UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING ON STATUS OF MEDICAL USE ACTIVITIES

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PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Friday, January 22, 1993

The Commission met in open session, pursuant to notice, at 2:00 p.m., Ivan Selin, Chairman, presiding.

COMMISSIONERS PRESENT:

IVAN SELIN, Chairman of the Commission
KENNETH C. ROGERS, Commissioner
FORREST J. REMICK, Commissioner
JAMES R. CURTISS, Commissioner
E. GAIL de PLANQUE, Commissioner

STAFF SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

WILLIAM C. PARLER, General Counsel

JAMES TAYLOR, Executive Director for Operations

HUGH THOMPSON, DEDO

ROBERT BERNERO, NMSS

CARLTON KAMMERER, Director, Office of State Programs

RICHARD CUNNINGHAM, Director, Division of Ind. & Med. Nuclear Safety, NMSS

VANDY MILLER, Assistant Director, State Agreements Program

JAMES LIEBERMAN, Director, Office of Enforcement

JOHN GLENN, Chief, Med., Acad. & Comm. Use Safety Branch

P-R-O-C-E-E-D-I-N-G-S

2:00 p.m.

CHAIRMAN SELIN: Good afternoon, ladies and gentlemen. The Commission is pleased to be here to receive a briefing from the NRC staff concerning the regulation of the medical use of byproduct materials.

In connection with this briefing, the staff has provided the Commission an information paper, quite a long and thorough paper called "Aspects of the National Medical Use Program Related to Prevention of Misadministrations." Copies of this paper are available at this time in the conference room.

Today's briefing will include a discussion of current regulatory practices of the NRC and the agreement states directed to prevent medical misadministrations. The briefing will also address issues raised in this area by the series of articles published in the week of December 13th in the Cleveland Plain Dealer.

It goes without saying that the Commission is intensely interested in this matter and we're greatly concerned that our regulatory program meet both the test of public scrutiny and the need for health and safety protection. As a matter of fact, our concern about the program lead to Commission-initiated review starting last

September which I'm sure Mr. Bernero will discuss at some length this morning.

Given the past events, the recent over exposure and subsequent patient death following a recent administration in Indiana, Pennsylvania and a number of other events, there can be no doubt as to the importance of our role in this area. I'd like to emphasize that our role in this area is not one of deciding medicine of efficacy of doses of diagnosis or prescriptions, it is to review the processes of our licensees to make sure that those medical processes ordered by physicians which involve nuclear byproducts are, in fact, carried out the way they are ordered with due attention paid to the health both of the patients and of the health workers. We have a limited but very important function, charter in this area and we'll concentrate on both the limitations and the depth of our program within this charter.

We must assure that our regulatory program for medical use activities is upgraded, its effectiveness continues to be improved, even as technology evolves and completely new procedures and equipment come into use. It's especially important that we assess our current activities at this time to see what more may need to be done.

I assume, Mr. Taylor, that one of your

topics will be the overall plans at different levels and different time periods for continuing and sharpening this evaluation.

Commissioners, do you care to make any point?

Mr. Taylor?

MR. TAYLOR: Good afternoon.

Mr. Chairman and Commissioners, I'd like to introduce those at the table. Jim Lieberman from the Office of Enforcement, Vandy Miller and Carl Kammerer from the Office of State Programs, my deputy for this area Hugh Thompson, from the Office of NMSS, Bob Bernero, Dick Cunningham and John Glenn. We're all involved in this program and I thought we'd get the widest representation we could specifically for questions.

Mr. Chairman, you noted the extensive paper which is available at the entrance to the meeting room. This paper was a culmination of weeks of effort. But I would like to emphasize that some of the material was put together over a period of just several weeks and particularly with the agreement states and some of the numbers were obtained telephonically and through fax. So, I think these have to be looked at in the view of further verification by the agreement states as this paper gets distributed.

CHAIRMAN SELIN: That's reasonable, but it was very useful even in a preliminary stage to have those numbers available.

MR. TAYLOR: That's right. I would appreciate if the Commission would look at those in a more preliminary sense. It was a great effort particularly to the agreement states, which are 29, and to try to put a sensible paper together.

With that opening thought, we'll go into the detailed portion of the briefing and Bob Bernero can begin.

MR. BERNERO: Thank you, Jim.

Members of the Commission, today we're discussing the medical use program, but particularly related to misadministrations in the practice of medicine.

(Slide) May I have the first slide, please?

We have an outline in the slides that covers two pages. For starters, I hope to cover the key milestones in the current medical use regulatory program because I think they set an important context for the Commission and the members of the audience to understand the purpose of the program and the guiding policy of it. I will also cover our efforts to identify, evaluate and to prevent misadministrations. Then Carl Kammerer will

cover the state programs. Recall that with evolution over the years we now have approximately twice as many medical licensees in the agreement state programs as we have in our own program.

(Slide) Then we will return -- I will return to discuss the misadministration issues raised by the Plain Dealer and then on that second outline slide you can see I will then speak to the reevaluation initiative, some of which you referred to, Mr. Chairman, and the observations for further consideration. Our Commission paper, which is available at the door, ends with observations, not really conclusions but observations of things that are going on, evaluations and there are some very important points to be made in that portion of the briefing.

CHAIRMAN SELIN: Before you go on, Mr. Bernero, I failed to note, I'm sorry, that there are a couple of other public meetings to be held in the next two weeks in this series. Next week we will be receiving a report from the investigation of the incident in Indiana, Pennsylvania and some related investigations and the week after that we'll be briefed by our Advisory Committee on the Medical Use of Radioisotopes. So, we'll have these other two meetings scheduled and eventually we'll have a --

MR. TAYLOR: There's also a meeting with the agreement states.

MR. BERNERO: Yes, a week from today.

MR. TAYLOR: Right. That's the 29th.

MR. BERNERO: The 29th.

CHAIRMAN SELIN: So, this one meeting, although very important in itself, is even more important as one of a number of building blocks in this overall program.

MR. BERNERO: Part of the set, yes.

(Slide) If I could have slide 3, the key milestones, there are three milestones over the last 14 years that I think reflect the NRC's policy and requirements for the identification and reduction of errors resulting in misadministration.

The first of these is the 1979 medical policy statement. That policy statement was quite a lot of work in development and it basically set out three principles, that the NRC would regulate to provide for the radiation safety of workers and the general public as distinct from patients. Secondly, that the NRC would regulate to provide radiation safety of the patient where risk warranted it and where extant practices were inadequate. You know, practices for control of procedures with patients. Lastly, the third principle

was that the NRC would recognize but minimize intrusion. The NRC was consciously trying to avoid excessive intrusion into the practice of medicine. Obviously regulating the field is going to constitute some intrusion nonetheless.

Now, a second milestone actually took a longer time to develop. In 1980, the first misadministration reporting rule. It actually started in the 1970s, in the early 1970s under the AEC and through the transition from AEC to NRC and then through the incidence, particularly the Riverside Hospital incident in 1976, a great deal of attention was put on this and finally by 1980, in concert with the development of the policy statement of 1979, the first misadministration rule was put out. It basically set down a standard for when a misadministration should be reported, whether diagnostic or therapeutic misadministration, and it also included perhaps the most controversial part, was a requirement to notify the attending physician and the patient unless the attending physician made a medical judgment that the patient should not be notified for medical reasons.

The third milestone is the most recent one and it is listed here on this slide as the 1992 quality management program. It actually became effective January

27th, 1992. That rule, which we call the shorthand QM rule, represented the culmination of an extensive debate about how NRC should regulate medical practice and I think it's best to define it in a very simple way. It is the NRC requiring a rigorous formal program on the part of the licensee to minimize errors and that we would, by requiring that program, then have the ability to inspect and to hold the licensees to compliance with or adherence to the program they set. We don't set down a prescription of how to practice medicine, the licensee does. But the important thing is that there is a program that has rigor, procedures, requirements and that we then have a basis to say, "Say what you intend to do and do what you intend to do."

Another point that was important in the '92 milestone was that there was a sharper focus on the higher risk procedures, the definition of misadministration and reportable misadministrations was focused on the therapy and large diagnosis doses where you have significant consequences possible.

(Slide) May I have slide number 4, please?

Now I'd like to discuss the NRC efforts for identification, evaluation and prevention of misadministrations, starting with the way we identify them.

As I just said a few moments ago, back in the 1970s we debated long and hard about how to identify or hear of misadministrations and we set up a misadministration reporting requirements rule and we have been trying to make that framework for reporting clearer and clearer, more sharply focused for these years since 1980 and that, in fact, is why we changed the definition of misadministration in the 1992 QM rule to focus on high-risk or high-impact procedures.

We also have a variety of techniques, including the review of records at the facilities and interviews of licensee staff. We inspect and often check records and can discover the records of procedures that perhaps should have been identified and as in all of the things that we regulate, there is a process by which allegations are raised. In all of our licensed activity, allegations will come up from time to time and we follow these allegations. We follow up by inspection or investigation if need be and that can involve records checks, that can involve interviews with licensee staff. In other words, there are a number of pathways by which we can discover misadministrations that should have been reported.

Nevertheless, I would be compelled to say, we have no qualms in saying there are probably

misadministrations that aren't reported. Our yield of reports is certainly not 100 percent. One of the things I would just register here as an aside, under the new QM rule we're getting reports of more misadministrations already. The rigor of the QM rule is now narrowing the focus to a treatment by treatment basis rather than the entire campaign of treatment for a patient. In other words, if a patient is supposed to get 2,000 rad to a tumor and the first application of 500 rad is mistakenly made 800 rad, it's still within the ultimate prescription. But under the new regulations, under the new procedures, there has been an exceedence and that would be reported and we're beginning to see reports like that.

So, we're looking deeper and we're identifying more misadministrations in that fashion.

COMMISSIONER REMICK: Bob, to help me understand some of the things you just said, I assume when you were talking about looking at records and reports and inspections, you were referring to the NRC licensees, not agreement state, or are you --

MR. BERNERO: Oh, yes, yes. Actually --

COMMISSIONER REMICK: It would be helpful in making your statements if you --

MR. BERNERO: Okay. I'll try to do that.

Much of what I say applies to both NRC and agreement states. But as a matter of practice, what I'm saying about the particulars of inspection or enforcement applies to NRC licensees and Carl will be giving the corollary information on the agreement state licensees.

COMMISSIONER CURTISS: Bob, before you go on, would it be fair to say that in paraphrasing what you've just told us, that under the recently adopted QM rule that you have a greater confidence than we had in the past that when an administration occurs, misadministration occurs, as we now define that under the QM rule, that that will actually be reported and hence the database that we have is one of high credibility?

MR. BERNERO: I would say that in my personal opinion that is the case. The greater rigor that comes with that rule and the greater specificity by going to the licensee's own procedures and treatment by treatment rather than whole campaign. I think that will give us a greater rigor of reporting and then, of course, the treatment by treatment simply adds to the number because in the previous regime a licensee might have defined an initial treatment of 800 rad as simply a correctable thing. Change the prescription to be 800 and then divide up the remaining 1200 rad and the patient ultimately receives still 2000 rad.

COMMISSIONER CURTISS: Second question. Is there any evidence to suggest here, at least under the new QM rule, that misadministration reporting is less than we would like to see because of the terminology that we have used, the use of the term "misadministration"?

MR. BERNERO: I'm not sure -- there has been a lot of adverse reaction to misadministration rather than what we use elsewhere, a reportable event. We've had a debate on whether we should call them reportable events or misadministrations. But I don't know of any evidence that they are not reported because of the name, of the pejorative implication of the name.

COMMISSIONER CURTISS: Okay.

MR. BERNERO: (Slide) If we go to slide 5, we have the efforts to evaluate misadministrations. I would just recall for the Commission that when we look at a misadministration our primary objective, according to our own policies, is to discover the root causes so that whenever information may be gleaned from this event is used to prevent the occurrence of other similar events, generic issues, weaknesses in practice, whether licensing practice or regulatory practice.

Now, we have a scaled response to the evaluation of misadministrations. When they are reported, we set up inspections and those special

inspections can range from, oh, simply having the regional inspector go out there ahead of the usually scheduled inspection to check on things or sometimes these are for more serious events, they are escalated to include either an augmented inspection team, sometimes happens, or now the one that was mentioned earlier, the incident investigation team for the Indiana, Pennsylvania event. There, of course, a death was involved. It was a very grave occurrence and we established an incident investigation team and that's consistent with the management practices for event follow-up that we have.

Now, we generally look to the engagement of medical consultants. We have used medical consultants for many years and especially on a more complicated or serious misadministration we engage one of our medical consultants to assist and they assist in the investigation, they identify any special expertise we might need to understand the significance of the event or the complications of the event and they are a valuable adjunct for consultation with the other physicians involved. You know, the licensee and other related medical authorities. They are not and have never been used by us as an evaluation to second guess or reevaluate whether the prescribed dose was the right prescribed dose or to say would they follow this regime of treatment or

not. They're not for that purpose. Their medical expertise is applied to our understanding the event and its causes.

Now, we have in the past also, by just custom, often used them to communicate with affected people. Now, our rules require that the licensee notify the referring physician and the patient subject to the conditions in the regulations and we often communicate using our medical consultants. When other people are exposed, that's a very difficult issue. That is the case in Indiana, Pennsylvania. You'll hear more about this later.

Other people, not the patient, not the doctor, but people nearby, attendants in the nursing home or truck drivers or other people, are inadvertently exposed to radiation and you get into a system where you need to notify those people. We use our medical consultation service to assist those people who may have been exposed to determine the significance of the exposure they suffered. You know, if someone received 100 or 150 rem whole body dose inadvertently, there are blood tests that can be run to determine medical needs that would ensue from that kind of a dose. So, the medical consultants often have that role.

I would make the observation here, I'll come

back to it later, that although we have used medical consultants for many, many years, I don't think we have all that clear a discipline or statement of requirements, what is your job, what do we expect from you, what is your role, what are the limits on your role and so forth. That's one of the things that's coming out of all these investigations, that we are not too sure what we're asking for and certainly the medical consultants are often not too sure what we're asking them to do.

COMMISSIONER de PLANQUE: Bob?

MR. BERNERO: Yes.

COMMISSIONER de PLANQUE: Before you go on, is there always a process or is there a procedure for follow-up on the fate of the patient or others exposed in terms of harm or death?

MR. BERNERO: No, I would say it's not a clear procedure or follow-up on the fate of anyone exposed, either in medicine or in other activities. There is a general process of discovering the consequences. In the previous memorandum to the Commission where we discussed the Riverside Hospital events, our medical consultants followed up for I believe two of the deaths and then it was going on and on and there was an exchange of debate.

This was a very grave event. No one ever

questioned that. It was a whole series of misadministrations and it was clearly capable of going as far as causing death. The medical follow-up by NRC stopped after about two or three of those fatalities. Other fatalities ensued and I think the ultimate follow-up, it's a number close to 16 or 18 deaths in that one set. But NRC --

CHAIRMAN SELIN: I might just correct you for the record. According to Doctor Polycove's report, there were ten deaths where the radiation was clearly at least a complication and then 18 more where there were signs of radiation damage but not necessarily contributed to the death. Very large numbers.

MR. BERNERO: Yes. Yes. It depends on how one would bin them. Of course, these are all cancer patients, and so there are deaths that are clearly not attributable, deaths that might have had some contribution from radiation and deaths that are clearly related to the radiation.

CHAIRMAN SELIN: I realize this event was a long time ago, but I was struck by the independence with which the medical consultant made major decisions about whether to follow up and how to follow up, apparently not under supervision from the NRC. I mean beyond the medical question about what happened versus how long to

keep up and who to talk to about this. I assume that wouldn't happen again.

MR. BERNERO: Well, again, I think we're troubled by the ambiguity of what do we expect the medical consultant to do and what do they expect us to obtain from them. This is quite a bit different from medical misadministration, but there's a very good case in point. The last incident at Sequoyah Fuels released oxides of nitrogen to the atmosphere. You were briefed on that not long ago. In the emergency response follow-up, I was involved with the region and AEOD on how do we do the emergency response and we talked to EPA and the state authorities and everybody. We ended up getting medical consultants out to the field to provide technical assistance on the physical or clinical effects of oxides of nitrogen. Frankly, I don't think any of us had a clear idea of what we were doing. We just felt like we ought to help and we were providing assistance to the state and local authorities.

I think what you see there as well as in the medical field is a lack of a clear role, lack of a clear definition.

MR. THOMPSON: That's true. Mr. Chairman, I can assure you that the oversight that we give today to these types of incidents are quite a bit more -- we're

sensitive to these type issues with respect to follow-up and we would clearly be in consultation with the region and with the team if, in fact, it had to be an IIT or AIT. With respect to guidances, how far they went up in particular with the case in Indiana, we were there giving some directions and concurring with the role that Doctor Flynn played in that role. So, we would have a lot more dialogue than occurred I think in the Doctor Sanger case.

MR. BERNERO: Yes. That's --

MR. TAYLOR: And, of course, the regulations now require going through the referring physician and assuring these patients are informed too.

MR. BERNERO: Yes.

MR. TAYLOR: That did not exist at the time of Riverside.

CHAIRMAN SELIN: Commissioner Curtiss?

COMMISSIONER CURTISS: Just two observations on this question of using medical consultants, and I do think there are two separable issues here.

As I understand the Agency's practice, we turn to the use of medical consultants to give us a perspective on a particular event that we might not be able to obtain given the expertise of the staff here within the agency. In my view, that's a commendable thing to do. Some of these events involve issues that I

think necessitate going to a member of the fraternity or sorority, the medical community if you will, to ensure that we fully understand the events and deal with the sensitivities that we have talked about and that your paper addresses in some detail.

The first issue I guess I see is that there's a careful balance to be struck between ensuring that we have somebody who is able to bring that expertise to a particular event and give us an evaluation that is reflective of a contemporaneous expertise that the individual has in the medical community. I'm not Oak Ridge is capable of doing that in every case and the medical consultants provide us with that expertise.

But the balance, it seems to me, to be struck here and the purpose that we retain a medical consultant for, at least we have used them in this context in the past, is for them to give us an objective assessment of what occurred in a particular event so that in carrying out our regulatory responsibilities we can then take that objective assessment and act accordingly. I guess my sense has been that there are instances where it's difficult to separate one's role in the medical community and perhaps an unwillingness to be objectively critical in the context of evaluating the particular event from our desire to have that kind of objective

evaluation.

So, it's a judgmental question that it seems to me needs to be addressed in the context of each specific case where we retain a consultant to ensure that we have somebody who has the sufficient expertise, but at the same time is able to step out of the role that he or she plays in the medical community, a practicing doctor in many cases, and give us an objective and, if necessary, critical evaluation of the event. I'm not sure that's been done in every case in the context of some of the reports that I have read.

Secondly, it seems to me, and Bob I think you touched on this point squarely, that the issue of defining the procedures, of defining the groundrules that govern or guide the conduct of the medical consultants is a matter that probably deserves further attention. I have read the recent letter, in fact I just received it today, from Doctor Sanger that details laying out in some detail -- actually, it's a letter to the Chairman, I should say, that lays out in some detail areas where he's concerned that the procedures haven't been fully explicated. It seems to me that question as well, and I hear you saying, deserves some further attention if we can define in greater detail what the groundrules are.

Here, in the case of one who we have used

over several years, there's some evident lack of understanding as to what those rules are and perhaps that's something we can address.

MR. BERNERO: Yes. I might just add, there's a job of work in our shop that is suspended because the project manager is on the IIT for Indiana, Pennsylvania and it arose from the previous IIT and it does involve the role of the medical consultants and this is notifying people other than the patient. The Amersham IIT was a radiation source that was loose in shipment. There was no licensee directly involved in it. We ended up backtracking and reconstructing doses to people all over the country and we used our medical consultants to communicate with those people, to inform them of their radiation exposure and for whatever medical attention they needed, blood tests and so forth, through their companies, like the truck drivers.

CHAIRMAN SELIN: If you'd just stop for a second, I'd add another category to Commissioner Curtiss' analysis. It's sort of included in the first point. But traditionally, as far as I can see, we've used the medical consultants to help us in our regulatory effort, but now we seem to be moving and I think it's probably the right direction to use the medical consultants more or less the way you discussed, Mr. Bernero, which is to

reconstruct not only enough cases to figure out that a failure was made and either a licensee has failed to do his job or our regulation needs improvement, but to go to the point of looking at each individual that was exposed and at least get some assessment of how much radiation and perhaps how much damage at that point to turn over to the physician and his or her -- I mean the patient and his or her physician.

MR. BERNERO: Yes. Well, we use the consultant there, but we also have expertise in staff to reconstruct the doses, the health physicists who do that. But again I would go back and be the first to admit that we need to define the role, the responsibilities much more clearly than we have now. There's too much ad hoc decision making.

COMMISSIONER REMICK: Bob, before you leave that, going back to my earlier question, has there ever been a case where we have an NRC-initiated special inspection use of medical consultants or review licensing reports in agreement states, NRC initiated, or do we leave that to the responsibility of the agreement states? I assume it's that.

MR. BERNERO: To my knowledge, we've never done an IIT or unique thing. We provide technical assistance. I'll let Carl answer it.

MR. THOMPSON: Just to mention, we do have some federal licensees in agreement states.

COMMISSIONER REMICK: That I understand.

MR. THOMPSON: You're talking about the agreement state licensees.

COMMISSIONER REMICK: Right.

MR. KAMMERER: We don't know of any.

MR. BERNERO: Yes. We will provide technical assistance from time to time which includes special inspection or technical support in hearings or something like that, but I know of no --

CHAIRMAN SELIN: We should point out that this Indiana, Pennsylvania was the first time we've ever done an IIT for a medical licensee agreement state or direct licensee period.

MR. TAYLOR: That's correct.

MR. BERNERO: (Slide) May I have slide 6, please, Jim?

In our efforts to prevent misadministrations, we of course have regulatory requirements that would set the discipline for the medical practice. Here I would just like to emphasize once again the quality management rule. I really think that a quality management rule, after all of the controversy we had with it, in the long run will be

looked upon by both sides, by us and by the regulated community as a sound process, a sound procedure because it challenges the medical community to set the standards, to set the procedures or requirements and then to adhere to them, to implement them fairly and rigorously. That's, in my view, the primary way to prevent misadministrations within human frailty limits.

We, of course, have inspection and we will continue to use that. Training, part of our inspection, it's an important part of our inspection, is to make sure that the licensees not only specify the training required but that it's there, that personnel turnover doesn't undermine it, that they have people currently trained in the procedures with the equipment that they have. I think you will hear a dramatic demonstration of the difference of training when you hear that IIT report because there are actually two events in it.

On the enforcement --

COMMISSIONER REMICK: Excuse me, Bob. How do we determine the adequacy of the training? Is it something that they specify and then we inspect to see if they are carrying out what they specify or do we have regulatory mandated --

MR. BERNERO: It's some of both.

COMMISSIONER REMICK: -- ours?

MR. BERNERO: Yes, it's some of both. We have training and qualification requirements in the regulations and, in fact, that in itself is an area of some debate about how far should we go, what sort of training. We have chronic arguments with some members of the community that we demand too much, cardiologists are too busy to do certain kinds of training or something. So, we have certain specified training requirements and they need to be established and validated. But also, there's very important training in specific equipment, especially nowadays. Medical devices, some of them are very complex. It's not a simple teletherapy machine with a shutter and it opens and closes with a timer. They're much more complex.

Now, if I could turn to slide 7 --

CHAIRMAN SELIN: Before you go --

COMMISSIONER ROGERS: You didn't say anything about the enforcement program.

MR. BERNERO: Yes. I'm going to talk about the enforcement program on slide 7.

CHAIRMAN SELIN: Before you go on, one way of rephrasing what you just said about the QM approach is that we rely on the licensee to establish a program, presumably some program we can review for adequacy and then we audit his performance against that program. Do

we go a step further? Do we have an independent way to check on a sample basis the misadministration reporting? Do we depend entirely on the licensee's reporting of misadministration and rates or do we have some type of audit on that?

MR. BERNERO: Well, as I said earlier, we have an inspection process that might discover -- if they record the procedure, we have an inspection process that could discover an unreported misadministration, but that's only if they recorded it. Then there is also the allegation process, which is not uncommon to have an allegation that something happened and they didn't record it either. We have a mechanism to follow up on that.

(Slide) Now, the enforcement program, I want to move to slide 7 because I think it warrants a particular attention. There are two underlying principles of our enforcement program and this is not unique to medicine, but if I would say it in a manner specific to medicine, we want to encourage licensees to prompt identification and lasting corrective action. That's principle number one. This is the identification of misadministrations, of course reporting them. Then we want to deter them by using sanctions. This is the idea of setting up the lesson for others, the lesson for others to see.

We do have escalated enforcement in the medical arena and medical activities using the medical circumstances, over exposures of patients or significant potential over exposures of patients, loss of control of sources in particular. You know, you get these high radiation sources if for some reason or other the proper safe control of the source is lost.

Misadministration for failure to follow a procedure. We had an unfortunate misadministration at Tripler Army Hospital in Hawaii where a procedure called for the technician to verify that a woman patient was neither pregnant nor nursing. Due to distraction and -- they had a procedure. There was no question. The hospital had a procedure, the technician was following it. There was a distraction and the investigation revealed that he went back to the wrong step or never got back to it. He failed to ask the question, "Are you nursing a child?" A large dose of iodine was administered and since the mother was nursing a child, the child's thyroid was severely damaged, in fact destroyed, in that misadministration.

So, we have escalated enforcement and had it there for failure to follow procedures. It's a forecast of the QM rule, willful violations or what is sometimes discovered, breakdown of control, breakdown of

management. Many times a single event may betray this, but sometimes our inspections will betray it. You go into a facility and you find that the radiation safety officer isn't really doing the job or the radiation safety committee isn't doing the job and there's a host of small events, each one not a very big event but in the aggregate what it betrays is a breakdown of management control. So, we get into escalated enforcement there too in medical licensees.

Now, we are reconsidering the civil penalty assessment process. We're trying to focus on the root cause and we think that the enforcement process we have is reasonably effective, but we are consulting with others, in particular the Advisory Committee on the Medical Use of Isotopes. We're hearing views from them that, "Well, the dollar value of civil penalties really isn't that big a dollar value when you're a big licensee. It's more the press coverage or the bad image, the press release that hurts more than the dollar." Of course, in other licensing cases, that's often the case.

We're reconsidering the whole enforcement process, what we should do, how we should put these sanctions out. It's not clear to me at this time. Jim Lieberman is here and could speak with greater expertise about what the prognosis might be. But I would just

leave it myself as it's under reconsideration and it is a very significant and a knotty problem.

MR. THOMPSON: I would just say the ultimate enforcement action is obviously to suspend the license for those facilities for which we really have not --

CHAIRMAN SELIN: But I don't wish to ask any body to try to guess what the changes will be, but I think it would be useful, Mr. Lieberman, if you'd just take a minute to talk about the two or three points in the current enforcement process that you think -- not the conclusions but where you think there are potential weaknesses that are to be reexamined. What are the symptoms that lead you to do this reexamination?

MR. LIEBERMAN: Currently we use civil penalties as the basis for our escalated enforcement actions. Most of our civil penalties, as Mr. Bernero said, are not very large for some relatively large institutions. Civil penalties have been effective for many cases to get lasting corrective action, primarily because of the negative publicity. The question that we're looking at is whether there should be a greater financial impact on civil penalties with the hope that that might provide a greater deterrence for other licensees to improve their performance and therefore maybe expend the resources and the effect to look at

their programs, to improve their performance before incidents occur or before we have inspections. So, for the larger licensees, we are looking at the question of whether we should have larger civil penalties.

Now, the medical community has suggested that instead of civil penalties we use some form of probation to get the attention of licensees who need to improve their performance. We'll also look at that as we look at the mix of ways we can improve sanctions to get the attention of the poor performers in advance of an actual incident.

CHAIRMAN SELIN: Commissioner de Planque?

COMMISSIONER ROGERS: I'd just like to say something on this. I hope you'll look very hard at what ways that you can escalate enforcement and be very tough in addition to dollar amounts. It seems to me there's a very serious question of whether it isn't counterproductive on these large -- to consider large civil penalties when the cost of medical treatment already is very, very high, and whether that, in fact, is really serving the public interest. There's no question in my mind that when enforcement must be escalated it really should take place.

I have a serious question personally about large dollar penalties in terms of the impact on the

ability of that hospital, if it's usually a hospital, to deliver health care in other areas. It seems to me that it's very easy to take a shortcut here and hit them with a very large civil penalty, but I think that in dollar terms that in fact may seriously negatively impact the ability of that facility to deliver health care in other areas. It seems to me we ought to be aware of that because the whole question of the cost of health care is a very, very big issue today, as you know, and this is something I think we ought to be alert to.

MR. LIEBERMAN: I think that's a good point. Currently the civil penalties for a medical institution is relatively low and in part because we're considered the non-profit nature of the hospitals. We wouldn't be considering increasing the civil penalties for the smaller institutions, it would be for the larger broad-scope licensees. But I think your point is a good one that we'll definitely have to consider.

COMMISSIONER REMICK: I share in Commissioner Rogers' reservations about large dollar penalties. The logic of what the staff just presented led me to conclude that you would probably say a larger press release was a -- but if that's the greatest impact, and I believe it probably is, the publicity, certainly it seems to me logic leads us to consider are there other

penalties besides dollars that might be a better deterrent. Dollars is the easiest thing for us to think about, but there might be innovative ways of doing it.

CHAIRMAN SELIN: Well, we're not going to prejudge what your answers are, but we are very interested in what you see the problem was. In fact, I sort of heard you say that you have the feeling that the impact on the organization which is singled out, whether it's the publicity or the dollars, is pretty strong, that you don't get a lot of recidivism from individual organizations.

MR. LIEBERMAN: That's correct.

CHAIRMAN SELIN: So, you seem to be suggesting that you're concerned about the deterrent effect on other organizations rather than the return to the given -- poor behavior by the given licensee. Did I misunderstand that?

MR. LIEBERMAN: No, you're entirely right. It's relatively rare that once we have a civil penalty that that same licensee within a few years would have another significant issue. We do regularly inspect licensees once they've had a civil penalty to make sure that corrective action has been effective. So, at least for a few years anyway, the performance almost always improves, which is the purpose.

MR. BERNERO: I'd like to turn it over to Carl Kammerer now to cover the agreement state aspects of the program.

CHAIRMAN SELIN: Okay. Hold on.

COMMISSIONER CURTISS: I have a question. I apologize for going back to the previous issue. It's not on the enforcement question, but on this issue of the extent to which we have confidence that misadministrations, if they are occurring, are reported to the agency. It's the question the Chairman raised on the earlier graph.

Bob, I understood you to say that if a misadministration occurs that is not reported, we wouldn't know about that and we probably wouldn't have any way of getting at that issue today. Would you expand on that?

MR. BERNERO: No, no. I wouldn't guarantee it, but there's an alternative. If it's not reported and it's an event that should be reported, it is possibly in the hospital records and subject to discovery by inspection, that, "Why didn't you report this?" In addition, even if it's not recorded and subject to discovery that way, it is not uncommon to have an allegation that a concerned person, a staff member or someone who is aware of it raises an allegation with the

NRC and we pursue the allegation and if need be conduct an investigation --

COMMISSIONER CURTISS: Okay.

MR. BERNERO: -- and discover it that way. I don't know how many are undiscovered. I don't know how I can know that. It's just that, as I said, I think the process is already sufficiently sensitive to start picking up the new kinds of reports that we're getting with the QM rule --

COMMISSIONER CURTISS: Yes, I was going to emphasize on that point because I think the QM rule establishes a pretty airtight process that will enable us if we have the inspection resources and focus on the question, first, and second if the RSO is carrying out his or her responsibilities that we've got a pretty airtight process in Part 35 to identify instances where misadministrations are occurring if they're not getting reported. It's worth emphasizing because the impression has been created, and maybe it was true several years ago, that these activities are going on and we're not aware of the events.

As I read Part 35, every -- Part 35.32 in particular, every administration of a dose, not a misadministration but every administration of a dose in five specified categories has to be recorded by the

party, the licensee administering the dose. Those records then have to be retained under (d)(1) of that provision for three years, second. And third, there has to be a mechanism in place for the licensee to audit compliance where the RSO, I think, will play a significant role to ensure that there aren't any misadministrations and if there are they're getting reported.

Unless we've got a problem with licensees failing to prepare written directives, which is sort of the entry into this set of provisions, unless the licensees are not preparing written directives, it seems to me that that mechanism in 35.32 is pretty airtight, and on that threshold question of preparing a directive. Now, frankly, it seems to me that our role is to audit the work of the RSO in ensuring that those written directives are actually prepared for every administration as defined in 35.32.

MR. BERNERO: Well, I think the QM rule is a very strong process because if the licensee is not preparing written directives as required, that is, of course, discoverable by inspection. Then, of course, if they prepare them, then misadministrations are quite readily discoverable by inspection.

CHAIRMAN SELIN: Our figures seem to show

that for every 10,000 therapeutic administrations there, on average, are three misadministrations. It's a very small number and it's also a very small sample. So, it would be very hard to find misadministrations not reported, except through procedural techniques such as you're talking about as opposed to statistical sampling. The cost would be astronomical to try to sample administrations to see if it would be four or five to 10,000 instead of 3.

MR. BERNERO: Carl?

CHAIRMAN SELIN: Mr. Kammerer, you seem to have the floor.

MR. KAMMERER: Thank you, sir.

Mr. Chairman, Commissioners, the first thing I want to do is to improve upon the answer I gave to Commissioner Remick. I was just handed a note from Kathleen Snyder who says that technical assistance in the misadministration case in Arizona, which you'll hear about a week from today, was given, that medical consultant for the NRC was asked to come out and do some work there.

COMMISSIONER REMICK: No, my question was NRC-initiated. I assume that if somebody asked us, we'd be more than willing to help. I was just curious and I was trying to distinguish from what Bob was saying, are

we talking about just NRC licensees or also agreement states. I assumed he was talking again about NRC.

MR. KAMMERER: All right. Thank you.

Before we begin, I wanted to do just a brief overview of the agreement state program. I'll be covering the following topics: the scope of the agreement state program; adequacy and compatibility; agreement state reviews; reporting and exchange of information; regional results of our reviews; and observations and recommendations for future review. I'll be discussing the information that we've collected from the agreement states and as the EDO said at the beginning here, this is the first time we've collected this information in one place in a summary fashion concerning inspections, enforcement, investigations and events reporting for the agreement states.

In the area of misadministrations, the agreement states, for the first time, were to have this reporting requirement in place by April of 1990. So, the 1991 data is the first such compilation. We've gathered this information in a very short period of time, since mid-December, and I want to stress that it's unanalyzed and raw data. If the data, however, says anything to us in our current review, it is that we have to institutionalize this reporting so that we can identify

trends in the agreement state and eventually compare them with NRC data to identify generic situations. We also intend to make this kind of information available to the agreement states.

(Slide) The slide two shows the national licenses. This is the scope of the national medical license program. You can see it in the color up above but not so much in your slides that the license category for this program include the broad medical, community hospital, private practice and clinics and teletherapy. About 6,500 medical licenses in these categories nationwide and the agreement states regulate 4,500 approximately.

As you can see from the red and brown, dark colors, four of the states have the largest number of medical licenses. They are agreement states in California, Texas, Florida and New York.

Adequacy and compatibility. The Atomic Energy Act requires the states to be adequate and compatible before the agreement is signed for discontinuance of the NRC authority. The agreement states also agree to use their best efforts to maintain a program that is adequate to protect public health and safety and compatible with NRC program.

In the SECY paper 92-243, the compatibility

paper, the staff suggests that the issues of enforcement and investigations be examined during the development of this compatibility policy. So, states are evaluated based upon guidelines or core criteria. The guidelines were first published in 1981. They were updated again in 1987 and the most recent version of that was published in May of 1992.

So, here are some of the core indicators from which the 30 guidelines flow. As you can see up there, the statutes and regulations, budget, management, staff and training and so on. The guidelines include 30 indicators for evaluating agreement state program areas. The indicators are separated into two categories. Category 1 indicators address program functions which directly relate to the state's ability to protect public health and safety. Category 2 indicators are those areas which have program functions that provide essential technical and administrative support to the primary functions.

In reporting findings, the Office of State Programs indicates the category of each comment made. If no significant category 1s are provided, this will indicate that the program is adequate to protect public health and safety. If one or more category 1 comments are noted as significant, the state will be notified of

those deficiencies and that it may seriously affect the state's ability to protect the public health and safety. If a state fails to have compatible regulations within the three year time frame, they will not be found compatible.

NRC works with the Conference of Radiation Control Program directors to put new regulations into what is called suggested state regulations for more adaptable use by the states.

(Slide) Slide 4 is the agreement state reviews. Some of the items covered in the agreement state reviews are the inspection findings, enforcement, investigation and events reporting. We have reviews every approximately two year cycle with a visit in between those two. Office of State Programs provides oversight and has internal procedures which are used for evaluating the states for adequacy and compatibility. The procedures set forth, the general objectives for conducting the review, the procedures contain questions asked of and information obtained from the states in certain areas during the reviews. This information and the adoption of regulations is used to determine the adequacy and compatibility of the programs and their compatibility with the Nuclear Regulatory Commission.

Review teams are always headed by the

regional state agreements officer and range in size from one to eight members, depending on the complexity of the issues and the size of the program to be reviewed. Teams may include additional support from Nuclear Material Safety and Safeguards, the regions, the Office of General Counsel and also other state programs.

The following areas that we'll be looking at are not matters of compatibility. However, they are reviewed in terms of adequacy as we do our reviews of each of the state radiation control programs.

Inspection is a category 1 indicator and according to our review procedures an assessment is made of the ability of the state to maintain an inspection program adequate to assess the licensee compliance with state regulations and license conditions. This assessment is made by accompanying new inspectors on their inspections, reviewing compliance files and noting overdue inspections, among other items. When overdue inspections are identified, the State Programs Office requests that a state develop a plan to eliminate the problem. This plan is reviewed and monitored and Iowa is a recent good example of that procedure. They had a number of overdue inspections and a lack of staff and the state was required to formulate an action plan and to make a monthly report to the NRC, to us. We in turn

reported that information to the EDO and progress is being made on that.

COMMISSIONER REMICK: Carl, for clarification, you're talking about going along with the new inspector on some of their first inspection visits. Our staff does that or we see that the state regulatory body does that for new inspectors? That wasn't quite clear.

MR. KAMMERER: It's both.

COMMISSIONER REMICK: Both. But we do sometimes go out and observe their inspections?

MR. KAMMERER: Yes. In the case of Iowa, we're doing that. It's more or less an OJT type arrangement where our technical staff is going along with their more junior staff and handling complex licensing and inspection actions.

COMMISSIONER REMICK: Now, is this because we've identified some deficiencies and we're trying to help them get up to speed or is that something we would routinely do as part of our oversight?

MR. KAMMERER: It's something we routinely do and it's a part of our (d)(2) procedures that require the state personnel to accompany their brand new people and train their people and bring them adequately up to speed as a competent inspector. But the other part

applies as well.

Additionally, in order to meet the review criteria in this area of inspection frequency, the agreement states inspection frequencies can be no less than that of the Nuclear Regulatory Commission. Agreement states make pre-licensing visits, depending on the complexity of the license, potential hazard from the licensee's facility or for a new license. For medical licensees, over 2,000 inspections were performed over the last reporting period. There was a small percentage in overdue inspections and we calculated those to be about two percent.

Another area that's covered in our procedures is the enforcement area. It also is a category 1 indicator. In evaluating the enforcement program for the agreement states, the review criteria indicate that the enforcement program should be sufficient to provide substantial deterrent to licensee non-compliance with regulatory requirements. The staff reviews the state's enforcement letter filed to see, for example, if enforcement letters are issued within 30 days. They have appropriate regulatory language and clearly specify the areas of non-compliance. Specific questions in the area address escalated enforcement actions, civil penalties issued and the number of

enforcement conferences.

You'll note that 22 of the 29 agreement states have civil penalty authority. Twenty-seven have escalated enforcement, while 25 have severity levels. The states have issued 103 civil penalties in the last reporting period.

The investigation program, also a category 1 indicator covered in our internal procedures, all of the agreement states have investigative functions as part of their regulatory program. Office of State Program procedures also include criteria for evaluating a state's ability to handle incidents or alleged incidents. These criteria include prompt evaluation to determine the need for on-site investigation and clear documentation of the incident and/or the allegation. Other questions in this area address procedures for evaluating wrongdoing.

In 1989-'91 review cycle, the states conducted 123 investigations, 32 of which resulted in enforcement actions. Again, we will include both enforcement and investigations in the compatibility study coming up soon.

Events reporting is the next category. It too is a category 1 indicator on our internal procedures. States have adopted requirements for their licensees to report certain events to the NRC, as shown on the next

slide.

(Slide) Reporting and exchange of information. Internally here the NRC staff meets monthly to discuss the events that occurred in NRC and agreement state license programs. The licensees must report significant events to the agreement states in accordance with Part 20. In their agreement, signed by the Chairman and by the Governor, states commit to share information with the Nuclear Regulatory Commission. In addition, our written communications with states encourage them to report events to us. The states annually summarize all events and transmit them to the Nuclear Regulatory Commission.

Again, states have adopted NRC-related rules and policies and through the routine reviews and other communications throughout the year, states and NRC routinely exchange information.

As you can see on this slide, we routinely transmit PNs, information notices, bulletins out to the states. We hold conferences on various subjects as the need arises and involve the states in early rulemakings. That is to say we involve the states early in the rulemakings.

In the area of misadministrations, a total of 480 were reported in 1991. Four hundred and sixty-

three were diagnostic, 17 were therapeutic. Out of these, two therapeutic misadministrations were classified as abnormal occurrences.

(Slide) Recent agreement state reviews, looking at the chart there that shows how we reviewed the states by region. On January 1st, 1993, 24 of the 29 states, approximately 83 percent, were found to be adequate as of their latest review. In five or 17 percent, the finding was withheld.

COMMISSIONER REMICK: Carl, in that area, how long do we allow ourselves to withhold the findings of adequacy or compatibility before we would institute proceedings to retain or restore our authority in these areas?

MR. KAMMERER: In that case, we do not have any written internal procedures, but in a judgment of talking with the Chief Executive Officer, the governor of the state and all of the people below him, if it's their determination that they will -- that they desire to have a program and make the choices to have an adequate and compatible program, whether it's staff that needs to be added or regulations gotten up to speed or whatever, if they're making progress on that we're willing to help them along. When you say how long, we have two cases over the years that have gone on for what seems to me

like about three review cycles. That's kind of stretching it. We'd like to see action taken by the states far earlier than that and that's one of the areas we're going to recommend that we try to find a way in which both our office and the states can be stronger about getting their act together much more quickly.

In the Iowa case, I think I'll touch on it a little bit later, it is something that was over two review cycles and our later discussions with them have them turning their program around and certainly making every effort to do so. So, we don't have a written standard on that.

COMMISSIONER REMICK: Okay.

COMMISSIONER CURTISS: Carl, in your discussion of the two issues that we look at, adequacy and compatibility, it's obvious to me how a state, once we approve an agreement, might find itself in a less than adequate position. Resources are strained, qualified people are not available, budget cuts lead to less than adequate staffing, a whole host of circumstances that might have a state find itself on the other side of the line insofar as adequacy is concerned.

On the compatibility side, what I hear you saying is that prior to granting a state agreement state status, we review the basic legal framework, if you will,

the statute and the regulations that the state in turn proposes to use in carrying out its authority for the purpose, as you've laid out in some detail, of satisfying ourself that the program is compatible as we evaluate that process. Recognizing that that decision gets made as a prerequisite to granting agreement state status, is it possible, have we confronted situations where once a program is declared to be compatible and they're off and running and assuming it's adequate at the front end, that a state after that could lapse into incompatibility, and if so how?

MR. KAMMERER: By regulations, by lack of passing regulations. The point you're making is that up front we have the largest stick. Before somebody wants an agreement state, an ability to carry on the functions as an agreement state, clearly they have to fill in all the right squares. They have to have all of the proper regulations, they have to have even the staff. All of those are put in the Federal Register. Everybody is notified as to the quality of the state before we enter into the agreement.

In both the legislation, Atomic Energy Act, and in our agreements that we sign with those various states, there is the best efforts clause where you have achieved both adequacy and compatibility before becoming

an agreement state and then we use our best efforts, it's in those two documents, to maintain adequacy and compatibility.

COMMISSIONER CURTISS: Yes, but on the compatibility front, it sounds to me like it requires some sort of affirmative action by the state --

MR. KAMMERER: Yes.

COMMISSIONER CURTISS: -- rather than just not passing a budget or letting things develop to the point where they're inadequate. It requires some affirmative action to change a regulation or to modify a statute that we have previously evaluated in the context of our compatibility review?

MR. KAMMERER: No, as we come up with new regulations.

MR. THOMPSON: We will change our regulations. In each one of those regulations that we change, we evaluate whether we require the state to adopt exactly the same regulations or they can have one more stringent or we would just encourage them to do it but not make it a requirement.

COMMISSIONER CURTISS: Then the incompatibility rises potentially when a state does not adopt regulations after the program is originally approved?

MR. THOMPSON: Correct. And some states have a much more cumbersome process to adopt regulations than we do.

COMMISSIONER CURTISS: Okay.

MR. KAMMERER: That's why we allow three years for adoption of new regulations that are required for compatibility. When there are problems in a state program, in the states programs, the Office of State Programs documents the finding with a letter to the appropriate state officials and then meets with senior officials in the Executive Branch and in some cases to the governor of the state to expedite the changes.

I brought up the recent Iowa example as a good one to feature. The regional administrator and I participated in an excellent briefing conducted by the regional state agreements officer in the State of Iowa. The state radiation control program manager and two senior levels above him were present at that meeting. I spoke to the governor and to his staff and Jim Taylor signed our detailed findings letter to the governor. So, we put a lot of attention on making sure that to the extent that we can that changes are made.

(Slide) Slide 7 are observations and recommendations for further review.

COMMISSIONER ROGERS: Before you go to that,

Carl, just on the slide with your data on it, two questions. One is the labeling of the columns. I'm a little confused here on the column labeled A. Is that number that are found adequate or is it what it says it is, compatibility, that are compatible?

MR. KAMMERER: It is adequacy. The first one are the adequacy and compatibility. The second one --

COMMISSIONER ROGERS: The next one is adequate.

MR. KAMMERER: And the last one is findings withheld.

COMMISSIONER ROGERS: All right. So, the explanation at the bottom is a little in error there, that A doesn't mean compatibility.

MR. KAMMERER: Very well.

COMMISSIONER ROGERS: But that's just to clarify the meaning of those columns. But have you found that any of the programs that have not -- are there any programs that have been found not to be compatible that the incompatibility resides in the medical area? You're talking here about general everything, all of our --

MR. KAMMERER: I would think that that answer is no because the agreement states have not had to be compatible with that regulation. The date was 1990

and then the new quality management rule is not going to be until 1995.

COMMISSIONER ROGERS: That's right. But are there any other areas where there's an incompatibility in the medical --

MR. KAMMERER: The State of Washington? There may be a state that doesn't have the rule, the State of Washington. I'm not quite sure.

COMMISSIONER ROGERS: Well, it would be interesting to know whether the lack of compatibility, wherever it is, includes the medical area and how many of those states?

MR. KAMMERER: I'll have to get that.

COMMISSIONER ROGERS: On whether it's basically in the materials area rather than the medical area?

MR. TAYLOR: We'll get that.

COMMISSIONER ROGERS: Yes, I'd like to see that number.

COMMISSIONER CURTISS: At the briefing on the 29th, when we get into this in more detail, and going back to the question that I raised earlier, it might be helpful, maybe even off line, to explain to me how we end up in a situation that I think we have in Utah where the program in one respect has not been declared to be

compatible, but they have their authority and it wasn't a result of anything that we adopted subsequent to the approval of the Utah agreement. I don't want to pursue it in detail here, but I raised the earlier question because it does seem to me that in that particular case we have a situation where with respect to the land ownership issue this is not medical, it's low-level waste, we've got a program that concerns us from a compatibility standpoint but not as a result of something that we subsequently adopted after the Utah agreement was approved. We can pursue that in more detail, but I don't know why that is.

MR. KAMMERER: So, in the observations and recommendations, we offer the following. Compatibility issue clearly needs to be addressed. We need to look at the wrongdoer rule. We also need to look at alternative regulatory measures which will shorten the time it takes for states to implement significant regulatory improvements pending the codification of the rules. What I'm thinking about here is we've recently learned about the alarm rate meter and the great improvements that are made there, and perhaps one of the ways we can get a quicker turnaround here is to have agreement states encourage agreement states to use license conditions or something like that while they still go on the business

of getting their rules in shape.

It would be useful to have a national database to track incidents and misadministrations and we will review our policies for the withholding of findings, some of the points that you've made, Commissioner, of the adequacy and compatibility. Then also we'll completely review all of our procedures and, of course, there are a lot more lessons to learn from this information gathering.

CHAIRMAN SELIN: Before we get off this, I would just like to make a couple of general comments. There have been a number of reviews, GAO review, et cetera, both our own materials program and the medical program. Without getting too deeply into it, the two findings that seem to have happened with the agreement program that resonate quite strongly, the first is that, as you've indicated indirectly, Mr. Kammerer, in the past we've concentrated mostly on the process and not on the results. We've kept good track of whether people do their inspections in time and whether they have training, but not what the results are and haven't really done comparisons state to state or agreement versus non-agreement on, say, misadministration rates or other things like that.

MR. KAMMERER: Exactly.

CHAIRMAN SELIN: I think it's to be commended that you start using these data on a regular basis, et cetera.

MR. KAMMERER: I concur.

CHAIRMAN SELIN: The second is that I guess people like deterrents to be used every now and then because it's been noted that we've never disqualified a program one way or another. I don't think your objective should be to disqualify programs, but there is some question.

On the other hand, some of the outside criticisms have been that we do more of a job of reviewing the agreement state programs than we do of reviewing our own programs in a systematic way about how late are inspections, how well do people carry out the processes and this all suggests the desirability of, on the one hand, doing some more performance oriented work in the state programs, on the other hand having somewhat more equivalent rules unless there's really a clear difference about why the state should be expected to do something that we don't expect ourselves to do. But the end results do have to be programs which at least at a certain level are less different from agreement states to our own states.

The last thing I'd just like to say is of

all the things that should have a high level of regional variation and where we should probably go with a fairly light foot, I think enforcement is one of them because if the role of enforcement is to deter, presumably the agreement states have a much closer idea than we do in Washington or in the regional offices about what deters and what doesn't deter the licensees. So, a high degree of compatibility might not be called for in the enforcement program. The key thing is the results, not saying if you do something you will pay the same penalty whether you're in Alabama or in New York.

But that was very interesting.

MR. KAMMERER: Well, thank you. You touched on one point there that I'd like to just expand upon a little bit and it says that we've never taken a program back. While that is true, the Idaho example is, I believe, an excellent example, absent written procedures for sure, of just what to do to assure that the citizens of the State of Idaho are well protected.

In reading that documented file of a couple of inches thick, there are a great number of letters back and forth between myself and various officials in the government there, in talking with the governor himself and the clear thing we were trying to establish over a long period of time to be sure is for that chief

executive to make the decision, do I want the program or don't I? Then in the case if I do, what are the things that I need to do in order to get a quality program back on track? And if I don't, we let them know what that alternative is and I think the last piece that encouraged the decision to be made rather quickly was sending our letter over that said, "In 48 hours we want to hear what your plan is." We gave them an extension for a couple of weeks, but the decision came back the other way and were prepared with a Commission paper to come to the Commission. We didn't start action right then. We'd been doing it all along and it was before the Commission in a matter of a few days and the decision was agreed to. So, the citizens were protected by having the NRC pick up that responsibility and do the job.

MR. THOMPSON: I'd like to respond. I agree with you, Mr. Chairman, and I'll be working with both State Programs and NMSS to evaluate and try to take the best part of both of the program reviews and make sure that we apply those to evaluating both programs and where there are differences we understand and can justify why don't we take a different approach to those. That's part of the process we learned from this, as well as from the GAO effort.

COMMISSIONER REMICK: Before proceeding, I

have a question that I'm hoping the General Counsel can help me out on and if not today, perhaps subsequently. As I read Section 274, and I see words that when we agree to an agreement state status, that that's a discontinuance of the Commission's regulatory authority and those to me are very strong words, but at the same time I realize we have some oversight responsibility. Is there any easily defined line of what is our authority once we agree to agreement state status?

MR. PARLER: Our authority is, as you pointed out, discontinued. The maximum leverage is before the agreement is executed to discontinue the authority. After the agreement is entered into and if thereafter for whatever reason the program deteriorates to such an extent that in this Agency's judgment the responsibilities are not being carried out to protect the citizens in the state and the public health and safety, there is a procedure that is set forth in Section 274 of the Atomic Energy Act to reacquire the authority which has been discontinued to the state.

That is a part of the background, I think, that Mr. Kammerer was talking about for the state, but the thing was worked out without having to go through the process that is called for by 274.

However, since the authority is

discontinued, it cannot easily be taken back just because, say, the Commission might think on a particular day that the program is not adequate and as of that day the program should be reacquired. There is a discipline process that has to be gone through.

MR. KAMMERER: Commissioner Remick, there's one more thing to add to Bill's point.

COMMISSIONER REMICK: Yes.

MR. KAMMERER: The legislation requires that we periodically review the agreement states. So, we still have a responsibility in that.

COMMISSIONER REMICK: I agree. No, I agree with that. The point I was really trying to get at, I asked the question have we ever initiated a special investigation on our own in an agreement state or have we ever hired a consultant to go look at an incident in a state without being requested. I assume we would not have the authority to do that.

MR. PARLER: There is -- I think that if we believe that there is something that needs to be examined to see whether the overall authority that we have, which includes the authority to discontinue authority in specific areas, whether the stewardship over that which has been discontinued is adequate, that we could do that. There have been -- there was a situation some years ago,

the details of which I am not familiar with, but within the State of New Mexico about a mine or a mill. The situation there was such that I think that that was examined in cooperation with the states and an agreed to resolution of the problem was reached.

I think yes, we could do that, but not frequently.

MR. TAYLOR: I can recount one event which was at an irradiator in Georgia a few years back, an agreement state. Late in the day, in the evening -- this was the cesium capsule issue. We were in discussion with the state, but we became concerned that appropriate surveys had not been taken at the exit of the irradiator and there were not state personnel available to do the surveys. I made the decision and informed the state that we had people and we sent people out that night to take surveys, contamination surveys outside because this was in an industrial park and we were concerned that any contamination, cesium, might be tracked further. So, we acted. In that case, the state did not have, for some reason or the other I can't recall, but we moved that night with our own equipment, did a survey, of course advised the state promptly and worked together with the state for the remainder of our involvement there.

COMMISSIONER REMICK: I'm glad to hear that.

MR. TAYLOR: It would be rare, but I think in that case we did act in the public interest.

MR. PARLER: I would think that in any example such as this where the event that is being examined could have interstate consequences as far as the protection of the public health and safety is concerned, that this Agency would have authority and an role to play.

COMMISSIONER REMICK: Thank you.

MR. BERNERO: (Slide) I'd like to resume, if I could have slide 14.

The Cleveland Plain Dealer series addressed these issues extensively in the month of December.

COMMISSIONER REMICK: Comment to staff. Numbers on the pages would be helpful.

MR. BERNERO: Yes, my regrets that I didn't. They're handwritten numbers I'm using. It's the one Cleveland Plain Dealer series title.

Much of what we've already said speaks to the principal issues raised in that series, but I'd just like to summarize the issues here and hit some highlights on them before we get to our conclusions or observations.

Basically, we see the series as focusing on us and the agreement states in three general categories or three general issues, the first being oversight. The

oversight issue being characterized as small resources are dedicated to the medical program, not enough people, not enough expertise presumably, that fines are small, that the amount is too small to be significant, that there's no follow-up on wrongdoers, people who have done something wrong. There is inadequate reporting, that information isn't shared with the states, that general oversight challenge.

The second issue concerned follow-up of patients subject to misadministration and the argument being that we didn't know about the consequences, that it raised the question of our responsibility to focus not only on the circumstances of misadministration but the consequences, especially following the patient to determine did the patient ultimately die of the radiation. That in particular on the Riverside Hospital events, and thirdly the expansion of the NRC regulatory purview, the article series had a good number of incidents that were with linear accelerators, which are used for teletherapy purposes, and as I recall it even said that we repeatedly refused to regulate such devices.

(Slide) So, if I could just take the next slide and touch on the three issues, just highlight some of the concerns, the NRC and agreement state oversight,

Carl has just explained to you the agreement states so my remarks are going to focus on NRC as a pattern.

First of all, as far as the resources we dedicate to this, we told you in the Commission paper we just sent up that we have 74 individuals in staff directly involved. This is licensing and inspection and, you know, support individuals, dedicated to the extent that 41 full time equivalents per year are dedicated to the regulation of nuclear medicine. That is approximately one-third of our materials regulation program and they constitute approximately one-third of our materials licenses.

We also have about a million dollars in program support to assist in medical regulation. Now, these are fairly well-qualified people. We have, as you know, a medical doctor on staff as a visiting fellow, but our own staff are non-medical doctors, but many of them have advanced degrees including doctorate degrees. They're generally health physicists or physicists. And we retain medical consultants, of course, as we were discussing earlier.

Our inspection activities are --

COMMISSIONER de PLANQUE: Bob?

MR. BERNERO: Yes?

COMMISSIONER de PLANQUE: Before you go off

the FTEs, does that 41 include the FTEs required to oversee the agreement states medical program or is that an additional --

MR. BERNERO: No, no. This is our program.

Now, our inspection activities --

CHAIRMAN SELIN: That's one FTE for every 50 licensees is basically what it works out to.

MR. BERNERO: Yes.

CHAIRMAN SELIN: And how many therapeutic administrations are you talking about?

MR. CUNNINGHAM: In round numbers, 200,000.

MR. BERNERO: Yes, something like that.

MR. CUNNINGHAM: Roughly.

COMMISSIONER de PLANQUE: That's nation-wide?

MR. BERNERO: Yes, nation-wide estimates, and you'd say a third of them are in -- that's a very crude estimate, because, as Carl Kammerer showed you, the four big population states are agreement states, so that I would tend to lean toward more like a quarter.

CHAIRMAN SELIN: Well, it's a third of the license -- we have a third of the licensees. Maybe we have a third of them.

MR. BERNERO: Yes. It depends on which one you would use.

CHAIRMAN SELIN: Okay.

MR. BERNERO: But we do scale our inspection priority anywhere from a nominal annual basis of inspection to every four years depending on the size of the activity, a broad license, a big facility versus a small community hospital or an individual licensee. Frequently we have to use specific judgment to scale that, because it is possible to have individual licensees who are going bankrupt or aging, you know, elderly doctors who have sources, teletherapy machines where you have to give a lot of extra attention. But, as a general rule, we scale the inspection frequency to the size or scope of their licensed activity.

And then, of course, we do have extensive enforcement and investigation activities, so in general I would respond to the challenge that there is inadequate oversight as saying we do have extensive oversight. It isn't dozens and dozens of inspectors for any one state. We review this every year through the process. It's an allocation of resources process and we have to make that judgment every year and from time to time we do shift and increase the emphasis or increase the inspection frequency or something like that.

(Slide) If I could turn to slide 16 and just touch on the follow-up with patients, we talked

about this quite a bit before. I would recall for you that misadministration reporting has been a requirement for NRC licensees now for 13 years and the agreement states have come into it more recently. The data that are available, you will see, for agreement states cover only one year. They're really in the misadministration reporting start-up mode, whereas NRC has a longer period of reporting.

Mr. Chairman, you referred to the notification data, you know, their reporting data as being fairly sparse, 10^{-3} or 10^{-4} annual frequency is our best estimate, somewhere in there, and they're not many. And when you start looking at individual states, I would just say with a caution that it's very hard to get meaningful data at these low numbers or sparse figures.

We do require in misadministration reporting that the misadministration be reported to the patient or to the referring physician and giving the referring physician the option to withhold the information from the patient if it's deemed medically justifiable. We do follow up on that. We try to follow up to make sure that those notifications are made and, similarly, we have the procedure that I referred to earlier of reporting exposures to people.

You know, we have clear regulations for

reporting exposures of workers within a licensed operation, but where inadvertent exposure victims, victims of inadvertent exposure from a source traveling across the country in a truck that fell out of its shield or, in the case of this more recent incident in Indiana, Pennsylvania, other residents of the nursing home that were inadvertently exposed, we have a less rigorous process, for sure, for notifying those people. We often use the medical consultants to do that and --

CHAIRMAN SELIN: Can you just stop for a second?

Mr. Kammerer, is it a requirement of agreement states that they also require that patients in the agreement states be notified if there's been a misadministration, what the amount is and the likely medical effect?

MR. KAMMERER: I don't know that fine detail, but the answer is yes for notification.

CHAIRMAN SELIN: See, I was struck. It's truly anecdotal and the Riverside event was a long time ago, but basically the government stopped investigating what happened to the patients when we had enough information to say that there was a serious problem, rather than saying we should look at each patient to see if anything should be --

MR. PARLER: Mr. Chairman, a prior chairman of this agency told the Congress that they were going to look at each patient. I just thought I would bring that out to you, sir.

CHAIRMAN SELIN: Well, that's a long time ago.

MR. PARLER: Right.

CHAIRMAN SELIN: So the question is, do we do that now? There was also a case that was brought up in an agreement state where an agreement was made between the hospital and somebody else and one of the conditions was that the information effectively not be given to the patients. Now, things happen. I understand that they can happen, but one of the things I'm concerned about is how systematically we follow up on the follow-up provision both in NRC licensees. The policy is clear, but the practice is not so clear to me.

MR. BERNERO: Well, I would question whether we have a clear statement of the purpose and the extent of our follow-up for patients. Are we stopping at the point of ensuring that they are notified or are we continuing to observe the patient or to monitor the patient's progress toward ensuring appropriate medical care? We are not doing the later.

CHAIRMAN SELIN: Without getting into the

later, it's just clear that we do have an obligation to do the former.

MR. BERNERO: Yes.

CHAIRMAN SELIN: And one of the question I hope you review answers us whether we can be assured that we are systematically doing the former. The later one, when you make a recommendation what you think we ought to do, then the Commission will probably speak on what it believes ought to be done.

MR. BERNERO: Yes, indeed. The way I would put it is we have to have a sharp definition of what our scope of follow-up and the extent and purpose of that follow-up is and that the procedures are being rigorously followed.

I was using the example a few minutes ago about reporting extraneous, that is non-patient exposures. That is in a real state of confusion for us right now, because we don't have a rigorous system of who does what, who reports it. But the follow-up of the patients as we saw at Riverside and as we see even in cases today, we don't have a long-term medical follow-up. We have an arrangement whereby on a voluntary basis a patient may be monitored in an epidemiological program, but the NRC does not have a clear procedure for long-term follow-up.

COMMISSIONER CURTISS: Bob, could I pursue that? There are two discrete questions here that I think we're talking about and there's some confusion.

We have a policy that provides for initial notification of the patient and that policy I think is one that's well-established and I think reaffirmed in the QM rule. There's a separate, maybe related, but nevertheless a separate issue, and I think Mr. Parler's comment touched on this question, and that is what is our obligation with respect to following up on a patient who has been the subject of a misadministration from the standpoint of beyond initial notification?

The policy, as I understand it, and it's a relatively old policy but it is a policy that in the exchange of communications back in the late '70s seem to suggest clearly what the policy was, is that we follow up on the patients to the extent necessary to carry out our regulatory responsibilities. Now that may not require us, the argument goes, to follow up with respect to each patient to ensure that they get adequate medical care. That might be the doctor's responsibility, some would argue. Nor does it require, and the Cleveland Plain Dealer series focused in particular on this point in a critical way, nor does it require, the argument goes, for us to follow up on each patient to determine whether, in

the event of death, as everybody will at some point encounter, that death was caused by the misadministration that occurred and that the patient under the current policy would be informed of.

I guess my question here at this point is really twofold. I read the discussion in the SECY paper and it goes on for some length beginning on page 14. I read that discussion as laying out several pros and cons of what you call long-term patient follow-up with perhaps a heavier emphasis on the cons, but nevertheless a discussion of the pros and cons of long-term patient follow-up.

Now, my questions are really two-fold.

One, this is a paper which the Office of General Counsel has concurred in.

MR. PARLER: Well, there's no legal objection to it.

COMMISSIONER CURTISS: I guess the first question -- I'm sorry, no objection to the paper.

MR. PARLER: That position was arrived at after much internal effort and discussion and qualifications in the words.

COMMISSIONER CURTISS: Us lawyers need to be careful about the terms we use.

MR. PARLER: That means that all of the

facts and stuff in here about what is going on for current practices, these numbers from agreement states, et cetera, I cannot vouch for those.

COMMISSIONER CURTISS: Okay.

MR. PARLER: Given the input that we had and what these folks say that they are embarked on doing, I have no legal objection to that.

COMMISSIONER CURTISS: Okay. I had a specific question. Maybe it picks up on that point. In laying out the pros and cons of long-term patient follow-up in the development of the policy in this area and in suggesting, as I think you're going to, that this be something that would be evaluated by an external group, do I infer from what we have before us that the question is basically a policy question and that we have a range of legal options ranging from what I've just described as the policy in the late '70s to something much more aggressive? Essentially, it comes down to a policy question?

MR. PARLER: Certainly the near-term actions, as distinct from the longer-term actions where your characterization was the same as my understanding that perhaps for the longer-term the cons were presented with greater weight than the advantages, what governs me is that the Commission has decided unequivocally that the

patients have a right to know when they have been involved in a serious misadministration, unless this information would be harmful to them. There's nothing ambiguous about that. That has been the policy that this Commission has adopted since 1980. And even before that policy was adopted, the Commission prior to that time advised the Congress in a particular situation that it would indeed follow up on patients that were involved in a serious misadministration.

COMMISSIONER CURTISS: Inform the patient that they had -- or the referring physician?

MR. PARLER: Yes.

COMMISSIONER CURTISS: But the question that I'm raising and the reason I make the distinction between the two is because there is a difference in my view between the initial notification, which I think you've summarized as I understand it, and the question of whether we have an obligation, legal, or whether it's a policy choice for what you refer to in this paper as long-term, after the initial notification, long-term patient follow-up to the point even of determining through, let's say, an autopsy what that patient died of.

MR. PARLER: Well, whatever it is that the Commission believes, at least in my judgment, that they have to do to make sure that the patients who have been

involved in a serious misadministration have been given adequate knowledge that the Commission has gotten about the situation. When you go beyond that, then I don't think there are any legal requirements that are involved over the long-term. That's why in this paper there's a sentence added that, for the short-term things, that the General Counsel, the OGC, believes that these arguments for the notification and the advice and so forth are persuasive.

CHAIRMAN SELIN: Do you want to hear Mr. Bernero's answer?

MR. BERNERO: I would just like to add, by the way, the citation that Bill Parler just made is low on page 16, if you wanted to refer to it, about that being persuasive for the short-term.

In order to respond to the question, I would like to put it in a framework and go back to the Riverside Hospital incident and the confused history that followed it and ending with Doctor Polycove's memorandum about what was the final count, you know, the three categories of deaths attributable to that series of misadministrations.

In the original follow-up, the short-term follow-up, our medical consultants were looking at pathology and following the cases and got to two deaths

which clearly established the gravity of the misadministration. This was a very serious misadministration or series of misadministrations and they got to two deaths and that, in my mind, is a way for the Commission to say, "Yes, we know this is serious. The consequences are grave of this sort of mistake or misadministration."

Then, if you go through that correspondence, you can see the confusion. "Where are we going to get the people and who's going to do it and do we do autopsies and what-have-you?" The follow-up which came and was summarized in Doctor Polycove's report -- not that we did the follow-up, but the way it was done -- said, "Ultimately one can categorize all of the victims of misadministration as ones who died of the original cancer, ones who died of the cancer but quite probably with a significant contribution or deleterious effect of the over-irradiation, and lastly those who died of over-exposure."

And you may recall that even in one of those cases -- I think you questioned it some time ago, Mr. Chairman -- we're talking about something like 25 to 50 percent over-exposure, not a real big leap. You know, you're dealing with high radiation right on the threshold of very serious damage to the person because you're

trying to damage the tumor. Now in that context I would say that, from what we learned from General Counsel, the short-term arguments are persuasive. Yes, that's clearly a legal obligation and we don't question that at all.

But the long-term follow-up is something that I think the Commission would want to make as a policy choice, look at the alternatives and then turn and ask General Counsel in that context, "Is this a good idea or is this a viable alternative? Do we have either the legal authority or the legal compulsion to do it?"

COMMISSIONER CURTISS: The reason I raised the question, and I think it's clear that after we originally notify the patient, which is legally required and there's no disagreement about the question that arises as to what extent do we undertake a long-term follow-up of individual patients, if we have a legal obligation to do something more than what we're doing right now, I personally wouldn't support referring this to an outside group to examine the pros and cons, if we've got something that we need to be doing that we're not currently doing right now. I don't understand Mr. Parler to be saying that.

And so the remaining question, then, is whether in examining the pros and cons and defining the extent to which we would pursue long-term patient follow-

up whether there's a question about our legal authority, not our legal compulsion but our legal authority to extend beyond what we have defined to date as the purpose of our role.

MR. PARLER: May I say something or not?

CHAIRMAN SELIN: You certainly may and, if Commissioner de Planque agrees, you may do so right now. Please do.

MR. PARLER: These longer-term things are good questions. One of my problems is that I have not been able to clearly understand what our practice has been for the short-term, whether in this event where there were 400 people that presumably suffered serious misadministration were they notified. What were they notified about, et cetera? That's what bothers me, sir.

COMMISSIONER de PLANQUE: It's still not even clear to me if we can answer the question. Where there has been a misadministration, is there a radiation-related harm or death as a result?

CHAIRMAN SELIN: I'd like to follow up on that observation, if I might. There are two things that I'm concerned about in addition to the questions that Commissioner Curtiss raised. One is this distinction between short and long-term isn't as clear as it sounds.

For instance, if there was a

misadministration and we tell the patient what it was and how much it was, et cetera, that might let us off the hook in general. But if you know that a couple of people have been killed, you might have a very different view of when you have enough information in the short-run, in other words whether just knowing the radiation at that point is enough or whether you need to monitor for a while even to meet the "short-term."

When you do your review, I'd like you to do two things we haven't discussed. The first is off the topic so far, and that is we have the sentence that says, particularly in the case of a therapeutic misadministration, that the patient must be apprised of the misadministration no later than 24 hours after its discovery unless, A, the referring physician says he'll do something or other or, B, based on the medical judgment, telling the patient would be harmful.

I've heard from anecdotal information that we've taken too generous a view as to when the patient need not be told, in other words somebody saying, "Oh, don't worry about it. It wasn't such a big deal," et cetera. I mean, the statement is very clear that somebody has to say it would be harmful to tell the patient. The patient is in such a delicate frame of mind that telling that patient at this point might impede his

or her recovery.

Would you look in practice to see if we've applied that tough a standard or we've been put off by a much more casual standard?

COMMISSIONER REMICK: In what time frame would you look at that?

CHAIRMAN SELIN: Whatever reviews --

MR. BERNERO: In the required notification.

CHAIRMAN SELIN: No, no. Commissioner Remick -- there's no sense in going back to the Riverside event, but when you look at the recent events have we been pretty rigorous at telling the patients or do we accept a much lighter excuse for not telling the patient than would be called for by the rules?

MR. TAYLOR: Go ahead, Hugh. I think you should --

MR. THOMPSON: Yes. Mr. Chairman, I just wanted to make sure the record reflected that there was no follow-up reporting requirement for the patients at Riverside. We clearly have that responsibility today and we would clearly do that follow-up.

CHAIRMAN SELIN: No, I'm sorry. Nothing I was talking about was suggesting Riverside. I just want to make sure when you look at these cases that you do a reasonable post-audit about, if we didn't tell the

patient, that we had what you would today feel was sufficient --

MR. BERNERO: Yes. In our current activities, the way the reporting requirement is structured, we are really deferring to the judgment of the referring physician to make that conclusion and we don't override it.

MR. TAYLOR: We can get that information for you.

MR. BERNERO: We can review that, and that's a significant factor.

CHAIRMAN SELIN: The second is sort of an analytical suggestion. When you look at what you believe are the pros and the cons of longer-term follow-up, I would like you to apply that as if there were a Riverside today. In other words, in a really serious event where a couple of people have been known to have been killed, don't just take the dry legal analysis and say what are our obligations, short-term versus long-term, but say, if we followed this policy, what would that tell us about a new Riverside? You know, would we stop after two people? Would we continue to follow people? So that you have a sort of a meta experiment to say, if we applied this policy, if this case happened today and if we applied this policy, is it intuitive account or intuitive that

we'd be coming up with the right answer?

I mean, I go on the general view, to paraphrase the General Counsel, that we are obligated due to the short-term involvement. We have vast authority and therefore, should we choose on a policy basis to do the long-term follow-up, that nobody would say we're not allowed to do it, but that we have flexibility about why would we do it and how does it support the regulatory function. At least, that's my going in view and therefore I'm very interested, as I'm sure the other Commissioners are, in the policy pros and cons as well as legal.

MR. BERNERO: In fact, I was answering Commissioner Curtiss' question citing Riverside because it is -- not to rediscover or redo Riverside, but to use it as a hypothetical experiment.

CHAIRMAN SELIN: Right.

MR. BERNERO: If we had it to do over again, what makes sense? What would be sound policy as well as what would be legally required?

MR. THOMPSON: I would like to add one comment in the discussion with respect -- excuse me.

CHAIRMAN SELIN: Commissioner de Planque?

COMMISSIONER de PLANQUE: I would also ask for some clarification of what the situation is in the

agreement states, because, if you look on the follow up of patient section and on page 15, it says, "A special note: some agreement states do follow-up inspections after serious administrations," and it's not clear to me what the situation there is in terms of patient follow up, what's the policy.

MR. KAMMERER: It's basically the same as the NRC and there's only, I'm believing, two or three that have gone beyond.

CHAIRMAN SELIN: Mr. Thompson?

MR. THOMPSON: I think there was a question on how far do we go to evaluate. One of our responsibilities to evaluate the significance of an over-exposure to the individuals goes to the potential enforcement actions. Obviously, the death or loss of an organ elevates the enforcement actions that we take, so it is incumbent upon us to evaluate the significance of the over-exposures in order for us to take the appropriate enforcement action where appropriate.

COMMISSIONER CURTISS: Just an observation on that. I mean, if your point here is -- take Riverside and you've got 400 people, and I'll defer to the lawyers here on this, or these lawyers, if the magnitude or nature of the enforcement action that we take requires us to understand in a long-term context beyond the short-

term notification and relatively limited period of time what the ultimate disposition of each individual was in terms of whether there was a fatality directly attributable to the radiation over-exposure over an extended period of time, that deserves some careful analysis by the enforcement arm because it suggests that enforcement action would need to be deferred until you've got that information. That almost implies that we've got a legal obligation to do long-term follow-up so that we know what the magnitude is.

CHAIRMAN SELIN: Let's not get too far out. There are a lot of interesting questions. They're very important policy questions we would like your advice on, et cetera, taking into account one of the regulatory functions is the enforcement. Don't try to make a judgment whether two fatalities would lead to one enforcement action or four would lead to another one, but, just as you go through this, take a look at some real things that have happened and see what would the results have been had we had these policies at the time and do they match or go against your intuition as to what good regulation would be.

It's clear there's a lot of stuff to look at. I mean, that's the one clear conclusion of this discussion.

Maybe you'd want to continue with your analysis of the Plain Dealer --

MR. BERNERO: Yes.

(Slide) I'd like to go to slide 17 and just touch on the third major issue, the expansion of our purview. The Plain Dealer suggested that NRC should regulate all medical uses of radiation, especially linear accelerators, because of the history of mishap with them.

Now the Cleveland Plain Dealer, as I recall, said we refused repeated requests to regulate that. We know of no formal request that anyone ever made for us to regulate that. I do note here that the issue of natural and accelerator-produced radioactive material was before the Commission a few years back. We produced a report on that subject to discuss the pros and cons. It was focused on discrete sources.

The Conference of Radiation Control Program directors suggested that we ought to seek regulatory authority over discrete sources, things like radium needles, quite different from linear accelerators, and we went through a process of self-review, discussion with the Commission. We referred that issue to the CIRRPC, the Committee on Interagency Radiation Research and Policy Coordination, and we have declined to pursue that regulatory authority.

CHAIRMAN SELIN: Commissioner Curtiss has pointed out that either I might be less than clear or I might, God forbid, actually be suggesting something that's a bad idea in my remarks.

I'd like to make clear I'm not saying that part of this review about how far we go beyond the immediate notification has to be part of your internal review. Just, you know, you'll come back to us and you'll say, "Here are the questions we want to do on the internal review and the external review, et cetera." And when you do that question, I'd like you to follow some of the logic that I put out, but I'm not suggesting that it's necessarily an immediate short-term need to address this question of follow-up tracking. We're open to suggestion from the staff.

MR. BERNERO: I'm just going to turn to the reevaluations. I think it's a good idea.

(Slide) Slide 18. I make a somewhat artificial distinction here between technical or narrow evaluations and management evaluations of broad programmatic character.

As an example of the technical evaluations that I think are important the Commission should be aware of, we have a few contracts and technical activity within the staff to look at risk analysis and human factors

associated with medical administration. The technology changes year by year. The devices become more powerful, higher energy density you might say, where more radiation can be deposited on a solid tumor in a shorter period of time by the use of advanced technology. And we're looking at the human factors of using such equipment and looking at risk analysis to see if there are insights there that would help us a great deal in how we regulate.

A word of warning. We're looking at devices and, under the law, the Food and Drug Administration has authority over devices. We have authority over how devices are used, and the states have certain authority also, and so it gets to be a bit murky there. But we're doing technical evaluations that can be useful to all of us, all the regulatory parties.

COMMISSIONER REMICK: Along that line, not in the same vein that you're using risk analysis here, I understand what you're saying, but has any thought been given to whether it's practical or not to have some kind of overall guidance in the medical area about the concept of a safety goal like we now use in the reactor area where it helps us at least put things in perspective? Has any thought been given on the practicality? I realize it might be difficult, but in the reactor area it was difficult too to come up with something that might be

a goal by which we judge success or lack of success in these areas? I'm just asking has thought been given. I'm not asking you for a solution.

MR. BERNERO: Just for background, in the debate on the QA rule which ultimately became the QM rule and the suppression of misadministration rate, in that debate there was a great deal of discussion of what is the real rate of mishap or misadministration and why can't it be pushed further toward zero and the Commission itself was involved in that debate. The data are sparse. It's very difficult to make a broad judgment like that.

We also have been looking and our medical visiting fellows are pulling together the context mishap rates or error rates or fatality rates associated with medical procedures in general. I think you all realize that simply going under a general anesthetic is a relatively hazardous operation.

I was advised in my own case. I took a thallium stress test a little over a year ago and the cardiologist advised me that I had one chance in a thousand of very serious result to that test, in other words keeling over on the treadmill and dying from the stress. So we're looking to that as a context for are we trying to get a safety goal that is unrealistic or that's not achievable.

COMMISSIONER REMICK: Is that zero? Is zero a safety goal? Is it a risk that is no greater than other medical procedures? I'm just questioning. Has anybody given thought if there is a way of approaching this --

MR. BERNERO: Yes, we are giving that thought.

COMMISSIONER REMICK: -- to give us some perspective on judging on whether we are doing an adequate job or not?

MR. BERNERO: And as you said, when I spoke of risk analysis here, I was talking about --

COMMISSIONER REMICK: I understand.

MR. BERNERO: -- sensitive engineering risk analysis of devices.

COMMISSIONER REMICK: That I understand. You just reminded me of the question.

COMMISSIONER de PLANQUE: May I just add?

COMMISSIONER REMICK: Yes.

COMMISSIONER de PLANQUE: In that context, if you look at the rate of misadministration which, if my numbers are correct, are about one in 10,000 for both diagnostic and therapeutic, that's the rate of misadministration. If you're looking at a comparison with something like the risk of death from anesthesia,

it's the death rate or the harm which is, again, a significantly lower number --

MR. BERNERO: Exactly.

COMMISSIONER de PLANQUE: -- that you need to compare.

MR. BERNERO: Yes. You have to compare mishap with mishap, death with death or whatever consequence.

CHAIRMAN SELIN: But at the same time, it's just the mishaps. We're not looking at the places where the prescription is intrinsically risky. I mean, we're not talking about the right dose was applied but the patient became ill because of that. I mean, it's just a very small part that we're looking at.

MR. BERNERO: It's a very narrow context.

One of the Cleveland Plain Dealer events that was reported in there was not a misadministration. It was an argument that the doctor prescribed too severe a radiation dose to treat the cancer and that that led the patient to despair and suicide. Our system is unable to discern that.

We also have, in technical evaluations of the narrow type, incident investigation reports. The brachytherapy incident in Pennsylvania is a salient example. You'll hear about that shortly.

(Slide) If I could turn to slide 19, I'd like to talk about the more generic programmatic things.

The Chairman mentioned at the outset an NRC initiated evaluation. Last summer in management consideration the staff decided that a nuclear medical activities management plan was an appropriate thing to do. In order to clarify our role, try to focus on the safety issues and pick up many of the things, we developed an issues paper. The plan we were following, we informed the Commission last September, I think, about what we were doing.

We developed a medical issues paper and have already had extensive discussion of that paper with the Advisory Committee on Medical Use of Isotopes last October, with the agreement states also last October, with our regional staff management in November, last November, and we're proceeding to develop what we thought was the right evaluation and conclusions to come forward to the Commission.

I must admit that we did not have all of the right issues with today's perspective, that events have overtaken that plan to a substantial event, and the Commission itself has directed us to do further evaluations catching that one in midstream and you've

admonished us to coordinate the further evaluations with this, so we now have what amount to three evaluations in process. This one I would call a line management program management plan.

(Slide) And then, if you turn to slide 20, on December 21st the Commission instructed us to do two oversight reviews, the first review by NRC senior management on the effectiveness of the existing program and that one to be particularly coordinated with our own line management one and we're trying to work out just how to do that right now.

And then secondly, a review by an external group, the Commission calling for a review of the adequacy and appropriateness of the current framework of regulation and, as we said in the paper, we have initiated contact with the National Academy of Sciences and their broad spectrum of capability. We're looking into that and we believe that we can come up with an appropriate plan in the near future and of course we'll be coming to the Commission as you requested for how to do that and whether it will serve the purpose you seek.

So we have three independent audits or three oversight reviews going on all in some sense of coordination, I hope, in the coming months. I would expect the internal one and the internal NRC manager

oversight to have a time scale of months to completion, whereas the external review would be much, much longer, more like one or two years to review, so we should be prepared for that.

(Slide) Now if I could turn to slide 21 and just summarize, in the Commission paper itself we had a concluding section that we entitled "Observations and Further Considerations." I would just like to highlight that we enumerated in the paper a number of aspects -- Carl Kammerer spoke to some of them -- where analyses of program effectiveness or needs stand unsatisfied for improvements in program effectiveness. Those we intend to go forward with, but I want to single out the two as perhaps the more knotty problems that we need to deal with.

One is the evaluation of regulation of devices. This is going to come out especially clear. I think the need will be shown in the IIT review when Carl Papparello reports on that, because that's right at the heart of the affair, the regulation, how the device was regulated. That's going to be a very difficult problem institutionally. What are the various agency responsibilities, authorities? Is this the right way to do it and how is the public safety interest best served.

And the other is of course what we've

discussed extensively already, the policy for patient follow-up. What are we really trying to do? What is the scope? What is the extent of it? And I want to try and work that -- both of these issues, but especially that one on patient follow-up -- into the internal reviews and not simply sit back and wait for a one to two year external review.

CHAIRMAN SELIN: The first review or the second review?

MR. BERNERO: Into both, if I can, but we have a tough row to hoe there. I don't think it would be proper for the Commission to sit back and say, "Let an external body take a year or two to review it before we pursue the matter." I think it's timely that we do it ourselves. At least, we certainly want the independent view --

CHAIRMAN SELIN: Let me just say one thing to this, Bob. However you decide to do the policy thing, I think your first level review has got to at least ascertain what we do today, what we really do today.

MR. BERNERO: Exactly.

CHAIRMAN SELIN: As opposed to what the papers do today, with some critique there. Whether you'd want to raise the policy issues there or do your middle level internal review, I think, is open.

Commissioner Rogers?

I'm sorry, did you have anything further?

MR. BERNERO: No, no. That concludes it.

CHAIRMAN SELIN: Mr. Taylor, did you have any other --

MR. TAYLOR: We have nothing further.

CHAIRMAN SELIN: Commissioner Rogers?

COMMISSIONER ROGERS: Well, it's been a very helpful, I think, and detailed discussion.

I don't really have very much. I wonder if in any way you have considered the possibility -- I think the issue has been raised maybe in the Cleveland Plain Dealer, I don't know -- of the question of tracking chronically bad practitioners in this area and in any way we can or should play a role there in identifying those people, at least calling the attention to the proper authorities in these matters.

MR. BERNERO: Yes, we have, and we have a wrongdoer rule and I think Jim Lieberman is better qualified to explain what we have done. That's a fairly recent change.

MR. LIEBERMAN: We do have the wrongdoer rule. That provides for taking action against and tracking people who make a deliberate decision to violate requirements. Many of the problems that we see in the

medical area as well as other areas is not so much deliberate noncompliance but sloppy work.

COMMISSIONER ROGERS: Sloppiness, yes.

MR. LIEBERMAN: Lack of caring, lack of attention to detail.

We're considering, and this is truly at a very early stage of consideration, what can we do to get a better idea about radiation safety officers or authorized users who tend to have repetitive problems. There are Privacy Act considerations that we'll have to consider. There may be some other legal type issues, but we are planning to look into that matter.

COMMISSIONER ROGERS: Well, I'm glad to hear that.

The question of the National Academy of Sciences study, it seems to me that that's a very important activity to carry out, but it's also going to take some time. You've said that. I don't think we can wait for that. I think it will be a very valuable addition once it has taken place, but these things usually take several years. It's very hard to see how it could be done in less than two years, the way they normally operate at any rate. And by the time we would be able to incorporate any of the results of that, it's two to three years and I don't think we can wait for that

before we take serious account and stock of where we are and what we ought to be doing right now. So I think that's an excellent initiative, but I don't see any way in which we can wait for it.

I don't think I have any other questions or comments.

CHAIRMAN SELIN: Commissioner Curtiss?

COMMISSIONER CURTISS: I just have three specific questions.

First, picking up on Commissioner Rogers' question about wrongdoers, the situation that we typically encounter -- and I've seen this come up more in the context of reactor enforcement proceedings -- is a case where we get into a particular situation and somebody's engaged in conduct that troubles us and that also troubles the licensee and the licensee typically will release the individual. And when the enforcement package comes before us or comes before the Agency, that consideration, the individual is no longer employed by the licensee, is taken into account generally when the enforcement action is under consideration.

It might be worth taking a look at a case where we haven't proceeded all the way to a formal finding of wrongdoing but where the action is taken at an earlier stage, an individual is released. We recognize

that that's an important step that the licensee has taken and in fact our enforcement action takes account of that, but the individual has the potential for showing up at some other licensed facility, not a formal wrongdoer but nevertheless somebody that perhaps there ought to be a mechanism for us to at least inform those who are hiring these individuals and let them make their own judgment of the situation as we understand it. It might be worthwhile, as I say, in the context of what you're taking a look at, Jim, if you'd focus on that.

Second, the one area that you did not mention here that I'd just like to emphasize, my impression in looking at the University of Cincinnati and Riverside events is that in both of those cases it was astounding to see the degree of tension that had arisen between the RSO and those who were engaged in the conduct of authorized activities.

I guess what I would encourage you to do, based upon that and in view of I think our mutual experience that the RSO plays a critical role and where the RSO has established an effective working relationship within the licensed operation, that can go a long ways towards addressing some of the concerns that in the case of those two events we found were traceable at least in part to something that had arisen that created a great

deal of attention, tension, and lack of communication between the RSO and those engaged in the conduct of authorized activities.

I don't know whether that needs to be addressed in the context of our inspection activities or as a matter that you could or should take up in the internal review, but I'd like to see your thoughts on how we might improve or focus on that very crucial relationship.

MR. BERNERO: Well, from time to time in cases other than the two you mention we have situations of RSO either falling into neglect and not doing the job or the RSO being bypassed by the practitioners or users, especially in a large scope license. I can recall instances where we've gone after that as a characteristic of management breakdown.

COMMISSIONER CURTISS: That's a recipe for trouble.

MR. BERNERO: Safety management breakdown is a very serious problem, especially when they bypass, when they ignore the restrictions that the RSO tries to put on them.

COMMISSIONER CURTISS: I'd be interested in seeing your recommendations in the internal review that you have underway as to whether there are steps that need

to be taken to encourage or foster or whatever a much more productive working relationship between the RSO and the authorized users.

Dick?

MR. CUNNINGHAM: We are working on a guide specific to medical RSOs and we can incorporate some of these kinds of thoughts in that guide.

COMMISSIONER CURTISS: Okay. One final question going back to the notification of patients.

The QM rule requires that for those patients that are notified of misadministrations, which is every patient except for the ones where the doctor determines that it's not appropriate, that within 15 days the patient is to be notified in writing of that either through a summary of the event or through the report that's submitted to the NRC. Do we currently or do we have plans to audit the written reports that are prepared to ensure that the process of notifying the patient, except in those rare cases, is actually going on and notification is getting through to the patients?

MR. GLENN: Currently it's looked at as a part of the inspection process. If it's a special inspection looking at a particular misadministration, that may be looked at. In terms of an audit by the Headquarters group of the regions and how well that is

done, we have not done that.

I did have Mark Rottman, our other visiting medical fellow, look through the documents that we had available to us here in Headquarters. And the documents he was looking at, in the great majority of cases, the individual had in fact been informed on time. Now, the actual documents that were sent were not there and so we did not look at those.

COMMISSIONER CURTISS: Okay. It's pretty obvious from the discussion earlier that there's a legal obligation and it's reflected in this provision in the QM rule that the patient be notified. It might be worth looking at the feasibility in the conduct of your inspections of conducting an audit specifically on the patient notification question. It was one of the main points in the Cleveland Plain Dealer series and a source of some vulnerability if the patients aren't being notified.

That's all I have.

COMMISSIONER REMICK: On page 2 of the SECY -- you don't have to refer to it, it indicates that the causes of these administrations, talking about therapeutic misadministrations, can be characterized by insufficient supervision, deficient procedure or failure to follow procedures, inattention to detail and

inadequate training. In a briefing that Commissioner Curtiss and I had with the staff back some weeks ago in this general area, I asked the question if it was possible to take the misadministration data and break it down into those bins. I thought it would be helpful. The fact that I don't see it here, I assume the answer is that you were not able to do that. Is it a question of not being able to do it at all or in the time span that we were -- time.

MR. CUNNINGHAM: It was the time.

COMMISSIONER REMICK: But you do have the data. It could be broken down that way.

MR. TAYLOR: We'll try to do that.

MR. BERNERO: But a word of caution. I would wonder as to the validity of it. Remember we're dealing with relatively small numbers here.

COMMISSIONER REMICK: And a little bit of data is better than no data in this case.

MR. BERNERO: Yes. But we do have --

COMMISSIONER REMICK: It's just to give me an -- I'm trying to get some feeling for it.

MR. BERNERO: -- the ability because actually we made this summary characterization from the data.

COMMISSIONER REMICK: Yes.

MR. BERNERO: We just didn't sort it out.

COMMISSIONER REMICK: I'm just trying to get a feeling for how it breaks down.

MR. THOMPSON: I'll add one thing, that we do have a contract with the Idaho National Engineering Laboratory looking at misadministrations and they sent out a team to look at about a half dozen misadministrations that occurred in the last year. In May we're expecting a document from them that will describe the root causes and the lessons learned from those particular studies. So, we'll have a small sample that will do that.

COMMISSIONER REMICK: Okay. And I appreciate your saying you will get that data. I realize that there are five of us here throwing out many ideas for you to do. We do have a process called an SRM.

MR. TAYLOR: We'll look forward to that, sir.

COMMISSIONER REMICK: I want to get the Chairman's attention here. Chairman, what is your intention here? Will we be issuing an SRM based on this meeting or do you foresee that --

CHAIRMAN SELIN: No, I would prefer not to do one based on this meeting because basically what we have is a lot of individuals saying, "Here are things

that are important to me," and the staff has already developed a project plan for going ahead. So, I assume that they will look at the transcript and the discussions and take these into account as they go on and then we have two more meetings in the immediate future.

MR. BERNERO: Yes. The subsequent meetings are quite important for the process.

COMMISSIONER REMICK: Okay.

CHAIRMAN SELIN: So, really I was thinking about what would an SRM say and it would be a whole lot of Commission X said this and Commissioner Y said that, you know, look at these points as opposed to here's real guidance.

COMMISSIONER REMICK: Okay. I say lots of luck to the staff then. But I do appreciate it. It's been an excellent briefing from my standpoint and I really appreciate it.

COMMISSIONER ROGERS: Could I just ask a question? Commissioner Remick talked about page 2. Could somebody tell me what a deterministic health effect is? I have an idea, but --

MR. BERNERO: The usual term is non-stochastic, meaning it's not a cancer that showed up from a low level of radiation in the past that is most probably due to that radiation or is probably due to it.

But it's like someone gets 1,000 rad to the thigh and it leaves a very visible deterministic effect. You know, it burns a hole in your thigh.

MR. CUNNINGHAM: Where you have tissue damage or organ function damage, deterministic effect there. Acute effects as opposed to --

COMMISSIONER ROGERS: It's really a short term --

MR. CUNNINGHAM: Yes, as opposed to the--

COMMISSIONER ROGERS: Short-term evidence really of effect.

MR. CUNNINGHAM: Yes, as opposed to the stochastic effects which are random cancer induced -- radiation-induced cancers.

COMMISSIONER ROGERS: Okay.

CHAIRMAN SELIN: Commissioner de Planque?

COMMISSIONER de PLANQUE: I'll be quick since we've discussed most of the major issues on my mind. I would just say that, Bob, you alluded to the fact that you have looked at some comparative numbers in other practices of medicine and I would be grateful for seeing those because I think it really helps us to have some perspective here. I'll be back to you with some detailed questions too.

But I would like to thank you all very much

for the effort in putting this together. I know you did it under very difficult and trying circumstances in a very short period of time and I think it gives us an excellent -- he's laughing at very short period of time. You can go to sleep now. It really helps us to deal with these issues.

CHAIRMAN SELIN: I'd like to make a couple wrap-up remarks, if I might.

The first is just some background. It is true we're talking about a relatively small number of therapeutic administrations. If I figure this out right, it's about 20 per year in the states that we regulate and if it were the case that the number of misadministrations, proportional number of licensees, that would be about 60 or so nationwide. So, just in terms of therapeutic administrations, we're not talking about a huge problem. Most specifically, the newspapers have been criticized for scaring people off meetings. Nobody should conclude from this that sick people with cancer should not go to hospitals and get therapeutic treatment because of the probability of a misadministration. But I don't think that was the intention of the articles. It's not certainly the intention of our review. I think we noticed ourselves last summer and the press has certainly sharpened our

attention and given some real flesh and bones to some theoretical problems that there are weaknesses in these programs. We see a lot of weaknesses in the control programs and we see weaknesses or inconsistencies in the way we regulate these programs. So, the conclusion shouldn't be therapeutic radiation is bad for your health, but rather there is room for improvement both in the licensee's actions and most particularly in our actions and our relations with the agreement states. I think that's the principal conclusion.

Then from the presentations that we've had today, we see a range of things to be investigated, places where we need better to determine what the current situation is, places where management changes can be made, places where policy questions have to be brought up and most specifically places where we know a lot about what we think the policy is, but we perhaps could learn a little more about what's actually happening, the feedback on the empirical information. There was a lot of work done. I sort of missed the point as to why it's so funny that it was done in a short time, but there was a big paper done on a very timely basis that was quite informative. As you can see, the Commission is very interested in this work. You've sparked a lot of discussion, a lot of speculation, and I hope that your

reviews will be able to systematically go through this speculation and the questions that you put to yourselves and come up with systematic answers. Not just one of these or one of those, but an overall approach that says, "Here's a good approach and therefore here are how various questions get answered."

So, we look forward to your work and as affected by the follow-up in the next couple of weeks. So, this is a very good start on what's been a longstanding sort of nagging problem.

Thank you very much.

MR. BERNERO: Thank you.

(Whereupon, at 4:26 p.m., the above-entitled matter was concluded.)