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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.)

CERTIFICATE OF TRANSCRIBER

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

TITLE OF MEETING: BRIEFING ON STATUS OF MEDICAL USE ACTIVITIES

PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: JANUARY 22, 1993

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

Carol Lynch

Reporter's name: PETER LYNCH

MEDICAL USE PROGRAM RELATED TO PREVENTION OF MISADMINISTRATIONS

ROBERT M. BERNERO
CARLTON C. KAMMERER
VANDY L. MILLER

JANUARY 22, 1993

MEDICAL USE PROGRAM RELATED TO MISADMINISTRATIONS

1) KEY MILESTONES IN THE CURRENT MEDICAL USE REGULATORY PROGRAM

2) EFFORTS TO IDENTIFY, EVALUATE & PREVENT MISADMINISTRATIONS

3) AGREEMENT STATE PROGRAMS

4) MISADMINISTRATION ISSUES RAISED BY <u>PLAIN DEALER</u>

MEDICAL USE PROGRAM RELATED TO MISADMINISTRATIONS (CONTINUED)

5) RE-EVALUATION INITIATIVES

6) OBSERVATIONS FOR FURTHER CONSIDERATION

KEY MILESTONES IN THE CURRENT MEDICAL USE REGULATORY PROGRAM

- 1979 MEDICAL POLICY STATEMENT
  - RECOGNIZE BUT MINIMIZE INTRUSION

- 1980 MISADMINISTRATION REPORTING RULE
  - NOTIFICATION OF REFERRING PHYSICIAN

- 1992 QUALITY MANAGEMENT PROGRAM AND MISADMINISTRATION RULE
  - FORMAL PROGRAM TO MINIMIZE ERRORS
  - REVISED DEFINITION

EFFORTS TO IDENTIFY MISADMINISTRATIONS

- REPORTING REQUIREMENTS
- REVIEW OF RECORDS DURING ROUTINE INSPECTIONS
- INTERVIEWS OF LICENSEE STAFF

EFFORTS TO EVALUATE MISADMINISTRATIONS

- SPECIAL INSPECTIONS
- MEDICAL CONSULTANTS
- REVIEW LICENSEE'S REPORTED EVALUATIONS

EFFORTS TO PREVENT MISADMINISTRATIONS

- REGULATORY REQUIREMENTS
- INSPECTION FOR SAFETY AND COMPLIANCE
- ENFORCEMENT PROGRAM
- TRAINING

ENFORCEMENT PROGRAM

- ENCOURAGE IDENTIFICATION AND CORRECTION OF VIOLATIONS
- DETER VIOLATIONS FROM INITIALLY OCCURRING
- ESCALATED ENFORCEMENT
- RECONSIDER CIVIL PENALTY ASSESSMENT PROCESS

CLEVELAND PLAIN DEALER SERIES

- NRC OVERSIGHT
- FOLLOW-UP OF PATIENTS SUBJECT TO MISADMINISTRATION
- EXPANSION OF NRC REGULATORY PURVIEW

NRC AND AGREEMENT STATE OVERSIGHT OF LICENSES

- TRAINING AND QUALIFICATIONS OF PERSONNEL
- INSPECTION ACTIVITIES
- ENFORCEMENT/INVESTIGATION ACTIVITIES

FOLLOWUP OF PATIENTS

- REQUIRED NOTIFICATION OF NRC
- REQUIRE REFERRING PHYSICIAN/PATIENT NOTIFICATION
- MEDICAL CONSULTANTS
- NEED TO DEFINE PURPOSE AND EXTENT

EXPANSION OF NRC PURVIEW

- PLAIN DEALER PROPOSED NRC REGULATE ALL MEDICAL USES OF RADIATION, ESPECIALLY LINEAR ACCELERATORS

- ISSUE OF NARM RECENTLY CONSIDERED FOR DISCRETE SOURCES

RE-EVALUATION INITIATIVES

- TECHNICAL EVALUATIONS
  - RISK ANALYSIS AND HUMAN FACTORS (CONTRACTS)
  - INCIDENT INVESTIGATION REPORT ON BRACHYTHERAPY INCIDENT
- MANAGEMENT EVALUATIONS

INTERNAL MANAGEMENT PLAN

- CLARIFICATION OF NRC'S ROLE
- FOCUS ON SAFETY ISSUES
- PROVIDE OPERATIONAL FLEXIBILITY
- MAINTAIN EFFECTIVE COMMUNICATION

ADDITIONAL INDEPENDENT AUDITS

- REVIEW BY NRC SENIOR MANAGER - EFFECTIVENESS OF EXISTING PROGRAM

- REVIEW BY EXTERNAL GROUP - ADEQUACY AND APPROPRIATENESS OF CURRENT FRAMEWORK

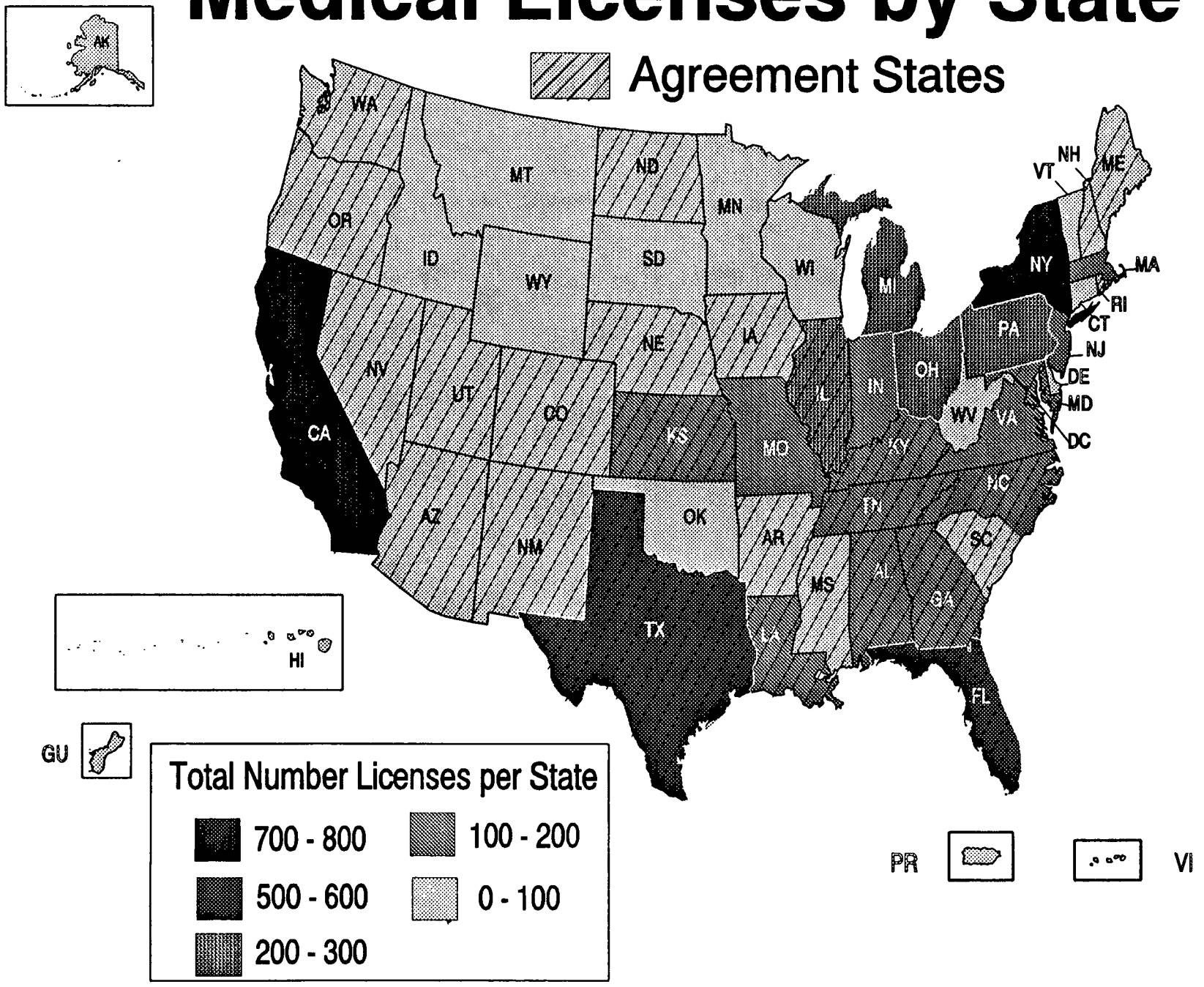
OBSERVATIONS FOR FURTHER CONSIDERATION

- GENERAL MANAGEMENT
  - ANALYSES OF EFFECTIVENESS
- EVALUATE REGULATION OF DEVICES
- POLICY FOR PATIENT FOLLOWUP

AGREEMENT STATE PROGRAMS

1. SCOPE OF AGREEMENT STATE PROGRAM
2. ADEQUACY AND COMPATIBILITY
3. AGREEMENT STATE REVIEWS
4. REPORTING AND EXCHANGE OF INFORMATION
5. REGIONAL RESULTS OF REVIEWS
6. OBSERVATIONS/RECOMMENDATIONS FOR FUTURE REVIEW

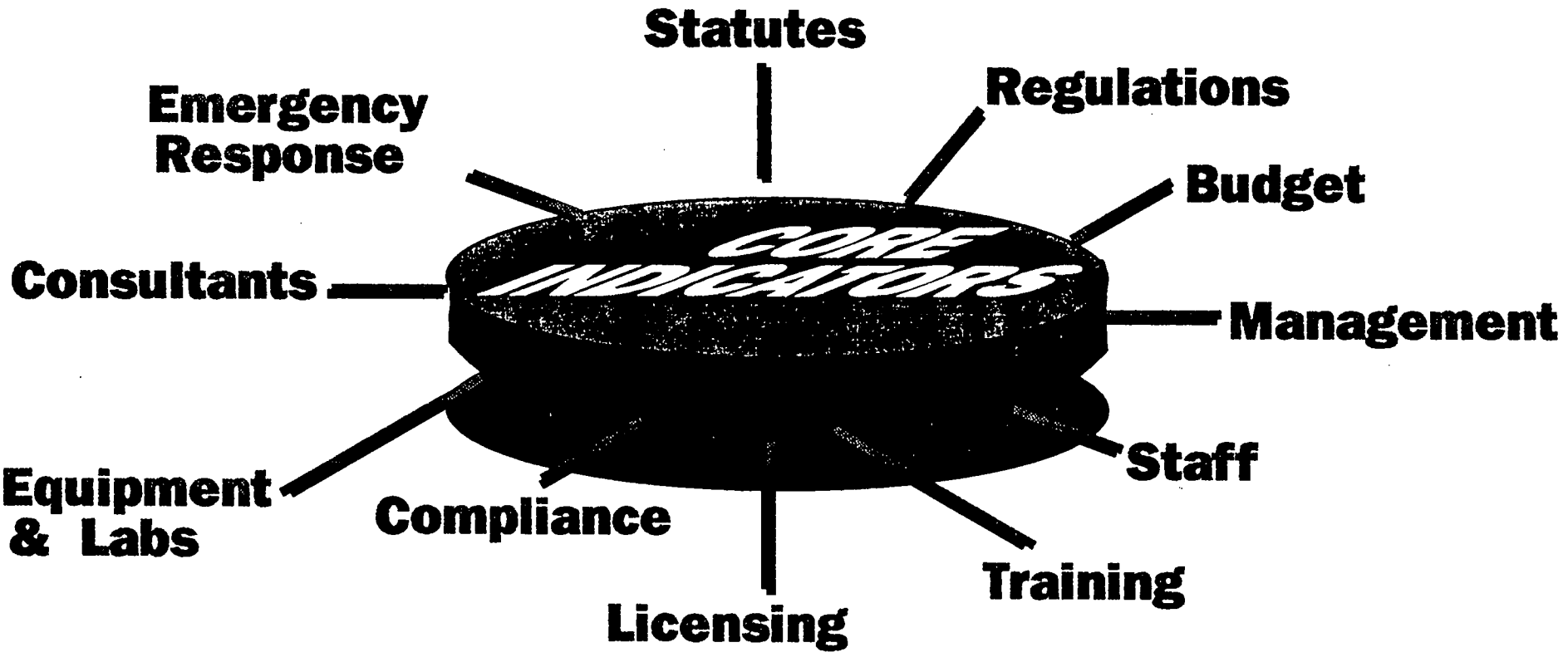
Medical Licenses by State



ADEQUACY AND COMPATIBILITY

- Agreement commits State to best efforts to maintain adequate and compatible program (Section 274d. (2))
- Criteria and Guidelines to evaluate States approved by Commission and published in Federal Register
- OSP performs routine reviews of Agreement States every 18-24 months and visits Agreement States every year
- NRC maintains continuous oversight of and provides technical assistance to Agreement States

CORE INDICATORS
GUIDELINES CRITERIA



AGREEMENT STATE REVIEWS

- Inspection Findings
  - Pre-licensing Visits
- Enforcement Findings
- Investigation Findings
- Events Reporting
  - Misadministrations

REPORTING AND EXCHANGE OF INFORMATION

- Events Reporting and Briefings
- PN's, Information Notices and Bulletins
- Conferences
- Early and Substantive Involvement in Rulemakings

RECENT AGREEMENT STATE REVIEWS
REGIONAL RESULTS

REGION	#AGREEMENT STATES	#A & C	#A	# FW
I	5	2	1	2
II	8	5	2	1
III	2	1		1
IV	9	4	4	1
V	5	3	2	
TOTAL	29	15	9	5
		(52%)	(31%)	(17%)

NOTE: DATA CURRENT AS OF 1/1/93. A&C - ADEQUACY AND COMPATIBILITY, A - COMPATIBILITY , FW - FINDING WITHHELD

OBSERVATIONS/ RECOMMENDATIONS FOR FUTURE REVIEW

- Compatibility issue still to be determined

  - levels of investigations
  - levels of enforcement

- Wrongdoer Rule as it applies to Agreement States

- Less than three year actions for significant rules

- National Database for incidents and misadministrations

- Review Policy on Withholding Adequacy and Compatibility Findings

January 19, 1993

POLICY ISSUE
(Information)

SECY-93-007

For: The Commissioners

From: James M. Taylor
Executive Director for Operations

Subject: ASPECTS OF THE NATIONAL MEDICAL USE PROGRAM RELATED TO PREVENTION OF MISADMINISTRATIONS

Purpose: To provide the Commission with information about the status of the national (NRC and Agreement States) medical use program, regarding prevention of serious radiation injury or death caused by medical misadministrations, and current activities related to this aspect of its regulatory program. Particular attention is directed toward medical radioisotope therapy as the principal practice in which serious radiation injury or death has been observed.

Summary: This paper provides background and discusses issues associated with the current national material regulatory practice for those aspects of the medical use program related to prevention of misadministrations. Several major issues, currently under review by NRC and Agreement State staffs, were recently raised in a series of articles, dated December 13-17, 1992, in the Cleveland Plain Dealer and are discussed herein with associated implications. These include: 1) effectiveness of NRC's and Agreement States' oversight of medical use of byproduct material; 2) followup of patients subject to misadministrations; and 3) expansion

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NOTE: TO BE MADE PUBLICLY AVAILABLE AT COMMISSION MEETING ON 1/22/93

of NRC's regulatory purview. Other program areas discussed are: training and qualifications and NRC budget resources for NRC and Agreement State personnel involved in the medical use program; and NRC's and Agreement States' inspection, enforcement, and investigation activities. A brief description of the staff medical management plan as well as the goals of two independent audits, internal and external, of the medical use program is provided. The staff has provided preliminary observations and recommendations on specific issues for future consideration.

Background: NRC currently administers approximately 2000 licenses for the possession and use of byproduct materials for medical applications, and Agreement States administer approximately 4500 licenses. The medical use of byproduct material has experienced infrequent overexposures of patients resulting in deterministic health effects; NRC medical consultants concluded that some of these misadministrations directly resulted in or contributed to the cause of death. These incidents have occurred in radioisotope therapy (i.e., teletherapy, brachytherapy, and radiopharmaceutical therapy) and with diagnostic uses of iodine-131 in excess of 30 microcuries. A staff summary regarding NRC-confirmed patient deaths associated with radiation overexposure has been transmitted to the Commission in a memorandum dated January 8, 1993, entitled "Patient Deaths Attributed to Medical Radiation Exposure."

The medical application of radioactive material for therapy may involve the deliberate exposure of individuals to high doses of radiation (e.g., 5000 rad to a tumor volume). Errors in the administration of a therapeutic quantity of radioactive material can result in misadministrations to the patient, as well as unintended exposure of licensee personnel and members of the general public. The causes of these misadministrations may be characterized by insufficient supervision, deficient procedures or failure to follow procedures, inattention to detail, and inadequate training. Over the years, NRC has modified its medical use regulatory program to add specific requirements and to increase its oversight to reduce the likelihood of misadministrations. Two of these requirements, the 1987 misadministration reporting criteria and the 1992 quality management program and misadministration rule, are a matter of compatibility for Agreement States.

KEY MILESTONES IN THE DEVELOPMENT OF THE CURRENT REGULATORY PROGRAM TO HELP REDUCE THE LIKELIHOOD OF OCCURRENCE OF MISADMINISTRATIONS:

In SECY-92-175, "Annual Report on Medical Use Program," the staff identified several key milestones or turning points in the evolution of the entire medical use program. Specifically, the following three milestones reflect NRC's policy and requirements for the identification and reduction of errors resulting in misadministrations.

o 1979 Medical Policy Statement

This policy addresses the Commission's general intention regarding the regulation of the medical uses of radioisotopes. The Commission stated: 1) NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public; 2) NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate; and 3) NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine. The Commission applies this policy to development of regulations governing the medical use program, licensing, and to the development of related inspection and enforcement policies, although the final regulations take precedence over the policy statement.

o Misadministration Reporting Requirements

NRC published a proposed rule, in 1973, to require misadministration reporting. Between 1976 and 1979, NRC staff was made aware of several incidents, some of which contributed to deaths of patients. Because of an error by licensee personnel in the calibration of a teletherapy unit at Riverside Methodist Hospital in Columbus, Ohio, more than 400 individuals were exposed. These incidents ranged from minor to serious errors involving teletherapy and brachytherapy applications. In response, NRC amended its regulations to require activities intended to reduce the likelihood of occurrence of errors. These amendments included: 1) a rule to require annual calibration and monthly spot-checks of teletherapy units (44 FR 1722); and 2) a rule requiring surveys of patients after the removal of temporary implants (43 FR 55345). The Agreement States were encouraged to adopt these regulations, but no degree

of uniformity between NRC and the States was required. The Conference of Radiation Control Program Directors, Inc. has developed suggested State Regulations and a number of Agreement States have adopted them into their rules.

The 1973 proposed rule to require misadministration reporting was withdrawn because of the elapsed time, and another proposed rule was published in 1978. The final misadministration reporting rule became effective in November 1980. For various reasons, including the different methods of enacting State regulations, this rule was not made a matter of compatibility for the Agreement States. The rule required misadministration reporting and recordkeeping and, for therapy misadministrations, notification of the referring physician and patient or responsible relative (or guardian), unless the referring physician personally informed the licensee either that he would inform the patient, or that, in his medical judgment, telling the patient or patient's responsible relative (or guardian) would be harmful to one or the other, respectively. The Commission's stated purpose in requiring misadministration reports to NRC was to identify their causes in order to correct them and prevent their recurrence. This would be accomplished by notifying other licensees of generic issues, and, if appropriate, changing NRC regulations to prevent specific types of errors. In addition, the Commission noted that the misadministration recordkeeping and reporting requirement was necessary to protect patients and stressed the importance of notification of the referring physician and patient.

In 1986, 10 CFR Part 35 was revised (effective April 1987), which included a change in the criteria for reporting diagnostic misadministrations. This revised rule was the first time misadministration reporting was made a matter of compatibility for Agreement States, effective April 1990. The "Quality Management Program and Misadministration" rule, which became effective on January 27, 1992, revised the definition of, and reporting requirements for, diagnostic and therapeutic misadministrations of byproduct material. The Commission restated the importance of the requirement to notify the patients so that they, in consultation with their personal physician, are allowed to make timely decisions regarding remedial and prospective health care. The January 1992 revised rule will become a requirement for compatibility for Agreement States in January 1995. Results of misadministration analyses have been published in NRC reports and information notices, summarized in medical publications and discussed in workshops with NRC medical licensees and Agreement States.

Enclosure 1 contains statistical information on the types (i.e., diagnostic and therapeutic) and number of misadministrations for different categories of NRC licensees (1989-1991). Over this period the number of diagnostic misadministrations reported by NRC licensees has remained essentially constant. Over the past 10 years, the average number of reported diagnostic misadministrations was 403 per year. Reported therapeutic misadministrations, however, increased from 10 in 1989 to 24 in 1990, and then declined to 19 in 1991. The 1990 and 1991 numbers are higher than the 10-year average of 11 per year, cited in NUREG-1272, "Office for Analysis and Evaluation of Operational Data 1991 Annual Report." As noted in SECY-91-139 (Enclosure 2), this increase could be attributed to several factors, including: (1) an increase in the number of new and complex brachytherapy procedures performed, including remote afterloading procedures; (2) increased licensee awareness of NRC reporting criteria and the importance of timely reporting; and (3) escalated enforcement actions against licensees for failure to report. Although the data have not been characterized in this paper, a detailed analysis of trends in, and causes of, misadministrations, was previously discussed in enclosure 1 of SECY-91-139. In addition, enclosure 3 provides the 1991 misadministration information, for four categories of licensees, by individual State.

o 1992 Quality Management Program and Misadministration Rule

NRC amended its regulations, effective January 27, 1992, to require implementation of a quality management (QM) program, to provide high confidence that byproduct material or radiation from byproduct material is administered as directed by an authorized user physician. The performance-based rule was to enhance patient safety while allowing the flexibility necessary for proper medical care. The rule amended regulations for therapeutic administrations of radiopharmaceuticals, therapeutic application of radiation from sealed sources, and the administration of radioactive sodium iodide. Licensees are required to have written policies and procedures to meet five specific objectives: 1) that, prior to administration, a written directive is prepared; 2) that, prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive; 3) that final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives; 4) that each administration is in accordance

with the written directive; and 5) that any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

Discussion: CURRENT ISSUES AND REGULATORY PRACTICE:

o Cleveland Plain Dealer Series

The series of articles in the Cleveland Plain Dealer raised the question of the extent of NRC's and Agreement States' knowledge of incidents as well as several major issues currently under review by NRC including: A) effectiveness of NRC's oversight; B) followup of patients subject to misadministrations; and C) expansion of NRC's regulatory purview. The articles allege that NRC was unaware of the extent of some misadministrations (and/or failed to take appropriate actions in response) in which deaths and serious injuries resulted. Enclosure 4 contains a summary of reports on the incidents identified in the Plain Dealer series. That analysis provides information, regarding licensees under NRC and Agreement State purview, on each incident that identified a patient in addition to any followup action taken by NRC and the licensee.

A. NRC Oversight

The Cleveland Plain Dealer articles criticized NRC for devoting only a small percentage of resources to the medical use program. Further, the Plain Dealer concluded that fines are low and doctors implicated in criminal conduct are not disciplined. NRC licensees were accused of not reporting misadministrations in the time required by the regulations. Also, it is stated that NRC and Agreement States often fail to share information.

NRC exercises oversight of medical use licensees through its inspection and enforcement of licensee implementation and compliance with its regulatory program. NRC does not have direct management control or day-to-day contact with medical licensees. The following paragraphs discuss the application of NRC and Agreement States resources to oversight of medical activities.

1. Training and Qualifications of Personnel and Budget Resources

NRC Medical Use Program: The FY93 nuclear materials safety budget includes 41 direct staff[1] full-time equivalents (FTE) involving effort by 74 staff individuals and $1000K in program support funding, to support medical program activities. The program currently includes 74 technical staff professionals exclusive of managerial positions, nearly all of whom have bachelor's degrees, primarily in health physics or radiation protection; 22 have master's degrees; and an additional 8 have doctoral degrees. Approximately half of the staff have prior work experience in a medical program. The staff has, on average, 6 1/2 years of NRC experience. In addition, job-related didactic technical training is provided to NRC staff and may include: 1) general health physics; 2) diagnostic and therapeutic nuclear medicine; 3) teletherapy and brachytherapy; 4) whole body counting/internal dosimetry; and 5) inspection procedures.

NRC nuclear materials license reviewers and inspectors are expected to complete a regional journal before they are given their licensing signature authority or inspector qualifications. These journals typically include sections covering: 1) administrative matters; 2) relevant parts of the Code of Federal Regulations; 3) the Atomic Energy Act and Energy Reorganization Act; 4) the NRC Inspection Manual (focus on nuclear material program); and 5) relevant "Standard Review Plans."

New licensing reviewers receive direction and review from senior reviewers and supervisors in their earliest assignments. Licensing signature authority is granted after a sufficient number of assisted and independent reviews for each of the various categories of materials licensees. Similarly, junior inspectors initially accompany senior inspectors as part of the qualification process to conduct independent inspections.

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[1] This number includes one Medical Visiting Fellow.

Agreement State Program[2]: Commission training for States was specifically authorized by Congress in 1959, when Section 274 of the Atomic Energy Act was enacted and signed into law. Congress recognized such training was needed to assist States to prepare for entering into an Agreement with the Atomic Energy Commission (now NRC) and to maintain programs that are adequate to protect public health and safety and are compatible with the NRC's program.

State radiation control personnel regularly attend NRC-sponsored training, to improve their technical and administrative skills and, thus, their ability to maintain high quality regulatory programs. In FY87, NRC provided training to students in its State training program with a budget of $522,000. In FY92, NRC budgeted $816,000 for State training. The need for this training has increased as the number of Agreement States has increased, as more States express an interest in becoming an Agreement State, as changes in technology regarding use of radioactive materials and new regulatory initiatives are being developed, and as staff turnover occurs (enclosure 5 provides the annual training budget and the number of State personnel trained each year).

NRC training for States includes: 1) basic training in the fundamentals of radiation protection; and 2) procedural instruction in licensing, inspection, and other radiation protection regulatory activities. NRC offers courses such as "Health Physics" (5 weeks), "Radiation Protection Engineering", and "Medical Uses of Radionuclides." In addition, workshops are conducted throughout the year, as the need arises, in special topics, such as radiopharmacy rulemaking, patient release criteria, extension of QM rule to pregnancy and breastfeeding, and low-level waste (LLW) regulation. Improvements and new initiatives in the NRC materials program (such as Part 20, Part 35 and LLW) necessitate an increased need for training of Agreement State staff, as well as NRC staff.

Several courses are held jointly with NRC staff, to allow licensing and inspection personnel from Federal and State government to exchange information and experience. Some of the courses are contracted for and others are developed and presented by the Office of State Programs (OSP) staff, with

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[2] The discussions regarding Agreement States is of the materials program as a whole and not specific to the medical use program, unless otherwise stated.

the assistance of other NRC and Agreement State staff (e.g., "Licensing" and "Inspection Procedures").

Agreement States do not depend solely on NRC for training of staff. States provide on-the-job training for their staff in areas such as administrative practices, radiation control, radiological emergency training, and LLW disposal. In addition, training courses provided by the Environmental Protection Agency, the Food and Drug Administration (FDA), and the Federal Emergency Management Agency are used by State Radiation Control Programs whenever possible; however, other Federal agency training has limited applicability to Agreement State programs. In addition, some State employees accompany other Agreement States on inspections, or visit NRC headquarters or NRC regional offices, to obtain on-the-job training in the licensing and inspection of radioactive materials.

State in-house training efforts are neither substitutes for, nor duplications of, NRC training. They are mutually complementary. Taken as an integrated whole, the training helps ensure that State staffs are suitably qualified to carry out Agreement State programs in accordance with the Commission Policy Statement for adequacy to protect public health and safety.

Qualifications of Agreement State Staff: NRC guidelines call for professional staff in the Agreement States to hold a bachelor's degree or equivalent training in the physical and/or life sciences. Additional training and experience in radiation protection for senior personnel, including the director of the radiation protection program, should be commensurate with the type of licenses issued and inspected by the State. All of the Agreement State program managers or others in key positions (Program Director, (Program Administrator, and Division Chiefs) have bachelor's degrees in the physical and/or life sciences; 19 have Master's degrees; and 7 have doctoral degrees. At the time an agreement is signed, all qualifications of the Agreement State staff, including applicable course work, are listed in the Federal Register. As part of their initial training, new State inspectors are accompanied by NRC staff. In addition, NRC examines qualifications of the new staff and recommends additional training in certain areas, as appropriate.

2. Inspection Activities

The purpose of inspections is to determine if licensed programs are conducted in accordance with NRC requirements and specific provisions of the license, and if licensed activities are conducted in a manner that will ensure the health and safety of workers and the general public. Inspectors are instructed to ascertain compliance by direct observation of work activities, interviews with workers, and observation of workers performing tasks regulated by NRC (e.g., radiation surveys). Additionally, information in licensee records is reviewed to determine compliance with recordkeeping and other requirements.

Currently, each licensed program is categorized by a program code, which determines the priority, or frequency of routine unannounced inspections. In addition, announced or unannounced special inspections may be performed to determine the circumstances surrounding a particular incident. The inspection frequency for medical use licensees varies from once each year (e.g., broad-scope medical programs) to once every 4 years (e.g., private practice-custom) depending on the scope of the licensed program. Generally, the larger the scope of, or the more hazardous the licensed activities, the more frequent the inspection.

Inspection frequency is also a function of available financial and personnel resources, and thus is periodically re-evaluated. Therefore, refocusing inspection efforts by increasing inspection frequency for certain program codes requires additional resources for implementation. Enclosure 1 presents data, for 1989-91, on the number of licenses, inspection frequency, number of inspections, and number of diagnostic and therapeutic misadministrations for the four major categories of medical licenses: medical broad-scope licenses; community hospitals; private practices and clinics; and teletherapy licenses. Over this period, the number of medical licenses in these four categories declined by 3 percent from 2252 licenses to 2186 licenses. Since 1991, the number of these licenses has declined an additional 8 percent to 2002 licenses (the staff notes that the amendment of 10 CFR Part 171 to accommodate full-cost recovery was implemented in 1991 and may have contributed to this decrease). The inspection frequency was increased for most major categories of medical licensees in 1989 and for community hospitals in 1991. The number of inspections conducted by NRC staff for broad scope, community hospital,

private practice/clinics, and teletherapy licenses increased by 30 percent from 859 inspections in 1989 to 1118 inspections in 1991.

Agreement State Program: In general, the 29 Agreement State Radiation Control Programs (RCPs) maintain an inspection program adequate to assess licensee compliance with State regulations and license conditions. The RCP maintain statistics which are adequate to permit Program Management to assess the status of the inspection program on a periodic basis. There is at least semiannual inspection planning for the number of inspections to be performed, assignments to senior and junior staff, assignments to regions, identification of special needs and periodic status reports. When backlogs occur, the Programs develop and implement plans to reduce the backlog. The plans identify priorities for inspections and establish target dates and milestones for assessing progress. The plans are reviewed by OSP staff. With regards to inspection frequency, the Agreement States must inspect at a frequency that is no less than NRC. In addition, some Agreement States inspect more frequently than NRC. Enclosure 1 also presents data on the number of licenses and number of inspections in Agreement States.

3. Enforcement and Investigation Activities

The purpose for taking enforcement actions against medical licensees is the same as for other NRC licensees and is described in the NRC Enforcement Policy. There are two primary purposes for escalated enforcement actions: 1) to encourage the prompt identification and lasting correction of violations; and 2) to deter violations from initially occurring. An enforcement program with deterrence, including sanctions and the associated negative publicity, is important because it may provide an incentive to a licensee to expend the effort and resources to improve its performance in advance of an NRC inspection.

A graduated approach to sanctions is used, based on the Severity Levels of the violations which are described in section IV of the Enforcement Policy and its eight supplements. The threshold for taking escalated enforcement action is generally any violation categorized at Severity Level III. In the medical area, this Severity Level is frequently reached, based on: overexposures or substantial potential for an overexposure; loss of control or improper disposal of other than insignificant types or quantities of radioactive material; misadministrations resulting from

failure to follow the procedures of the QM program or failure to report a misadministration; breakdown in the control of licensed activities based on recurring violations or numerous violations that demonstrate a lack of attention to licensed activities; or willful violations. These types of violations are described in the examples found in Supplements IV, VI, and VII of the Enforcement Policy. Enclosure 6 contains statistics for escalated enforcement cases for Calendar Years 1989-1991.

As to current activities, in SECY-92-395, "Proposed Change to the General Statement of Policy and Procedure for NRC Enforcement Actions, 10 CFR Part 2, Appendix C," the staff has proposed changes to the examples for categorizing misadministrations, in Supplement VI, to focus more on the root cause of misadministrations. This change would place more emphasis on programmatic weaknesses (i.e., deficiencies in such things as procedures, supervision, staffing, or training), rather than the isolated actions of a single individual, without the presence of management or programmatic weaknesses. However, even in the absence of such weaknesses, escalated action would be taken if there were a death or serious injury caused by the misadministration. All cases involving violations of the Quality Management rule, including misadministrations, are being reviewed by the Office of Nuclear Material Safety and Safeguards (NMSS) and the Office of Enforcement, to ensure consistency of approach. If the Commission approves the changes to the Severity Levels, these reviews will be especially important in cases involving programmatic weaknesses, to ensure consistency of approach.

The staff is also considering changes to the assessment process. Currently, Table I of the Enforcement Policy designates a base penalty for each type of licensee. Medical institutions have a base penalty of $5000 and individual doctors or clinics have a base penalty of $1000. However, it is recognized that, within these classes of licensees, there is a wide range of sizes and abilities to pay. As a result, the amounts of the civil penalties do not, in themselves, have much deterrent value[3] with larger licensees. While it is clear that licensees wish to avoid

[3] The deterrent value is the focus here because the current sanctions in the vast majority of cases have been effective in gaining lasting corrective action once NRC identifies the violations. The experience in appearing before NRC in an enforcement conference, receiving the civil penalty action, and the attention generated by adverse publicity has resulted in relatively few repeat violations for several years after an escalated action.

the negative publicity associated with the civil penalty process as much as the actual dollar amount, more substantial base penalties may, due to the financial burden, provide additional deterrence by encouraging licensees to review their programs, hire consultants, or increase staff to better comply with requirements.

In regard to civil penalties, the staff has recently solicited the opinion of the Advisory Committee on Medical Uses of Isotopes (ACMUI), regarding civil penalties. The ACMUI's consensus was that the dollar amount of most civil penalties is relatively small when compared to the total budgets of most medical licensees, especially institutional licensees, and thus is not likely to constitute an effective deterrent. The associated press release was seen as the more effective deterrent, but, according to the ACMUI, concern over the negative publicity associated with the press release may cause licensees not to comply with the reporting requirements. Some ACMUI members stated that instituting "probationary" periods, or putting a facility on notice of the potential loss of its license for major programmatic problems would be a more effective deterrent. The staff will consider those views in developing recommendations to revise the assessment process.

There have also been several misadministrations where the Office of Investigations (OI) has investigated the events surrounding the misadministration. Since 1985, there have been twenty OI investigations related to medical misadministration with 9 cases substantiated. Synopses of the OI cases involving misadministrations are provided in Enclosure 7.

Agreement State Program: Most Agreement States have provisions for the levying of monetary penalties. Normally, enforcement letters are issued within 30 days after inspections and use appropriate regulatory language clearly specifying all items on noncompliance and health and safety matters identified during the inspection and referencing the appropriate regulation or license condition being violated. Enforcement letters specify the time period for the licensee to respond indicating corrective actions and actions taken to prevent recurrence (normally 20-30 days). Most States have written procedures for handling escalated enforcement cases of varying degrees. While the Agreement States enforcement program is reviewed for adequacy during the biennial reviews, the investigation program is reviewed for status and general programmatic information. Impounding of material is done in accordance with State administrative procedures and opportunity for hearings are provided to

ensure impartial administration of the radiation control program. Enclosure 6 includes statistics for enforcement cases and investigations in Agreement States. The Agreement States also conduct investigations of misadministrations, as they believe are warranted.

4. Agreement State Adequacy and Compatibility Reviews

As part of an agreement whereby NRC relinquishes its regulatory authority for source, byproduct, and special nuclear material in less than critical quantities, and the State assumes that authority, a commitment is made by the State to use its best efforts to maintain a program that is adequate to protect the public health and safety and compatible with the NRC program. A description of the criteria and process for determination of adequacy and compatibility is provided in enclosure 8.

On January 1, 1993, 24 of the 29 States were adequate (15 of the 24 States were both adequate and compatible) and in 5 of the 29 States a finding was withheld. (See attachments to enclosure 8 for statistics on Agreement State Programs). The Commission has allowed States 3 years for the adoption of new regulations which are required for compatibility, to provide them with the necessary lead time to make needed changes. When there are problems with the adequacy and/or compatibility of a State's program, OSP staff 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, with the Governor of the State, to expedite necessary changes.

B. Followup of Patients Subject to Misadministrations

The series in the Cleveland Plain Dealer raises the question of NRC responsibility to determine not only the circumstances, but the magnitude of the consequences of activities it authorizes, particularly when NRC knows there has been a series of serious misadministrations involving numerous patients. This, in turn, raises the issue whether NRC's current regulatory practice with regard to patient followup should be retained or changed. NRC's regulatory program is designed to ensure that the patient receives the dose of radiation or the dosage of radioactive material prescribed by the physician. NRC does not regulate the appropriateness or effectiveness of prescribed dose or prescribed treatment.

Part 35 requires licensees to notify NRC within 24 hours of the discovery of a therapy misadministration. In addition, NRC requires the licensee to notify the referring physician and the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. After NRC receives initial notification from the licensee, a determination is made whether to conduct an inspection. The regulatory practice described below is the current basis for that inspection effort. As a special note, some Agreement States do followup inspections on serious misadministrations. However, none have a written policy.

In response to a reported misadministration, the staff may take several actions. For misadministrations involving very high doses or multiple patients, the staff may form and charter either an Incident Investigation Team or an Augmented Inspection Team. For less significant misadministrations, prompt special inspections may be conducted before the next scheduled inspection. A determination is also made as to whether other members of the public, such as family members, other patients, and healthcare workers, came into contact with the patient or in some other way were exposed to radiation. One purpose is to ensure persons potentially exposed in excess of 100 mrem are informed so they can seek appropriate medical evaluation. The circumstances of every misadministration are to be reviewed during an inspection.

When evaluating misadministrations, NRC staff attempts to: 1) determine the root cause of the failure; 2) determine whether corrective actions have been taken; 3) take appropriate enforcement action where violations of regulatory requirements contributed to the misadministration; and 4) ascertain whether the referring physician and patient (or responsible relative), as required, are notified. Whenever members of the general public have been exposed as a result of the special circumstances involved in the misadministration, the staff requires the licensee to evaluate the exposures and make appropriate notifications. After analysis of the results of the evaluation of a misadministration, NRC staff may: 1) share generic findings with NRC and Agreement State licensees using similar equipment or procedures and other Federal agencies, as applicable; and 2) propose modification of its own regulations and procedures, to prevent recurrence, if necessary.

NRC staff obtains the service of a medical consultant for any serious misadministration (and on a case-by-case basis for other incidents) to: 1) assist in the investigation activities following misadministrations and overexposures; 2) recommend where to obtain additional medical skills for appropriate followup; and 3) consult with physicians performing patient medical followup, to obtain information related to the misadministration. NRC does not retain the medical consultant to evaluate the appropriateness of the prescribed treatment, or its medical effectiveness. NRC has procedures for voluntary participation in the Department of Energy's long-term morbidity study of individuals involved in radiation accidents, including misadministrations.

Before further discussion, the term "patient followup" needs to be clarified. The term can have two meanings: first, evaluating the immediate and short-term consequences, to the patient(s) or others, of receiving a dose other than that prescribed by the physician and second, evaluating the long-term consequences to the patient(s) or others. Each of these meanings can have different ascribed regulatory purposes which are discussed below.

There are a number of regulatory purposes for which it is necessary to determine the immediate and short-term consequences pursuant to NRC's statutory mandate to protect public health and safety. The Commission needs to know the magnitude of the consequences of errors associated with the activities it authorizes. The consequences are relevant in determining the appropriate enforcement sanction in the particular case. The significance of the consequences determines the need for an Abnormal Occurrence report pursuant to Section 208 of the Energy Reorganization Act of 1974. Further, the magnitude of the consequences may be a consideration in determining the adequate level of regulatory oversight and allocation of NRC resources. It also advances an objective of the misadministration reporting rule; to facilitate informed healthcare decisions by patients (or responsible relative) who need to know the likely consequence of the misadministration in consultation with their referring physician. The Office of General Counsel (OGC) believes these reasons for immediate and short term followup are persuasive. NMSS believes that current practice meets these regulatory purposes.

It has been suggested that another and different regulatory purpose for determining the short-term consequences may be that NRC has a humane obligation to assist those who may have been injured by providing a program for identifying those patients affected by errors and notifying their

physicians (e.g., memorandum from Peter L. Strauss to Commission dated August 5, 1976 (Enclosure 9)). This purpose would derive from the NRC statutory mandate to protect public health and safety and the notification aspects were addressed in the 1980 misadministration reporting requirements. Any expansion of the possible role for NRC in assisting the injured patient would require careful definition. For example, assuring the patient and/or referring physician is aware of the misadministration and its consequences (insofar as they are known) and making the patient's physician aware of available expertise represents the modest effort to assist the patient as is the current practice. On the other hand, at the extreme, one could hypothesize an NRC peer review of existing patient management and recommending subsequent treatment or support to the patient in civil law suits against the licensee. In these cases, the case-specific nature of each misadministration, and associated variables, could require detailed medical knowledge, possibly confidential, about the patient, and a spectrum of medical skills, to enable NRC to make appropriate recommendations and initiate remedial action. This extreme position would appear to be inconsistent with the 1979 medical statement provision about minimizing intrusions into the practice of medicine, and could also entail NRC liability to the patient. No one, to our knowledge, has suggested such an extreme role for NRC.

The issue is when is it appropriate for the NRC to cease its followup activities. After the Riverside incident, the staff concluded that once the root cause for the error was known and after determining that the error did have significant consequences, such as severe injuries or deaths, no further investigation into the consequences was necessary on a patient-by-patient basis. Since Riverside, the NRC has changed its regulations and practices to now determine, in the short term: 1) the root cause and whether the error had some significant consequences, 2) the magnitude of the evident consequences, 3) the notification of the referring physicians and patient (as required) and 4) a modest effort to provide some medical consultative assistance to the attending physician. It should be noted that the NRC's current practice is that following notification to the referring physician and patient (as required), subsequent follow-up is a physician-patient matter. The deviation in the dose given in some misadministrations is of such magnitude that the conclusion of radiation-induced injury or death is evident. In other cases, more time may be required before effects are evident. Further actual determination of cause of death or injury may be difficult or impossible to determine in some instances.

Turning now to long-term consequences and followup of patient(s) or others, a regulatory purpose would be to add to the knowledge about the long term effects of large radiation doses. This regulatory purpose is derived from the NRC's statutory mandate to protect public health and safety. This knowledge might be used as the basis for regulatory changes. In addition, knowledge about organ impairment or death resulting from very serious or multiple exposures might serve to focus attention on the seriousness of misadministrations and prompt licensees to take corrective actions more promptly or extensively. There are several counter arguments to the above stated regulatory purpose for long-term followup. More detailed knowledge of long-term consequences is highly unlikely to result in any regulatory changes beyond those that may be identified by immediate or short-term consequences. Furthermore, long-term followup may require long-term communication with the person exposed or his/her physician through consulting or staff medical professionals. There could be significant resource implications in going beyond current regulatory practice to do long term followup in this area. This could require expansion of the medical related specialties currently utilized as consultants. In addition, an extensive recordkeeping system would need to be established. Additionally, various scientific organizations currently review data on consequences and risks to individuals exposed to radiation. A staff effort could duplicate their work and only would be applicable to a small specific population.

Another regulatory purpose for followup on the long-term medical consequences of individuals subject to a misadministration is to assist those who may have been injured in obtaining appropriate medical care. The arguments in favor and opposed to this purpose are essentially the same, as set out above, for providing assistance to patient(s) with regard to immediate or short term consequences.

C. Expansion of NRC Regulatory Purview

The Cleveland Plain Dealer articles raised the issue that NRC repeatedly has declined to regulate electrically generated forms of radiation, such as X-rays. There is no statutory basis for NRC regulation since these devices do not involve byproduct material. The staff is unaware of any formal request for NRC to regulate X-ray or other electric radiation-producing devices for medical uses. There has been no Commission decision on this issue.

The NRC regulation of the medical use of radioactive material is limited to byproduct material, source material, or special nuclear material. NRC's statutory authority to regulate the domestic medical uses of byproduct material is found in the Atomic Energy Act of 1954, as amended. Section 81 of that Act authorizes NRC "... to issue general or specific licenses to applicants seeking to use byproduct material ... for medical therapy ... or other such useful applications as may be developed."

The issue of expanding the scope of NRC regulation to include naturally occurring or accelerator-produced radioactive material (NARM) has been raised on numerous occasions in the past. In May 1988, the Conference of Radiation Control Program Directors, Inc. (CRCPD) requested NRC to seek legislative authority to regulate and license NARM. Following the recommendations discussed in SECY-88-64, "Naturally Occurring and Accelerator-Produced Radioactive Materials," NRC referred the issue of Federal regulation of NARM to the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) for purposes of developing an integrated policy and agency assignments on NARM. The results of the Policy Subpanel on NARM review were forwarded to the Commission as part of the quarterly report of current CIRRPC activities (SECY-92-423). The subpanel did not identify risks caused by discrete NARM, that would warrant expanded Federal authorities. However, a comprehensive review of the Atomic Energy Act and other Federal authorities was suggested as timely to achieve uniformity in radiation protection. Some members of the subpanel did recommend that the Atomic Energy Act be expanded to include NARM for consistency of controls, although there is not a clearly defined risk.

If NRC were to explore the issue of expanding NRC regulation and oversight of the medical use of all radioactive material and radiation sources, the extent to which the authority should be expanded would need to be defined in terms of the sources of ionizing radiation. This expansion could possibly include: 1) NARM; 2) accelerator-produced radioactive material; 3) cyclotron-produced radioactive material (e.g., radioisotopes used for Positron Emission Tomography); 4) linear accelerators; 5) orthovoltage X-ray machines; and/or 6) diagnostic X-ray machines. All of the above items are under some degree of jurisdiction of other Federal and/or State agencies.

STAFF MEDICAL MANAGEMENT PLAN:

The staff is currently developing a management plan for the reassessment of the medical use program. A key component of the management plan is continuation of the staff initiatives previously identified to senior management and the Commission (memorandum dated September 24, 1992, to the Commission from James Taylor), as well as others that have emerged as the result of continuing interaction with the regulated community. In addition to these initiatives, the staff has identified other program areas that should be reviewed to determine if substantial changes would improve the medical use program. A "Medical Issues" paper was prepared by the staff and discussed with the ACMUI and representatives of the Agreement States in October 1992, and with NRC regional management in November 1992. The management plan is scheduled to be forwarded to the Commission in the next few months.

RE-EVALUATION INITIATIVES:

o Risk Analysis and Human Factors

NRC currently has several contracts in place with national laboratories and private entities to evaluate the risks associated with emerging medical technologies and the human error component of misadministrations. These include: 1) a contract for the investigation of certain therapy misadministrations, to analyze the root cause(s); 2) contracts to evaluate the contribution of the human-machine interface in brachytherapy and teletherapy performance errors; and 3) contracts to evaluate quality assurance and risk associated with brachytherapy procedures and devices, and gamma stereotactic surgery. These efforts could result in revised equipment and operating procedures, and form the basis for revised regulations and revision of inspection procedures and frequency. Contract work has yet to be completed.

o Incident Investigation Report on Brachytherapy Incident

An Incident Investigation Team (IIT) has reviewed the circumstances surrounding the misadministration and subsequent patient death involving a high-dose rate afterloader brachytherapy procedure in Indiana, PA. The report of the IIT is scheduled to be completed January 29, 1993.

o Medical Use Program Audits

Two independent audits will be conducted of NRC's medical use program, as directed by the Commission in a Staff Requirements Memorandum dated December 21, 1992, in addition to the staff medical management plan. They will include an internal review, to be conducted by a NRC senior management representative; and an external review of the program, to be conducted by an independent entity. The audit conducted by the NRC senior management representative is expected to commence within the next few months and will focus on whether the existing programs, including oversight of the Agreement State program, are being effectively implemented. This review will be coordinated with the staff management plan.

A meeting was held on January 7, 1993, between NRC staff and Dr. Kenneth Shine, President, Institute of Medicine, National Academy of Sciences (NAS), to explore the possibility of NAS conducting the external review. The goal of this review is to develop an assessment of the adequacy and appropriateness of the current framework for medical use of byproduct material. It will include an in-depth review of the basic regulatory rules, policies, practices, and procedures.

OBSERVATIONS AND FURTHER CONSIDERATIONS:

1. The staff believes that, since the Riverside incident, NRC has significantly improved its program for the regulation and oversight of the medical use of byproduct material for NRC and Agreement State licensees. This program has been continually reevaluated and responsive to evolving technologies and lessons learned from incidents in the medical use program.

2. The staff observes that the reported frequency of occurrence of misadministrations is low. The Commission is concerned with errors that may lead to misadministrations and, in the QM rule, has focused on those procedures where the radiological risk from mistakes can be significant. The Plain Dealer and others allege that misadministrations are underreported. The staff believes the issue of level of reporting needs to be evaluated especially as the Agreement States adopt the new reporting requirements.

3. The staff believes that continuing re-evaluation is necessary and has undertaken initiatives to improve the effectiveness and oversight of its licensing, inspection, and enforcement programs. This includes evaluating whether there are adequate resources currently assigned to these programs.

4. The staff believes that the issue of expanded followup of patients subject to misadministrations involves complex policy issues and requires our reconsideration. To gain an additional perspective, the staff believes this issue should also be referred to the group performing the external review.

5. The staff observes that NRC, FDA, and the Agreement States have programs and procedures to review medical devices. The staff believes that the adequacy of the review of medical devices should be reconsidered and should include all of the programs. Here, too, the staff believes the issue should be referred to the group performing the external review.

6. In SECY-91-039, "Evaluation of Agreement State Compatibility Issues," the staff provided the Commission with recommendations for review of the policy on compatibility of Agreement State programs. As part of that analysis, the staff will review the need to include Agreement State investigation and enforcement programs.

7. The staff will evaluate the need to reassess the civil penalty process and increased base civil penalties.

8. The General Accounting Office has conducted an audit of the national materials program and the draft statement of facts has been circulated to Program Offices.

Coordination: This paper has been coordinated with the Office of the General Counsel, and that office has no legal objection.

Note: This Commission paper should be made publicly available at the Commission briefing scheduled for Friday, January 22, 1993.

James M. Taylor
Executive Director
for Operations

Enclosures:
1. NRC and Agreement State Licensee Inspection and Misadministration Data: 1989-1991
2. SECY-91-139
3. NRC and Agreement State Misadministration Data by State and License Type for 1991
4. Reports on Incidents identified in the Plain Dealer series
5. Annual Training Budget for Agreement State Personnel
6. Escalated Enforcement Data for 1989-1991
7. Synopses of OI Investigation of Misadministration Cases
8. Statistics on Adequacy and Compatibility of Agreement State Programs
9. Memorandum dated August 5, 1976 from Peter Strauss to the Commission

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Enclosure 1

NRC and Agreement State License Inspection
and Misadministration Data

1989 - 1991

NRC MATERIALS LICENSEE INSPECTION &
MISADMINISTRATION DATA: 1989-91

1989	# Lic.	Inspection		Misadministration	
		Freq. (years)	#	D	T[1]
Medical Broad	114	2/1[a]	73	84	3
Community Hospitals	1438	3	511	327	3
Pvt. Practice/Clinics	453	5/4[a]	137	11	0
Teletherapy	247	3/1[a]	138	0	4
Total Medical Lic.	2252	Varies	859	422	10
Other Materials Lic.	5347	Varies	1725	0	0
TOTAL	7599		2584	422	10
Other NMSS Licenses	NA		205		

1990	# Lic.	Inspection		Misadministration	
		Freq. (years)	#	D	T
Medical Broad	118	1	110	85	6
Community Hospitals	1429	3	523	338	9
Pvt. Practice/Clinics	476	4	119	17	0
Teletherapy	237	1	182	0	9
Total Medical Lic.	2260	Varies	934	440	24
Other Materials Lic.	5452	Varies	1592	0	0
TOTAL	7712		2527	440	24
Other NMSS Licenses	502		177		

[1] The number of therapeutic misadministrations for 1989 and 1990 differ from SECY-91-139 (table 2) because I-131 that was prescribed in the diagnostic range but administered in the therapeutic range was included under diagnostic misadministrations in this enclosure.

1991	# Lic.	Inspection		Misadministration	
		Freq. (years)	#	D	T
Medical Broad	119	1	105	79	12
Community Hospitals	1389	3/2[b]	675	350	5
Pvt. Practice/Clinics	464	4	153	12	0
Teletherapy	214	1	185	0	2
Total Medical Lic.	2186	Varies	1118	441	19
Other Materials Lic.	5462	Varies	2298	0	0
TOTAL	7648		3416	441	19
Other NMSS Licenses	478		197		

a- TI 2800/16 became effective Jan. 1989. It increased inspection frequencies in several categories of medical licensees.
b- TI 2800/21 became effective Feb. 1991. It increased inspection frequency for community hospitals.

AGREEMENT STATE INSPECTION PROGRAM

Totals for Review Cycle 1989 through 1991

Major License Category	Number of Licenses[1]	Number of Inspections Completed[1]	Number of Overdue Inspections[2]
Broad Medical	80	92	4
Community Hospital	2866	1368	67
Private Practice/ Clinic	742	378	4
Teletherapy	235	166	9
Total Medical Licenses	3923	2004	81
All Other Materials Licenses	9647	4644	211
TOTALS	14555	8513	304

[1]Entries do not sum to the column totals as several Agreement States do not record data by license category. For these states, only the totals are included.

[2]Inspections must be conducted by the Agreement States at least as frequently as would be conducted by the NRC for the same category of licensee.

Enclosure 2

SECY-91-139

Response to Staff Requirements Memorandum Regarding
An Analysis of Misadministrations and Reporting Thresholds

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~~SECY~~ SECY-91-139

POLICY ISSUE
(Information)

May 15, 1991

For: The Commissioners

From: James M. Taylor
Executive Director
for Operations

Subject: RESPONSE TO STAFF REQUIREMENTS MEMORANDUM REGARDING AN ANALYSIS OF MISADMINISTRATIONS AND REPORTING THRESHOLDS

Purpose: In the staff requirements memorandum (SRM) following the Annual Briefing on the Medical Use Program, the staff was requested to submit an analysis of trends in, and causes of, misadministrations and to respond to questions on abnormal occurrences and reporting thresholds.

Background: The Nuclear Regulatory Commission (NRC) staff briefed the Commission on the medical use of byproduct material on February 12, 1991.

In the SRM, dated March 6, 1991, resulting from this briefing, the Commission requested that the staff submit an analysis of trends in, and causes of, medical misadministrations, and provide responses to several questions raised during the briefing. This paper includes the staff analysis of misadministrations and responds to the questions on abnormal occurrences (AOs) and reporting thresholds. The Office of Nuclear Regulatory Research Commission paper transmitting the medical quality assurance (QA) rulemaking will address the NRC's support of the National Council of Radiation Protection and Measurements' efforts on assessing

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NOTE: TO BE MADE PUBLICLY AVAILABLE IN 10 WORKING DAYS FROM THE DATE OF THIS PAPER

the health significance of medical misadministrations. The remaining issues in the SRM, tracking data on enforcement actions and the human factors study by Syncor International, will be addressed in a separate Commission paper scheduled for submission in July 1991.

The enclosure contains the staff's analysis on misadministrations including two tables of data.

Discussion: Analysis of Misadministrations

The diagnostic use of radiopharmaceuticals involves the administration of a variety of pharmaceuticals of varying chemical composition, radioisotopes and dose ranges, depending on which organ or organ system is to be imaged. Diagnostic misadministrations have been reported in a variety of clinical procedures, primarily those using technetium-99m and iodine-131 excretion, uptake, imaging and localization agents. Therapy misadministrations include misadministrations as a result of teletherapy, brachytherapy (manual and remote afterloading), and radiopharmaceutical therapy procedures. Radiopharmaceutical therapy procedures typically include the use of iodine-131 or phosphorus-32 in millicurie quantities. For the purpose of this analysis, therapy misadministration data also include those procedures where the misadministration involves the administration of therapy-equivalent doses where diagnostic doses were intended.

The staff analysis of misadministrations (enclosed) is primarily based on data reported to NRC by its licensees for the calendar years 1987 through 1990. Complete data for 1990 are not yet available, and an estimate of total reports was based on reports received for 11 months. This misadministration reporting requirement was made an item of compatability for Agreement States effective April 1, 1990. The Office for Analysis and Evaluation of Operational Data is working with State Programs to develop a uniform reporting system for Agreement States.

An analysis of the trends in misadministrations reported to NRC over the last four years indicates that there has not been a significant change in the number or type of misadministrations for diagnostic procedures from year to year. Conversely, an increase in the number of therapy misadministrations was observed. This increase could be

attributed to several factors, including: (1) an increase in the number of new and complex brachytherapy procedures performed including remote afterloading procedures; (2) increased licensee awareness of NRC reporting criteria, the importance of timely reporting, and (3) escalated enforcement actions against licensees for failure to report. These factors are offered as possible explanations for the increase in therapy misadministrations for 1990. However, it is important to exercise caution when drawing conclusions from a limited data base regarding the increase, which may be a statistical fluctuation.

Heightened licensee awareness results from NRC staff conduct of numerous licensee workshops and meetings with professional societies, such as the Society of Nuclear Medicine, American College of Nuclear Physicians, American College of Radiology, and American Association of Physicists in Medicine, as part of the QA rulemaking. In addition, the NMSS Newsletter and professional society publications describe NRC requirements, inspection results, events that have resulted in misadministrations, and enforcement actions.

The primary types of diagnostic and radiopharmaceutical therapy misadministrations involve administration of the wrong pharmaceutical, wrong amount, or administration to the wrong patient. These misadministrations resulted from miscommunication amongst the licensee staff, errors in the preparation and administration of radiopharmaceuticals, inattention to detail, inadequate training in specific licensee procedures, failure to follow procedures, lack of, or inadequate procedures, and inadequate supervision. Brachytherapy and teletherapy misadministrations were primarily caused by errors and oversights in the treatment planning process, patient identification and set-up, failure to follow procedures, lack of, or inadequate procedures, and inadequate supervision. Since the underlying causes of diagnostic and therapy misadministrations appear to be human errors, the focus of regulatory review or action should be, to the greatest extent possible, focused on human factors. Relevant portions of this analysis will be incorporated into the QA rulemaking package.

AOs and Reporting Thresholds

From 1988-1990, there were 38 medical AOs that involved diagnostic and therapy misadministrations. The current guidance to the staff for identifying medical misadministration events as AOs is based on the amount of radiopharmaceutical or radiation dose to an organ or to the whole body. The criterion is the ratio of administered to prescribed radiopharmaceutical or radiation dose.

One of the questions raised during the annual medical briefing and in the SRM was whether a threshold dose level, such as the thyroid dose associated with 30 microcuries of iodine-131, would have resulted in any of the 38 AOs falling below the reporting threshold.

Thirty microcuries corresponds to a thyroid dose of approximately 50 rem (ICRP Publication 53, "Radiation Doses to Patients from Radiopharmaceuticals"). If both the 30 microcurie and 50 rem organ-dose trigger levels were applied to the 38 misadministrations designated as AOs between 1988 and 1990, 33 of the events would continue to be classified as AOs. The breakdown is as follows:

(1) the four diagnostic events not involving iodine would have been eliminated (with a 50 rem organ-dose threshold);

(2) 8 of the 9 diagnostic events involving iodine would continue to be classified as AOs because of the 30 microcurie and 50 rem organ criteria. The ninth diagnostic event would not be classified as an AO. Although it exceeded the 30 microcurie threshold, it resulted in less than a 50 rem thyroid dose because the patient's hypothyroid condition resulted in significantly decreased uptake; and

(3) the 25 therapy misadministrations designated as AOs would have been reported as such.

The SRM also questioned how a threshold dose level would compare to AO reporting criteria for non-medical radiation exposures, and if the health consequences from inadvertant doses were reported in a like manner for medical and non-medical events.

The current AO selection criteria for non-medical overexposure events specify values that are 5 times the annual limits given in 10 CFR Part 20, (i.e., 25 rem whole body; 150 rem skin; and 375 rem to feet, ankles, hands, or forearms; or equivalent exposures from internal sources).

The recently revised 10 CFR Part 20 employs a more modern method of dose calculation which involves the use of tissue weighting factors and effective whole body dose equivalent. This method attributes specific weighting factors to organs or tissues, representing the fraction of the total stochastic risk resulting from irradiation of that organ or tissue when the whole body is uniformly irradiated. However, dose to organs which might be below a reporting threshold using tissue weighting factors for assessment of stochastic risk could be of such magnitude that deterministic effects (non-stochastic) might be initiated. For this reason, the revised 10 CFR Part 20 uses a capping dose of 50 rem for organs (other than the lens of the eyes) to prevent deterministic effects.

If 5 times the limits contained in the new 10 CFR Part 20 are used as the AO criteria, the AO reporting requirements would be:

- 25 rem effective dose equivalent;
- 250 rem for the sum of the deep-dose equivalent and the committed dose equivalent to any individual organ or tissue, other than the lens of the eye, e.g., thyroid;
- 75 rem eye dose equivalent; and
- 250 rem shallow dose-equivalent to the skin or to each of the extremities.

If a 50 rem threshold radiation dose (e.g., 30 microcuries I-131 thyroid dose) were adopted as a reportable AO, it would be equal to the revised 10 CFR Part 20 limits for the committed effective dose equivalent for organs (as cited on previous page). This threshold is greater than the current 25 rem whole body criterion because for non-medical events, the organ dose criterion is assumed to be the same as the whole body.

A comparison can be made for AOs involving teletherapy misadministrations and AOs involving exposures of radiographers to external radiation. AO 89-11 involved the exposure of a radiographer to 93.4 rem localized to his right hip; AO 89-03 involved the exposure of an individual's left

femur to 250 rem from a teletherapy machine; and AO 90-12 involved the exposure of a radiographer's assistant to 5000 to 7000 rem, localized to the skin of the neck. These AOs discuss in a similar manner health effects such as erythema and damage to skin tissue, increased fatigue and possible bone marrow suppression, or lack of observable effects.

In summary, over 86% of the medical misadministrations designated as AOs between 1988 and 1990 exceeded a 50 rem organ dose. For procedures involving the use of iodine-131, this equates to a 30 microcurie reporting threshold resulting in a 1.5 rem effective dose equivalent. This threshold is more conservative than the current 25 rem whole body criterion for non-medical events; however, the health effects from individual doses are reported in a like manner for medical and non-medical events.

Coordination: The Office of the General Counsel has reviewed this paper and has no legal objection.

James M. Taylor
Executive Director
for Operations

Enclosure:
Staff Analysis of
Misadministrations

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STAFF ANALYSIS OF MISADMINISTRATIONS

INTRODUCTION

The staff analyzed diagnostic and therapeutic misadministration data for the calendar years 1987 through 1990. Of the 2300 Nuclear Regulatory Commission (NRC) licensees authorized to perform diagnostic and therapy procedures, an annual average of 339 (or 15 percent) reported misadministrations. The number of patients involved in these misadministrations annually averaged 472 (some reports involved more than one patient). NRC received an average of 405 diagnostic misadministration reports annually during these 4 years, ranging from 393 to 415. Complete data for 1990 are not yet available, and an estimate of total reports was based on reports received for 11 months. However, this estimate is consistent with previous years, and it is expected that the number of licensees reporting and the number of patients involved will not fall outside of the expected range. See Enclosure 1, Table 1 for reporting data.

For the purpose of this analysis, therapy misadministration data also include those procedures where the misadministration involves the administration of therapy-equivalent doses where diagnostic doses were intended. For example, 2 of the 9 reported for 1990 were the result of the misadministration of diagnostic dosages of iodine-131. An analysis of therapy misadministration reports submitted by NRC licensees during these 4 years, revealed a total of 66 therapy misadministrations, ranging from 12 to 27 anually, with the following breakdown: 25 teletherapy, 21 brachytherapy, 20 radiopharmaceutical therapy procedures (16 involving iodine-131). See Enclosure 1, Table 2 for a breakdown of the types of misadministations reported.

STAFF ANALYSIS OF CAUSES

Diagnostic

The two primary types of diagnostic misadministrations appear to be the administration of the wrong radiopharmaceutical and the administration of a radiopharmaceutical to the wrong patient (for 95 percent of diagnostic reports). The root causes reported by licensees continue to be errors associated with the preparation and administration of radiopharmaceuticals, inadequate training in specific licensee procedures, inattention to detail, failure to follow procedures, lack of, or inadequate procedures, and inadequate supervision. Errors include: improper labeling of syringes, shields, and vials; not verifying the radiopharmaceutical label or radioactivity prior to injection; misunderstanding a physician's order; faulty processing of nuclear medicine requests; and inadequate verification of patient identity.

Radiopharmaceutical Therapy

A review of radiopharmaceutical therapy misadministration reports revealed that many of the errors resulted from failure of the authorized user to review the

medical history of the referred patient, to determine the suitability of a particular clinical procedure, miscommunication amongst the licensee staff, or misinterpretation of the physician's orders. This brought about two common errors: the wrong radiopharmaceutical and the wrong dosage.

Therapy

There are various causes of therapy misadministrations due to the complexity of the brachytherapy and teletherapy treatment-planning process. Misadministrations in therapy primarily involve administered doses differing from the prescribed dose by more than 10 percent, or a dose to the wrong part of the body. The causes include: staff miscommunication regarding the area for treatment; errors during simulation; selection of the wrong sealed source; selection of the wrong source activity; wrong information entered into the treatment planning computer; misinterpretation of a computer error message before treatment commenced; misinterpretation of the prescription; arithmetic errors in dose calculations; use of the wrong data in dose calculations; misreading treatment time; and failure to positively identify the correct patient.

In general, most misadministrations of any type can be attributed to: failure to follow procedures, or lack of, or inadequate procedures; inattention to detail; inadequate training in specific licensee procedures, and inadequate supervision.

CORRECTIVE ACTIONS PROPOSED BY LICENSEES

For diagnostic misadministrations, approximately 50 percent of the corrective actions proposed by licensees include the retraining of personnel in specific procedures. Other corrective actions include the development and implementation of new procedures aimed at detecting and reducing errors, such as, labeling and identifying radiopharmaceuticals stored in lead shields or untagged reagent kits; identifying sealed sources and the activity of each; processing of physician referral requests; and patient identification. Two less frequently cited corrective actions are the reprimand of personnel and increased or improved supervision. The technologist preparing or administering the radiopharmaceutical appears to be the person primarily involved in most misadministrations involving diagnostic dosages.

The most frequently cited corrective actions for teletherapy misadministrations include: retraining of personnel in specific procedures; redundant patient identification; verification/double checks of dose calculations and patient set-ups; and routine chart checks. The technologist, dosimetrist, physicist, or authorized user might be primarily responsible for therapy misadministrations, depending on the treatment modality, or in what stage of the treatment plan the error occurs.

TABLE 1

MEDICAL MISADMINISTRATIONS REPORTED
TO NRC FROM 1987 THROUGH 1990

	1987	1988	1989	1990*	Total	Avg
No. of Reports	423	405	417	442	1687	422
No. of Patients	459	470	486	---	1415	472
No. of Licensees Reporting	348	344	326	---	1018	339

* Data are incomplete for 1990; the number of reports is an estimate for the entire year based on 11 months of data. The reports have not yet been reviewed in sufficient detail to report number of patients and number of licensees reporting.

TABLE 2

MEDICAL MISADMINISTRATIONS
CATEGORIZED BY TYPE FROM 1987 THROUGH 1990

	1987	1988	1989	1990*	Total	Avg
Therapy	14	12	13	27	66	17
a. Teletherapy	6	5	4	10	25	6
b. Brachytherapy	3	5	5	8	21	5
c. Radiopharmaceutical Therapy**	5	2	4	9	20	5
Diagnostic	409	393	404	415	1621	405

* Data are incomplete for 1990 and are based on 11 months of reports.

**Includes misadministrations of prescribed diagnostic dosages that resulted in unintended therapy-equivalent doses.

Enclosure 3

NRC and Agreement State Misadministration Data
by State and License Type for 1991

1991 MISADMINISTRATIONS BY STATE AND LICENSE CATEGORY

I. AGREEMENT STATES

STATE	Broad Medical			Community Hosp.			Private Practice/Clinic			Teletherapy	
	# Lic.	Diag.	Ther.	# Lic.	Diag.	Ther.	# Lic.	Diag.	Ther.	# Lic.	Ther.
Alabama	2	0	0	82	7	1	28	2	0	6	0
Arkansas	1	0	0	58	12	0	11	0	0	5	0
Arizona	2	1	0	34	16	1	43	1	0	2	0
California	8	6	1	677	50	3	0	7	0	25	0
Colorado	1	0	0	50	12	1	14	0	0	0	0
Florida	3	7	1	207	59	0	256	11	0	35	0
Georgia	0	0	0	118	0	0	55	0	0	16	0
Iowa	1	1	0	40	6	0	7	0	0	2	0
Illinois	14	6	0	154	19	0	30	0	0	23	0
Kansas	1	0	0	69	0	0	34	0	0	0	0
Kentucky	3	1	0	66	8	0	20	1	0	10	0
Louisiana	1	0	0	90	0	0	80	0	0	0	0
Maryland	3	6	0	43	14	0	64	1	0	15	1
Maine	0	0	0	26	0	0	1	0	0	1	0
Mississippi	1	0	1	76	0	0	6	0	0	7	0
North Carolina	5	7	1	98	8	0	21	2	0	6	2
North Dakota	1	0	0	16	0	0	0	0	0	0	0
Nebraska	1	1	0	30	5	0	13	0	0	3	0
New Hampshire	0	0	0	27	5	0	1	0	0	2	0
New Mexico	1	3	0	21	2	0	18	0	0	1	0
Nevada	0	0	0	11	1	1	15	1	0	1	0
New York	12	0	1	236	25	0	379	0	0	66	2
Oregon	1	4	0	40	12	0	11	0	0	1	0
Rhode Island	2	4	0	10	3	0	10	0	0	0	0
South Carolina	1	0	1	52	1	0	9	0	0	4	0
Tennessee	1	0	0	128	9	0	30	0	0	11	0
Texas	16	8	0	358	34	0	116	4	0	21	0
Utah	2	0	0	20	6	0	3	0	0	0	0
Washington	2	0	0	45	2	0	17	1	0	1	0
TOTAL	86	55	6	2,882	316	7	1,292	31	0	264	5

1991 MISADMINISTRATIONS BY STATE AND LICENSE CATEGORY

II. NRC STATES AND FEDERAL FACILITIES IN AGREEMENT STATES

STATE	Broad Medical			Community Hosp.			Private Practice/Clinic			Teletherapy	
	# Lic.	Diag.	Ther.	# Lic.	Diag.	Ther.	# Lic.	Diag.	Ther.	# Lic.	Ther.
Alabama	1	0	0	1	0	0	0	0	0	0	0
Alaska	0	0	0	6	0	0	1	0	0	0	0
Arizona	0	0	0	3	0	0	0	0	0	0	0
Arkansas	1	0	0	0	0	0	0	0	0	0	0
California	6	4	0	5	6	0	0	0	0	1	0
Colorado	2	0	0	1	0	0	0	0	0	1	0
Connecticut	3	0	1	37	10	0	29	3	0	5	0
Delaware	0	0	0	9	1	0	6	0	0	1	0
District of Columbia	6	6	1	8	4	0	8	1	0	5	0
Florida	2	0	0	3	0	0	0	0	0	0	0
Georgia	2	0	0	4	1	0	0	0	0	0	0
Guam	0	0	0	1	0	0	0	0	0	0	0
Hawaii	1	0	1	14	3	0	4	0	0	0	0
Idaho	0	0	0	20	1	0	0	0	0	0	0
Illinois	2	2	0	2	1	0	0	0	0	1	0
Indiana	3	4	0	88	23	0	16	0	0	17	0
Iowa	1	1	0	1	0	0	0	0	0	0	0
Kansas	0	0	0	0	2	0	0	0	0	0	0
Kentucky	2	1	0	1	0	0	0	0	0	0	0
Louisiana	1	0	0	2	0	0	0	0	0	0	0
Maine	0	0	0	26	9	0	2	0	0	1	0
Maryland	1	2	0	4	0	0	1	0	0	0	0
Massachusetts	13	6	0	80	7	0	11	0	0	8	0
Michigan	7	8	0	136	36	0	81	4	0	13	0
Minnesota	4	1	0	45	7	1	2	0	0	7	0
Mississippi	0	0	0	2	0	0	1	0	0	0	0
Missouri	5	12	0	89	14	0	10	0	0	18	1
Montana	0	0	0	19	5	0	3	0	0	0	0
Nebraska	1	0	0	1	0	0	0	0	0	0	0
Nevada	1	0	0	0	0	0	0	0	0	0	0
New Hampshire	0	0	0	1	0	0	0	0	0	0	0
New Jersey	3	0	0	95	34	2	59	0	0	15	0
New Mexico	1	0	0	0	0	0	0	0	0	0	0

II. NRC STATES AND FEDERAL FACILITIES IN AGREEMENT STATES (cont'd)

STATE	Broad Medical			Community Hosp.			Private Practice/Clinic			Teletherapy	
	# Lic.	Diag.	Ther.	# Lic.	Diag.	Ther.	# Lic.	Diag.	Ther.	# Lic.	Ther.
New York	3	0	0	6	2	0	0	0	0	3	0
North Carolina	1	0	0	4	0	0	0	0	0	0	0
North Dakota	0	0	0	1	0	0	0	0	0	0	0
Ohio	9	10	2	160	51	2	40	0	0	27	0
Oklahoma	4	1	0	55	9	0	8	0	0	11	0
Oregon	0	0	0	2	0	0	0	0	0	0	0
Pennsylvania	12	9	3	191	68	0	69	0	0	15	1
Puerto Rico	1	0	0	22	2	0	15	0	0	5	0
Rhode Island	1	0	0	0	0	0	0	0	0	0	0
South Carolina	0	0	0	3	0	0	0	0	0	0	0
South Dakota	0	0	0	14	2	0	1	1	0	0	0
Tennessee	1	0	0	3	3	0	0	0	0	0	0
Texas	4	4	2	6	1	0	1	0	0	2	0
Utah	1	0	0	0	0	0	0	0	0	0	0
Virginia	3	0	0	81	18	0	26	0	0	10	0
Virgin Islands	0	0	0	1	0	0	0	0	0	0	0
Vermont	0	0	0	14	4	0	0	0	0	1	0
Washington	1	1	0	3	2	0	0	0	0	1	0
West Virginia	1	0	1	40	9	0	10	0	0	4	0
Wisconsin	5	8	1	64	16	0	9	0	0	4	0
Wyoming	0	0	0	15	1	0	0	0	0	0	0
TOTAL	116	80	12	1389	352	5	413	9	0	176	2

Enclosure 4

Reports on Incidents Identified in the
Plain Dealer Series

CLEVELAND CLINIC, CLEVELAND, OHIO

OF PATIENTS: One

PATIENT: Philomeena McNeeley

SYNOPSIS OF PLAIN DEALER ARTICLE:

The Plain Dealer reported that, during cobalt-60 teletherapy treatment for a rare blood and bone marrow disorder, Ms. McNeeley received a seventy percent overdose due to a mistake by the physicist, in which the incorrect distance from the source to the patient was used in the dosimetry calculations. As a result of the overdose, Ms. McNeeley received burns to over fifty-five percent of her body and was admitted to Cleveland Metropolitan General Hospital burn unit on November 11, 1986, for treatment. She died on November 18, 1986 with burns over 90% of her body.

INFORMATION KNOWN BY NRC PRIOR TO PUBLICATION:

On October 6-8, 1986, a 58-year-old female patient, receiving teletherapy treatments for bone marrow disease, received a total dose of 2,000 rad instead of the prescribed dose of 1,200 rad, a 67% overexposure. The misadministration was due to an error in calculating treatment time. The physicist who performed the calculations used the distance from the cobalt-60 radiation source to the patient, instead of the distance from the exterior of the radiation therapy device to the patient.

The patient was discharged on October 10, was readmitted on October 20 for symptoms believed to result from the radiation exposure, discharged, and readmitted on November 10 to another facility with skin burns. The patient died on November 18, 1986. The licensee did not detect the error until November 11 when a patient chart check was performed, and the event was not reported to NRC until November 17.

A panel of NRC medical consultants, consisting of two physicians and a physicist, reviewed the case and concluded that the radiation treatments had "minimal effect, if any, upon the fatal outcome of her disease." The panel of consultants indicated that the skin burns were not attributable to the radiation treatment, but to a variety of drugs given to the patient prior to and in addition to her radiation therapy.

The licensee had an existing policy which required dual verification of all dose calculations prior to the first day of treatment; however, it was not followed in this case. As a result of this misadministration, the original policy was revised to include: 1) all dose calculations will be independently performed, and that 2) prior to each treatment, this will be verified; 3) treatment data will be reviewed weekly by the chief technologist; and 4) quarterly audits by the Radiation Safety Committee would be performed for a year and then annually thereafter.

NEW INFORMATION FROM PLAIN DEALER:
None
INFORMATION GATHERED SINCE PUBLICATION:
None
PATIENT FOLLOW-UP:
Follow-up by was done by a panel of NRC medical consultants. The patient's

relatives and the referring physician were notified.

NRC ENFORCEMENT ACTION:

NRC promptly issued a Confirmatory Action Letter documenting the revised policy as described above. NRC identified two violations were identified for which a civil penalty of $2500 was imposed.

LICENSEE HISTORY:

- The teletherapy license was originally issued in June 1956, and terminated December 17, 1990.

- Other therapeutic misadministrations

  1) On February 15, 1990, NRC was notified that on February 8, 1990 a patient received a teletherapy dose 50% greater than prescribed. Initially, the physician prescribed a total of 9 treatments of 278 rem each to the cervical spine area. Following the first two treatments, the physician decided to stop treatment completely and wrote "stop treatment" on the first page of the treatment chart. Not seeing the note on the first page, the technologist turned to the second page to check the treatment parameters and administered a third treatment of 278 rem. The staff became aware of the stop treatment order later that same day.

     The cause appeared to be the lack of a clear mechanism for documenting any changes in prescriptions prior to subsequent treatment. The licensee's corrective actions included enhanced quality assurance procedures and retraining of staff.

     NRC conducted a special inspection and an Enforcement Conference was held with the licensee. A civil penalty of $6875 was proposed and paid by the licensee. The referring physician was notified, but not the patient or the relatives because "it was determined by the referring physician that this was a misadministration in the technical sense and not in the medical sense relative to patient care".

  2) On January 17, 1992, the licensee reported that a patient received a radiation dose 57% greater than prescribed in a therapeutic treatment. The patient was prescribed 2676 rad in a brachytherapy gynecological procedure using 5 Cesium-137 sealed sources loaded in a Fletcher-Suit applicator; however, 2 of the 5 sources implanted had an activity greater than intended and yielded a treatment area radiation dose of 4205 rad.

     The error was discovered by the licensee shortly after the brachytherapy sources were explanted on January 17, 1992. The referring physician of the patient was notified, a second similar treatment planned for the patient may be altered, based on clinical effects from the first treatment.

     A special inspection was conducted January 28-29, 1992 and found no violations of NRC regulatory requirements. A medical consultant reviewed the event.

3) On April 24, 1991, the licensee reported a therapeutic misadministration. The patient received a brachytherapy treatment dose 32% lower than the dosage prescribed. The misadministration occurred because the dose calculations were based on a tumor distance of 1.0 cm, instead of the prescribed distance of 1.5 cm. Consequently the licensee ordered Ir-192 sources of a lower strength than that required. The error was identified by the licensee on April 23, 1991, during a post treatment review. The referring physician and the patient have been notified, and no further treatment is planned. RIII reviewed the event during an inspection conducted between May 18, 1991, and June 18, 1991. No violations were identified with respect to the misadministration.

OHIO VALLEY HOSPITAL, STEUBENVILLE, OHIO

OF PATIENTS: One

PATIENT: Jean Matalik

SYNOPSIS OF PLAIN DEALER ARTICLE:

The Plain Dealer reported that Ms. Matalik had a hole burned in her chest during five weeks of cobalt-60 treatment for breast cancer ending in March 1988. As a result of her injuries, she developed depression and committed suicide in August 1989. It further reports that the doctor claims that he advised her to go to another hospital in Pittsburgh to be treated with a linear accelerator, because it would be safer*. She refused to go because of the long drive, so he treated her with the Cobalt-60 unit which required a larger dose.

INFORMATION KNOWN BY NRC PRIOR TO PUBLICATION:

On September 14 and 15, 1992, an NRC inspector performed an unannounced safety inspection of Ohio Valley Hospital prompted by concerns raised by one of the Plain Dealer reporters regarding a possible teletherapy misadministration, in which a patient received cobalt-60 radiation beginning on February 11, 1988, totaling a dose of 7500 rads, instead of the prescribed total dose of 5000 rads.

The inspector examined the patient's treatment chart to review the prescription, treatment plan and treatment records. The review determined that the patient was prescribed and received 5000 rads to the tumor volume at a depth of 5 centimeters; therefore, a misadministration had not occurred. The maximum dose to tissue was at the skin and was approximately 7500 rads.

Transcripts of depositions for the malpractice case involving this patient's treatment reviewed by the inspector did not indicate that the patient received a dose of radiation that differed from what the physician prescribed. However, the patient exhibited significant radiation effects. The physician apparently was aware of and considered the risk of such damage when he approved the treatment plan prior to initiation of treatment.

NEW INFORMATION FROM PLAIN DEALER:
None
INFORMATION GATHERED SINCE PUBLICATION:
None
PATIENT FOLLOW-UP:
None, since a misadministration did not occur.
NRC ENFORCEMENT ACTION (IF ANY):
None, since a misadministration did not occur.
LICENSEE HISTORY:

- The license was terminated September 20, 1991.
- There were no reported therapeutic misadministrations.

* Tissue damage frequently occurs as part of radiation treatment, due to the fact that the tissue overlaying the tumor will receive a higher dose than the deeper tumor volume. For lower energy photons the maximum radiation dose is

delivered just at or below the skin. As the energy of the photons is increased, as with a linear accelerator, the difference between the maximum dose further below the skin and the tumor dose is decreased. The use of a linear accelerator with its higher energy photons can deliver a specified dose to a tumor with less damage to surrounding tissue, that is the case for cobalt-60 in some instances.

OVERLOOK HOSPITAL, SUMMIT, NEW JERSEY

OF PATIENTS: One

PATIENT: Connie Norris

SYNOPSIS OF PLAIN DEALER ARTICLE:

The Plain Dealer reported that during treatment for Hodgkin's disease with a Linear Accelerator in 1984, Ms. Norris's spinal cord was overexposed because the doctor failed to shield her spinal cord. As a result, by June 1985, Ms. Norris was paralyzed from the neck down and now lives in a nursing home.

INFORMATION KNOWN BY NRC PRIOR TO PUBLICATION:
None
NEW INFORMATION FROM PLAIN DEALER:
All of the information in the Plain Dealer.
INFORMATION GATHERED SINCE PUBLICATION:

NRC Region I, contacted the Radiation Safety Officer (RSO), and was informed that in 1984-85 a 30 yr old female was treated with a Linac for Hodgkin's disease. According to the RSO, she received the prescribed dose of 4000 rads to the mediastinum and 4200 rads to the cervical region. Within 2 months she developed paralysis and sued the hospital. An expert witness for the hospital testified that the abrupt onset of the patient's paralysis indicated that the paralysis was not caused by radiation induced transverse myelitis. Testing undergone by the patient suggested the patient might have multiple sclerosis, but additional testing was refused by the patient so that confirmation was not obtained (according to the RSO). The patient won the case. She is still living and is still paralyzed.

PATIENT FOLLOW-UP:
None, not within NRC regulatory purview.
NRC ENFORCEMENT ACTION:
None, not within NRC regulatory purview.
LICENSEE HISTORY:

- The licensee has been licensed since 1956.
- The licensee is inspected every three years.
- Escalated Enforcement Actions

  EA 91-163, $3125 Civil Penalty issued for October 1991, I-131 misadministration. Patient was administered 2 mCi I-131 instead of 300 uCi I-123.

- Other Therapeutic Misadministrations

  1) On November 1, 1991, the NRC headquarters duty officer informed the NRC Region I office that the misadministration occurred at the Overlook Hospital in Summit, NJ. A 27 year old female patient was to have undergone a thyroid uptake study and scan involving the administration of 300 uCi of I-123. Although the responsible physician intended to perform a thyroid uptake study using 300 uCi of I-123, he erroneously requested that the patient be administered 2 mCi of I-131 for a whole body scan. The nuclear medicine technologist, responsible for administering the dose to the patient,

questioned the physician as to the exact study requested. The physician confirmed that a whole body scan using 2 mCi of I-131 was requested. The dose was administered on October 30, 1991. On November 1, 1991, the physician, upon reviewing the results of the study, discovered that he intended to perform an uptake study using 300 uCi of I-123. The appearance of an imaged thyroid triggered the realization that a wrong study had been performed. The patient, when asked by the licensee prior to administering the dose, stated that she was not pregnant and was not nursing. NRC Region I contacted an NRC medical consultant on November 1, 1991 to review the 1) the quantification of the dose to the patient; 2) the biological significance of the dose; 3) the potential future patient care; and 4) the actions to prevent recurrence. The patient and referring physician were notified. Region I dispatched an inspector to examine the circumstances surrounding the misadministration, the licensee's corrective actions, and the licensee's actions to prevent recurrence.

An NRC inspection was performed on November 6, 1991. During the inspection, two violations were noted concerning 1) the failure to review the supervised individual's use of byproduct material; and 2) the failure to follow a procedure concerning written orders for performing iodine studies.

An Enforcement Conference with the licensee was held November 26, 1992. The NRC staff reiterated the importance of comprehensive actions to be taken by the licensee to prevent similar incidents and stated that the conference should focus on the factual details surrounding the incident. The licensee accepted the NRC findings with the exception of an apparent violation concerning failure of the authorized users to review supervised individuals' use of byproduct material. The licensee stated that the incident was a result of failure to follow department procedures. The $3,125 civil penalty listed above was imposed on December 12, 1991.

2) On June 1, 1990, NRC was notified that on May 14, 1990, a patient was intended to receive approximately 100-500 microcurie of iodine-123 for a diagnostic thyroid scan but inadvertently received 1.4 millicurie iodine-131 for a whole body scan. The original order for the study was orally transmitted from the referring physician's office by telephone. The patient brought the written prescription to the hospital outpatient department and then proceeded to the nuclear medicine department. The prescription was not received in the nuclear medicine department until after the study was completed. When the prescription was received, the error was discovered. The administered radiation dose to the patient's thyroid from the iodine-131 dosage was approximately 1,820 rad, instead of the intended 4 rad from a 300 microcurie dosage of iodine-123.

The referring physician was notified, it is not known whether the patient was notified. The licensee's corrective actions included establishing a procedure requiring receipt of a written prescription by the nuclear medicine department prior to administering any iodine for studies.

PENNSYLVANIA REGIONAL CANCER CENTER, INDIANA, PENNSYLVANIA

OF PATIENTS: One

PATIENT: Mildred Colgan

SYNOPSIS OF PLAIN DEALER ARTICLE:

The Plain Dealer reported that during treatment for cancer of the rectum using an Omnitron HDR Brachytherapy unit, Ms. Colgan was exposed to 200,000 to one million rads when a piece of the radioactive iridium-192 broke off and was accidently left inside Ms. Colgan undetected for four days as opposed to only a few minutes. As a result of the overexposure, Ms. Colgan died November 20, 1992. The Plain Dealer also reported that the source went undiscovered until November 27, 1992, when it was detected in a waste truck entering a landfill after the source in the catheter had been disposed of in normal trash.

INFORMATION KNOWN BY NRC PRIOR TO PUBLICATION:

NRC was notified December 1, 1992 that a 3.7 curie iridium-192 source was left inside a patient for four days. The whereabouts of the source was not known until it triggered a portal monitor at a waste facility on December 1, 1992. Three workers at the facility received approximately 350 mR each while locating and isolating the source.

The treatment took place on November 16, 1992 and the patient died on November 21, 1992. Based on the patient's medical records, the preliminary conclusion by the NRC's medical consultant was that the patient either died as a result of exposure to radiation, or that radiation exposure was a major contributor to her death. Nursing home residents and staff, as well as visitors, were exposed to radiation. Blood samples taken from employees, residents and visitors of the nursing home and employees of the waste facility were all negative for acute radiation effects. In addition, Oak Ridge chromosome studies on blood samples from six individuals showed exposures were less than the statistical detectable limit for any one individual.

Subsequent investigation found that a short piece of the cable containing the iridium source had broken off and remained in one of the catheters which had been implanted in the patient. Although a wall-mounted area monitor alarmed when the treatment was completed, the licensee's staff believed the device was emitting a false signal and chose to ignore it.

NEW INFORMATION FROM PLAIN DEALER:
None

INFORMATION GATHERED SINCE PUBLICATION:
NRC Incident Inspection Team.

PATIENT FOLLOW-UP: An NRC medical consultant was sent to review the circumstances and interview both the patient's attending physician and the radiation oncologist. The referring physician and the patient's family were notified. The body has been exhumed and the NRC medical consultant observed the autopsy. Autopsy results are pending. The exposure of the other individuals exposed have been evalutated.

NRC ENFORCEMENT ACTION:
NRC is still investigating the case, however a Confirmatory Action Letter (CAL) was issued to modify the license. Additional enforcement action is being considered by the staff.

NRC ACTIONS

An NRC Bulletin issued to all Omnitron users on December 8, 1992 which requested that licensees either discontinue using the units or immediately implement the following actions in conjunction with any use of the unit: 1) Survey patients with an appropriate survey following treatment to confirm that sources were removed; 2) Have written emergency procedures describing actions to be taken and appropriate staff and resources available to implement those procedures should the source not return to the shielded container at the conclusion of treatment; and 3) Ensure that personnel are trained in both the routine use of the device and the emergrency procedures to return the source to a safe condition.

An Information Notice issued to all medical licensees on December 17, 1992, informed licensees about concerns associated with releasing brachytherapy patients without positive assurance that all implant material has been removed from patients before their release. NRC is continuing investigation of the incident in cooperation with the FDA.

LICENSEE HISTORY:
- The NRC license was issued on August 3, 1990.
- The inspection frequency for this licensee is three years; one inspection was conducted on 9/4/91.
- There have been no escalated enforcement actions for this licensee.
- There have been no previous misadministrations reported by this licensee.

RIVERSIDE METHODIST HOSPITAL, COLUMBUS, OHIO

OF PATIENTS: 413

PATIENTS: Twenty-eight patients were named by the Plain Dealer series.

SYNOPSIS OF PLAIN DEALER ARTICLE:

The Plain Dealer reported that the radiation physicist at Riverside started using the wrong graph paper to calculate the strength (activity) of the cobalt-60 teletherapy unit and as a result overdosed 413 patients for the period from September 1974 to January 1976. Of these 413 patients the Plain Dealer reported that radiation overexposure contributed to the deaths of 28 persons and one person lost a leg.

INFORMATION KNOWN BY NRC PRIOR TO PUBLICATION:

On April 18, 1976, the licensee reported that during the period March 1, 1975, to January 30, 1976, two hundred and fifty-five patients received radiation doses from a Co-60 teletherapy unit in excess of the intended dose (average of nineteen percent with a forty percent maximum greater exposure than prescribed). The NRC Region III office conducted an investigation on April 20-22 and May 12-13, 1976, into the reported overexposures. The investigation disclosed that some three hundred and eighty-five patients received exposures in excess of 10% above the prescribed amounts. These overexposures resulted when a hospital staff physicist prepared erroneous data regarding the teletherapy unit source output, and used this data in computing patient exposure time information which was furnished to the radiation therapist physicians. Furthermore, the licensee management control system did not assure that the output of the teletherapy unit source was being accurately and competently determined and that patient exposure calculations were accurate. An NRC medical consultant reviewed three autopsy cases and attributed excess radiation exposure as a major contributor to death in two cases (discussed below).

1. A 25 year old pregnant patient was being treated for Hodgkin's disease with radiation therapy to the mediastinum, bilateral supraclavicular, and axillary areas and the neck. She received 19 treatments in 33 days. The initial calculated and actual doses are as follows: mediastinum, 3420 and 4708 rads; supraclavicular, 3708 and 5546 rads; and axillary 3519 and 4314 rads, respectively. The patient was admitted to hospital 30 days after completion of treatment with increasing respiratory difficulty, characteristic of a severe form of the adult respiratory distress syndro me. Death occurred 60 days after completion of radiation therapy attributed, by an NRC medical consultant, to acute radiation pneumonitis.

2. A 48 year old patient received Co-60 teletherapy treatment following removal of a pseudomucinous cystadenocarcinoma of the left ovary. The patient received 33 treatments in 45 days with a Co-60 teletherapy unit. The prescribed dose was 2950 rads to the entire abdomen with an additional dose of 1780 rads for the pelvic region (total of 4930 rads). The actual administered dose was 3676 rads to the entire abdomen and 6242 rads to the pelvic region. Four months after completion of treatment, the patient was admitted to the hospital with unrelieved diarrhea and low abdominal pain. Death occurred two weeks later with the major pathological findings of: radiation enteritis, reactive serofibrinous peritonitis, and stenosis and fibrosis of the bowel.

It was determined by an NRC medical consultant that death was due to enteritis associated with fibrosis ulceration and peritonitis due to excessive radiation which was unrecognized until well after completion of therapy.

3. The NRC medical consultant also reviewed the case of a 52 year old patient who received 34 treatments in 50 days to the neck for a total prescribed dose of 5100 rads. Recalculation showed the actual dose administered to be 5768 rads. The patient later developed metastases to the mediastinum after which the patient received 25 treatments to the midline chest for a total prescribed dose of 5000 rads. The actual dose delivered was 5596 rads. Death occurred approximately one year later. It was determined by the NRC medical consultant that death was due to the progress of his cancer.

The staff briefed the Commission on the incident on August 2, 1976. Subsequently, on May 19, 1977, NRC issued a proposed rule to require teletherapy licensees to: 1) have a qualified expert perform full calibration measurements on each teletherapy unit at least once each year; 2) perform spot-check measurements on the output of their units at least monthly; and 3) report to the NRC radiation doses that differ from the prescribed dose by more than 10 percent. The final rule, which became effective July 9, 1979, required 1) full calibration measurements on teletherapy units at least once each year and following any repair of the unit that includes removal of the source or major repair of the component associated with the source exposure assembly and prior to treating humans; 2) spot check measurements at least monthly; 3) correction of calibration of teletherapy output for physical decay at intervals not to exceed one month; 4) dosimetry systems used to calibrate the teletherapy units are properly calibrated; and 5) the licensee to determine that a person is an expert qualified by training and experience to calibrate teletherapy units.

NEW INFORMATION FROM PLAIN DEALER:
Number of deaths.

INFORMATION GATHERED SINCE PUBLICATION:
NRC's Medical Visiting Fellow contacted the deputy coroner. REACTS and the deputy coroner indicate 10 deaths.

PATIENT FOLLOW-UP:
Autopsy reports of three individuals were reviewed by the NRC medical consultant. A decision to discontinue patient follow-up was made after these reviews.

NRC ENFORCEMENT ACTION :
On July 14, 1976, the NRC issued an order modifying the license for Riverside Methodist Hospital. This order required the licensee to conduct full calibrations of each teletherapy unit at intervals not to exceed one year, spot checks of the teletherapy units at intervals not to exceed one month, and maintain records of all calibrations and spot checks. In addition, an NRC bulletin was issued to all NRC-licensees who used NRC-licensed teletherapy units. The bulletin advised licensees to perform a comparison test between unit measured output and calculated output. Where there were variances, the licensee was to perform a full calibration. Agreement States were informed of the NRC action and similar actions on their part was requested.
In an effort by NRC and licensees to verify the calibration methods of the output of the licensee's teletherapy units, thermoluminescent dosimeters were sent to about 300 licensees which were returned for evaluation. Based on the

evaluations, teams of NRC inspectors were sent to all licensees in which the exposures differed by ± 5% compared to the expected exposures. All discrepancies were satisfactorily resolved.

LICENSEE HISTORY:

- The NRC(AEC) license was issued for teletherapy on November 30, 1965, and terminated on May 3, 1982.

- Other therapeutic misadministrations

  A therapeutic misadministration of I-131 occurred on August 2, 1991. A 10 mCi dose of I-131 NaI was ordered for a hyperthyroid patient, and only 8.7 mCi was administered. The cause of the event was failure to assay the dosing container post administration to ascertain that the entire prescribed amount was administered to the patient. The missing 1.3 mCi was found on the rubber septum of the dosing vial. The licensee is taking appropriate corrective action to prevent future incidents of this nature. The referring physician was notified and decided not to return the patient for additional I-131.

TRIPLER ARMY HOSPITAL, HAWAII

OF PATIENTS: One

PATIENT: Rensly Phillips

SYNOPSIS OF PLAIN DEALER ARTICLE:

The Plain Dealer reported that in June 1990, a technologist gave Ms. Phillips, a lactating woman, a dose of iodine-131 without asking if she was breastfeeding. The patient's infant daughter then ingested the breast milk, destroying the baby's thyroid gland. The Plain Dealer also reported that Ms. Phillips was not informed of the mistake until she read about it in a newspaper in Guam.

INFORMATION KNOWN BY NRC PRIOR TO PUBLICATION:

On June 19, 1990, a mother who was breastfeeding inadvertently received a dosage of 4.89 millicurie of iodine-131 that resulted in an unintentional radiation dose to her infant's thyroid gland estimated at 30,000 rad and a dose to the infant's whole body of 17 rad. The error was detected on June 21 when the patient returned to the medical center for a whole body scan. The root cause is that the technologist and physician failed to confirm that the patient was not breastfeeding prior the administration. Part of this communication was hindered by the fact that the patient arrived at the medical center from a very remote South Pacific island (Truk). Communication between island physicians was poor and Tripler physicians were not aware that the mother had given birth on June 1, 1990.

The licensee's corrective actions included revision of quality assurance procedures to more accurately document information regarding pregnancy and breastfeeding status of female patients.

NEW INFORMATION FROM PLAIN DEALER:
None
INFORMATION GATHERED SINCE PUBLICATION:
None
PATIENT FOLLOW-UP:

An NRC medical consultant visited Tripler, met with the patient's physician and staff then analyzed the information. The licensee notified the patient and arranged for long term follow-up care of the infant.

NRC ENFORCEMENT ACTION (IF ANY):

An Enforcement Conference was held and a Notice of Violation (NOV) and Imposition of Civil Penalty (CP) in the amount of $5,000 was issued for violation of 10 CFR 35.25(a)(2) for failure of the supervised personnel to follow procedures and instructions of the supervising authorized users. The violation was categorized as a Severity Level I problem (the most significant level). After reviewing the licensee's response to the NOV, NRC staff reconsidered the amount of the CP and consulted with the Commission. An Order imposing a CP in the amount of $2,500 was issued and paid by the licensee.

LICENSEE HISTORY:

- The license was issued prior to 1960.
- The license is inspected annually
- Other Escalated Enforcement Actions

  a. Enforcement Conference held Sept. 24, 1981, no civil penalty

     An inspection was performed on July 23, 24, and 27, 1981. Four patients appeared to have been administered Tc-99m containing more than 5 microcuries Mo-99 per dose.

  b. Severity Level III violation issued Dec. 30, 1992. No Civil Penalty was issued. An inspection was conducted November 4 and 5, 1992. There was a failure to adequately inventory iridium brachytherapy seeds between August 1989 and June 1992, resulting in 14 seeds being unaccounted for. The fourteen seeds had the potential to cause an unplanned exposure.

- Other therapeutic misadministrations

  1) On June 17, 1986, a 54-year-old female patient received a dosage of 3.09 millicurie of iodine-131 instead of a prescribed dosage of 50 microcurie iodine-131 for a thyroid imaging procedure. The misadministration was the result of misreading the consultation sheet. The radiation exposure associated with the administered dosage was estimated to be 2,472 rad to the thyroid, 0.43 rad to the ovaries, and 1.45 rad to the whole body. The patient was notified and hospitalized for observation. The licensee stated that the exposure to the thyroid might result in some degree of impairment in its function.

  2) On April 26, 1991 NRC was notified of a therapeutic misadministration that occurred on October 16, 1987, a 30 year old female was prescribed intracavitary brachytherapy treatment for cancer of the cervix. The prescribed treatment time was 50 hours for a total of 5300 cGy to the vaginal apex. The radiation oncology service physician inadvertently scheduled the removal for 74 hours, but detected the error and removed the sources at 72 hours. The resulting dose was 7632 cGy. The referring physician was notified October 26, 1987 and offered no comments. Neither the patient nor her family were informed of the error. The patient later died on February 11, 1990 due to urosepsis secondary to renal obstruction by recurrent tumor. NRC conducted a special inspection during the period June 3 through July 26, 1991. The two identified violations were not cited because the criteria specified in the Enforcement Policy for non-cited violations were satisfied.

UNIVERSITY OF WISCONSIN HOSPITAL AND CLINICS, MADISON, WISCONSIN

OF PATIENTS: One

PATIENT: Lois Nelson

SYNOPSIS OF PLAIN DEALER ARTICLE: The Plain Dealer reported that in 1986, during treatment for bladder cancer, Ms. Nelson's digestive tract was severely burned, and as a result of the trauma, Ms. Nelson's husband Robert committed suicide in December 1991.
INFORMATION KNOWN BY NRC PRIOR TO PUBLICATION:
In February 1989, NRC Region III received an allegation concerning Ms. Nelson's possible overexposure in 1986. An NRC inspector then contacted the State of Wisconsin's Department of Health and Social Services and was informed that the source of Mrs. Nelson's radiation treatments was a linear accelerator.
NEW INFORMATION FROM PLAIN DEALER:
Husband committed suicide
INFORMATION GATHERED SINCE PUBLICATION:
None
PATIENT FOLLOW-UP:
None, not under NRC reguylatory purview.
NRC ENFORCEMENT ACTION (IF ANY):
None, linear accelerators are not under NRC regulatory purview.
LICENSEE HISTORY:

- The licensee has an NRC (AEC) license since August 8, 1956
- The license is inspected annually.
- Escalated Enforcement Actions

    1) EA 86-179, $1250 civil penalty imposed following loss of seven iridium-192 seeds used in animal experiments conducted between June 26 and August 21, 1986.

    2) EA 90-098, $7500 civil penalty imposed after a May 2, 1990 inspection found that on two occasions during the period April 1989 through March 26, 1990, a High Dose Rate Afterloader was used to treat patients and a trained operator was not present and at least 35 treatment plans did not have the treatment time calculations independently verified.

- Other therapeutic misadministrations

    1) On February 8 and March 16, 1990, NRC was notified of two therapy misadministrations that occurred on February 7 and March 15, 1990, respectively, due to a common cause. Erroneous information was entered into a computer that controlled the treatment location of sealed sources used in a remote afterloading brachytherapy device. The second event resulted in the wrong part of a patient's body receiving a therapy dose.

        In the first case, a 42-year-old patient was scheduled to receive a total of four treatments of 1,620 rem each, two to each side of the vaginal area, for a total of 3,240 per side. The first dose to the right side was correctly administered, but erroneous treatment parameters was entered into the computer for the second dose,

resulting in a single dose of 2,500 rem to the right side; therefore, the total dose to the right side was 4,120 rem or 27% higher than prescribed.

The second case involved a 66-year-old patient that was scheduled to receive a total of four treatments of 400 rem each to the bronchial area. Incorrect information was entered into the computer for the first treatment, resulting in the incorrect placement of the iridium-192 source. The treated area was about 3.5 inches from the intended area. When the error was discovered, the licensee repeated the procedure, and the remainder of the treatments were performed without incident.

The licensee prepared a quality assurance/quality control program to include dual verification at several key intervals of treatment planning and administration. In addition, training of personnel was verified by examination. The referring physicians and the patients involved were notified.

2) On November 27, 1991 NRC was notified of a misadministration involving the licensee's MicroSelectron HDR afterloading brachytherapy device (HDR) which occurred on November 27, 1991, to a male out-patient during final treatment for cancer of the nasal septum. The treatment card was taken from the wrong patient file. After the treatment began it was noted that there was a disparity between the one and one-half minute treatment time indicated the prescribing physician and the 400 second treatment time indicated by the physicist. Based on the disparity the physician directed the physicist to stop the treatment. The physicist and physician then discovered that the wrong treatment card had been used.

   As a result of using the wrong treatment parameters the patient's lips received an excessive dose of 76 rads. The physician informed the patient of the error. As of December 17, 1991, the patient had not exhibited any adverse effects as a result of the misadministration.

   NRC conducted a special safety inspection on December 17, 1991 in response to the therapeutic misadministration. An NRC medical consultant was contacted to evaluate the case. No violations of NRC requirements were identified during the course of the inspection.

Enclosure 4

BILL CLINTON
GOVERNOR

Arkansas DEPARTMENT OF HEALTH

4815 WEST MARKHAM STREET • LITTLE ROCK, ARKANSAS 72205-3867
TELEPHONE AC 501 661-2000

M JOYCELYN ELDERS, M.D.
DIRECTOR

January 11, 1993

Carlton Krammerer, Director, Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Carlton:

This letter is in response to the request for comments regarding statements attributed to me in the series of articles which appeared in the Cleveland Plain Dealer.

In the series of articles, I found reference to comments attributed to me in two places:

I. I do not know the date of this article, it was entitled

> "X-ray Victim Cringes at Idea of Safe Dose". I am quoted as indicating that I believe some of the problems the public has with radiation issues are associated with a lack of understanding of the issues, which is, in my opinion, directly related to the amount or type of public information that has been made available. Those of us dealing with radiation issues may not have been as proactive as we should have been in providing accurate, clear, and unbiased information to the public about radiation uses, risks and uncertainties. I think we have been slow to respond to comments that misdirect or mislead or to inaccurate information. The quote attributed to me appears to be accurate although it was made in reference to LLW issues and not medical issues.

II. Article dated 12-13-92 entitled "Maryland Hushed Up Twenty Patients Deaths".

> This section addressed my concern with the misadministration rule; the fact that Arkansas does not routinely levy fines for noncompliance and, that we may not have an effective regulatory structure.

- The first part of the quote is accurate in terms of what I said but it is taken somewhat out of context. As best I recall the conversation I addressed the fact that the States sometime disagree with the NRC on issues. The statement had to do with regulation promulgation and policy development. During this discussion I referred to the fact that the first misadministration rule included diagnostic misadministration reporting requirements which created problems because we also regulate x-rays and, to be consistent, had to develop diagnostic misadministration rules for x-ray - which proved difficult.

- Regarding the fact that we do not routinely fine licensees or registrants: While true, I take serious issue with implication in the article that this means a less serious commitment to radiation safety on our part. To my knowledge, they did not talk to Arkansas' medical consumers to determine if they had concerns about the health care services they receive. It is the policy to fine only for severe infractions of regulations that imply or implicate malfeasance or when a facility will not comply with the regulatory requirements. I believe that my statement was misunderstood and/or misused by the reporters.

  We have an aggressive inspection program and violations of regulatory requirements are identified; but, violations having the potential for health or safety impacts either on employees, patients or other individuals in the facility are rare. When these have occurred we have found facilities to be responsive and responsible in their reaction to the circumstances, quickly bringing them to correction.

  Arkansas has several small hospitals in rural areas without strong financial bases that are providing excellent medical care to our population in these areas. We believe our policy represents the best interests of the health of our people by fostering compliance through cooperation and education, not financial penalty.

  While we have not had an incident in our state of the nature of the incidents reported in the articles in The Plain Dealer, certainly no one can guarantee that we would never have such an incident in the future. However, I remain confident that we have the regulatory structure, philosophy and commitment in place such that the potential for these events is minimal and if an incident occurs necessary remedial activities will be available to quickly and effectively minimize the impact of the event.

Sincerely,

Greta J. Dicus

Greta J. Dicus, Director
Division of Radiation Control
and Emergency Management

Enclosure 4

STATE OF ILLINOIS
DEPARTMENT OF NUCLEAR SAFETY
1035 OUTER PARK DRIVE
SPRINGFIELD, ILLINOIS 62704
217-785-9900
217-782-6133 (TDD)

Jim Edgar
Governor

Thomas W. Ortciger
Director

January 15, 1993

Mr. Jim Myers
State Agreements Program
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

RE: YOUR FAX REQUEST FOR INFORMATION DATED DECEMBER 22, 1992

Dear Mr. Myers:

The Plain Dealer article on page 14A of the Sunday, December 13, 1992 edition referred to a statement made by Wayne Kerr as follows: "Similarly, Illinois, which has one of the larger agreement state programs and licenses about 400 medical institutions, has fined just one medical institution for a radiation violation since becoming an agreement state in June 1987."

Only one medical institution has been fined for violations of its radioactive materials license. However, Illinois has used other enforcement methods to achieve corrective measures. These include management conferences and orders to cease use of radioactive material. Also, civil penalties (fines) have been issued to 36 facilities for violations regarding unaccredited individuals. Four of these were nuclear medicine and three were radiation therapy.

All of the other references to the State of Illinois that appeared in the Plain Dealer articles were for a facility and individual (V.A. Medical Center, Hines, IL) that were under U.S. Nuclear Regulatory Commission license not the State of Illinois jurisdiction.

If you have any further questions, feel free to call me at (217) 785-9935.

Sincerely,

Steven C. Collins

Steven C. Collins, Chief
Division of Radioactive Materials

SCC:sjk

ENCLOSURE 4

NC

DIVISION OF RADIATION PROTECTION
Raleigh, North Carolina
Phone: 919/571-4141

FAX 919/571-4148

FACSIMILE TRANSMITTAL COVER SHEET

TO: Jim Myers

ADDRESS: NRC - OSP - St. Agreements Prog.

FAX #: (301) 504-3502

FROM: Mel Fry

SUBJECT: your 12/17/92 FAX on Plain Dealer Article

DATE: 12-22-92

NUMBER OF PAGES (Including Cover Page): 1

Should you have any problems with this transmittal, please call:

Mel Fry (Name) at (919) 571-4141 (Telephone Number)

Dr. Robert E. Zipf, Jr. is still Director of Laboratories at Nash General Hospital, Inc. in Rocky Mount, NC & has a General License for IN VITRO Testing, # 64-048-G last inspected 9/18/85; one item of non-compliance (disposal records) was cited and corrected.

Revision 2, 02/06/91

proof

ENCLOSURE 4

Fax (301) 504-3502

ARIZONA
RADIATION REGULATORY AGENCY

4814 South 40th Street
Phoenix, Arizona 85040

DATE: 1/15/93

FACSIMILE TO: Jim Myers, State Agrmt Prog.

FROM: Wainright, Prog Mgr - Rcm/X-Ray
FACSIMILE NUMBER: (602) 437-0705
VOICE NUMBER: (602) 255-4845

SUBJECT: Submission to explain Plain Dealer's insertion of "Desert Samaritan Hospital's" mis administration which occured on November 1, 1989.

COMMENTS: It might be interesting to note that Jack Hansen looked over our actions during his annual review in June 1991 and approved it. In addition he checked out our actions when NRC + they supported the actions and would have imposed a similar $12,000 civil penalty.

NUMBER OF PAGES INCLUDING COVER SHEET: 15

ENCLOSURE 4

SIGNIFICANT CASES IN ARIZONA AS REPORTED IN THE PLAIN DEALER NEWSPAPER ARTICLE SERIES

1. Name of Facility:

Desert Samaritan Hospital and Health Center, Mesa, Arizona.

2. Number of Patients Involved:

One.

3. Name of Patient:

Mrs. Deborah Lane.

4. Synopsis of Plain Dealer Article:

In November, 1989, homemaker Deborah Lane, mistakenly received 100 millicuries instead of 100 microcuries of Iodine-131 for a thyroid scan. The overdose, equal to 1000 times more radiation than her doctor had prescribed, was caused by a series of mistakes at the hospital.

It was enough to contaminate the Lane's car, home and family.

Lane had to be placed in a special isolation area while the radiation wore off.

She was also asked by the hospital officials to supply a list of everyone she had contact with, especially the ones she kissed.

When Lane finished the list, the hospitals chief nuclear medicine technologist responded, "My, you're a kissy person, aren't you?"

The Arizona Radiation Regulatory Agency (ARRA) fined the hospital $12,000,.00.

5. Information Known by the State Prior to Publication:

Included as enclosure 1, 3 enclosures sent to Mr. Jack Horner, Region V Agreement State Liaison and enclosure 2, (NUREG-0090, Volume 13, No. 2, April - June, 1990 AOR Reports).

6. New Information From Plain Dealer Article:

None.

7. Information Gathered Since Publication:

Discussions with the current Radiation Safety Officer indicate that a suit initiated by Deborah Lane against Desert Samaritan Hospital had been settled and the amount of settlement was unknown.

8. Patient Follow-up:

ENCLOSURE 4

No action has been taken by at this Agency to follow-up on the patients condition. This is a medical issue and is probably being addressed by Desert Samaritan Hospital and the responsible physician.

9. State Enforcement Action:

ARRA conditionally imposed a civil penalty of $14,000.00, mitigated $2,000.00 of it and finally imposed a civil penalty of $12,000.00. The $12,000.00 civil penalty was paid on January 24, 1990.

10. License History:

No significant findings which would indicate a generic problem that would have caused the problem which occurred on November 1, 1989,

WAW/lj

ENCLOSURE 4

ARIZONA
RADIATION REGULATORY AGENCY

Rose Mofford
Governor
Charles F. Tedford
Director

4814 South 40 Street Phoenix, Arizona 85040 (602) 255-4845

May 2, 1990

Mr. Jack W. Horner
Regional State Agreements Representative
U.S. Nuclear Regulatory Commission, Region V
1450 Maria Lane, Suite 210
Walnut Creek, California 94596

Dear Jack:

Enclosed for your information is an Abnormal Occurrence Report (AOR) (Enclosure No. 1) for the Misadministration which occurred at Desert Samaritan Hospital (License No. 7-106) on November 1, 1989. Also enclosed is the written summary (Enclosure No. 2) and a list of chronological events (Enclosure No. 3) to include actions that were taken by Syncor International Corporation, the radiopharmacy which supplied the Iodine-131.

If you have any comments or questions, please contact this Agency at (602) 255-4845.

Sincerely,

Charles F. Tedford
Director

Enclosures
waw:CFT:svc

cc: Vandy Miller
Assistant Director State Agreements Program
Lloyd Bolling

Enclosure 1.

ENCLOSURE 4

ENCLOSURE 1

EVENT REPORT FOR MATERIAL LICENSEES

This information is submitted in support of USNRC's Misadministration and ADR Report Programs

LICENSEE NAME Desert Samaritan Hospital LICENSE NO. 7-106 PAGE NO. 1

LOCATION OF EVENT
FIXED X FIELD _____

ISOTOPE AND AMOUNT
ISOTOPE Iodine-131 AMOUNT 100 millicuries

EVENT DATE YR MO DA	REPORT DATE YR MO DA	OTHER LICENSEES INVOLVED
89/11/01	90/4/27	NAME Syncor International Corp. LICENSE NO. 7-123

TYPE OF EVENT
CHECK ALL BLOCKS THAT PERTAIN

( ) LOSS OF PACKAGE EFFECTIVENESS OR CONTAMINATION
( ) THEFT OR LOSS OF LICENSED MATERIAL
( ) OVEREXPOSURE OF INDIVIDUAL TO RADIATION
( ) OVEREXPOSURE OF INDIVIDUAL TO RADIOACTIVE MATERIAL
( ) EXCESSIVE LEVELS OF RADIATION OR CONCENTRATIONS OF RADIOACTIVE MATERIAL
( ) SAFETY FAILURE OF GL DEVICE
( ) LEAKING SOURCE
(X) MISADMINISTRATION
( ) URANIUM MILL OCCURRENCE
( ) TRANSPORTATION INCIDENT
( ) OTHER _____

Reciprocity GL Information

Agreement State or NRC License Agreement or N/A _____

DESCRIPTION OF EVENT

Please refer to enclosed Chronological Events (Enclosure #3) and written Summary (Enclosure #2)

ENCLOSURE 4
ENCLOSURE 2

AGREEMENT STATE MEDICAL DIAGNOSTIC MISADMINISTRATION:

On November 1, 1989, at Desert Samaritan Hospital, Phoenix, Arizona, a patient scheduled for the administration of 100 microcurie capsules of Iodine-123, was administered 100 millicuries of liquid Iodine-131 and sent home for 24 hours until normal imaging was scheduled.

When the patient returned the next day (November 2), the imaging camera flooded out, which indicated a large overdose, and the Arizona Radiation Regulatory Agency (ARRA) was immediately notified. The patient was immediately hospitalized and isolated, as is the case for thyroid ablation dose patients. The patient's family was contacted and bioassays were obtained to determine Iodine-131 thyroid burdens. The Chief Nuclear Medicine Technologist and an Agency representative performed a survey and decontamination of the patient's home. Wipe tests were obtained to verify the efficiency of the decontamination efforts. The family thyroid burdens, while above the action level for radiation workers (0.4 μCi), were not considered a serious health threat.

Discussions with management, Chief Nuclear Medicine Technician, and the two Nuclear Medicine Technicians indicated the following violations:

1. The patient had been administered a therapeutic dose of Iodine-131 and allowed to go home (an unrestricted area).

2. The Iodine-131 dose had not been assayed in the dose calibrator prior to administration.

3. There was a failure to compare the Iodine-131 dose label with the physician's order.

4. The incoming radiopharmaceutical package, when received, had not been surveyed.

5. Records for incoming radiopharmaceuticals were not maintained in an adequate fashion.

These actions were required by hospital license conditions but were not performed because of a series of human errors. These violations were also listed in the Notice of Violation sent to Desert Samaritan Hospital.

To prevent reoccurrence, the Agency placed an order on the hospital which reduced the total amount of Iodine-131 that could be possessed at one time from 500 millicuries to 100 microcuries (0.1 millicuries). In addition, the Agency proposed a $14,000 Civil Penalty

against the hospital for failure to perform required procedures.

The Agency also investigated Syncor International, Inc., the radiopharmacy that dispensed the radiopharmaceutical dose to the hospital. The investigation showed that the records of the telephone order for the Iodine-131 were not written legibly such that the units could be differentiated (μCi or mCi); the type of intended medical procedure (diagnostic or therapeutic) was not shown. Neither the hospital employee who placed the order nor the pharmacy person taking the order could be identified. The Agency cited Syncor and imposed an order which limited them to not dispensing any dose of Iodine-131 in excess of one millicurie unless a written order from the client licensee was in the possession of the radiopharmacist dispensing the dose.

The radiopharmacy responded on December 11, 1989, and informed the Agency that the following policies would be observed when Iodine-131 therapy orders were received and dispensed:

1. All orders for Iodine-131 therapy doses must be taken and confirmed by a pharmacist that the order is for a therapy dose.

2. A patient name must be obtained at the time that the order is taken and must be entered on the prescription label before the dose is dispensed.

3. All Iodine-131 therapy doses must be calibrated using the K factor and must be within 10 percent of the prescribed dose.

Additionally, it was suggested that all liquid Iodine-131 therapy doses be dispensed in a plastic screw top septum-vial. A therapy administration straw, which can be inserted through the septum without opening the vial, can be used in conjunction with the vial.

The Agency issued a license amendment to Syncor on January 10, 1990 which stated the following:

1. All orders for Iodine-131 in quantities greater than one millicurie shall be taken by a pharmacist who shall verify the dose as a therapy dose and repeat the order back to the individual that placed the order.

2. The patient's name shall be obtained when the therapy dose is ordered and shall be on the prescription label prior to dispensing the dose.

3. The name of the client representative ordering the therapy dose, the patient's

ENCLOSURE 4

name and procedure, and the name of the pharmacist accepting the order shall be recorded on the telephone order pad.

The order limiting Syncor dispensing any dose of Iodine-131 in excess of one millicurie was withdrawn on January 9, 1990, because of Syncor's internal policy, the Agency's license amendment, and an inspection conducted by the Agency on November 20-22, 1990.

On January 10, 1990, the Agency received a letter from Desert Samaritan Hospital admitting to Violation Nos. 1, 2, 3, and 5 and disagreeing with Violation No. 4 (package not being surveyed). Contained in the letter were amended administrative procedures for the Nuclear Medicine Department. The Agency sent a letter back to Desert Samaritan Hospital mitigating Violation No. 4 from $3,000 (a Category II violation) to $1,000 (a Category III violation) and imposing a resultant civil penalty of $12,000. A check from Desert Samaritan Hospital in the amount of $12,000 was received by the Agency on January 24, 1990.

An enforcement conference was held with Desert Samaritan Hospital on January 31, 1990, at which time the findings of the civil penalty were readdressed. A letter from Desert Samaritan Hospital was received by the Agency on February 15, 1990, recommitting to amended Nuclear Medicine Department administrative procedures. Based on this letter, amended Nuclear Medicine Department administrative procedures and the enforcement conference, the order restricting Iodine-131 possession limits to 100 microcuries was rescinded on March 9, 1990.

ENCLOSURE 4

CHRONOLOGY OF EVENTS I-131 INCIDENT

1000 Wednesday, November 1, 1989: A patient scheduled for the administration of 200 microcurie capsules of Iodine-123 was administered 100 millicuries of liquid I-131 and sent home.

0900 Thursday, November 2, 1989: Patient returned for thyroid scan. Results of the scan indicated a problem. ARRA notified by telephone that a diagnostic misadministration had occurred at Desert Samaritan. Initial information included the information that the patient was to have been given a diagnostic dose of 100 microcuries of Iodine-131 for a substernal thyroid scan but when the scan indicated a larger amount (later determined to be 100 millicuries) it was decided to notify the Agency.

1400 - 1700 Thursday, November 2, 1989: The Chief Nuclear Medicine Technologist and an Agency representative performed a survey and decontamination of the patients home. 13 wipes were obtained to determine efficiency of the decontamination efforts. A bioassay was performed on all residents of the patients home. All had a detectable uptake of Iodine. Patient was hospitalized in isolation following routine hospital procedures for ablation dose patients.

0900 Friday, November 3, 1989: Conducted interview of the Chief Nuclear Medicine Technician and Management of Desert Samaritan Hospital.

1000 Friday, November 3, 1989: Called the NRC Region 5 and advised of situation.

1100 Friday, November 3, 1989: Smear results received indicating that decontamination was successful except for the patients Master bath sink counter top and telephone. The Chief Nuclear Medicine Technician was notified and stated that she would inform the patients husband.

1300 Friday, November 3, 1989: Conducted interview of the radiopharmacy Manager.

Saturday Morning, November 5, 1989: Patient less than 5 mr/hr at one meter and was discharged from Desert Samaritan Hospital.

Monday Morning, November 6, 1989: Called Mr. Jack Horner and informed him of the situation.

0900 Monday, November 6, 1989: Returned to Syncor and interviewed all radiopharmacists and drivers involved in the preparation and delivery of the dose to Desert Samaritan Hospital.

Tuesday November 7, 1989: Syncor International Corporation issues nationwide I-131 therapy order policy.

a. All orders for I-131 must be taken by a radiopharmacist and confirmed that it is a therapy dose.

b. Patient name must be obtained and on the prescription label before dose is dispensed.

c. All I-131 therapy doses must be within 10% of prescribed dose.

d. Suggested all liquid I-131 therapy be dispensed in a plastic screw top septum vial.

0830 Thursday, November 9, 1989: Returned to Desert Samaritan Hospital and individually interviewed both technicians involved while in the presence of DSH management.

1000 Thursday, November 16, 1989: Notified the Chief Nuclear Medicine Technologist of Desert Samaritan Hospital that the Agency considers the incident to fall under the requirement of R12-1-423 in which a written report must be given to the Agency within one month vis-a-vis reporting a diagnostic misadministration no later than 10 days after the end of the quarter in which the misadministration occurs.

1615 Thursday, November 16, 1989: Telefaxed draft copy of the results of interviews to Mr. Jack Horner NRC Region 5.

November 21, 1989: Agency placed an order on Desert Samaritan Hospital limiting total I-131 to 100 microcuries.

November 22, 1989: Agency placed an order on Syncor modifying Iodine-131 procedures by license amendment.

> "The licensee shall not dispense any dose of Iodine-131 in excess of one millicurie unless a written order from the client licensee is in the possession of the radiopharmacist dispensing the dose."

December 5, 1989: Notice of violation and proposed civil penalty letter sent to Desert Samaritan Hospital identifying 5 violations:

1. Release of patient administered 100 millicuries of Iodine-131 to an unrestricted area. $4,000 civil penalty proposed.

2. Failure to assay dose prior to administration. $3,000 civil penalty proposed.

3. Failure to compare dose label with physicians order. $3,000 civil penalty proposed.

4. Failure to perform survey of incoming radiopharmaceutical package. $3,000

civil penalty proposed.

5. Failure to maintain acquisition records. $1,000 civil penalty proposed.

January 9, 1990: Order to Syncor modifying Iodine-131 procedures terminated.

January 10, 1990: Syncor amendment #54 issued modifying Iodine-131 order procedures.

a. All Iodine-131 orders = to or > 1 millicurie are taken by a pharmacist who shall verify the dose and repeat the order back to the individual ordering the dose.

b. Patients name obtained with therapy dose ordered and put on prescription label.

c. Name of client representative ordering dose, patients name and procedure and name of pharmacist accepting the order placed on the order pad.

January 10, 1990: Letter received from Desert Samaritan Hospital admitting to findings 1, 2, 3, & 5 and refuting finding #4 and amending administrative procedures of the nuclear medicine department.

January 22, 1990: Letter from the Agency to Desert Samaritan Hospital mitigating finding #4, to a $1,000 civil penalty, and order imposing a civil penalty of $12,000.

January 23, 1990: Performed specific inspection of Desert Samaritan's dose calibrator and its associated records, and survey meters.

January 24, 1990: Received $12,000 civil penalty payment from Desert Samaritan Hospital.

February 15, 1990: Received letter from Desert Samaritan Hospital with commitment to change procedures (attached).

March 8, 1990: Draft order to, and amendment of, Desert Samaritan Hospital license.

Apr-June 1990

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ENCLOSURE 4

NRC - The NRC conducted a special inspection on June 27-29, 1990, to review the circumstances of the misadministration and to evaluate the licensee's radiation safety and management control programs (Ref. 7). The inspection also covered an earlier therapy misadministration in which a patient received less than the intended dose. In this misadministration, a patient received a dose that was 12 per cent less than that intended during a treatment series February 15 through April 3, 1990. A Notice of Violation was issued for two instances of failure to report the misadministrations within the required time period. The inspection also identified a concern about staff shortages that may adversely affect the licensee's radiation therapy program. The NRC requested the hospital's response to this concern.

This item is considered closed for the purposes of this report.

* * * * * * * *

AGREEMENT STATE LICENSEES

Procedures have been developed for the Agreement States to screen unscheduled incidents or events using the same criteria as the NRC (see Appendix A) and report the events to the NRC for inclusion in this report. For this period, the Agreement States determined that one of these events was an abnormal occurrence.

AS90-1 Medical Diagnostic Misadministration

Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health and safety can be considered an abnormal occurrence.

Date and Place - November 1, 1989; Desert Samaritan Hospital; Phoenix, Arizona

Nature and Probable Consequences - On November 1, 1989, a patient scheduled for the administration of 100 microcurie capsules of iodine-123 for a diagnostic thyroid scan was mistakenly administered a therapeutic dose of 100 millicuries of iodine-131 and sent home for 24 hours until normal imaging was scheduled.

When the patient returned on November 2, the imaging camera flooded out, which indicated a large overdose. The hospital immediately notified the Arizona Radiation Regulatory Agency (ARRA). The patient was immediately hospitalized and isolated, (the standard practice for thyroid ablation patients). The patient was discharged on November 5, 1989.

The patient's family was contacted and a bioassay was performed to determine the thyroid body burden of each family member. The thyroid burdens were above the action level for radiation workers (0.4 microcurie) but the level was not considered a serious health threat to any family member.

Enclosure 2

A hospital employee and an ARRA representative surveyed and decontaminated the patient's house. Wipe tests were used to verify the efficiency of the decontamination.

Cause or Causes - There were several causes for this event. The hospital staff:

- o did not assay the dose in the dose calibrator prior to administering it,
- o did not compare the iodine-131 dose label with the physician's order, and
- o did not maintain adequate records of incoming radiopharmaceuticals.

In addition, ARRA cited the hospital for allowing a patient who had been administered a therapeutic dose of iodine-131 to go home.

Syncor International, Inc., the radiopharmacy that dispensed the dose:

- o did not record the telephone order for iodine-131 legibly so that the units for microcurie and millicurie could be differentiated, and
- o did not record the type of intended procedure (diagnostic or therapeutic).

Actions Taken to Prevent Recurrence

Agency - The ARRA placed an order on the hospital that reduced the possession limit for iodine-131 from 500 millicuries to 100 microcuries (0.1 millicurie). The ARRA also cited Syncor and imposed an order limiting them from dispensing any dose of iodine-131 in excess of 1 millicurie unless a written order from the client licensee was in the possession of the radiopharmacist dispensing the dose. Later, the ARRA sent a Notice of Violation to the licensee and imposed a civil penalty in the amount of $12,000.

Hospital - The hospital amended its Nuclear Medicine Department administrative procedures and paid the civil penalty in full. The order restricting iodine-131 possession limits to 100 microcuries was rescinded by the ARRA on March 9, 1990.

Radiopharmacy - The radiopharmacy adopted policies to be used when iodine-131 therapy orders were received and dispensed. The ARRA issued a license amendment incorporating required procedures for orders for more than 1 millicurie of iodine-131. The order limiting the amount of iodine-131 that could be dispensed was withdrawn by the ARRA on January 9, 1990.

This item is considered closed for the purposes of this report.

* * * * * * * *

MARYLAND DEPARTMENT OF THE ENVIRONMENT
Radiological Health Program

TO: Jim Myers --USNRC

FROM: Carl Trump, Jr.
(410) 631-3301

DATE: January 21, 1993

---

1. NAME OF FACILITY: Sacred Heart Hospital of Cumberland, Maryland

2. NUMBER OF PATIENTS INVOLVED: Thirty-three (33)

3. NAMES OF PATIENTS: Not disclosed due to confidentiality

4. SYNOPSIS OF PLAIN DEALER ARTICLE:

   - Entire article written about Sacred Heart Hospital addressed entities other than Sacred Heart Hospital.
   - The article failed to report that all patients were diagnosed as terminally ill prior to the initiation of therapy treatments.
   - Patients' identities are never disclosed to outside agencies and are kept in strict confidence.
   - Under advisement by the Attorney General's Office of the State of Maryland, the Maryland Department of the Environment (MDE) drew up a Consent Agreement that was agreed to and signed by the attorney representing Sacred Heart Hospital, MDE's Assistant Attorney General, Neil Quinter, and the Radiological Health Program's Administrator, Roland Fletcher.

5. INFORMATION KNOWN BY THE STATE PRIOR TO PUBLICATION:

   Complete investigation was conducted by staff members of the RHP.

6. NEW INFORMATION FROM THE PLAIN DEALER ARTICLE:

   None.

7. **INFORMATION GATHER SINCE PUBLICATION:**

None.

8. **PATIENT FOLLOW-UP:**

According to hospital information, all patients treated during the 1987-88 incident time frame are deceased.

9. **STATE ENFORCEMENT ACTION:**

- Consent Agreement signed by attorneys representing Sacred Heart Hospital and MDE.
- Civil Penalty was invoked against Sacred Heart Hospital totalling $15,000.00 and $2,000.00 reimbursement fee. Settlement was for $9,500.00.

10. **LICENSEE HISTORY:**

An earlier therapeutic misadministration occurred at Sacred Heart Hospital during the period of August 9-26, 1988. Dr. Cynthia Brown, radiotherapist, was responsible for the treatment program in this case as she was during the misadministrations of thirty-three (33) patients. This case involved radiation doses to the wrong area of the skull.

CET:dpn

State of California — Department of Health Services

Memorandum

Date : January 21, 1993

To : Jim Myers
State Agreements Program
Office of State Programs
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555

From : Radiologic Health Branch
601 N. 7th Street
P.O. Box 942732
Sacramento, CA 94234-7320

Subject : Agenda for Commission's Briefing January 29, 1993.

Summary of outline covering material gathered by California's Radiation Control concerning the Plain Dealer articles:

Facility Name:	Alta Bates Hospital, Oakland, CA, and West Coast Cancer Foundation, San Francisco.
Patient:	Dwight Golstein
Article Synopsis:	Patient died following a therapeutic treatment that was double the dose prescribed.
Information the State Had:	Prior to this article, the State Program knew that the patient had died following his treatment.
New Information:	The State found out during a preliminary investigation that the patient was treated by a Co^{60} teletherapy machine and an error was made by the consultant Medical Physicist that caused a doubling of the dose delivered. It now appears that the hospital tried to cover the event's details.
Patient Followup:	A copy of the patient's death certificate will be obtained.
Enforcement action:	Pending completion of assist investigation by NRC, special investigator.

License History: Authorized to use teletherapy by Amendment # 69
source was exchanged April 19, 1990.

Donald E. Bunn, Chief
Enforcement and Compliance

Date and Place - June 27, 1988; The Fairfax Hospital, Falls Church, Virginia.

Nature and Probable Consequences - A patient was administered 2.7 millicuries of I-131 MIBG rather than the intended dose of 500 microcuries of I-131 MIBG.

I-131 MIBG is currently an Investigational New Drug and is used in a relatively new and rarely ordered diagnostic study performed at the hospital. Prior to the administration, the technologist involved, who was unfamiliar with the correct amount to administer, checked both the literature which accompanied the shipment and the department's procedure manual. However, even though the correct dose was listed in the procedure manual, the technologist missed it and assumed that the entire vial of 2.7 millicuries was to be administered.

The misadministration resulted in an estimated adrenal medullae dose of 268.4 rads, as calculated in accordance with literature supplied by the United States Food and Drug Administration. The thyroid burden should be negligible because the thyroid had been blocked with Lugols prior to the administration of the I-131 MIBG, as prescribed in the protocol.

The licensee stated the patient exhibited no adverse health effects.

Cause or Causes - The cause is attributed to the technologist's error in overlooking the proper dosage as listed in the department's procedure manual.

Action Taken to Prevent Recurrence

Licensee - The technologist was admonished and retrained.

NRC - NRC Region II telephoned the hospital for additional details on the incident. The incident will be reviewed during the next NRC inspection at the hospital.

This item is considered closed for the purposes of this report.

* * * * * * * * *

NUREG-0090
Vol. 11, No. 3
July - Sept. 1988

AGREEMENT STATE LICENSEES

Procedures have been developed for the Agreement States to screen unscheduled incidents or events using the same criteria as the NRC (see Appendix A) and report the events to the NRC for inclusion in this report. During the third calendar quarter of 1988, an Agreement State (Texas) reported the following abnormal occurrence to the NRC:

AS88-3 Medical Diagnostic Misadministration

Appendix A (see the general criterion) of this report notes that an event involving a moderate or more severe impact on public health or safety can be considered an abnormal occurrence.

Date and Place - May 17, 1988; West Houston Medical Center, Houston, Texas.

Nature and Probable Consequences - A patient was scheduled to be administered 30 microcuries of iodine-131 in capsule form for a diagnostic scan of her thyroid. Instead she was administered 30 millicuries of iodine-131 in capsule form. This resulted in an estimated dose to the thyroid of over 30,000 rads; such a dose would be expected to destroy the thyroid's function. The event was investigated by the Texas Department of Health, Bureau of Radiation Control (the "Agency").

After the patient's doctor ordered a diagnostic thyroid scan, the technologist mistakenly ordered a dose of 30 millicuries of iodine-131 on Sunday May 15, leaving the order on an answering machine. The pharmacist on duty the next day took the order but could not fill it because therapy doses are ordered from the manufacturer individually. He called the technologist to explain, and she agreed to postpone until the next day, May 17. When the dose arrived, she placed it in the dose calibrator and was perplexed by the high count rate she obtained, but administered the dose and told the patient to come back the next morning for her scan. The technologist mentioned the high count rate to the doctor, who apparently didn't get enough information to realize the potential problem and told her the count rate was relative.

On Monday May 16, she had ordered 30 millicurie doses for two other patients to be administered on May 18 and was informed it was too late to change the delivery but that there would still be 27.5 millicuries (quantity reduction due to radioactive decay) on the 19th, when the dose was to be administered. When she checked with the doctor, informing him of the 27.5 millicurie dose, he corrected her saying she meant microcuries. She still didn't realize her mistake. Later, on the evening of May 17th, she ordered a 30-microcurie dose and was told it could be delivered right away. She asked why she had to wait for the others and was reminded they had been 30 millicuries. She then realized her mistake and notified another physician on the hospital staff, who after consulting with the patient's physician, called the patient back to the hospital and administered a blocking agent about 12 hours after the original dose was administered. However, the blocking agent was felt to have little effect.

The hospital's estimate of the dose to the thyroid was 30,000 rads. The Agency's calculations indicated a thyroid dose of approximately 34,000 rads. The hospital is performing follow-up examinations of the patient. No prognosis for the patient was available at the time of the Agency's report to the NRC.

Cause or Causes - The Agency's investigation indicated several contributing factors to the misadministration. The hospital performs relatively few thyroid scans and they are all performed using microcurie quantities of iodine. Scans using other radionuclides require millicurie quantities.

The technologist placing the order was not as experienced as the technologist who normally performed the scans. She had already performed several scans using millicurie quantities of other radionuclides and when the thyroid scan was ordered, went to her procedures manual for the quantity to be ordered. When she placed the order, she apparently didn't realize she was saying millicuries and continued to confuse millicuries and microcuries until after the dose was administered.

Actions Taken to Prevent Recurrence

Licensee - The licensee is rewriting its protocol for nuclear medicine scans to list each procedure with the activity and form of the material to be used. In addition, the licensee is instructing any firm supplying therapy doses of radiopharmaceuticals that they are to be prepared only when the order is accompanied by a written prescription signed by the physician user authorizing the procedure or verbal, personal authorization is obtained by the pharmacist from the physician-user.

Agency - At the time of the Agency's report to the NRC, the Agency was still reviewing the incident to determine the appropriate enforcement action.

This item is considered closed for the purposes of this report.

* * * * * * * *

Enclosure 4

KRISTINE M. GEBBIE
Secretary

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
DIVISION OF RADIATION PROTECTION
Airdustrial Center, Bldg. 5 • P.O. Box 47827 • Olympia, Washington 98504-7827

January 15, 1993

Mr. Vandy Miller
Assistant Director for
State Agreements Program
U.S. Nuclear Regulatory Commission
Office of Governmental & Public Affairs
Mail Stop: WF-3-D-23
Washington, D.C. 20555

Dear Mr. Miller Vandy

This is in response to your request for background information on radiation overexposures and/or statements contained in the Cleveland "Plain Dealer" Newspaper series. There are three references in the article to the state of Washington. The first is a quote by our X-Ray Program Manager; reference to two incidents involving a Therac 25 Linear Accelerator in Yakima, Washington; and last a reference to a Riverside Hospital patient whose home is currently in this state.

The X-Ray Program Manager is quoted in the December 12, 1992 issue of the "Plain Dealer". He notes that "X-rays just haven't been given the rigorous regulation that isotopes have gotten". This statement was made to the reporters for the "Plain Dealer" several months ago in response to their inquiries regarding the two incidents occurring in Yakima, Washington. Even though we believe greater control over therapy machines is warranted, it is highly likely that in these incidents, no inspector or facility staff could have, in the routine discharge of their duties, discovered the flaw in the computer software which lead to these incidents. It is also possible that a tougher standard would still not have prevented these incidents.

Nationally, there were a number of incidents involving the Therac 25 during the 1986 and early 1987 timeframe, including the two in Yakima. These were the basis for action by the Food and Drug Administration, CDRH, requesting the manufacturer to notify all users to discontinue use until corrective actions were approved and implemented. The 1987 Yakima incident was reported and investigated immediately by the state of Washington. Ultimately, it was attributed to a combination of software, hardware and operator errors. The direct cause of the problem was a mismatch within the machine between target position and recognition of beam condition. In retrospect, the earlier incident was probably also attributable to a Therac 25 malfunction, but this went undetected until the time of the second incident because the resulting reddening of the patient's skin was originally thought to be a rash. (See page 98 in the "Proceedings of the 19th Annual Conference on Radiation Control" - CRCPD, where we reported the results of our investigations.)

The final reference to the state of Washington is in association with a patient treated at the Riverside Hospital and only incidentally lives in the state of Washington. Any information regarding this overexposure and follow up should be referred to the appropriate regulatory agency for the Riverside Hospital.

If you have any other additional questions about these incidents, please let me know.

Sincerely,

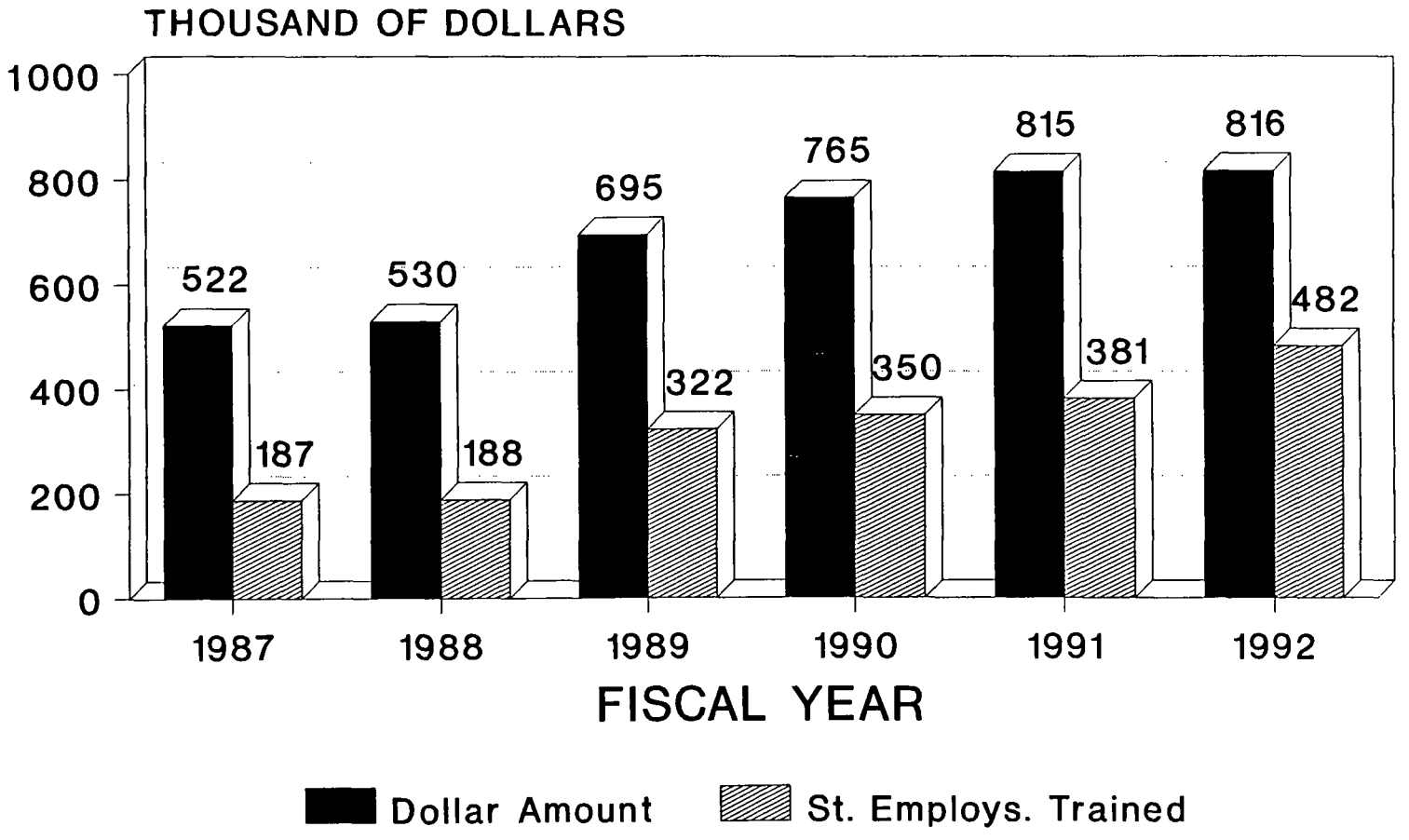
T.R. Strong, Director
Division of Radiation Protection

TCF:amw

Enclosure 5

Annual Training Budget for
Agreement State Personnel

NRC TRAINING BUDGET FOR STATES



Enclosure 6

Escalated Enforcement Data for 1989 - 1991
and
Enforcement and Investigation Data for
Agreement States

NRC MATERIALS LICENSEE ESCALATED ENFORCEMENT DATA: 1989-91

1989		BASIS FOR ESCALATED ACTION					
Types	Total Escalated Cases	Misadmin-istration	Over-exposure	Manage-ment Breakdown	Loss of Control	Willful-ness	Other
Medical Broad	4	1	0	1	2	0	1
Community Hospitals	14	1	0	10	0	2	1
Private Practice/ Clinics	10	0	1	7	1	0	2
Telether.	5	0	0	3	0	0	2
Other Materials Licenses	37	N/A	7	13	7	7	7
TOTAL	70 (33)[a]	2 (2)	8 (1)	34 (21)	10 (3)	9 (2)	13 (6)

1990		BASIS FOR ESCALATED ACTION					
Types	Total Escalated Cases	Misadmin-istration	Over-exposure	Manage-ment Breakdown	Loss of Control	Willful-ness	Other
Medical Broad	13	1	1	5	5	0	1
Community Hospitals	22	3	0	12	1	8	1
Private Practice/ Clinics	2	0	0	2	0	0	0
Telether.	6	5	0	2	0	0	0
Other Materials Licenses	45	N/A	13	9	10	12	5
TOTAL	88 (43)	9 (9)	14 (1)	30 (21)	16 (6)	20 (8)	7 (2)

1991		BASIS FOR ESCALATED ACTION					
Types	Total Escalated Cases	Misadmin-istration	Over-exposure	Manage-ment Breakdown	Loss of Control	Willful-ness	Other
Medical Broad	9	1	0	4	1	1	2
Community Hospitals	12	2	0	6	1	3	0
Private Practice/ Clinics	3	0	0	1	0	2	0
Telether.	1	0	0	1	0	0	0
Other Materials Licenses	39	N/A	4	9	7	10	10
TOTAL	64 (25)	3 (3)	4 (0)	21 (12)	9 (2)	16 (6)	12 (2)

[a] Numbers in parentheses refer to total medical cases.

AGREEMENT STATE TOTALS FOR 1989 - 1991

INCIDENT[1] REPORTING PROGRAM

Review Cycle	Licensees	Incidents reported to State	On-site inspections of incidents	Incidents reported to NRC
87 - 89	13802	1475	878	610
89 - 91	14555	1927	1251	793

INVESTIGATIONS OF ALLEGATIONS[1]

Review Cycle	Allegations	Allegations investigated	RESULTS (investigations ending with enforcement action)
87 - 89	126	114	15
89 - 91	123	123	32

ENFORCEMENT PROGRAM

Review Cycle	Civil penalty	Impoundments	Criminal penalty	Enforcement conference	Orders issued
87 - 89	112	20	1	51	68
89 - 91	103	18	0	126	93

[1]A number of Agreement States do not distinguish between incidents and allegations for investigation or record keeping purposes. The data from these states is included under "incidents" only.

Enclosure 7

Synopses of OI Investigation of
Misadministration Cases

December 23, 1992

MEMORANDUM FOR: William D. Hutchison
Assistant to the Director
Office of Investigations

FROM: Betsy S. Barber
Office of Investigations

SUBJECT: SYNOPSES FOR MISADMINISTRATION CASES WHICH WERE SUBSTANTIATED; BREAKDOWNS BY YEAR CLOSED AND PROGRAM CODE

Attached at Tab A per your request are synopses for nine misadministration cases which were substantiated either by OI or other independent investigators. Eight of the nine cases were substantiated by OI. The Ellis Fischel State Cancer Center (EFSCC) case was substantiated by an investigation by the EFSCC Radiation Safety Committee; however, OI did not conduct a full-scale investigation thereafter. The following is a list of those cases:

1-84-034	Thomas Jefferson Univ. Hospital
1-85-014	Mercy Hospital
1-92-009	Rhoda H. Cobin, M.D.
2-87-011	St. Mary's Hospital
2-91-013	U.S. Veterans Affairs Medical Center
3-85-002	Bloomington Hospital
3-87-003	Edward Hines, Jr., VA Medical Center
3-90-005	Ellis Fischel State Cancer Center
3-91-004	Copley Hospital

The chart at Tab B breaks down the 20 misadministration cases by year closed, beginning in 1982 (the year of OI's inception). The same misadministration cases broken down by program code are as follows:

Program Code 02110/Medical Institution Broad - 5 cases
Program Code 02120/Medical Institution Limited - 10 cases
Program Code 02200/Medical Private Practice Limited - 2 cases
Program Code 02300/Teletherapy - 3 cases

A listing of the 20 misadministration cases is attached at Tab C. A comparison of this list of misadministration cases was made with the more extensive list prepared by J. Hunt of all cases involving hospitals, clinics, or their employees in response to a FOIA request (see memorandum dated 3/11/92 to Dick Lavins, ADM). It should be noted that the reason that the FOIA-response list is longer than the above listing is that many of the cases involved violations other than misadministrations.

Attachments:
As stated

Distribution: s/f RPT (OI Miscellaneous)
r/f BSB r/f JHunt

OI
BBarber:bb
12/23/92

Title: THOMAS JEFFERSON UNIVERSITY HOSPITAL:

ALLEGED MANAGEMENT CONCEALMENT OF MEDICAL MISADMINISTRATION OF RADIOPHARMACEUTICALS

Licensee:

Thomas Jefferson University
Philadelphia, Pennsylvania 19107

Docket No.: 30-2941

Case Number: 1-84-034

Report Date: May 21, 1986

Control Office: OI:RI

Status: CLOSED

SYNOPSIS

This investigation was initiated based upon an allegation from a Nuclear Medicine Technologist at Thomas Jefferson University Hospital. The Technologist alleged that four or five diagnostic misadministrations had occurred at Thomas Jefferson within the past six months and the Department Head had not reported the matters to the Radiation Safety Officer (RSO) or the NRC.

The OI investigation revealed that three diagnostic misadministrations had occurred at Thomas Jefferson University Hospital in May and October 1982 and in December 1983. These three misadministrations had not been reported to the NRC. The investigation revealed, however, that the three incidents had been reported to the RSO shortly after the occurrences and that it had been his decision, in consultation with the Nuclear Medicine Department Head, not to report the matters to the NRC.

The RSO and the Nuclear Medicine Department Head stated that the three incidents had not been reported to the NRC because, at the time, they had not considered them to be misadministrations. In two of the instances, the Department Head contacted the referring physicians who subsequently requested scans be performed. Thus, the RSO and the Department Head felt that since some diagnostic value could be gained even though the wrong patient or the wrong pharmaceutical had been injected, the matters did not constitute misadministrations. In the remaining case, the RSO and the Department Head had not, at the time, thought that it was a misadministration since the proper radiopharmaceutical had been injected even though the necessary preparatory injection had been omitted. Both the RSO and the Nuclear Medicine Department Head now acknowledge that they were wrong and that these matters should have been reported to the NRC as misadministrations.

None of the Nuclear Medicine Technologists involved in the misadministrations said that they were prohibited from contacting the Radiation Safety Office or the NRC. The Technologists also stated that they had not been told to "cover up" misadministrations. In fact, written reports had been prepared concerning each of the misadministrations.

No disciplinary action was taken against the alleger for reporting these matters to the NRC. Subsequent to this allegation, she voluntarily left her employment at Thomas Jefferson University Hospital.

MERCY HOSPITAL, WILKES-BARRE, PENNSYLVANIA:

ALLEGED FAILURE TO REPORT A DIAGNOSTIC MISADMINISTRATION AS REQUIRED BY 10 CFR PART 35

Licensee:

Mercy Hospital
25 Church Street
P. O. Box 658
Wilkes-Barre, PA 18765

Docket No.: 030-02971

Case Number: 1-85-014

Report Date: November 12, 1985

Control Office: OI:RI

Status: CLOSED

SYNOPSIS

This investigation was initiated based upon a request from the Regional Administrator, Region I, that an investigation be conducted into an alleged failure on the part of the Mercy Hospital, Wilkes-Barre, Pennsylvania (licensee), to report a diagnostic misadministration in violation of 10 CFR 35.

On May 8, 1985, Region I received an anonymous telephone call alleging that the Mercy Hospital's Nuclear Medicine Chief Technician injected the wrong patient with a radiopharmaceutical on May 8, 1985. The Code of Federal Regulations, Title 10 of Part 35.43 requires the licensee to report diagnostic misadministrations, in writing, "within 10 days after the end of the calendar quarter," July 10, 1985. The Code further requires written notification of the misadministration to the patients' "referring physician." No report of a diagnostic misadministration was received by the NRC from the licensee on or before July 10, 1985, and a Region I inspection team was sent to the hospital on July 17, 1985. The inspection did not confirm nor disprove the anonymous allegation. During the NRC inspection, the Chief Nuclear Medicine Technician told the NRC Inspectors that the hospital had not had any misadministrations since June 1984, and the incident had been reported to the NRC.

This investigation determined that a diagnostic misadministration did occur at Mercy Hospital on May 8, 1985, and the misadministration was not reported to either the NRC or the patient's referring physician as required by 10 CFR 35.43. Interviews established that the misadministration was mistakenly administered to the patient by the Chief Nuclear Medicine Technician and reported by her to the hospital's Medical Director of Radiology, who is also the Hospital Radiation Safety Officer (RSO). In a sworn statement, the RSO admitted that the failure to report the misadministration was a deliberate act on his part done with the knowledge that the incident required NRC notification.

This investigation further determined that the Chief Nuclear Medicine Technician deliberately lied to NRC Inspectors during an inspection on July 17, 1985. In a sworn statement, the Chief Nuclear Medicine Technician testified that she lied to the NRC Inspectors when they asked her if any misadministration had occurred since June 1984, because she was told not to report the May 8, 1985, misadministration by the Medical Director of Radiology/RSO.

Title: RHODA H. COBIN, M.D.:

ALLEGED MISADMINISTRATION AND FALSE INFORMATION TO THE NRC IN A LICENSE RENEWAL APPLICATION

Licensee:

Rhoda H. COBIN, M.D.
44 Godwin Avenue
Midland Park, New Jersey 07432

Docket No.: 030-14950

Case Number.: 1-92-009

Report Date: October 30, 1992

Control Office: OI:RI

Status: CLOSED

SYNOPSIS

On April 8, 1992, the Regional Administrator (RA), U.S. Nuclear Regulatory Commission (NRC), Region 1, requested that the Office of Investigations (OI) determine if a licensee (a medical doctor) deliberately violated NRC regulations involving the use of radiopharmaceuticals and deliberately misled the NRC in a May 22, 1990, letter supporting a license renewal application dated July 3, 1989. The apparent violations were identified during a February 7, 1992, routine, unanhounced NRC safety inspection.

The OI investigation concluded that the doctor deliberately failed to either repair or replace her dose calibrator when the constancy error exceeded 10 percent. However, there is insufficient evidence to conclude that the doctor knowingly misadministered doses to any of her patients.

The OI investigation also determined that, at times, between 1987 and the February 7, 1992, NRC inspection, the doctor deliberately violated the NRC regulation requiring her to have both a high range and low range survey instrument at her facility. However, there is insufficient evidence to conclude that the doctor deliberately misled the NRC with her assertions about the instruments in the May 22, 1990, letter.

REPORT OF INVESTIGATION

Title: ST. MARY'S HOSPITAL:

WILLFUL MISADMINISTRATION OF NUCLEAR MEDICINE

Licensee:

St. Mary's Hospital
P. O. Box 620
Norton, Virginia

Docket No.: 030-20156

Case No. 2-87-011

Report Date: May 25, 1988

Control Office: OI:RII

Status: CLOSED

SYNOPSIS

This investigation was initiated upon the request of the U.S. Nuclear Regulatory Commission (NRC), Region II Regional Administrator to resolve an allegation that a nuclear medical technologist employed at St. Mary's Hospital (SMH), Norton, Virginia, had intentionally administered a dose of diagnostic radioactive isotope in excess of the prescribed amount. It was alleged that the employee administered excessive doses on two occasions on March 12, 1987, in apparent violation of the requirements of 10 CFR 30.51 and Nuclear Regulatory Guide 10.8 Appendix G as incorporated into the SMH license.

The alleger in this matter received information that a nuclear medical technologist at SMH was misadministering radiopharmaceuticals in the process of conducting radioimage scans. Upon receipt of this information the SMH Radiation Safety Officer (RSO) conducted a Radiation Safety Committee (RSC) meeting where dose limitations were specifically discussed. On the following day, the RSO reviewed two scans conducted by the nuclear medical technologist and calculated extensive overdoses. Three co-workers also gave evidence that the nuclear medical technologist had overdosed patients on previous occasions. One of the co-workers confronted the nuclear medical technologist on one occasion and was told that excessive doses are routinely administered by nuclear medical technologists to speed up the scan procedure. Another former co-worker who trained under the nuclear medical technologist testified that she was taught to routinely administer an excessive dose of isotope but to record the correct prescribed dose on the isotope control log.

In a sworn statement to the NRC, the nuclear medical technologist admitted that he did, in certain instances, inject a dose of isotope in excess of the prescribed amount. The nuclear medical technologist asserted that he had the permission of radiologists at his previous two places of employment to use his own judgment as to when a larger dose of isotope was required for an acceptable image. Investigation revealed that none of the radiologists had discussed, nor would they have permitted such a practice. The nuclear medical technologist said in his sworn statement it was his practice to use a larger dose of isotope when the patient was overweight in order to overcome the effects of the fat tissue. Several radiologists refuted this statement and said there was no medical basis for exceeding the prescribed dose of radioisotope in any case. None of the nuclear medical technologist's former co-workers had ever heard of such a practice nor had he ever discussed such an issue with them. The general consensus was that the larger dose served only to speed up the scan process for the convenience of the nuclear medical technologist and that it was not a common or acceptable practice.

Although the nuclear medical technologist admitted to giving excessive doses in certain cases, it was observed that he never recorded an amount higher than the prescribed dose. At one point in his sworn statement, the nuclear medical technologist said he recorded the actual dose administered. At another point in the interview, he said he rounded off the administered dose to the nearest whole number and then contradicted himself again later when he said he wrote down the intended dose on the log.

Based upon information obtained during the course of this investigation, it was determined that the nuclear medical technologist made a practice of misadministering diagnostic radiopharmaceuticals and concealed that practice by entering false data on required records. The nuclear medical technologist further tried to conceal his wrongdoing by intentionally making false statements to the NRC which were later refuted by witnesses. Prompt action was taken by the SMH RSO in reporting this violation when she discovered the practice and there does not appear to be any wrongdoing or prior knowledge on the part of the responsible licensee management.

Title: U.S. VETERANS AFFAIRS MEDICAL CENTER:

ALLEGED MISADMINISTRATION OF NUCLEAR MEDICINE

Licensee:	Case No.: 2-91-013R
U.S. Veterans Affairs Medical Center 700 S. 19th Street Birmingham, Alabama 35233	Report Date: Sept. 14, 1992 Control Office: OI:RII
Docket No.: 030-01204	Status: CLOSED

SYNOPSIS

On October 9, 1991, the Regional Administrator, U.S. Nuclear Regulatory Commission (NRC), Region II, requested that the Office of Investigations (OI) initiate an investigation regarding a possible misadministration of radiopharmaceuticals (RPs) by a nuclear medical technologist (technologist) at the Veterans Affairs Medical Center (VAMC), Birmingham, AL. The OI was also asked to determine if the technologist failed to measure RP doses and whether the Radiation Safety Officer (RSO) properly investigated the charges when they were brought to his attention.

Based on the evidence developed during the investigation, which included the results of a polygraph examination, it was determined that the technologist deliberately injected excessive doses of RP into several patients during the period July 22-26, 1991. It could not be determined which specific patient(s) recurred the misadministration due to a failure on the part of an assistant supervisor to respond to the allegation in a timely manner. The investigation by OI determined that the licensee failed to properly investigate the alleged misadministration and that the RSO deliberately concealed the incident from the NRC and VAMC Radiation Safety Committee (RSC).

The evidence also supports the allegation that the medical technologist failed to measure the RP doses during the week in question as required. However, there is insufficient evidence to substantiate that any specific dose was not measured.

The evidence confirmed that the technologist failed to record approximately 100 patient doses from September 1989 through July 1991. The missing patient doses were identified on a regular basis by the technologist's supervisor and recorded in a personal file which was not made available to the NRC. The supervisor and the chairman of the RSC were both aware that a large number of patients were listed in the personal file; however, they did not correct the patient dose logs nor did they make the personal file available for inspection. By withholding this file, they deliberately failed to provide the NRC with complete and accurate information since they were aware of the technologist's failure to keep required records. Because the supervisors failed to take corrective action in the face of a known and continuing violation on the part of the technologist, the licensee failed to supervise the technologist and is, therefore, also responsible for his violations.

The VAMC RSO deliberately concealed the alleged misadministration by reporting the matter to the NRC and the VAMC RSC as a record-keeping error. The RSO deliberately avoided an investigation into an alleged misadministration and, therefore, violated an NRC regulation requiring him to do so.

Title: BLOOMINGTON HOSPITAL

(1) ALLEGED WILLFUL FAILURE TO REPORT DIAGNOSTIC MISADMINISTRATIONS; AND (2) ALLEGED WILLFUL IMPEDIMENT TO NRC INSPECTORS THROUGH MATERIAL FALSE STATEMENTS AND THROUGH THE WITHHOLDING OF RECORDS REQUESTED BY NRC INSPECTORS

Licensee:

Bloomington Hospital
Bloomington, Indiana

Docket No. 030-01644

Case Number: 3-85-002

Report Date: April 28, 1986

Control Office: OI:RIII

Status: CLOSED

SYNOPSIS

On December 31, 1984, NRC Region III (RIII) requested that an investigation be initiated regarding the results of an October 1984 NRC RIII inspection of the Bloomington Hospital Nuclear Medicine Department, Bloomington, Indiana. The inspection was prompted by allegations that the Bloomington Hospital Radiation Safety Officer (RSO) had willfully disregarded NRC reporting requirements regarding diagnostic misadministrations. Further allegations were received by NRC RIII that the Bloomington Hospital RSO had willfully impeded the NRC RIII inspection by directing Bloomington Hospital staff technologists to mislead the NRC inspectors. It was further alleged that the Bloomington Hospital RSO willfully impeded the NRC inspectors by failing to provide for review certain nuclear scans requested by the NRC inspectors, which were, in fact, available at the time of the inspection activity.

The Office of Investigations (OI) investigation revealed that four patients were misadministered between the dates of October 14, 1983, and August 3, 1984. It was further revealed that the required NRC reports regarding the diagnostic misadministrations were not performed.

The investigation further revealed that Bloomington Hospital's RSO is an experienced medical doctor, knowledgeable in the field of nuclear medicine and familiar with NRC reporting requirements. It was learned that appropriate reports regarding diagnostic misadministrations had been made prior to the questioned time period (October 14, 1983, to August 3, 1984) and following the questioned time period.

Regarding the allegations of the RSO impeding the NRC inspectors during the October 1984 NRC RIII inspection, the following was revealed. The RSO directed the Bloomington Hospital staff technologists to respond to the NRC inspectors by denying that unreported misadministrations had occurred. This action by the technologists would have corroborated the RSO's false statements to the NRC inspectors denying unreported diagnostic misadministrations. One of the technologists responded to the NRC inspectors as directed by the RSO.

It was further revealed that the RSO was observed, by a Bloomington Hospital technologist during the October 1984 inspection, removing nuclear scans from a patient's file and placing said film into the patient's x-ray file. The film had been requested by the NRC inspectors for review. Regarding this particular patient, the RSO denied that a misadministration had occurred and was observed by the NRC inspectors altering the date on the patient's file from the date of the alleged misadministration to the date of the administration of the properly prescribed radiopharmaceutical for which scans were provided. A subsequent search by Bloomington Hospital records personnel revealed the nuclear scans, which revealed the misadministrations, were found inside the patient's x-ray folder.

On a separate occasion, during the NRC RIII October 1984 inspection, the RSO was observed by a second technologist reviewing nuclear scans from the file of another patient which had been requested by the NRC inspectors. The inspectors were subsequently informed by the RSO that the requested film was unavailable. However, a subsequent search by hospital personnel revealed the requested film was available for immediate inspection by the NRC inspectors. The film, when reviewed against the referring physician's request, revealed evidence of a misadministration.

The RSO was also observed by a technologist altering a patient's history card during the NRC RIII inspection to reflect the administration of a radiopharmaceutical which had not been prescribed by the patient's referring physician. The personal history card, according to the hospital's records chief, is a key to the patient's file and reflects the referring physician's order. The cards are maintained by records personnel, not the medical staff, and ordinarily reflect only the referring physician's orders. The effect on the NRC inspector of altering the personal history card, was to provide legitimacy to the nuclear scans found to have been evidence of misadministrations. The NRC inspectors recognized the discrepancy on the patient's personal history card between the time of the October 1984 inspection and the subsequent requested OI investigation.

In a November 1, 1984, response to a NRC RIII request for an investigation to be conducted by the President of Bloomington Hospital, one particular patient's alleged misadministration was denied by the President, who referenced the patient's referring physician as justification for his findings. Subsequent investigation revealed that the patient's referring physician denied the statements attributed to him by the President and further supported the original allegation that a misadministration appeared to have occurred.

The RSO, who initially had denied any unreported misadministrations to the NRC inspectors, acknowledged to NRC:OI investigators that he was aware of the misadministrations and had not, for a variety of reasons, reported to the NRC as required. The RSO denied any attempt to mislead or impede the NRC inspectors, stating that the inspection was unexpected, stressful, and that he could not recall what was said during the inspection.

Title: EDWARD HINES, JR., VETERANS ADMINISTRATION MEDICAL CENTER

ALLEGED WILLFUL FAILURE TO REPORT DIAGNOSTIC MISADMINISTRATIONS AND ALLEGED WILLFUL MATERIAL FALSE STATEMENTS

Licensee:

Edward Hines, Jr. Veterans Administration Medical Center
Hines, IL 60141

Docket No. 030-01391

Case Number: 3-87-003

Report Date: November 4, 1987

Control Office: OI:RIII

Status: CLOSED

SYNOPSIS

On February 10, 1987, the Office of Investigation (OI) Field Office, Region III (RIII), received a Request for Investigation from the RIII Acting Administrator. The request evolved from anonymous allegations that three unreported misadministrations involving diagnostic radiopharmaceuticals occurred at Edward Hines, Jr., Veterans Administration Medical Center (HMC) during the week of August 4-8, 1986. An HMC Board of Investigation (BI) concluded that only one misadministration may have occurred and requested NRC assistance. Due to the conflicting statements received during the NRC:RIII inspection of this matter, the case was referred to OI.

The first alleged diagnostic misadministration involved the administration of Technetium-99m diethylenetriaminepentaacetic (Tc-99m DTPA), a brain scanning agent, rather than the one intended, Technetium-99m medronate diphosphonate (Tc-99m MDP), a bone scanning agent. Evidence revealed that the alleged misadministration was brought to the attention of the HMC Section Chief of Clinical Nuclear Medicine (SCCNM) (a physician Board-certified in nuclear medicine) by the Acting Chief Technologist (ACT). It was further revealed that after the SCCNM became aware of the alleged misadministration, the SCCNM claimed that he had changed the prescribed bone scan to a brain scan. The SCCNM then identified and represented the brain scan to the patient's referring physician as the originally prescribed bone scan, never indicating to the referring physician that the SCCNM had at any time changed the original order or that a misadministration had occurred.

The second alleged diagnostic misadministration involved the administration of a radiopharmaceutical, gallium-67 citrate, not regulated by the NRC, to the wrong patient. Again, the alleged misadministration was brought to the attention of the SCCNM by the ACT. After the SCCNM was notified of the alleged misadministration, the SCCNM obtained a Consult (an HMC physician's order form for a diagnostic study) from an HMC staff physician ordering a scan to validate the injection of the wrong patient. The staff physician had no knowledge that the patient had already been allegedly misadministered when he completed the requested Consult for the SCCNM.

The third alleged diagnostic misadministration involved the administration of a radiopharmaceutical (Tc-99m MDP) rather than the intended gallium-67 citrate. This alleged misadministration was also brought to the attention of the SCCNM by the ACT. Following the third alleged misadministration, the ACT also informed the MMC Chief of Nuclear Medicine (CNM) of the alleged misadministrations and advised the CNM that reports had not yet been initiated, although the ACT had previously reported the incidents to the SCCNM.

The SCCNM directed a technologist to support the SCCNM's explanation of the events regarding the alleged first misadministration when the technologist was questioned by the CNM. The technologist admitted that he had lied to the MMC:BI and to the RIII inspectors regarding the facts of the first alleged misadministration out of fear of contradicting the SCCNM. Further evidence revealed that the Chief Technologist observed the SCCNM remove and discard a key document relative to the alleged first misadministration from the patient's nuclear medicine file just prior to the RIII inspection.

During this investigation, evidence also revealed that several nuclear medicine staff members obstructed the MMC:BI. One former staff member refused to testify to the MMC:BI; another staff member admitted concealing pertinent information; and a third staff member admitted lying to the MMC:BI and to the RIII inspectors.

The OI investigation identified evidence which allowed the NRC to conclude that three patients received diagnostic misadministrations, two of which, though reportable, were not reported to the NRC. It was established that the misadministrations were brought to the timely attention of the SCCNM, who willfully failed to report the misadministrations as required by the NRC. It was also established that the SCCNM made material false statements by denying that the misadministrations occurred; destroyed evidence of one of the misadministrations by removing a key document from a nuclear medicine file prior to the RIII inspection; and impeded the NRC by directing a technologist to make false statements to the NRC. The SCCNM also attempted to influence the testimony of the ACT by suggesting that the ACT not recall pertinent facts when questioned by the MMC:BI or the NRC.

Title: ELLIS FISCHEL STATE CANCER CENTER:

FAILURE TO REPORT A MISADMINISTRATION

Licensee:

Ellis Fischel State Cancer Center
115 Business Loop 70 West
Columbia, Missouri 65203

Docket No.: 030-02274

Case Number: 3-90-005

Report Date: February 1, 1991

Control Office: OI:RIII

STATUS: CLOSED

DETAILS OF INVESTIGATION

Purpose of Investigation

This investigation was initiated on March 16, 1990, at the request of the Nuclear Regulatory Commission (NRC) Regional Administrator, Region III (RIII), who alleged that certain personnel at Ellis Fischel State Cancer Center (Ellis Fischel), Columbia, Missouri, had covered up a misadministration that occurred in October 1987. The event was discovered by the licensee during an audit of the Nuclear Medicine Department and was subsequently reported to the NRC as a misadministration with a potential willful concealment of facts. The intent of the investigation was to determine whether the alleged cover-up was the action of one or more persons and if management had any direct involvement in the concealment of the facts.

Background

On September 12, 1989, the NRC received documentation of a licensee audit from Ellis Fischel indicating that a former staff member, Angel GARCIA, M.D., had allegedly covered up a diagnostic misadministration on October 12, 1987. On December 12, 1989, an announced NRC safety inspection was conducted at Ellis Fischel to review the circumstances surrounding the reported misadministration and the alleged cover-up as reported. Gary SHEAR, Senior Radiation Specialist, RIII, substantiated that a patient had inadvertently been given a misadministration (injection of Tc-99m oxidronate) and that the Head of Nuclear Medicine, Dr. GARCIA, apparently in an attempt to conceal this fact, subsequently issued a requisition for a bone scan. The event was reviewed by Ellis Fischel's Radiation Safety Committee, which subsequently concluded that not only did the misadministration occur but that it was covered up by Dr. GARCIA. Based on NRC's safety inspection and review, they concluded that there was no evidence of management complicity in the alleged cover-up.

Closure Information

The Office of Investigations (OI) has conducted a preliminary inquiry into the allegation and has determined that although the case warrants further investigation into potential wrongdoing on the part of Dr. GARCIA, this case is being administratively closed by OI due to the lack of investigative resources in accordance with Commission-approved policy as prescribed in SECY-85-369. Furthermore, on September 26, 1990, Ellis Fischel requested termination of their license because their programs were being taken over by the University of Missouri. All future license activities will come under the broad scope license of the University who will have primary regulatory and safety oversight of the remaining Ellis Fischel personnel. Dr. GARCIA is no longer employed by Ellis Fischel and has last been known to be practicing medicine unrelated to nuclear activities in the State of Georgia.

Title: COPLEY HOSPITAL:

ALLEGED MATERIAL FALSE STATEMENTS IN THE REPORTING OF A DIAGNOSTIC MISADMINISTRATION AND RESPONSE TO A CONFIRMATORY ACTION LETTER

Licensee:

Copley Hospital
Washington Highway
Morrisville, Vermont 05661

Docket No.: 030-17125

Case Number: 3-91-004

Report Date: February 21, 1992

Control Office: OI:RIII

Status: CLOSED

SYNOPSIS

On March 29, 1991, the Office of Investigations received a Request for Investigation from the Regional Administrator, U.S. Nuclear Regulatory Commission (NRC), Region I, concerning a possible material false statement made in a Diagnostic Misadministration Report (DMR) dated August 14, 1990. The DMR was mailed to the NRC from Copley Hospital (CH), Washington Highway, Morrisville, Vermont, an NRC licensee. On June 19, 1991, the investigation was expanded to determine if the licensee also provided false information to the NRC in an April 1, 1991, response to an NRC Confirmatory Action Letter (CAL) dated March 1, 1991.

This investigation determined that although the DMR was inaccurate, neither the technologist who prepared it nor the radiologist who signed it deliberately intended to deceive the NRC.

It was concluded, however, that the Radiation Safety Officer (RSO), carelessly disregarded NRC regulatory requirements by failing to conduct an thorough investigation of the cause of the misadministration and accurately documenting and reporting the cause.

This investigation also substantiated that the CH April 1, 1991, response to the NRC CAL was inaccurate. There was insufficient evidence, however, to conclude that the inaccuracies were known to be false and were deliberately reported falsely by either the RSO or other CH officials.

The investigation was to determine if false statements were made to the misadministration report to the NRC or during the NRC inspection into the matter; if false statements were made, who was responsible and what was their intent; and whether the capsule that was administered to the patient was even measured at all prior to administration to the patient. In addition, OI should also determine the level of management involvement if any wrongdoing is confirmed. It also requested that OI attempt to determine if doses were administered to patients on other occasions without the required dose assay being performed.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS

YEAR CLOSED	MISADMINISTRATIONS (NUMBER OF CASES)	PERCENTAGE OF TOTAL CASELOAD
1982	0	-
1983	0	-
1984	0	-
1985	1	0.74
1986	2	1.64
1987	2	2.25
1988	3	2.44
1989	1	0.93
1990	0	-
1991	2	2.82
1992 (thru 10/31)	5	4.39
OPEN as of 10/31	4	2.53
TOTAL/PERCENTAGE	20	1.37
NUMBER SUBSTANTIATED	9 (45% of Cases)	

TAB B

PSS/S/12/23/92

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS
CASE DATA AS OF 11/30/92 - ALL REGIONS
MISADMINISTRATION CASES BY PROGRAM CATEGORY

CASE NO.	FACILITY	OPENED	CLOSED		ISSUED	REFERRED	ACTION	ALLEGATION
** PROGRAM CODE 02110								
* REGION 1								
1-84-034	THOMAS JEFFERSON UNIVERSI	12/11/84	05/21/86		05/21/86	/ /		MANAGEMENT CONCEALMENT OF MEDICAL MISADMINISTRATIO OF RADIOPHARMACEUTICALS
1-92-046R	PENNSYLVANIA, UNIVERSITY	11/30/92	/ /		/ /	/ /		ALLEGED MISADMINISTRATION AND FALSIFICATION OF RECORDS
* REGION 2								
2-91-013	V. A. MEDICAL CTR.	10/10/91	09/14/92	S	10/09/92	10/10/92	RVL	ALLEGED MISADMINISTRATION OF NUCLEAR MEDICINE
* REGION 3								
3-86-014	UNIVERSITY OF CINCINNATI	12/22/86	10/27/88		11/10/88	/ /		WILLFUL FAILURE TO REPORT A THERAPEUTIC MISADMINISTRATION
3-87-003	HINES VA HOSPITAL	02/18/87	11/04/87		11/13/87	11/13/87	CON	WILLFUL FAILURE TO REPORT DIAGNOSTIC MISADMINISTRATIONS AND WILLFUL MATERIAL FALSE STATEMENTS
** PROGRAM CODE 02120								
* REGION 1								
1-85-014	MERCY HOSPITAL	07/23/85	11/12/85		01/31/86	01/31/86	DEC	MATERIAL FALSE STATEMENT CONCERNING UNREPORTED MISADMINISTRATION
1-92-040	BETH ISRAEL HOSPITAL	08/11/92	11/13/92		/ /	/ /		ALLEGED MISADMINISTRATION AND AN OVEREXPOSURE
* REGION 2								
2-87-011	ST. MARY'S HOSPITAL	06/24/87	05/26/88		07/01/88	07/01/88	CON	MISADMINISTRATION OF NUCLEAR MEDICINE
* REGION 3								
3-85-002	BLOOMINGTON HOSPITAL	01/03/85	04/28/86		06/09/86	06/09/86	CON	WILLFUL FAILURE TO REPORT MISADMINISTRATIONS AND WILLFUL IMPEDIMENT THRU MATERIAL FALSE STATEMENTS AND WITHHOLDING INFO
3-88-010	OTTO C. EPP MEM. HOSPITAL	08/18/88	06/22/89	D	07/10/89	/ /		FAILURE TO REPORT MISADMINISTRATIONS
03-88-011	TRINITY LUTHERAN HOSPITAL	10/20/88	12/08/88	A	12/08/88	/ /		WILLFUL FAILURE TO FOLLOW PROCEDURE

TAB C

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF INVESTIGATIONS
CASE DATA AS OF 11/30/92 - ALL REGIONS
MISADMINISTRATION CASES BY PROGRAM CATEGORY

CASE NO.	FACILITY	OPENED	CLOSED	ISSUED	REFERRED	ACTION	ALLEGATION
3-90-005	ELLIS FISCHEL CANCER CTR	03/16/90	02/01/91	A 02/01/91	/ /		MATERIAL FALSE STATEMENT BY OMISSION
3-90-008	ST. MARY MEDICAL CTR.	04/27/90	06/06/91	U 06/07/91	/ /		FAILURE TO REPORT ALLEGED THERAPEUTIC MISADMINISTRATIONS TO NRC
3-91-004	COPLEY HOSPITAL	04/01/91	02/21/92	03/12/92	/ /		ALLEGED FALSE STATEMENTS
* REGION 5							
5-92-006	V.A. MEDICAL CENTER	03/30/92	06/02/92	/ /	/ /		ALLEGES CLAIMS I&E AND MISADMINISTRATION AT LOMA LINDA V.A. MEDICAL CENTER
** PROGRAM CODE 02200							
* REGION 1							
1-92-009E	COBIN MD., REGBA E.	04/14/92	10/30/92	11/19/92	/ /		ALLEGED MISADMINISTRATIONS AND FALSE INFORMATION TO THE NRC IN A LICENSE RENEWAL APPLICATION
* REGION 3							
3-91-009	OLSON MEDICAL IMAGING	06/05/91	/ /	/ /	/ /		ALLEGED MATERIAL FALSE STATEMENTS AND FALSIFICATION OF DOCUMENTS
** PROGRAM CODE 02300							
* REGION 1							
1-92-007	DOENEE MD., G. ANTHONY	04/02/92	05/14/92	05/14/92	/ /		ALLEGED MEDICAL MISADMINISTRATIONS
* REGION 3							
A3-86-011	CLEVELAND CLINIC	12/10/86	10/09/87	10/09/87	/ /		MISADMINISTRATION
3-92-043	OHIO VALLEY HOSPITAL	09/11/92	11/27/92	/ /	/ /		ALLEGED FAILURE BY PHYSICIAN TO REPORT A MISADMINISTRATION THAT OCCURRED IN 1986

Enclosure 8

Statistics on Adequacy and Compatibility
of Agreement State Programs

Adequacy and Compatibility of Agreement State Programs

NRC's criteria for Agreements with States under Section 274 of the Atomic Energy Act of 1954, as amended, detail the principal programmatic elements of adequacy and compatibility. The initial criteria was published in the Federal Register in 1981 and was most recently amended in 1992. The Office of State Programs provides oversight of the Agreement States and has procedures for evaluating them for adequacy and compatibility. To assure continuing adequacy and compatibility of Agreement State Regulatory Programs, on-site, routine reviews and visits are conducted at appropriate intervals. A routine review is scheduled approximately every two years with each Agreement State and a visit scheduled the year opposite the review. For each routine review a formal evaluation of adequacy and compatibility is prepared and provided to the State. Visits to the States are used to assist them in addressing radiation issues and to monitor their progress in resolving recommendations from the previous routine review.

The routine reviews identify current or potential program deficiencies with recommendations to correct the program deficiencies and facilitate consistency among Regulatory Programs by exchange of ideas between States and the Federal Regulators. The Commission is informed of the results of the reviews and copies of the review correspondence to the States are placed in the NRC Public Document Room and the States' Local Public Document Room. Other NRC offices are invited to participate and are involved in many of these reviews to assure technical evaluation of all aspects of the Agreement State Program.

There are 30 indicators for evaluating Agreement State Program areas. Guidance as to their relative importance to an Agreement State Program is provided by categorizing the indicators into two categories. Category I indicators address program functions which directly relate to the State's ability to protect the public health and safety.

Category II indicators address program functions which provide essential technical and administrative support of the primary program functions. In reporting findings to State Management, the NRC will indicate the category of each comment made. If no significant Category I comments are provided, this will indicate that the program is adequate to protect the public health and safety and is compatible with the NRC's program. If one or more Category I comments are noted as significant, the State will be notified that the program deficiencies may seriously affect the State's ability to protect public health and safety and that the need for improvement in particular program areas is critical. The NRC will also make a statement that we are unable to make a finding of adequacy and compatibility at this time.

If a State fails to have compatible regulations in place in the three-year time period they will not be found compatible. The term adequacy refers to public health and safety issues while the term compatibility refers primarily to regulations. A program may be evaluated as adequate to protect the public health and safety but not compatible.

FIVE YEAR STATISTICS ON AGREEMENT STATE REVIEWS
December 21, 1992 (Draft Revision)

ALABAMA

YEAR	1987	1988	1989	1990	1991	1992
FINDING	A&C	Visit	A	Visit	A&C[ah]	Visit

ARIZONA

YEAR	1987	1988	1989	1990	1991	1992
FINDING	No Visit	A&C[a]	Visit	A&C[a]	Visit	A

ARKANSAS

YEAR	1987	1988	1989	1990	1991
FINDING	Visit	A&C	Visit	Visit	A&C[ai]

CALIFORNIA

YEAR	1987	1988	1989	1990	1991	1992
FINDING	A&C	Visit	A&C	Visit	A&C[aj]	Visit

COLORADO

YEAR	1987	1988	1989	1990	1991	1992
FINDING	FW	Visit	FW	Visit	A&C	Visit

FLORIDA

YEAR	1987	1988	1989	1990	1991	1992
FINDING	A&C	Visit	A&C	Visit	A&C	Visit

GEORGIA

YEAR	1987	1988	1989	1990	1991	1992
FINDING	A&C	No Visit	A	No Visit	A&C	Visit

[a]Finding of compatibility contingent on final adoption of certain regulations, which usually occurs within 90 days
[h]Alabama has not adopt regulations for compatibility as of 12/14/92
[i]Arkansas adopted regulations for compatibility in 6/1/92
[j]California's proposed regulations were turned down by the legislature and will need to be resubmitted. Expected resubmittal date 2/93.

IDAHO

YEAR	1987	1988	1989	1990-VISIT	4/26/91
FINDING	A&C	Visit	Visit, A&C	PROBLEMS	TERMINATED

ILLINOIS

YEAR	1987	1988	1989	1990	1991	1992
FINDING	Visit, A&C	No Visit	Visit	A&C[b]	Visit	A&C[b]

IOWA

YEAR	1987	1988	1989	1990	1991-FU	1992-FU
FINDING	Visit	A&C	Visit	FW	Visit, FW	FW

KANSAS

YEAR	1987	1988	1989	1990	1991	1992
FINDING	A&C	Visit	A&C	Visit	A	Visit

KENTUCKY

YEAR	1987	1988	1989	1990	1991	1992
FINDING	No Visit	A&C	Visit	A	Visit	A&C[ak]

LOUISIANA

YEAR	1987	1988	1989	1990	1991	1992
FINDING	A&C	Visit	A&C	No Visit	A	Visit

MAINE

YEAR	1992	1992
FINDING	AGREEMENT EFFECTIVE 4/1/92 - A&C	Visit

MARYLAND

YEAR	1987	1988	1989	1990	1991	1992
FINDING	A	Visit	A	Visit	A	Visit

[a]Finding of compatibility contingent on final adoption of certain regulations, which usually occurs within 90 days
[b]Contingent upon resolution of the 1 millirem per year rule issue
[k]Kentucky's regulation for decommission has not yet become effective as of 12/14/92

MISSISSIPPI

YEAR	1987	1988	1989	1990	1991	1992
FINDING	A&C	Visit	A&C	Visit	A&C[al]	Visit

NEBRASKA

YEAR	1987	1988	1990	12/90-FU	1992
FINDING	Visit	A	FW	A&C	FW

NEVADA

YEAR	1987	1988	1989-FU	1990	1991	1992
FINDING	Visit	A&C[c]	A&C	A&C	A&C[am]	Visit

NEW HAMPSHIRE

YEAR	1987	1988	1989	1990-FU	1991	1992
FINDING	Visit	Visit	FW	FW	A&C	FW

NEW MEXICO

YEAR	1987	1988	1989	1990	1991	1992
FINDING	Visit	A&C	Visit	A	Visit	A

NEW YORK TEAM REVIEW PERFORMED ON ALL NY AGENCIES IN 1990 UNABLE TO MAKE FINDING OF A&C AT THAT TIME ON THE WHOLE PROGRAM

NEW YORK CITY HEALTH

YEAR	1987-FU	1988	1989	1990	1991
FINDING	A&C	A&C	A[d]	FW	Visit

NEW YORK STATE HEALTH

YEAR	1987	1988	1989	1990	1991
FINDING	No Visit	A	Visit	FW	Visit

[a]Finding of compatibility contingent on final adoption of certain regulations, which usually occurs within 90 days
[c]Finding of compatibility contingent on final adoption of enforcement procedures
[d]New York City Department of Health adopted regulations and found compatible in 8/90 prior to the 10/90 review
[l]Mississippi adopted regulations for compatibility in 11/15/92
[m] Nevada adopted regulations for compatibility in 12/9/91

NEW YORK DEPARTMENT OF LABOR

YEAR	1987	1988	1989	1990	1991
FINDING	A&C	Visit	A	FW	Visit

NEW YORK DEPARTMENT OF ENVIRONMENTAL CONSERVATION

YEAR	1987	1988	1989	1990	1991
FINDING	A&C	Visit	FW	FW	Visit

NORTH CAROLINA

YEAR	1987	1988	1989	1990	1991
FINDING	A&C	Visit	A&C	Visit	Visit, A&C[an]

NORTH DAKOTA

YEAR	1987	1988	1989	1990	1991	1992
FINDING	A	No Visit	FW	Visit	A&C[ae]	Visit

OREGON

YEAR	1987	1988	1989	1990	1991	1992
FINDING	A	Visit	A&C	Visit	A&C	Visit

RHODE ISLAND

YEAR	1987	1988	1989	1990	1991	1992
FINDING	A&C	Visit	A&C[a]	Visit	A&C	Visit

SOUTH CAROLINA

YEAR	1987	1988	1989	1990	1991	1992
FINDING	No Visit	Visit	A&C	Visit	A&C	Visit

TENNESSEE

YEAR	1987	1988	1989	1990-FU	1991	1992-FU
FINDING	No Visit	A	FW, Visit	FW	FW	FW

[a]Finding of compatibility contingent on final adoption of certain regulations, which usually occurs within 90 days
[e]North Dakota adopted regulations for compatibility in 1992
[n]North Carolina adopted regulations for compatibility in 6/19/92

TEXAS

YEAR	1987	1988	1989	1990	1991	1992
FINDING	Visit	A&C	Visit	A	Visit	A&C[ao]

UTAH

YEAR	1987	1988	1990	1991-SPECIAL	1992
FINDING	No Visit	A&C	A&C	FW	A&C[f]

WASHINGTON

YEAR	1987	1988	1989	1990	1991-FU	1992
FINDING	A&C	A&C	Visit	A	FW	A&C

[f]Contingent upon resolution of licensing actions for Envirocare LLRW disposal license

[o]Texas' regulation for decommission has not yet become effective as of 12/14/92. They are expected to be adopted in May or June of 1993.

Note: 1. For routine reviews, "A&C" represents a finding of adequacy and compatibility, "A" represents a finding of adequacy only and "FW" represents that the finding was withheld or that the staff was not able to make a finding that the time of the review. "FU" represents a follow-up review. "Visit" represents the meetings held between NRC and Agreement State between the routine reviews and is usually informal. Correspondence to the State only occurs when there are major problems identified.

Enclosure 9

Memorandum dated August 5, 1976 from
Peter Strauss to the Commission

August 5, 1976

MEMORANDUM FOR: Chairman Rowden
Commissioner Mason
Commissioner Gilinsky
Commissioner Kennedy

FROM: Peter L. Strauss, General Counsel

SUBJECT: AUGUST 2, 1976 BRIEFING ON RIVERSIDE HOSPITAL INCIDENT

In my view the results of this meeting represent an appropriate first step to deal with the most pressing immediate problem disclosed by the incident, namely the fact that because of calibration errors many teletherapy patients throughout the country are probably receiving doses significantly different from those prescribed. The concluding emphasis of the meeting rightly focused on the need to be sure that these machines are calibrated correctly now and henceforth.

While the Commission obviously has a paramount concern that future damage be avoided, it also seems clear that action should be taken to identify and remedy where possible the human consequences of past errors in dosages. More attention to this subject appears to be needed than the August 2 briefing provided. It is my impression from the briefing and from the documentation of this incident that physicians of Riverside Hospital patients who received a dose substantially different from the one prescribed are being notified of this fact. It was not clear from the briefing, however, that an organized effort is being planned to identify patients elsewhere and provide notification and follow-up, where the NBS study or future NRC evaluations indicate a likelihood that doses in error have been delivered. I recognize that there is a major resource problem in accomplishing this task in view of the fact that 25,000 or more patients may be involved. As was recognized at the briefing, there are also sensitive questions concerning possible liability of the hospitals. Nevertheless, the "potentially explosive" nature of the affair makes it prudent as well as humane for the NRC in its position of radiation safety leadership to make a substantial effort to assist those who may have been injured.

contact:
E.L. Slaggie
492-8155

NRC consultant Dr. Saenger, in his letter of May 26, 1976, indicates that many months of study are needed, once an erroneously dosed patient is identified, to consider fully the needs of the patient. Thus a program for identifying patients affected by these errors and notifying their physicians is needed promptly and probably should commence during the NRC program for correcting existing calibration errors. Once the latter program is effectively underway, the question of how best to proceed with identification and notification might be the subject of a future Commission briefing.

cc: Ben Huberman
SECY (2)
Lee Gossick
R. J. Voegeli