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NUCLEAR REGULATORY COMMISSION

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING BY AGREEMENT STATES ON THEIR ACTIVITIES

IN MEDICAL USE AREA

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PUBLIC MEETING

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Nuclear Regulatory Commission

One White Flint North

Rockville, Maryland

Friday

January 29, 1993

The Commission met in open session, pursuant to notice, at 2:00 p.m., the Honorable IVAN SELIN, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

IVAN SELIN, Chairman of the Commission

KENNETH C. ROGERS, Member of the Commission

JAMES R. CURTISS, Member of the Commission

FORREST J. REMICK, Member of the Commission

E. GAIL de PLANQUE, Member of the Commission

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

WILLIAM C. PARLER, General Counsel

HUGH THOMPSON, Assistant Deputy Executive Director for Operations

G. WAYNE KERR, Chairman, Organization of Agreement States

TOM HILL, Past Chairman, Organization of Agreement States

MARY CLARK, Chairman Elect, Organization of Agreement States

CARL KAMMERER, Director, Office of State Programs, NRC

AUBREY GODWIN, Director, Arizona Regulatory Agency

EDGAR BAILEY, Chief, Radiologic Health Branch, State Department of Health Services, California

ROLAND FLETCHER, Administrator, Rad Health Program, Department of Environment, Maryland

DAVID LACKER, Chief, Bureau of Radiation Control, Texas Department of Health

P R O C E E D I N G S

(2:03 p.m.)

CHAIRMAN SELIN: Good afternoon, ladies and gentlemen. The Commission is meeting at this time to receive a briefing on the activities of the Agreement States in the regulation of the medical uses of byproduct materials within their borders. This is the second in a series of briefings for the Commission on medical use regulation.

Just a week ago, the Commission received a briefing from our own staff on NRC activities in this area. On February 8th, we will receive a briefing on the results of the staff investigation of the therapy misadministration incident that occurred last November in Indiana, Pennsylvania.

On February 9th, the Commission will hear from the NRC staff's Advisory Committee on Medical Uses of Isotopes, and on February 22nd we will be briefed on a proposed rulemaking on the preparation and use of pharmaceuticals. We assume that all these murky issues will become crystal clear towards the end of February. We hope you will help us in arriving at an understanding of these issues today.

The incident in Indiana, Pennsylvania and the subsequent patient death, the recent series of articles

published in the Cleveland Plain Dealer, and a number of other items have heightened the Commission's already keen interest in this critical area of our regulatory responsibility.

We look forward today to hearing the views of the Agreement States representatives who share many of these regulatory responsibilities and, in fact, have the further responsibility of integrating radioactive material regulation with other radiation regulation.

We certainly appreciate the efforts that you've made to be here with us today. I see that we have today representatives of the Organization of Agreement States, including Chairman Kerr, representatives of the States of Arizona, California, Maryland and Texas, carefully chosen in alphabetical order. You are all welcome. Do we have any introductory comments?

(No response.)

Mr. Thompson, would you care to start the proceedings?

MR. THOMPSON: Yes, thank you, Mr. Chairman and Commissioners. This is an appropriate opportunity for us to just take a moment to reflect back over since the Commission assigned the responsibility for the oversight of the Agreement State programs about a little over a year ago, to the EDO staff. And during that period of time,

the emphasis has been to fully integrate the Agreement States programs in our rulemakings as well as state programs within our own organization. And we made a very conscientious effort to do that both in the rulemaking as well as the day-to-day activities.

One of the important area that we have had an effort on underway is in the medical area. We've had two workshops, one in July in Atlanta. We also had as part of the all Agreement States meeting in October, a full day meeting on the medical issues. So, the medical area is one that, as you indicated, properly has been receiving a lot of attention by the Commission and by the staff.

Today's briefing will be in two parts. First we will hear from the Organization's leadership, and then we will hear, on the second part, with the specific states that were identified with some incidents in the Cleveland Plain Dealer's article.

With that, I will turn it over to Mr. Kerr, and then we will introduce the second presenters at the second phase. Wayne?

MR. KERR: Thank you. Mr. Chairman and members of the Commission, we are pleased to be here today to discuss with you a matter of mutual interest, the regulation of nuclear materials. I am accompanied by Tom Hill, the Past Chair, on my right, and Dr. Mary Clark,

Chair Elect, from the State of Florida.

I plan to make some general remarks addressing certain regulatory issues and then some remarks related specifically to Illinois. Then I will ask Mr. Hill and Dr. Clark to make their remarks.

The words "protection of the public health and safety" are few in number, but carry a lot of responsibility. Words similar to those are found in the Atomic Energy Act as well as the legislation of each of the Agreement States, and we all take them very seriously. We appreciate the efforts of NRC in assisting us and in trying to keep us coordinated to the extent necessary to carry out that essential responsibility. It is not an easy task for you to deal with 29 sovereign states and, as you know, some of us are very sovereign.

There has been considerable effort expended by NRC and the Agreement States in the last few months to address problems associated with materials regulatory programs. Some relate to information gathering, medical regulation, investigations, and some to enforcement. These problems may be real in some cases and in others may be only perceived. But I urge everyone to focus on the proper target, and that is, are the regulatory programs of both the NRC and the Agreement States adequately protecting the pubic health and safety as required by the

Atomic Energy Act for you, and by Section 274 of the Act and our own state laws for us? We have stated on previous occasions that we believe it inappropriate to place too much emphasis, however, on processes and procedures. The purpose of my general remarks are to highlight some areas where we have different approaches perhaps, but maintain the same public health and safety objective.

I want to focus on four items in particular that have been the subject of some recent discussions. First, is information gaps. We hear that some -- the public, the Congress, the NRC, maybe others -- may not know everything about each Agreement State program in the detail that is known about NRC programs. However, we don't believe it necessary for such detailed information to be maintained in some centralized fashion. It's not that we have anything to hide, our files are essentially an open book to the NRC. But knowledge of every detail should not be necessary, and we don't believe that Section 274 of the Atomic Energy Act contemplates that kind of oversight.

Second is the subject of investigations. There apparently is some concern that Agreement States don't do investigations or that we don't do them with the same procedural rigor as the NRC. I'm certain that they all do perform investigations of incidents, but not necessarily following the rigorous procedures that you have. We

certainly do investigations in Illinois, but we do not have a staff dedicated to investigations. I'm aware of only one state that does. Texas has had such a unit since 1981. But we get the job done anyway and, it sometimes can be argued, with more vigor than NRC. State programs do have the advantage of being in closer proximity to the regulated facilities, and in the case of facilities that also use x-ray machines, we inspect those facilities for all sources of radiation, with the result being a more frequent presence. As a result of an NRC suggestion, Illinois does have an Incident Review Committee which meets monthly to review events involving either radioactive materials or electronic product machines.

Third is enforcement. Enforcement practices no doubt vary among the Agreement States which, in part, is due to our sovereign nature. Some may find methods of enforcement that are effective without civil penalties. Most, like the NRC, do find civil penalties useful. But, in any event, our processes may vary, but the goals are the same. I'd like to give you three examples.

Several years ago in the days of low-level waste crises, Nevada returned a defective shipment of waste to an NRC shipper. Since the shipment came from an NRC licensee, Nevada could have referred it to NRC for enforcement action and waited two or three months for

possible imposition of a civil penalty, but they found the action they took was both prompt and effective.

A major university in California had significant problems in their radiation safety program over a period of years in the 1980s. Administrative actions such as restrictive license conditions and management conferences did not fully correct the situation. The university was placed on probation, a fine of $25,000 was imposed, and a fellowship in radiation safety was established at $25,000 per year for three years. Subsequently, a $65,000 penalty was imposed for additional violations. California did follow rigorous court proceedings in the latter stages of that case. Currently, the licensee is operating satisfactorily.

On Thanksgiving Eve last year, Illinois issued an emergency order to a medical institution to cease operations due to lack of authorized users, no approved RSO being available, and no commitment to procedures regarding selection of patients, prescribing doses and interpreting results. The elapsed time from when our inspector confirmed these problems to the time of issuance of the order was a matter of hours. And one of our IDNS inspectors personally delivered the order on Thanksgiving Day. Now, these cases may be a little unorthodox, and may be lacking in procedural niceties, but are they effective?

We think so.

I might add as an aside that I understand Mr. Ben Hayes, the Director of your Office of Investigations, visited the state of Washington last summer and reviewed their enforcement practices, and he found that although they differed from NRC's, they were just as effective. And I think it would be nice if that were put in writing to the State of Washington.

I've left the most intractable subject for the last. That is the issue of regulation of medical uses of radioactive materials. Although the Agreement States have differed with the NRC on some aspects of the issue, I'm sympathetic to your attempts to resolve it. The issue is greatly complicated by the players involved -- NRC, the FDA, the Agreement State regulators, the medical licensing boards, the state pharmacy boards, and not the least of which are the medical practitioners and the patients. I think the difficulty partly stems from the differences of opinion as to each of those groups' roles and a lack of clarity about their respective authority.

The medical issues paper was presented at the public meeting on October 29, 1992, in Baltimore, and was, in my opinion, a good initial effort at trying to sort out the issues. I personally believe one of the most important tasks is to establish clearly the respective

roles of these various organizations, and I urge you to work toward that goal expeditiously.

The quality management and medical misadministration rules are interrelated and do have significant impact on Agreement States. Our main differences with NRC have been over the level of detail required and, in some cases, with specific provisions. The Agreement States tend to disagree with the level of compatibility assigned to these rules and in general to medical rules. We feel that a Division 3 category is more appropriate since the issues, by and large, are matters between each Agreement State and its licensees. Medical licensees do not generally work across state lines nor make products entering into interstate commerce. Therefore, there is not a need for the same degree of uniformity as may affect radiographers or source distributors, for example.

Now, I want to briefly address some aspects of the Illinois regulatory program. We have been an Agreement State since June, 1987, and regulate about 800 specific licensees. Of these, we consider 97 to be major licenses. Each review of our program by NRC since 1987 has concluded that it is adequate to protect the public health and safety.

The program is administered by 16 health physics

professionals and four clerical. Other managerial and technical support is provided by three health physicists and two administrative. Additionally, laboratory services, instrument calibration, and assistance in decommissioning projects are available through another office in IDNS. The state operates for our own use and for use by other states, a calibration lab accredited by CRCPD. We have a comprehensive fixed lab facility which supports all the functions of the Department, and have a mobile lab for field use.

We have a fee schedule structured differently than NRC's, but it is expected to recover about 35 percent of our costs in FY 1993. A few categories of licensees are on a full cost recovery basis.

We took 698 licensing actions in 1991 and 756 in 1992. We do pre-licensing visits for those with complex actions and, when deemed necessary, do obtain clarifying information. We performed 13 in the last two years.

Our inspection priority system for specific licensees is similar to NRC's except our maximum interval is four years. Thus, we are nearly identical on the high priority licensees, but more frequent than NRC on the lower priority licensees. We conducted 375 inspections in 1991 and 300 in 1992. We issued three orders in the last two years as follows: First, a physician for unsupervised

use of radioactive material resulting in a hearing and a civil penalty of $12,500; an industrial firm for multiple repeat violations. A hearing was held and a civil penalty of $4700 imposed; and a suspension order to the hospital that I previously mentioned, for using material with no authorized users, no RSO, and an improper license.

Our civil penalty procedures are specified specifically in our regulations, and are based on licensee compliance history, severity, and negligence. In addition, we held two management conferences in these two years.

Our medical reporting rule -- and that's known as misadministration in the NRC parlance -- is essentially the same as NRC's with only minor differences. In 1991, we had 25 recordable but non-reportable diagnostic events. In 1992, we had six recordable events and one reportable therapeutic event.

Our x-ray program is large, covering some 24,000 machines at 9500 facilities. About half the machines are inspected each year, and they are subject to various fees and civil penalties. We register accelerators and lasers, and regularly inspect accelerator facilities.

Illinois has had a radiologic technologist accreditation program since 1984. We accredit radiographic technologists, chiropractic techs, nuclear

medicine techs, and radiation therapy techs. There are currently about 8700 technologists accredited in Illinois. Of these, about 800 are nuclear medicine techs and about 500 are therapy technologists, which includes x-ray, accelerator, teletherapy, and brachytherapy.

Civil penalties in the tech accreditation program have been available since 1989. Penalties for technologists are $250 for the first violation, $500 for the second, and $1,000 for others. Employers' penalties are $500 for the first, and $1,000 for all subsequent. Since 1989, we have assessed $32,250 in penalties against 57 technologists and 36 employers, most of which have been in the last 12 months. Of these 57 technologists, four have been in nuclear medicine and three in radiation therapy. We have a number of additional ones pending, but there have been no suspensions or revocations to date.

There are 27 states plus Puerto Rico which have implemented certification programs, although they may vary in scope and detailed provisions. Of these, 17 are Agreement States.

I would like to close by announcing that the Organization of Agreement States Executive Committee, we three, have decided to appoint two committees to operate over the next few months, one to address a variety of the medical issues, many of which you've heard about already

last week and are currently the subject of lots of discussion; the other is a data gathering committee to review the kind of data that NRC requests to see if we can avoid any duplication and simplify and see, you know, the merit of that information to the Agreement States.

Now, I would like to ask Mr. Hill to make his remarks, if I may.

COMMISSIONER de PLANQUE: Before you go on --

MR. KERR: Yes?

COMMISSIONER de PLANQUE: -- I'd like to ask a question about the accreditation programs. If you look at the numbers, about 30 percent of the Agreement States have credentialing programs through medical -- nuclear medicine technologists, and only about 10 percent of the states regulated through the NRC program have such programs.

The hypothesis has been made that you would expect to see the rate of misadministrations to be about the same in the Agreement States as the non-Agreement States. I wonder what you would say about the influence of the accreditation programs on misadministration. Would you think that that would be something that should be taken into consideration if you look at that hypothesis?

MR. KERR: Well, I don't know that there is any connection. We don't know either. The one therapy misadministration that we had in 1992, was due to the

technologist not reading the order that was changed by the doctor after he first gave it. On the diagnostic, I do not know because we only basically have the therapy reported to us. But it's something that I think various people ought to consider. There are other states that have possible plans for adopting accreditation programs at this time, but they may not all vary. They may be different than ours, I'm not sure of the scope of all of them, but they all have some -- these 27 have accreditation programs.

COMMISSIONER de PLANQUE: It is a striking difference in the percentages, and one wonders how you could measure the effectiveness of those programs in that regard.

MR. KERR: Well, let me just say that of those that we issued civil penalties to, all have been for lack of accreditation, not having the accreditation when they started to work, or something like that. They were not penalties on cases that have happened.

COMMISSIONER de PLANQUE: One other question. You mentioned the review committee and that you have one in Illinois. Is this something that you would recommend that all the states have?

MR. KERR: Well, I don't know. We talk about a lot of trivial stuff. In fact, you know, very few are

really incidents -- we call it the Incident Review Committee -- but a lot of it are things like encountered sources, when the alarms go off at a trash yard, contaminated metal, those kinds of things, we get a fair number of those -- material has gone from the hospital to the local dump and they have a detector, and it ends up with baby diapers and so forth. So, we cover a lot of things and see what we can learn from it, but it's something that certainly others could consider.

COMMISSIONER de PLANQUE: Okay.

COMMISSIONER REMICK: Mr. Kerr, before you proceed, I had a question related to something you mentioned in your statement. On the enforcement example in California, you mentioned that there was a fellowship in radiation safety. Do you know to what -- and I infer from that that that state must have the ability to use fines for purposes like that. If that is the case, do you know how many states have that provision where they can, through their enforcement action, get something like fellowships or other type of remedial action, use of those funds?

MR. KERR: The two gentlemen from California can probably answer better, but let me just say I think it was part of a negotiated settlement, and I used it to illustrate. It was something I thought rather unique and

kind of interesting to have them do that.

COMMISSIONER REMICK: I know some states have that ability in other areas, not necessarily in radiation, where they can use enforcement action to negotiate something like a research program related to the area where the fine or the enforcement action was taken. You don't have an idea how many states have that ability?

MR. KERR: Certainly, our state doesn't have anything explicit to say you can go negotiate those kinds of ancillary programs. I don't know whether they would find the authority to do that or not. Frankly, I'd have to ask our counsel whether we could or not.

COMMISSIONER REMICK: Thank you.

CHAIRMAN SELIN: Mr. Hill? Thank you very much, Mr. Kerr.

MR. HILL: Thank you, Mr. Chairman and members of the Commission. It's a pleasure meeting with you again, continuing our discussion of issues of mutual concern. Since I met with the Commission on June the 11th, 1991, to discuss compatibility issues, we have participated in meetings and workshops with NRC. The Agreement States provided early input into NRC rulemakings, most notably, Parts 34 and 35. Today, I must report to you that the Joint NRC-Agreement State Committee recommended by the Agreement States to develop a

compatibility strategy has not yet been established.

Next, I want to briefly discuss Georgia's Radioactive Materials Program.

CHAIRMAN SELIN: You can't just come off that point like that.

(Laughter.)

MR. HILL: I understand that there may be some meetings or something forthcoming in the future that would work to develop for the Agreement States and the NRC to jointly work on compatibility, I hope so, whenever.

CHAIRMAN SELIN: I really need to say something at this point, that with all due respect, the reason that we're so interested in the Agreement States program is not because of the sovereignty of the individual states, it's because we understand that conditions vary from state-to-state and that, in principle, provided the states meet certain prerequisites, that in many cases they are in better position than we are to figure out what's the best way to carry out agreed objectives for the regulatory programs, in this case in the medical programs, and specifically in medicine, to provide some coordination for different sources of radiation, so that people who are injured through radiation aren't treated differently if the radiation comes from an electromagnetic device versus if it comes from a byproduct piece.

And the question -- we hope we are, and we certainly intend to be, pretty liberal on the question of compatibility, that it's not to -- we really don't care if there's a uniform set of enforcement procedures from state-to-state. We're not regulating commerce so that physicians will pick a state to practice in based on the enforcement procedure, what we're really interested in is effective regulation. And if individual states have a better insight as to how to carry things out in that state than we do, so much the better.

What we are interested in, and one of the reasons that Mr. Thompson alluded to, is to integrate the Agreement State program with our own program in the sense of learning from each other, that one of the benefits is we have 30 different regulatory programs, 29 Agreement States' plus ours, to learn from, instead of just one. So, we are very interested in pushing the compatibility work and identifying as few issues as possible that need to be strict compatibility, and as many where some local flexibility cannot only be allowed and enforced, and the reason we want the data is not to follow up on the individual misadministrations, but to get some idea of how things are working, to look at the states as a set of states, not to review each of the 29 states individually.

Now, one of the places where we feel there has

to be some more work done just to make sure that things are more or less compatible, is in the question of informing patients. We do feel that this is not something that should vary on local customer, or local information. When patients have suffered a misadministration, we feel very strongly that their physician and the individual, absent some overwhelming medical reason, should get this information.

So, we are very anxious that this work on compatibility proceed. We are pleased that so much of the actual registration is in the hands of -- I'm sorry -- inspection and regulation is in the hands of the Agreement States, and we don't want things arbitrarily to be considered first category of compatibility, if there's no good reason to do that. So, we do need to make sure that whatever the mechanism, this committee or some other mechanism, goes forward to work on that point.

MR. HILL: We agree, and we wish to continue to work with the Commission in moving forward on those issues.

MR. THOMPSON: Mr. Chairman, I might add, in response to the Commission's approval for us to take a new look and then to generic a process for compatibility, we intend to fully encompass the Agreement State, the leadership and the Agreement State efforts in that effort.

So, we clearly intend to do that, and I think that's consistent with the Commission's guidance to do that.

CHAIRMAN SELIN: Thank you, Mr. Hill.

MR. HILL: Thank you. Georgia has been an Agreement State for 23 years. As of this past December, we have 519 licenses as compared to 596 in June of 1990. Our current staff includes six technical, two administrative support, and one manager. Additional support for laboratory services and emergency response is available within the Department. The Radioactive Materials Program, unlike Radiation Control Programs in other states, does not have responsibility for registering and inspecting x-ray machines or generators of nonionizing radiations.

During calendar year 1992 we conducted 124 inspections and completed 819 licensing actions. A total of 539 of those licensing actions administratively amended or added a license fee condition. Twenty-nine percent, or 81, of the remaining licensing actions were new or renewal applications.

Georgia's inspection priority system is essentially the same as NRC's. In November of 1990, after several years of effort, the program eliminated its inspection backlog. To date we have completed all scheduled inspections. I'm not optimistic that we can

keep inspections from becoming backlogged. A revision of our rules and regulations and their adoption by the board, in accordance with our Administrative Procedures Act, must be completed this year.

Fees. In fiscal year '92, the Radioactive Materials Program received approximately 50 percent of its funding from fees, the remainder from the state's general fund. Beginning fiscal year '93, this past July 1st, the program is 100 percent supported by fees. The fee schedule adopted by the Board of Commissioners is similar to NRC's fee schedule. The notable exception is that our annual fees are approximately one-third of NRC's fees.

Our rules and regulations provide for enforcement, including civil penalties. All enforcement activities including the assessment of civil penalties must be conducted in accordance with the Georgia Administrative Procedures Act.

And as an aside here, addressing the question about alternate penalties or fees that Commissioner Remick mentioned a moment ago, we will frequently, in our procedures, use a consent order in which a civil penalty or a dollar amount can be assigned and negotiated, and those types of things similar to what California used have not been used, but I think they could be if management so wished to use that approach in a consent order.

In 1992, licensees and companies reported 18 incidences. These were investigated, and all but one are closed. Reports of three diagnostic medical misadministrations were received in 1992.

One final comment. In 1985, while attending an NRC sponsored workshop on large irradiators, I learned that the NRC Regional Materials staff and the Agreement States had some of the same problems with NRC's headquarters. I challenge the NRC to review its Regional Materials Licensing and Inspection Programs using the same criteria that has been developed and used to evaluate Agreement States. Who knows, from such a review NRC may discover the equivalent of five additional Agreement States. Therefore, the compatibility that is worked out between the NRC and the Agreement States may be beneficial within and have application within the NRC. Thank you.

CHAIRMAN SELIN: For your information, Mr. Hill, we have finally gotten around to notice that recommendation, and we have asked the staff to do at least the same type of review of our own programs that we do on Agreement States. There's no reason that the workload indicators and the process indicators should be all that different from one to the other. So, we find mills of regulation turn slowly, but I think we've finally gotten around to that recommendation.

MR. HILL: Thank you.

COMMISSIONER de PLANQUE: On that point, I think that it wasn't even a new idea then. A little digging in the files indicated that back in '79 when Mr. Kerr was on the Agreement States program staff, a similar recommendation went forward. Could you enlighten us at all why nothing happened at that time?

(Laughter.)

MR. KERR: That's really getting old for a person of my age to remember, but I remember in general that we brought the subject up, and I don't remember any specific words that came back, but I think they were along the lines, well, we look at similar factors when we go out and review the regions.

The other thing is, I'm not exactly sure when regionalization of the materials program took place. I don't remember the date. So, there could have been some crossover there when things -- certainly, I remember the pilot program started in Region III and went for a few years before it was extended to the other regions.

COMMISSIONER de PLANQUE: And there were differences in terms of inspection versus licensing, so that would --

MR. KERR: Well, yes, right, the regions always had the inspection, but the licensing program, too. And,

so, I don't remember specifically, but I certainly do know that it did come up.

COMMISSIONER de PLANQUE: So, nothing in particular we should learn today from what happened then?

MR. KERR: I guess, as the Chairman has indicated, it's sometimes useful to review all the past documents to see if we, you, or whoever, has done what we said we would do.

CHAIRMAN SELIN: Absolutely. I should point out that our main emphasis is not to try to find patterns among our five regions, but if we have programs that do the same things that the Agreement States programs do, they should be basically subjected to the same type of measurement. It's more to look for consistencies, or explain inconsistencies, between our programs and the Agreement States, than differences among our five regions.

MR. HILL: Okay. Dr. Clark?

COMMISSIONER REMICK: Excuse me, Mr. Hill, two questions. Is it safe for me to assume the reason that there's been a substantial decrease in the number of licensees is 100 percent fee recovery?

MR. HILL: I think that plays a very, very large part in it because I've graphed the drop of our licensees over time, you can see a definite drop each time the fee structure has changed, in number of licensees terminating,

and even those who didn't pay the first time they were invoiced, when the second invoice went in, the termination request would come in.

COMMISSIONER REMICK: The other thing, you indicate that you do not have responsibility for x-ray machines and other generators, and nonionizing radiation. Who does that in the State of Georgia?

MR. HILL: The Department -- I'm in the Department of Natural Resources. That responsibility lies with the Department of Human Resources, Office of Regulatory Services.

COMMISSIONER REMICK: I see. Any views on whether ideally that should be combined or not?

(Laughter.)

MR. HILL: Well, two and a half years ago, we were split apart. Legislation went forward that removed the Radioactive materials Program from Human Resources, and placed it in Natural Resources. Keep in mind that when the Department of Natural Resources was formed in 1972, part of the Environmental Radiation Monitoring Program went to the Department of Natural Resources shortly thereafter, and a few years later emergency response responsibility went there. And now, several years later, the Materials Licensing Program has been moved to that department.

COMMISSIONER REMICK: I see. A related question, as I'm sure you're aware, there are some who feel that the NRC should have the authority over, such things as x-ray machines, linear accelerators, and linear accelerator produced radioactive materials. Do you have any views on that? Is that something that you think might be a good idea or not? Any views on that matter?

MR. KERR: Well, I saw the comment in The Plain Dealer article, and I, as Mr. Bernero indicated last week, never heard of such a thing when I was around here, and I don't remember hearing it from anywhere else. Frankly, I don't know where they got that idea. It really had never entered in my thought that that should be done. It's quite a different -- the x-ray program is quite different than the Materials Regulatory Program, it operates a lot differently, and it's very huge, very large program. So, I don't see any particular need to do it that way.

COMMISSIONER REMICK: Anybody agree or disagree with that?

DR. CLARK: I was going to say I agree with Wayne, the issue is very different. I mean, you turn the machine off and there's no more radiation. And also the nature of the inspection is very different. The surveys of x-ray machines is just a very different sort of investigation than a radioactive materials inspection.

COMMISSIONER REMICK: I agree it's different. I'm not sure that that is compelling reason.

MR. HILL: One comment I'll make though, on that line. We work with the Department of Human Resources. They do register, for instance, accelerators, and we do license the material that they produce.

COMMISSIONER REMICK: I see. Um-hmm. In the area of x-ray machines, I'm just curious, do you have particular trouble with universities using them for research, in which they modify the x-ray machines?

MR. KERR: I don't recall that that's been a particular problem in Illinois.

COMMISSIONER REMICK: Okay. Thank you.

COMMISSIONER ROGERS: Just before we leave this -- I mean, maybe I'm stepping into something I shouldn't step into, but your reference to the same problems that you have that the regional NRC people have with headquarters, what kind of problems are these?

MR. HILL: In discussions in the meeting, we were talking about licensing and inspection procedures, reviewing assistants' approaches to things that when we were being reviewed, it was those types of things. We felt that -- a statement has been made earlier that the states are closer to their licensees, some of the regional folks felt that they were closer to their licensees, had

a better relationship with them, like the states feel that they do, compared to what I was hearing from their comments in our discussions, that they felt that headquarters had, and that they were -- could not operate, I'm assuming because of procedures or something on that line, in a way that they felt comfortable and they felt would be effective. Now, that's the way I recall it from eight years ago.

COMMISSIONER ROGERS: Well, the relationship is very different to headquarters, of our regional offices and the Agreement States, and if you have -- and it's a little difficult for me to see exactly what the same problems are there. I mean, maybe that's a smaller list that might -- I'm sure that regional offices of NRC have their own particular reasons to be unhappy with headquarters that have nothing to do with the kind of reasons that you might be unhappy with NRC headquarters.

And, so, when you say that they had the same problems, I'm looking at an overlap there between the two classes and what that amounts to.

MR. HILL: I think maybe I can give you one specific type example. We in the Agreement States, we in Georgia, and I'm assuming in other Agreement States, use license conditions. Sometimes we do not use one that is a standard condition that is appropriate for that, and as

some of the regional licensing folks felt that they were, as I recall, restrained somewhat from using nonstandard license conditions or the approval process to get those done would have been difficult. That is, I think, one type of example that I could give that might be a little more specific.

MR. KERR: Let me just comment, Commissioner Rogers. We have some regions also. We have a region in Glenelyn right across the street from your regional office, where we have both x-ray and materials inspectors, and then we have two regions that have single x-ray inspectors in them, and there's always some tension between regions and headquarters, about us versus them, or we don't get enough guidance, or you're not clear, and, well, that's headquarters, we'll do our own thing -- you know, I'm sure you're well aware that managing regions takes a lot of effort to -- a lot of them are administrative type things, but some are interpretations. But, you know, today in the days of fax machines and so on, we can do a lot, but there's still always that relationship there that has to be watched.

CHAIRMAN SELIN: Dr. Clark.

MR. KERR: Yes, Dr. Clark.

DR. CLARK: Thank you, Wayne. Mr. Chairman and members of the Commission, I would also like to take this

opportunity to explain briefly my state's radiation protection program. Florida became an Agreement State in 1964, and we currently have over 1100 specific licenses. Approximately half of these are for medical purposes. In addition, we have over 500 general licenses. We inspect medical licenses with greater frequency than does the NRC in most categories. Last year, we inspected over 500 licensees.

We have ten technical staff dedicated for licensing activities, and ten support staff that is clerical/accounting sort of staff responsible for both inspection and licensing activities. We also have 11 full-time equivalent radioactive materials inspectors, and I'll explain in more detail later how our inspection staff is organized.

Besides regulating radioactive materials, we also register and inspect x-ray machines and accelerators as well as certify all radiologic technologists in the state, of which there are about 30,000 certificate holders, 15,000 of them are active certificate holders.

There are also over 30,000 x-ray tubes, over half of which are medical, and 200 medical accelerators registered in Florida. The medical machines are inspected annually. There are approximately 32 full-time equivalent inspectors statewide for machine inspection.

When we inspect medical facilities for either radioactive materials or machine-produced radiation, we also verify that the radiologic technologists are properly credentialed. We do register laser devices. And I would mention that our misadministration rule does apply to both machine-produced radiation and radioactive materials.

Conducting timely inspections is one of our most important responsibilities. To accomplish this as well as to maintain the ability to respond promptly to reports of radiation accidents or incidences, we have ten area and satellite offices throughout the state. This means that with the exception of Key West, there is an inspector well within 100 miles of any location in the state.

Most of our inspectors perform both x-ray surveys and some radioactive materials inspections, although we do have more senior inspectors conducting primarily the materials inspections.

Approximately two-thirds of our radioactive inspections are unannounced. Pre-license visits are performed for significant license applications and renewals. New licensees who do not receive pre-license visits are hand-delivered their licenses by an inspector, at which time reviews of the facility and procedures are performed. We want to make sure if there is supposed to be two locks, there are two locks, for example. Last

year, there were 40 pre-license visits and 150 hand-delivered licenses.

Our program is fee-supported with our fee schedule not tied to that of the NRC's. We took about 1300 licensing actions in 1991, and about 1400 in 1992. We have the authority to administer fines for the radioactive materials, x-ray and radiologic technologist programs, and we do administer fines.

Let me conclude my remarks by saying that we believe our state's regulatory activities and the integration of them provides the necessary expertise and ability to protect the public health and safety.

CHAIRMAN SELIN: Thank you. Before we -- do you have some questions?

MR. KERR: No, just go ahead, any questions for us.

CHAIRMAN SELIN: I just wanted to ask you to think about one proposition. You talked about data before. As I tried to explain, we're not so much interested in individual state data in more detail so that we can review, we're interested in trends information and overall patterns, both to learn from and to see if there are noted discrepancies in the Agreement States as a whole versus our own regulating as a whole. And we've assume that we're going to collect these data from the individual

states and integrate them in our Office of State Programs, but it's possible that the Organization of Agreement States might decide to take a more active role in collecting some of this data across your universe and working with our Office of State Programs, and we would be open to suggestions as the most efficient way of getting some of these data together on a regular -- relatively as painless as possible fashion.

MR. KERR: The committee we intend to establish will have fairly broad freedom to explore any of these things, and some items were mentioned upstairs this morning, too.

We as the Organization of Agreement States really don't have much authority. We can sit here and say something about other Agreement States, but we don't have the authority to tell them to do anything or make them do anything, we are more or less a focal point for you folks and so on, but certainly we'll consider all those comments.

CHAIRMAN SELIN: But you're the alternative to the NRC, and that might give you a certain amount of status.

(Laughter.)

MR. KERR: Yes.

CHAIRMAN SELIN: Any other questions?

COMMISSIONER de PLANQUE: I have a question. Again, on the data, speaking in general for the Agreement States, are there any problems with the data that the states submit to the NRC? Are you getting adequate feedback, or are there any suggestions you'd like to make in this regard?

MR. KERR: Well, one of the things I'm going to have to look at on the feedback is how useful is the information to us? Are we getting it back, and how useful is it to us? I mean, I realize you have different reasons for wanting the data perhaps than we do, so they will be asked to look into that. And I don't know for sure about specific problems.

One that kind of bothers me a little bit, one of the things is allegation tracking. If we get an allegation, we tell the NRC and you track it. So, you're tracking the trackers, and I'm not sure, you know, why you really need to track how we do on a day-to-day or month-to-month basis about tracking allegations. You know, many of these turn out to be "no, never minds" anyway and, you know, they're just part of our regular program. But they'll look at a broad range of these things, Commissioner.

COMMISSIONER de PLANQUE: Okay. And one other area, that of voluntary standards produced by the

professional societies. There's always the question of are those voluntary standards applicable instead of given rules or regulations. How do you feel the Agreement States function in this area? Are they taking more or less advantage of voluntary standards that are out there?

MR. KERR: Well, I think on the material side, it's not so much the national standard. We basically, you know, follow the NRC pattern by and large now. On the x-ray side and the certification, our certification program accepts national standards of the various certifying organizations. We do not do independent certification per se, you know. If they certify them, then we do that and we have continuing education requirements. But it was a fairly well established system before we ever got in the business. And, so, we decided to proceed to accept that.

COMMISSIONER de PLANQUE: Okay. Thank you.

COMMISSIONER ROGERS: Have you made comparisons of medical misadministrations reported in each of your states, on a per-procedure basis, and made any comparisons with NRC regulated states?

MR. KERR: No. First, Commissioner, in terms of our own state; I'm not sure what the others have done, I don't think so. Our rule only went in effect in July, 1991. Now, we were continuing to get reports from the NRC rule that was in place when we became an Agreement State.

A licensee would call us up and say, "Hey, we got this, do you want to hear about it?" We said, "Well, you're not required, but please go ahead and send it in, we'd like to see it". So, that's why we were able to report some data from the past years in that interim period. But, no, we have not done any comparison on procedure-by-procedure.

COMMISSIONER ROGERS: Do you have any interest in doing it?

MR. KERR: Well, I don't know, we haven't really had -- we've had one therapy misadministration is all we've had, and the rest have been what we call recordable events, which are not required to be reported to us. They have to maintain the records and so on, and they're subject to review and inspection. At this point in time, I'd say we've not considered it. I'm not sure whether we would or not.

COMMISSIONER ROGERS: Well, if you were to look at the percentage of recorded events that you have, and made a comparison with other states or other states under NRC regulation, and you found a significant difference, would that bother you?

MR. KERR: Well, I think it would certainly raise questions. I'm not so sure whether it would bother me, you know. You have heard from the community about the whole business of misadministration reporting,

particularly the diagnostic that used to be there, on whether it really serves a useful purpose. And many in the medical community, of course, feel that they're at a very low frequency to start with. Certainly, the serious therapy ones, you know, we investigate the ones that are therapy, and that's where I think we would focus the attention.

On the diagnostic ones, I'm not so sure that it would be that much --

COMMISSIONER ROGERS: Well, if we just talk about the therapy.

MR. KERR: Well, yeah. Well, see, the situation is with us, we consider a therapy misadministration, we would review it like we would some other incident if it was non-medical, and what lessons we might learn from that we don't know at this point since we've only had one, but it certainly deserves more consideration.

COMMISSIONER ROGERS: Well, but I'm coming to the point that if there's a question about whether these are really being reported accurately or correctly, you don't have much of a comfort factor to go by by just simply saying you have the low number or low percentage -- compared to what? I mean, what's the average that one expects, and the fluctuations in that average from state-to-state around the country? Unless you know what that

is, I don't know how you can feel very comfortable that it's a low number. I mean, even though it's a small absolute number, I don't know that you really have much comfort that you have an adequate reporting system.

MR. KERR: Well, I think time will tell in our state because the reporting system has only been there for a year and a half, but --

COMMISSIONER ROGERS: Well, I think it's an important question to be able to answer for yourself.

MR. KERR: Yes.

DR. CLARK: I would say that one would first need to look at, when looking at the data, how one uncovers the misadministrations, that I would first look at the categories in which they are found, whether they've been reported, whether it's as a part of the inspection, whether it's anonymous complaint, reported by either the physician, someone else in the hospital, or a technologist there, the physicist. Then I would also categorize the cause -- I think Wayne alluded to that -- the causes of the misadministrations, before I would be able to determine whether the lack of reporting or the lack of numbers of misadministrations was the result of an inadequate reporting system.

COMMISSIONER ROGERS: Well, fine. I mean, that's certainly the right thing to do, but the question

is, what are you comparing it to, to give you some feeling that your process of examining these things is uncovering everything? It's an absolute, you know, it's just a deterministic absolute approach, and you don't have any kind of reference point, base point to look at. I would be worried about that.

MR. KERR: Well, I don't have anything else to add at this point.

COMMISSIONER ROGERS: Yeah.

MR. KERR: Appreciate your comment.

CHAIRMAN SELIN: Thank you very much. We're very pleased that you've set up --

COMMISSIONER REMICK: Excuse me, Mr. Chairman.

CHAIRMAN SELIN: Oh, excuse me, Commissioner Remick.

COMMISSIONER REMICK: A couple of questions to all three of you, as you choose to answer. Do you find the fines that you're able to issue for misadministrations or violations, are adequate to assure adherence to your regulations, or make corrections, or is it more the stigma of the associated publicity, or is it a combination of the both?

MR. KERR: Well, I think in all the cases we have, the two fines in the one medical and one industrial, and then the tech fines, I don't think we've had repeats

of those. So, you know, so far we'd say, okay, I got their attention and presume it's adequate. Now, if we had repeats, then that would certainly raise a different question.

COMMISSIONER REMICK: But do you know if it was the amount of fine or the publicity associated with the issuance?

MR. KERR: Well, the fines, you know -- let me just mention particularly on the techs, looked rather small. I said $250. Well, those techs make about $23,000 or $25,000 a year, and that's 1 percent of their salary. Now, it's not a lot of dollars to us, but I think for those of us sitting around this table, if we were asked to give 1 percent of our salary as a fine, it would be more than pocket money. So, it's not, you know, terribly big in the absolute terms, but they're operating in a different salary scheme than we are. I don't think those techs that got those fines will probably repeat going out and working without their proper accreditation.

COMMISSIONER REMICK: Yes.

MR. HILL: We have received a fee as the result of a consent order, not a civil penalty hearing, a consent order, and we have not had a repeat of that violation, but in this case it was the licensee's failure to renew a license and to work toward a renewal of that -- it was an

industrial license -- and the penalty, the dollar value -- it's kind of hard to call it a penalty -- the dollar value was low compared to what that industry has paid many times before for emission of hazardous material out of stacks.

CHAIRMAN SELIN: Commissioner Remick, are you through?

COMMISSIONER REMICK: Yes.

DR. CLARK: My response would be very similar to Wayne's, that when we administer fines, we do find whether or not excessive in terms of thousands and thousands of dollars. I think that does work to achieve compliance. For example, with the technologists, I think you find that facility -- you find the facility as well as the technologist, you do find that that facility is much less likely -- in fact, never -- going to hire again an improperly credentialed technologist.

COMMISSIONER REMICK: Okay. Mr. Kerr, you indicated that you do perform inspections of therapeutic misadministrations. I would appreciate the others responding in that area. And also, each of you, do you follow up with the individual patient? To what extent do you follow up, how far with individual patients?

MR. KERR: We have not performed a follow-up on the patient.

MR. HILL: We have not followed up on -- with

the patient either.

COMMISSIONER REMICK: But you do perform an inspection --

MR. HILL: We would perform an inspection for a therapeutic misadministration. Before the Rad Materials Program and the x-ray program were split up, there was a therapeutic misadministration from an accelerator which was inspected and followed up on.

COMMISSIONER REMICK: Okay.

DR. CLARK: We also perform inspections, and then we require as part of our investigation, a plan, a follow-up plan, to the -- while we don't follow up ourselves on the patient, we require there be a follow-up plan by the facility.

COMMISSIONER REMICK: Thank you very much.

CHAIRMAN SELIN: Thank you very much, you folks. We're pleased that you've set up this Medical Use Subcommittee, and expect to have a lot of contact with it. I think that will be very useful for everybody around the table. Thank you very kindly.

MR. THOMPSON: Mr. Chairman, the next portion of the briefing will be by the four Agreement State program managers who have their programs or incidents under their responsibilities identified in The Cleveland Plain Dealer. We will, I guess -- let's see, I think we have an order

for David, I think Dave is right here -- musical chairs, this is the musical chairs. Ed, you're in the middle; Roland, I think you're on the far end by Carl; and, Aubrey, I think you're right there by --

CHAIRMAN SELIN: Whoever said they don't administer these programs closely?

(Laughter.)

COMMISSIONER ROGERS: Micromanagement.

(Whereupon, the panel stepped back from the table and the next panel came forward.)

MR. THOMPSON: The briefing sequence that we have selected today will be first by Mr. Aubrey Godwin, from the Arizona Program; then by Mr. Edgar Bailey, who is in the middle here, who is a certified health physicist from the California program; Mr. Roland Fletcher, from the Maryland program; and then Mr. David Lacker, from Texas. Aubrey?

MR. GODWIN: Mr. Chairman, Commissioners, I'm Aubrey Godwin, from the Arizona program. I've been there since September, so I'm fairly new, and I hope they voted to confirm me today in the Senate.

(Laughter.)

MR. GODWIN: I'm not real sure.

MR. THOMPSON: But he does have a long history with the program, so he's not that new in the area.

MR. GODWIN: Certified in health physics, and worked with Alabama for 30 years, so I'm sort of talking about two different programs.

I thought I would go to Commissioner Rogers's question just a little bit if I could. One of the things we did in Alabama as a part of our review, was go into and look at patient records and compare the patients logged in on their record dose versus what was being logged in in the nuclear medicine or in the therapy department, and compare that to the prescription to make sure there was a consistency in that. And on occasion we did find some even before the misadministration rule went into effect, and this would -- it wasn't a great percent, but it did give us a little bit of confidence that we had checked and that they knew we would be there looking at it. So, that did help us a little bit and give confidence there.

Going on to the Arizona program, we really are going to talk about two events. The first event, the Desert Samaritan Hospital, was passed out and you all have a written statement on it, and I also provided some more information relative to the Good Samaritan Hospital, it's actually two different facilities, and if it's all right, Mr. Chairman, I'll just sort of rush through the first one and then try to stay a little bit of time on the second one.

Looking at the first slide -- make that the second slide -- we're talking about the Desert Samaritan Hospital. (Slide)

And we're just briefly going to talk about the situation there. Third slide. (Slide) Moving quickly on the slides there.

Describe the event, few things that contributed to it, and what we've done. The problem was to keep up with the current status until we get to the second one. Next slide, please. (Slide)

Okay. This particular event involved a call to the radiopharmaceutical company asking for a dose. It was supplied at 100 millicuries instead of 100 microcuries. The technician didn't check things, and subsequently gave it to the patient, resulting in an estimated 200,000 rads to the thyroid, with roughly 170 rads whole body. This occurred in November of 1989.

The woman had five children -- that was involved -- had five children in the home. The critical dose was to the four- and five-year-old children, and their dose was 3 rads to thyroid, and we estimated 2 millirads whole body. Next slide. (Slide)

COMMISSIONER REMICK: Excuse me. What was the source of the thyroid exposure to --

MR. GODWIN: Iodine 131.

COMMISSIONER REMICK: No, but what was the transfer mechanism?

MR. GODWIN: Oh, just contamination within the home.

COMMISSIONER REMICK: I see.

MR. GODWIN: The patient was home with 100 millicuries, and you lose rather quickly. The technician did not confirm what the dose -- calibrate what the dose was. They looked at it. They had some question. Although we subsequently did not leave this as a finding so far as compliance was concerned, but still the question was there, how well the survey was conducted, or did they conduct a survey of the incoming package. A side question related to whether the shielding was supplied for the incoming package that was normal for a therapeutic dose, and all indications was there was no shield in there, which should have been there for a millicurie type dose. They did not compare the doses as prescribed, was the root cause of that. Next slide. (Slide)

When we went over to the radiopharmaceutical company and looked there, we couldn't read his writing either. Also, they had no methodology of confirming what the prescribed dose would be versus what was ordered, so they didn't check it out either, and they did not even identify who'd received the order, who had made the order.

It was just a little note, here it comes. They also did not put the name on the prescription for this type thing, which sometimes happens. Next slide. (Slide)

This resulted in a $12,000 civil penalty to the facility, and for a short time a reduction to using over 100 microcuries of iodine. That subsequently was lifted after they demonstrated they were able to institute necessary safety programs. Next slide. (Slide)

The radiopharmaceutical company was initially issued an order that required them to confirm the therapy dose for Iodine 131 if it was over 1 millicurie, must have patient's name, and the name of the individual ordering the dose, so we'd have a little bit clearer understanding of what's happening there. They subsequently adopted that procedure nationwide, I understand, and that's just part of the iodine condition now. Next slide. (Slide)

Good Samaritan Hospital is a teletherapy exposure. This particular facility had one cobalt unit and two particle accelerators. The event was on the cobalt unit. Next slide. (Slide)

In this particular event, they lost their medical physicist, and they had a dosimetrist who was doing -- 75 percent of the time was related to dose calculation and 25 percent was to other duties, and they had a 25-percent time consultant coming in. It resulted

in using their computer. They entered the wedge factor effectively twice and, therefore, it lengthened the exposure time, and ended up with up to a 40 percent increase in radiation. I should point out that we list four patients there. Three of the patients would be misadministrations, one of them died during the treatment, did not complete the treatment, so never became a misadministration in the technical sense.

We did request assistance from NRC, and we requested that, I believe, in September, and we received it in November of, again, '89, so these events are sort of overlapping. The medical physicist did not indicate that it was a radiation cause and effect related to the patient's death, but there was a patient death involved here.

CHAIRMAN SELIN: It wasn't a misadministration because all that was kept track of was the cumulative dose?

MR. GODWIN: That's correct.

CHAIRMAN SELIN: But the actual intensity was much higher than --

MR. GODWIN: Was higher, that's correct.

CHAIRMAN SELIN: But that may be a weakness in how we define misadministration.

MR. GODWIN: Well, you know, it just didn't get

to the endpoint. Next slide. (Slide)

MR. THOMPSON: Mr. Chairman, I think in the new medical misadministration rule, we have changed that aspect.

COMMISSIONER ROGERS: It would be each step in the full procedure, would it not?

MR. THOMPSON: That's correct.

MR. GODWIN: The contributors, you know, they didn't understand. You had several successive users of this particular computer program who didn't understand how it was plugged into the program. It was a loss of communication, really, is where it fell down.

And also some contributors was that the Radiation Safety Committee, for example, wasn't meeting when it was supposed to. They would meet without the radiation safety officer or the administrative folks. They'd meet without anybody from oncology. And even after the event, they didn't aggressively get involved for a while. So, we had several events that contributed to it. Next slide. (Slide)

You all did provide a medical physicist. That's really not an enforcement action, but it's the only place we could plug it quickly into the slides here. We initially proposed a $3,000 civil penalty after their response to that, and some more factors led us to believe

that they were not being very aggressive, and the penalties revised upward. Then we made some other discoveries. And it was proposed at $7,000. At that point, they got real aggressive on things.

We also discovered a problem where we were trying to issue a citation in which we were saying that the intentional exposure under a medical prescription is okay, but anything above that would not be okay. And there were some quirks about how it was set up, and our attorney general did not feel that we had as good as case as the way this particular set of events set up, as we should have. So, subsequently, we did not pursue the civil penalty. However, we have conditioned the license, and they have been in compliance since then. They've kept a full-time medical physicist on staff. So, we got their attention. Did not go through with the civil penalty.

And I think I'll wrap it up at this point, unless you all have some questions. I wanted to just hit these rather quickly.

CHAIRMAN SELIN: What I'd like to do is go through all the pieces, and then we might have some questions across-the-board. Mr. Bailey?

MR. BAILEY: Mr. Chairman, Commissioners, I am Edgar D. Bailey. I'm Chief of the California Radiologic Health Branch. California has been an Agreement State

since 1962. We have approximately 2,300 radioactive materials licenses, with an annual budget in the department, or within the Rad Health Branch, of between $6 and $7 million. We collect our operating expenses 100 percent on fees, and for about the past three years we've been donating to the general fund about $1 million a year, to help out the deficit we have.

We also register x-ray machines. We probably have 58,000 facilities of that type. We also certify technologists, both x-ray technologists and nuclear medicine technologists, and probably unique, I think, is that we also certify doctors to use x-ray machines. They actually have to come in and get a permit from us in addition to their medical license, before they can take x-rays. In that group, we have about 58,000, in the docs and techs.

We also have somewhat over 1500 nuclear medicine technologists. We operate out of three regional offices and three county offices.

The incident I'm here to describe today to you is one that occurred, resulted in a death on August 21st, 1988, of Dwight Gregory Goldstein, II, who died at Children's Hospital in Oakland, California. According to the death certificate, the death was caused by respiratory failure, and I quote, "due to, or as a consequence of

radiation damage".

In September, 1992, several members of the staff of the Radiologic Health Branch, including myself, were contacted by a reporter from The Plain Dealer. The reporter asked for our files and information related to this 1987 cobalt-60 teletherapy misadministration at Alta Bates Hospital in Oakland which resulted in the death of a nine-year-old boy.

At the time of the reporter's calls to RHB, we had no information regarding the alleged incident. In response to questions from RHB staff regarding the reporter's accusations, representatives from Alta Bates Hospital assured them that the reporter's claims were erroneous. On September 9, 1992, I personally talked to a representative of the Risk Management Department at Alta Bates Hospital. When I was talking to some of the people here, they said I might point out that the Risk Management Department is essentially the department that attempts to limit the liability of the hospital. There may not be any safety engineers located in that department, so there's a little different connotation to risk.

CHAIRMAN SELIN: Different management of risk.

MR. BAILEY: It's a question of whose risk it is.

(Laughter.)

MR. BAILEY: At that time, I was told that the incident involved treatment with a linear accelerator, not a teletherapy unit. I was also told that the dose prescribed was the dose delivered. I was also told that the dose was delivered to the correct location. In addition, I was told that the dose was a palliative treatment of a terminal patient with neuroblastoma, and led to believe that in general the whole thing was simply a malpractice suit.

This information was provided to me even though we discussed the fact that the medical misadministration reporting regulation had become effective in California on October 5, 1989, nearly two years after the incident occurred.

On December the 13th, as you're all aware, the first in the series of The Plain Dealer articles was published. The lead story was about the incident at Alta Bates Hospital. Somewhat to our surprise, there was no pick-up by the local Bay Area newspapers or television stations. And I'm not saying that that -- at first, tended to lend some credibility to the information we'd received from the hospital because, you know, we didn't go to the mass, "Hey, do you believe this story or not". However, on January 6 of this year, due to increasing concern that we didn't have all the facts, the manager of our regional

office in Berkeley went to Alta Bates Hospital and found that we had not been told the truth in the earlier contacts with the hospital. He found that in essence the newspaper article was correct in what it had reported as having occurred. Contact two days later with the West Coast Cancer Foundation, which was the consulting medical physics group which developed the treatment plan for the patient, collaborated the new information.

The following is the sequence of events as we now believe they occurred. The child was referred to Alta Bates Hospital by Children's Hospital of Oakland for treatment for -- and if there are any physicians here, please forgive my pronunciation -- of rhabdomyosarcoma because Children's Hospital did not the appropriate radiation therapy equipment.

A treatment plan for the child was developed by West Coast Cancer. This medical physics group worked under contract to Alta Bates because the hospital did not employ staff medical physicists. The treatment plan involved a series of complex treatments covering a part of the face and upper neck. That is to say, the treatment was to occur over several days with multiple beams and a number of fields.

Treatment of the patient began on December 4, 1987, and continued on a daily basis, except for the

weekends, for 15 treatments ending on December 24. The patient developed what has been described as "a sore" in his mouth, and with the holidays approaching were told that they decided to halt the treatment to allow the patient to improve. When the patient returned in January, the face and neck contours had changed so much that a new treatment plan was ordered.

As it turns out, the same physicist at West Coast Cancer Foundation was drawing up the treatment plan. When he drew it up, he noticed that there was a significant difference in the numbers from what he had done in December. He looked at them and found that basically what had happened in December was that the time of treatment was twice as long as it should have been, which resulted in the prescribed dose of 180 rads per day, when in fact about 360 had been delivered each day.

On January 28th, the West Coast Cancer Foundation notified the staff oncologist at Alta Bates Hospital of the mistake, and the radiation oncologist filed a written hospital incident report with the hospital's Risk Management Department on February 5th.

No additional radiation therapy treatments were given. The child died seven months later. An autopsy was performed, but at this time we do not have a copy of that.

On March 1st, 1988, a routine inspection had

been conducted at West Coast Cancer. The radioactive materials license issued to the group is for the possession and use of three small calibration or check sources. The actual activity of preparing treatment plans or doing the calculations is not a licensed activity per se, but is included in the authorization to the hospital for the teletherapy treatment of humans. Medical physicists are not licensed in California at this time, although there is an effort underway this year by the medical physicists to get state licensure similar to what they were able to get in Texas a couple of years ago.

During the inspection at West Coast Cancer Foundation -- there's a question we ask on all of our inspections basically, and that is, are there any usual occurrences or incidents that have occurred that haven't been reported to us or haven't been mentioned. The RSO at that time, the Radiation Safety Officer, responded that there had been none. When asked about this response in January of this year, he said that he had not mentioned it because the case was in litigation. And that certainly raises a little bit of concern with us about how many other cases we weren't told about because they possibly were in litigation.

On June 20th and 21st, 1990, we did a routine inspection at Alta Bates. A review of the Radiation

Safety Committee's minutes show no reference to this misadministration. And this year in January, when we questioned the RSO, she said that she and the chairman of the Radiation Safety Committee only became aware of the misadministration when we called them to get information in 1992. Although the head of the radiation oncology unit must have known about the incident when it occurred, it appears that he did not inform the RSO or the committee even though he was a committee member. He has since left the staff of the hospital.

It should be noted that the West Coast Cancer Foundation is no longer the consulting medical physics group to the hospital.

It is reported that West Coast Cancer Foundation, or the radiation oncologist, and the hospital have settled lawsuits with the patient's family. The doctor and/or West Coast Foundation has reportedly settled for half a million dollars and the hospital reportedly settled for $30,000. I think in our looking at both of those numbers, they are extremely small and then therefor somewhat questionable to the accuracy of those settlement numbers.

Following discussions with Mr. Kammerer of the Office of State Programs, I fax'd him a letter on January 14th requesting assistance from NRC of an investigator

from the Office of Investigations to help us thoroughly investigate what appears on the surface to be a deliberate attempt to cover up the occurrence of this apparent misadministration. On January 22nd, Mr. Ben Hayes, your Director of Office of Investigations, instructed his staff in Region V to assist California in its investigations. We held our first meeting with the assigned investigator, Mr. Eugene Power, in Sacramento last Monday.

In addition to Mr. Power, RHB is seeking the assistance of our Licensing and Certification unit. They are the organization within the Department of Health Service that are responsible for the licensing and regulation, the overall licensing and regulation, of hospitals. And it appears at this time that there may be some violation of their reporting requirements because they were not notified of this incident when it occurred.

Our Office of Legal Services has already assigned an attorney to work on this, and he has contacted the Attorney General. It is the intent of RHB that a thorough and complete investigation of his entire incident will be conducted, and that if violations of California laws and regulations are identified, the case will be referred to the AG or the district attorney as appropriate, for their action. At the present time, the investigation is ongoing.

It is clear to me that there are difficulties that exist in investigating and taking meaningful enforcement action in incidents like the one I've described. There are a few recommendations or suggestions that I believe would be helpful.

The first is that misadministrations should be violations. At the present time only the failure to report them is a violation. One has to cite failures to follow procedures such as does assay, patient identification, and so forth.

We have, in our law on nuclear medicine technologists, we have words to the effect that the license or certificate may be revoked, denied, suspended by the state for among other things, incompetence or negligence in performing nuclear medicine technology functions. I think it would be appropriate if that were a reason to suspend a nuclear medicine license or an authorized user from a license. If you have a series of misadministrations, and we have at least one hospital where that's occurred, we've had a series of them, it may be time to say, okay, we're going to suspend them and get the program in line.

Secondly, consideration should be given to requiring medical licensees to report the filing of malpractice suits against the licensee or named users on

the license. This would follow the precedent already set of requiring licensees to report the filing of bankruptcy actions.

Third, consideration should be given to requiring that each Agreement State have inspectors or investigators who are peace officers. The Food and Drug Administration already requires such of certain state food and drug personnel. These state investigators should be required to have training similar to that provided to NRC investigators.

And, fourth, ont that's not on here is, we really need to develop a common database and implement that database system in Agreement States and in NRC. This go-around certainly illustrated the lack of uniform data and consistency in what it means.

That concludes my remarks. Mr. Donald Bunn, our Chief of Enforcement and Compliance, is with me today. He and I would be happy to answer any questions you might have.

CHAIRMAN SELIN: Before we go on, Mr. Bailey, I'll tell you one thing -- there are many things that are troubling about your report, of course, but the one thing that's particularly troubling, we've sort of assumed that the records are available if you only take the trouble to find them and that therefor the probability of gross

underreporting of misadministrations or something like that is quite low. But you've really described a situation where the records just weren't there. And I wonder if you'd care to comment on that.

MR. BAILEY: Well, I guess, two things. First of all, we did not have a misadministration reporting rule at the time.

CHAIRMAN SELIN: I'm talking about within the institutions, even if they don't report them to the agency, that if one goes in and looks at their records, one should have a very high probability of finding them. That doesn't seem to be the case in the situation that you're describing.

MR. BAILEY: Yeah. I think what we may have more often than we'd like to admit is that within a hospital, you have a contract radiation oncology group that is semi-independent of the nuclear medicine program and, therefore, the information may not be fed in. We may have a very special case here where one individual, for whatever reason, chose not to inform the rest of the committee. From the information we have, it was clearly -- it seems like it's clear that he would have reported that to the committee of which he was a member, but according to what we know at this point, he did not. So, that's one of the things that certainly is disturbing to

us, too, when we start looking at what goes on in hospitals. I think we've got other examples where contract therapy groups come in and they are independent from the nuclear medicine group, and they pretty much run their own show, unfortunately.

CHAIRMAN SELIN: Mr. Godwin?

MR. GODWIN: Mr. Chairman, in Alabama, we found that you really had to dig to get always to the bottom of the record. We had at least one incident in which a hospital threatened to use risk management as a way to hide records, but they decided not to after some discussions.

In Arizona, apparently the situation is essentially similar there. There've been some cases where they're saying it's in litigation and they don't want to discuss it until it gets through litigation. So, you can have these situations occur.

COMMISSIONER CURTISS: Let me just ask one question here. I don't want to go into the details of this. Do you have the capability within the staff of your state to conduct investigations generally of events like this?

MR. BAILEY: Yes, in general, we do. What may be another unique feature of the California regulation, the law enacting, the Radiation Control Act, makes it a

misdemeanor to violate the law or any regulations promulgated thereunder. So, in theory at least, every single violation can be a criminal violation as well as a civil cause of action. So, from that standpoint, yes, we do go in quite often.

What we have here, though -- and those we pretty much handle and get the information that we need. What we don't have are really trained legal investigators, people who are used to taking depositions and that sort of thing. We felt that this was a serious enough thing, and it was outside the normal regulatory reg violation because we felt that we'd been misled, that we asked for assistance from you all to help is with -- to make sure that we didn't mess it up, essentially.

COMMISSIONER CURTISS: Okay.

CHAIRMAN SELIN: Thank you. Mr. Fletcher? You guys aren't sitting in alphabetical order, very confusing.

MR. FLETCHER: Mr. Chairman, good afternoon, members of the Commission. My name is Roland Fletcher. I'm the Administrator of the Radiological Health Program in Maryland. Maryland became an Agreement State in 1971. We currently have 521 licenses in effect. We also regulate x-ray machines. We have 4400 x-ray facilities. It comes to about 13,000 x-ray tubes.

We also do other things with a staff of just a

little under -- just a little over 30. But the reason that I'm here this afternoon is to go over the incident that occurred at Sacred Heart Hospital back in 1978 -- actually, it happened over the period September, 1987, to October, 1988. During that period, 33 of 39 patients being treated for intercranial lesions -- and let me note here that all of these patients, all 39, had been diagnosed as terminally ill -- they received fractional radiation doses that were 75 percent excessive to the doses prescribed. Now, why did this happen?

The cause has been found to have been the fact that in March, 1987, a cobalt-60 source exchange occurred at the hospital. The new source was 7645 curies. That was what it was recorded assayed on March 29th. And all of the computer files for the use of this new source were updated save one, and that was the file regarding the use of tremors. And the reason that file was not updated was because the radiotherapist insisted that the health physicist who was installing the new program did not have to update that file, it was never used, and as a result that file was not updated to reflect the new source, the new concentration. So, the file retained information that was pertinent to the old source rather than the new.

Upon the request of therapy technicians of Sacred Heart Hospital to their consultant, Mid Atlantic

Radiation Services, and their concern for the 33 patients, a complete review was conducted by the consultant, which uncovered the patient overexposures. Confirmation was made on October the 26th, 1988. It was at that time that we were notified by Sacred Heart's vice president the next day, of the 33 patient overexposures. He added that all of the cobalt-60 schedule treatments had been suspended pending an ongoing investigation. Notification of all attending physicians and families were being carried out according to the vice president's information.

Now, let me point out here, as is the case in almost every misadministration situation, what we had to respond to was the fact of the report of the misadministration, not the misadministration itself, the time period of the reporting. The reporting was not done in accordance with the regulations, and that is a limitation, but we did respond promptly with investigation of the entire situation, and found that the physician, the radiotherapist, had actually been using the program using tremor bars that had not been updated, and that's why the actual dose being given was excessive.

Of course, we recognized that this was a very serious incident and notified, you know, all of those on our staff, and conducted a very thorough investigation which lasted quite a bit of time. We wanted to make sure

that the hospital followed through. We did not feel qualified to follow through in medical diagnosis, or medical prognosis, medical treatment, but we wanted to make sure that the hospital, and the hospital did assure us repeatedly that the attending physicians were notified, and the attending physicians were to therefor notify families. But that was the level of follow through that we followed. Our concern was to ensure that the hospital itself corrected the situation and put rules in place to ensure that it didn't happen again.

CHAIRMAN SELIN: But did, in fact, this information get transmitted to the attending physicians and to the patients?

MR. FLETCHER: That's what we were told. We did not personally check to make sure it happened, but the hospital administrator said that it did.

CHAIRMAN SELIN: Do you know today whether this happened or not? There was something in the paperwork that suggested that this information wasn't transmitted for confidentiality purposes, or some other reason.

MR. FLETCHER: No. The information that was reported in the paper -- the information we have is that the attending physicians did tell the families, but we didn't personally check to find out if that happened.

CHAIRMAN SELIN: Do your rules require that the

patients or the families be told?

MR. FLETCHER: No, not by us.

CHAIRMAN SELIN: Are your rules silent on whether the patient has to be informed, or do they require that the patient be informed by the hospital? What's the status of your rule on informing the patient?

MR. FLETCHER: I think our rules are silent on whether or not the actual families have to be informed.

COMMISSIONER CURTISS: If, and when, you come into compatibility with Part 35, your rules will have to do that.

MR. FLETCHER: Yes.

COMMISSIONER CURTISS: So, if you're not compatible now, Part 35 requires you to do that. Whether they did before, I don't know.

MR. FLETCHER: Right. We're in the process of --

MR. TRUMP: This is Carl Trump, of the State of Maryland. Our regulations do require that families of those suffering or recurring misadministrations are notified. That question was repeatedly asked of the administration, and we had the assurance of the administration on all occasions that the attending physicians of those patients being treated for those type of brain tumors were notified, even to the point where two

attending physicians were out of town at one point. They pressured the physicians upon return to the hospital, to notify those families. So, yes, they were, but we do not exactly go to those families themselves and ask the next of kin or the families or friends per se, if they had been notified by the attending physician.

(Whereupon, Chairman Selin left the Commission meeting room.)

COMMISSIONER ROGERS: Just continue.

MR. FLETCHER: Okay. We continued the investigation. It was initiated on October 28th. In order to ensure that we had a complete evaluation of the patients, we brought in a medical oncologist as a consultant, to review the patient records. We also brought in a medical physicist to examine the program that had been put on the treatment program, to verify that that was actually the cause of the misadministrations.

We went through the hospital procedure as far as the Radiation Safety Committee programs were concerned. The hospital was very willing and cooperative to do everything they needed to do to correct the situation. As I said, we worked on this investigation for almost a year. The hospital's action, they terminated the radiotherapist responsible for the misadministrations. They hired a new oncologist. And they hired the Mid Atlantic Radiation

Services as a weekly consultant.

As a result of this event, we produced a letter on September 8th, 1988, to Sacred Heart Hospital, seeking corrective actions and pursuit of a $15,000 civil penalty, and recovery of $2,000 paid to the consultants.

On a request from the hospital and in consultation and advice with the Attorney General's Office and the MD staff at that time, we reached a consent agreement with the hospital in November of 1989. The settlement -- we accepted a settlement of $7500 against the penalty and, of course, the $2,000 recovery that we had previously sought. In the consent agreement, we had stated, or we had agreed that we would not -- would actively seek to release the information regarding this event, in protection of the families that had been involved.

In late spring of this year, late May, we were contacted by the Cleveland Plain Dealer regarding the situation that had occurred at Sacred Heart in 1988. In consultation at that time, we provided them with a summary of the events, but we also provided them with a copy of the consent agreement which, at that time, we were still recognizing.

We examined the request. We examined the file. We looked to see how we could meet the request from the

Cleveland Plain Dealer and, at the same time, protect those families, and we came to the conclusion that that could be done. We would just protect the families named, and that was the decision that we made in late 1992, and we released that information.

COMMISSIONER ROGERS: All right. Shall we move on to Mr. Lacker, please?

MR. LACKER: Thank you. Mr. Chairman and members of the Committee, my name is David Lacker. I have with me Richard Ratliff, who is the Director of our Division of Compliance and Inspection.

It's interesting, January the 10th of this year was the 30th anniversary of our signing an agreement with the Commission, and March the 1st of this year will be the 30th anniversary of the effective date of that agreement, and I've been there all that time -- (laughter) -- which may be indicative of something, I'm not sure.

(Laughter.)

But we do appreciate the opportunity to meet with you and discuss these issues.

I would like to just make one brief comment to some discussions earlier when the three Organization of Agreement States people were up here and talking about how penalties could be adjusted.

While our administrative penalties rules don't

say that we can direct that they put money into a certain aspect, we propose a penalty for violations, then our Office of General Counsel can negotiate what those penalties will be. And on one occasion, we had in an industrial setting required that in lieu of money given to the state, they spend certain money on their radiation safety program. So, that's the flexibility we have, just as an item of interest.

I was asked to briefly talk about two misadministrations that occurred in Texas, West Houston Medical Center. The Plain Dealer article is essentially correct in everything it says about that. The event was a patient was given a 30 millicurie instead of 30 microcurie Iodine 131 dose. The technologist who normally worked in the nuclear medicine department wasn't there, and a back-up technologist had received appropriate training in nuclear medicine, and was presumed capable of doing her job.

When the doctor order the thyroid scan, the technologist ordered 30 millicuries from a nuclear pharmacy rather than 30 microcuries, and did not recognize the error, although there was a delay in getting the dose to the hospital when the pharmacy explained that it had to be postponed because they couldn't change the delivery on the day it had originally been requested.

When the dose arrived, the technologist placed it on a dose calibrator, was perplexed by the high rate count, and commented to the physician, and he didn't really recognize the problem, and they went ahead and did it, did the examination. The patient was given the capsule, to go home, take the 30 millicurie dose, which should have been 30 microcuries, and then return the next day for the scan.

Actually, after the dose was given, the technologist later on in the day called to order for the next day, and ordered 30 microcuries as appropriate for the scan, the next scan, and was told that it would be there the next -- be delivered right away, and she wondered why. The pharmacist said, well, because the other order was for 30 millicuries, not -- this is 30 microcuries. The technologist did recognize she had made a mistake. She notified another physician on the hospital staff, and that physician consulted with the patient's physician and called her back to the hospital and administered a blocking agent, but it was 12 hours after and it was a little bit late to do much good.

Estimates were that the thyroid received approximately 30,000 rads. That was estimated by the hospital. Our calculations estimated approximately 34,000 rads, which is well within normal range or difference for

that kind of a dose. The hospital is performing follow-up on the patient. We have not heard recently on the status of that patient. We will be checking as a result of this, to find out what the hospital has done.

We did not issue any penalties to the hospital because of this particular incident. They had had a good compliance history. They had not had any significant noncompliance -- I think two or three minor items of noncompliance over a four-year period. They agreed to change their procedures to prevent this kind of thing from happening in the future, and that's the status of that.

I was also asked to talk about one that doesn't deal with byproduct material, but deals with an accelerator incident at East Texas Cancer Center --

COMMISSIONER de PLANQUE: Before you go on to the next one, Texas has a credentialing program for technologists, is that correct?

MR. LACKER: Yes, it's not run by our bureau, though.

COMMISSIONER de PLANQUE: Okay.

MR. LACKER: It's run in a separate --

COMMISSIONER de PLANQUE: Was this technologist credentialed?

MR. LACKER: At the time, this -- I don't believe the technology credentialing law was in place.

COMMISSIONER de PLANQUE: At that time.

MR. LACKER: I think it was put in in '87.

COMMISSIONER de PLANQUE: And was there any action taken at all with regard to the technologist?

MR. LACKER: She is no longer at the hospital. I don't know whether she resigned or was discharged, but we didn't take any action as an agency. The East Texas Cancer Center at Tyler operated a Thayerac 25 accelerator, and it is computer operated, and we received a report of this overexposure, or misadministration, on April the 8th of 1986, and we did not have a reporting rule in place. The licensee voluntarily reported it. And we felt like we had pretty good reporting even before the rule was in place, on these kinds of things.

A patient was being treated on the right side of his face with the accelerator. The operator pressed the treatment button, the machine shut down and indicated malfunction 54 on the screen. The operator went into the room, and the patient was struggling to get up. He complained of a sharp pain in his ear and a warm sensation. He said he saw a flash of light. Later he suffered from nausea and vomiting. The physicist went on to report that another incident had occurred on March the 21st to another patient who was receiving a treatment in the scapular area. The machine had shut off automatically

before the treatment was complete, displaying malfunction 24. Again, the patient reported that he felt a burning sensation and was trying to get off the table. The patient actually got off the table and was in the entrance to the treatment room when the operator reset and tried to initiate another treatment.

During our investigation, we discovered that at the time of the first incident, the intercom to the treatment room wasn't working and the television monitor was not plugged in. There were two technologists working with the machine at the time of treatment, and through some miscommunication neither of them had hooked up the TV monitor.

The physicist reported that after the first incident, he requested that the manufacturer look into the problem. The manufacturer's representative could not recreate the malfunction 54, and found no problem with the accelerator. An electrical engineering firm was called to look into the possibility of an electrical shock, but found no electrical problems.

After the second incident, the physicist was successful in recreating the incident. Both patients had been scheduled for electron therapy. The operator incorrectly entered proton therapy, which automatically set the energy at 25 MEV. After the prescription was

entered, the computer verified the treatment parameters. The operator, in making the corrections, did so before verification was complete, resulting in the machine being partially set for x-ray therapy and partially set for electron therapy.

Both patients received an unmodified electron beam with an energy of 25 MEV. Both developed skin lesions to the treated areas. The first patient complained of partial paralysis of the left arm and leg, and currently -- this is at the time of this report -- exhibited signs of Horner Syndrome. Both patients have subsequently died. The second patient died of a grand mall seizure. An autopsy was performed, but the report we didn't have, and I have not seen that report yet.

We immediately reported the incident to the Food and Drug Administration, since this was a medical device, and they regulate medical devices. And the one thing I want to comment about was that there was an indication in The Plain Dealer article that there was some time before FDA made corrections, but that wasn't exactly true. While the new procedures were finalized and the corrections were made to software sometime later, all of the people who owned these types of machines in this country were notified of these incidents -- there was also one in Washington, I believe -- and were given some procedures to

follow to be sure that it didn't happen, at least orally. So, they were working on getting the issue corrected all that time.

Again, we issued a notice of violation citing the facility for not maintaining visual contact which was a requirement of their license, during the treatments, again, based on their compliance history, and this was basically a software problem with the computer. We did not issue any civil penalties or administrative penalties. That concludes my report.

COMMISSIONER CURTISS: Do you have civil penalty authority?

MR. LACKER: We have what we call administrative penalty authority, which is $10,000 per day per violation, max. That is graduated down under the terms of the law -- it's a complex procedure -- where you give credits and faults. You can increase or decrease based on certain factors -- bad compliance history or good compliance history and those sorts of things.

We have civil penalties through the courts, which is the way it's stated in Texas statute. That is up to $25,000 per day per violation, and then we have criminal penalties also.

COMMISSIONER CURTISS: Can you tell me just off the top of your head, let's say over the past five or ten

years, how many administrative penalties you have issued?

MR. LACKER: Just happen to -- (laughter) -- 29 administrative penalties, two criminal penalties, and 32 civil actions.

COMMISSIONER CURTISS: And the time frame for that is?

MR. LACKER: That's -- what is it, Richard?

MR. RATLIFF: This is Richard Ratliff. That's going to be from about 1987 through current time period.

COMMISSIONER CURTISS: Okay. Do you have a dollar amount on the administrative penalties?

MR. LACKER: No. I think it -- I don't have that data with me, unless Richard just recalls it.

MR. RATLIFF: I can address that if you'd like.

COMMISSIONER CURTISS: Would you, please?

MR. RATLIFF: On the administrative penalties, they go from a low of $500 to a high of -- let me get the right number here -- $625,000. The large one was for a waste processor who was not following procedures and we had multiple problems. This is a variety of industrial, primarily the radiographers, waste licensees, and then the medical that we have are primarily x-ray registrants -- dentists, chiropractors, veterinarians. On the administrative penalties, the low is from $500 and the high is up to $83,000. The $83,000 was a radiography

penalty, but we mitigated a $16,500 cash penalty, and then required the company each year for three following years, to put money into additional safety beyond what was required by the regulations.

What's not noted in here, though, we had four what we called "death" penalties in that we revoked licenses, which we felt was the ultimate because then they went out of business.

COMMISSIONER CURTISS: I have some other questions.

COMMISSIONER ROGERS: Please go right ahead.

COMMISSIONER CURTISS: Actually, the questions that I have are fairly limited, but I'd like to address them to the group as a whole, and ask each of you if you could address these questions.

First, could you tell me what your authorized staffing level currently is, and whether you are up to your authorized staffing level with your programs? Secondly, if you know what your attrition rate currently is, I'd be interested in knowing that. And then, third, with respect to each of these incidents that you've talked about, I guess I'd be interested in knowing for a period of time leading up to the incident, whether the scheduled inspections that you had under your program had been conducted in accordance with the schedule called for, and

we can go in whatever order you'd like.

MR. LACKER: Since I was last first, I'll be first last.

(Laughter.)

Staffing in Texas, we have 141 authorized positions. We have about six or seven vacancies, I don't know the exact number. We've been pretty fortunate in being able to keep most of our positions filled 'til now.

With regard to -- would you repeat the second --

COMMISSIONER CURTISS: Attrition rate.

MR. LACKER: Attrition rate is not very high, as you can see. We've had -- (laughter) -- we're fortunate in that people like --

COMMISSIONER CURTISS: Present company excluded.

MR. LACKER: Well, yeah. We have had turnover, obviously, but it's probably around 7 percent per year average, over the last -- since 1981 when we grew from a baby to an adult program. The second question.

COMMISSIONER CURTISS: The third question was, for the two events that you talked about, were the inspections that were scheduled under your program to normally be conducted, done, undertaken?

MR. LACKER: They were current at the time, yeah.

COMMISSIONER CURTISS: They were current. Okay.

MR. BAILEY: California has something in the neighborhood of 100 authorized positions through both my branch and the counties we contract with for staff. We, at the present time, have approximately 25 vacancies, and have had for the -- essentially all of this year.

COMMISSIONER CURTISS: One-fourth of your positions are currently unfilled?

MR. BAILEY: Actually, I think that the number within our department is like 30 percent of the ones within Department of Health Services. The counties have been a little more fortunate. The California budget situation has been devastating to everyone. As of July of this year, we will go in a special fund where our fees actually pay for our program, where we actually take in the money and spend the money directly on our program.

The attrition rate really hasn't been very high except in two areas. One is other programs funded by federal dollars that people go into because those programs can hire people and we can't, under hiring freezes because we are presently in the general fund. The other area is in the area of clerical support and, because of the projected layoffs and stuff within the State of California, it has been very difficult within the Department of Health Services, which is one of the agencies slated for the largest cuts percentagewise, for

anyone to come to work there because of the union situation where the last one in is the first one out if there's a cut in hiring. So, those two things have really impacted us.

Both of the licensees that we talked about in our situation had been inspected proper interval and were current. I would like to mention one thing about the university that was mentioned earlier. The fellowships were actually administered by the university.

COMMISSIONER REMICK: Was it part of a consent agreement?

MR. BAILEY: It was part of a consent agreement. That one was one that almost got out of control. There was -- I don't know -- it was a 180-something count indictment, criminal indictment, which named professors and so forth. And then later on after there was a settlement, there was a truck driver who was stopped, and the DA in the county wanted to make sure that that truck driver went to jail, he wanted somebody in jail. And, so, that got real nasty before it got all settled.

One of the ones which I think we've just gotten this pst month, which is sort of unique, is a technologist who committed what we call a misadministration but you all wouldn't, that he used a dirty needle, and HIV needle on a non-HIV patient, got a suspension of their certification

for one year, with a three-year probation, 45 days actual suspension, required to attend infectious disease control courses, and refresher nuclear medicine courses, and required to report to us quarterly.

One advantage we have being in the health department is when we get into these medical issues, we have doctors in our hierarchy who can act as witnesses, as we had in this particular case. We also are seeing a great deal of support in pursuing the Alta Bates thing from the medical community itself.

MR. GODWIN: Well, we have a small program in Arizona. We have 20 authorized positions. We are currently negotiating with the legislature to up to 1.4 FTE because -- well, the governor's office does not believe they can appropriate FTEs and they want to, and they've taken our vacancy rate, is what they are basically doing.

We have a 26 percent attrition rate.

COMMISSIONER CURTISS: You are up at your authorized level?

MR. GODWIN: I believe I have one slot left, but I'm not funded for it yet.

COMMISSIONER CURTISS: Okay.

MR. GODWIN: Okay? We have a 36 percent attrition rate --

COMMISSIONER ROGERS: Per year?

MR. GODWIN: This year. That's because we had a 24 percent reduction in staff over the last two years. And that's the latest figures out of the personnel group. It's actually changed a little bit in the last two or three months since I've been there, but up until, say, through September, that's what it was. The state has a budget problem. The materials programs does not pay all of their way in Arizona, nor is it appropriated into a separate fund. It's part of the general fund appropriation. So, we must go through the legislature and to the governor's office, budget office, as does every executive agency, and make our case. And in all honesty, being candid across the country -- and I'm going to sort of switch hats and talk about as a Conference of Radiation Control Program Directors, chairmen, across the country, state radiation control agencies have a problem in that they are just not very visible. If you do your job, you don't get any problems, you don't get any money.

There are several states -- I say several -- some states, the governor's office or the health office or whichever, has elected to do away with the radiation programs, and that's occurring in states -- there's consideration being made today. Montana is one state where that's being considered. So, you know, we just have

to face things are real thin, so when you go in as a part of your review, you're going to have to overcome a set philosophy that says we're going to reduce the size of state government, we're going to reduce spending, we don't have the money, and show that this particular program is meaningful and cost-effective for the state to be a part of it. And you've got to go to the top officials, I mean to the governor himself. You've got to go to the legislature, the chairmen of the various committees, the Speaker of the House, President of the Senate, those kind of things. It's a very tough sell thing.

At the time of these events, we were up-to-date on our inspection schedule, and they were approximately on time. I believe at that time there was a two-year interval for those inspections. I think the teletherapy has switched to one year since then. I may be wrong on that, but they were up-to-date the best we know.

MR. FLETCHER: In Maryland, authorized staffing, as best I can calculate, we have 19 professional staff and four clerical staff. Now, I say it that way because as you -- you know, being here in Maryland, we are also under some very tight funding constraints, and what happens is if any of our positions become vacant, at least thus far, they are not filled. So, even though our authorized -- what we have onboard right now is 19, however, a few --

you know, 12 or 13 months ago, that number would have been 21. So, our authorized level adjusts as the needs of the budget dictate.

COMMISSIONER CURTISS: As your actual employees attrit, I guess, your authorized level goes down.

MR. FLETCHER: Right. Yes. Currently, that's the way it happens. We have added to that what we call our contractual employees. We have three technical and one clerical there. As far as attrition is concerned, we've lost three people over the last 12 months, and the problem is that the pool isn't very deep. Even if we were permitted to go out and replace some of these people, they are just not out there. And the salaries that most of us, most states can offer, just aren't attracting a lot of people to go into the field. So, as far as our scheduled inspections at the time of this event, I'm going to have to ask Carl to address that.

MR. TRUMP: The particular hospital, Sacred Heart, was inspected by myself only less than two years before, and at that time our inspection frequency for hospital programs was about four years. So, that really wasn't due to be inspected again for perhaps a year or year and a half later.

COMMISSIONER CURTISS: Okay. Thank you. That's all I have.

MR. GODWIN: If I could add just one more comment. Regarding salaries, the typical way that state personnel groups work both in Alabama and it seems to be the same thing in Arizona and talking to the states in the southeast, virtually every one of them operated this way, they compare salaries state-to-state and, in Alabama's case, they specifically stated, they would not try to match federal salaries. I mean, you could bring in all the federal salaries you want, but they absolutely would not consider in doing the averaging to try to figure things out. As a result, your states are comparing their salaries, but we aren't losing people from state-to-state for the most part. There are a few that shift like I did, from Alabama to Arizona, but in most cases, people are going either to federal government, DOE, in some cases yourselves, or to private industry. So, if you don't do your salary comparison with the private industry where people are going, you never have an opportunity to do anything other than serve as a great training course. And you all train a lot of folks for various things.

COMMISSIONER CURTISS: Yes.

MR. GODWIN: And it's very difficult to convince the legislature that it takes a year to train a good health physicist, and that that's money that you've just lost.

COMMISSIONER REMICK: I'd like to take advantage of the fact that you represent agencies in four states plus experience in a fifth state, and ask a couple of questions, and I'll try to be brief by telling what my assumption is and you tell me if I'm wrong.

My first assumption is that in all five cases, you have follow-up inspections or investigations of therapeutic misadministrations. Is that a correct assumption?

MR. GODWIN: Yes.

MR. BAILEY: Yes.

MR. FLETCHER: Yes.

COMMISSIONER REMICK: I will assume that you do not, as an agency, follow up on individual patients from a medical standpoint, from an agency standpoint, am I correct in that assumption?

MR. GODWIN: Yes.

MR. BAILEY: Sort of. In one of our recent therapy misadministrations -- we've had eight since the rule went into effect -- we did require that a follow-up plan be developed for the patient.

COMMISSIONER REMICK: But you did not, as an agency, you required the licensee --

MR. BAILEY: We did not develop that plan. We required that a consultant physician be hired to do that.

COMMISSIONER REMICK: Okay.

MR. GODWIN: In the case where it's not a misadministration but where you have someone, if you would, injured on the job like an industrial radiography where they may need to have some medical follow-up, we may follow it long enough to assure that our licensee or registrant -- this is certainly true in Alabama -- would carry through and get the individual offered care that they needed. To me, it would seem like we have an obligation to use our medical consultant's capabilities, whatever you say, to identify the ones who are injured and make sure there is a care opportunity for them. It's long-term information, so it's everybody's ballgame right now.

(Whereupon, Chairman Selin returned to the Commission meeting room.)

MR. FLETCHER: Please, if I may, sometimes incidents that we are talking about here serve as lessons learned in some cases, and more recently we have followed up on -- once again it was not a patient, but it was an individual who was overexposed to an accelerator, and we have followed up on that individual. We've gotten cooperation of the doctor to keep us informed of how that has gone. But, once again, this is --

COMMISSIONER REMICK: You're not paying the

doctor, though.

MR. FLETCHER: No, we're not paying the doctor. We're just following up to see how his condition progresses.

COMMISSIONER REMICK: One final question, The Plain Dealer, if I recall, there's an allegation that the Agreement States and the NRC do not share information. To what extent do you believe that is true and, if it is true, do you have any suggestions on how that situation might be improved?

MR. GODWIN: Overall, I feel that the NRC staff does a better job of sharing information than some other agencies, frankly. I think that the thing that confuses the public is the fact that there are several different federal agencies involved in the overall radiation mix.

FDA does a great job of working with the state in which an incident is reported, and they get the information and they work pretty well getting it out through the profession, working through the manufacturers and things like that, but sometimes just due to their system -- and I don't want to try to throw any stones at them -- the other states may not hear about it until several months after the event, which is sometimes a bit of a problem. But for most things, NRC is pretty good on. I mean, we all have our problems from time to time, but I

think most often they do pretty good. In some cases, too much, frankly.

(Laughter.)

MR. FLETCHER: I was about to say, you know, we sometimes get stacks and stacks and thick documents from the NRC on certain things. And we understand that you don't know what part of it might be to our use, so you give us the whole thing and let us sort through it, and we understand that.

There was at one time concern that some of the more high priority press releases and announcements that come from the NRC, sometimes the states weren't given enough notice to be prepared for the fallout from those. That situation also has improved, and I just encourage the NRC to keep on giving us the notice, because ofttimes our phone starts ringing before our fax starts working.

COMMISSIONER REMICK: Any differences or an agreement?

MR. BAILEY: I think the only comment that I -- or the thing that I notice that there was some complaint about really was in specific names, and I think we don't generally put an individual's name in something, and that may be a shortcoming particularly where you have an incident that you decide someone caused. And I understand the sensitivity of putting the name in. And, so, in a lot

of cases, unless you actually issue an order, that name never appears, and so we don't know who it is, and I think that was one of the things --

MR. LACKER: Yeah. This is one of the real problems we see, is that identifying individuals. You are obviously going to be in a tort situation once that individual knows what's happened. You require that person to be notified, or his family, his or her family. It gets a little sticky when you make those names available in the public domain, under those circumstances, or potentially. Our legal counsel generally says be very careful what you do and let go.

COMMISSIONER REMICK: Thank you very much. It's been a very, very help presentation.

MR. LACKER: Thank you all very much. We appreciate your time.

CHAIRMAN SELIN: We're not done yet.

COMMISSIONER de PLANQUE: We're not done yet. Well done.

(Laughter.)

CHAIRMAN SELIN: I'm sure you'll still appreciate the time.

COMMISSIONER de PLANQUE: We just touched on the subject of having multiple regulatory bodies and boards all connected in some way or another in the medical field.

Is this posing a problem for you and, if it is, do you have any recommendations as to what should be done with the problem of dealing with multiple bodies?

MR. LACKER: I think this goes to a subject that was mentioned about the nonbyproduct -- reactor byproduct materials regulation. I think the Conference of Radiation Control Directors and the Agreement States in general have sort of pestered the NRC for years, to get involved in those things -- not the electronic radiation devices, but the radioactive materials type -- NORM and NARM and whatever else acronyms there are.

We do have a problem in some areas between the relationships with EPA and NRC. We have some problems in the relationships between perhaps FDA and NRC and EPA, and then on down the alphabet soup. There are some, but generally those are not, in my opinion, insurmountable situations.

I think what we really need, though, is one lead agency at the federal level, who can set standards across-the-board for radioactivity, and then we can all trail along and be on the same wavelength on those kinds of things. Obviously, I don't think it would be appropriate for the NRC to be in the electronic x-ray end of the thing, but I certainly think that it would be appropriate for you to look at whether or not your should regulate

these high energy accelerators.

COMMISSIONER de PLANQUE: Yes.

MR. GODWIN: On the high energy accelerators, you have a semi-entre because a lot of them have depleted uranium as shielding. Now, whether our friend the General Counsel down there would be happy with you extending the radiation from the electronic part as being the overall -- radiation from the use of the product would be, I guess, a different issue -- but there is a difference between the high energy accelerators and how you need to approach their evaluation, and x-ray equipment.

COMMISSIONER de PLANQUE: Yes.

MR. GODWIN: In Alabama, we handledd it as a part of our materials program because we really saw the need to have it in that high energy range, but even then there was a lot of little quirks to it, but that would be one area that could be of some interest.

Now, FDA does have some general manufacturing requirements, but they do not look any at all at the user end of it. And it's just very short on training out there.

If I might just digress a second, I understand that 36 percent now was the overall program -- the attrition rate that I mentioned -- it was probably on the order of 5 to 8 percent in the materials program because

we kept feeding people over into the materials program to keep it up. What we got behind was the regulations, and that's where we used to rent out people to do the regulation work up.

MR. BAILEY: I make a comment about the accelerators, if I may. I don't remember -- I've got it written in pencil here. When we went through, we found that there are about ten times as many therapy accelerators as there are teletherapy units in California, and I think that is a fairly good ratio when you look at the number of facilities with materials licenses versus the number of facilities with x-ray equipment. Over the years, in my experience, it's been about 10-to-1 the number of facilities.

I was really quite surprised that there wasn't a smaller number of teletherapy units, quite frankly. I understand -- I talked to your Region V, and you all only have one teletherapy licensee left in Region V. So, I think most of the people that you have in teletherapy will be going to accelerators.

COMMISSIONER de PLANQUE: Okay.

CHAIRMAN SELIN: Just about that, could you follow up a little, why do they go to accelerators? Are they better devices, or are they more generously regulated?

(Laughter.)

MR. BAILEY: Well, let me start, number one, there's no fee associated with accelerator, to speak of. Number two, there's no regulation to speak of in many -- certainly, not in federal facilities, or very little. And number three, I think there are some definite advantages in using accelerators for therapy. They are a more versatile instrument.

MR. GODWIN: Higher dose output is a big one.

MR. BAILEY: Yeah, higher dose output, varying energies, varying modalities of treatment, electrons or x-ray beams. So, there are definitely some real reasons to go to accelerators.

COMMISSIONER de PLANQUE: I'd also like to ask you the same question I asked the earlier panel, and that is on credentialing. In your state, you have a mixed bag of credential programs. Do you see any connection between that and potential for misadministrations? Can you prove a connection that would give some value to these credentialing programs?

MR. BAILEY: I would say that in our case we may never be able to separate them out because our credentialing program went in about the same time the nuclear medicine reporting went in. I think intuitively we all feel the better someone is trained, the more likely

they are to make a stupid -- or --

COMMISSIONER de PLANQUE: The less likely they are.

(Laughter.)

MR. BAILEY: Yeah.

COMMISSIONER de PLANQUE: It's getting late.

MR. BAILEY: One of the premises is, if you know how to do it right, you're more apt to do it right than if you don't know how to do it right and just luck into doing it right.

MR. FLETCHER: Our experience, of course, in this particular situation was with the physician, the radiotherapist. The physicist in this instance, did not feel enough -- that they had enough authority to correct the radiotherapist. So, I don't think, at least in this instance, it was a problem with the nuclear medicine person. We do have credentialing, but the credentialing in Maryland is under the Health Department rather than under the Department of Environment, and there is still, in many cases, some debate about grandfathering and et cetera that have not totally been resolved. I think it will at least give us a higher level of reassurance, if you will, that the persons who are working in these programs are better qualified.

MR. GODWIN: Well, I'm going to start with

Alabama experience. Alabama did not have credentialing. I don't know that our misadministration rate was particularly any different, so I'm not sure that credentialing is the key. However, while I was there we often thought about and seriously considered listing as part of the people named on the license, the technicians, because we kept seeing a lot of operation, particularly in the diagnostic area, and although the individual doses are fairly low, if you get a lot of them, you spread that same effect out some -- it shows up some.

These people are -- a lot of times are working fairly alone. We had a lot of circuit-riding radiologists in nuclear medicine, people in Alabama, and your university types don't understand the problems they run into. They will talk to and get the information they need to select a patient and prescribe the dose and then come around and interpret it later, but they don't -- they're not right there. They are doing these things by phone. They are talking to the referring physicians by phone. They are looking at the records today and they are doing the injections tomorrow. The technician represents a rather important piece of the picture in nuclear medicine, and even in your teletherapy work, most oncology groups in Alabama, the radiologist would come in and, for the first treatment or two, set things up, make sure everything was

going right, but there may be several treatments where it's strictly up to the therapy technician. So, you do have some need, I think, to have that individual closely involved, particularly if you're going to depend upon the records, that you're later going to see some misadministration. If you have that licensed individual somewhere where you can take away their benefit or some material thing from them, they'll have better interest in keeping those records right.

So, I think there is some consideration can be given to that. I'm not sure we ought to make a push on it, but it certainly ought to be something to think about.

In Arizona now, switching hats again, we do have a credentialing program, and the technicians do have licenses, and we do have some way to come back. We haven't seen any need to go back, and the numbers are so small that you'd be looking at only a small number of situations that I don't think you can draw any conclusions out of yet.

MR. LACKER: In our case, the radiologic technology certification, I don't know that there's a correlation that we could make there. The medical radiation physicist licensing law just actually became effective the first of this year, so we don't have anything. I think the potential is much better that we'll

have better qualified people making these decisions in the hospitals than we have in the past, with the certification program. It's not run by our bureau, but it's within the Department of Health.

COMMISSIONER de PLANQUE: I have just one last question, I'd appreciate your comments. With all the attention being paid to some of these cases in the past, are there any particular lessons learned that you'd like to share with us, or any comments that you'd like to make, having gone through this exercise?

MR. FLETCHER: Well, you're looking in my direction, so I'm going to start. The answer to your question is yes, we still feel that protection of patient records and patient names, et cetera, should be maintained, and our law, I think, supports us in that. But we were under a different advisory position then. In fact, we were under, for the majority, different staff all the way through the department. And the conclusion that was come to in 1988, I'm relatively sure would not be the conclusion that we'd come to in 1993, even though the process of coming to the conclusion would be the same. So, there is a lesson learned there, and we do learn well.

MR. GODWIN: Well, I think that the same conclusion can be drawn from any incidence that you investigate. You always end up looking back and saying,

"Gee, I wish I'd documented better. I wish I'd taken a little more time to assess that". You always run into that kind of second-guessing.

I think the use of your medical consultant, when to call them in, is a very critical thing. You really need to clearly define what you're going to use them for, and I sort of outlined what I would look at.

In Alabama, we did on occasion use some of our medical advisory committee as our medical consultant, and what we would try to do is scope out the injuries and then make sure that there was a care opportunity for anyone who was injured.

We did not go into the epidemiological or long-term follow-up. I'm not sure where that should be other than maybe CDC or something like that. That may be a better place for it because -- I'd want to be very careful we didn't end up like the syphilis study where they ended up doing a long-term study and some portions of it were denied treatment so they could just see the effects. And I would certainly hesitate to have anything like that created.

Of course, we all know that there are cancer registries and there are other registries. I believe DOE has some registries that are established, but they are all related to occupational workers, so I'm not sure how this

would work in the general public.

MR. LACKER: From my point of view, I think the key lesson we've learned from this most recent exercise is that we need to do what we're doing with the working groups that are established, and that is get our data-gathering uniform so that we can make sense out of the data we gather, and not have all this different information floating around that when you try to put it together it's apples and oranges.

MR. BAILEY: I think one thing that's come out of this and some recent incidents that we've investigated is really the need for, from my standpoint, trained investigators in some of these, who are trained maybe not even in health physics, but are trained in doing investigations and taking statements.

The technician that I mentioned, in retrospect, if we'd done a real thorough investigation there, there would have probably been some rather severe penalties against the hospital. But the hearings officer said, you know, it was an accident waiting to happen, the way the hospital was running their program. So, I think that's the main thing that's come out of the series with us, that we do need trained investigative skills.

COMMISSIONER de PLANQUE: Okay. That's all I have. Thank you very much.

CHAIRMAN SELIN: Commissioner Rogers?

COMMISSIONER ROGERS: Yes. I was a little concerned about, I think it was the comment you made, Mr. Bailey, about the independence of the oncology departments in some hospitals from their nuclear medicine groups. They are both under the same radiation safety officer, aren't they, in the hospitals? They really have -- they are obligated, and should be obligated, to follow the same procedures and guidelines and reporting rules. How common do you think that is?

MR. BAILEY: I don't know. It may be that we just had a couple of them occur very recently, you know, and when we looked at the oncology group, they basically came in and practiced oncology, and they had their sources and, yes, the RSO may lead test them and that sort of thing. The RSO might provide the film badges, but basically they do their own thing.

An example is that the oncologist would end up ordering the iridium seeds, for instance, and the oncology group essentially handles the shipping back of those to the supplier. And then when they turn up missing, the RSO says, "Well, hey, nobody told me about it". So, I think we may find, if we look -- it's one of those things, you're almost afraid to look for fear of what you would find. That's my feeling right now, that we really need to

look and see who these groups report to. If they are separate companies coming in, separate medical groups, then I see a real potential for miscommunication. And I think Aubrey here mentioned in some of the hospitals he was familiar with, they actually had separate licenses.

MR. GODWIN: There have been occasions. I think that's by far the minority, where there would be separate licenses, to the extent where you might even have a different RSO. But I think that all regulatory programs are discouraging that arrangement. I know of no one that would really -- that would be toward the exception side.

If you look at the case at the Good Samaritan, there was a problem in that the radiation safety committee was meeting without the oncology group. Well, it was meeting without the radiation safety officer, too, as far as that goes. So, you do have situations where the hospital group gets very bureaucratic and compartmentalized --

COMMISSIONER ROGERS: Oh, I know that very well.

MR. GODWIN: Universities are tough on that, too, so you have to --

COMMISSIONER ROGERS: I was associated with a hospital at one time as a trustee, and I know very well about those things. I'm just wondering to what extent some of these difficulties get called to the attention of

either the board of trustees or board of directors if they are a for-profit organization.

It's been my experience that once the trustees of a hospital know about some of these difficulties, they get very, very upset, and the risk management group which may be under the executive director of the hospital, have to worry about some other risks at that point, and I would say that I personally feel that it's very important to get these difficulties called to the very highest attention in the organization, and then that's going to do -- hopefully it will do a lot of good. I think in the instances I've seen, you know, the directors of a hospital, the trustees of a hospital, are public spirited citizens, and they are very concerned about the image of that organization, and its quality. And when they hear about some of these things, they get very upset. And some of the things that your mentioning of the disconnect between the oncology department and the nuclear medicine department, the turf battle over this kind of thing, I think that a board would get very, very upset about that kind of thing. And to what extent they can really stop it is another matter, but I would call attention to the highest levels of the organization when one sniffs out some kind of a disconnect of that sort because it certainly is intolerable.

MR. BAILEY: Well, I think --

MR. GODWIN: It's public spirit --

MR. BAILEY: Excuse me, Aubrey. I think that -- we asked the hospital administration to acknowledge that the radiation safety officer has the authority to stop any procedure, you know, and that's acknowledged in the application, and that sort of thing. However, politically within the realm of the hospital, he may have some limitations. But one thing that I think we could do possibly is lay out more specifically the requirements, training requirements for the radiation safety officer in medical facilities. We have it for industrial radiographers and all these other pretty well laid out, the training they have to meet and all this sort of thing, but we don't really -- we have for the users, the medical training that's necessary, but we really don't have anywhere spelled out clearly what the radiation safety officer training should be. And maybe we need to go even higher than just the administrator with the authority of the radiation safety officer.

MR. GODWIN: It was the routine practice in both Alabama and Arizona that we dealt with the administrator, certainly on the exit interview. He was available, and all correspondence related to compliance went to the administrator. Further, if there was any management oriented problems, we had to have that management level,

it was not just, you know, maybe, or farm it off or something, we had to go into that.

Universities, like I said -- I don't want to harp on them particularly -- but they do have a lot of the institutional restrictions to communications, and they quite often try to cut the radiation safety officer out of certain operations, and we routinely went to the president of the university and told him, "If you want the license, you will stop it". And I can recall two or three conversations with presidents of universities, with their lawyers there, and usually the other party there said, "What's this state agency telling another state agency what to do", but never once did we get legally challenged by the lawyers relative to what we were doing.

MR. BAILEY: One other thing I might mention, we did a study following the HIV case misadministration that we had. I think it was at 20 or 21 hospitals where we went in with the infectious disease control people, and what we found in the majority of those hospitals was a lack of routine infectious disease control in the nuclear medicine departments. It was the nuclear medicine department was sort of aside, the infectious disease control people didn't come in there, and so there were many cases where -- just a simple example where they were recapping the needles instead of putting them in sharps

containers, and risking being punctured with an HIV needle. And a lot of nuclear medicine right now is related to HIV-positive patients.

MR. GODWIN: I would also say you could do a similar operation relative to the boards of pharmacy. In Alabama, we conducted joint investigations with our board of pharmacy on nuclear pharmacy, and both groups ended up finding the pharmacist made a few mistakes. The total fine was about $20,000.

COMMISSIONER ROGERS: And I think also a point that Mr. Bailey made that's come out here from the lessons learned question of Commissioner de Planque, of the necessity for establishing common databases. I personally would really like to urge that the organization, the Agreement State Organization, look very seriously at how it can do that. Yes, you don't have absolute authority over anybody, but I think the point the Chairman made very early on, it's a good way to avoid attention from the NRC, to do things yourself. And I think that I would certainly encourage you to think about ways of developing common databases among all of your members, and to be willing and happy to share those with NRC. I think there are some serious questions as to the credibility of some of the numbers that we have been kicking around, and unless there's some systematic way of developing databases, they

are always going to be challenged. So, I think that -- I know cost is always a factor in these matters, but I think that by thinking of ways to do it that are not necessarily costly but do represent a conscious attention to trying to do things on a common basis, that we will develop nationally a much better sense of where we stand here that I don't think we have today at all. But I thank you very much, I think it was a very informative meeting.

CHAIRMAN SELIN: Yes. First of all, we all want to thank you for coming forward. This can't have been too pleasant to come down on a public meeting and lay out the anatomy of a series of serious misadministrations, but I think we've all learned a lot from this. I hope you also have learned something from this. We thank you for coming forward on this.

I do have a few remarks to make before we cut off. Number one, that it is true that these misadministrations are a very low incident rate, and usually they are in doing therapy, you are dealing with very sick people. So, the question about whether one should undergo the medical procedure or not is really not a relevant question for the patients. Of course they should undergo the procedure. But it doesn't follow that we should then look the other way and say these are tolerably low rates and considering that this is dangerous

medicine and dangerous diseases, that this is a small cost to pay because we are talking about misadministrations, we are talking about mistakes. We are not talking about sometimes you do a treatment and, on a statistical basis, occasionally it will cause more harm than good, that's understood, but this is not the subject of these meetings.

There is clearly room for improvement in the practice of the practitioners, in the practice of the regulators. We all have something to learn.

The second, the number of areas that have come out are bothersome, and I hope Mr. Bernero is taking notes as I go through this list. First, my confidence in the report itself has been shaken somewhat. I had assumed, obviously naively, that all this misadministration data are clearly in the records if you just go to look for it and, therefore, the numbers that we have are probably pretty accurate. And you've had a couple of powerful examples where that's not the case. In Mr. Bailey's case, he had specific questions to ask and he got false answers, and he couldn't go through the records and just say, "Ah, here's some difference". So, just the basic data that we're working with, even if you get down to the roots and not to derive statistics leave one nervous.

The second is the responsibility of the organization question that you've gone through cases over

and over again where nobody is clearly responsible, where the responsibility is shifted between the physicians, the people doing the calculations, the people delivering the medicine.

The third is this whole question of chronic offenders. It seems to come up over and over again that there are chronic offenders, and our mechanism really doesn't catch them and follow them, that we are oriented towards the licensees and not towards the offenders. But if we are going to do the root cause analysis and we find not just lack of training, but specific people who are cavalier or otherwise ill-trained, there has to be a way to follow up on them and do something about that.

The fourth are the organizational problems in the facilities that you've talked about, the role of the RSO or, in particular, the lack of a role of an RSO. We found in the Indiana incident that the RSO really didn't do his job, and nobody checked on it. At other places, the RSO was cut out.

The fifth is this issue of identifying and informing patients of the situation, what's been done to them. Mr. Godwin's point is a very good point. It's not just enough to tell them what the dose is and what's happened, in many cases it's to make sure that this is translated into good medical advice. We can't just assume

that the attending physician knows exactly what to do with this and walk away from the situation.

Another thing is a conflict between what are perceived as legal risks and good regulation, with the tendency of the regulators to step back when a tort case may be involved, or a question of privacy. Health and safety is the first issue, and we need some clear guidelines to not be scared off by the thought that, oh, my, you're going to play into the hands of the tort lawyers. Tort lawyers have plenty of tools, you don't have to worry about giving them an extra tool, they'll do fine with or without us. We need to protect the patients and not worry about the tort impact.

Another is the lack of clear definition of the role of the medical consultants. It's come up in our own investigations. It's come up in your discussions. You've given us some good advice on this point.

A third major area is that we see room for management improvements in how we and how the Agreement States run their programs, not just how the practitioners and the related facilities are run, and that's clearly the main emphasis that we have to put on.

And then the fourth area is to look for comparability. I didn't say compatibility, I said comparability between what the Agreement States do and

what the NRC does in the programs that we regulate, that there are a lot of different organizations, a lot of different local factors but, in fact, the medicine and the physics are the same throughout. And, so, if one group finds that some of these innovations make a lot of sense, we should all learn from these. And if there are differences, they should be because there are real distinctions and not just because the history is different.

And, finally, I have to tell you that I've been on a number of boards of directors, and the boards of directors, they may have high objectives, but they don't want to be embarrassed and they don't want to be sued, and going to a board of directors when there is a serious problem is a very effective mechanism. Somehow that gets reflected very quickly into action. So, all in all, this has been an illuminating session.

We have felt, as you know, for quite a while, that there's something awry here. Each event, as we find events ourselves, as we get the newspaper articles, as we talk to our colleagues, puts a little more concrete push on this. It's not that we're trying to scare patients. I mean, people keep saying we should somehow put a gag rule on this operation because we're scaring patients. That's not the objective, and that's not the outcome. We

live in a society where we believe that putting information on the table will lead to improvements and not just to sensationalism, and I think it's our obligation to follow up on that approach.

So, thank you very much for coming in. I found it illuminating, and I'm sure the rest of the Commission has as well.

MR. GODWIN: Thank you.

MR. BAILEY: Thank you.

(Whereupon, at 4:40 p.m., the meeting was adjourned.)

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

TITLE OF MEETING: BRIEFING BY AGREEMENT STATES ON THEIR ACTIVITIES IN MEDICAL USE AREA

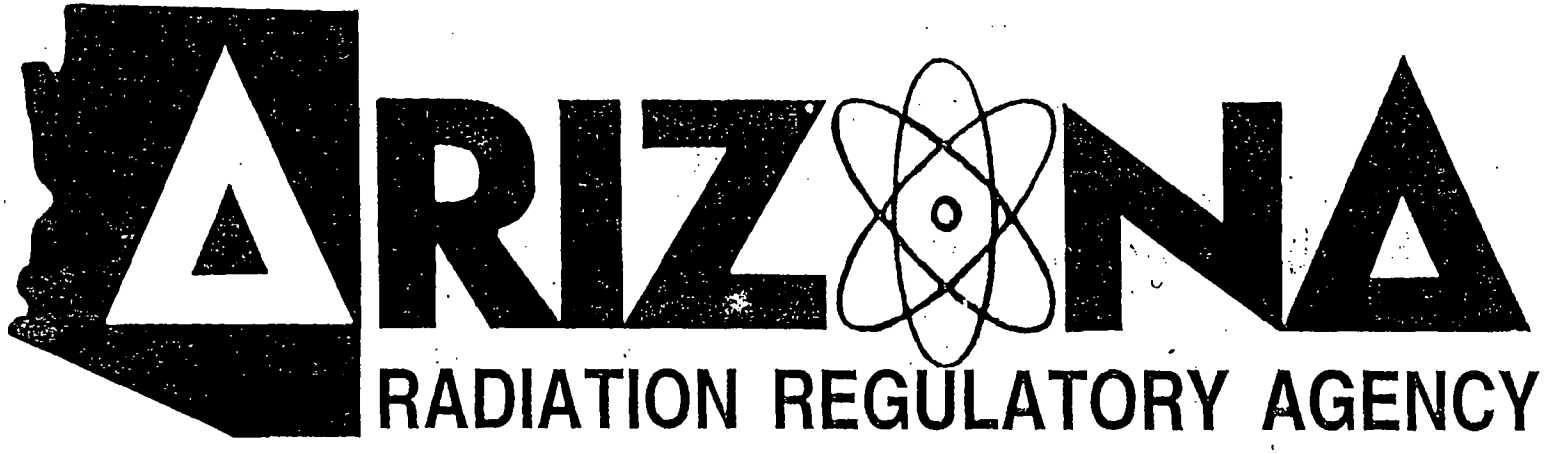
PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: JANUARY 29, 1993

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

Phyllis Young

Reporter's name: PHYLLIS YOUNG


ARIZONA
RADIATION REGULATORY AGENCY

Remarks by G. Wayne Kerr, Chairperson
Organization of Agreement States
before
U.S. Nuclear Regulatory Commission
January 29, 1993

Mr. Chairman and members of the Commission. We are pleased to be here today to discuss with you a matter of mutual interest - the regulation of nuclear materials. I am accompanied by Mr. Tom Hill of Georgia, Past Chair of the Organization of Agreement States (OAS) and Dr. Mary Clark of Florida, Chair-Elect of the OAS.

I plan to make some general remarks addressing certain regulatory issues and then some remarks related specifically to Illinois. Then I will ask Mr. Hill and Dr. Clark to make their remarks.

The Organization of Agreement States is a loose affiliation of the 29 Agreement States whose main purpose is to address issues of common concern and to serve as a centralized point of contact for NRC on generic issues.

The words "protection of the public health and safety" are few in number, but carry a lot of responsibility. Words similar to those are found in the Atomic Energy Act and in the legislation of each Agreement State. We all take them seriously. We appreciate the efforts of NRC in assisting us and in trying to keep us coordinated to the extent necessary to carry out that essential responsibility. It is not an easy task for you to deal with 29 sovereign States and, as you know, some of us are very sovereign.

There has been considerable effort expended by NRC and the Agreement States in the last couple of months to address problems associated with materials regulatory programs. Some relate to information gathering, some to medical regulation in particular, some to investigations, and some to enforcement. These problems may be real in some cases and in others, only perceived. I urge everyone to focus on the proper target. Are the regulatory programs of both the NRC and the Agreement States adequately protecting the public health and safety as required by the Atomic Energy Act (AEA) for you and by Section 274 of the AEA and our own State laws for us? As we have stated on previous occasions, we believe it inappropriate to place too much emphasis on processes and procedures. The purpose of my general remarks are to highlight some areas where we may have different approaches, but maintain the same public health and safety objective.

I want to focus on four items in particular that have been talked about recently. First, information gaps. We hear that some - the public, the Congress, the NRC - may not know <u>everything</u> about each Agreement State program in the detail that is known about NRC programs. However, we don't believe it necessary for such detailed information to be maintained in some centralized fashion. It's not that we have anything to hide - our files are almost an open book to NRC. But knowledge of every detail should not be necessary. We don't believe Section 274 of the Atomic Energy Act contemplates that kind of oversight.

Second is the subject of investigations. There apparently is some concern that Agreement States don't do investigations or that we don't do them with the same procedural rigor as the NRC. I am certain all Agreement States do perform investigations of incidents. Some may not follow the same rigorous

procedures as NRC. We certainly do investigations in Illinois, but we do not have a staff solely dedicated to investigations. I am aware of only one State that does. Texas has had such a unit since 1981. But we get the job done anyway, and it can be argued with more vigor than NRC. State programs have the advantage of being in closer proximity to the regulated facilities, and in the case of facilities that also use x-ray machines, we inspect these facilities for all sources of radiation with the result being a more frequent presence. As a result of an NRC suggestion, Illinois does have an Incident Review Committee which meets monthly to review "events" involving either radioactive materials or electronic product machines.

Third, I want to briefly address enforcement. Enforcement practices no doubt vary among the Agreement States, which in part is due to the sovereign nature of States. Some may find methods of enforcement that are effective without civil penalties. Most, like NRC, find civil penalties useful. In any event, our processes may vary from those of NRC, but the goals are the same. Let me give some examples. Several years ago in the days of low-level waste crises, Nevada returned a defective shipment of waste to an NRC shipper. Since the shipment came from an NRC licensee, Nevada could have referred it to NRC for enforcement action - and waited two or three months for possible issuance of a civil penalty. But they found the action they took was both prompt and effective.

A major university in California had significant problems in their radiation safety program over a period of years in the 1980's. Administrative actions such as restrictive license conditions and management conferences did not fully correct the situation. The university was placed on probation, a fine of $25,000 was imposed, and a fellowship in radiation safety was

established at $25,000 per year for three years. Subsequently, a $65,000 penalty was imposed for additional violations. California followed rigorous court proceedings in the latter stages of this case. Currently, the licensee is operating satisfactorily.

On Thanksgiving Eve last year, Illinois issued an emergency order to a medical institution to cease operations due to lack of authorized users, no approved Radiation Safety Officer being available, and no commitment to procedures regarding selection of patients, prescribing doses and interpreting results. The elapsed time from when our inspector confirmed these problems to the time of issuance of the order was a matter of hours. One of our IDNS inspectors personally delivered the order on Thanksgiving Day. These cases may be a little unorthodox, and sometimes lacking in procedural niceties. Are they effective? We think so.

I have left the most intractable subject for last. That is the issue of regulation of medical uses of radioactive materials. Although the Agreement States have differed with the NRC on some aspects of this issue, I am sympathetic to your attempts to resolve it. The issue is greatly complicated by the number of players involved - NRC, FDA, Agreement State regulators, medical licensing Boards, State Pharmacy Boards, and not least of which are the medical practitioners and the patients. I think the difficulty partly stems from differences of opinion as to each of those groups' roles, and a lack of clarity about their respective authority. The Medical Issues paper presented at the public meeting on October 29, 1992 in Baltimore was, in my opinion, a good initial effort at trying to sort out the issues. I personally believe one of the most important tasks is to establish clearly the respective

roles of FDA, NRC, and the licensing Boards, and I urge you to work toward that goal expeditiously.

The quality management and medical misadministration rules are interrelated, and do have significant impact on Agreement States. Our main differences with NRC have been over the level of detail required by the NRC rule, and in some cases with specific provisions. The Agreement States tend to disagree with the level of compatibility assigned to these rules and in general to medical rules. We feel that a Division 3 category is more appropriate, since the issues by and large are matters between each Agreement State and its licensees. Medical licensees do not generally work across State lines, nor make products entering into interstate commerce. Therefore, there is not a need for the same degree of uniformity as may affect radiographers or source distributors, for example.

Now, I want to briefly address some aspects of the Illinois program. Illinois has been an Agreement State since June 1987, and we regulate about 800 specific licensees. Of these, we consider 97 to be major licenses (e.g., broad licenses, laundries, LLW, manufacturing and distribution, teletherapy, nuclear pharmacies, Category IV irradiators). Each review of our program by NRC since 1987 has concluded that it is adequate to protect the public health and safety.

The program is administered by sixteen health physics professionals and four clerical. Other managerial and technical support is provided by three health physicists and two administrative. Additionally, laboratory services, instrument calibration services, and assistance in decommissioning projects are available through another office in IDNS. The State operates for our own

use and for use by other States, a calibration laboratory accredited by CRCPD. We have a comprehensive fixed laboratory facility which supports all the functions of the Department. We also have a mobile lab for field use.

We have a fee schedule structured differently than NRC's, but it is expected to recover about 35% of our costs in FY 1993. A few categories of licensees are on a full cost recovery basis.

We took 698 licensing actions in 1991 and 756 in 1992. Pre-licensing visits are conducted for complex actions and when deemed necessary to obtain clarifying information. We performed thirteen such visits in the last two years.

Our inspection priority system for specific licensees is similar to NRC's except that our maximum interval is four years. Thus, we are nearly identical on the high priority licensees but more frequent than NRC on the lower priority licensees. We conducted 375 inspections in 1991 and 300 in 1992. We issued three Orders in the last two years as follows:

1. A physician for unsupervised use of radioactive material resulting in a hearing and a civil penalty of $12,500;

2. An industrial firm for multiple repeat violations. A hearing was held and a civil penalty of $4,700 imposed; and

3. A suspension order to a hospital for using licensed material with no authorized users, no RSO, or valid license (transfer of ownership without IDNS approval).

Our civil penalty procedures are specified in our regulations, and are based on licensee compliance history, severity, and negligence. In addition, we held two management conferences in these two years.

Our medical reporting rule (misadministration in NRC's parlance) is essentially the same as NRC's with only minor differences. In 1991, we had 25 recordable but non-reportable diagnostic events. In 1992, we had six recordable events and one reportable therapeutic event.

Our x-ray regulatory program is large, covering some 24,000 machines at 9,500 facilities. About one-half of the machines are inspected each year. They are also subject to various fees and civil penalties. We register accelerators and lasers, and regularly inspect the accelerator facilities.

Illinois has had a radiologic technologist accreditation program since 1984. We accredit radiographic technologists, chiropractic technologists, nuclear medicine technologists and radiation therapy technologists. There are currently about 8,700 technologists accredited in Illinois. Of these, about 800 are nuclear medicine technologists and about 500 are therapy technologists (includes x-ray, accelerator, teletherapy, and brachytherapy). They are subject to renewal every two years, and 24 hours of continuing education credits are required every two years.

Civil penalties in the tech accreditation program have been available since 1989. Penalties may be applied to both the technologist and his or her employer. Penalties for technologists are $250 for first violation, $500 for second, and $1,000 for others. Employers' penalties are $500 for first violation, $1,000 for second and subsequent violations. Since 1989, we have

assessed $32,250 in penalties against 57 technologists and 36 employers, most of which have been in the last twelve months. Of these 57 technologists, four have been in nuclear medicine and three in radiation therapy. We have a number of additional ones pending. There have been no suspensions or revocations to date.

There are 27 states plus Puerto Rico which have implemented certification programs, although they may vary in scope and detailed provisions. Of these, seventeen are Agreement States.

I will next ask Mr. Hill and Dr. Clark to present their remarks.

Remarks by Thomas E. Hill, Manager
Radioactive Materials Program
Georgia Department of Natural Resources
before
U.S. Nuclear Regulatory Commission
January 29, 1992

INTRODUCTION

Good afternoon, Mr. Chairman and members of the Commission. It is a pleasure meeting with you again, continuing our discussion of issues of mutual concern. Since I met with the Commission on June 11, 1991 to discuss compatibility issues, we have participated in many meetings and workshops with NRC. The Agreement States provided early input into NRC rule makings. Most notably, Parts 34 and 35 rule makings. Today, I must report to you that the joint NRC/Agreement State Committee recommended by the Agreement States to develop a compatibility strategy has **not** yet been established.

I will briefly discuss Georgia's Radioactive Materials Regulatory Program.

PROGRAM SIZE AND DESCRIPTION

Georgia has been an Agreement State for twenty-three (23) years. As of December 31, 1992 we have 519 licenses compared to 596 in June of 1990. Our current staff includes six (6) technical, two (2) administrative support and one manager. Additional support for laboratory services and emergency response is available within the Department. The Radioactive Materials Program, unlike the Radiation Control Programs of other states does not have responsibility for registering and inspecting x-ray machines or generators of nonionizing radiations.

WORK LOAD & PRIORITY SYSTEM

During CY 1992 we conducted 124 license inspections and completed 819 licensing actions. A total of 539 of those licensing actions administratively amended or added a license fee condition. Twenty-nine percent (29%) or (81) of the remaining licensing actions were new and renewal applications.

Georgia's inspection priority schedule is essentially the same as NRC's. In November of 1990, after several years of effort, the Program eliminated its inspection back log. To date we have completed all scheduled inspections. I am not optimistic that we can keep inspections from becoming back logged. A

revision of our Rules and Regulations and their adoption by the Board, in accordance with our Administrative Procedures Act, must be completed this year.

FEE

In FY 92 the Radioactive Materials Program received approximately 50% of its funding from fees, the remainder from the state's general fund. Beginning FY 93, which began this past July 1st, the Program is 100% supported by fees. The fee schedule adopted by the Board of Commissioners is similar to the NRC Fee Schedule. The notable exception is that our annual fees are approximately one-third (⅓) of yours.

ENFORCEMENT AND CIVIL PENALTIES

Our Rules and Regulations provide for enforcement, including civil penalties. All enforcement activities including asessment of civil penalties must be conducted according to the Georgia Administrative Procedures Act.

EVENTS/COMPLAINTS/MISADMINISTRATIONS

In 1992 licensees and companies reported eighteen (18) incidents. Investigations were conducted. All but one have been closed. Reports of three (3) diagnostic medical misadministrations were received in 1992.

One final comment. In 1985, while attending a NRC sponsored workshop on large irradiators, I learned that the Regional Materials staff and the Agreement States had the same problems with NRC headquarters. I challenge the NRC to review (inspect) it's Regional Materials Licensing and Inspection Programs using the same criteria developed and used to evaluate Agreement States. Who knows, from such a review NRC may discover the equivalent of five (5) additional agreement states. Therefore, the compatability strategy developed by the yet to be established joint NRC/Agreement State Committee may be applicable within NRC.

Thank you.

STATEMENT TO THE

UNITED STATES NUCLEAR REGULATORY COMMISSION

by

Edgar D. Bailey, C.H.P.
Chief
California Radiologic Health Branch

January 29, 1993

Mr. Chairman and Commissioners, I am Edgar D. Bailey, Chief of the California Radiologic Health Branch.

On August 21, 1988, Dwight Gregory Golstein II died at Children's Hospital in Oakland, California. Death was caused by respiratory failure "due to, or as a consequence of radiation damage".

In September 1992, several members of the staff of the California Radiologic Health Branch (RHB) including myself were contacted by a reporter from The Plain Dealer, a Cleveland, Ohio, newspaper. The reporter asked for the RHB files or information related to a 1987 cobalt-60 teletherapy misadministration at Alta Bates Hospital in Oakland which resulted in the death of a nine-year-old boy.

At the time of the reporter's calls RHB had no information regarding the alleged incident. In response to questions from RHB staff regarding the reporter's accusation, representatives of Alta Bates Hospital assured them that the reporters claims were erroneous. On September 9, 1992, I personally talked to a representative of the Risk Management Department at Alta Bates Hospital who told me that:

1. the incident involved treatment with a linear accelerator and not a teletherapy unit;

2. the dose prescribed was the dose delivered and therefore no misadministration occurred;

3. the dose was delivered to the correct location;

4. the dose was a palliative treatment of a patient with terminal neuroblastoma; and

5. the case was simply a malpractice suit.

This information was provided to me even though we discussed the fact that the medical misadministration reporting regulation had become effective in California on October 5, 1989, nearly two years

after the incident occurred.

On December 13, 1992, the first in the series of The Plain Dealer articles was published, and the lead story was about the misadministration at Alta Bates Hospital. Somewhat to our surprise the story about Alta Bates Hospital was not picked up by the local Bay Area newspapers or television stations.

On January 6, 1993, due to increasing concern that RHB did not have all the facts concerning this incident, the Manager of the RHB Regional Office in Berkeley went to Alta Bates Hospital and found that RHB had not been told the truth in its earlier contacts with the hospital. He found that in essence the newspaper article was correct in what it reported as having occurred. Contact on January 8, 1993, with the West Coast Cancer Foundation (WCCF), the consulting medical physics group which developed the treatment plan for the patient collaborated the new information.

The following is the sequence of events as we now believe they occurred.

The child was referred to Alta Bates Hospital by Children's Hospital of Oakland for treatment of rhabdomyosarcoma because Children's Hospital did not have the appropriate radiation therapy equipment.

A treatment plan for the child was developed by WCCF. This medical physics group worked under contract to Alta Bates Hospital since the hospital did not employ staff medical physicists. The treatment plan involved a series of complex treatments covering a part of the face and upper neck. That is to say, the treatment was to occur over several days with multiple beams and a number of fields.

Treatment of the patient began on December 4, 1987, and continued on a daily basis (except for weekends) for 15 treatments ending on December 24, 1987. The patient developed what has been described as "a sore" in his mouth, and with the holidays approaching the treatment was halted to allow the patient to improve. When the patient returned for treatment in January 1988, there was enough change in the face and neck contours that a new treatment plan was ordered.

The medical physicist at WCCF who did the treatment plan happened to be the same one who had done the earlier treatment plan calculations. After the new calculations were completed, he compared them to the previous ones and noted a large discrepancy between the two sets of data. Upon further checking he discovered that the earlier set prepared in December 1987 was the one in error. The error was in the treatment time calculation. At this time it is believed that the prescribed dose was 180 rads per day but that in fact a dose of 360 rads per day was delivered on each of the fifteen treatment days.

On January 28, 1988, the WCCF notified the staff radiation oncologist at Alta Bates Hospital of the mistake. The radiation oncologist filed a written Hospital Incident Report with the hospital's Risk Management Department on February 5, 1988.

No additional radiation therapy treatments were given. The child died seven months later on August 21, 1988. An autopsy was performed, but RHB does not have a copy of it at this time.

On March 1, 1988, a routine inspection was conducted of WCCF. The radioactive materials license issued by RHB to WCCF is for the possession and use of three small calibration or check sources. The actual activity of preparing treatment plans or doing the calculations is not a licensed activity per se, but is included in the authorization to use a teletherapy unit for the treatment of humans. Medical physicists are not licensed by California as a profession at this time; however, unrelated to this incident is an effort by the medical physicists themselves to get a state law passed that would require state testing and licensing of the profession similar to the law passed in Texas a few years ago.

During the inspection of WCCF in response to the inspector's question regarding whether there had been any unreported incidents or unusual occurrences since the last inspection, the radiation safety officer (RSO) responded that there had been none. When asked about this response on January 8, 1993, he said that he had not mentioned it because it was in litigation. This leads RHB to wonder if there are other incidents or misadministrations that were not or have not been mentioned since they are "in litigation".

On June 20 and 21, 1990, a routine inspection was conducted at Alta Bates Hospital. A review of the Radiation Safety Committee minutes revealed no record of the incident. In response to the question regarding unreported incidents or unusual occurrences, the hospital's RSO reported none. On January 7, 1993, the RSO said that she and the chairman of the Radiation Safety Committee only became aware of the misadministration when RHB called to try to get information about the incident in 1992. Although the head of the radiation oncology unit must have known about the incident when it occurred, it appears that he did not inform the RSO and the Radiation Safety Committee even though he was a member of the committee. He has since left the staff of the hospital.

It should be noted that the WCCF is no longer under contract to Alta Bates Hospital.

It is reported that the WCCF, the radiation oncologist, and the hospital have all settled lawsuits with the patient's family. The doctor and/or WCCF reportedly settled for $500,000 and the hospital reportedly settled for $30,000.

Following discussions with Mr. Carlton C. Kammerer of the Office of State Programs, I FAXed him a letter on January 14, 1993, requesting the assistance of an investigator from the Office of

Investigations to help the California RHB thoroughly investigate what appears on the surface to be a deliberate attempt to cover up the occurrence of this apparent gross misadministration. On January 22, 1993, Mr. Ben B. Hayes, Director of the Office of Investigations, instructed his staff in Region V to assist California in its investigations. We held our first meeting with the assigned investigator, Mr. Eugene Power, in Sacramento on Monday (January 25, 1993) of this week.

In addition to Mr. Power, RHB is seeking the assistance of the Licensing and Certification Branch (L&C) of the California Department of Health Services (DHS). L&C is the organization within DHS that has the responsibility for the hospital licensing and the regulation of hospitals within California. As such, it has regulations that require the reporting of "unusual events". At this time it appears that there is a possibility that there were L&C violations associated with this incident.

The DHS Office of Legal Services has already assigned an attorney to assist on this case and contact has been made with the California Attorney General. It is the intent of RHB that a thorough and complete investigation of this entire incident be conducted and that if violations of California laws and regulations are identified, these will be prosecuted to maximum extent permitted under California law.

At the present the investigation is ongoing.

It is clear that there are difficulties that exist in investigating and taking meaningful enforcement actions in incidents like the one I have described. There are a few recommendations or suggestions that I believe would be helpful.

1. Misadministrations should be violations. At the present time only the failure to report them is a violation. One has to cite failures to follow procedures such as dose assay, patient identification, etc.

2. Consideration should be given to requiring medical licensees to report the filing of malpractice suits against the licensee or named users on the license. This would follow the precedent already set of requiring licensees to report the filing of bankruptcy actions.

3. Consideration should be given to requiring that each Agreement State has inspectors or investigators who are peace officers. The Food and Drug Administration already requires such of certain state food and drug personnel. These state "investigators" should be required to have training similar to that provided to NRC investigators.

That concludes my remarks. Mr. Donald Bunn, Chief of Enforcement and Compliance, is with me today. He and I would be happy to answer any questions you may have.

The attached paper was provided by NMSS at the all Agreement States meeting in October 1992.

MEDICAL ISSUES PAPER

The following paper on "Medical Issues" raises a variety of issues in the NRC's medical use program. The purpose of this paper is to stimulate discussion on these and possibly other issues as part of the development of a proposed medical use management plan to be presented to the Commission. The discussion of issues within this paper does not necessarily represent official NRC policy.

The staff appreciates that there may not be an ultimate resolution of some of these issues but recognizes a need to address them. Specific items that are beyond the scope of the staff's management plan for the medical use area have been excluded.

MEDICAL ISSUES

Introduction

Several recent rulemakings by the Nuclear Regulatory Commission in the area of the medical use of byproduct material have prompted criticism and opposition by certain elements within the medical community. These include: 1) the "Interim Final Rule" (effective August 23, 1990) which amended regulations, in response to a petition for rulemaking, related to the preparation of radiopharmaceuticals and the therapeutic use of radiopharmaceuticals; and 2) the "Quality Management (QM) Program and Misadministration" rule (effective January 27, 1992) which requires, in part, that licensees submit a written certification that a QM program had been implemented. The Commission has been working to effectively resolve these safety issues and to alleviate the associated concerns of the medical community while maintaining communication with the involved parties (meetings with ACMUI, professional organizations, and Agreement States). Despite these efforts, certain segments of the regulated medical community perceive the Commission as arbitrary and pursuing unnecessary rulemaking that they believe could needlessly interfere with the practices of medicine and radiopharmacy.

In order to resolve current anticipated issues, NRC staff has begun a reassessment of the overall medical use program and initiated a number of actions to address the more pressing problems. Comment and advice is being solicited in meetings with the ACMUI and representatives from the Agreement States, to be held in October 1992, on issues relevant to the regulation of the medical use of byproduct material. This document highlights certain program areas which should be reviewed at these public meetings to determine if any changes are necessary to improve the medical use program. There may be other programmatic issues and alternative approaches to regulation not yet identified by the staff which may need to be discussed and evaluated at these meetings.

The outcome of these discussions with the ACMUI and the Agreement States representatives will culminate in a paper to the Commission outlining the staff's proposed "medical use management plan" for Commission consideration and direction. It may include the following:

1. A formulation of long term objectives and an umbrella policy under which those objectives are to be achieved. This will include any proposed revision of the current Medical Policy Statement.

2. A strategy for achieving the objectives which consists of:

   a. Completion or redirection of ongoing activities intended to address regulatory changes petitioned by the medical community as well as those recently identified by the staff.

   b. Assessments based on periodic meetings with the ACMUI, Agreement States, NRC regional management, the medical community (to include physicians, physicists, nurses, and technologists), and the general public. These assessments will consider the status, direction, and improvement of the program as well as staff assessment of performance under recently adopted programmatic changes.

c. Identifying, evaluating, and, if appropriate, undertaking new initiatives resulting from these periodic assessments.

d. Provision for an annual update and modification of the plan, a report to the Commission, and adjustment based on Commission direction.

The staff plans to complete the initial phases of this program review in 1992 and to forward the management plan to the Commission in January 1993. Once Commission direction has been provided, the staff will establish periodic meetings with the above mentioned groups (2b) to gather information and consider their input in any further modifications to the medical use program.

Issues within the Medical Use Program

To facilitate review of the issues we have four fundamental areas, with each area containing multiple subissues. Several of these subissues cannot be compartmentalized into specific program areas and therefore there may be some overlap amongst the four major areas. This paper raises questions for open-ended discussions at the public meetings.

The text of this paper outlines the fundamental areas, and specific topics are referred to appendices for more detailed analysis. The paper also includes a discussion of efforts currently underway which are related to issue resolution.

1. NRC's Role in the Regulation of the Use of Byproduct Material in Medicine

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 the 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". Furthermore, Section 81 directs that "The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefore or approved by the Commission". Section 161b generally authorizes NRC to issue such regulations and orders regarding the use of byproduct material "as the Commission may deem necessary or desirable ... to protect health or to minimize danger to life or property". Whereas NRC's statutory authority is clear, the degree of regulation in exercising that authority may vary in accordance with the administrative prerogative of the Commission.

The NRC issued a policy statement in 1979 to guide its regulation of the medical uses of radioisotopes (Appendix A). This policy addresses the central question as to the level of regulation the NRC considers necessary to exercise its authority in this area. The Commission applies this policy to development

of regulations governing the program (Appendix B), licensing, and to the development of related inspection and enforcement policies (Appendix C), although the final regulations take precedence over the policy statement. There are many issues related to the medical policy statement that are discussed in the appendices.

2. Operational Flexibility

An effective regulatory scheme needs to establish a balance between clear, understandable regulations and a level of operational flexibility for both the licensees and regulatory organizations (e.g., NRC, Agreement States). While meeting the NRC's concerns with protecting the public health and safety, which includes occupational workers, patients, and the general public, the medical community is concerned with providing competent, timely, and cost-effective care to their patients. A physician may need to modify a treatment for a specific patient and therefore an effort needs to be made to ensure that the regulations do not needlessly restrict a physician from prescribing the best treatment without a time consuming review process. However, there are many safety practices that are routine and should be formalized to ensure uniform standards of radiation protection which allow personnel to handle radioactive material in a way that limits exposure to themselves and members of the public as low as reasonably achievable (ALARA) and helps prevent misadministrations.

10 CFR Part 35 (Medical Use of Byproduct Material) contains both prescriptive and performance based regulations (Appendix B). The regulations will be reviewed to determine if they need to be modified to allow greater flexibility while providing sufficient clarity and specificity to adequately protect public health and safety. A related aspect that may need to be revisited and possibly clarified is the responsibility for supervision of individuals in the safe use of byproduct material and the training and experience criteria for individuals using byproduct material (Appendix D). NRC's broad authority also extends beyond the immediate medical community and patient to the general public. Therefore, it is important that the NRC communicate with workers, patients, and members of the general public as well as directly with licensees regarding the effectiveness of its regulatory program (Appendix E).

3. Regulatory Relationships

There are multiple regulatory agencies and organizations involved with the regulation of nuclear medicine and radiation oncology. These include, in part: the Agreement States, the U.S. Food and Drug Administration, and various state Boards. In non-Agreement States, there may be two different sets of regulations for medical use of byproduct material and all other radioactive material. The need for uniformity of practice by co-regulators and an avoidance of duplication may apply not only to safety practices but to national standards for calibrations and equipment such as medical devices. Communication between co-regulators and delineation of responsibilities would assist the efforts to attain uniformity. Specifically, there may be means other than current regulations to achieve effective and efficient requirements and/or regulations. This will encompass various aspects of the regulatory program including 10 CFR Part 35 (Appendix B), inspection and enforcement

procedures (Appendix C), and training and supervision issues (Appendix D).

4. Professional Relationships

The NRC seeks good communication and interaction with different professional groups and associations. The ACMUI provides advice on the practicality and impact of standards and guidelines related to protection of the public health and safety. The ACMUI also provides advice and recommendations on NRC proposals for the development and/or amendment of standards and criteria for regulating and licensing uses of radionuclides in human subjects including medical research, diagnosis and therapy. The Commission has expanded the representation on the ACMUI and scheduled it to meet more frequently as a group.

In addition to the ACMUI, other professional organizations, such as the American College of Nuclear Physicians (ACNP) and the American Society of Therapeutic Radiology and Oncology (ASTRO), are a resource that contribute during rulemakings. Some of these organizations have developed voluntary standards and audit programs that may be endorsed to some extent in the future in NRC regulatory guides (Appendix C). By maintaining open communication with different organizations, the NRC staff hopes to be able to react promptly as new technologies emerge so that regulations can be modified to accommodate them.

The Medical Visiting Fellows Program is a recent effort initiated by the Commission to improve communications with the professional community. Myron Pollycove, M.D. joined NRC in late October 1991, and Mark Rotman, PharmD. in early December 1991 as the first two Fellows. The staff anticipates that NRC's knowledge of the medical community and its relationship with its members will continue to improve by utilizing the Fellows in their role as liaison (Appendix E).

Ongoing Efforts

There are several ongoing efforts which are intended to address regulatory changes petitioned by the medical community as well as those identified by the staff, that will continue subject to possible redirection in the reassessment process. The Commission has previously been briefed on all these issues and has provided direction to the staff. The direction and status of these ongoing efforts are summarized as follows:

1. Radiopharmacy Rulemaking

In June 1989, the ACNP/SNM filed a petition for rulemaking to amend 10 CFR Part 35 to "correct regulatory incompatibility and permit the traditional practice of nuclear medicine and nuclear pharmacy." Elements of the petition involving strict adherence to the package insert were addressed in the interim final rule, effective August 23, 1990. Remaining issues which must be resolved are: the practice of nuclear pharmacy including compounding; the use of radiolabelled biologics; and the use of byproduct material for human research. Draft

rule language has been discussed with both the ACMUI and the Agreement States representatives and the working draft has undergone substantial change as a result. The staff plans to submit a proposed rule to the Commission for review in November 1992 and anticipates that the proposed rule may be published for comment in early 1993.

2. Preparation of Inspection/Enforcement Guidance for QM rule

Regional personnel have been instructed to conduct performance-based inspections on QM programs. Formal guidance for the regions is being prepared as a temporary instruction. In addition, the enforcement policy for the QM rule is being modified on an interim basis in order to place the primary focus on programmatic failures of QM programs rather than on individual, isolated mistakes leading to misadministrations. This interim policy will be submitted to the Commission for review and approval. This inspection and enforcement policy also will be discussed during a public meeting scheduled for November 9, 1992 with the ACNP/SNM and other organizations involved with the use of byproduct material affected by the QM rule.

3. Contract to review submitted QM programs

A statement of work for a contract to review all the submitted QM programs has been prepared and provided to three national laboratories for their submission of proposals. The contract is expected to be awarded in January 1993 and have a duration of 24 months. The contractor will review the QM programs in accordance with a Standard Review Plan prepared by NRC staff. Following each review, a letter will be sent to the licensee submitting a QM program identifying weaknesses or omissions or a satisfactory submittal.

4. Completion of Broad Scope Guidance including Standard Review Plan

On June 4, 1992, a Policy and Guidance Directive was issued providing guidance on licensing medical facilities with broad scope programs in order to eliminate certain confusion that had existed since 10 CFR Part 35 was revised in 1987. A Standard Review Plan for applications for Type A licenses of broad scope has also been drafted and includes medical broad scope facilities. This should be issued to the regions in the near future. Concurrently, a draft Regulatory Guide (revision to Reg. Guide 10.5) is being prepared and will be published for review and comments.

5. Public meeting with ACNP/SNM to explain QM rule and ACNP audit program

As part of the override of OMB's disapproval of the information collection requirements for the QM rule, the Commission approved the staff's proposal to hold a public meeting with the ACNP/SNM to describe the recordkeeping and reporting requirements associated with the rule. The staff will hold this meeting on November 9, 1992 and will invite other professional associations such as American Association of Physicists in Medicine (AAPM), American College of Radiology (ACR), and

ASTRO. This meeting will address the requirements of the rule and the related inspection and enforcement guidance being developed. In addition, the ACNP practice audit program will be reviewed and discussed as to the extent NRC can use industry's self-auditing guidelines.

6. Elimination of Recordkeeping Requirements for the Interim Final Rule

NRC issued the Interim Final Rule, effective immediately, on August 23, 1990, to amend its regulations related to the preparation of radiopharmaceuticals and therapeutic uses of radiopharmaceuticals. The rule provides latitude under NRC regulations for: 1) certain physician-directed departures from the FDA-approved package insert instructions for preparation of radiopharmaceuticals; and 2) in the case of radiopharmaceuticals for therapeutic use, departures from the package insert instructions regarding indications and methods of administration if certain requirements are met, including a recordkeeping requirement for the departures. The NRC staff has reviewed the documentation collected to date and after consulting with FDA has concluded that the major trends in departures are clear and collection of additional data would not reveal any significant new information. Consequently, a proposed rule eliminating the recordkeeping requirements was published on June 11, 1992. Public comments have been analyzed and a final rule was approved by the Executive Director for Operations and published in the Federal Register on October 2, 1992.

7. Review and Modification of Abnormal Occurrence (AO) Reporting Criteria

The staff has undertaken an effort to review and revise the current reporting criteria for AOs. A presentation was made to the ACMUI by a contractor representing Oak Ridge Associated Universities in May 1992 at which time the ACMUI recommended a number of changes to the contractor's proposal. These recommendations have been reviewed and a proposed major revision will be presented to the Commission in 1993. A status report will be given to the ACMUI during the October 1992 meeting.

8. Rulemaking on the Administration of Byproduct Material to Pregnant and Breastfeeding Women

This rulemaking was reviewed with the ACMUI at the May 1992 meeting. The ACMUI recommended certain changes in the rule language and associated guidance. The staff proposed to the Commission in May 1992 that this be a performance-based rule, modifying the QM rule and adding to the definition of misadministration. More recently, the staff met with the Agreement States to review the issue. The staff is planning to submit the proposed rule and corresponding guidance to the Commission in December 1992.

9. Rulemaking for Release Criteria for Radioactive Patients

Three petitions have been filed with the NRC requesting revision of the release criteria in 10 CFR 35.75 for patients receiving radiopharmaceutical therapy or permanent implants in. The staff is

currently addressing this issue. The primary issue is to resolve the inconsistency between 10 CFR Parts 20 and 35 in terms of the dose limits for individual members of the general public. Furthermore, the release criteria will be clarified taking into consideration the guidelines set forth in NCRP Publication No. 37. The proposed rule will allow medical use licensees some additional flexibility on releasing patients. The staff plans to present the approach to resolving these petitions and draft rule language to the ACMUI in October 1992.

Items to be Excluded from Consideration

The following issues raised by certain members of the medical community extend beyond the scope of the staff's review of the medical use program and are therefore to be excluded from consideration during the development of a management plan:

1. Amending the Atomic Energy Act ("the Act") to either exempt the regulation of the medical use of byproduct material, source material, or special nuclear material, or expand NRC's authority to include naturally or accelerator-produced radioactive material (NARM).

2. Compliance with, compatibility of, or repeal of The Clean Air and Water Acts' levels of effluent releases.

3. Low level radioactive waste and mixed medical waste issues.

4. Changing or eliminating NRC annual fees.

5. Commission's position regarding compatibility with Agreement State and NRC regulation of the medical use of byproduct material.

APPENDIX A

MEDICAL POLICY STATEMENT

Background

On February 9, 1979 (44 FR 8242), the NRC issued a statement of general policy to guide its regulation of the medical uses of radioisotopes (Medical Policy Statement). The Commission stated:

1. The 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. The 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. The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

The rationale behind these three statements is discussed in the enclosed final policy statement.

Discussion

Since this policy statement was published, there have been a number of key NRC regulatory initiatives that have been opposed by members of the medical community. In the development of these rulemakings, the Medical Policy Statement has been reviewed[1]. However, different interpretations of the policy statement have led to conflicting opinions between members of the NRC staff, the Commission, and the medical community. Following the Annual Briefing on the Medical Use Program on June 1, 1992, the Commission requested, in an SRM dated June 23, 1992, an analysis of whether the evolution of NRC's medical use program has been consistent with the 1979 statement of Commission policy, and whether any changes to the medical policy statement are warranted. The staff's analysis will be addressed in the medical use management plan. Concurrently, the Commission requested that the ACMUI assess whether NRC's regulatory program for the medical use of byproduct material was consistent with the three principles in the medical policy statement.

The staff believes that a review of the medical policy statement should focus on whether the prevailing rationale is different today, and whether there is a proper emphasis on safety and health, while allowing sufficient flexibility to deal with the dynamics of medical technology and the practice of medicine. Are the three principles in the medical policy statement appropriate? If not, what parts of the medical policy statement should be revised? Since the policy statement is subject to reinterpretation as the Commission changes, is it sufficiently specific to keep the medical use program on track while allowing accommodation of technological development?

The Medical Policy Statement is reviewed during each rulemaking initiative. Should a line item be included in the statements of consideration of any new rule to discuss its relationship with the medical policy statement?

[1] It should be noted that regulations take precedence over statements of policy.

APPENDIX B

10 CFR PART 35

Background

In 1983, the staff proposed a revision to 10 CFR Part 35, which was much more performance-based than previous requirements. After publication of the proposed rule in 1983, the Commission directed the staff to redraft the rule with more prescriptive requirements. NRC published the final rule on October 16, 1986 and the current 10 CFR Part 35 became effective on April 1, 1987. The purpose for the revision was to bring all the medical use licensing requirements together in one place. Previously, these requirements were found in license conditions, regulatory guides, and the former 10 CFR Part 35. The new Part 35 contains both prescriptive and performance-based requirements.

The terms "performance-based" and "prescriptive" are both relative. One performance-based part of the rule, which is a recent addition, is the Quality Management (QM) Program which lists five general objectives. The licensee may use discretion in determining how to meet these objectives. In general, licensees can improve parts of their programs, meeting the performance-based parts of the regulation, without having their licenses amended. This can be done either through ministerial changes or QM program improvements. Other parts of Part 35 are also performance-based to varying degrees. The ALARA program sets out minimum standards but does not give exact words. The licensee may choose to adopt the more prescriptive approach set out in Regulatory Guide 10.8. In contrast, the leak testing criteria specified in 10 CFR 35.59 is very prescriptive with no flexibility.

10 CFR Part 35 prescribes requirements and provisions that provide for the protection of the public health and safety, to include workers, patients, and the general public. Sections of the rule that protect the worker from devices, beams, and radiation sources include: syringe shields (35.60); ALARA program (35.20); surveys (35.50, 35.70, 35.641); leak tests (35.59); and teletherapy interlock checks (35.615). Protection of the patient scheduled for radiation associated procedures is provided by requiring: Quality Management procedures (35.32); measurement of each dose prior to administration (35.53); survey of patient after removal of temporary implants (35.406); and safety checks of teletherapy machines and rooms (35.615). Finally, there are sections that pertain to protection of the general public and patients not scheduled for radiation procedures such as: surveys to release radiation areas to unrestricted use (35.315, 35.415); release criteria for patients receiving doses of radioactivity (35.75); QM procedures for redundant means of verifying patient identity (35.32); and surveys of waste areas and temporary implants (35.70).

Discussion

The use of 10 CFR Part 35 and specific license conditions provides a flexible licensing system that can be used to address new technologies and rare or unique situations. Are there new issues that should be incorporated or added into the current rule?

The prescriptive parts of 10 CFR Part 35 are very task specific, allow little flexibility or room for interpretation, but also make it easier for both licensees and NRC inspectors to determine regulatory compliance. The performance-based parts provide the licensee with a great deal of flexibility and results in lack of uniformity. Is the rule, or are parts of the rule, too prescriptive or not detailed enough? Should the rule be entirely performance-based? What techniques should NRC use to identify potential new rulemaking endeavors? What level of research and analysis should be used to make the decision to go forward with rulemaking?

Are there any other provisions of 10 CFR Part 35 that interfere with effective regulation of the medical licensees? For example, the information collection requirements required in the QM rule are considered by some members of the medical community to impose an undue burden on licensees. Is there evidence that either the submittal of QM programs or the subsequent recordkeeping requirements have posed such a burden? The QM Rule also contains definitions for misadministrations and recordable events. The term "misadministration" was used to convey that a mistake in the administration of byproduct material or radiation has occurred. Other less significant events are termed "recordable events". Is there evidence that the use of the term "misadministration" has had a negative impact on the practice of medicine or directly resulted in medical malpractice suits? In view of the fact that the QM rule addresses quality assurance issues, some members of the medical community argue that this is an encroachment on the practice of medicine. Are there any examples that this is the case?

APPENDIX C

INSPECTION AND ENFORCEMENT

Background

Section 161 of the Atomic Energy Act authorizes NRC to conduct inspections and investigations and to issue orders as may be necessary or desirable to promote the common defense and security or to protect health or to minimize danger to life or property.

Inspection

Inspection procedures are detailed in NRC Manual Chapter 2800. The objectives of inspections are to determine if licensed programs are conducted in accordance with NRC requirements, and to determine 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 whether a licensee is in compliance with specific provisions of the license and the regulations by direct observation of work activities, interviews with workers, and demonstration of work practices by a worker in performing tasks regulated by the NRC. Additionally, information in licensee records is reviewed to determine compliance with recordkeeping requirements. The focus of the inspection is on the observation of the performance of licensed activities.

Enforcement

The Commission published the general statement of policy and procedure for NRC enforcement actions on March 9, 1982 (57 FR 9987). Since that time, the enforcement policy has been revised several times, most recently in February 1992. The purpose of the enforcement policy for medical use of byproduct material is to promote and protect the radiological health and safety of the public, including that of patients and employees, and the environment. This is accomplished by the following mechanisms:

1. Ensuring compliance with NRC regulations and license conditions
2. Obtaining prompt corrective action of violations and adverse conditions affecting safety
3. Deterring future violations and occurrences of conditions adverse to safety
4. Encouraging improvement of licensee performance, to include prompt identification and reporting of potential safety problems

The basic sanctions available to NRC are notices of violation, civil penalties, and orders of various types. A notice of violation (NOV) is a written notice outlining the violations and usually requires a written response from the licensee. The nature and extent of the enforcement action is intended to reflect the seriousness or severity level (SL) of the violation involved. There are five severity levels of violations which reflect safety and regulatory concern, a SL I violation being the most significant (e.g. substantial failure to implement the QM program resulting in patient death) and a SL V violation being minor (e.g. isolated failure to maintain records).

Because the NRC wants to encourage and support licensee initiatives for self-identification and correction of problems, NRC may exercise discretion and refrain from issuing an NOV and/or civil penalty under certain circumstances.

Discussion

The purpose of the NRC inspection and enforcement program is to identify and correct significant radiation safety problems within a program. NRC inspectors may not necessarily review and sample all aspects of a medical use program during an inspection. They can review, in part or in whole,: 1) organizational structure and program administration by the licensee; 2) the QM program and licensee audits; 3) training of employees in the use of radioactive materials, which includes measurement of doses, contamination and radiation control, proper storage, receipt and shipping, and waste handling; 4) reports and notifications of misadministrations and worker exposures; and 5) records of surveys, instrument checks and material control. The depth of the review is based on identification of problem areas, safety significance and indication of a programmatic breakdown in the area under review. Do NRC inspections focus on those aspects of a program which are most important to radiation safety? Does the NRC policy of unannounced inspections achieve its purpose of reviewing radiation safety practices as they are normally performed?

There are various incentives to licensees for violations that have less safety significance including self-identification and prompt corrective action. Under certain circumstances, non-cited violations (NCVs) can be documented in field notes, an inspection report, or a Form 591. Additionally, NRC inspectors may exercise discretion to issue an NOV using a Form 591 at the inspection site under certain circumstances. In contrast, if there are multiple SL IV and SL V violations, they may be aggregated as a larger problem to emphasize to the licensee the importance of effective management of licensed activities and operation of its overall radiation safety program. Is NRC placing the appropriate emphasis on the use of NCVs and Form 591s?

Violations that are classified as SL III or higher typically result in an enforcement conference, and possibly a civil penalty and press release. These mechanisms are used to obtain corrective action and act as a deterrent against future violations. If a civil penalty is assessed, various mitigation and escalation adjustment factors are applied which include: identification (licensee or NRC), corrective action to prevent recurrence, past performance, prior opportunity to identify, multiple occurrences, and duration. There are also other mechanisms available to rapidly handle a potentially safety significant situation such as the use of confirmatory action letters or orders. Is the current inspection and enforcement program effective in identifying and correcting radiation safety concerns? Which aspects of the inspection and enforcement program are most effective? Are civil penalties and press releases an adequate deterrent? Do existing requirements allow sufficient flexibility to deal with emerging problems or unforeseen circumstances without resulting in violations?

In the medical use area, there has been a question of whether voluntary accreditation and audit programs could be substituted for NRC inspections of performance based programs. The NRC is aware of six voluntary audit programs

in the U.S. that have developed quality assurance audit programs. These include the following:

1. College of American Pathologists (CAP) - CAP offers a voluntary accreditation service involving a complete audit of Nuclear Medicine Programs.
2. Radiological Physics Center (RPC) - RPC's charter is to review patient treatment records, internal consistency of institutions, dosimetry systems, and screening programs with output measurements using TLD's.
3. American College of Radiology (ACR) - ACR has been involved in the development of QA requirements through their voluntary Accreditation of Radiation Oncology Programs. The ACR accreditation involves a site visit where inspectors review charts of patients treated within the past years for certain diseases, review patient treatment (modality, method of treatment, recalculations), and issue a report of their findings. ACR also offers accreditation of Nuclear Medicine Departments.
4. Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) - The QA program that JCAHO recommends is a generalized quality improvement (QI) program. JCAHO conducts surveys of healthcare organizations which involve reviews of each organization's quality assurance program(s). Data collected by JCAHO is made available to both federal and state agencies.
5. Health Care Financing Administration (HCFA) - HCFA is responsible for accreditation for purposes of Medicare/Medicaid reimbursement. A major factor in HCFA's process is prior accreditation or removal of such by JCAHO.
6. American College of Nuclear Physicians (ACNP) - The ACNP uses a "practice audit program" that is available to any nuclear medicine physician or department to provide an assessment of the quality of nuclear medicine practice.

These programs would need to be reviewed to determine if they are equivalent to the needs of NRC's regulatory program. Some of these may have to undergo significant modifications to be compatible with NRC regulations and inspection and enforcement programs. Should the NRC recognize these voluntary programs, in full or in part, and waive or reduce the frequency of inspections if the licensee participates in an independent audit program? Should NRC take enforcement action on the basis of the findings of these audits?

In conclusion, the following questions are of primary concern: What inspection methods and enforcement options provide the greatest incentive for maintaining and improving effective safety programs? Is there an appropriate balance between regulatory compliance and program safety? If not, what steps/actions could be taken to achieve an appropriate balance?

APPENDIX D

MEDICAL SUPERVISION INCLUDING RELATED TRAINING AND EXPERIENCE ISSUES

Background

Medical use licenses are unique in the sense that justification for the use of radioactive material in the practice of medicine requires that all use be at the direction of a physician. Historically, supervision of the use of licensed material for medical purposes has been restricted to physicians. Consequently, NRC's training and experience criteria has focussed primarily upon physician authorized users. In the earliest days of medical uses of radioactive materials, the physician was frequently the only individual who provided the training to and oversight of any other personnel. Current practice frequently differs from this model. Training and certification programs now exist for other specialties in medical use of radioisotopes. These include: nuclear medicine technology, radiation therapy technology, medical physics, nuclear pharmacy and therapy dosimetry. In many licensed programs, the actual involvement of the physician authorized user has in practice become more narrowly focused on the selection of patients, medical procedure and prescribed dose.

The day-to-day supervision of radiation safety is more frequently assigned to one of these other specialists than to the physician authorized user. The NRC staff, recognizing that the physical presence of the physician authorized user is not necessarily required for safe use of material, has accepted a varying range of involvement by physicians. This creates compliance and enforcement problems when the physician user has so little involvement that the claim of adequate supervision appears to a reasonable person to be insupportable. However, adequate supervision is often being exercised by a non-physician who has substantial training in radiation safety. In practice, NRC inspectors have had difficulty documenting truly unsupervised radiation safety programs as opposed to adequate programs with small involvement by the named authorized user.

Training and experience has been and will continue to be an on-going issue for the NRC particularly in light of the supervision issue. An Advance Notice of Proposed Rulemaking regarding training and experience for all individuals involved with the medical use of byproduct material was published in the Federal Register in May 1988. The Commission received 94 comment letters in response. Using this information and the results of a contractor study on training and experience criteria for personnel involved in the medical use of byproduct material, the staff prepared an analysis and proposed course of action which was presented at the July 10, 1990 meeting of the Advisory Committee on Medical Uses of Isotopes (ACMUI). At that meeting, the ACMUI voted against modifying NRC requirements for physicians who perform only limited nuclear procedures, and recommended that NRC do nothing about required training and experience criteria for technologists and other non-physician workers unless additional data indicated that specific required training of these groups could minimize reported events.

NRC policy currently requires that every authorized physician user receive training adequate to supervise a radiation safety program, with the result

that primary and secondary care physicians must invest considerable post-residency time toward radiation safety training to qualify as an authorized user who can directly order and interpret scans. However, the techniques of nuclear imaging have matured to the point that other physician specialists wish to request and perform nuclear medicine procedures and interpret the results of nuclear images in the course of the practice of their specialty. Thus, the NRC is in the path of access to and control of these procedures. The NRC involvement in authorizing physicians is expected to play an ever increasing role in the reimbursement of physicians and therefore NRC could be increasingly the focus of a professional turf battle. An example of this is the controversy between nuclear medicine physicians and cardiologists specializing in nuclear cardiology as to what they believe NRC considers to be the necessary qualifications to interpret nuclear scans. In an effort to address this, the Board of Internal Medicine examiners is currently developing a board certification in imaging cardiology which includes training in radiation safety and protection.

Discussion

The NRC and its predecessor, the Atomic Energy Commission, have required physicians to have didactic, practical and clinical training and experience before authorization to use byproduct material for medical purposes. Currently, 10 CFR Part 35, Subpart J outlines specific criteria for training and experience for Radiation Safety Officers, physician authorized users and teletherapy physicists. These include either board certification or specific time in three areas: classroom and laboratory, supervised work experience, and clinical experience. Should training and experience requirements be general and basic radiation sciences and radiation safety or should they remain more specific to the users' intended use of material? Are the current criteria necessary if the physician does not bear the primary responsibility for radiation safety? If needed, could the training and experience requirements for a physician user not seeking authorization to supervise radiation safety be less than the current six month program? Is the training and experience of an authorized user physician sufficient to qualify him/her as an RSO?

NRC has a "preceptor" process in place for documentation of training received by physician applicants who are not certified by one of the professional boards currently recognized in Part 35, Subpart J. There is some concern that this process requires no commitment by the preceptoring individual regarding the quality of the documented training. The staff has embarked on two endeavors to evaluate the current preceptor process for physician authorized users: 1) Myron Pollycove, M.D., Medical Visiting Fellow, is discussing with the medical community such issues as the type and quality of training needed by physician applicants, the feasibility of task-oriented training requirements, and the mechanism for defining the qualifications needed by the trainer; and 2) revising Supplements A and B to NRC Form 313, "Application for Materials License", to solicit a more detailed description of the training received by the applicant and to require certification by the preceptor that the training occurred as documented and was successfully completed by the physician to be designated as an authorized user. Should NRC become involved in monitoring the adequacy of consultant radiation safety courses, residency programs, and board certification courses as they relate to radiation safety?

Current NRC training requirements for an authorized user of a radiopharmaceutical, generator, or reagent kits for imaging and localization studies include either: 1) board certification; or 2) 200 hr classroom and laboratory, 500 hr supervised work experience, and 500 hr of clinical experience not to be completed in less than six months. With each new development in the medical use of isotopes, practitioners from affected medical specialties want to take advantage of the new technologies. Are the criteria listed in 10 CFR 35.920, "Imaging and localization studies" in need of revision or clarification? Similarly, the development of new therapeutic radiopharmaceuticals has focused attention on NRC's current training and experience requirements for the use of radiopharmaceuticals in therapy (board certification or 80 hr classroom and laboratory and supervised clinical experience) and the need to assess the adequacy of those requirements. Are the criteria listed in 10 CFR Part 35.930 sufficient for physicians who wish to be authorized to use radiopharmaceuticals for therapy?

Training and experience of personnel who handle byproduct material, other than the physician, Radiation Safety Officer, and teletherapy physicist, is not addressed in 10 CFR Part 35. NRC recognizes that other individuals involved in the use of byproduct material in the practice of medicine (e.g. technologists, physicists, nurses, dosimetrists, etc.) may have certification or registration credentialling requirements. However, as in the case of physician authorized users, there must be an alternative to these credentials. Should there be some minimum level of training and experience described in Part 35 for <u>any</u> of the personnel involved in the medical use of byproduct material? Since technologists perform the majority of isotope handling, should there be a minimum training and experience requirement for technologists who use byproduct material for diagnostic and/or therapeutic procedures? Should some radiation training and experience be required of other individuals who handle byproduct material and patients treated with byproduct material (e.g., nurses, volunteers)?

Separation of physician supervision from radiation supervision would permit consideration of changes to the regulatory program. Approval of remote sites where it is difficult to retain specialized physician services could be accommodated more easily if a qualified technologist were available to supervise day-to-day handling of byproduct material. Should the NRC require the physical presence of a qualified radiation supervisor (physician, physicist, pharmacist or technician) at all times when byproduct material is being used? Should there be some minimal level of training for authorized supervisors who are responsible for the day-to-day safety issues associated with the administration of byproduct material? What level of training would be necessary for authorized supervisors under circumstances when a single physician may supervise several facilities, or even remote facilities using modern communications equipment? Should NRC issue licenses where the only physician authorized user is available only by phone if a qualified technologist is on site?

At a recent workshop on medical issues with Agreement State representatives in Atlanta, several participants suggested elimination of any requirements for medical authorized users to be physicians only and to have authorization of use based solely on an individual's radiation safety training and/or responsibility. If the NRC should elect to authorize non-physician radiation supervisors on medical licenses, is a separate category of authorized user

physician needed? If the NRC allows a non-physician authorized supervisor to bear the primary responsibility for radiation safety, does NRC need to continue to evaluate physician training and experience?

These types of considerations would involve re-examination of the duties and responsibilities of the radiation safety officer (RSO) and perhaps the development of training and experience criteria for individuals other than physicians who might be classified as authorized supervisors. What should NRC do to further define the duties and responsibilities of the RSO and should there be a testing process specific to serving in this capacity?

APPENDIX E

COMMUNICATION

Background

NRC has various means available to communicate with the regulated medical community. Workshops, bulletins, licensing actions, inspections, and enforcement actions provide interactive communication between the NRC and the licensees. The NMSS newsletter is a quarterly publication that is mailed to all materials licensees, Agreement States, and interested parties. The newsletter contains articles on subjects of regulatory interest, describes significant enforcement actions, and lists recent Regulatory Guides, Information Notices, and Federal Register notices. In addition, the staff prepares and mails Information Notices to medical licensees to inform them of specific events, safety issues, and NRC actions that have safety significance. Generic letters are used as a means to address specific topics of importance to all licensees.

NRC licensees and the general public have the opportunity to provide input on new regulations under consideration through a public comment period for Advance Notices of Proposed Rulemakings and Notices of Proposed Rulemakings that are published in the Federal Register.

Discussion

The NRC has means to provide information to and communicate with the regulated community, however, the communication is directed to the licensee rather than the individuals directly involved with the use and handling of byproduct material. There is a perception among some in the regulated community that the communication does not always get down to the individual user level in language that is readily understood. Should NRC be responsible for communicating directly with the individual user or should the licensee be responsible for communicating to the user what the NRC has sent to licensees? Is there a mechanism by which NRC can improve two-way communication between NRC and all groups of the medical community (including those users in Agreement States) and the general public?

The staff regularly conducts and participates in licensee workshops that stress safety and compliance issues. Are the number and scope of NRC workshops adequate to meet licensees' needs?

In addition, the staff provides presentations to seminars and meetings sponsored by professional organizations as well as publishing articles in professional publications. Attendance at professional meetings allows the staff to meet with licensees in a neutral environment. Should NRC increase its participation and/or attendance in professional seminars and meetings? Is there value in NRC staff meeting with licensees in a neutral environment?

The communications listed above are mailed to all of the Agreement States. Many of these documents are not passed on to individual licensees. Is there a way to improve communication with Agreement State licensees?

The ACMUI provides insight into the medical communities' views regarding

rulemakings and some policy decisions. Recently, the Commission has directed the staff to expand the representation on the ACMUI to include groups other than the medical community (e.g. patient rights advocate). Is the ACMUI membership now broad enough to represent the varied interests in the regulation of the medical use of byproduct material?

NRC implemented a Medical Visiting Fellows program in 1991. The Fellows have been instrumental in improving communications with members of the medical community through ongoing interactions at professional and ACMUI meetings, as well as other opportunities, and providing feedback to NRC staff on key medical use issues. The staff anticipates that NRC's knowledge of the medical community and its relationship with its members will continue to improve by utilizing the Fellows in their role as liaison. Has this program been viewed positively by the medical community?

At this point in time, the only communication NRC has with the general public on medical issues (those who are receiving the radiation exposure) is through Federal Register notices. Should public meetings be noticed in a publication more readily available to the medical community (e.g., professional journal, newsletters) and the general public (e.g., major newspaper) than is the Federal Register?

NRC is currently conducting a materials licensees regulatory impact survey. This study requires looking at the 9 largest material licensees in each of the fuel cycle, commercial, and medical areas to assess the impact of regulations on their operations. What other surveys or measures could NRC use to assess the impact of its rules in maintaining or increasing safety in the use of byproduct material?

APPENDIX F

OTHER ISSUES

Are there any other programmatic issues and alternative approaches to regulation not yet identified by the staff which should be discussed and evaluated?

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Are there any other programmatic issues and alternative approaches to regulation not yet identified by the staff which should be discussed and evaluated?

APPENDIX A

MEDICAL POLICY STATEMENT

Are the three principles in the medical policy statement appropriate?

If not, what parts of the medical policy statement should be revised?

Since the policy statement is subject to reinterpretation as the Commission changes, is it sufficiently specific to keep the medical use program on track while allowing accomodation of technological development?

Should a line item be included in the statements of consideration of any new rule to discuss its relationship with the medical policy statement?

APPENDIX B

10 CFR PART 35

Are there new issues that should be incorporated or added into the current rule?

Is the rule, or are parts of the rule, too prescriptive or not detailed enough?

Should the rule be entirely performance-based?

What techniques should NRC use to identify potential new rulemaking endeavors?

What level of research and analysis should be used to make the decision to forward with rulemaking?

Are there any other provisions of 10 CFR Part 35 that interfere with effective regulation of the medical licensees?

Is there evidence that either the submittal of QM programs or the subsequent recordkeeping requirements have posed an undue burden on medical licensees?

Is there evidence that the use of the term "misadministration" has had a negative impact on the practice of medicine or directly resulted in medical malpractice suits?

Are there any examples that the QM rule is an encroachment on the practice of medicine?

APPENDIX C

INSPECTION AND ENFORCEMENT

Do NRC inspections focus on those aspects of a program which are most important to radiation safety?

Does the NRC policy of unannounced inspections achieve its purpose of reviewing radiation safety practices as they are normally performed?

Is NRC placing the appropriate emphasis on the use of NCVs and Form 591s?

Is the current inspection and enforcement program effective in identifying and correcting radiation safety concerns?

Which aspects of the inspection and enforcement program are most effective?

Are civil penalties and press releases an adequate deterrent?

Do existing requirements allow sufficient flexibility to deal with emerging problems or unforeseen circumstances without resulting in violations?

Should the NRC recognize voluntary accreditation and audit programs, in full or in part, and waive or reduce the frequency of inspections if the licensee participates in an independent audit program?

Should NRC take enforcement action on the basis of the findings of these audits?

What enforcement options provide the greatest incentive for maintaining and improving effective safety programs?

Is there an appropriate balance between regulatory compliance and program safety? If not, what steps/actions could be taken to achieve an appropriate balance?

APPENDIX D

MEDICAL SUPERVISION INCLUDING RELATED TRAINING AND EXPERIENCE ISSUES

Should training and experience requirements be general and basic radiation sciences and radiation safety or should they remain more specific to the users' intended use of material?

Are the current criteria necessary if the physician does not bear the primary responsibility for radiation safety? If needed, could the training and experience requirements for a physician user not seeking authorization to supervise radiation safety be less than the current six month program?

Is the training and experience of an authorized user physician sufficient to qualify him/her as an RSO?

Should NRC become involved in monitoring the adequacy of consultant radiation safety courses, residency programs, and board certification courses as they relate to radiation safety?

Are the criteria listed in 10 CFR 35.920, "Imaging and localization studies" in need of revision or clarification?

Are the criteria listed in 10 CFR Part 35.930 sufficient for physicians who wish to be authorized to use radiopharmaceuticals for therapy?

Should there be some minimum level of training and experience described in Part 35 for <u>any</u> of the personnel involved in the medical use of byproduct material?

Since technologists perform the majority of isotope handling, should there be a minimum training and experience requirement for technologists who use byproduct material for diagnostic and/or therapeutic procedures?

Should some radiation training and experience be required of other individuals who handle byproduct material and patients treated with byproduct material (e.g., nurses, volunteers)?

Should the NRC require the physical presence of a qualified radiation supervisor (physician, physicist, pharmacist or technician) at all times when byproduct material is being used?

Should there be some minimal level of training for authorized supervisors who are responsible for the day-to-day safety issues associated with the administration of byproduct material?

What level of training would be necessary for authorized supervisors under circumstances when a single physician may supervise several facilities, or even remote facilities using modern communications equipment?

Should NRC issue licenses where the only physician authorized user is available only by phone if a qualified technologist is on site?

If the NRC should elect to authorize non-physician radiation supervisors on medical licenses, is a separate category of authorized user physician needed?

If the NRC allows a non-physician authorized supervisor to bear the primary responsibility for radiation safety, does NRC need to continue to evaluate physician training and experience?

What should NRC do to further define the duties and responsibilities of the RSO and should there be a testing process specific to serving in this capacity?

APPENDIX E

COMMUNICATION

Should NRC be responsible for communicating directly with the individual user or should the licensee be responsible for communicating to the user what the NRC has sent to licensees?

Is there a mechanism by which NRC can improve two-way communication between NRC and all groups of the medical community (including those users in Agreement States) and the general public?

Are the number and scope of NRC workshops adequate to meet licensees' needs?

Should NRC increase its participation and/or attendance in professional seminars and meetings?

Is there value in NRC staff meeting with licensees in a neutral environment?

Is there a way to improve communication with Agreement State licensees?

Is the ACMUI membership now broad enough to represent the varied interests in the regulation of the medical use of byproduct material?

Has the Medical Visiting Fellows program been viewed positively by the medical community?

Should public meetings be noticed in a publication more readily available to the medical community (e.g., professional journal, newsletters) and the general public (e.g., major newspaper) than is the Federal Register?

What other surveys or measures could NRC use to assess the impact of its rules in maintaining or increasing safety in the use of byproduct material?

GOOD SAMARITAN HOSPITAL

REGIONAL MEDICAL CENTER

PHOENIX, ARIZONA

- DESCRIPTION OF EVENT
- CONTRIBUTORS TO THE EVENT
- ENFORCEMENT ACTIONS
- CURRENT STATUS

DESCRIPTION OF THE EVENT

- FOUR PATIENTS RECEIVED UP TO 40 % EXCESS RADIATION.

CONTRIBUTORS

LICENSEE

- MISUSED COBALT-60 WEDGE FACTOR.
- FAILURE TO MONITOR THE RADIATION SAFETY PROGRAM AS COMMITTED TO IN THE LICENSE.

ENFORCEMENT ACTIONS

LICENSEE

- USNRC PROVIDED A MEDICAL PHYSICIST CONSULTANT.
- PROPOSED A $3,000 CIVIL PENALTY, REVISED UPWARD TO $7,000 AFTER FIRST RESPONSE AND RECEIPT OF ADDITIONAL INFORMATION.
- ENFORCEMENT CONFERENCE.

CURRENT STATUS

- HIRED A FULL TIME MEDICAL PHYSICIST AND ASSURED PROPER STAFFING OF THE ONCOLOGY DEPARTMENT.
- INSURED THAT THE RADIATION SAFETY COMMITTEE WAS PROPERLY ATTENDED AND SUPPORTED BY ALL PRIMARY RAM USERS.
- INSURED THAT THE WEDGE FACTORS

WERE PROPERLY USED IN CALCULATING PATIENT EXPOSURE TIMES.

- INSURED THAT ALL ELEMENTS OF THE GOOD SAMARITAN RADIATION SAFETY PROGRAM WERE PROPERLY EVALUATED AND ANY SHORTFALLS CORRECTED.
- LICENSEE IN COMPLIANCE.

DESERT SAMARITAN HOSPITAL AND

HEALTH CENTER

MESA, ARIZONA

- DESCRIPTION OF EVENT
- CONTRIBUTORS TO THE EVENT
- ENFORCEMENT ACTIONS
- CURRENT STATUS

DESCRIPTION OF THE EVENT

- PATIENT RECEIVED 100 MILLICURIES INSTEAD OF 100 MICROCURIES.
- AGENCY ESTIMATED 211K RADS THYROID AND 167 RADS WHOLE BODY TO PATIENT
- AGENCY ESTIMATED 3 RADS THYROID AND 2 MILLIRADS WHOLE BODY DOSE TO 4 TO 5 YEAR OLD CHILDREN, LESS TO OLDER CHILDREN

ISSUES

- AUTHORIZED USER DUTIES
  - SELECT
  - PRESCRIBE
  - INTERPRET

- USER DUTY VS GOVERNMENT DUTY
  - CALIBRATION OF OUTPUT
  - ENTERING IMPROPER DATA
  - SOFTWARE ERRORS

MEDICAL CONSULTANTS

1. ACCIDENTS
   - A. DEFINE ALL INJURIES
   - B. ASSURE CARE OPPORTUNITY
   - C. LONG TERM (?)

2. MISADMINISTRATIONS
   - A. DEFINE ALL INJURIES
   - B. ASSURE CARE OPPORTUNITY
   - C. LONG TERM (?)

CONTRIBUTORS

LICENSEE

- FAILED TO CONFIRM DOSE WITH DOSE CALIBRATOR
- FAILED TO SURVEY INCOMING PACKAGE
- FAILED TO COMPARED PRECRIBED DOSE WITH DELIVERED DOSE

RADIOPHARMACEUTICAL SUPPLIER

- FAILED TO RECORD THE TELEPHONE PRESCRIPTION LEGIBLY
- FAILED TO CONFIRM DOSE FOR THERAPY USE
- IDENTITY OF INDIVIDUALS INVOLVED IN TELEPHONING THE PRESCRIPTION NOT RECORDED
- NAME OF PATIENT NOT IDENTIFIED IN RADIOPHARMACY RECORDS

ENFORCEMENT ACTIONS

LICENSEE

- $12,000 CIVIL PENALTY
- POSSESSION LIMIT FOR IODINE 131 REDUCED TO 100 MICROCURIES FROM 500 MILLICURIES

RADIOPHARMACEUTICAL SUPPLIER

- MUST CONFIRM THERAPY DOSE IF IODINE 131 GREATER THAN 1 MILLICURIE ORDERED
- PATIENT' NAME MUST BE ON PRESCRIPTION
- NAME OF INDIVIDUAL ORDERING THE DOSE

CURRENT STATUS

- LICENSEE IN COMPLIANCE
- PATIENT - LICENSE SETTLED LAWSUIT, DETAILS NOT AVAILABLE
- ACTIVITY RESTRICTION HAVE BEEN LIFTED
- RADIOPHARMACEUTICAL SUPPLIER CONTINUES SPECIAL REQUIREMENTS FOR IODINE 131 THERAPY DOSES