. SIEGEL: We talked about the issues of where the threshold should be set. There are rules in place.

MS. BROWN: So if someone were to let that patient out early and he comes and sits next to me on the bus, I'm in trouble, right? That's what I'm saying.

DR. SIEGEL: On a very long bus trip.

MS. BROWN: If I'm pregnant, I'm going to be very concerned.

DR. SIEGEL: No matter what the dose? One of the problems that people who use radiation in medicine always have to deal with is the concept that there is no dose, no matter how small, that can be considered safe. We are bathed in radiation continuously. We all get 300 millirems a year from ionizing radiation and radon in our houses. Whether we like it or not, we can't do anything about it. Most of us are married. We pick up an extra 10 millirems a year by sleeping next to another human being, or a few millirems per year, and we choose

to do that.

So the concept that no risk from radiation is acceptable, which I have personally heard some environmentalists speak sitting across the table from me, is a little bit extreme. We have to acknowledge that for society to achieve some good with radiation society, not just the individual patient, is going to incumber some potential exposure. It's just there.

MS. BROWN: I agree. I hope you didn't think that was my point.

DR. SIEGEL: I didn't.

Let's go on. The next slide is not one that's a dig at the Plain Dealer, although I re-read the articles last night and I actually only found one place where the issue of this slide was a concern to me. It's more, if you will, an object point for the Commission itself and for the staff, and that is, there is a tendency to refer to the medical use program as the nuclear medicine program.

Carol Marcus, who will be here tomorrow, and I are very proud of what we do, and we call it nuclear medicine. I'm also a diagnostic radiologist. Mel Griem and Dan Flynn are very proud of what they do, and they call it radiation oncology. The two are not the same. They acknowledge that

what they do is intrinsically much more dangerous nearly all of the time from a radiation safety point of view than what I do, which is more dangerous because I could just make a bad diagnosis which actually is the way people really get in trouble from nuclear medicine or diagnostic radiology procedures. Much less likely from the radiation.

I would just hope that the Commission and the Commission staff would be careful to distinguish the two specialties. If you want to regulate us, you should understand that we are a little different. Well loggers would be upset if we called them radiographers or reactor operators. The same applies in the medical program.

MR. GLENN: Do you have a proposed generic term for us? Radiation medicine? Would that be a good one?

DR. SIEGEL: Sure. If you like.

DR. GRIEM: That covers both.

MR. BERNERO: Or nuclear medical activities.

DR. SIEGEL: No, because that says nuclear medicine again, and then it will automatically be assumed to equal nuclear medicine. If you are going to miscall anything, then label it radiation oncology so that they get the bad press.

DR. GRIEM: The diagnostic imaging people use magnetic resonance. They used to call it nuclear magnetic

resonance. People were so scared that it has now become magnetic resonance imaging. They took the "nuclear" out because of the bad connotation.

DR. SIEGEL: The next issue is the issue of patient notification as a result of misadministrations.

We all know that the NRC has required patient notification for misadministrations for almost 13 years now and with the quality management rule the components of patient notification have been crystallized in some ways. What I propose to do with this slide is to make some comments from the Advisory Committee perspective about where we think patient notification fits in.

The first is that truth telling is in fact the standard of care. When doctors make mistakes truth telling is what doctors are taught ethically to do. Fraudulent concealment cannot ever be considered the standard of care and in fact becomes a reprehensible act when bad care results in tort proceedings. Fraudulent concealment can be one very important piece of evidence that is used against a malpracticing physician.

The responsibility for notifying patients who have been subjected to medical injury is a physician responsibility, an institutional responsibility where an institution is

involved, a hospital or a treatment center.

The NRC regulations that are already in place already exceed the usual extent of government intervention in the process of medical truth telling. To the best of my knowledge -- and I have now checked with hospital attorneys, university attorneys, professional society attorneys -- I am not aware of any other federal agency that requires patient notification as a result of an event that occurs during the course of medical practice. If that point is wrong, I would like to see it corrected by anything any of you all know now.

The concept that the NRC is inadequately protecting the patient is in fact really in the wrong direction because NRC rules make it more difficult for physicians who choose to conceal to conceal. There is an NRC audit mechanism; there are NRC inspections; and there is the risk of being exposed not only by a malpractice attorney, but by a big federal agency.

You are going to tell me about reporting devices, but that doesn't involve telling the patient. Go ahead.

MR. HAMILTON: Under the Safe Medical Devices Act of 1990, FDA has authority to institute patient notification when a medical device constitutes some danger or some harm to the patient. If it's not clear that the manufacturer or the facility has the resources to do that, then the FDA would have

to go back and the government would actually notify the patients. There is patient notification.

DR. SIEGEL: But it's not required within 24 hours as a matter of FDA regulations currently.

MR. HAMILTON: That's true.

DR. SIEGEL: Judy.

MS. BROWN: I don't have any problem with the content of this statement but I do want to dissent on the tone, because it makes it seem like it's a bad thing.

DR. SIEGEL: I didn't say it was a bad thing. If my tone came across that way, I didn't mean it to.

MS. BROWN: Or, "Gee, we have to do this and nobody else has to." I'm hoping the rest of the world will approach the standard and go in your direction. If you want to present that as a dissenting opinion.

DR. SIEGEL: I think one thing that is increasingly getting clear to me as we talk is that the notion that I'm going to make the whole presentation is less clear and I may well just go through the material as quickly as I can and we may decide before the day is over that each of you should have a chance to make commentary about what I just said in the way of amplification or dissenting opinion. We'll come back to that later. Because it's going to be hard for me to capture

all of the dissent in my comments. This one was a matter or the tone of my voice.

MS. BROWN: Not the tone of your voice, but "already exceed."

DR. SIEGEL: They do. That's a true statement.

MS. BROWN: Yes. I would see you reading that and saying "and at least one of us thinks that the rest of the world should come up to that speed."

DR. SIEGEL: It's actually in the revised slides. The concept is actually coming down the line under the regulatory purview issue.

MS. BROWN: I apologize for not reading ahead.

DR. SIEGEL: That's okay.

Next point. With respect to patient notification, the place where the NRC logically can intervene to determine if notification occurred and if notification was adequate is the licensee's report, because the quality management rule now requires that the patient either get a copy of the report that was sent to the NRC or the NRC get a copy of the alternative report that was given to the patient.

Correct?

MR. GLENN: Correct.

DR. SIEGEL: Therefore the NRC with the aid of

medical consultants, who I believe should be brought early into the process when there is any reasonable likelihood of injury, can make a determination: was that patient properly informed or was that patient inadequately informed?

That's where I think the NRC should intervene. Not sending an IIT out for every -- I'm not saying that anything is wrong with an IIT -- but not sending one out for every misadministration to make sure that the doctor talks to the patient with NRC people in the room. There is a perfectly logical way to address this problem that will work quite effectively.

MR. CAMPER: Why don't we add to that, Barry, that we are currently preparing information notices to go to the medical community that will reiterate the requirements currently in Part 35 for patient notification. I think that will go out in the very near future.

DR. SIEGEL: The next slide deals with an issue of what are the justifications for not informing a patient. Mark Rottman (phonetic) is not here. Do we have a better handle on his numbers yet, on what fraction of misadministrations result in the patient not being informed? The number was somewhere in the 10 percent range.

MR. CAMPER: We have some other information that I

would have to characterize as preliminary information, not a complete analysis as of yet. We have gone back and taken a look at therapeutic misadministrations that have occurred over the last three years. We are still communicating with our regions to get detailed answers.

Preliminary information indicates that the referring physician was informed something on the order of 80 percent or so, the patient was informed 80 to 90 percent, but the number we don't have a complete handle on yet is that about 50 percent of the time it appears, based upon preliminary information, that in fact a written notification was provided to the patients in those instances where the patient was informed. We need to further analyze that information, but it appears to be roughly 80 to 90 and 50 percent.

DR. FLYNN: Will it depend whether the state is an agreement state or an NRC state in terms of an agreement state which has not adopted yet the quality management rule and doesn't have to integrate that until 1995, or may not do it in the exact same fashion as the NRC states?

MR. CAMPER: There was a notification requirement previously in the misadministration requirement as well.

DR. FLYNN: I know there is. Is it the same as is in the quality management rule?

MR. CAMPER: There is a slight difference. The difference in terms of notification to the agency is different. The patient notification, though, is essentially the same, I think, as before.

DR. SIEGEL: I think the written part is modified.

MR. CAMPER: That's right. You can provide now a summary as compared to the detailed misadministration report. That's one subtle different. The other difference is the notification process to the regulatory agency is different. The notifying of the referring physician and the notifying of the patient is the same.

DR. GRIEM: In the accidents and misadministrations that you have analyzed are you seeing a certain system error or human error? Can you characterize any of this from the last three years? What is happening? Is it that a filter is being left out? What are the common errors, and are these human errors or machine errors or machine failures? What would you say? And are some of those fixable?

MR. CAMPER: We've jumped from the question of the notification to the actual misadministrations themselves?

DR. GRIEM: Yes. You said you had looked at the last three years.

MR. CAMPER: We looked at them. What we have been

looking at is the question of this issue of was the referring physician notified, was the patient in turn notified, and did the patient then receive a written notification. That's what this particular analysis is focused upon as opposed to the misadministrations themselves, what caused them, and this type of thing.

I do think, though, that historically we have got a pretty good handle on what is going on with most misadministrations.

MR. GLENN: It's clearly human error. The Indiana, Pennsylvania, incident where there was a machine failure that precipitated the incident is the rare occurrence. Most often it is a communications error, simply someone not recognizing a problem that causes most of these misadministrations.

DR. SIEGEL: A machine failure precipitated the incident but human error resulted in the injury.

MR. GLENN: There is always human error involved.

MR. PAPERIELLO: I have read recently a compilation that the staff gave the Commission of abnormal occurrences. I think what I am struck by is the really serious cases, something like Riverside Methodist or the one that happened in Maryland several years ago, is the common mode failure.

In other words, an error is made and it affects a lot

of patients. In particular, you don't tell the computer that you use for planning therapy that you've changed your source. Or you don't decay the source properly. That, in my mind, results in greater consequences to a greater number of people than the case where a technician irradiates the left lung rather than the right lung. In many cases that's caught before you complete the whole series, but the events which seem to have the greatest amount of injury to the greatest number of people involve some kind of common mode failure.

Just an observation.

DR. SIEGEL: Thank you.

Larry.

MR. CAMPER: One other observation. Again, these things are in the early stages and I need to characterize it as such.

One of the things we are doing right now as a result of the QM rule is that we have what we call a QM Review Committee. Every violation that occurs throughout the five regions that are associated with the quality management rule are reviewed by this committee. We do this for a number of reasons. We really wanted to find out what impact the QM rule was having: Were licensees putting in place proper QM programs, and the like? Were we seeing programmatic problems as opposed

to isolated instances where a mistake simply happens, it's an oops, I didn't mean to do that kind of thing?

Ultimately we will compile all these findings into a document we will share with the regulated community. We will brief the Commission in due course, and what have you.

I must admit I think that those of us on the QM review committee, which includes Dr. Glenn and I and some others, have been somewhat struck that the misadministrations that occur are really not stand-alone events where an error is simply made. Much of the time there are programmatic problems. Either the QM program was not properly developed to cover all the contingencies, or a QM program was developed that was quite adequate and would stand up to good scrutiny and peer review, but that the technologists involved were not informed as to the details of the quality management program. In some cases we find radiation safety officers have an inadequate awareness of their QM program.

I think we are finding that the QM program has really identified not only the proper focus, but we think in time will give us information to share with the community that will further fine tune this thing so that hopefully we will be able to further reduce the number of misadministrations.

So we really are not finding this great frequency of

stand-alone mistakes in the absence of programmatic problems.

DR. SIEGEL: Steve.

MR. COLLINS: The medical regulations are really no different from the industrial regulations in that they assume that mechanical failures can occur, and so you've always got this backup procedural method. In this case it's always use this calibrated survey meter to do an independent check.

You've had two incidents. One place the guy did exactly what the regulation required and you had no adverse effects because they took effective remedial action on the spot.

This other place they didn't believe their instruments. They didn't even use the independent survey instrument. That's the same thing that has caused the major problem in industrial radiography. They didn't use the equipment that was there and available to them and they got hurt as a result of it.

Going back to assuring patient notification, it's indicated that out of this small number of misadministrations that occur there may be up to 20 percent where the patient ends up not getting notified for some reason. Is there anything in the QM rule or any of the NRC regulations that are being developed that would specify what kind of documentation would

need to be in place as to the reasons why the patient wasn't notified?

MR. CAMPER: The regulation is very emphatic on that point. It basically says that the referring physician is to inform the patient unless he determines in his or her medical judgment that it would be harmful to the patient.

As we look again at this preliminary information -- I keep emphasizing that, because we have not completed the analysis yet -- there are two observations I would make.

One is that I think in some cases when the patient hasn't received a written notification it was because there was some confusion on behalf of the licensee once they had informed the referring physician and the referring physician indicated they were going to inform the patient. This question of the written notification subsequently going to the patient is something there was some confusion about. In their minds perhaps it wasn't clear whether they were to provide it or whether the referring physician was going to provide it. It's incumbent upon the licensee to do that. I'm simply saying I think that's an area where some confusion exists.

The second point is that we have gotten some feedback that indicates that referring physicians in some cases felt that the exposure that occurred as a result of the

misadministration did not carry with it any deleterious effects and therefore in their opinion it wasn't worth informing the patient about. Technically that does not satisfy the requirement in Part 35.

As this thing proceeds and we gather more information and look at this more closely, it may be that it will be appropriate for us to go back out and get a handle on this very problem you are talking about and maybe clarify what is acceptable and what is not acceptable.

MR. COLLINS: That was one of the things I was getting at. You could have an extremely good reason but not satisfy the rule right now. That's a shortcoming of the rule that needs to be fixed.

Another one is, since the referring physician is not usually a licensee or the radiation oncologist, that means he's not a licensee or an authorized user, which means under the law in the state I work for now we can't really get at that physician anyway. We have no jurisdiction over that particular physician.

DR. SIEGEL: Let me have Part 35. Who has got it?

DR. FLYNN: I have the one little clause I would like to read, if you wouldn't mind:

Whether the licensee notified the patient, the

patient's responsible relative or guardian, and if not, why not. If the patient was notified, what information was provided to the patient.

MS. BROWN: Are you reading the regulation?

DR. FLYNN: Yes.

MR. COLLINS: It says if not, why not. You've got to document your reasons.

DR. FLYNN: Here is the section here: Unless the referring physician personally informs the licensee either that he will inform the patient or that based on medical judgment telling the patient would be harmful.

MS. BROWN: What does it say about the patient's family or next of kin? What would be the harm in telling them? Does that also extend to the family?

DR. FLYNN: I don't think it should.

MS. BROWN: I don't either.

DR. SIEGEL: It's in the regulations, though.

MS. BROWN: It seems too easy an out to me for the referring physician to just say, in my judgment it would do harm to the patient. I don't necessarily accept that the referring physician is the adequate patient advocate all the time. So I wonder why there isn't some requirement to tell somebody who would act as a patient's advocate, or in lieu of

that, have more hoops to jump through to bypass telling the patient or the patient's family member or someone who could really serve as an advocate.

MR. COLLINS: I think I'm going to disagree with that some. It is the referring physician. That's not the physician that is giving the radiation treatments. That is a physician whose primary interest with regard to that patient is what's best for that patient. He doesn't have any responsibility with regard to whether or not that administration of radiation was right or wrong. He's the patient advocate at that point.

DR. SIEGEL: You are getting at the heart of a very, very complicated -- by complicated I don't mean to imply that it's murky and it can't be dissected -- ethical issue which relates to the quality of the physician/patient and the physician/patient family relationship. In those instances where that relationship is nothing more than a contractual "I don't know you from beans but I'll provide the following service" your very aggressive patient advocate role makes sense. In circumstances where a physician has the trust of a family and has been that family's physician for years and years and years, that physician is potentially indeed in a position to make a judgment that this family will gain no benefit from knowing that the radiation therapy department at this hospital

made the following mistake that injured grandma.

MS. BROWN: I just said that I didn't necessarily accept that the referring physician is always in the position to be the patient advocate.

DR. SIEGEL: I understand, but I think that past experience teaches me that if we try to write a government regulation that gets into the middle of that relationship we will invariably mess it up, because we will not effectively think of all the circumstances in the right way. That doesn't mean you shouldn't try and you shouldn't deal with the issues.

MS. BROWN: Right now we don't even have to write it. Right now they don't even have to write down anyplace, do they, why they chose not to?

DR. SIEGEL: Yes, they do.

MR. GLENN: They do.

DR. SIEGEL: Let me go on with the next slide. The next slide says justification for not informing the patient.

First of all, let me just tell you that the standard of care in a legal sense is that there is no legal compulsion to inform the patient or the patient's family if there is no actual injury or likelihood of injury. Once again, that is exceeded by the current NRC regulatory requirements to inform the patient unless the referring physician makes the judgment

that doing so would actually harm the patient.

MS. BROWN: How is it documented or who goes back and says why did you make this decision?

DR. SIEGEL: I am proposing that the report to the NRC is the proper focus of trying to decide whether there was adequate justification for not informing the patient. If your report currently does not require that to be stated, then your reporting form needs to be modified.

I can think of circumstances where it would be pretty easy. Palliative therapy being given with no hope of cure. Even in circumstances with a very, very high strung, nervous, reactive patient, simply telling them anything may make the patient worse.

Let me just read you something from a medical risk management textbook. Admittedly, risk management is written from the perspective of doctors protecting what they do. I'm sure you can find another textbook written for plaintiffs' attorneys that will have a different set of rules and guidelines.

This is what doctors are actively being taught as part of medical risk management:

There is no legal duty to disclose negligence that caused no injury.

The title of this chapter, by the way, is "When there is Obviously Negligence."

Indeed, in some circumstances such disclosure may harm a patient. For example, a patient who is told of negligence in medical care may become obsessed with the possibility of future negligence, become fearful of all medical care -- to wit, the concerns that were raised about the Plain Dealer series -- and cooperate less with treatment advice.

In addition, a patient who is informed of negligence may assume a negligent cause for any future complications and be more likely to initiate unwarranted litigation.

You may say, well, who cares? Go for it.

MS. BROWN: No, I don't say who cares. I think those are good reasons. I would like to see that doctors are saying I did not inform the patient not solely because I thought to do so would cause more harm than good, but because I thought this patient may take the information and refuse further necessary care. Something more than just as required now, as I understand it, to do so would do more harm than good. That to me is too easy an out. I'd like to see why and some requirement that they say why. There could be a million reasons and I'd like to know whatever that individual referring physician's judgment was.

DR. SIEGEL: How would you adjudicate that?

DR. FLYNN: In the regulation it says if you do not report to the patient, why not; give reasons to the NRC.

DR. SIEGEL: That's in the regulatory guide or in Part 35?

DR. FLYNN: Part 35.

MS. BROWN: It seems to me you can say to do so would do more harm than good and get off on that.

DR. FLYNN: No. You have to give more reason than that.

I would consider this to be an extremely small minority of cases. Let me give a point to you. I think that the referring physician will act as an advocate to the patient, but if he doesn't, you have the report to the NRC and the NRC can turn this over to a medical consultant. The medical consultants, at least in my experience, have been giving appropriate advice to the NRC. They are not protecting some radiation oncologist they don't know.

You have to trust somebody. You have several layers. You have the referring physician trying to protect the patient; you have the NRC getting a report that the NRC can turn over to any medical consultant they wish or internally themselves look at it and decide whether that was appropriate or not. They are

going to be the final judge.

MS. BROWN: And you think that is something that is going to ensure that the patient gets notified somehow. The medical consultant is not going to do it if the referring physician doesn't deem it beneficial.

DR. FLYNN: Some of the misadministrations can cause probable injury, but some of the misadministrations, let's say for palliative care, involve maybe a dose which is slightly outside the guidance of what needs to be reported which will not cause any harm to the patient. Those should also be reported to the patient except in some small minority of cases where the referring physician believes that notification will be harmful. The double check on that is that the NRC gets that report, and then they can choose any medical consultant they want as a third opinion.

MS. BROWN: Can the NRC tell me how they are listed?

DR. SIEGEL: If you get a misadministration report that says the referring physician judged that the patient should not be informed because, what kind of "becauses" do you get? That's what Judy is asking.

MS. BROWN: Yes.

DR. FLYNN: We've seen some where it may be an improper answer, that it was a mistake and there was no harm to

the patient.

DR. SIEGEL: "Because I might be sued."

MR. GLENN: No. You can follow up and instruct them to notify the patient if you wish.

MS. BROWN: I'd like it at the front end, not at the back end.

DR. SIEGEL: Except for one thing. We're talking about, at least under NRC's purview, with the new misadministration reporting requirements a relatively small number of events each year each of which carries a radiation dose where the dose itself may indeed have some potential to harm the patient. Through analysis by staff either in the regions or at headquarters and with the appropriate use of medical consultants, if you think medical consultants can indeed help to adjudicate this, it should be possible to analyze each event on line and make a decision whether or not the justification for informing the patient makes sense. If not, as part of a management conference with the licensee you say, explain to us why you didn't do this, and we disagree with you.

MS. BROWN: Does NRC have the resources to do that?

DR. SIEGEL: They have unlimited resources. They just raise the user fees and then they have more resources. I

had to get that in.

MR. CAMPER: I got a note from a member of the Office of General Counsel who had expressed concern that something may have been said that was misleading about this reporting requirement. If you will just bear with me for a moment, I'm going to read exactly what the regulation says. There was a concern that we were saying that the referring physician had a responsibility to inform the patient. He does if he informs the licensee that he's going to do so, but it is the licensee's responsibility to see that this happens. But let me just read it so there will be no confusion.

The licensee shall notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery unless the referring physician personally informs the licensee either that he will inform the patient or that based on medical judgment telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care, as a result of misadministration

because of any delay in notification.

The next point.

If the patient was notified, the licensee shall also furnish within 15 days after discovery of the misadministration a written report to the patient by sending either a copy of the report which was sent to NRC or a summary of the misadministration report.

MS. BROWN: Is there more in the regulatory guide that says you have to list the reasons other than just say "in my medical judgment informing the patient would be harmful"?

MR. CAMPER: No.

MS. BROWN: I'm left with the same point. I don't like that. Maybe we just agree to disagree and you saying Ms. Brown has a dissenting opinion.

DR. FLYNN: I'm looking at five misadministrations right now involving radiation oncology. This is very current. I don't see in a single one of those five a reason not to notify the patient and in each case the patient was notified, but if they weren't, when I write up my end of it I would specifically look to that.

I see this as one out of a hundred cases. The patient who is suicidal, who gets a slight deviation in dose, which is not going to harm the patient, who is going to die in

30 days with their metastatic cancer, and the reason for that radiation was to take away some of the bone pain they are getting --

MS. BROWN: All good reasons. I agree.

DR. FLYNN: The five cases I'm looking at right now there is absolutely no reason not to notify the patient, and in fact in all five cases the patient was notified.

MR. COLLINS: That's the point I was trying to get a little bit earlier. There is not a list of reasons for an NRC inspector to check against to see if these were adequate reasons. The NRC and all the states typically have health physicists, not physicians. Now the NRC has one consultant physician, which is fairly new, or one visiting fellow to look at these things. Your HPs still aren't the right people and our state HPs aren't the right people for looking at these reasons. It is independent physicians that need to be looking over and it's not typical NRC staff and state staff that could do this.

DR. SIEGEL: We do have to retype one slide, slide 5. I think I'm hearing a consensus. I want to add a third bullet on that slide. Maybe we can just add it. There will be enough room: Very few circumstances would justify not notifying patient under current NRC requirements.

I agree with Dan completely. If the rule stands that says you must notify unless doing so would harm, that's a very small fraction of the events. Nonetheless it still exceeds the current legal duty in general medical malpractice, not related to NRC regulations.

MR. CUNNINGHAM: I don't think there is a disagreement between what Judy is saying and what Dan or you are saying. I do think that as we gain experience with this quality management rule there will be an elaboration of guidance on what is acceptable reporting to the patient and what is not acceptable. I don't think we can ever develop a checklist that says this is acceptable or not acceptable, but there can be more guidance. That's one of the things on the to-do list.

The other thing I wanted to mentioned was the function of the visiting fellow, although he is very helpful in situations like this, is not to evaluate the misadministration reports. This is one where we would use our medical consultants, including members of this Advisory Committee.

I don't think that the number of misadministrations reported under the QM rule is going to be sufficiently large that it is going to be a significant impact on any resources we have.

MR. CAMPER: I would add one more point to that to embellish what Mr. Cunningham said, Steve, and that is we have used medical consultants to look at misadministrations for a long time now. In fact, if one goes back and looks at the ones we have been looking at recently that occurred in that last three years, we used consultants about 30 percent of the time. We have been using medical consultants in a number of misadministrations for sometime now.

MR. GLENN: I thought I was hearing one more consensus, and that was that if there is in fact a case where it is decided not to inform the patient that we should involve a medical consultant to review that decision.

MS. BROWN: Yes.

MR. COLLINS: Yes. That's what I was saying, and either the ACMUI or a member of it would be a good place to look for those people.

DR. SIEGEL: Actually, the focus of using medical consultants with respect to misadministrations is a theme that is repeated on these slides over and over. As I pointed out in the Commission briefing in July, one of the reasons that the Advisory Committee was opposed to Policy Statement No. 3 is that the NRC is not licensed to practice medicine and if you want to get into these issues that are really medical

judgments, you need to take advantage of physicians whose expertise and judgment you trust.

MS. BROWN: One of us liked No. 3.

DR. SIEGEL: I know you did. Judy dissented again, for the record.

MS. BROWN: Thank you.

DR. SIEGEL: Next slide, No. 6, "Content of Patient Notification."

I would say that I think the patient should be informed in full of all of what happened and also of all reasonably probable medical consequences.

This is an issue that there is very little problem in understanding how to do that with respect to deterministic effects of radiation, but it's a little bit trickier when you get into the issue of stochastic effects. What I propose to do tomorrow is just make some points about that, because I think, speaking stochastically, the probability that we can figure out where the threshold ought to be set is zero. That's a policy issue, not a scientific issue.

There are two things related to stochastic effects.

First of all, the reasons for wanting to make full information about stochastic effects might be twofold. One is because you would believe that they are medicolegally relevant,

that the patient deserves to know that they have a certain probability of developing a cancer at some time in the future because that's an important piece of information for their lawyer to use in recovering damages from the physician who did the bad thing.

MS. BROWN: And for themselves to use to tell their physician to watch that particular organ.

DR. SIEGEL: That's the next thing. But in fact you have to get to very high doses before either or those makes sense.

First of all, from a tort point of view -- I know there is at least one lawyer in the room -- you have to actually be injured before you can collect for injuries. Although there is some psychological injury related to worrying about future cancer, that is less often awarded than an injury for a cancer that actually occurred. The more likely than not test will often apply except in circumstances of strict liability, which is not likely to arise in these medical events.

Consequently, you have to get up to a very high stochastic probability using the probability of causation tables even when you have a cancer in hand to be able to use that information in a proactive medicolegal way. So the

patient probably is not benefited very much by being told that you have a one percent chance of developing a cancer at some time in the future.

From a patient follow-up point of view, Judy, since you raised the point, here's how the information would have to be used. You would need to tell a patient -- and I think most physicians would think that this would not be really in the patient's interest -- you have a 22 percent lifetime chance of developing cancer. Based on the fact that we just gave you a 10-rem whole body inadvertent exposure, which we really didn't mean for you to have, you now have a 23 percent lifetime chance of developing radiation-induced cancer.

Medical follow-up wouldn't change at all for one percent; it probably wouldn't change for a 10 percent increment; it might change with a doubling.

MS. BROWN: Are there medical situations -- I guess this would be more in radiation oncology -- where a certain organ would need to be watched more closely?

DR. SIEGEL: Those are deterministic effects.

MS. BROWN: "You might get breast cancer in 20 years because of what we just did"?

DR. SIEGEL: That's stochastic.

MS. BROWN: That's what I'm asking.

DR. SIEGEL: This is why I don't think we can set a threshold. This is a policy debate that I don't think we are going to resolve in the next hour and a half.

DR. GRIEM: There is some data from breast cancer where women have been treated and now they are looking for how many more cancers were induced because they got the treatment. This was recently published in the New England Journal of Medicine. And they couldn't find it. It has been done. The 100,000 women who have been treated for cancer of the cervix at various centers in the world have been followed up for 30 years, and it turns out there is a little increase in leukemia and myeloma in that group. But they are alive to have this happen 20 to 30 years later.

MS. BROWN: I understand your point and appreciate it.

DR. GRIEM: I think you finally come to one of these medical decision-making things. If you don't treat, the answer is obvious.

MS. BROWN: I'm just asking is there a reason to tell the patient that would be medical, that you ought to have more frequent pap smears or mammograms because of what just happened here today. That's all.

DR. FLYNN: It would have to be a case-by-case basis.

For example, if the prescribed dose was 5,000 centigrade to the pelvis and instead a misadministration occurred during the third week whereby the dose was exceeded by 20 percent for that week and they got instead of 1,000 centigrade that week they got 1,200, so they got a total of 5,200 for the whole course of treatment instead of 4000, they are going to be followed in the traditional manner whether they got 5,000 or 5,200 for complications that can occur during treatment which would occur even if they were treated properly.

MS. BROWN: If this Committee can't come up with any medical reason, I accept that there aren't any.

DR. FLYNN: The answer is they have to be followed anyway.

MS. BROWN: You're supposed to get a mammogram every year after age 40 anyhow, but there is no situation where this patient because of what happened ought to be getting more frequent something.

DR. FLYNN: Not unless something else occurs, like the wrong site is treated to such a dose that that organ at that other site which is outside the cancer, like the lens of the eye, is going to be subject to some problem.

DR. SIEGEL: That's the deterministic effect.

DR. FLYNN: Right.

DR. SIEGEL: I think we would all agree that for deterministic effects and where you have exceeded thresholds where you can predict quite logically that the deterministic effect has a high likelihood of occurring that you must in fact inform the patient. In fact the next point on the slide says the patient notification should include clear instructions regarding the need for follow-up and the need for continuing care.

The only point I was trying to get into is I personally do not know where to set the threshold with respect to stochastic effects, and in fact, I think that that threshold is a difficult one because there is a probability of inducing lifetime cancer phobia that can be disabling. That doesn't mean people shouldn't be well informed, but if there is a substantial majority of individuals who are sufficiently unable to deal with probability concepts that if you tell them you've got a one percent higher chance of lifetime developing cancer, that will incapacitate them. I don't know whose interest that is in.

MR. ALMOND: Barry, the NCRP issued last year, September, NCRP Statement No. 7, the probability that a particular malignancy may have been caused by a specified radiation. In that they say it is not possible on the basis of

medical evaluation to unequivocally prove or disprove a claim that a specific malignancy was caused by a specified radiation exposure, which we know.

They have what is called the probability of causation. There is no way before the fact of figuring out what that is. It's an after the fact thing. If the cancer shows, you can say that there is a specific probability that it might have been caused by, but you still don't know even when you've done the calculation here.

So the NCRP has addressed this, but it is retrospective and there is no way of doing it looking into the future.

DR. SIEGEL: This little quote here from American Jurisprudence, Proof of Facts, an interesting chapter on radiation injuries with respect to causation says, "Causation for a late radiation injury is more than merely complicated; it is indeterminate." It goes through a series of legal tests that would be required to prove that the injury resulted from the negligence under such cases.

Peter, do you have a comment you want to make?

MR. CRANE: A question. My name is Peter Crane. I'm not a doctor and I don't hold myself out as a medical expert.

If we know that of the 5,000 kids irradiated at

Michael Reese Hospital who were followed, who got head and neck radiation in the neighborhood of 750 rads, 2,000 of them would wind up with thyroid abnormalities of which a third are malignant, and if we know that the Marshall Islanders who were irradiated in the Bravo blast of March 1954 at Bikini now are showing up with extremely high numbers of thyroid abnormalities, retrospectively I think we can go back and link that illness to those exposures.

DR. SIEGEL: There is no argument that radiation causes cancer. All respectable scientists agree with that.

MR. CRANE: Let me finish my paragraph, or sentence, or whatever.

If that is so, is it not also so that if you know that a certain person has received inadvertent radiation in large doses to the head and neck that there may be no immediate visible harm but there may be a risk of thyroid neoplasms down the road and that warrants that person be followed with palpation of the neck every year or so? That was Ms. Brown's question?

DR. SIEGEL: The answer to your question is yes, there probably is, but it would be difficult certainly in the time we have available to say exactly what the threshold should be for each case. If presented with the specific facts of a

particular patient, if you tell me that a four-year-old, or better yet, let's say a four-week-old has a 20 rem exposure to the thyroid gland, then I would recommend that that patient have thyroid follow-up.

On the other hand, if you tell me that a 50-year-old had one rem exposure to the thyroid gland or even the same 20 rem, I would recommend nothing different be done. It will be difficult to come up with a clear set of rules when to inform related to stochastic, because they will need to incorporate age, organ and dose in all cases. I think it's very complicated. That doesn't mean that patients shouldn't be informed.

MS. BROWN: Can you say what you just said, that it's difficult and it's complicated?

DR. SIEGEL: What I said at the beginning is that this is a complicated policy issue, and frankly, it's one that I still think is best adjudicated on a case-by-case medical reviewer basis.

DR. FLYNN: I think, Judy, that for a misadministration where something like this comes up I hope the NRC will choose the proper medical consultants. If it's nuclear medicine, choose an expert in nuclear medicine who can advise what additional steps might happen in the case of a

four-year-old as opposed to someone who is 85 years old.

I think what Barry is saying is that it would be so difficult to try to come up with all the rules and guidelines and thresholds ahead of time that it's better to address everything on a case-by-case basis.

MR. PAPERIELLO: I would like to make an observation. It goes beyond the patient. I speak as a health physicist outside of nuclear medicine. If we know that somebody has received a significant inadvertent exposure to radiation, not just in the practice of medicine, I think in my mind the question that arises is what is our responsibility, the NRC's and the licensee's responsibilities for providing an equivalent communication to the patient?

Let's suppose I'm a graduate student and I happen to be labeling with iodine and something happens and I wind up getting a 50 or 100 rem exposure to the thyroid because the research went badly? I've never had a case that big, but I've had cases where there has been overexposure.

The question then is, the same situation. How they got there is different but the ultimate physiological effects are the same. I'm concerned about that but it's a bigger issue than just patients. It's also anybody who gets an exposure. In the case of Indiana, Pennsylvania, we did send letters to

everybody that we evaluated dose for, but that was an ad hoc thing and there is not a policy that addresses how we do that.

DR. FLYNN: In Indiana, Pennsylvania, for example, Judy, I arrived there before Carl had arrived. There was one dietician there who was pregnant. I felt that she did not receive a significant dose. I can do a little basic physics, having had a physics background originally. But because she was pregnant I was worried that she would do something foolish and then we'd have two deaths instead of one. So I got the chromosome studies on her also sent out. It came back negative, and the blood test was negative. That was so she wouldn't do something foolish.

DR. GRIEM: Dr. Siegel, I would like to get back to the Michael Reese situation for a moment. At the same time the treatment for the tonsils was being done with radiation there were four surgeons, each one of them doing a tonsillectomy a day. So about 1,000 tonsillectomies were being done a year. Then you've got to say, well, a tonsillectomy is not necessarily a benign procedure surgically with the anesthetics and so forth. This was a time before penicillin when this was being done for prevention of mastoid disease and so forth. So the control series really is about 5,000 surgical tonsillectomies, and that control series has never been

followed up. It was a big tonsil center.

DR. SIEGEL: Nonetheless, Peter, your point is well taken. The whole point of the slide is to emphasize that knowing what to tell patients about stochastic effects or occupational workers or members of the general public is not an easy matter. It's a complicated policy issue.

By the way, my pediatrician did not believe in radiating tonsils. Consequently my tonsils were removed at Michael Reese Hospital at about the same time that they could have just as easily been irradiated. So I'm a member of the follow-up group and I don't think I have thyroid cancer yet.

Steve.

MR. COLLINS: If we are ready to move on, I was wondering, what does "medicolegally relevant" have to do with the radiation protection or something NRC has authority over? You've got it listed.

DR. SIEGEL: The issues with respect to stochastic effect notification. Potential concerns that one could raise is that a patient needs to have all of that information because it will help them take a legal action; they also need to have that information because it will help them taken an appropriate course of medical follow-up. The only point I was trying to make is that in the case of stochastic effects neither is

clear.

Next slide, Patient Follow-up. Medical consultants can and should help to evaluate reports of misadministrations and extending to the issue of helping to design follow-up.

I think that when deterministic effects are likely that a follow-up plan should indeed be necessary and laid out for the patient as part of what the patient was informed, and as I just said 30 seconds ago, whether the follow-up plan exists for a stochastic effect will depend on the particular likelihood of a stochastic effect, which, of course, can only be assessed in a probabilistic sense.

The evaluation by the NRC of patient notification should include a consideration of the follow-up plan: Has the licensee laid out a proper plan for at least transmitting to the referring physician?

An important issue that comes up in this context is the patient isn't going to stick with the licensee for their follow-up. In the case of a misadministration they are going to run, not walk, as fast as they can to some other practitioner, because they won't necessarily want to stick with the licensee who has just injured them. The licensee nonetheless has the responsibility for making some advice about what the likely injuries are and getting that into the hands of

the patient and the patient's care givers. I believe that.

On the other hand, I don't think NRC follow-up intervention should go any further than looking at the focus of the report to the patient. The NRC should not itself get into the business of patient follow-up and exit interviews with patients to find out what they were told and what their level of comprehension is of these events. If the NRC wants to get in that business, then I think we need a fundamental change in the way the federal government and the state government oversees everything that happens in medicine and with respect to medical misadventures. That's just getting too far down into the process to make sense both in terms of the need to protect patients and the use of federal resources.

Now, dissent, please.

MS. BROWN: Do you think I'm going to dissent? I'm just going along whole hog here the whole time.

I agree that NRC follow-up intervention should go no further, but I wonder what parts of the follow-up plan could be included as appropriate. I'm thinking particularly of the economics of following somebody and giving them extra tests. I'm thinking specifically of the Tripper baby. Who is paying for his medical bills lifelong? Does anybody even let that family know that they have a right to not incur those costs?

That should be part of the follow-up plan where appropriate or deemed necessary by the medical consultant or whoever. I would like to see that someplace.

DR. SIEGEL: Let's go back to the point that was on the original slides that you asked me to remove. Do we really think that patients and their attorneys are defenseless?

MS. BROWN: As far as I know, in the Trippler incident they don't have an attorney. I don't think they did anything.

DR. SIEGEL: They do in fact have an attorney and it is my understanding that they are in fact suing Trippler.

MS. BROWN: Is this well after the fact? How after the fact is that, years or so?

MR. PAPERIELLO: A couple years, maybe.

MS. BROWN: I understood that they didn't, so I'm wondering how old my information is.

DR. SIEGEL: What are you asking for? What the Trippler baby needs is a lifetime supply of thyroid hormone.

MS. BROWN: And a doctor to administer it.

DR. SIEGEL: No. You take a pill. You don't need a doctor to administer a pill. It needs a periodic check. An annual supply of thyroid hormone currently runs probably $25 to $50 a year. Fortunately, Synthroid is one of the cheapest

medications around.

MS. BROWN: No generic.

DR. SIEGEL: Yes, there is, absolutely.

MS. BROWN: Don't you need somebody to titrate that on occasion?

DR. SIEGEL: For openers and then periodically maybe once a year.

MS. BROWN: That's exactly it. That's the kind of thing that I would look for a medical consultant to say.

DR. SIEGEL: So would I.

MS. BROWN: Is that in here and I've missed it, the economic consequences?

DR. SIEGEL: You are saying you want the NRC to provide?

MS. BROWN: No, I certainly don't. I want them to let the patient know or let anyone know that this is going to be the likely economic consequence to the family of caring for this person who has had this misadministration happen to them and that, further, this probably is the right place to pick the pocket, the institution, the licensee, somewhere they should go to get those funds.

MR. COLLINS: That's not a radiation safety question at all.

DR. SIEGEL: I think you are getting into a pretty tricky issue in terms of laying out a compensation plan at the point of notification which occurs within 15 days of the event. You are jumping the gun.

MS. BROWN: Yes, but that gun never gets brought up again. It's left smoking. So five years later these people figure out it's real expensive.

DR. SIEGEL: The American way is to not take responsibility for anything that happens to you. The American way is to assume that if you are injured in any way, shape or form you find an attorney and sue somebody. That, unfortunately, is the American way, and consequently people don't need help getting compensated for medical injuries.

MS. BROWN: By and large I agree it's a litigious society, but I have a personal friend whose parent is a nurse and said, when she was totally messed up by the medical situation, well, you know, he was only human; I'm not going to sue him; that can happen to anybody. She is stuck with the consequences of this and incurring the medical bills too because she didn't want to take any course of action. I'm just saying someone should apprise them of that.

DR. SIEGEL: If you want to develop a no-fault approach to compensation of people who are injured, then go for

it. We are getting into the issue of medical malpractice and what our society's response to it should be, and that's really not the focus, I don't think, of the NRC.

As you will see in a moment, we are forgetting the big picture. We are forgetting the big picture of all of medicine. As my friend E.E. Cummings once said, nothing, not even the rain has such small hands.

When we realize that this is such a tiny fraction of all medical care, we've got to prioritize this in terms of the national big picture. I think whether the NRC is the focus for making sure that patients get compensated adequately for things that go wrong in medical care is very questionable.

MS. BROWN: Maybe not making sure, but at least letting the family know that this is going to have some consequence.

DR. SIEGEL: Could that policy debate please occur at the level of Capitol Hill, the White House, and the Department of Health and Human Services?

MS. BROWN: Well, maybe Capitol Hill could pick it up from here.

DR. SIEGEL: Indeed, and that's intentional. I just don't see that as an NRC focus.

Bob.

MR. BERNERO: I would like to have a clarification. If I understand what I've heard, the report on the misadministration should include enough information about recommendations for follow-up care or follow-up treatment in order that the NRC at that point and at that point only can make suitable review and comment on that, to say that's essentially on the mark or no it's not.

DR. SIEGEL: That's the logical point of first intervention. Anticipating your concern, there will be certain events where the NRC might say it's too early to tell and we on a negotiated case-by-case basis want to get further information from the licensee about what happened. To build a regulatory system that has periodic follow-up set up as a given I think does not make sense, but I can acknowledge certain circumstances under which the NRC might say, you know, at 15 days out we don't really know for sure what's going on here, and your information to the patient may not be adequate; we would like you to report back to us in six months about what is going on.

One of the things that happens with your licensing actions is that you sit down with licensees across a table as part of those lovely conferences that we all enjoy so much and you do have an opportunity to work out a logical settlement to

an individual problem.

Continue.

MR. BERNERO: If we regulate a circumstance where a licensee has to report to the patient on proper follow-up to the misadministration, and that's the 15-day sort of cycle, and the patient goes to another physician or another practitioner for that follow-up care, are you suggesting that in some circumstances the NRC might follow the patient?

DR. SIEGEL: I don't think so. I don't think the NRC wants to set up a clinic. I can think of -- well, maybe I can't think. Dan, Mel, what do you think?

DR. FLYNN: I guess my question is there is the 15-day report, there is the report that the patient gets, and then if new information becomes available, let's say with an NRC medical consultant, that it may be recommended that a couple of additional steps be in the follow-up plan as a recommendation. It may not be the only recommendation, but a recommendation.

As long as the patient gets that and the patient has that in their hand, then they and their family and their referring physician and their attorney, or whoever they want to get involved, can make sure. As long as the patient is notified of a follow-up that has been recommended.

It may be modified. The 15-day plan may not be the

total plan. Maybe something else amends that plan. For example, if the NRC through its medical consultants review it and come with some additional recommendations, that may be incorporated in the follow-up plan. As long as the patient gets it, then that should be the end of it.

When we follow up patients who are treated for cancer, we may see a patient every three months, and then after awhile it's every six months; then after awhile it's every year. Then, depending on the patient's condition, how far they travel, how much trouble you put them to coming in for this follow-up visit, we follow them more frequently or less frequently depending on many, many factors. I don't think you can regulate how often, because the decision as to when the patient's next visit should be is determined on that visit.

MS. BROWN: I wouldn't at all suggest that you regulate how often or regulate anything specific but that you include in the follow-up plan if there is an economic consequence that that be somewhere included. That's all. "It's going to cost you a bundle to monitor this for the rest of your life." I think someone should tell the patient if that is a possible outcome.

DR. SIEGEL: I may let you make that as a dissenting point.

MS. BROWN: Thank you. If we are trying to reach consensus here, we're going to be here a long time. So if you could just let me dissent, that would be fine.

DR. SIEGEL: That's fine.

MR. CAMPER: During the 22nd of January briefing for the Commission there was a great deal of discussion about the role of the NRC medical consultant.

MS. BROWN: Which one was that?

MR. CAMPER: The 22nd of January where the staff briefed the Commission.

At that time Mr. Bernero was commenting about the role and us taking a look at the role and redefining the role and making clear what the role of the consultant is to be. I suspect tomorrow from the Commission you will get a number of questions along this line.

The staff has currently already initiated some efforts to go back and look at Manual Chapter 1360, which is the medical consultant. In due course we are going to perhaps modify that chapter. As we do that, I'm certain it will come to the Committee and get specific recommendations on what the role of the consultant can be. So there will be ample time to iron out the details.

DR. SIEGEL: I think we have already indirectly

answered that. The consultant should evaluate whether the patient was adequately informed, whether the justification for not informing the patient makes medical sense, whether the patient has been told of all the reasonable consequences, and whether the patient has been provided with guidance as to what kind of medical follow-up is necessary short of economic consequences.

You can say that one yourself.

MS. BROWN: Dissent.

MR. BERNERO: I would just remind you that this discussion is focused on those who have been exposed to radiation beyond plan in the medical environment and use of medical consultants in dealing with those who are victims of unintended radiation in the non-medical environment: radiographers, people in the fuel cycle of plants, or wherever. That manual chapter reconsideration involves those as well.

DR. GRIEM: I think each situation has to be taken on a case-by-case basis. Currently there are a number of cancer chemotherapeutic agents which have profound influence on the response of the tissue. For instance, with Methotrexate and radiation in childhood leukemia we've already identified how to put these two together and how not to put these two together and when you do it wrong what the outcome is. I think before

each particular case you may need to get specific consultants in a particular area. I think you are going to have to do it on a case-by-case basis.

DR. SIEGEL: Okay.

The next slide states that an NRC-sponsored follow-up registry or other data gathering mechanism is potentially appropriate to address unanswered scientific questions. But I can't think of any.

In other words, I don't think a patient registry for misadministrations is going to tell us anything more about the stochastic likelihood of developing cancer, because we all know that the size of the population we need to study is so large. I think we know as much about the deterministic effects of ionizing radiation as we are likely to know for the near term. This is as well studied a series of effects as any. In fact, it's hard for me to conceive why the NRC would want to get into a registry business.

DR. GRIEM: Dr. Siegel, in the children's cancer study group they are looking at all children that have been treated, and they have a late effects follow-up group. It's a very tightly controlled proposition. Julio Dangou (phonetic) runs the radiation effects on children who have been treated and it has been going on for 10 or 15 years. So I think there

are people out there.

Likewise the radiation therapy oncology group has a late effects of neutron radiation. There have been about 5,000 patients treated for neutron radiation and about another 5,000 treated for proton radiation in Russia and elsewhere. These are all being followed up at the present time. There are databases that can be used for specific situations like this.

DR. FLYNN: I think it's very important to have a registry of accidents. Let's say a source falls out of the applicator upon insertion into the Fletcher suit and it happened in New Haven, Connecticut, and let's say it happened in Colorado, and if it happened again Seattle, Washington, it's important to know that a focus to the practitioners should be at those areas, at those points along the treatment process where events have occurred in the past and to be more diligent at that point.

DR. SIEGEL: I think this Committee is on record that even though no physicians are in love with the concept of misadministration reporting and potentially exposing themselves to malpractice litigation, it is entirely appropriate for the federal government to take a role in looking at the big picture to try to define if there are systematic or programmatic problems that only a national perspective can give you the data

to address. Any individual practitioner, the probability that he or she will encounter the event often enough to form an opinion about what's wrong is pretty unlikely.

A national focus addresses that. Consequently, even though we hate having government interfering with the way we do our business, that kind of data gathering is appropriate. The FDA does it a different way. The FDA requires the manufacturers, at least for drugs, to continue to collect data on side effects and then report those back to the FDA for modifications of the labeling as they are uncovered. Now, with devices there is a mandatory requirement for institutions to report device defects or failures, and that's how the FDA gets a handle on what is going wrong with devices.

The FDA, on the other hand, does not require, as Don pointed out earlier, that the patient be notified under those circumstances.

You had a comment, Dick?

MR. CUNNINGHAM: Just to follow up what Dr. Flynn said. We do record misadministrations and we do send out information notices based on analyses to notify people.

I think it's also important to note that we do fund research on human factors related to brachytherapy, teletherapy, radiopharmaceutical therapy. We are also funding

research at Lawrence Livermore Laboratories in Idaho on the human-machine interface with some of these devices where there is a human failure. So it goes well beyond just looking at instruments. We are trying to understand better what happens with the human-machine interface that can lead to accidents and prevent it by design.

DR. SIEGEL: The second part of this little phrase says NRC follow-up registry is not needed to address medicolegal or regulatory issues.

First of all, regulatory. It seems to me highly unlikely than an NRC follow-up mechanism of the small numbers of patients even if we extend to agreement states would gather the kind of data over time that would cause you to change your regulations. It would be an expensive effort for very little gain.

I'm not sure what I meant by medicolegal. Sally, we are going to cut the "or regulatory issues" and paste it over "medicolegal."

DR. FLYNN: Would you object if the first sentence said "NRC-sponsored follow-up patient registry"? On the patient registry I agree with you.

DR. SIEGEL: I wouldn't object. Would you object if I said it so that it's one last thing Sally won't have to

retype? Can I just remember to say it? And if I don't, when you speak you can make the point. I'm trying to only make changes that are additions and won't cause us to have to retype the whole slide, but if you feel strongly, we'll do it.

DR. FLYNN: No. It's all right.

DR. SIEGEL: I'll remember.

Then the point, assuming you all agree with me, that the NRC's role need not extend to that of becoming the plaintiff's attorney in these issues, that the government intervention should stop at the point of making sure that the information gets out there, and then we've got a perfectly good system with lots of muscle in the United States for defending people who have been injured.

DR. GRIEM: Is there a place along the way for some of the new technology that is being developed on certain linear accelerators to prevent the filter being not placed in correctly and so forth?

There is a whole bunch of new check devices being developed on what you might say are third or fourth generation linear accelerators. We have one right now and we have two Ph.D. students looking at this whole question of, okay, now this is in place and computer controlled and the machine can't be turned on until everything matches what the particular

patient's recipe should be. These two Ph.D. students are looking at the question of how much more accurate is the treatment and whether some of this which is being developed by one of the manufactures can be retrofitted on cobalt machines to bring them up to, say, 1994 or 1995 standards. I think that is something that the NRC could encourage.

DR. FLYNN: I don't think that all the errors are being made in treatment verification systems. I think the wedge or the filter isn't being put in in the first place. I think the cobalt machines are dwindling away as they are aging. It would be extremely costly to refit the current 400-and-some odd cobalt machines with these systems. I don't know what Dr. Almond thinks about this.

MR. ALMOND: I tend to agree with you. That whole question of computerized quality assurance or control of linear accelerators is a very, very tricky subject. Just the verification that those computer programs are going to do what they say they are going to do without faulting on you is a very difficult subject. It's what got the THERAC 25 situation. They went through that program and through that program and it was a good program and it wasn't going to fail. And yet it failed.

Certainly people are looking at that. That, I think,

is one way of doing it. But there is an easier way, and that is you make sure that your people are trained and they follow certain procedures and do their job right, and that's a whole lot less expensive than putting on expensive computers to do it.

DR. GRIEM: Should these people be recertified?

DR. SIEGEL: Which people?

DR. GRIEM: The people running the machines. What do you do in Illinois?

MR. COLLINS: We have a technologist accreditation requirement where the techs do have to be accredited. That's the term that we use. They maintain that by obtaining CEU credits to get it renewed every two years.

DR. FLYNN: I think there is something I need to bring out at this point. A lot of times the big programs, the larger centers may report an occasional misadministration while treating thousands of patients. The reasons why they may discover the misadministration is because they have a large physics group; they have a different physicist checking the chart every week. What I worry more about is the small, isolated center with one physicist, and how will he discover his own error to even know to report it.

It may be the centers that don't report any

misadministrations are the ones that you have to worry about if they have limited staff, if they don't have the redundancy built into their system to discover the misadministration. Those are the centers I would worry more about. I don't know how you get to that.

DR. SIEGEL: That brings me to the next slide. The next slide is intentionally blank but it was one of the questions that was asked: under-reporting of misadministrations.

I think it is safe to say that as an Advisory Committee we have no better data about under-reporting of misadministrations than the NRC currently does, but the smart money is on letting the quality management rule work itself through and let it be the source of gathering better data.

You now have a system in place that will bring all the states into line in another couple of years. You have an audit system in place where licensees are required to look at what they are doing, and you now have inspectors specifically instructed to go out and look and see whether the audit is working and whether things are being missed.

To speculate now that 20 percent or 50 percent or 5,000 percent of misadministrations are being under-reported frankly doesn't make a lot of sense. My personal belief is

that it's a very small number and that most people in fact do report misadministrations. But that's my personal ambiguous data.

DR. FLYNN: I think most do report them that know about them. Some may not. But maybe more don't report them because they are never discovered.

The American College of Radiology patterns of care study showed that the outcome and some of the quality issues became more important the smaller the center. I hope the NRC will look into the future as to those small licensees who lack redundancy, who lack the backup system whereby Dr. Smith is checking Dr. Jones or Physicist Johnson is checking Physicist Smith. It's the centers that have a lack of redundancy which are most at risk for having misadministrations that are never discovered.

DR. SIEGEL: Which is worse, covering up a misadministration or being too stupid to know that you made a misadministration?

MS. BROWN: Covering up is worse.

DR. SIEGEL: I'm kidding. It's a rhetorical question before the break.

Bob.

MR. BERNERO: I'm not sure it's worse. I think

Riverside is a classic example of not discovering.

DR. SIEGEL: Let's take a 10-minute break.

[Recess.]

DR. SIEGEL: If we can come back to order, John has a statement to make.

MR. GLENN: The first is to note for the record that Peter Almond has joined the discussion. He is a member of the Advisory Committee.

The other thing is to correct the statement I made about CIRRPIC and whether there had been any request for us to involve ourselves in some of the non-byproduct material aspects. I said that it had been limited to accelerator produced isotopes. That was slightly incorrect. What the CRCPD had actually requested was discrete sources of NARM. So that would be discrete sources of either naturally occurring or accelerator produced isotopes but it would not include environmental sources of NARM, such as radium and uranium that occurs naturally in soil.

DR. SIEGEL: But they didn't ask you to regulate linear accelerators.

MR. GLENN: No. We were never asked to regulate machines.

DR. GRIEM: Would you regulate two minute oxygen

produced on a cyclotron?

DR. SIEGEL: No. It's not a byproduct material.

MR. GLENN: We certainly don't now.

DR. GRIEM: It's accelerator produced.

MR. GLENN: If that had gone through, I think there certainly is a potential that we would have.

MR. COLLINS: Radium needles and radiopharmaceuticals.

DR. JONES: We still have the radioactive drugs.

DR. SIEGEL: We can save this discussion for March 5th down at the Parklawn Building when PET radiopharmaceuticals become the focus.

Next slide, NRC Regulatory Purview. Let me just tell you what points I plan to make here.

One of the points the Plain Dealer raised was the expansion of NRC's regulatory purview. We were asked the question: should that occur?

The point I want to make is to once again point out that byproduct radioactive material is not uniquely hazardous in comparison with other ionizing radiation used in medicine. There is nothing special about byproduct material. It's just that the Atomic Energy Act limits NRC's authority to byproduct material insofar as medicine is concerned. That authority is

really remarkably limited.

Let me give you some data. These are estimations but nonetheless they are interesting. These data I obtained with the help of the American College of Radiology, who tapped into the 1991 Medicare database which they have sitting out there on their computer.

If you take all radiology codes, the entire 7000 series in current procedural terminology, and subtract from it the ultrasound codes, which don't involve any ionizing radiation, the Medicare database has 87 million procedures performed in 1991. That's diagnostic radiology, nuclear medicine and radiation therapy.

All oncology procedures, the entire 7700 series in CPT, is 6.3 million. All nuclear medicine procedures plus brachytherapy is 3.9 million. An estimate could be made that of the remaining oncology procedures, which are teletherapy, about 20 percent of those are cobalt, as Dan alluded to earlier, and 80 percent are done with linear accelerators.

So that you end up with, of all radiology procedures, about 6 percent under NRC regulatory authority, or at least the authority given by the Atomic Energy Act. And that's an overestimate, because for nuclear medicine I'm including, because I had no clean way of excluding it, non-byproduct

material.

Now if you say one-third of the licensees are in the NRC, you are down to two percent. You indirectly have some control over the other four percent by way of your negotiated agreements.

So I am led back to my E.E. Cummings quote, and I'm saying there is nothing more dangerous intrinsically about byproduct material.

Admittedly, the procedures that NRC regulates, particularly the teletherapy and the brachytherapy, have potential to do more harm than most diagnostic procedures, but not all. There is substantial concern in the medical community about cardiac catheterizations, for example, that run into fluoroscopy doses that approach 50 to 100 rads and may in fact induce deterministic effects as a result of diagnostic procedures.

Consequently, the Committee would say that there really does need to be some look at a need for uniform national standards -- not necessarily regulations; I use standards as a starting place -- relating to all diagnostic and therapeutic uses of ionizing radiation in medicine and this is an important policy issue that the government needs to deal with.

The question that I posed is, what is the appropriate

forum and whether the forum is the existing structure of the Atomic Energy Act or whether the forum is some much broader policy look at radiation use in medicine probably beginning in a Capitol Hill or White House level. That is something I simply lay on the table, because I'm not prepared to answer that question, and I don't think any of us would be.

I'm not going to say this tomorrow, but one thing that troubles me is kind of this idea that, well, we can't worry about the rest of medicine, we don't have any authority over the rest of medicine.

In a sense that is kind of wrapping yourself in the Atomic Energy Act and developing tunnel vision as a result of it. I think Atomic Energy Act tunnel vision is not sensible when we've got big time national priorities that we have to look at for all of medical care. We are about to enter an upheaval in American medicine. The initials HCFA, I am now told, stand for Hillary Can Fix Anything.

[Laughter.]

DR. SIEGEL: Maybe she can fix this one. But big changes are going to occur in American medicine over the next five years. Rather than have ionizing radiation use in medicine, rather than have patient notification in medicine limited to the tiny little focus of the Atomic Energy Act, this

ought to be looked at on a national basis for all of medicine.

That's really what I believe. Sure, Congress could pass a quick law to just give all radiation to NRC, but to do that without thinking about -- not that Congress ever passes any quick laws -- but to do that without looking at the overall programmatic effects on all of medicine would be a mistake. The cost-benefit has to be done with the big picture in mind and not with a small focus in mind.

MR. CAMPER: Let the record show that Dr. Siegel is only an adviser to the agency and not a member of the staff.

[Laughter.]

DR. SIEGEL: As a member of this Committee I've developed a very warm relationship with most of the staff and have now met and developed a relationship with several of the Commissioners. I'm not trying to put you all out of business. You can just move down to Health and Human Services, which is maybe where this ought to be. Maybe where this ought to be.

MR. CAMPER: I was thinking about your comment about the First Lady, actually.

DR. SIEGEL: I heard that on nighttime television somewhere.

[Laughter.]

DR. SIEGEL: There are actually two versions of slide

10, one with the question mark "forum" and one without, but I actually think that the issue of whether the Atomic Energy Act is the forum for debating this issue is an appropriate thing to leave in.

Are you with me, Sally?

MS. MERCHANT: I'm with you. Is that what we are going to do?

DR. SIEGEL: Yes.

MS. BROWN: I'm sorry. I lost you.

DR. SIEGEL: There are two slides ten, one with ?" forum" and one without that bullet, and I want to leave the bullet in, because I want to raise specifically the question of the forum.

MS. BROWN: Sure. Go ahead.

DR. SIEGEL: I wasn't sure what you all would want to do it, so I made two slides. So that slide ten gets thrown away when we Xerox.

At this point in the program I was planning on turning things over to Dan, who wanted to make some specific statements relating to the regulation of brachytherapy based on his extensive experience as a consultant to the IIT that investigated the Indiana, Pennsylvania, event. And if these slides don't work for you, we'll change them tonight.

DR. FLYNN: No, they work.

I think the NRC Bulletin No. 92-03, which was released on December 8 and was put together very quickly and done very well, had three requested actions of Omnitron 2000 users to solve this problem, at least for Omnitron 2000.

One was to make it very clear to the licensees, although they should have known it already, that there should be a radiation survey of the patient with the appropriate instrument to confirm that all sources have been removed.

This isn't new. This was a recommendation that is in the American College of Radiology quality assurance program given to everyone that uses radiation in 1991. Of course that's a voluntary standard.

And that this survey should be done immediately before removal of the patient from the shielded room and appropriately documented with initials and a signature. Something that would only take a few moments in time.

Secondly, that the licensee should not conduct any procedure from which a decoupled source could not be removed expeditiously from the patient and placed in a shielded condition; that written emergency procedures are in place and assure the appropriate staff and equipment are available immediately at the site of the HDR procedure to implement these

emergency procedures.

All this is common sense and it does not require a great deal of effort.

Section 3 involved the training, which can be a little bit tougher issue to address.

Certainly the first two steps, surveying the patient and having the appropriate staff and the appropriate equipment to emergently remove a source, such as was done in the second incident with Omnitron 2000, is absolutely mandatory.

I know that was my opinion and the NRC agreed. They put together this bulletin which I helped with. But I also talked to the people in my professional societies. There was unanimous agreement. There was no doubt or hesitation that this should be done.

Making a survey of a patient after an HDR procedure, if that source is in place -- you do not have to do a five-minute toe to head survey. You only have to turn on the instrument and it goes off scale. That only requires one second or two seconds of your time.

DR. SIEGEL: I thought Carl's comment in the IIT briefing about using a micro-roentgen meter to detect the source in the dumpster was pretty good when you said that they could detect it from 100 meters away.

DR. GRIEM: I would like to make one comment. This was done in a Midwestern state and unfortunately the detector was faulty. It involved a radium source and so the patient went home with the radium source in and two weeks later finally it was discovered.

DR. SIEGEL: You're saying the survey meter was faulty?

DR. GRIEM: Yes. In other words, the battery was down or something.

DR. SIEGEL: But then the fault had to have developed from the time the survey meter was checked prior to its implementation on a particular day of use and its actual use on that day.

DR. GRIEM: The point is I think you need two devices. In the case of the London accident on a linear accelerator they had one power supply for two detectors and the power supply went bad and about eight patients were burned.

DR. SIEGEL: Do you require two devices?

MR. GLENN: No. We do require a daily operational check.

MR. COLLINS: A dedicated check source to check it with a radiation source to make sure it functions properly before you actually use it to do the survey.

DR. SIEGEL: That's what I just said. If you check the survey meter in the morning and then you are releasing the patient at three o'clock in the afternoon and it died between the morning and three o'clock in the afternoon --

MR. PAPERIELLO: I guess it's theoretically conceivable, but it's pretty unlikely. When you turn it on you do a battery check. That's going to certainly tell you whether or not something drastic happened to the electronics. Most survey meters will show background radiation. You know what the background radiation is. If you don't get it, you say there's got to be something wrong with this meter. This thing is really a go-no go. It's not a little bit of radiation.

MR. ALMOND: But you really have a backup in your room monitor.

DR. SIEGEL: Yes, but they don't require room monitors.

MR. GLENN: Yes, we do. The licensing guide does talk about the room monitor. There was some confusion as to whether that was in place of the hand-held survey meter. We have a legal interpretation that the regulation does in fact require the personal survey with the survey meter.

Let me raise another issue. The question has come up whether the room monitor is the right way or should we require

something like alarming rate dosimeters to be worn by personnel. You might want to at some point give us some suggestions along that line. We will probably come back to you in the spring meeting with more specific proposals of the staff.

DR. SIEGEL: Where is the room monitor requirement in Part 35?

MR. GLENN: It's not. It's a part of a licensing guide.

DR. SIEGEL: Part of what I meant with my first bullet in the slide I prepared for you was in addition to you making a specific point also right now subpart (g) really deals mostly with brachytherapy before HDR was really conceived and that subpart (g) needs to be reworked, or subpart (g)(1) needs to be developed that specifically addresses HDR. I know you agree with that because we have talked about that.

DR. FLYNN: Yes.

DR. SIEGEL: I'm proposing that we as an Advisory Committee would in fact recommend that, that it not get lost in a regulatory guide, because it's pretty important.

DR. FLYNN: Right. The point I was making is that I've asked the officers of the Society of Brachytherapists and I've talked to the President of Astro and I've talked to the

people in the ACR; I talked to the chairman of the Education and Training for HDR. It's just unanimous opinion that there is no problem in translating this Omnitron 2000 bulletin to all HDR.

I think the only mistake that I made in giving the NRC advice in trying to look at loopholes was whether the term "appropriate staff" should be replaced by the medical radiation physicist and the radiation oncology physician.

I think it should be, because I think some people are going to try to do the loophole, saying that some 19-year-old technician is the "appropriate staff" and I'm going to be in my car driving, a half hour away.

DR. SIEGEL: That's why I put the second bullet on the slide for you.

DR. FLYNN: The medical community in radiation oncology is very embarrassed about this accident. They felt it should not have happened; it's not representative of the community; and that people who are doing this treatment need to recognize their obligation to take specific steps.

With HDR you don't have time to react if you are a half hour away. This is like someone doing brain surgery who then decides during a critical part of the operation that it's okay to leave to go somewhere else and let the intern do the

next five steps of the brain surgery. I think he cannot delegate that responsibility to somebody else. I think it's important that he has to be physically present there.

Let's say in another patient like this in some other accident like Indiana. If the catheters are sewed to the patient, sewed to their skin, sewed to their brain, the technician is not trained to surgically remove with suture removal kits the catheters if the source has broken off inside the catheter. So the physician has to be there and we shouldn't allow that to be bypassed.

DR. GRIEM: If this is being introduced into the brain, should there be some sort of neurosurgical backup?

DR. FLYNN: I hope that the radiation oncologist would be able to just cut the sutures and pull the catheters out if he had to. I would have no trouble pulling the catheters our.

DR. SIEGEL: Peter.

MR. ALMOND: I just wanted to comment on the general thing. My state, which is an agreement state, has already required that we submit to them quality assurance procedures that include all of this, including room monitoring, including surveying the patient, and including a whole list of procedures that they wanted to see. They were on this very, very quickly.

DR. FLYNN: As a matter of fact, when Dick Cunningham and John Glenn called me before I even left Boston to go to Indiana we had made sure that we had a log book. We all of a sudden had a log book within one hour, voluntarily doing all these things to make sure the medical physicist did not let the technician use the survey instrument. The physicist wanted to do it every single time. Although the room monitor is checked every day and it's not ignored, they felt it important.

DR. SIEGEL: Do you want to continue with the slide?

DR. FLYNN: I'm not sure about the adequacy of RSO training, adequacy of medical physicist training, adequacy of ancillary personnel training. That's going to be a major issue.

DR. SIEGEL: If you will recall our discussion at the last meeting under medical issues, I think there was consensus on the Committee that not just anybody can be an RSO on any type of license and that I shouldn't be an RSO on your brachytherapy license and you probably shouldn't be an RSO on my nuclear medicine license.

You don't necessarily have the training needed to supervise me and vice versa, but a health physicist with the right kind of experience could be an RSO for both of our licenses. Particularly in the setting of brachytherapy and HDR

brachytherapy it's important that the RSO have the right kind of background. Medical physicists right now are not currently licensed.

MR. ALMOND: Except in the State of Texas.

DR. SIEGEL: Except in the State of Texas, and they can be certified by the American Board of Radiology and the nuclear medicine folks by the American Board of Science in Nuclear Medicine. But here is a very important person in the therapy team, also a professional, and much akin to the way you are thinking potentially about the licensing of authorized radiopharmacists, considering authorized physicists might be a parallel professional licensing activity.

DR. FLYNN: I think too much reliance is placed on the RSO. Let's say in terms of the Indiana, Pennsylvania, accident. I think the key thing is that people who are on site in the trenches, the radiation oncologist, the medical radiation physicist, and the radiological technologist -- the RSO has to make sure that the program is in place and the program is being implemented and followed, but he's not going to be the one on site to do the checks and to actually remove the source if it breaks off. It has to be the radiation oncologist together with the medical radiation physicist. The RSO has to make sure that that program is in place and that

they are doing what they should be doing.

I think the key person in HDR is going to be the physician and the physicist. Usually it's three. In our institution it's the physicist, the physician and the technologist, three people. It could be other people watching, the resident and somebody else, but there are three people minimum at the console during the treatment.

MR. ALMOND: I have to disagree a little bit with what you said about the RSO, especially if it's a large institution. One person is RSO. He should work, in our case, through the isotope committee where the various users sit and make sure that the program is working. I got the impression what you said that you need an RSO in nuclear medicine and an RSO in brachytherapy. Did I misunderstand you?

DR. SIEGEL: Maybe so. I am trying to recall the focus of the discussion at the last meeting. It really came up in the issue of relatively small licensees and what kind of person could be the RSO in a very small entity licensee. In a broad license institution an RSO is a person who directs a staff of assistant RSOs and it's a full-time job, and needs to be. It usually will end up being a health physicist who won't be either a radiation oncologist or a nuclear medicine physician but needs to be a little bit of a policeman, needs to

be a good health physicist, needs to know how to write letters and manage a team and correspond with the NRC and correspond with the EPA and the local and state authorities. It requires a set of management skills that the average physician probably would have trouble fulfilling in a big institution.

On the other hand, in a nuclear medicine office practice the nuclear medicine solo practitioner can be his own RSO essentially, and in fact is, because a radiation safety committee isn't required under those circumstances.

DR. FLYNN: The RSO needs to know what has to be done, without any question. He has to know all the details of the HDR regulations, whatever they might be. For example, in the second Pennsylvania accident it was the physicist who removed the source from a catheter that was taped to the skin. What happens if that was a patient where it was an interstitial implant and the catheters were sutured to the skin? The physicist wouldn't be feeling comfortable about doing something invasive surgically.

DR. SIEGEL: Absolutely.

DR. FLYNN: I don't know. Was the physician there?

MR. PAPERIELLO: The physician was present at the console.

DR. FLYNN: All right.

DR. GRIEM: Suppose it broke off in the esophagus?

MR. PAPERIELLO: The catheter could have been immediately removed.

DR. FLYNN: It's inside the catheter.

MR. PAPERIELLO: This was an endobronchial treatment. In other words, it's a closed catheter. It couldn't have fallen out in the lung. As soon as the patient was moved out of the room and surveyed the second time, the catheter was immediately removed. But it still would have been a sizeable exposure.

DR. GRIEM: I have a second question. Suppose this high dose rate after-loader device is in a truck and it drives around to 20 different hospitals. Should there be 20 licenses? Should there be one RSO in the truck? How do you handle the truck?

DR. SIEGEL: Are you asking me?

DR. GRIEM: No.

MR. GLENN: You are recommending that the physicist and the doctor be physically present, right?

DR. GRIEM: In the truck.

MR. PAPERIELLO: Does anybody know whether this is practical? I know this licensee that was involved at Indiana tried it and discontinued it quickly. When you think about the

need to install the device in a shielded room and there is a computer on one side of the wall and this thing on the other side of the wall, is it practical?

DR. GRIEM: I sent the announcement which came in a nice glossy package to NRC.

MR. GLENN: There is a manufacturer who is in fact designing such a truck.

MR. ALMOND: But does the device stay in the truck?

MR. GLENN: Actually, there are two different manufacturers and there are two different modalities. One, the truck would be the shield and it would stay in the truck.

MR. ALMOND: I would empty the parking lot.

MR. CAMPER: We've had manufacturers come in to meet with the staff to discuss this concept of mobile HDR. We know that as we look at Part 35 and adjust it to deal with HDR in general we're going to have to take a long hard look at what we are going to do about the mobile, because it is in fact coming.

DR. FLYNN: Doesn't the Department of Transportation regulate the transporting of source and the device that that source is in?

MR. PAPERIELLO: But they would only worry about if the device was involved in an accident.

DR. FLYNN: Suppose the truck crashed?

MR. PAPERIELLO: That happens all the time. Radioactive material is moved in interstate commerce and there are rules for that along with all other hazardous materials.

The issue in my mind is not whether you can move the source safely. You certainly can do that. That's the easiest part. The question is the quality assurance in a mobile situation of assuring the patient gets the right dose and all the health physics and the medical physics and things like that that are done and not the issue of safely transporting it, because the sources are shipped to the machines when they are changed out.

MR. GLENN: The other point is that in fact industrial radiography is using radium sources of 100 curies plus routinely, and that can be dealt with. The use of the machine is a different thing.

DR. SIEGEL: Can I propose a strategy, that we delete bullets three through five from this slide and not really address the training as an issue that we've adequately debated?

I think there is a sense that we all think that especially for high dose rate brachytherapy that training is a very important issue and that making sure the radiation safety officer is fully up to speed on HDR is important, making sure

that the medical physicist has been trained is important, and that the technologist and nurses, when we get into the low dose rate situation -- I know you've made that point before -- are important, but I think my sense is that these are things that we should probably talk out at some length before we just casually drop something on the Commission and then find the staff requirements memorandum appearing a week later saying develop rules for medical physicist licensure. I would like to debate them in full at a subsequent Advisory Committee meeting.

DR. FLYNN: I agree with you.

MS. BROWN: Does that preclude bulleting them here? This is our one opportunity to bring them to their attention.

DR. SIEGEL: No, it's not.

MS. BROWN: We talked about that last time.

DR. SIEGEL: We've kind of got a built-in annual opportunity to talk to the Commission, at least in theory.

MS. BROWN: There seemed to be some urgency last time when Dan was talking about it, like the sources that fell out and the nurses.

DR. SIEGEL: I don't want to kill the slide. We could even make this read "adequacy of training" and then just have one bullet at the end and let Dan say a few words about where he considers the gaps are.

By identifying specific people on the team right now the implication is that we are in five minutes endorsing that the NRC ought to be licensing all these people. We have on previous discussions said that we didn't think it was appropriate or necessary and we are willing to re-explore it, but let's not do it in five minutes is what I'm proposing.

Dick, you had a comment?

MR. CUNNINGHAM: Yes. I think this was addressed in much broader terms in the medical management plan that we are developing, and that is both adequacy of training and responsibilities. For example, there was a question whether the authorized user physician should be responsible for everything that happens in the nuclear medicine or radiation oncology facility. Should that responsibility be more explicitly defined with responsibilities for an RSO, a medical physicist, and what have you, and coupled with their training?

This incident, the IIT evaluation gives us more detailed knowledge of a particular procedure, namely, brachytherapy. But I think this is a more broad question that needs to be looked at. I think if you take three, four and five bullets out and just note that this is part of a broader issue that is going to be addressed by the staff and by the Advisory Committee, it might be sufficient.

DR. FLYNN: Oncology radiology has a group working on physics right now in terms of what is necessary for the physicist in HDR. They had also credentials for physicians. They are debating as to what the credentials should be for a physician who performs HDR. Should he have a fellowship training? Should he have specialized training? Is the low dose rate brachytherapy training he had adequate enough? So some of these issues are being debated by the professional societies in terms of training.

In terms of the practitioners who are out there, who are actually doing it, who have a license to do it, I think certainly guidance should be provided by someone. I think it has to be the NRC in terms of mandatory guidance and not just the ACR.

I think maybe the right way to do that is in Reg Guide 10.8. The weaker practitioners who meet the standards to keep doing this but who may be in a gray area where their training may not be as extensive as others, they may need some more firm guidance as to what they should be doing. What should the physicist be capable of doing? What should the RSO be doing? What should the nursing staff be doing for brachytherapy in terms of more firm guidance than some of the practitioners have at present?

I think Reg Guide 10.8 could help them, because those will cause, I think, weaker practices in terms of quality assurance to become stronger.

When I've talked to RSOs, I've said the nurses are afraid to go in the room. Why don't you tell them about time distance shielding? The answer I got from one RSO is, well, it's not in 10.8 and I don't have to.

They are going by 10.8 as if it's carved in stone, and that's all they have to know, what the sources look like and get people out of the room who shouldn't be there and keep people in the room who should be there, the patient, and go through a few steps and think that 10.8 is all that is necessary, and because these weaker practices are using 10.8 in such a serious fashion, then we had better make 10.8 stronger.

DR. SIEGEL: Judy.

MS. BROWN: I'm not sure this fits in here with this slide, but I was concerned about how many times problems with RSOs came up during the material that we viewed on the videos, the Oncology Services Corporation where the guy didn't even show up at one of the facilities for six or seven months, where they are being bypassed by the different departments with territoriality. Can we, should we, whatever, somehow address the problem that seems to be pretty real out there, that RSOs

aren't able or responsible for what they are supposed to be doing?

MR. CAMPER: The staff is in the early stages of developing a NUREG on the duties and responsibilities of radiation safety offices and how to properly conduct the various types of audits. At some point in that process we would bring that to the Committee for your input and thoughts on it.

MS. BROWN: I remember someone made a comment to one of the Commissioners who had stated that it's not going to be fast enough, and I wonder if there is that same sense of urgency here. I certainly felt it. If we are talking about a number of years, whether we as a committee could help the effort along instead of the staff asking us when its time comes whether we make an issue of it and push it.

MR. PAPERIELLO: It goes beyond nuclear medicine. I feel more akin to a radiation safety officer in terms of job function than any of the other people that are involved in the thing, because it's similar to what I do and have done over a number of years. Somebody mentioned both management ability, bit of a policeman and will. It's easy to write down technical qualifications for an RSO. A medical physicist in most cases may be technically very well qualified to be an RSO but not

qualified by inclination of will and management ability.

In the case of Oncology Services, the RSO was a certified health physicist and in addition was certified by the American Board of Radiology and the American Board of Physicists in Medicine. He was an excellent medical physicist. I don't think, and I give a very personal opinion here, that by will he wanted to be RSO, which means playing cop to a certain extent when you have all these satellite facilities. His interest was medical physics, which is a different discipline in terms of a goal than a radiation safety officer.

So there is more to it than just written academic qualifications. It deals with personality and will. I come from Chicago, so we use the word "clout," which is a factor. We have had a number of problems over the years in universities where the radiation safety officer didn't have clout. Where he was put in the organization he could be very easily thwarted by those above him. It's a complicated issue.

DR. SIEGEL: But is it your sense, Carl, that it is a pervasive problem or it's a problem in occasional licensees?

MR. PAPERIELLO: It's occasional. It's not a pervasive problem. And it's not just the RSO; it's the institution. Sometimes they don't give the RSO the authority, so they don't want the RSO to do his job. Not in reality.

They will usually be a cop. They don't want him to be a cop. Or they just overload the person.

In other words, the RSO responsibilities are an ancillary duty to a dozen other things the person has to do. A manager of a branch office of a company that has a lot of satellite facilities, not necessarily nuclear medicine, being also the RSO may have economic goals that compete with his RSO responsibilities and a lot of other things. I've seen that happen. Not just in nuclear medicine. That is a problem.

DR. SIEGEL: He's doing it too. You keep saying nuclear medicine.

MR. PAPERIELLO: I'm sorry.

DR. SIEGEL: I'm going to cure you of it, though.

MS. BROWN: Can you tell me, Larry, what is the time table for this NUREG?

MR. CAMPER: To complete the entire process would probably take us 12 to 24 months.

MS. BROWN: Does that include comment periods and everything else, or just drafting it up?

MR. CAMPER: It wouldn't go through a comment period per se. We have developed a task force that consists of regional personnel and headquarters personnel. The task force will meet late next month. We've also developed a charter that

we are going to use if we need to to get additional outside contractual support from perhaps something like the Health Physics Society or the American Association of Physicists in Medicine. So it's a little bit different process than the rule-making process.

As this whole thing unfolds, if we find that there are RSO problems that we can specifically identify, be they with HDR or be they with something else, we have mechanisms available to us to get information out or to demand things of licensees if need be in a prompt fashion.

The reason we are doing the NUREG is the very thing that Dr. Paperiello is pointing out. Effective radiation safety management in the medical institutions is a complex problem. It is multifaceted, as Dr. Siegel has pointed out. I believe that a lot of institutions and institutional management really doesn't fully understand what we expect of RSOs.

The reason to put it into a NUREG is so that you have a comprehensive document. We might, for example, talk about what are some of the person power implications of radiation safety staffs and different sizes of institutions, and who are the best kinds of players to assist the RSO in their job; this idea of the RSO having autonomy to carry out their responsibilities and making it clear to institutional

management that you must do this.

It's a very complex thing and it will take some time. But we will react if need be to specific issues.

MS. BROWN: I still think some kind of Band-Aid could be applied in the interim before you overhaul the procedure, because it seemed like a real problem, especially what they were saying about within hospitals and universities with competing departments. Disconnecting the RSO is one of the terms used.

DR. SIEGEL: You are basing that on 20 years worth of Plain Dealer reporting.

MS. BROWN: No, not the Plain Dealer at all. I'm basing this on the Commissioners talking to the agreement states and the staff report and the fact that you scratched into the surface of this one situation which the IIT looked at and you find out that the person hadn't been there for six or seven months at one of the satellite facilities. I'm basing it on that.

DR. SIEGEL: My sense, based on discussions that we've had previously, is that that is not a major problem; that is an occasional problem.

MS. BROWN: But you all come from great institutions.

DR. SIEGEL: It's not a problem at all at my

institution. I've got an RSO who is a policeman and he does a great job, and he's also a good manager.

MS. BROWN: And you give him respect.

DR. SIEGEL: I'm saying the word "occasional" means it's an occasional licensee who has that problem.

MR. ALMOND: It's clearly spelled out in Part 35 what the RSO's responsibility is, the organizational structure, what the radiation safety program should be. It's very clearly spelled out here. It is a complex problem and it's really the implementation of this which sometimes runs afoul because it can get complex and it may get complex without you realizing it, especially if you've got an expanding program. You do have a mechanism for dealing with it.

MR. COLLINS: And it was not complied with in the case where all these troubles occurred.

DR. GRIEM: Could Region I have spotted this coming down the road like a train and saying, gee, I smell trouble, there are 15 units out there, or whatever it is, and we had better go and check up on them?

MR. PAPERIELLO: What happened was this. They did the initial inspection after one facility where the RSO resided and had his office got a unit. The staff there was knowledgeable.

There was a possible clue in that they did not pursue whether or not there was a written training program. But the people were knowledgeable. We emphasize performance-based inspections and the staff could perform. When they questioned the six individuals who were involved in use of the device, from the medical physicist to the user to the technicians, they were knowledgeable. They knew it.

DR. FLYNN: But that was at one facility.

MR. PAPERIELLO: One facility.

Two months later the license was amended to add six more facilities. Actually they added more but some of them were in agreement states. They went out and bought nine or ten Omnitron units and put them in all their facilities. That's where the problem began.

Absent a strong formal system, there was no assurance that at each of these various other facilities --they are not really satellites; they are just separate facilities -- the training and the knowledge base was the same as in the home office. They were still developing procedures at the time of the IIT. This is a year after they got the machines.

From my viewpoint as an NRC regulator it should have been a flag to us. And it's not just in the medical area. It can be in radiography. I've seen the problem years ago in

nuclear pharmacies. When a business like this mushrooms the control problem is different. Where we should have intervened as an agency is when that amendment was so significant it should have been, in terms of the inspection program, looked on as a new license, and it wasn't.

DR. GRIEM: You wouldn't do that with nuclear reactors, would you?

MR. PAPERIELLO: We live at a nuclear reactor. It's a different issue.

We talked earlier about the denominator. I don't consider the RSO problem to be pervasive when you consider the denominator, but when it occurs it is a common mode problem, what I call a common mode problem. Now all kinds of things can happen because a major protection that you have you've lost. Particularly in a big institution where the RSO isn't functioning, you can have a problem where somebody labels; you can have a problem in radiation medicine; you can have a problem in the biology department, in the physics department. You have a lot of opportunities for bad things to happen by just one person not performing their function, and couple it with a radiation safety committee that doesn't do their audit function.

DR. FLYNN: I think in this accident it doesn't take

another regulation for an RSO to realize internally within himself that he had better do site visits, he had better make sure that people are trained, and hopefully he has the capacity to supply the NRC with accurate calculations as to dose.

I believe it's pretty clear that that has not happened, including a month or two later and still unable to provide accurate doses.

I am very concerned about either the competence or the honesty of the data that is being reported by the licensee. I think to blame it all on the fact that we don't have enough regulations is not addressing the point in this particular accident.

I think to have a coroner with no radiation training whatsoever to go out on his own and obtain a medical physicist and come up with much more accurate numbers in a matter of a couple days than this big corporation can come up within a couple of months is quite amazing.

DR. SIEGEL: Would it be safe to say, Dan, that what you could address tomorrow is the Indiana, Pennsylvania, event and as part of the reason for your speaking briefly would be to say that questions are raised with respect to training of RSO, medical physicists, ancillary personnel, and that we recognize as a Committee that this is being looked at as part of the

medical issues paper and will want to participate in helping to guide the NRC in that process?

We're not going to resolve this now. These are pretty complex issues that we have talked at length about before and probably will talk at length about again.

And, Judy, it's not a coverup. It's not a desire to sabotage it.

MS. BROWN: I didn't infer that.

DR. SIEGEL: I know you didn't, but there is a limit to how much we can logically accomplish today and also logically accomplish in what is a limited period of time briefing tomorrow.

MR. CAMPER: Just a footnote to that. At the upcoming ACMUI meeting in May the agenda will be heavily laden with brachytherapy and radiation therapy issues. So we will be exploring this in a lot more detail.

DR. SIEGEL: Which leads Dan to his next slide.

What I am trying to do by way of your last two slides is give you an opportunity to make on the record before the Commission some of the recommendations you've already made as part of your medical consultant's report.

DR. FLYNN: I'll do that.

DR. SIEGEL: Your recommendations are on the record

already. They are in the public document room or will be eventually, but this gives you a chance to do it before the Commission, to get some interplay and some questioning directly from them. So do your thing.

DR. FLYNN: I think the medical consultant should be a member of the IIT for serious misadministrations. The appropriate medical consultant chosen, that is, for nuclear medicine area problems, a nuclear medicine physician.

DR. SIEGEL: He means nuclear medicine.

DR. FLYNN: This time I mean nuclear medicine.

A nuclear pharmacist for nuclear pharmacy problems; a radiation oncologist for radiation oncology problems. Not only for the IIT, but for any of the misadministrations, I think to make a judgment as to the probability of injury is not necessarily an easy judgment to make. I think for that reason it would be helpful to have the appropriate medical consultant who is well matched to whatever the problem is.

MR. CAMPER: Did I hear you say for all misadministrations?

DR. FLYNN: For all misadministrations. A medical consultant does not have to fly on site. He may only have to spend one or two hours reviewing a document.

DR. SIEGEL: I think that's what we are recommending.

DR. FLYNN: Right.

DR. SIEGEL: We are really saying that if you get a misadministration report, you ought to fax it to the appropriate medical consultant. He or she may need to go somewhere and get help looking into the problem, but most of the time it will be, yes, I agree that they said the right things in that report.

DR. FLYNN: Right. In the future, depending on the number of misadministrations, if necessary, if the economy comes into play, one could use the medical visiting fellow program as a filter. In that respect, I think that the medical visiting fellow program should be balanced in terms that there is a radiation oncologist as part of that program in addition to a nuclear medicine physician.

On ACMUI membership my point with this is that it should be balanced in terms of realizing that we all come from different backgrounds. I think there should be equal representation from nuclear medicine-related areas, which includes nuclear pharmacy and cardiology, and radiation oncology-related areas, which includes brachytherapy and teletherapy and medical radiation physics.

Because some of these issues are really complex, I think it requires more than one or two opinions to address

them. That's why I'm constantly making phone calls to subcommittees in our medical societies to get additional advice and guidance. I think since the therapy issues are obviously of equal importance as the nuclear medicine issues that the membership should be balanced right down the middle.

MS. BROWN: How big do you envision the committee given that we are getting X number of new members? How many new members?

MR. GLENN: Three.

MS. BROWN: How big do you think we would have to be to balance it?

DR. FLYNN: I think that if the Committee becomes too big it would be hard to manage. There are some individuals on the Committee who I would classify as neutral. In other words, not being either radiation oncology or nuclear medicine. The FDA representative, the member representing the public, the states representative as being so-called neutral, but as far as the rest of us, there is a tilt right now of either two or three more in nuclear medicine-related areas versus radiation oncology areas.

DR. SIEGEL: I think I may have said this at a meeting previously or in discussions with staff. As the Committee has evolved under its new role of meeting more

frequently, having a civilian chairman rather than an NRC staff chairman, and we've had an opportunity to talk to the Commission, we have evolved into trying to tackle issues of policy rather than just tackling issues of technical advice. If you will remember, discussion about whether the Committee should be expanded at all were met with some concern because how can we have consumer representatives if you want us to give medical advice? That will just dilute the value of our advice.

In truth, there may be some correctness to that point if we are giving technical advice only, but clearly not if we are giving policy advice.

Even though this violates Clintonomics and the new approach to reduction of advisory committees, I wonder if we would want to consider having technical advice working groups that would strictly deal with working out the nuts and bolts of technical issues. Subcommittees, if you will, for brachytherapy, radiation oncology issues. That might include consultants who are not members of the Committee. Another subcommittee that would deal specifically with nuclear medicine-related technical issues, and then bring that back to the whole Advisory Committee, let the members who are on the subcommittee carry it to the whole Advisory Committee, and sort

of not use all 15 people to work through technical details, but rather use all 15 people to look at technical details from a policy point of view.

That's just a thought I throw out on the table for Bob and Dick's digestion, for something you ought to think about.

As we get bigger and bigger it's going to be harder and harder to reach intelligent conclusions about technical issues. When we talk about what a nuclear pharmacist is supposed to do it probably is very boring to you, and when we get into the nuts and bolts of HDR brachytherapy, I'm going to listen politely, but it's going to be hard for me to express an expert opinion. I can have an opinion as an expert in radiation medicine but not as an expert in HDR. Judy, no offense. You can't have an expert opinion at all.

MS. BROWN: We'd all be in real trouble.

DR. SIEGEL: But you can certainly have an important policy perspective, and that's why you are on the Committee.

We may want to think about how the Committee operates within the limits of your budget and how you want us to be effective for you.

Bob.

MR. BERNERO: I would just say on the current

Clintonomics that we have no inclination at this time to reduce this Committee.

MR. ALMOND: A couple of comments. Perhaps you've already done this. There are within the professional and scientific organizations a lot of the technical stuff being worked on, and that is a resource this Committee has made use of in the past and should make use of again.

With regard to bullet No. 1, I have nothing against that, but I would like to see it say medical consultants and other professionals where appropriate. I've been on the physics ones and it's very clear that you at times need someone on hand who can delve into the intricacies of computer programs or whatever that is going on.

MR. PAPERIELLO: The IIT procedure does allow for doing that. In fact, when you deal with nuclear power plants we can bring in people from the vendors, GE, Westinghouse, and from utilities and things like that. So there is no hesitation to do that.

MR. ALMOND: I understand that. This is sort of a statement from the Committee and I would like to see that just a little broader than it is here.

MR. PAPERIELLO: I would make an observation, and I'm talking about my region. We generally use medical consultants

for serious misadministrations. I want to say all of them, at least therapeutic misadministrations, and we use medical consultants for serious exposures. Not just medical exposures, but rather occupational worker exposures.

DR. FLYNN: Having a physician on site at the time of an accident, somehow there is a transfer of information that occurs at that point in time from a physician to a physician. I'm not saying why that should be as opposed from a physician to a health physicist.

We are so used to in medicine transferring medical records back and forth. It's just a common habit that the radiation oncologist will turn over the entire records to me before any of them become lost or misplaced. I can go to a nursing home and all of a sudden the entire medical records are turned over to me. They would not be turned over to a physicist, whether it's a nuclear medicine IIT or whatever. There is something that occurs when a physician is on site in terms of being able to gather the information that would become difficult if the physician wasn't there. The communication occurs from a physician to a physician and you can somehow get information that you wouldn't otherwise get very easily. At least that's what my experience was in Pennsylvania before you arrived.

DR. SIEGEL: Judy, did you have comment?.

MS. BROWN: Not on this slide. Are we done with this slide?

DR. SIEGEL: I have a question. What's the difference between an IIT and an AIT?

MR. PAPERIELLO: IIT is the highest level team. It's headed usually by somebody like myself, somebody in the Senior Executive Service. This was an unusual one. We used people from the region. Usually you don't use people from the region, and your charter goes beyond just what the licensee did wrong. You also take a look at the whole waterfront.

DR. SIEGEL: Internal affairs, as it were.

MR. PAPERIELLO: Yes, in a sense.

I had to look at how the region in fact licensed and inspected this facility as well as looking at the way the NRC regulates HDR and that sort of thing. So the charter is broader than an AIT.

MR. BERNERO: Barry, I would like to clarify that even further. A regular inspection and an augmented inspection team are relatively similar. They differ only in level of effort and focus. The responsibility for investigation or analysis rests still with the line organizations who are put in place to do that work.

In the IIT the responsibility for inquiry is taken away from the line organizations and put in a specially formed organization with senior management and under the direct control of the Executive Director. It's separated from me or from Tom Murley, whoever is regulating that arena. That is quite significant in order to have true independence.

DR. SIEGEL: Judy.

MS. BROWN: I have two concerns that I don't think we have addressed and wondered if we should. One would be in response to the Cleveland Plain Dealer article, and that's about bad doctors moving to another state, which concerns me greatly. I might go to someone and not know that he has messed up.

DR. SIEGEL: It wasn't on our specific list of questions.

MS. BROWN: The general heading "Response to Plain Dealer Article," I thought that was a pretty big part of the Plain Dealer series that this can happen.

MR. CAMPER: That is an interesting point, Judy. I was struck by the fact that they said a physician can cause a misadministration or be involved in a misadministration and move on. It's unusual for the physician to cause the misadministration. There are certain cases where a physician

will in fact be the one that actually performs the misadministration, but more times than not it's someone working under the supervision of the authorized physician user.

You may argue in some cases the authorized physician user wasn't actively involved to the degree that they should have been, and I think that does hold up in cases of iodine radiation therapy.

MS. BROWN: Is there any kind of registry, some kind of Better Business Bureau kind of thing I could check?

DR. FLYNN: Yes, there is. The way it is working now in Massachusetts and many other states -- and Mel can speak to this -- is that if Mel comes to Massachusetts to practice radiation oncology, he puts in an application for licensure in Massachusetts. Massachusetts asks him what other states has he ever been practicing in. Massachusetts contacts every one of those states, the boards of medicine, and they will now get a history of, let's say, malpractice cases or various things, like was he ever an impaired physician, on drugs, or whatever. That happens now.

MS. BROWN: That's great, except I don't live in Massachusetts.

DR. FLYNN: It's not just Massachusetts.

MS. BROWN: What is it? How far?

DR. FLYNN: Credentialling is a big issue in medicine now.

MR. COLLINS: It's outside the purview of the NRC or any of the state radiation regulatory agencies. There is no black list maintained by radiation regulatory agencies with regard to their practice. It's totally medical boards that track who does what kind of practice.

MS. BROWN: So it's up to the individual states.

DR. SIEGEL: As part of the hospital credentialling process you are required to indicate whether you have ever been convicted of a felony, indicted for some sort of malfeasance, license been suspended.

MS. BROWN: How did I misread the article then? It seemed that those questions were not asked.

DR. FLYNN: This is today, not back then.

DR. SIEGEL: Things have changed. The physician credentialling process has gotten much more stringent.

The Plain Dealer folks are gone for me to holler at them specifically. Their approach allows for no penance. Their approach suggests that once you did something wrong you are branded and you can't ever pay your duty and get back in the business of recognizing the error of your ways and being a doctor again.

MS. BROWN: I see your point, and that you could do more training or something. As a consumer, I would like to know between Dr. X and Dr. Y who may have been cited before, because I'm going to choose Y. I'd like to know where I could find that information. I don't think it should be impossible for me to get.

DR. SIEGEL: Let's see what level you can find out with respect to malpractice action at the moment in terms of the national database.

MS. BROWN: Or any of the things. You mentioned the criminal or the substance abuse.

DR. SIEGEL: Criminal records you can get, can't you?

MS. BROWN: I guess. I don't know. It seems overwhelming.

DR. SIEGEL: I think that it is reasonable for the NRC and the states to share information about actions but I do think that the system has to have a built-in way for people to have paid their penalty and then go on about their business.

MS. BROWN: You look at it that way and I look at it as just hanging out a shingle in another state, not paying their penalty and going about their business.

DR. SIEGEL: The Plain Dealer quotes the example of Maynard Freeman who was a nuclear medicine physician at the

Heinz VA Hospital in Illinois who willfully covered up several diagnostic misadministrations, which are events that in fact resulted in the typical diagnostic misadministration effect, namely, no harm, but likely for reasons of fear induced by NRC regulations, he chose to cover them up. It would have been far easier just to report them. It would have been a no-action problem. He ended up having a felony conviction. He got his penalty for the felony conviction. Does that mean he should never practice medicine again? Does he have to be a truck driver now?

MS. BROWN: No. It just means that if I had my druthers and he's not the only doctor in town, I don't want to go to him.

DR. SIEGEL: Maybe the Texas radiological health authorities didn't know about it, but I find it hard to believe how the State of Texas licensing authorities when he got his medical license couldn't have known about it, because you are required to say whether you have been convicted of a felony when you apply for a medical license. If he didn't tell the State of Texas, then he committed another felony.

DR. FLYNN: They don't turn down your license for that reason. They ask you to explain it. They most likely grant it if you have paid your dues, whatever that might be.

DR. SIEGEL: Judy, I don't disagree with your concept and I think that sharing information is relevant within all the limits imposed by the Privacy Act and all the other things. I'm a little bit -- not a little bit. I'm a lot objecting to the concept of radiation medicine physicians out there with scarlet M's branded on their forehead that say "misadministrators." I just think we need to strike the balance somewhere.

MS. BROWN: I would agree on a balance.

DR. SIEGEL: Part of my response to reading those things last night was, who finds investigative reporters when they misadminister the news?

MS. BROWN: My last question was something that was raised in the videos and I didn't think the staff response was very clear, at least not to me. They said that one of four of the patients that were involved in a misadministration in Arizona, Good Samaritan Hospital, was not recorded as a misadministration because the patient died. That was in the agreement states video.

MR. BERNERO: I thought it said it wasn't reported to the patient because the patient died. That's my recollection of it.

MS. BROWN: That makes sense. I was pretty clear

that they were saying it wasn't reported as a misadministration and that there was some kind of loophole or something.

MR. BERNERO: It's similar to the Indiana, Pennsylvania, Mrs. Colvin. Of course her family was informed through the whole process.

MS. BROWN: I'll look back on the video tonight. Thanks.

MR. COLLINS: Do you want to strike that name from the record?

MS. BROWN: It's everywhere.

DR. SIEGEL: It's in every newspaper in the United States, unfortunately.

Bob.

MR. BERNERO: I would also like to register a concern about the reporting of misadministration. I thought that was the line of the question. The Trippler Army Hospital case I believe to this day is technically not a misadministration because the patient wasn't the one who suffered the maiming; it was the child. We have problems with the definition of the medical unit or the person.

DR. SIEGEL: If we want to spend the next half hour on it, we can go through my notes here on the Plain Dealer series. There were things that were, as I said earlier, just

bad prescriptions that resulted in injury that were not in fact misadministrations. They made a lot of point about, gee, how come the NRC didn't know about things that the NRC didn't know about, but there was no requirement that you had be told about some of those things.

The article loses sight of the fact that there were a series of signal events each of which led to a signal correction. There has been progressive progress in the development of the program in response to the events.

MS. BROWN: That might be important to say tomorrow.

DR. SIEGEL: It has actually been said repetitively. It was said in the staff policy document and it really is true.

MR. COLLINS: There is no news in what government agencies or big business did right. That doesn't sell. They're not going to print that part.

DR. GRIEM: Aren't there some other models, the thalidomide thing, the DES proposition, and now we have the cocaine babies? There is going to be a lot of this. There is probably some model that will come out of the FDA or some shared responsibilities that will say what you do with the unborn child.

DR. SIEGEL: We have been through that.

Tomorrow. The briefing is at 9:00. Is there a sense

that each of you wants to say something specifically after I and then Dan finish our little bits?

The only reason I singled out Dan was because of the fact that he was on the IIT and had made some recommendations.

DR. FLYNN: My two slides will just take a couple of minutes.

DR. SIEGEL: I am going to try to capture as many of your dissenting points as I can.

MS. BROWN: I think that worked well the last time. I'm happy with that. I don't need to speak directly unless spoken to.

DR. FLYNN: Will the entire presentation be given, which might take 20 minutes, and then questions? Or will it be broken up?

DR. SIEGEL: The presentation will be given until one of the Commissioners in fact asks a question, based on past experience. I'm going to answer the questions as best I can. I think to the extent that it's possible the presentation will tie together better if we can give it and then answer questions, but I have no control over that and I know better.

Did you have a comment, Bob?

MR. BERNERO: I was just going to say that as a practical matter how it will work out. They tend to drive

dialogue during the presentation.

DR. SIEGEL: That's fine. I'll just have to try to remember what it was I wanted to say, which is fine.

Any other comments or concerns?

[No response.]

DR. SIEGEL: Thanks for coming here on a snowy Sunday.

MR. GLENN: I declare the meeting officially closed.

[Whereupon at 5:40 p.m. the meeting was adjourned.]