

**UNITED STATES OF AMERICA**  
**NUCLEAR REGULATORY COMMISSION**

**Title:            BRIEFING BY NATIONAL ACADEMY OF  
                     SCIENCES ON REVIEW OF MEDICAL USE  
                     PROGRAM - PUBLIC MEETING**

**Location:        Rockville, Maryland**

**Date:            Tuesday, February 27, 1996**

**Pages:          1 - 62**

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1 UNITED STATES OF AMERICA  
2 NUCLEAR REGULATORY COMMISSION

3 - - -

4 BRIEFING BY NATIONAL ACADEMY OF SCIENCES  
5 ON REVIEW OF MEDICAL USE PROGRAM

6 - - -

7 PUBLIC MEETING

8  
9 Nuclear Regulatory Commission  
10 One White Flint North  
11 Rockville, Maryland  
12 Tuesday, February 27, 1996  
13

14 The Commission met in open session, pursuant to  
15 notice, at 2:00 p.m., Shirley A. Jackson, Chairman,  
16 presiding.  
17

18 COMMISSIONERS PRESENT:

19 SHIRLEY A. JACKSON, Chairman of the Commission  
20 KENNETH C. ROGERS, Commissioner  
21 GRETA J. DICUS, Commissioner  
22  
23  
24  
25

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1 STAFF SEATED AT THE COMMISSION TABLE:

2 JOHN C. HOYLE, Secretary of the Commission

3 MARTIN MALSCH, Deputy General Counsel

4

5 COMMITTEE MEMBERS PRESENT:

6 CHARLES E. PUTMAN, Chairman

7 KATE-LOUISE GOTTFRIED, Study Director

8 WILLIAM HENDEE

9 JOHN VILLFORTH

10 DAVID GOODEN

11 THEODORE PHILLIPS

12 GARY PENN

13 CARL PAPERIELLO, Director, NMSS

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

[2:00 p.m.]

1  
2  
3 CHAIRMAN JACKSON: Good afternoon, ladies and  
4 gentlemen. The Commission would like to welcome members of  
5 the National Academy of Sciences Committee for Review and  
6 Evaluation of the Medical Use Program of the Nuclear  
7 Regulatory Commission.

8 As you know, in July of 1993, the NRC requested  
9 that the National Academy of Sciences conduct a review and  
10 evaluation of the NRC's regulatory program for the medical  
11 use of byproduct material. At that time, the NRC requested  
12 that the National Academy of Sciences examine the broad  
13 policy issues which underlie the regulation of the medical  
14 uses of radioisotopes. The Commission was also interested  
15 in an examination of the overall risk associated with the  
16 use of ionizing radiation in medicine.

17 Finally, the Commission was interested in having  
18 the National Academy perform a critical assessment of the  
19 current framework for the regulation of the medical uses of  
20 byproduct materials.

21 Based on the assessments that I just mentioned,  
22 the Commission requested that the National Academy make  
23 recommendations for an overall uniform national approach to  
24 the regulation of ionizing radiation in medical applications  
25 as well as for appropriate criteria for measuring the

1 effectiveness of the regulatory program.

2 In December of last year, the Academy issued its  
3 report. Today the Commission will be briefed by the members  
4 of the Committee who prepared the report.

5 On behalf of all of the commissioners, I would  
6 like to thank each of you for taking the time to come and be  
7 with us today.

8 Before we begin, Commissioner Rogers or  
9 Commissioner Dicus, do you have any opening comments you  
10 would like to make?

11 COMMISSIONER ROGERS: Not at this time.

12 COMMISSIONER DICUS: No.

13 CHAIRMAN JACKSON: If not, you may proceed.

14 DR. PUTMAN: Thank you, Chairman Jackson. It is a  
15 pleasure for all of us to be here. And let me briefly  
16 introduce my colleagues.

17 On my far right, David Gooden, professor of health  
18 physics from Oklahoma.

19 John Villforth. Professor Villforth probably  
20 needs no introduction to this group, been very active in  
21 Washington for many years and serving in a variety of  
22 capacities.

23 On my immediate right is Dr. Bill Hendee, a  
24 physicist in research from Wisconsin.

25 On my far left is Gary Penn, staffmember at the

1 Institute of Medicine.

2 Then we have Kate Gottfried here on my left who is  
3 the executive director of the IOM study.

4 And, with that -- I'm sorry Ted.

5 Ted Phillips, University of California in San  
6 Francisco, radiation therapist.

7 What we have planned to do is for Kate Gottfried  
8 to introduce the topic with a few overheads.

9 Are we ready to do that, Kate, do you think? We  
10 had some trouble with the projector.

11 CHAIRMAN JACKSON: Just ask for what you want. It  
12 will appear if it is here.

13 MS. GOTTFRIED: Printouts of the slides were  
14 available when you entered the room so those -- all those  
15 slides will not be run through this afternoon in the  
16 interest of time to really get to the heart of the topic  
17 which is the discussion of the substantive issues contained  
18 in the report.

19 I want to thank you first for the opportunity to  
20 speak with you today and present on behalf of the Committee  
21 and we are very pleased to be here to enter into a dialogue  
22 with respect to the issues contained in our study.

23 The first slide, please.

24 [Slide.]

25 MS. GOTTFRIED: This is just a review, briefly, of

1 the statement of task, the three major goals that were set  
2 forward: To examine the broad policy issues that underlie  
3 regulation of the medical uses of radioisotopes; study the  
4 overall risks associated with the use of ionizing radiation  
5 in medicine, comparing the errors and consequences of the  
6 use of byproduct materials to other medical interventions  
7 and the use of byproduct misadministrations to properly  
8 conducted administrations; and, finally, an assessment of  
9 the current statutory or regulatory framework for regulation  
10 of medical uses of byproduct materials.

11 Next slide, please.

12 [Slide.]

13 MS. GOTTFRIED: I am sure we are all very familiar  
14 with the medical policy statement. That is just provided as  
15 it was a guideline to the Committee members during our  
16 deliberations throughout from day one, really, through the  
17 end of this study, keeping in mind what the NRC's policy  
18 statement reflected.

19 The next slide, please.

20 [Slide.]

21 MS. GOTTFRIED: The Committee's goals were to  
22 promote greater uniformity of regulation of all ionizing  
23 radiation in medicine, specifically the regulation of  
24 byproduct and nonbyproduct material. To shift the federal  
25 oversight to an agency experienced in matters of public

1 health and to further ensure adequate protection of the  
2 public's health and safety and to consolidate the regulation  
3 of all ionizing radiation in medicine by delegating  
4 regulatory authority for reactor-generated byproduct  
5 materials to the states, which presently regulate NARM or  
6 approximately 90 percent of radiation medicine.

7 The next slide, please.

8 [Slide.]

9 MS. GOTTFRIED: The Committee underwent a long and  
10 deliberative process with respect to developing a spectrum  
11 of alternatives that could be considered and then finally a  
12 focus on a particular alternative that would form the basis  
13 for the recommendations put forth in our report.

14 Before I discuss the particular alternative, I  
15 want to just touch briefly on the spectrum of alternatives  
16 to say that the Committee really wanted to look at as many  
17 options as possible before determining where the emphasis  
18 should be and, in fact, if you look in the report, there is  
19 alternative A through G.

20 The focus of the Committee, though, really  
21 centered on alternative C through F. And C, D, E and F  
22 really comprised the heart of the discussion and the  
23 deliberations of the Committee throughout the period that we  
24 undertook the study.

25 Alternative C really emphasizes state control.

1 Alternative D emphasizes -- and I will elaborate further on  
2 Alternative D -- but emphasizes authority delegated to the  
3 states with some federal oversight and guidance.

4 Alternative E reserves residual authority so in the instance  
5 where the states would have an opportunity to regulate, if  
6 in fact the state didn't regulate, the feds would have the  
7 opportunity to assume control over a particular state  
8 program. Alternative F really emphasizes central regulation  
9 of all ionizing radiation in medicine. Alternative G was  
10 really quite comprehensive and tied reimbursement and  
11 regulation issues all together under one central agency for  
12 all of medicine.

13 CHAIRMAN JACKSON: Could you comment briefly,  
14 though, on Alternatives A and B?

15 MS. GOTTFRIED: Certainly.

16 Alternative A, actually A-1 and A-2, A was the  
17 status quo with absolutely no change in the existing program  
18 as it is today, the medical use program of the Nuclear  
19 Regulatory Commission. A-2 was the status quo with a slight  
20 modification, which would be the elimination of 35.32 and  
21 .33.

22 And alternative B was what we entitled the *liaise*  
23 *faire* approach which was really no regulation to speak of  
24 and an open market to allow free enterprise to really take  
25 hold.

1           CHAIRMAN JACKSON: So you started from the premise  
2 that Alternative A, either in A-1 or A-2, was not really a  
3 viable alternative and therefore not to be considered?

4           MS. GOTTFRIED: Well, it was entertained as an  
5 option but it was the -- the pros to Alternative A were  
6 considered and the cons were considered and I believe the  
7 Committee felt that Alternative A did not really address the  
8 issue of uniformity with respect to byproduct and  
9 nonbyproduct material.

10           COMMISSIONER ROGERS: I guess, could you just give  
11 me a little better feeling about where the status of the  
12 Committee's goals -- what that was? I mean, when did the  
13 goals emerge and normally you start out with something as  
14 goals at the very beginning. On the other hand, these goals  
15 read a little bit like your final conclusions. So when did  
16 they emerge in the process as goals?

17           MS. GOTTFRIED: The goals emerged during the  
18 process, I would say about mid way through the -- by the  
19 third or fourth meeting. They were clarified, I should say,  
20 or crystallized. They were listed -- the sense that there  
21 was a disconnect between byproduct material and nonbyproduct  
22 material was apparent from the inception of the committee  
23 process.

24           COMMISSIONER ROGERS: It is just that if I look at  
25 two of the three goals, they seem to be very much like your

1 final conclusions rather than goals which you set in some  
2 way at the very beginning of the study with the expectation  
3 that something will emerge later on that will -- that will  
4 lead you to those goals.

5 These look as some rather firm conclusions as to  
6 where you are going to wind up.

7 MS. GOTTFRIED: Perhaps I should clarify when I  
8 say -- and "goals" may not be the best characterization.  
9 Committee goals, once the spectrum of alternatives had been  
10 considered, so there were goals that were derived after or  
11 during the discussion of the alternatives, not from the  
12 beginning of the Committee. As I said, they didn't really  
13 emerge until the third or fourth meeting. And so they may  
14 be better characterized as, I don't know, the Committee's  
15 outcome from the deliberative process with respect to the  
16 alternatives.

17 And, certainly, I mean, if we were going to go  
18 back to goals, per se, the initial goal, the overarching  
19 goal, was to ensure adequate protection of the public health  
20 and safety in conjunction with an efficient regulatory  
21 program.

22 The Committee really wanted to emphasize once, in  
23 fact -- well, regardless of what option we were going to go  
24 with, that federal regulation would be maintained in many  
25 respects. And so, if we could have the slide, please, the

1 prior slide --

2 [Slide.]

3 MS. GOTTFRIED: That elimination of the NRC's  
4 medical use program would not alter the basic structure of  
5 federal regulation and that the federal government would, in  
6 fact, retain responsibility for the generation, the  
7 transport, the nonmedical use, disposal of radionuclides and  
8 for the approval of radiopharmaceuticals and certification  
9 or approval of equipment that generates ionizing radiation.

10 The federal authority also would be maintained  
11 with respect to, and this is, again, from the report,  
12 once -- oh, sorry, the next slide, please.

13 [Slide.]

14 MS. GOTTFRIED: The NRC and its agreement states  
15 would continue to license the production of byproduct  
16 material for radiation-producing devices and  
17 radiopharmaceuticals within the medical context. The NRC  
18 and its agreement states would, as relate to the nonmedical  
19 use of byproduct material, that being the industrial,  
20 educational and nonmedical research areas, continue to  
21 license the production and use of byproduct material, that  
22 the DOT would continue to regulate the transported regulated  
23 materials and the EPA, of course, would continue to develop  
24 guidelines that set occupational and public exposure limits  
25 to be implemented by the respective federal agencies.

1           The FDA would continue to regulate the manufacture  
2 and labeling of radiopharmaceuticals and medical devices and  
3 would regulate the mammography program under the Mammography  
4 Quality Standards Act.

5           And, finally, slide, please.

6           [Slide.]

7           MS. GOTTFRIED: The last two areas where the DOD,  
8 the VA and the PHS would continue to be responsible under  
9 the regulations of the appropriate agencies for the safe use  
10 of radioactive materials and radiation producing machines  
11 within hospitals, their hospitals and laboratories.

12          And, finally, next slide, please.

13          [Slide.]

14          MS. GOTTFRIED: The Health Care Financing -- the  
15 next slide, please. Maybe I am reading faster than --

16          [Slide.]

17          MS. GOTTFRIED: The Health Care Financing  
18 Administration for Medicare and Medicaid and other federal  
19 agencies for other health care purchased from the private  
20 sector would continue to develop its reimbursement  
21 guidelines.

22          The Committee spent an extensive amount of time  
23 deliberating among particularly the Alternatives C, D, E and  
24 F and derived what we then termed the "preferred  
25 alternative." The preferred alternative, Alternative D --

1 next slide, please.

2 [Slide.]

3 MS. GOTTFRIED: -- is a regulatory structure that  
4 transfers authority to the states and identifies a federal  
5 agency other than the Nuclear Regulatory Commission to work  
6 in conjunction with the Conference of Radiation Control  
7 Program Directors or the CRCPD and other professional  
8 organizations to develop recommended state laws and  
9 regulations for all ionizing radiation in medicine.

10 This agency that would assume responsibility for  
11 federal guidance would, in fact, do the following  
12 activities: Assist states in establishing regulatory  
13 programs and train radiation control personnel, it would  
14 address the problematic incidents of national concern, it  
15 would educate the public of the benefits and risks of  
16 radiation medicine, conduct research so the science of  
17 radiation medicine continues to advance, collect risk data  
18 or act as a clearinghouse for that data, monitor the effects  
19 of deregulation.

20 Based on the preferred alternative, the following  
21 recommendations emerged from the Committee. There were  
22 recommendations made to the Congress, to the Nuclear  
23 Regulatory Commission, and then to the Conference of  
24 Radiation Control Program Directors and the states.

25 Following slides -- slide, please.

1 [Slide.]

2 MS. GOTTFRIED: The next slides are reportage of  
3 the various recommendations contained in the report and are  
4 provided for the benefit of the people attending the  
5 meeting. I know the commissioners have had an opportunity  
6 to review these.

7 Recommendations to Congress. The first  
8 recommendation is that Congress eliminate all aspects of the  
9 NRC's medical use program, 10 CFR Part 35 and those  
10 regulatory activities conducted under 10 CFR Part 20 that  
11 are applicable to medical uses.

12 Next slide, please.

13 [Slide.]

14 MS. GOTTFRIED: The second recommendation to  
15 Congress is that the Congress direct the Secretary of Health  
16 and Human Services to support, coordinate and encourage the  
17 following activities involving regulation of all ionizing  
18 radiation in medicine:

19 Support the operation of the Conference of  
20 Radiation Control Program Directors.

21 Next slide, please.

22 [Slide.]

23 MS. GOTTFRIED: Providing a venue for the review  
24 and evaluation of the suggested state regulations for  
25 control of radiation; assist states in implementation of

1 their regulations.

2 Next slide, please.

3 [Slide.]

4 MS. GOTTFRIED: Aiding in assessment of the  
5 effectiveness of state programs through the collection and  
6 analysis of data; helping develop survey methods by which  
7 the rate of adverse events for a wide range of procedures  
8 and devices might be measured.

9 Next slide, please.

10 [Slide.]

11 MS. GOTTFRIED: Monitoring the effects of  
12 deregulation; enhancing training and standards for health  
13 care personnel; and investigating future significant  
14 radiation medicine incidents.

15 Next slide, please.

16 [Slide.]

17 MS. GOTTFRIED: The next group of recommendations  
18 pertain to the Nuclear Regulatory Commission. The first  
19 recommendation is that the NRC immediately relax its  
20 enforcement of 10 CFR 35.32 and 35.33 through its present  
21 mechanisms.

22 Next slide, please.

23 [Slide.]

24 MS. GOTTFRIED: That the NRC initiate -- and this  
25 again is an issue of sequencing -- that the NRC initiate

1 formal steps under the Administrative Procedure Act to  
2 revoke Part 35 in its entirety if Congress fails to act  
3 within two years in response to the two recommendations  
4 provided to Congress and that were stated earlier.

5 Next slide, please.

6 [Slide.]

7 MS. GOTTFRIED: That the NRC separate the costs of  
8 formulating regulations from the costs of administering  
9 those regulations.

10 CHAIRMAN JACKSON: Would you comment a little  
11 further on that one?

12 MS. GOTTFRIED: That would be in the instance  
13 where the Congress had not acted and if the NRC's existing  
14 program were still in effect.

15 CHAIRMAN JACKSON: No, no, no, what do you mean by  
16 separating the costs of formulating from the costs of  
17 administering? What is the motivation there? Tell me more  
18 of what you are trying to get at.

19 MS. GOTTFRIED: Okay, I believe that issue relates  
20 to agreement states versus nonagreement states and the way  
21 in which funds were collected from the states and that all  
22 of the states are responsible for -- share the expense of  
23 formulations of regulations.

24 DR. PUTMAN: David, do you want to comment on  
25 that?

1 DR. GOODEN: I think part of the Committee's  
2 thought process there was that we would like to see the  
3 production of regulations and enforcement of those  
4 regulations separated and there not be fees on the licensees  
5 that gave an incentive to the NRC to do things in one way as  
6 opposed to the way they might do them were those fees not  
7 available.

8 CHAIRMAN JACKSON: You will have to be a little  
9 more lucid with me.

10 [Laughter.]

11 DR. PHILLIPS: I'm sorry.

12 The concern is that as more and more states become  
13 agreement states, the few states that are left are bearing  
14 the burden of writing the guidelines and regulations.  
15 Whereas, those guidelines and regulations really apply to  
16 all of the states and to be fair you should spread the cost  
17 of designing the rules over all the states and only charge  
18 the people that are nonagreement for the cost of actually  
19 administering their regulation and inspection. Whereas,  
20 everyone is benefitting from the design of the guidelines.

21 CHAIRMAN JACKSON: So you are suggesting in that  
22 that if everyone is benefitting from the design of the  
23 guidelines, that that cost should be passed on to the  
24 agreement states?

25 DR. PHILLIPS: That is what this -- yes.

1           COMMISSIONER DICUS: Did you consider or suggest a  
2 mechanism for doing that? Were you going to charge, for  
3 example, the state -- what were the discussions?

4           DR. PHILLIPS: There was a discussion, it didn't  
5 get into the final report, that one possibility, for  
6 example, under Option D or E would be that the new agency,  
7 whatever it is, might have a user fee for every user that  
8 would cover the costs of doing that.

9           COMMISSIONER ROGERS: I thought you said that you  
10 intended this should take place right away, even if there  
11 wasn't a new agency. That under the present circumstances,  
12 you would like to see that? That's what I heard; is that  
13 correct?

14          MS. GOTTFRIED: Yes, that's true.

15          COMMISSIONER ROGERS: So it has to be a mechanism  
16 that works under the present circumstances.

17          DR. PHILLIPS: Right, we did not get to the point  
18 of designing that mechanism.

19          COMMISSIONER ROGERS: Not so easy to see.

20          MS. GOTTFRIED: Correct.

21          COMMISSIONER ROGERS: For agreement states.

22          Why should they pay? Send them a bill, thank you  
23 very much, and they'll send it back to us.

24          DR. HENDEE: I don't think it is our  
25 responsibility to figure out the mechanism. What is fair is

1 fair here. We are trying to deal with what is fair to the  
2 states in terms of the regulations that are proposed.

3 COMMISSIONER ROGERS: Well, that's fine but, you  
4 know, reality is you have to do something about it and if  
5 you want to make a recommendation that somebody fix  
6 something, it is very helpful to have some thought go into  
7 how you might go about doing that. We all like, you know,  
8 ideal situations but sometimes we can't figure out a way to  
9 achieve them.

10 CHAIRMAN JACKSON: Why don't you go on.

11 MS. GOTTFRIED: The next slide, please.

12 [Slide.]

13 MS. GOTTFRIED: The final area of recommendations  
14 were made to the Conference of Radiation Control Program  
15 Directors and to the states. The first of these  
16 recommendations pertained to the CRCPD and that they  
17 incorporate into their suggested state regulations for  
18 control of radiation any relevant concepts from 10 CFR Part  
19 35 that are not already integrated in those suggested  
20 regulations.

21 Next slide, please.

22 [Slide.]

23 MS. GOTTFRIED: That all state legislatures enact  
24 enabling legislation to incorporate the regulation of  
25 reactor generated byproducts into existing state regulatory

1 programs.

2 Next slide, please.

3 [Slide.]

4 MS. GOTTFRIED: And the final recommendation made  
5 to the CRCPD and the states, that the CRCPD and the states  
6 continually reevaluate their regulations and procedures  
7 pertaining to radiation medicine to ensure congruence with  
8 evolving scientific understanding of radiation bioeffects  
9 and to be in accord with advances in knowledge regarding  
10 benefits and risks related to medical and biomedical  
11 research uses of ionizing radiation in medicine.

12 At this point, I would like to ask that we open up  
13 for discussion among all the Committee members and that,  
14 please, feel free to ask generic questions that anyone might  
15 want to answer or target at particular Committee members.

16 CHAIRMAN JACKSON: Thank you very much,  
17 Ms. Gottfried.

18 I am going to walk you through a series of  
19 questions that I would like to get your responses to.

20 Could you provide more insights on why the  
21 Committee, since we are talking about -- let's talk about  
22 the alternatives that you considered, but in particular  
23 focusing on Alternatives D and E, and I guess your report  
24 indicates that Alternative E has all the advantages of  
25 Alternative D but goes one step further by giving regulatory

1 authority to the federal agency, whatever it is, any but the  
2 NRC, in a situation of last resort.

3 Can you tell me a little more about the Committee  
4 thinking in that regard and why you settled on Alternative D  
5 in the end?

6 DR. HENDEE: We really debated many, many hours,  
7 especially among C, D and E, and also to some lesser extent  
8 F and there were many people who were on both sides of --  
9 some people supporting C and some people supporting E and we  
10 settled on D for the following reason, and let me just talk  
11 about D and E.

12 Our experience as Committee members, and many of  
13 us are quite experienced in the regulatory process, both  
14 within agreement states as well as within the NRC, and what  
15 we learned through our site visits and our public hearings  
16 and through other mechanisms of collecting information,  
17 caused us to believe that the process really could work,  
18 really could work, without regulatory oversight at the  
19 federal level and, in fact, does work quite well in many  
20 areas at the present time with the CRCPD and guidance to the  
21 CRCPD by various agencies such as the National Council on  
22 Radiation Protection and Measurements and others. It really  
23 works quite well.

24 We were worried that if, in fact, we were to  
25 support or to recommend that a federal agency maintain some

1 degree of regulatory authority over this process that it  
2 would cause some states -- it would discourage some states  
3 from fully participating in the process at the voluntary  
4 level because the feds could always step in and we thought  
5 that the way to really make this work was to not have a  
6 federal agency with some kind of last stopgap last resort  
7 regulatory authority over the process.

8 CHAIRMAN JACKSON: Okay, well, let me follow on  
9 with that. I mean, all of the alternatives, C through E but  
10 the one you chose in particular, place additional regulatory  
11 responsibility on the states and so my question is, what  
12 degree of consistency or uniformity in regulatory standards  
13 would be needed if the states were to regulate all ionizing  
14 radiation and how then will that level of consistency and  
15 uniformity be achieved given the different legislative  
16 frameworks within which the regulatory processes within the  
17 different states operate?

18 DR. HENDEE: Charles, let me answer that question  
19 quickly but I know other people will want to answer as well.

20 For 90 percent of the radiation sources that are  
21 used in medicine and biomedical research today, the NRC is  
22 not involved in those processes and they are monitored and  
23 regulated through a voluntary process or they are controlled  
24 through a voluntary process, just the way we have described  
25 Option D or Alternative D would work. So it is our belief

1 and it is through our experience that we believe that in  
2 fact there would be a large measure of uniformity for the  
3 remaining 10 percent, just as there is today with the 90  
4 percent that is related to machine-produced radiation and  
5 naturally occurring and artificially produced radioactivity.

6 DR. PUTMAN: The other aspect of the uniformity  
7 has to do with the significant role, not a superficial role,  
8 that we see for DHHS. We listed eight, I believe there were  
9 eight, roles and responsibilities to DHHS and we think the  
10 collaborative and integrated approach there is very  
11 important because a big part of it is collecting data,  
12 education, assisting the states. We recognize that there  
13 would undoubtedly be some states that, for a variety of  
14 reasons, may not be as far ahead as some other states and so  
15 there will have to be a mechanism in place to provide that  
16 education and that was one of the reasons that we suggested,  
17 of course, that DHHS might be the logical entity to do that  
18 since they are so close to health care in a variety of ways.

19 DR. PHILLIPS: I might clarify a little bit what  
20 you said about voluntary. I think what Dr. Hendee meant by  
21 voluntary, for the 90 percent that is not NRC, it is done by  
22 the states and of course these are individual state laws,  
23 many of which follow that which were developed by the CRPD  
24 but not mandated.

25 The other thing, the Committee looked at

1 uniformity in two ways. One, we felt very strongly that we  
2 need uniform regulation of all ionizing radiation. Not a  
3 very strict regulation of one small component which we have  
4 now, and perhaps less regulation of the 90 percent that is  
5 left over on the other hand.

6 We should have a uniform, risk-based approach to  
7 all ionizing radiation in medicine.

8 I didn't think the Committee felt that it had to  
9 be absolutely uniform from one state to the other.  
10 Regulation of medical practice varies from one state to  
11 another as each state's people and government feel it should  
12 be done for their people in their situation. And we felt  
13 that that kind of variation was not unhealthy, that it is  
14 part of the way things are done in this country.

15 CHAIRMAN JACKSON: What feedback did you obtain  
16 from all the states in terms of their willingness or  
17 capability to take on the roles, I guess.

18 DR. PHILLIPS: We did site visits, we were in  
19 contact with the program directors, we heard from the -- I  
20 mean, Kay could summarize all of the people who were invited  
21 to come. We invited all of the states to come testify --

22 CHAIRMAN JACKSON: But in the end, how many states  
23 did you actually --

24 MS. GOTTFRIED: Well, we spoke with a number of  
25 the states when we attended an annual meeting of the CRCPD

1 and got a variety of responses from the states in terms of  
2 their -- whether they thought, in fact, state regulation  
3 would be a good approach to dealing with these issues.

4 There wasn't any survey done of the --

5 CHAIRMAN JACKSON: There was no systematic --

6 MS. GOTTFRIED: Correct.

7 CHAIRMAN JACKSON: -- of each of the states?

8 MS. GOTTFRIED: Correct.

9 DR. PUTMAN: No.

10 CHAIRMAN JACKSON: So then my follow-on question  
11 is, what assurances do you have in terms of the capability  
12 of the states to -- to take on, you know, this additional  
13 responsibility?

14 DR. HENDEE: Well, the states already have 90  
15 percent of the responsibility.

16 CHAIRMAN JACKSON: Right. We are talking about  
17 the 10 percent that you are suggesting they give up.

18 DR. HENDEE: That's correct.

19 CHAIRMAN JACKSON: So I am asking in particular  
20 about that.

21 DR. HENDEE: We did not do a survey to ask that  
22 question of all of the states but in the site visits that we  
23 made, we discussed that issue, we discussed that issue with  
24 various directors of state programs at meetings and the  
25 feeling is that, in fact, this in many cases would allow

1     them -- many of the responses were that this would allow  
2     them to allocate their resources in a way that actually  
3     would lead to improved uniformity and therefore improved  
4     radiation control overall because, at the moment, in  
5     agreement states, a good portion of their resources are  
6     directed toward the 10 percent of radioactive byproduct  
7     material in order to be in compliance with the NRC and  
8     therefore a disproportionately small share of the resource  
9     is allocated toward the remaining 90 percent of radiation  
10    that they are responsible for.

11           CHAIRMAN JACKSON: Let me go on to talk about 10  
12    CFR Part 35. The Committee is recommending that the NRC  
13    initiate formal steps to revoke Part 35 in its entirety.  
14    Does the Committee believe that the NRC could proceed with  
15    this recommendation in the absence of congressional action?

16           DR. HENDEE: A lot of 10 CFR 35 is a matter of  
17    enforcement and the level of enforcement and we believe that  
18    the NRC could alter the intensity with which Part 35 is  
19    enforced and make quite a significant difference.

20           CHAIRMAN JACKSON: If the NRC were to rescind Part  
21    35 and without direction from the Congress, is there any  
22    assurance that other agencies, for instance HHS and FDA,  
23    would or could be authorized -- would be authorized to fund  
24    it or willing to assume this additional regulatory  
25    responsibility?

1 DR. PUTMAN: John?

2 MR. VILLFORTH: No, I don't think we asked the  
3 other federal agencies what they could pick up as a  
4 responsibility and I think the transfer of that from the NRC  
5 would be a congressional -- there would be a need for  
6 congressional activity.

7 I also want to point out that the recommendation  
8 was for 10 CFR 35.32 and .33. Not all of 10 CFR 35, the  
9 immediate relaxation of the enforcement activity, which was  
10 for .32 and .33 as it relates to the quality management and  
11 the reporting requirements.

12 COMMISSIONER ROGERS: Do you have -- if I could  
13 just ask one?

14 Do you have any measures other than seat of the  
15 pants as to whether relaxation of our enforcement of those  
16 sections would not lead to any diminution of public health  
17 and safety, any?

18 DR. PUTMAN: David?

19 DR. GOODEN: I think we have some evidence in that  
20 in that we did not see any particular difference in the  
21 regulation of the 90 percent of radiation medicine. To  
22 health effects there that reflects that portion of radiation  
23 medicine, the byproduct material which is controlled by the  
24 NRC --

25 COMMISSIONER ROGERS: Do you have any numbers, any

1 quantitative data to support that statement that we found it  
2 very difficult to get any kind of data to get numerical  
3 values for the rates at which misadventures take place. One  
4 can count the numbers but one doesn't know what the base is  
5 on which those numbers come about. And one concern that I  
6 have is that we don't have any measures here of exactly how  
7 well people are doing. We have a lot of anecdotal  
8 information and we have statements that people don't think  
9 or do think this, that or the other thing. But it is very  
10 difficult to get hard data and we are usually confronted  
11 with, in our congressional oversights, with our being able  
12 to assure the public that if we are relaxing some kind of a  
13 requirement that there is no effect on public health and  
14 safety.

15 And we have to have some basis to demonstrate that  
16 belief and I am just asking you, do you have any suggestions  
17 as to hard data that might support that other than just,  
18 really, a kind of anecdotal collection of feelings of folks  
19 that are not particularly convinced that those parts --  
20 those sections of Part 35 are doing much good.

21 DR. PUTMAN: Bill.

22 DR. HENDEE: Mr. Rogers, we share your  
23 frustration. We tried to look at this very, very hard. The  
24 difficulty is that there is not very much hard, quantitative  
25 data that either supports the need for Part 35 or would

1 support its not being present. It makes us believe,  
2 however, that if in fact Part 35 really had a major impact  
3 on reducing risk, then we would be able to see that and then  
4 we would have measurable data.

5 So in the event that -- in the situation where  
6 Part 35 addresses a situation where there is very low risk  
7 to begin with, it really hasn't had much impact in producing  
8 the risk and therefore our feeling is it will have very  
9 little impact if it weren't --

10 CHAIRMAN JACKSON: This is reducing the risk  
11 relative to what? I think the Committee agreed itself that  
12 there is a lack of a database that compares reactor  
13 byproduct material, you know, risk in terms of radiation  
14 exposure there, with accelerator-produced or even naturally  
15 occurring radiation and even comparing those to the risks of  
16 other medical modalities.

17 So that is why I am asking, when you talk about no  
18 net reduction in risk, it is risk with respect to what?

19 DR. HENDEE: I can only answer you back the same  
20 way I answered before, and that is that we have no evidence  
21 to suggest that there is any undue risk here associated with  
22 the use of these materials and we have no evidence to  
23 suggest that the implementation of Part 35 has reduced what  
24 was already a very, very low risk in comparison with other  
25 medical procedures.

1           CHAIRMAN JACKSON: But your Committee said that  
2 you actually didn't have data to compare it to other medical  
3 procedures?

4           DR. HENDEE: Other than just very limited, right.

5           DR. PHILLIPS: In radiation oncology there is some  
6 data. There has been a series of studies funded by the  
7 National Cancer Institute called Patterns of Care studies  
8 that have registered all radiation delivery equipment for  
9 therapy in the United States and looked at the process and  
10 looked at outcome and they have information for cobalt  
11 machines and for linear accelerators and there is no  
12 difference in the complication rates.

13           Now, we consider serious complications as those  
14 things that are reported. We can find no evidence that they  
15 are less for cobalt machines which are regulated by NRC and  
16 linear accelerators which are not. So that is on that  
17 subset of radiation therapy patients but it is not a huge  
18 number of diagnostic patients who get X-ray versus get  
19 nuclear medicine.

20           DR. PUTMAN: Formerly, data was collected by CRCPD  
21 not recently available. But as Dr. Hendee indicated, if you  
22 look at the agreement versus nonagreement, through not solid  
23 data but through the agencies, organizations within the  
24 states, the medical societies, et cetera, there does not  
25 appear to be any difference in the incidents between the

1 agreement and nonagreement. But you are right, we do not  
2 have real, hard data except the data I guess about three or  
3 four years ago from CRCPD.

4 MR. VILLFORTH: May I make an observation? That  
5 we did look at one database and that was collected by an  
6 organization outside of Philadelphia called the ECRI,  
7 Emergency Care Research Institute, that collected some of  
8 the FDA information for machine-produced radiation as well  
9 as material that came in from the NRC and I don't think that  
10 we found much. It was a very limited study.

11 CHAIRMAN JACKSON: Yes, how comprehensive was that  
12 database?

13 MR. VILLFORTH: Well, it was as much as was  
14 required to be reported to the Food and Drug Administration  
15 plus any voluntary reporting that came in from other  
16 sources, so it has limitations. Clearly, it has  
17 limitations. But it was one database we looked at. It  
18 wasn't particularly conclusive.

19 I would just make the other observation that in  
20 terms of 10 CFR 35.33, as you perhaps know, the Food and  
21 Drug Administration, as far as byproduct material in medical  
22 devices, seals, sources and medical devices, does have the  
23 intention, I believe, of moving ahead and incorporating  
24 something analogous to 10 CFR 35.33 into its provisions of  
25 the Medical Device Amendments of 1990. They would be

1 picking up the experience or duplicating, in effect, what  
2 you are doing and what they are doing for all sources of  
3 medical devices. This does not include nuclear medicine we  
4 are talking about.

5 CHAIRMAN JACKSON: But this is not in place as  
6 yet?

7 MR. VILLFORTH: This will be published for comment  
8 in perhaps months and I don't think any of us have been  
9 privileged to see the draft but I understand that is the  
10 direction they are going and it would need to be looked at.

11 The point is that the Food and Drug  
12 Administration, under its authority to the Medical Device  
13 Amendments, for collecting data from users they have  
14 traditionally had this responsibility of requiring  
15 manufacturers to report but, under the recent amendments,  
16 that has been transferred to users. I mean, the Congress  
17 has passed that on to users so there is an analogue, to some  
18 extent, of what you are planning to do or what you are doing  
19 with what FDA is planning to do.

20 One could envision that the fallback position, if  
21 the NRC were to pull out of 10 CFR 35.33, to use the  
22 information that ultimately might be coming in to the Food  
23 and Drug Administration. Again, as I understand it, this  
24 does not include radiopharmaceuticals because that is not --  
25 that -- drugs are separate from devices. I believe the

1 section that is in question is Section 5.19 of the code,  
2 (b) (1) (B) (ii), which I don't understand, but somebody may  
3 want to look this up and it reads that the Secretary or the  
4 Commissioner has authority for other significant adverse  
5 device experiences as determined by the secretary by  
6 regulation to be necessary to be reported. I think that is  
7 a result, perhaps -- the proposal for comment was probably  
8 as a result of some collaboration between the two  
9 organizations.

10 So this raises the question of whether there will  
11 be some redundancy in the reporting.

12 COMMISSIONER ROGERS: Excuse me, does that  
13 reporting give a base of patients treated and just as well  
14 as the number of misadministrations or mishaps or whatever  
15 you want to call them?

16 MR. VILLFORTH: There will be no denominator, to  
17 my knowledge. That's the problem, that's the problem. And  
18 I think until you have a denominator, you can't talk about  
19 comparative rates.

20 DR. GOODEN: You might appreciate that the only  
21 database that exists for misadministrations is the one from  
22 the NRC. The rest of radiation medicine does not have that  
23 type of database, personally, nor does most of other  
24 medicine.

25 CHAIRMAN JACKSON: Do you think that such a

1 database need not exist?

2 DR. GOODEN: We talked about addressing that issue  
3 in the report and maybe transferring that -- some of those  
4 responsibilities to the federal agency that might give  
5 oversight here. That it might be some wisdom in  
6 accumulating some of that data. Maybe not under the same  
7 premise as with the misadministration rule, but maybe under  
8 some other parameters.

9 CHAIRMAN JACKSON: The last time the Committee, I  
10 understand, addressed the Commission, it indicated that  
11 there was no response from groups representing patient  
12 rights. Do you now have input from groups representing  
13 patient rights and how do you address the issue of whether  
14 the patient rights will be adequately protected under your  
15 preferred alternative?

16 MS. GOTTFRIED: We don't have any additional  
17 information; that piece of information was elicited when we  
18 went forward with our public hearing and invited comment and  
19 testimony from any interested groups and we specifically,  
20 because we were concerned about patients' perspective and  
21 rights, focused attention on asking them to come and present  
22 before us and none of the groups, and we have a listing of  
23 the groups and the various organizations that we sent this  
24 letter to, but we actually also called as well, they didn't  
25 evidence an interest in coming to present; they didn't have

1 either the time, the interest or the resources, I suppose.  
2 That was our supposition because they just, after several  
3 calls, declined the invitation.

4 CHAIRMAN JACKSON: With respect to 10 CFR 35.32  
5 and .33, is your beef with the rule or having a rule or is  
6 it with how the rule is implemented?

7 DR. PUTMAN: Dave?

8 DR. GOODEN: I am not sure there is a beef with it  
9 at all. I think the Committee evaluated this thoroughly and  
10 found that the quality of management grew -- was unique to  
11 the practice of medicine in this country. It did not exist  
12 in any other place. And the Committee looked at this and  
13 tried to determine whether there was justification of having  
14 this unique parameter with byproduct material and I think we  
15 determined that was not the case.

16 CHAIRMAN JACKSON: How did you make that  
17 determination because doesn't it go back to the questions of  
18 Commissioner Rogers and I asked of you in terms of the case?

19 DR. GOODEN: Of data? Data? There is a database  
20 that exists with FDA and John may want to clarify this a  
21 little bit but it has reporting of certain misadventures  
22 also but those misadventures must cause serious body harm or  
23 death to the patient.

24 There is nothing in medicine other than the  
25 quality management rule that is a prescriptive dose-related

1 rule that requires reporting.

2 CHAIRMAN JACKSON: Why are you pressing  
3 specifically on that in terms of immediate action, 35, 32  
4 and 33, as opposed to having it done in a considered way as  
5 part of an overall deliberative process on all -- you know,  
6 all of your recommendations?

7 DR. GOODEN: Maybe someone else would prefer to  
8 address that and I can --

9 MR. VILLFORTH: Well, I would make the observation  
10 that there are ways you could do this. One extreme way  
11 would be for Congress to do it. The other way is for NRC to  
12 consider any changes through notice and comment rulemaking  
13 or the NRC might wish to choose this by some regulatory  
14 enforcement discretion as to how you implement some of these  
15 activities.

16 If there are alternatives to trying to accomplish  
17 the level of safety that you are concerned about, I think it  
18 is real. In terms of quality, that can, perhaps, be  
19 implemented through education as opposed to enforcement. If  
20 you are trying to change the behavior of individuals which  
21 is, to a large extent what you are dealing with in the  
22 quality management rules, it is a process, it is a behavior  
23 of the users and so forth.

24 That type of thing lends itself, perhaps, to  
25 education and the leads that you have demonstrated already

1 by getting the rule out on the table is very important. The  
2 question is, by pushing that to an enforcement environment,  
3 has it gone too far and the reactions I think we have gotten  
4 from the medical community is it has gone too far. It is  
5 not so much that the concepts of quality assurance and  
6 quality management aren't important; the question is, are  
7 these behavioral types of things necessarily enforced -- to  
8 be enforced.

9 CHAIRMAN JACKSON: But you are also recommending  
10 that we eliminate the inspection part of it and the  
11 inspection part of it relates to a database, in fact. I  
12 mean, it helps.

13 MR. VILLFORTH: I am not sure that will give you  
14 the denominators that you are talking about other than the  
15 number of facilities. I am not sure I understand.

16 CHAIRMAN JACKSON: Well, the point is I am lost  
17 because I don't see other mechanisms that have been  
18 proposed.

19 MR. VILLFORTH: Education --

20 CHAIRMAN JACKSON: That is not gathering data.

21 See, what we are interested in, what I am  
22 interested in, is regulation as it relates to risk and if we  
23 want to make an assessment of risk relative to whatever the  
24 denominators, if you want to flip it, the numerators are,  
25 the point is that that database has to exist.

1 The question is, how does one get at it.

2 MR. VILLFORTH: Can I ask a question back to you?

3 CHAIRMAN JACKSON: You can ask me whatever you  
4 would like.

5 MR. VILLFORTH: I guess we are as confused about  
6 Part 35 as you seem to be, in the following way.

7 CHAIRMAN JACKSON: I am not confused. I am  
8 confused about your recommendation relative to Part 35.

9 MR. VILLFORTH: Our recommendation is based on the  
10 fact that it is true, we don't have as substantial a  
11 database to look at the issue of risk as it relates to Part  
12 35 as you might wish. But we also know that you don't have  
13 it.

14 It seems to us that one should develop regulations  
15 based upon the identification of a risk that regulations are  
16 to address and not based upon a hypothesis that then you ask  
17 us to develop a database in order to do away with the  
18 regulation. It seems to me the regulation ought to be --  
19 depends more on the database than anything else.

20 So, you know, quality, the quality of management  
21 part of Part 35 is what we do every day in the practice of  
22 medicine. We are all very concerned about total quality  
23 improvement, about quality management practices. I don't  
24 think we need regulations to try to force that issue on us.  
25 We have to do that in order to compete effectively in a

1 managed care environment to begin with.

2 So I would like to ask the question back to you --

3 CHAIRMAN JACKSON: I am going to ask the question  
4 of Dr. Paperiello --

5 DR. HENDEE: Okay, what is your database --

6 CHAIRMAN JACKSON: -- since he is here, and have  
7 him go to the mic and speak to the issue.

8 DR. PAPERIELLO: Yes.

9 [Laughter.]

10 DR. PAPERIELLO: What is the precise question?

11 CHAIRMAN JACKSON: How can you help us get at this  
12 issue having to do with issues of this quality management  
13 rule, the database on which it rests and the need for having  
14 data relative to the risks we are trying to address?

15 DR. PAPERIELLO: Well, we have the -- we know the  
16 number of events. It is true we don't know the denominator.

17 In a report I gave to the Commission a couple of  
18 years ago, I used data that Dr. Pollycove gave me as well as  
19 data that the NCRP had put out in terms of the number of  
20 procedures because they were similar. And I gave the  
21 Commission an order of magnitude estimate which I believe  
22 was one in 4,000 or one in 6,000 procedures.

23 Now, if you really want the denominator, you would  
24 have to require our licensees, I believe, to provide us --  
25 report the information and do it on a very well-defined

1 basis because, for example, high dose rate brachiotherapy is  
2 a different encounter than low dose brachiotherapy or  
3 fractionated external beam radiation.

4 The path -- the failure is going to be different  
5 so you can't assume the error rate in one form is going to  
6 be the same as the other. In low dose rate brachiotherapy  
7 you have one encounter with the sources, in high dose rate  
8 it is fractionated two or three times. In teletherapy you  
9 might have 20 fractions and in nuclear medicine, your  
10 radiopharmaceutical, it may only be one. And so if you  
11 really wanted precise data you would have to have the  
12 licensees report. Then you would know the failure rate for  
13 those licensees as well as the administration rate. My  
14 opinion.

15 CHAIRMAN JACKSON: Thank you.

16 DR. PUTNAM: We did indicate that there was a  
17 political issue that DHHS or -- that happened to be the  
18 agency we suggested would take this responsibility on. Also  
19 with rates, one of our concerns is adverse effects from low  
20 treatment or low dose treatment when high dose treatment is  
21 more appropriate, and that becomes even more complicated and  
22 maybe Dr. Phillips could respond to that.

23 DR. PHILLIPS: I think I might say something about  
24 the whole problem.

25 We talked a lot about the need for a database for

1 the denominator to be part of it and aside from this pattern  
2 of pattern of cure study I have mentioned there really isn't  
3 any denominator data.

4           There are ways to get at it. I mean HCFA has  
5 information at least on the Medicare population on billings  
6 and all of the different codes that would describe whether  
7 it is HDR or LDR or what nuclear medicine procedure, so for  
8 that population I think it is possible to get at the  
9 denominator and with reporting through FDA or whoever of  
10 significant incidents I think we could come up with that  
11 information. I personally think it is an important thing to  
12 do and I agree that we don't have the information right now  
13 that would answer the question.

14           I just want to make a comment on the quality  
15 management. It is part of the requirements in every  
16 department because of the hospital accreditation that you  
17 have to have a very clearly defined quality management  
18 program. It was felt that a lot of the things in 35 require  
19 you to do excess documentation and repeat what you are  
20 already doing and being inspected for within your hospital  
21 and reporting every month every incident to our quality  
22 management committee, so that it's a redundant system at the  
23 present time and that is why it was felt to be onerous.

24           Did I answer your question well enough?

25           CHAIRMAN JACKSON: Thanks. Commissioner Rogers,

1 do you have some additional questions?

2 COMMISSIONER ROGERS: Oh, well, really just a very  
3 general one I think. You have made it very clear that you  
4 believe that at least some of NRC's regulations are unduly  
5 burdensome. I think we just heard that, but the question is  
6 really for us -- that's important but the fundamental  
7 question is have they adequately protected public health and  
8 safety or not?

9 One of my concerns with your report is that it  
10 doesn't seem to address that issue of whether NRC's  
11 regulations and its procedures which involve all of the  
12 regulatory paraphernalia, good and bad, that we have has  
13 adequately protected public health and safety in this area or  
14 not.

15 The whole -- not the whole but one of the reasons  
16 why we embarked on this study is really because there were  
17 some very serious questions raised and I think you even  
18 pointed that out in your study by Congressional committees  
19 as to whether NRC's regulations in fact were protecting  
20 public health and safety in this area, and there was a great  
21 deal of hullabaloo about it and newspaper articles and all  
22 sorts of things, and what we had hoped we might be able to  
23 learn along with other things, other good things that you  
24 have done here, is whether you have come -- you could come  
25 to any conclusions as to whether even though they may be

1 burdensome and unnecessarily burdensome, and I am not mixing  
2 that issue in, whether they in fact have adequately  
3 protected public health and safety or not, and whether they  
4 have fallen short on that account.

5 I would like to hear a little bit from you on that  
6 score.

7 DR. HENDEE: I would like to respond to that. Let  
8 me first, before I do, say that some of the most well-  
9 publicized cases such as the one in Indiana, Pennsylvania  
10 that we all know about, really does not reflect anything  
11 that the regulatory process can do much about.

12 It is very hard to regulate against ignorance.  
13 It's hard to regulate against stupidity and it's hard to  
14 regulate against intentional wrongdoing. Some combination  
15 of those factors were responsible for what happened in  
16 Indiana, Pennsylvania, and that is more often the case than  
17 not in the dramatic, well-publicized cases.

18 They oftentimes escape any kind of regulatory  
19 process, as you well know.

20 I believe in fact, and I think many members of the  
21 committee believe that the NRC process has interfered with  
22 the maximum risk reduction that could be achieved otherwise  
23 for the following reasons.

24 It concentrates on only 10 percent of the total  
25 usage of radiation in medicine and yet it captures almost in

1 many institutions the complete attention of the people that  
2 are responsible for radiation safety because it is so  
3 burdensome in terms of paperwork and in responding to the  
4 inspection process and to the enforcement process.

5 In my own institution I can tell you that's the  
6 case. Our radiation safety office spends almost all its  
7 time dealing with 10 percent of the issue and very little  
8 time dealing with 90 percent.

9 It is the uniformity problem. We need to find a  
10 way to develop a more uniform approach to the control of  
11 radiation, to the wise use of radiation in medicine overall  
12 and I think we would all agree to that.

13 Now the problem with that is that is now  
14 superimposed on a second problem, and that is the problem of  
15 allocation of resources, and we all know what problems  
16 health care institutions are going through these days, so  
17 the challenge is how do we develop a more uniform approach  
18 to the safe and wise use of radiation within the constraints  
19 of the limited resources to achieve that that we all have,  
20 and we believe that in fact the way to do that is not to  
21 escalate everything else up to the level that the NRC  
22 currently enforces the regulatory process on 10 percent, but  
23 is to take a wiser and more reasoned approach in a uniform  
24 fashion through the appropriate allocation of those  
25 resources that we have to look at the overall issue, the 100

1 percent usage, and our report really reflects what we as a  
2 committee believe is the way to achieve that and it is  
3 through the process that is described by Alternative D.

4 DR. PHILLIPS: I think, Commissioner Rogers, we  
5 did address the question of has the program worked. Now we  
6 obviously can't say that the very low incidence of  
7 significant occurrences that's outlined on page 119 is  
8 definitely due to the NRC, but we can certainly say whatever  
9 the system is -- the states, the NRC, the whole system --  
10 these events are very rare both in diagnostic -- like .002  
11 in NRC states and .00012 percent in agreement and  
12 nonagreement for diagnostic procedures. That is much lower  
13 than any other event that has been documented in medical  
14 drug administrations, for example, and it is extremely low  
15 in therapy as well -- .002 percent -- taking all the  
16 agreement and nonagreement states.

17 So I think that something is working. The present  
18 system is working in the sense that it is keeping the  
19 incidence and diagnosis in therapy low, but it seems to be  
20 as low in the agreement states as in nonagreement states and  
21 it seems to be low from what limited data we have for the  
22 non-byproduct applications, so I think that we have to stop  
23 at that point.

24 COMMISSIONER ROGERS: I have a couple of things  
25 that I would like to just explore with you.

1           In stating that Federal authority would be  
2 maintained in one of your slides you said the FDA would  
3 continue to regulate the manufacture and labelling of  
4 radiopharmaceuticals and medical devices.

5           Have you thought at all for example of who would  
6 deal with the regulation of activities involved with boron  
7 neutron capture therapy, which really involves a reactor?  
8 Have you -- I know that is a little special area right now,  
9 but it might be an example of what your thinking is on this.  
10 That seems to be one that doesn't quite fit into any of  
11 these nice little boxes that we have here.

12           DR. PHILLIPS: No, it doesn't, but I think --

13           VOICE: Cigarettes today, reactors tomorrow.

14           DR. PHILLIPS: I think our feeling was that should  
15 stay with NRC because it is so closely related to reactor  
16 operation. I mean it's not separable -- using the beam from  
17 the reactor and I don't think that could be separated out.

18           COMMISSIONER ROGERS: Well, you are recommending  
19 that there be some kind of a wonderful Federal oversight  
20 that is to accomplish a number of things but it will not be  
21 regulation. The regulation will be through the states, and  
22 that the Federal oversight will be there to assist in  
23 various ways, to promote good practices, develop  
24 regulations, collect data and so on and so forth, but won't  
25 really have any authority as such -- at least -- I don't

1 know. I mean you haven't made it clear I think as to  
2 whether it would or not, and I think we all know that in  
3 these days, and they probably aren't going to go away very  
4 soon, of constrained resources, that very often the only way  
5 that a Federal agency is going to get full participation is  
6 if it has some teeth.

7 I know from many, many times, if I can be  
8 permitted to refer to the reactor area, which is a different  
9 one but nevertheless it has some lessons in it, I know very  
10 well that many of our licensees have said, you know, we are  
11 very grateful that NRC has required that of us because if it  
12 wasn't required our Public Utilities Commission probably  
13 would disallow it as a cost, and yet we think it is a good  
14 thing to do.

15 I am afraid that that kind of situation can easily  
16 occur here if there is a Federal agency which is trying to  
17 do a good job but doesn't -- I mean particularly if you are  
18 talking about the collection of data because the collection  
19 of data costs money -- and that is one of the problems. One  
20 of the QM problems, rule problems, is that it is costing  
21 money and time and resources to do that and I frankly  
22 wouldn't give very much hope for a Federal agency that said  
23 please send us your data -- we need it for our database. I  
24 don't think that will happen. It will happen some places;  
25 in other places it won't. States that have tremendous

1 financial problems are going to say, well, can't really do  
2 that this year, and then you have got a gap in your database  
3 and so I just wonder whether you really have tried to think  
4 about the realities of what that recommendation would carry  
5 with it.

6 I don't think that -- maybe I'm wrong here, but I  
7 don't think in matters that involve health and safety and  
8 cost money that a Federal agency that has no authority is  
9 going to get very far.

10 DR. PUTNAM: I think I would have obviously agreed  
11 with you more five years ago. I do understand where you are  
12 coming from.

13 I think we are looking, truly at a different  
14 paradigm as it relates to health care delivery and the issue  
15 of where Medicare and Medicaid is and the longitudinal  
16 databases that are going to be required to make a lot of  
17 decisions in health care -- utilization costs, cost  
18 effectiveness, long term results, et cetera, so I think it  
19 will be simpler to put the data or collect the data that we  
20 are going to need into that database.

21 Obviously the relationship between the Federal  
22 government and the states as it relates to Medicare and  
23 Medicaid still has yet to be worked out.

24 I think though that the managed health care or the  
25 managed care corporations are those that are going to be

1 responsible for health care in the private sector need this  
2 database.

3 You can collect it related to adverse reactions  
4 but you really need it over the decisionmaking for  
5 reimbursement of those procedures, technologies that  
6 currently are being reimbursed and not really being perhaps  
7 assessed. That is a total different issue than what we are  
8 talking about, but one question is --

9 COMMISSIONER ROGERS: It may be a way of getting  
10 the data.

11 DR. PUTNAM: It may be a way of getting the data.  
12 Do we need to do all these things and so I think that is  
13 more likely now than it was a few years ago. John?

14 MR. VILLFORTH: I just want to make an observation  
15 about your saying that -- the difficulty of getting an  
16 agency, whoever it might be, to do these good things without  
17 some resources or support or a big stick or money or what  
18 have you.

19 I think one would need to go back and look at the  
20 history in the 27 years that the Conference of Radiation  
21 Control Program Directors has been around and look at the  
22 accomplishments that the states have had in protection in  
23 terms of machine produced radiation over the years, which  
24 was done without any mandatory requirements on the part of  
25 the Federal governments, without anything more than the

1 attempted assistance, whether instrumentation development,  
2 the ability to try to assist the states in processing data  
3 that might come in voluntarily -- all sorts of advice and  
4 cooperation and so forth, and that was done without money  
5 flowing to the states for that particular purpose, and I  
6 think if you look at the accomplishments in terms of what  
7 has been done to correct deficiencies of machines, radiation  
8 producing machines particularly in medicine, in that period  
9 a lot has been done without a big stick, without a lot of  
10 money other than the staff at the headquarters that may have  
11 been involved with developing instruments and data  
12 processing and so forth from a voluntary standpoint.

13           Nothing was passed on to the states to accomplish  
14 so I think if there is leadership -- and again, resources  
15 are tighter now than they were 27 years ago and it is more  
16 difficult, states have more pressures put on them -- but in  
17 principle I think that those programs at the state which are  
18 concerned about public health -- the Commissioner of Health  
19 of those states is concerned about safety of his or her  
20 citizens -- those sorts of programs have evolved and can  
21 continue to evolve and I am not so sure that they wouldn't  
22 happen in the program that we have outlined, but it does  
23 need a spark, leadership, and the willingness to work in an  
24 educational environment with the states. That is I think  
25 where we are coming from.

1           CHAIRMAN JACKSON:  If a state decided that it  
2    didn't want this responsibility, is that acceptable to your  
3    committee -- and there is no Federal agency that really has  
4    a real authority with teeth, as Commissioner Rogers would  
5    say -- is that satisfactory to your committee?

6           MS. GOTTFRIED:  Do you mean the responsibility of  
7    expanding their existing regulatory system --

8           CHAIRMAN JACKSON:  That's right.

9           MS. GOTTFRIED:  -- to include byproduct materials?

10          CHAIRMAN JACKSON:  That's right and they have  
11    decide they didn't want to do that.

12          MS. GOTTFRIED:  I think that the committee felt  
13    that it was a state's prerogative, in fact they wouldn't  
14    have access then to byproduct materials so in fact there is  
15    a -- there is not an opportunity to actually come in and  
16    assume responsibility for that state but there is some, for  
17    lack of a better word, punitive approach to dealing with  
18    those states that would not expand their existing programs.

19          CHAIRMAN JACKSON:  So given that, then why is this  
20    not an unfunded mandate that you either, you know, take it  
21    on and you pay for it or you can't have the goodies?

22          MS. GOTTFRIED:  Because there is a sense that the  
23    states would want to appeal to a uniform approach to  
24    regulating radiation in medicine and although it's only -- I  
25    guess one of the things the committee kept on coming back to

1 is it is such a minute area of radiation medicine in  
2 particular. We are talking about 10 percent of radiation  
3 medicine, and then you are talking about radiation  
4 medicine --

5 CHAIRMAN JACKSON: You're doing it, you mean, on  
6 an activity basis not a risk basis necessary?

7 MS. GOTTFRIED: Correct.

8 CHAIRMAN JACKSON: Or both -- but we have already  
9 been talking about data, so --

10 DR. PHILLIPS: Yes. We don't want to get back on  
11 the data argument.

12 I think it's not exactly unfunded because the  
13 states currently fund their programs from license fees and  
14 user fees.

15 MS. GOTTFRIED: User fees.

16 DR. PHILLIPS: And they would certainly be able to  
17 fund this new responsibility that same way, so you are  
18 giving them the opportunity to charge for what they have to  
19 do.

20 MS. GOTTFRIED: I think one of your major  
21 questions is if -- I'm sorry -- that if in fact we allow the  
22 states to make that determination as to whether or not to  
23 incorporate byproduct material, would the people in that  
24 state be at some disadvantage or unprotected, if you will,  
25 and that the states have the prerogative to determine what

1 areas they want to focus their attention on and in many  
2 respects I don't think we will learn the answer to that  
3 unless we give the states the opportunity to assume  
4 responsibility for this area of regulation and I think the  
5 whole issue -- we discussed this at the last meeting we were  
6 at -- that whole cost-benefit --

7 CHAIRMAN JACKSON: Different Commission.

8 MS. GOTTFRIED: Correct -- absolutely -- two-  
9 thirds different, one-third constant -- there is this whole  
10 issue of a cost-benefit analysis and how much in terms of  
11 resources need to be expended for what kind of a return and  
12 what return are we presently getting and given the  
13 unfortunate circumstances that many states are in with  
14 respect to allocation of resources, don't those states have  
15 the prerogative to make a determination as to where there  
16 resources ought to be focused.

17 CHAIRMAN JACKSON: But you didn't ask them all.  
18 Commissioner Dicus.

19 COMMISSIONER DICUS: Thank you. I have two or  
20 three questions or comments. I am not sure based upon just  
21 the exchange we have just had, you may have as good an  
22 understanding of the ability of the states to do this in  
23 terms of the resources that they are going to have available  
24 to them. There are some states that this may not be a  
25 problem. You know, they may be able to go to the fee

1 structure. They may be able to change their fee structures,  
2 but for many states this is a problem. It is very difficult  
3 to do because they are competing with all the other -- the  
4 radiation protection program may be competing with all the  
5 other programs with their state legislatures to get these  
6 funds.

7 Let me ask a question and go back to the issue of  
8 uniformity -- and I think you are aware of this. Within --  
9 and I am not talking about medical practice differences -- I  
10 want to talk about radiation protection programs'  
11 differences, there are variances now -- agreement states or  
12 nonagreement states within theme. There are variances in  
13 we're talking about whether it is a materials programs or  
14 the norm program or strictly just X-ray program.

15 The variances not only may be in the rules  
16 themselves, but the variances may be in the program and the  
17 implementation of that program and the resources that people  
18 have available, that the human resources, the level of  
19 training, the level of expertise.

20 There are even differences within states. There  
21 are states where say the X-ray program is in one state  
22 agency and the materials program is in another state agency,  
23 and those two agencies have inconsistencies.

24 I am not clear as I look at this, I am not clear  
25 where the process that you are recommending might really

1 change that and perhaps you could give me a little bit more  
2 background on your discussions that you think that a new  
3 Federal agency providing guidance can change this and under  
4 what authority? I mean how will it do it?

5 MR. VILLFORTH: I don't think -- I was going to  
6 say that I don't think that one could predict how it would  
7 be changed, and you described I think perfectly the  
8 diversity that presently exists.

9 I think the success of that program has been  
10 through the suggested state regulations and the fact that  
11 the states have worked together with their counterparts at  
12 the Federal government and their colleagues in the states to  
13 come up with whether it is non-ionizing or whatever  
14 regulations and have come up with what is sort of a  
15 consensus that this is the best way that the regulations  
16 should be prepared.

17 Then I think we recognize the reality is, that  
18 some states won't adopt those regulations. Some may not  
19 have any. Some may go even farther and become more specific  
20 in their regulations. I think the important thing is though  
21 that one comes out with a good regulation -- suggested state  
22 regs as the blueprint or the model and allow the states then  
23 to modify that as they see fit.

24 If State X wants to be more aggressive and go  
25 beyond that, that's their option. If they want to drop back

1 and become more relaxed, that is their option too, and it is  
2 done obviously through the regulatory process at the state  
3 with the input from the citizens, the consumer, the patient,  
4 the medical profession and so forth.

5 As far as the other point that you have raised,  
6 which is a reality and that is not only are the regulations  
7 on the books reasonably good and appropriate, consistent,  
8 but is the implementation -- is the enforcement of that in  
9 one state extremely aggressive, in another state  
10 particularly lackadaisical and how does one calibrate that?  
11 I think --

12 COMMISSIONER DICUS: That can affect this database  
13 that we want, too.

14 MR. VILLFORTH: Well, I'm a little confused about  
15 the idea of using regulations to collect data, personally.

16 CHAIRMAN JACKSON: We do it all the time.

17 MR. VILLFORTH: I have problems with that. I  
18 think -- I mean I would hope the regulations would be used  
19 to solve a problem and the problem would be public health --

20 CHAIRMAN JACKSON: Well, the database is an  
21 important part of that. I mean let's not lose sight of  
22 that, that you cannot quantify and understand risk --

23 MR. VILLFORTH: I understand.

24 CHAIRMAN JACKSON: -- without information.

25 MR. VILLFORTH: But if -- well, I won't -- we need

1 a beer some time to talk about this.

2 [Laughter.]

3 MR. VILLFORTH: So there certainly is the range of  
4 how this will be implemented but I think the checks and  
5 balances are at the state level in concert with the medical  
6 community and the patients and the citizens and the state  
7 legislature.

8 I think our feeling was that this is the place to  
9 start and that one could recognize that those variations  
10 would be acceptable within the state framework based on  
11 resources and the state's personality and so forth.

12 DR. HENDEE: Let me follow up with one other  
13 comment and I wonder if this is also true in your  
14 experience.

15 It is true that right now there are some states  
16 that are much more vigorous in their enforcement of non-NRC  
17 types of regulations over radiation than are some other  
18 states. New York and Texas come to mind as especially  
19 vigorous enforcement states.

20 I think it is also true though that in spite of  
21 the rather wide variation from state to state in looking at  
22 the non-byproduct material types of regulation and  
23 enforcement that there is far less variation in the  
24 institutions from one state to another, and that is because  
25 the use of radiation is governed not simply by what some

1 agencies, some regulatory agency says you can and cannot do  
2 but it is much more governed by a variety of voluntary  
3 accreditation processes such as the Joint Commission on  
4 Accreditation of Health Care Organizations and those types  
5 of responsibilities and even more importantly through the  
6 professional societies and the members of those professional  
7 societies that practice in those institutions, so in fact if  
8 you compare two states, one that has a very vigorous X-ray  
9 inspection program and another that has a much more laid-  
10 back X-ray inspection program, great differences in the  
11 level of enforcement, and yet when you look at the use of X-  
12 rays, either diagnostically or therapeutically, in terms of  
13 their medical applications, you will find a pretty  
14 widespread uniformity across those two states because the  
15 way the radiation is used, monitored and controlled and the  
16 way the risks are minimized is pretty consistent because  
17 that is a reflection of the professional activity and the  
18 non-regulatory mechanisms that are in place already.

19 COMMISSIONER ROGERS: Yes, in the institutions, I  
20 would agree, but not from -- necessarily from individual  
21 practitioners. I see enormous variations. In the  
22 institutions, the professionals in the institutions belong  
23 to professional societies, as you say. They meet with each  
24 other, exchange information. They check on each other in a  
25 sense. They act as a check on each other and what is good

1 practice is well recognized and that is the environment in  
2 which they work and that just sort of transfers around.  
3 That is the network, the professional network.

4 But then if you start to look at individual  
5 practitioners that may have an X-ray machine or something or  
6 a cobalt source that might vary enormously from state to  
7 state, depending on how vigorously the state enforced  
8 radiation protection regulations.

9 DR. HENDEE: Well, I think we would have to have  
10 some discussion of that and neither one of us has enough  
11 data to really be able to verify our position but that  
12 variation may be much less than we are led to believe and  
13 certainly the social pressures on those individual  
14 practitioners are such that if they are doing things that  
15 are out of the mainstream, they are certainly going to be  
16 encouraged to come into the mainstream, if nothing more than  
17 just on a competitive position with regard to their  
18 providing health care services.

19 COMMISSIONER DICUS: One other point. To go this  
20 route we are looking at either creating a new Federal agency  
21 or creating a new branch or part of an existing Federal  
22 agency and obviously there are costs associated with that.

23 Likewise, looking realistically at the potential  
24 at least of some more -- 50 plus radiation protection  
25 programs at the state level having to have statute

1 modifications and certainly perhaps regulation modifications  
2 and adopting new regulations or revising regulations is  
3 time-consuming and it varies of course from state to state  
4 depending on their administrative processes, but it is also  
5 extremely costly. It can run into the tens of thousands of  
6 dollars just to modify a regulation in real money as well as  
7 in the resources needed to do that.

8           When you have to take your people to do this, your  
9 people are not doing other things, so my question is did you  
10 calculate the costs and what are they and who is going to  
11 pay for it?

12           DR. PUTNAM: No, we did not calculate the costs.

13           Clearly in many of the states we think they  
14 probably do have the process in place. It is still additive  
15 but many of the states that have essentially taken over much  
16 of the responsibility for the basic aspects of radiation,  
17 this probably wouldn't be too excessive.

18           There indeed are states though, as we have said,  
19 that are going to need more, but we have not calculated that  
20 cost.

21           DR. PHILLIPS: Let me point out there that the 29  
22 agreement states already have these programs so that this  
23 should not be any additional costs for them and those are  
24 most of the big states population-wise so that the net  
25 cost -- you know, we didn't do a formal calculation -- would

1 only be to those states that are non-agreement and in the  
2 long run the costs that the users would save if we agree  
3 there is some over-regulation now and the fees that would be  
4 paid to the state hopefully lower than currently paid to the  
5 NRC, would make up for any additional costs.

6 COMMISSIONER DICUS: But even agreement states may  
7 find that they have to do some statute changes.

8 DR. PHILLIPS: Yes.

9 COMMISSIONER DICUS: Or some regulations, so they  
10 will have some costs.

11 CHAIRMAN JACKSON: I'd like to thank each of you,  
12 each member of the committee today and its study staff for  
13 your briefing and your report. It's been a truly  
14 stimulating discussion and it is clear that you have devoted  
15 many hours to the effort.

16 The issue of NRC's regulatory role in the medical  
17 uses of byproduct material is not a simple or a trivial one  
18 and the committee's report however will be of tremendous  
19 benefit to us in enabling the Commission to fully evaluate  
20 the merits of the various regulatory regimes for regulation  
21 and for use of byproduct material in medical uses.

22 Rest assured we will give careful and serious  
23 thought to your report as we deliberate and the committee  
24 and the study staff are to be commended for a product that  
25 advances our decision-making process in this important area

1 and we really appreciate your efforts.

2 COMMISSIONER ROGERS: Thank you very much. We  
3 appreciate it.

4 MS. GOTTFRIED: We would also like to thank the  
5 NRC Staff for providing us with a lot of information during  
6 the course of the two years and appreciate all the  
7 assistance provided.

8 [Whereupon, at 3:29 p.m., the briefing was  
9 adjourned.]

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CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: BRIEFING BY NATIONAL ACADEMY OF  
SCIENCES ON REVIEW OF MEDICAL USE  
PROGRAM - PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Tuesday, February 27, 1996

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Christopher Gitchell

Reporter: Michael Paulus



# National Academy of Sciences Institute of Medicine

Committee to  
Review and Evaluate the  
Medical Use Program of the  
United States Nuclear Regulatory Commission

# Committee Members

- ◆ Charles E. Putman, MD, *Chairman*
- ◆ Robert S. Adler, JD
- ◆ Byron Wm. Brown, Jr, PhD
- ◆ Jennifer Bucholtz, RN, MS, OCN
- ◆ Timothy Conlan, PhD
- ◆ Barbara Y. Croft, PhD
- ◆ Sister Rosemary Donley, SC
- ◆ David S. Gooden, JD, PhD
- ◆ William Hendee, PhD
- ◆ David Kuhl, MD
- ◆ Lester Lave, PhD
- ◆ Theodore Phillips, PhD
- ◆ Marcia O. Stevic, PhD, RN
- ◆ John Villforth
- ◆ J. Frank Wilson, MD, FACR
- ◆ Barry L. Zaret, MD

# Description of Study

**Objective:** 16 member interdisciplinary committee reviews and evaluates the USNRC Medical Use Program, specifically reactor-generated radionuclides.

**Methodology:** Commissioned papers  
Six Committee Meetings  
Public Hearing  
Quality Management Technical Panel  
Four Site Visits

# Statement of Task

Three major goals:

- 1 Examine the broad policy issues that underlie regulation of the medical uses of radioisotopes;
- 2 Study the overall levels of risk associated with the use of ionizing radiation in medicine, comparing the errors and consequences of--
  - a) the use of byproduct materials to other medical interventions, and
  - b) the use of byproduct misadministrations to properly conducted administrations;
- 3 Assess the current statutory or regulatory framework for regulation of medical uses of byproduct materials.

# Description of Study

(continued)

- 1 Examination of the overall risk associated with the use of ionizing radiation in medicine.
  - a) The frequency of errors and consequences associated with the use of licensed byproduct materials in relation to other medical procedures (such as chemotherapy, surgery, general anesthesia or administration of pharmaceuticals); and
  - b) Given the total use of licensed byproduct materials, the error rate, mortality and morbidity of misadministrations compared to administrations of licensed byproduct materials that are properly carried out.

# Description of Study

(continued)

- 2 Examination of the broad policy issues that underlie the regulation of radionuclides.
  - a) Adequacy of the 1979 Medical Use Policy Statement and the consistency of USNRC regulations and guidance with it;
  - b) Extent of USNRC's responsibility to the patient involved in a misadministration, including notification and follow up;
  - c) The appropriate role for the USNRC medical consultant in the medical use program;
  - d) Whether the USNRC's regulatory policy could more effectively promote better patient care or safer medical uses of radionuclides.

# Description of Study

(continued)

## 3 The USNRC seeks recommendations on:

- a) A uniform national approach to the regulation of ionizing radiation in all medical applications, and
- b) Appropriate criteria for measuring the effectiveness of the regulatory program(s) needed to protect public health and safety.

TABLE 2.1 Radiation in Medicine

Radiation Source	Origin	Applications	
		Diagnostic	Therapeutic
<b>Ionizing Radiation<sup>a</sup></b>			
Radioactive Materials			
<b>Reactor-generated byproduct material</b>	<b>Nuclear reactors</b>	<b>Nuclear medicine (radiopharmaceuticals)<sup>b</sup></b>	<b>Nuclear medicine (radiopharmaceuticals)<sup>b</sup> Teletherapy (sealed sources) Brachytherapy (sealed sources)</b>
Radium	Naturally occurring		Brachytherapy
Accelerator-generated radionuclides	Particle accelerators (linear accelerators, cyclotrons)	Nuclear medicine (radiopharmaceuticals)	Nuclear medicine (radiopharmaceuticals) Brachytherapy (sealed sources)
<b>Machine-Produced Radiation<sup>c</sup></b>			
X-radiation	X-ray machines	Radiography Fluoroscopy Computed tomography Dental x-rays	External beam x-ray therapy
High-energy particle radiation	Particle accelerators (linear accelerators, cyclotrons)		Electron, neutron, and positive ion therapy
<b>High-energy particle radiation</b>	<b>Nuclear reactors</b>		<b>Boron neutron capture therapy</b>
<b>Nonionizing Radiation<sup>d</sup></b>			
	Magnetic resonance imaging (MRI) machine	MRI scan	
	Ultrasound	Ultrasound scan	

NOTE: Sources or machines indicated in **bold** are subject to NRC regulation. All others may be regulated at the state level.

<sup>a</sup> Scope of Institute of Medicine study.

<sup>b</sup> Also subject to regulation by the Center for Drug Evaluation and Research and/or the Center for Biologics Evaluation and Research of the Food and Drug Administration (FDA).

<sup>c</sup> All devices are subject to regulation by the FDA's Center for Devices and Radiological Health.

<sup>d</sup> Uses of nonionizing radiation are included here for illustrative purposes only; they are not within the scope of this study.

# Medical Policy Statement

- ◆ 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.
- ◆ 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.
- ◆ The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be part of the practice of medicine.

# Subcommittees

- ◆ Data / Risk
- ◆ Education / Training
- ◆ Regulatory
- ◆ Quality Management

# Public Meeting

## Request for Written Testimony:

- ◆ 153 Letters Inviting Written Testimony
  - 124 Professional Associations, Societies, and Industries
  - 29 Agreement States
- ◆ 5 Unsolicited Responses
- ◆ 38 Respondents Submitted Written Testimony

# Public Meeting Presenters

Total Number: 15

- ◆ American College of Radiology
- ◆ Radiological Society of North America
- ◆ American Brachytherapy Society
- ◆ American Society for Therapeutic Radiology and Oncology
- ◆ American Roentgen Ray Society
- ◆ American Association of Clinical Endocrinologists
- ◆ American College of Nuclear Physicians
- ◆ Society of Nuclear Medicine
- ◆ American Association for Nuclear Cardiology Inc.
- ◆ American Association of Physicists in Medicine
- ◆ Conference of Radiation Control Program Directors
- ◆ Health Physics Society
- ◆ American Medical Association
- ◆ National Electrical Medical Manufacturers Association
- ◆ Mallinckrodt Medical Inc

# Site Visits

- ◆ Georgia
  - ◆ State Radiation Offices
  - ◆ County Departments of Health
  - ◆ Major University Medical Centers
  - ◆ Veteran's Administrations
  - ◆ Mid-Size Hospitals
  - ◆ Small Hospitals
  - ◆ Private Physician Practices
  - ◆ Pharmaceutical Companies
- ◆ Minnesota
- ◆ Massachusetts
- ◆ California

# Committee's Goals

- ◆ to promote greater uniformity of regulation of all ionizing radiation in medicine;
- ◆ to shift federal oversight to an agency experienced in matters of public health, and to further ensure adequate protection of the public's health and safety; and
- ◆ to consolidate regulation of all ionizing radiation in medicine by delegating regulatory authority for reactor-generated byproduct materials to the states, which presently regulate NARM-- 90% of radiation medicine.

# Federal Regulation

Elimination of the NRC's Medical Use Program does not alter the basic structure of federal regulation. The federal government would still retain responsibility for the generation, transport, nonmedical use, and disposal of radionuclides and for the approval of radiopharmaceuticals and certification or approval of equipment that generates ionizing radiation.

# Federal Authority Maintained

- ◆ the NRC and its Agreement States would continue to license the production of byproduct material for radiation-producing devices and radiopharmaceuticals in the medical context;
- ◆ the NRC and its Agreement States would, as relates to the nonmedical use of byproduct material (i.e., industrial, educational and nonmedical research), continue to license the production and use of byproduct material;

# Federal Authority Maintained

continued

- ◆ the Department of Transportation would continue to regulate the transport of radioactive materials;
- ◆ the Environmental Protection Agency would continue to develop guidelines that set occupational and public exposure limits to be implemented by the respective federal agencies;

# Federal Authority Maintained

continued

- ◆ the FDA would continue to regulate the manufacture and labeling of radiopharmaceuticals and medical devices;
- ◆ the FDA would continue to regulate the mammography program under the Mammography Quality Standards Act;

# Federal Authority Maintained

continued

- ◆ the Department of Defense (DOD), the Department of Veterans Affairs (VA), and the Public Health Service (PHS) would continue to be responsible, under the regulations of the appropriate agencies, for the safe use of radioactive materials and radiation-producing machines in their hospitals and laboratories; and

# Federal Authority Maintained

continued

- ◆ the Health Care Financing Administration for Medicare and Medicaid (and other federal agencies for other health care purchased from the private sector) would continue to develop reimbursement guidelines.

# Preferred Alternative

The committee preferred a regulatory structure that transferred authority to the states and identified a federal agency, other than the NRC, to work in conjunction with the CRCPCD and other professional organizations to develop recommended state laws and regulations for all ionizing radiation in medicine.

# Federal Guidance

The identified federal agency would:

- ◆ assist states in establishing regulatory programs and train radiation control personnel
- ◆ address problematic incidents of national concern
- ◆ educate the public of the benefits and risks of radiation medicine
- ◆ conduct research so that the science of radiation medicine continues to advance
- ◆ collect risk data (or act as a clearinghouse)
- ◆ monitor the effects of deregulation

# Recommendations

Recommendations were made to:

- ◆ The United States Congress
- ◆ The U.S. Nuclear Regulatory Commission
- ◆ The Conference of Radiation Control Program Directors and to the States

# Recommendations to Congress

- A1. Congress eliminate all aspects of the NRC's Medical Use Program, 10 CFR Part 35, and those regulatory activities conducted under 10 CFR Part 20 that are applicable to medical uses.

# Recommendations to Congress

continued

- A2. Congress direct the Secretary of Health and Human Services to support, coordinate, and encourage the following activities involving regulation of all ionizing radiation in medicine:
  - a. supporting the operation of the Conference of Radiation Control Program Directors;

# Recommendations to Congress

continued

- b. providing a venue for the review and evaluation of Suggested State Regulations for Control of Radiation;
- c. assisting states in implementation of their regulations;

# Recommendations to Congress

continued

- d. aiding in assessment of the effectiveness of state programs through the collection and analysis of data;
- e. helping develop survey methods by which the rate of adverse events for a wide range of procedures and devices might be measured;

# Recommendations to Congress

continued

- f. monitoring the effects of deregulation;
- g. enhancing training and standards for health care personnel; and
- h. investigating future significant radiation medicine incidents.

# Recommendations to the Nuclear Regulatory Commission

- B1. The NRC immediately relax enforcement of 10 CFR 35.32 and 35.33 through its present mechanisms.

# Recommendations to the NRC

continued

- B2. The NRC initiate formal steps under the Administrative Procedure Act to revoke Part 35 in its entirety, if Congress fails to act within two years in response to the two recommendations to Congress stated above.

# Recommendations to the NRC

continued

- B3. The NRC separate the costs of formulating regulations from the costs of administering those regulations.

# Recommendations to the Conference of Radiation Control Program Directors and to the States

- C1. The Conference of Radiation Control Program Directors incorporate into its Suggested State Regulations for Control of Radiation any relevant concepts from 10 CFR Part 35 that are not already integrated in those suggested regulations.

# Recommendations to the CRCPCD and to the States

continued

- C2. All state legislatures enact enabling legislation to incorporate the regulation of reactor-generated byproducts into existing state regulatory programs.

# Recommendations to the CRCPD and to the States

continued

- C3. The Conference of Radiation Control Program Directors and the states continually reevaluate their regulations and procedures pertaining to radiation medicine to ensure congruence with evolving scientific understanding of radiation bioeffects and to be in accord with advances in knowledge regarding benefits and risks related to medical and biomedical research uses of ionizing radiation in medicine.