

# UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION

Title: BRIEFING BY AGREEMENT STATES ON THEIR  
ACTIVITIES IN MEDICAL USE AREA

Location: ROCKVILLE, MARYLAND

Date: JANUARY 29, 1993

Pages: 116 PAGES

**SECRETARIAT RECORD COPY**

NEAL R. GROSS AND CO., INC.

COURT REPORTERS AND TRANSCRIBERS  
1323 Rhode Island Avenue, Northwest  
Washington, D.C. 20005  
(202) 234-4433

# DISCLAIMER

This is an unofficial transcript of a meeting of the United States Nuclear Regulatory Commission held on January 29, 1993 in the Commission's office at One White Flint North, Rockville, Maryland. The meeting was open to public attendance and observation. This transcript has not been reviewed, corrected or edited, and it may contain inaccuracies.

The transcript is intended solely for general informational purposes. As provided by 10 CFR 9.103, it is not part of the formal or informal record of decision of the matters discussed. Expressions of opinion in this transcript do not necessarily reflect final determination or beliefs. No pleading or other paper may be filed with the Commission in any proceeding as the result of, or addressed to, any statement or argument contained herein, except as the Commission may authorize.

NEAL R. GROSS  
COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVENUE, N.W.  
WASHINGTON, D.C. 20005

(202) 234-4433

(202) 232-6600

1 UNITED STATES OF AMERICA  
2 NUCLEAR REGULATORY COMMISSION

3 \* \* \*

4 BRIEFING BY AGREEMENT STATES ON THEIR ACTIVITIES  
5 IN MEDICAL USE AREA

6 \* \* \*

7 PUBLIC MEETING

8 \* \* \*

9 Nuclear Regulatory Commission

10 One White Flint North

11 Rockville, Maryland

12  
13 Friday

14 January 29, 1993  
15

16 The Commission met in open session, pursuant to  
17 notice, at 2:00 p.m., the Honorable IVAN SELIN, Chairman  
18 of the Commission, presiding.  
19

20 **COMMISSIONERS PRESENT:**

21 IVAN SELIN, Chairman of the Commission

22 KENNETH C. ROGERS, Member of the Commission

23 JAMES R. CURTISS, Member of the Commission

24 FORREST J. REMICK, Member of the Commission

25 E. GAIL de PLANQUE, Member of the Commission

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1     **STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:**

2             SAMUEL J. CHILK, Secretary

3             WILLIAM C. PARLER, General Counsel

4             HUGH THOMPSON, Assistant Deputy Executive  
5             Director for Operations

6             G. WAYNE KERR, Chairman, Organization of  
7             Agreement States

8             TOM HILL, Past Chairman, Organization of  
9             Agreement States

10            MARY CLARK, Chairman Elect, Organization of  
11            Agreement States

12            CARL KAMMERER, Director, Office of State  
13            Programs, NRC

14            AUBREY GODWIN, Director, Arizona Regulatory  
15            Agency

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

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

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

22  
23  
24  
25                    **NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

17 (No response.)

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 Chair Elect, from the State of Florida.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 certainly do investigations in Illinois, but we do not  
2 have a staff dedicated to investigations. I'm aware of  
3 only one state that does. Texas has had such a unit since  
4 1981. But we get the job done anyway and, it sometimes  
5 can be argued, with more vigor than NRC. State programs  
6 do have the advantage of being in closer proximity to the  
7 regulated facilities, and in the case of facilities that  
8 also use x-ray machines, we inspect those facilities for  
9 all sources of radiation, with the result being a more  
10 frequent presence. As a result of an NRC suggestion,  
11 Illinois does have an Incident Review Committee which  
12 meets monthly to review events involving either  
13 radioactive materials or electronic product machines.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 We think so.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

25 The program is administered by 16 health physics

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

15 We took 698 licensing actions in 1991 and 756 in  
16 1992. We do pre-licensing visits for those with complex  
17 actions and, when deemed necessary, do obtain clarifying  
18 information. We performed 13 in the last two years.

19 Our inspection priority system for specific  
20 licensees is similar to NRC's except our maximum interval  
21 is four years. Thus, we are nearly identical on the high  
22 priority licensees, but more frequent than NRC on the  
23 lower priority licensees. We conducted 375 inspections in  
24 1991 and 300 in 1992. We issued three orders in the last  
25 two years as follows: First, a physician for unsupervised

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 medicine techs, and radiation therapy techs. There are  
2 currently about 8700 technologists accredited in Illinois.  
3 Of these, about 800 are nuclear medicine techs and about  
4 500 are therapy technologists, which includes x-ray,  
5 accelerator, teletherapy, and brachytherapy.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

8 COMMISSIONER de PLANQUE: Before you go on --

9 MR. KERR: Yes?

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

10 COMMISSIONER de PLANQUE: Okay.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 kind of interesting to have them do that.

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

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

13 COMMISSIONER REMICK: Thank you.

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

16 MR. HILL: Thank you, Mr. Chairman and members  
17 of the Commission. It's a pleasure meeting with you  
18 again, continuing our discussion of issues of mutual  
19 concern. Since I met with the Commission on June the  
20 11th, 1991, to discuss compatibility issues, we have  
21 participated in meetings and workshops with NRC. The  
22 Agreement States provided early input into NRC  
23 rulemakings, most notably, Parts 34 and 35. Today, I must  
24 report to you that the Joint NRC-Agreement State Committee  
25 recommended by the Agreement States to develop a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 compatibility strategy has not yet been established.

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

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

6 (Laughter.)

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

25           Now, one of the places where we feel there has

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

3 CHAIRMAN SELIN: Thank you, Mr. Hill.

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

15 During calendar year 1992 we conducted 124  
16 inspections and completed 819 licensing actions. A total  
17 of 539 of those licensing actions administratively amended  
18 or added a license fee condition. Twenty-nine percent, or  
19 81, of the remaining licensing actions were new or renewal  
20 applications.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 MR. HILL: Thank you.

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

8 (Laughter.)

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

17 MR. HILL: Okay. Dr. Clark?

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

14 (Laughter.)

15 MR. HILL: Well, two and a half years ago, we  
16 were split apart. Legislation went forward that removed  
17 the Radioactive materials Program from Human Resources,  
18 and placed it in Natural Resources. Keep in mind that  
19 when the Department of Natural Resources was formed in  
20 1972, part of the Environmental Radiation Monitoring  
21 Program went to the Department of Natural Resources  
22 shortly thereafter, and a few years later emergency  
23 response responsibility went there. And now, several  
24 years later, the Materials Licensing Program has been  
25 moved to that department.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

18           COMMISSIONER REMICK: Anybody agree or disagree  
19 with that?

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

13 COMMISSIONER REMICK: Okay. Thank you.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

22 CHAIRMAN SELIN: Dr. Clark.

23 MR. KERR: Yes, Dr. Clark.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 opportunity to explain briefly my state's radiation  
2 protection program. Florida became an Agreement State in  
3 1964, and we currently have over 1100 specific licenses.  
4 Approximately half of these are for medical purposes. In  
5 addition, we have over 500 general licenses. We inspect  
6 medical licenses with greater frequency than does the NRC  
7 in most categories. Last year, we inspected over 500  
8 licensees.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

3 Our program is fee-supported with our fee  
4 schedule not tied to that of the NRC's. We took about  
5 1300 licensing actions in 1991, and about 1400 in 1992.  
6 We have the authority to administer fines for the  
7 radioactive materials, x-ray and radiologic technologist  
8 programs, and we do administer fines.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

23 (Laughter.)

24 MR. KERR: Yes.

25 CHAIRMAN SELIN: Any other questions?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

16 COMMISSIONER de PLANQUE: Okay. Thank you.

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

21 MR. KERR: No. First, Commissioner, in terms of  
22 our own state; I'm not sure what the others have done, I  
23 don't think so. Our rule only went in effect in July,  
24 1991. Now, we were continuing to get reports from the NRC  
25 rule that was in place when we became an Agreement State.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

10 MR. KERR: Yes.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

9 COMMISSIONER ROGERS: Yeah.

10 MR. KERR: Appreciate your comment.

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

13 COMMISSIONER REMICK: Excuse me, Mr. Chairman.

14 CHAIRMAN SELIN: Oh, excuse me, Commissioner  
15 Remick.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

20 COMMISSIONER REMICK: Yes.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

5 CHAIRMAN SELIN: Commissioner Remick, are you  
6 through?

7 COMMISSIONER REMICK: Yes.

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

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

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

25 MR. HILL: We have not followed up on -- with  
NEAL R. GROSS

1 the patient either.

2 COMMISSIONER REMICK: But you do perform an  
3 inspection --

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

9 COMMISSIONER REMICK: Okay.

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

15 COMMISSIONER REMICK: Thank you very much.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

7 (Laughter.)

8 COMMISSIONER ROGERS: Micromanagement.

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

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

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

22 (Laughter.)

23 MR. GODWIN: I'm not real sure.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

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

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

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

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

25           MR. GODWIN: Iodine 131.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

5 COMMISSIONER REMICK: I see.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

4 This resulted in a \$12,000 civil penalty to the  
5 facility, and for a short time a reduction to using over  
6 100 microcuries of iodine. That subsequently was lifted  
7 after they demonstrated they were able to institute  
8 necessary safety programs. Next slide. (Slide)

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

19 MR. GODWIN: That's correct.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 to the endpoint. Next slide. (Slide)

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

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

7 MR. THOMPSON: That's correct.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

20 The incident I'm here to describe today to you  
21 is one that occurred, resulted in a death on August 21st,  
22 1988, of Dwight Gregory Goldstein, II, who died at  
23 Children's Hospital in Oakland, California. According to  
24 the death certificate, the death was caused by respiratory  
25 failure, and I quote, "due to, or as a consequence of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 radiation damage".

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

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

22 CHAIRMAN SELIN: Different management of risk.

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

25 (Laughter.)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

24 Treatment of the patient began on December 4,  
25 1987, and continued on a daily basis, except for the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

25 On March 1st, 1988, a routine inspection had

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

23 Following discussions with Mr. Kammerer of the  
24 Office of State Programs, I fax'd him a letter on January  
25 14th requesting assistance from NRC of an investigator

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

6 CHAIRMAN SELIN: Mr. Godwin?

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

15 COMMISSIONER CURTISS: Okay.

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

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

25 We also do other things with a staff of just a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

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

25 CHAIRMAN SELIN: Do your rules require that the  
NEAL R. GROSS

1 patients or the families be told?

2 MR. FLETCHER: No, not by us.

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

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

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

12 MR. FLETCHER: Yes.

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

16 MR. FLETCHER: Right. We're in the process of -  
17 -

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

9 COMMISSIONER ROGERS: Just continue.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



1 Services as a weekly consultant.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

12 It's interesting, January the 10th of this year  
13 was the 30th anniversary of our signing an agreement with  
14 the Commission, and March the 1st of this year will be the  
15 30th anniversary of the effective date of that agreement,  
16 and I've been there all that time -- (laughter) -- which  
17 may be indicative of something, I'm not sure.

18 (Laughter.)

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

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

25 While our administrative penalties rules don't

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

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

20 COMMISSIONER de PLANQUE: Okay.

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

22 COMMISSIONER de PLANQUE: Was this technologist  
23 credentialed?

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 COMMISSIONER de PLANQUE: At that time.

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

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

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

15 A patient was being treated on the right side of  
16 his face with the accelerator. The operator pressed the  
17 treatment button, the machine shut down and indicated  
18 malfunction 54 on the screen. The operator went into the  
19 room, and the patient was struggling to get up. He  
20 complained of a sharp pain in his ear and a warm  
21 sensation. He said he saw a flash of light. Later he  
22 suffered from nausea and vomiting. The physicist went on  
23 to report that another incident had occurred on March the  
24 21st to another patient who was receiving a treatment in  
25 the scapular area. The machine had shut off automatically

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

11 COMMISSIONER CURTISS: Do you have civil penalty  
12 authority?

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 years, how many administrative penalties you have issued?

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

5 COMMISSIONER CURTISS: And the time frame for  
6 that is?

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

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

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

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

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

15 COMMISSIONER CURTISS: Would you, please?

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

9 COMMISSIONER CURTISS: I have some other  
10 questions.

11 COMMISSIONER ROGERS: Please go right ahead.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 we can go in whatever order you'd like.

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

4 (Laughter.)

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

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

10 COMMISSIONER CURTISS: Attrition rate.

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

14 COMMISSIONER CURTISS: Present company excluded.

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

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

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

25 COMMISSIONER CURTISS: They were current. Okay.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

10 COMMISSIONER REMICK: Was it part of a consent  
11 agreement?

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

18 We have a 26 percent attrition rate.

19 COMMISSIONER CURTISS: You are up at your  
20 authorized level?

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

23 COMMISSIONER CURTISS: Okay.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 COMMISSIONER ROGERS: Per year?

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

21           COMMISSIONER CURTISS:   Yes.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

10 MR. GODWIN: Yes.

11 MR. BAILEY: Yes.

12 MR. FLETCHER: Yes.

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

17 MR. GODWIN: Yes.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 COMMISSIONER REMICK: Okay.

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

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

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

25 COMMISSIONER REMICK: You're not paying the  
NEAL R. GROSS

1 doctor, though.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

3 (Laughter.)

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

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

17 COMMISSIONER REMICK: Any differences or an  
18 agreement?

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

17 CHAIRMAN SELIN: We're not done yet.

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

20 (Laughter.)

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 these high energy accelerators.

2 COMMISSIONER de PLANQUE: Yes.

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

12 COMMISSIONER de PLANQUE: Yes.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

21 COMMISSIONER de PLANQUE: Okay.

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 (Laughter.)

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 they are to make a stupid -- or --

2 COMMISSIONER de PLANQUE: The less likely they  
3 are.

4 (Laughter.)

5 MR. BAILEY: Yeah.

6 COMMISSIONER de PLANQUE: It's getting late.

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 would work in the general public.

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 CHAIRMAN SELIN: Commissioner Rogers?

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

19 COMMISSIONER ROGERS: Oh, I know that very well.

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

25           MR. BAILEY: Well, I think --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

1 MR. GODWIN: It's public spirit --

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005



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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

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

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

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

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

8 MR. GODWIN: Thank you.

9 MR. BAILEY: Thank you.

10 (Whereupon, at 4:40 p.m., the meeting was  
11 adjourned.)  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVENUE, N.W.

WASHINGTON, D.C. 20005

CERTIFICATE OF TRANSCRIBER

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

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

PLACE OF MEETING: ROCKVILLE, MARYLAND

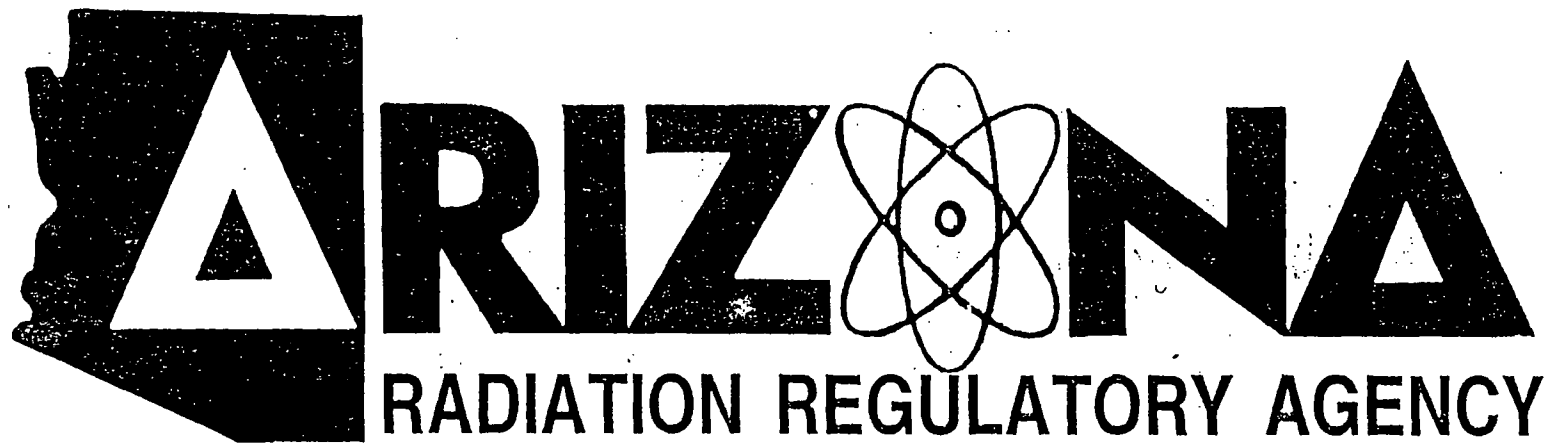
DATE OF MEETING: JANUARY 29, 1993

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

**NEAL R. GROSS**  
COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVENUE, N.W.  
WASHINGTON, D.C. 20005





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 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 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 1<sup>st</sup>, 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 ( $\frac{1}{3}$ ) of yours.

### ENFORCEMENT AND CIVIL PENALTIES

Our Rules and Regulations provide for enforcement, including civil penalties. All enforcement activities including assessment 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<sup>1</sup>. 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?

<sup>1</sup> 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 credentialing 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 any 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?**

## **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?**

## 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 any 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 MILLICURI**



## **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**