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

ANN RILEY & ASSOCIATES, LTD.
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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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BRIEFING BY NATIONAL ACADEMY OF SCIENCES

ON REVIEW OF MEDICAL USE PROGRAM

- - -

PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland
Tuesday, February 27, 1996

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

COMMISSIONERS PRESENT:

SHIRLEY A. JACKSON, Chairman of the Commission
KENNETH C. ROGERS, Commissioner
GRETA J. DICUS, Commissioner

STAFF SEATED AT THE COMMISSION TABLE:

JOHN C. HOYLE, Secretary of the Commission

MARTIN MALSCH, Deputy General Counsel

COMMITTEE MEMBERS PRESENT:

CHARLES E. PUTMAN, Chairman

KATE-LOUISE GOTTFRIED, Study Director

WILLIAM HENDEE

JOHN VILLFORTH

DAVID GOODEN

THEODORE PHILLIPS

GARY PENN

CARL PAPERIELLO, Director, NMSS

P R O C E E D I N G S

[2:00 p.m.]

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

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

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

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

effectiveness of the regulatory program.

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

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

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

COMMISSIONER ROGERS: Not at this time.

COMMISSIONER DICUS: No.

CHAIRMAN JACKSON: If not, you may proceed.

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

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

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

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

On my far left is Gary Penn, staffmember at the

Institute of Medicine.

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

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

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

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

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

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

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

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

The first slide, please.

[Slide.]

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

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

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[Slide.]

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

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[Slide.]

MS. GOTTFRIED: The Committee's goals were to promote greater uniformity of regulation of all ionizing radiation in medicine, specifically the regulation of byproduct and nonbyproduct material. To shift the 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 the regulation of all ionizing radiation in medicine by delegating regulatory authority for reactor-generated byproduct materials to the states, which presently regulate NARM or approximately 90 percent of radiation medicine.

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[Slide.]

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

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

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

Alternative C really emphasizes state control.

Alternative D emphasizes -- and I will elaborate further on Alternative D -- but emphasizes authority delegated to the states with some federal oversight and guidance. Alternative E reserves residual authority so in the instance where the states would have an opportunity to regulate, if in fact the state didn't regulate, the feds would have the opportunity to assume control over a particular state program. Alternative F really emphasizes central regulation of all ionizing radiation in medicine. Alternative G was really quite comprehensive and tied reimbursement and regulation issues all together under one central agency for all of medicine.

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

MS. GOTTFRIED: Certainly.

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

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

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

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

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

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

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

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

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

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

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

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

prior slide --

[Slide.]

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

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

[Slide.]

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

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

And, finally, slide, please.

[Slide.]

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

And, finally, next slide, please.

[Slide.]

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

[Slide.]

MS. GOTTFRIED: 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 its reimbursement guidelines.

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

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

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

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

Following slides -- slide, please.

[Slide.]

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

Recommendations to Congress. The first recommendation is that 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.

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[Slide.]

MS. GOTTFRIED: The second recommendation to Congress is that the 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:

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

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[Slide.]

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

their regulations.

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[Slide.]

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

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[Slide.]

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

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

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[Slide.]

MS. GOTTFRIED: That the NRC initiate -- and this again is an issue of sequencing -- that 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 provided to Congress and that were stated earlier.

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[Slide.]

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

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

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

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

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

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

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

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

[Laughter.]

DR. PHILLIPS: I'm sorry.

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

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

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

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

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

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

MS. GOTTFRIED: Yes, that's true.

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

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

COMMISSIONER ROGERS: Not so easy to see.

MS. GOTTFRIED: Correct.

COMMISSIONER ROGERS: For agreement states.

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

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

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

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

CHAIRMAN JACKSON: Why don't you go on.

MS. GOTTFRIED: The next slide, please.

[Slide.]

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

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

programs.

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[Slide.]

MS. GOTTFRIED: And the final recommendation made to the CRCPD and the states, that the CRCPD 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The other thing, the Committee looked at

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

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

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

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

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

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

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

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

There wasn't any survey done of the --

CHAIRMAN JACKSON: There was no systematic --

MS. GOTTFRIED: Correct.

CHAIRMAN JACKSON: -- of each of the states?

MS. GOTTFRIED: Correct.

DR. PUTMAN: No.

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

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

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

DR. HENDEE: That's correct.

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

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

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

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

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

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

DR. PUTMAN: John?

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

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

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

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

DR. PUTMAN: David?

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

COMMISSIONER ROGERS: Do you have any numbers, any

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

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

DR. PUTMAN: Bill.

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN JACKSON: Yes, how comprehensive was that database?

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN JACKSON: Do you think that such a

database need not exist?

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

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

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

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

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

DR. PUTMAN: Dave?

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

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

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

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

rule that requires reporting.

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

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

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

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

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

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

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

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

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

MR. VILLFORTH: Education --

CHAIRMAN JACKSON: That is not gathering data.

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

The question is, how does one get at it.

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

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

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

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

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

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

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

managed care environment to begin with.

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

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

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

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

DR. PAPERIELLO: Yes.

[Laughter.]

DR. PAPERIELLO: What is the precise question?

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

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

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

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

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

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

CHAIRMAN JACKSON: Thank you.

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

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

We talked a lot about the need for a database for

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

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

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

Did I answer your question well enough?

CHAIRMAN JACKSON: Thanks. Commissioner Rogers,

do you have some additional questions?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VOICE: Cigarettes today, reactors tomorrow.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN JACKSON: That's right.

MS. GOTTFRIED: -- to include byproduct materials?

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

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

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

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

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

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

MS. GOTTFRIED: Correct.

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

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

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

MS. GOTTFRIED: User fees.

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

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

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

CHAIRMAN JACKSON: Different Commission.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CHAIRMAN JACKSON: We do it all the time.

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

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

MR. VILLFORTH: I understand.

CHAIRMAN JACKSON: -- without information.

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

a beer some time to talk about this.

[Laughter.]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

DR. PHILLIPS: Yes.

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

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

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

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

and we really appreciate your efforts.

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

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

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

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 Gotchall

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
Ionizing Radiation[a]			
Radioactive Materials			
Reactor-generated byproduct material	**Nuclear reactors**	**Nuclear medicine (radiopharmaceuticals[b])**	**Nuclear medicine (radiopharmaceuticals[b])** **Teletherapy (sealed sources)** **Brachytherapy (sealed sources)**
Radium	Naturally occurring		Brachytherapy
Accelerator-generated radionuclides	Particle accelerators (linear accelerators, cyclotrons)	Nuclear medicine (radiopharmaceuticals)	Nuclear medicine (radiopharmaceuticals) Brachytherapy (sealed sources)
Machine-Produced Radiation[c]			
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
High-energy particle radiation	**Nuclear reactors**		**Boron neutron capture therapy**
Nonionizing Radiation[d]			
	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.

[a] Scope of Institute of Medicine study.
[b] 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).
[c] All devices are subject to regulation by the FDA's Center for Devices and Radiological Health.
[d] 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
- Minnesota
- Massachusetts
- California

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

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 CRCPD 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 CRCPD 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.