

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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BRIEFING ON OPTIONS FOR CHANGES TO
REGULATION OF NUCLEAR MEDICINE

- - - -

PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Thursday, July 29, 1993

The Commission met in open session,
pursuant to notice, at 10:00 a.m., Ivan Selin,
Chairman, presiding.

COMMISSIONERS PRESENT:

IVAN SELIN, Chairman of the Commission
KENNETH C. ROGERS, Commissioner
FORREST J. REMICK, Commissioner
E. GAIL de PLANQUE, Commissioner

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STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

WILLIAM C. PARLER, General Counsel

JAMES TAYLOR, Executive Director for Operations

RICHARD VOLLMER, Director, Office of Policy Planning

CHARLES NORELIUS, Region III

JOSEPHINE PICCONE, Senior Program Manager, Medical and Academic Section

JOHN TELFORD, Regulation Development Branch, NRR

DON HAMILTON, Food and Drug Administration

LLOYD BOLLING, Health Physicist, Office of State Programs

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

10:00 a.m.

CHAIRMAN SELIN: Good morning, ladies and gentlemen.

The Commission is meeting at this time to receive a briefing from the NRC staff and the non-NRC members of the task force concerning the very important subject of options for the regulation of the medical use of radiation in this country.

On May 6th of this year the Commission testified on the subject before the Senate Committee on Government Affairs, Chaired by Senator Glenn. Part of our testimony discussed the current situation with regard to the distribution of responsibility for regulating radiation medicine. Now, radiation medicine is a phrase which basically doesn't mean nuclear medicine and it doesn't mean radiation therapy. I'm not exactly sure what it does mean, but it's designed not to get us a letter from the American College of Physicians.

The fact that materials regulated under the Atomic Energy Act and therefore subject to control either by the NRC or by one of our 29 agreement states are used in only about a quarter of the cancer therapy treatments. Electronically generated radiation

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1 produced mostly by linear accelerators is used for the
2 other 75 percent of therapy treatments and is not
3 subject to regulation or control under the Atomic
4 Energy Act. This radiation is regulated at the user
5 level by the individual states without involvement of
6 the federal government and the distinction is the
7 responsibility of the federal government for devices
8 and for the handling of sources, but the key emphasis
9 today is on the application of radiation in medicine
10 and what regulation ought to be done at the federal
11 level.

12 Because of the disparity between the
13 really pervasive federal regulation of radiation
14 medicine from AEA sources as opposed to the device-
15 oriented regulation from other sources and for a
16 number of other reasons our testimony touched on what
17 appeared to be some of the fundamental options for
18 instilling a higher degree of uniformity in our
19 national regulatory scheme. We also promised Senator
20 Glenn that we would prepare a preliminary report
21 examining these options and provide it to him by this
22 coming August 6th, three months after the hearing.

23 At this point, the task force has
24 completed its work in conducting a preliminary review
25 of the available options to the regulation of the

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1 medical use of radiation and has prepared a report
2 documenting its efforts and results. It is this
3 report that is the subject of this meeting and the
4 Commission is, to say the least, very interested in
5 what the staff and the task force has found in its
6 inquiry into the area.

7 Copies of the staff's report are available
8 at the entrances to the meeting room.

9 Commissioners, are there --

10 COMMISSIONER de PLANQUE: No.

11 CHAIRMAN SELIN: Mr. Taylor, please.

12 MR. TAYLOR: Good morning. Mr. Vollmer
13 will give the presentation and introduce the members
14 of the task force. I would note that this report was
15 put together in a period of slightly in excess of two
16 months and that in my view it begins to frame the
17 issues but doesn't -- and lays the groundwork for what
18 could be future work by OPP and the staff, the rest of
19 the staff with regard to actions resulting from this
20 report.

21 With those thoughts, I'll ask Dick Vollmer
22 to begin the briefing.

23 MR. VOLLMER: Thank you.

24 Mr. Chairman, Commissioners, this morning
25 we would like to brief the Commission on the results

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1 of a task force effort and our report on medical
2 radiation protection.

3 First I'd like to introduce the members of
4 the task force to you. From your left, John Telford
5 from the Office of Research. Next to me, Josephine
6 Piccone from NMSS. On the other side of Mr. Taylor
7 are Chuck Norelius of Region III. Next to him is Don
8 Hamilton from the Center for Devices and Radiological
9 Health in FDA.

10 I might indicate that when we were first
11 given this assignment I met with Doctor Burlington who
12 testified also at the May 6th hearing, who is Director
13 of the Center for Devices and Radiological Health,
14 Rosenstein and Don to enlist their aid in the task
15 force effort. As a result of that meeting, Don became
16 a member of the task force to provide the FDA
17 perspective and to assure that FDA's role in the
18 medical uses of radiation was properly presented or
19 represented.

20 Also, next to Don is Lloyd Bolling of the
21 Office of State Programs.

22 Not at the table are Maria Schwartz,
23 Office of General Counsel, in back of Mr. Parler, and
24 Janet Lambert and Darrel Nash of my staff are sitting
25 behind us.

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1 All these people provided strong support
2 to the task force effort and will be able to respond
3 to the Commission's questions.

4 We also receive strong support from the
5 program offices.

6 (Slide) I'd like to turn now to slide 1
7 and provide a brief background on how we got where we
8 are today.

9 As the Chairman indicated, the May 6th
10 Glenn hearing in which the Commission testified, he
11 requested the Commission's advice on how the
12 regulation of all sources of medical radiation might
13 be done better and the Chairman agreed to provide a
14 preliminary report in three months and this task force
15 effort is the culmination of that activity.

16 As you had indicated, Mr. Chairman, this
17 review of ours was not to be limited to sources of
18 ionizing radiation strictly under NRC's purview, but
19 we were to look at all sources and take a look at the
20 best federal envelope or federal/state envelope for
21 handling that particular activity.

22 On May 17th the EDO provided a plan of
23 action to the Commission in which he established the
24 task force and indicated several options for change
25 that should be considered by the task force. We

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1 proceeded then to develop and get a stakeholder's
2 input on the plans, on our plans to evaluate those
3 options. The first effort in that regard was on May
4 20th when I met with most of the state representatives
5 at a public meeting which was chaired by State
6 Programs, a meeting which followed the annual meeting
7 of the Conference of Radiation Control Program
8 Directors. I got their views on a transcribed basis
9 to the options that were suggested in the EDO's memo
10 and on the general issue of regulation of medical
11 radiation. We received, I think, some good feedback
12 from that, which helped us in our further work.

13 The task force then formalized its plan to
14 respond to Mr. Taylor's May 17th memo and we sent a
15 tentative plan to you on June 2nd and the Commission
16 provided the task force with an additional direction
17 in an SRM dated June 10th and we proceeded on that
18 basis to develop our plans and programs to follow that
19 direction. In that the Commission requested that we
20 characterize the problems associated with medical
21 ionizing radiation to the greatest extent possible on
22 currently available information, identify options that
23 should be closely evaluated and suggest the database
24 necessary for a productive evaluation. So that we
25 took as our three directives, if you will, and

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1 proceeded with the main emphasis, of course, to
2 respond in terms of providing you with preliminary
3 options that might be viable to meet what we would
4 characterize as the problem that we have articulated.

5 (Slide) As additional background, I'd
6 like to indicate briefly the current regulatory
7 framework as shown on slide 2. When we talk about
8 medical radiation today and in our report, we are in
9 all cases referring to ionizing radiation and we're
10 not dealing with the subject of non-ionizing
11 radiation. As you indicated also, Mr. Chairman, when
12 we talk about medical radiation we're talking about
13 use of therapy and diagnosis and otherwise we will be
14 very specific when we talk about therapeutic uses or
15 diagnostic uses.

16 The NRC regulation is limited principally
17 to byproduct material used for diagnosis or therapy
18 and, as you indicated, in therapy this covers perhaps
19 25 percent or so of the administrations. Also
20 important to keep in mind is that we require reports
21 of misadministrations at the user level. FDA control,
22 on the other hand, regulates all devices and drugs but
23 at the manufacturer level and reports are required by
24 FDA of defective products in the event of death or
25 serious injury, but such reporting is through the

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1 manufacturer generally based on information from the
2 user.

3 Finally, turning to slide 3 --

4 COMMISSIONER REMICK: Dick, a question on
5 that.

6 MR. VOLLMER: Yes.

7 COMMISSIONER REMICK: Are there any cases
8 where source or special nuclear material is used in
9 diagnosis or therapy?

10 MR. VOLLMER: I'd like to ask Chuck.

11 MR. NORELIUS: The only use of those
12 materials in the medical area that I'm aware of is
13 source material being used as shielding for the
14 teletherapy units and SNM is used for pacemakers. But
15 other than that, I'm not aware of other uses of those
16 materials.

17 COMMISSIONER REMICK: Okay. I thank you.

18 MR. VOLLMER: (Slide) Okay. Turning to
19 slide 3, the states, who have a broad public health
20 and safety responsibility, have sort of a mixed set of
21 regulatory responsibilities in the medical radiation
22 area. In the NRC agreement states, the regulation of
23 medical radiation from byproduct material sources is
24 done with compatible programs, but NARM and machine
25 sources, that regulation depends on the state program

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1 itself. Most agreement states do exercise control
2 similar to that for byproduct material for NARM and
3 machine sources, but that is not necessarily the case.

4 State implementation of NRC requirements
5 also lags our implementation because, in many cases of
6 the need to implement them through legislation and
7 through their state process. So, this provides
8 perhaps another parameter, a variation in the state
9 implementation structure.

10 The programs in the non-agreement states
11 vary widely since the byproduct material users are NRC
12 licensees who must respond to our requirements. And
13 the users of non-byproduct sources need follow
14 whatever the state regulations are in effect. Some of
15 these are fairly strong. Some of these state programs
16 are fairly strong, but in some cases the state
17 programs are very minimal.

18 COMMISSIONER ROGERS: Is there any
19 generalization that you might be able to make about
20 the non-agreement states versus the agreement states
21 with respect to devices? Is all that you can say that
22 they vary greatly? I mean is there --

23 MR. VOLLMER: Well --

24 COMMISSIONER ROGERS: I mean even though
25 they vary greatly, is there something that is somewhat

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1 different in agreement states and non-agreement states
2 in the way they handle devices?

3 MR. VOLLMER: Again, I'd like to ask Chuck
4 to address that.

5 COMMISSIONER ROGERS: Just because in the
6 agreement states they presumably have an integrated
7 program whereas in the non-agreement states it's a
8 little different.

9 MR. NORELIUS: I don't know that there's
10 any further characterization that we could make. One
11 could probably do a study and pulse each of the
12 states. We did not do that. So, I think the best we
13 can say today is that they vary.

14 COMMISSIONER ROGERS: Okay.

15 CHAIRMAN SELIN: It's actually an
16 interesting question because in your report you
17 pointed out that it was a little vague who you were
18 talking about, but that some of the state programs had
19 taken NRC type programs which we had developed for the
20 source material devices and had analogous programs for
21 the non-source devices. That's actually a very
22 important observation because from first principles if
23 the program for the electronic devices is working so
24 well without NRC-type federal regulation, why should
25 we bother regulating the source type devices? If it's

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1 not working so well, maybe the regulations should be
2 extended to the non-electronic devices? It was sort
3 of the germ of an idea that says a little federal
4 regulation goes a long way, just as an example.

5 MR. NORELIUS: And that's part of the
6 dilemma that we had with the inability to really
7 articulate or compare the differences between programs
8 because of reporting requirements and other things,
9 the data set is lacking, to tell how much difference
10 in the health and safety perspective is accomplished
11 by the application of programs ala the NRC
12 requirements versus the things the states might set up
13 themselves. It's clear in some states that the
14 program is very minimal. They might have a very low
15 effort also, but on the other hand some of the states
16 are very strong in this area.

17 We didn't have the opportunity to do that.

18 CHAIRMAN SELIN: Well, you're not supposed
19 to be doing a study, you're supposed to be doing a
20 preparation for a study. But still, that raised
21 another question which at some point ought to be
22 addressed, and that is a more general question which
23 is do the non-AEA -- radiation, but non-AEA radiation
24 programs in agreement states, are they generally
25 stronger than those in non-agreement states? In other

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1 words, one of the basis for the agreement state
2 programs is that you would get a better overall
3 integrated radiation health program if the same
4 organization was responsible for all radiation health,
5 some of it under our standards and some of it on their
6 own? To the best of my knowledge, we've never really
7 tried to test that hypothesis.

8 MR. VOLLMER: It's my belief that that is
9 correct, but I'd ask anybody else who would like to
10 comment on that.

11 Lloyd?

12 MR. BOLLING: I would say that with regard
13 to the non-AEA materials, we would expect that they
14 would treat those materials the same as AEA materials.

15 CHAIRMAN SELIN: In the agreement states?

16 MR. BOLLING: Yes.

17 CHAIRMAN SELIN: Yes. But have we ever
18 looked to see if that's more true in the agreement
19 states than in the non-agreement states? In other
20 words, in the non-agreement states you have a real
21 partition of responsibility for radiation health. We
22 directly regulate one part, the states regulate
23 another part. Have we ever looked to see if the part
24 that the states regulate has benefitted in the
25 agreement states from being integrated across the

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1 board.

2 MR. BOLLING: Not to the extent that we've
3 looked at it in the agreement states.

4 CHAIRMAN SELIN: It seems to me that at
5 some point we should do that, having a little bit
6 outside your scope but not completely because that's
7 one of the major original justifications for the
8 agreement state program.

9 MR. VOLLMER: Yes. As I had indicated
10 earlier, the NRC licensees rather than state licensees
11 are under the state program. So --

12 CHAIRMAN SELIN: Okay.

13 MR. VOLLMER: -- I believe there is a
14 bigger difference, but I don't think we've quantified
15 it or really proved it out.

16 CHAIRMAN SELIN: Mr. Telford?

17 MR. TELFORD: There is somewhat of a
18 confounding influence that when you look at the
19 dichotomy between agreement states and non-agreement
20 states, it turns out that the states with the largest
21 number of medical use licensees, for example
22 California, Texas, New York, are agreement states.
23 So, if you look at the non-agreement states and look
24 at how many medical use licensees they have, I don't
25 think in general you find states with very many

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1 licensees. That's true of a large number of even
2 agreement states. I think I'm referencing some old
3 data that I did a couple years ago, but it's something
4 like 50 percent or 60 percent even of the agreement
5 states, if you look at the number of medical use
6 licensees they have, you have to get beyond that point
7 before you exceed 100 licensees. When you get to the
8 top five or six, you see hundreds, if not thousands of
9 medical use licensees. So, it's a little bit of a
10 strange comparison, so you have this confounding
11 influence.

12 CHAIRMAN SELIN: Pennsylvania, of course,
13 is not an agreement state and that's the large one.

14 COMMISSIONER REMICK: Ohio.

15 CHAIRMAN SELIN: Yes.

16 MR. VOLLMER: Okay. Thank you.

17 (Slide) Slide 4 provides our general
18 approach on how we develop the issues contained in our
19 report. Briefly we used the Glenn hearing transcript,
20 input from the May 20th meeting with the states,
21 guidance from the Commission, meetings with the NRC
22 staff and so on to formulate the question to be
23 addressed and the issues that would be related to
24 resolving that question. We then sent our
25 articulation of these issues to a selection of

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1 stakeholders in the practice and regulation of medical
2 uses of radiation, and I'll get to who those were in
3 a couple of slides, and requested their views on
4 whether the issues were correct and what would be
5 possible options for rectification of any problem
6 areas.

7 Now, based on the input we received, we
8 developed our findings and then broadly characterized
9 the problem as we saw it based on these findings. We
10 then looked at various options for resolution of the
11 identified problems and issues and selected a
12 preliminary set but not an all-inclusive set of
13 options, as I'll get to a little bit later.

14 (Slide) The next slide shows what we
15 believe to be the central question that deals with the
16 regulation of medical radiation protection and that is
17 whether the current system taken as a whole ensure
18 adequate protection in this area and it should be
19 noted that the question, while focusing on the issue
20 of public health and safety, encompasses several
21 variables, including the state/federal mix of
22 regulatory control, multiple sources of radiation, and
23 the diagnostic and therapeutic uses of medicine. The
24 question that we believe you asked us to answer and
25 what we believe Senator Glenn was asking is is the

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1 allocation of a responsibility in the regulation of
2 this activity adequate to meet the nationwide goal of
3 ensuring public health and safety from all sources of
4 radiation. So, from that we proceeded.

5 (Slide) And slide 6 lists the related
6 issues which are described in more detail in Appendix
7 B of our report. I think in the respondents to our
8 questions or to our request for input on these, there
9 were a few, if any, who stated that these issues were
10 not appropriate for consideration, although each
11 responding to our request had his own focus in terms
12 of the issues that were most important and that's what
13 you'd expect. But overall, I think uniformity and
14 regulatory oversight were the most discussed by the
15 respondents, followed by database and health and
16 safety. There wasn't a great deal of comment on
17 training and experience or communication except that
18 these were important issues that needed to be enhanced
19 and there's a good idea anyway.

20 I should indicate that in our request for
21 comments on these issues we had originally separated
22 out uniformity and regulatory oversight as two
23 separate issues as well as database and health and
24 safety as two separate issues. As you might expect,
25 the input we got so intertwined those two sets of

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1 issues that we just brought them together and have
2 combined them in the report and all of our subsequent
3 findings.

4 CHAIRMAN SELIN: I would just like to make
5 a point here. I think your statement of the issue is
6 the correct statement. In other words, I believe the
7 Commission would feel very differently if it thought
8 that by say extending or reducing both in a consistent
9 fashion the degree of our oversight we would improve
10 the health and safety of the public subject to this
11 medical radiation. I think we would be interested but
12 less interested if we saw that we could get a lot more
13 uniformity and a lot more regularity but without a
14 measurable difference.

15 In other words, if we had the data and it
16 turned out that risk factors for both AEA controlled
17 sources and non-AEA controlled sources were sort of
18 comparable even though the documents and the forms
19 would drive the practitioners crazy, we would have one
20 view as to the benefit of regularizing them. If there
21 were significant differences in the actual risk
22 factors, we would have a much stronger interest.

23 MR. VOLLMER: Yes.

24 CHAIRMAN SELIN: So, the way you've stated
25 it, I think, is an accurate statement.

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1 MR. VOLLMER: Thank you.

2 (Slide) The next slide, as I promised,
3 shows the sectors that we contacted and a list of the
4 actual contacts as provided in Appendix C of the
5 report. We attempted to get a representative cross
6 section of all the affected stakeholders and, of
7 course, the states were an important one and the NRC
8 Advisory Committee on the Medical Uses of Isotopes,
9 also important. I might indicate we held a public
10 meeting I believe on July 8th with ACMUI and it was
11 done telephonically but here and some members of the
12 public attended that meeting and a report on that
13 meeting has been issued by the Committee. We, of
14 course, took their views into consideration here also.

15 Other stakeholders, federal regulatory
16 agencies. That really is FDA and the NRC. There were
17 several federal medical licensees, the service
18 agencies who are licensees of the NRC. We got input
19 from them. We got input from a number of professional
20 societies, medical equipment and radiopharmaceutical
21 manufacturers and the a voluntary health organization.
22 We got some input from the American Cancer Society.

23 So, these are all listed in our appendix--

24 CHAIRMAN SELIN: The voluntary health
25 organization was the Cancer Society?

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1 MR. VOLLMER: That was the American Cancer
2 Society, yes.

3 CHAIRMAN SELIN: Was there any discussion
4 with people who aren't from the medical profession and
5 medical community?

6 MR. VOLLMER: No, sir. We didn't go --

7 CHAIRMAN SELIN: Information groups or any
8 such groups?

9 MR. VOLLMER: No. That was our limited
10 set and about as much as we could handle. But we
11 didn't -- oh, that's right. Excuse me. Thank you.

12 Judith Brown of ACMUI did provide and
13 you'll see her comments are included in that. So,
14 thank you. Yes.

15 COMMISSIONER ROGERS: With regard to the
16 professional societies' comments, they usually take
17 their time in responding to things very carefully
18 because they have to usually survey their members and
19 so on and so forth. How official were the responses
20 that you got from the professional societies and how
21 detailed?

22 MR. VOLLMER: Let me ask Josie Piccone to
23 respond to that.

24 MS. PICCONE: Yes. These responses were
25 from the governmental affairs people or groups of

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1 these societies. In a couple of cases, input was from
2 the professional subcommittee of the societies who
3 normally would have responded at any rate. In most
4 cases the professional societies do not go out and
5 survey their membership so that the responses would
6 come through these routes at any rate. Some of the
7 groups were able to send material to several people
8 and received input from a number of people. Obviously
9 the time was short. They had about not quite a two
10 week turnaround and they all indicated that in their
11 responses that these were preliminary responses and
12 they were just looking at the broad issue and that's
13 how their responses came back. But we didn't expect
14 more than that as well.

15 COMMISSIONER ROGERS: I think that's
16 pretty good. When I survey their members, I really
17 didn't mean all their members. I meant they usually
18 have to survey all the members of an appropriate
19 committee. But even that very often takes a lot of
20 time.

21 MS. PICCONE: Well, several of the
22 responses that we did receive were a result of that --

23 COMMISSIONER ROGERS: Yes.

24 MS. PICCONE: -- that they had gone to
25 their either governmental relations committee or

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1 professional committees in which a number of members
2 contributed to the response.

3 COMMISSIONER ROGERS: Thank you.

4 CHAIRMAN SELIN: Mr. Vollmer, let me come
5 back to who we talked to at the states' level.

6 MR. VOLLMER: Yes.

7 CHAIRMAN SELIN: Could you go a little
8 more into the people? Did they include people that
9 you would normally think of as patient advocates or
10 consumer advocates?

11 MR. VOLLMER: Lloyd, why don't you tell
12 the Chairman who we sent these to.

13 MR. BOLLING: Yes. We sent the five
14 options with solicitation for additional comments or
15 views on these different matters to the rad control
16 directors of the 50 agreement and non-agreement
17 states. We got responses from 22 and the responses
18 were both to our solicitation by letter as well as
19 from the May 20th meeting in San Francisco, the public
20 meeting.

21 CHAIRMAN SELIN: The trouble with this
22 contact list is that everybody on the list has got a
23 stake in the status quo and we don't have equal
24 representation from the people who might be -- or not
25 even equal, even unequal representation other than one

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1 person is a member of the advisory committee. What
2 would be involved if the Commission asked you to try
3 to canvas a set of people that might have more radical
4 use -- I mean every one of these people are either
5 regulators or people who are being regulated and it's
6 not unreasonable to believe that they've grown
7 comfortable with the current system.

8 How would you go about if you had to go
9 out and systematically get views from people who might
10 be less interested in the status quo?

11 MR. VOLLMER: Well, I would likely try to
12 contact a couple public interest groups and see what
13 interest they would project in doing that. Perhaps
14 some additional help from HHS and other federal
15 agencies would help that. But I'd be happy to put
16 together some sort of plan for that.

17 MR. TAYLOR: Work only with the Federal
18 Register type --

19 CHAIRMAN SELIN: Also, what about say at
20 the state level or other levels. There must be
21 consumer groups or people who are consumer advocates
22 or people who'd be more likely to reflect the
23 population that we haven't hit at this point. Is that
24 right, Lloyd?

25 MR. BOLLING: I'm not familiar with those

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1 groups.

2 CHAIRMAN SELIN: Commissioner de Planque?

3 COMMISSIONER de PLANQUE: Let me just ask
4 a follow-up on that because I see where you're headed.
5 When you solicited the opinions of the states, as an
6 example, what information did you send them to ask for
7 their comments on? I thought I heard you say the five
8 options. Was there much more background material that
9 you submitted to them?

10 MR. BOLLING: There was additional
11 background material. I believe it's part of the
12 package here, isn't it?

13 MR. VOLLMER: It's the issues.

14 COMMISSIONER de PLANQUE: It's the issues.

15 MR. VOLLMER: It's actually our Appendix
16 B, the issues. I might indicate too that we were
17 originally thinking about going the Federal Register
18 notice route, but because of time and scope we didn't
19 do that and we selected to stay within OMB limitations
20 a rather limited set to --

21 CHAIRMAN SELIN: You are very gracious
22 based probably on the fact that you don't yet have
23 tenure on the Commission, but we gave you very little
24 time and very strong constraints on what you can do.
25 But at least I'm having some second thoughts about it

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1 at this point now.

2 Just to follow this train of thought in an
3 open fashion, I was impressed that what you got you
4 used not so much as votes but as anecdotal information
5 that would be useful for follow-up. So, it's not as
6 if we said that of our respondents 98 percent thought
7 the system was terrific and only two percent thought
8 it would be changed. But you go into people that have
9 a lot of substantive information, got a lot of
10 anecdotal information, you put it in a reasonable
11 collage to say, "These are observations that ought to
12 be followed up," and you basically did what you could
13 do given the guidance we gave you. But when it's so
14 starkly laid out who we've talked to and the fact that
15 you've gone much further than I personally thought you
16 would be able to in soliciting opinions from a number
17 of people and following up on that, then the imbalance
18 becomes starker than it seemed at the point.

19 It is true and the record ought to show
20 that you asked for permission to go out in the Federal
21 Register and that was denied. That was denied.

22 Please continue.

23 MR. VOLLMER: Thank you.

24 (Slide) Now turning to the findings,
25 which start on slide 8, we're not surprised to find

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1 what we found on the first bullet, that is
2 inconsistencies in the overall regulatory framework.
3 We could have found out without too much study
4 because, as we indicated, we have two federal agencies
5 and one set of states who are major players and that
6 doesn't necessarily create the inconsistencies but
7 there's a great deal going on out there which
8 inherently at the user level drives one to set up
9 different programs for different activities.

10 Since the NRC obviously has a strong
11 regulatory role for its licensees and for the
12 agreement states, this provides an opportunity for
13 those that are not required to fall within those
14 regulations to do things differently. I think we
15 articulated before how much that happens in the broad
16 general sense, but certainly not in the specific sense
17 because we just don't know right now and I think
18 that's something we would like to learn.

19 But as I indicated before with the
20 difference in focus of the FDA and NRC regulations
21 also, theirs is being focused at the manufacture level
22 and much of ours is being focused at the user level.
23 As I indicated, since the states deal differently with
24 different sources of ionizing radiation or at least
25 can within their purview, this results, for example,

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1 in significant differences in reporting requirements.
2 So, it's difficult to get a complete set of data under
3 the current structure.

4 Not that I'm suggesting that one would
5 have to have a complete set of data in order to make
6 a better judgment than we could make on whether or not
7 there's a health and safety problem, but certainly we
8 couldn't do that but I think one could use available
9 data, could use the information, the enhanced
10 reporting that FDA is going to be asking for, and I'll
11 get to that in a minute, to in the fairly foreseeable
12 future to get a better handle on that without going
13 necessarily to a very, very complete data set.

14 CHAIRMAN SELIN: Could I just stop you for
15 a second?

16 MR. VOLLMER: Yes, sir.

17 CHAIRMAN SELIN: We're reasonably well
18 aware of what the strengths and limitations are in the
19 AEA controlled things. We think we have reasonably
20 good misadministration data from the NRC directly
21 licensed states and the expectation that in the next
22 several years we'll get comparable data from the
23 agreement states. We know how weak the denominator
24 is, the information on proper administrations, but at
25 least there are some crude estimates for that.

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1 Is the situation noticeably worse for the
2 linear accelerators as far as misadministrations or
3 overall figures?

4 MR. VOLLMER: I'd like to ask Don Hamilton
5 to address that.

6 MR. HAMILTON: The Center for Devices and
7 Rad. Health has a legislative mandate to operate a
8 medical device reporting program that looks at all
9 medical devices and would include in the radiation
10 medicine area not only the teletherapy units but also
11 linear accelerators. We surveyed the database in that
12 program for both AEA and non-AEA areas and we find
13 that it's not too much unlike what we see as far as
14 NRC saying that they -- what is it, 25 percent of the
15 area. We see about three times as many reports in the
16 accelerator area as we do in the teletherapy arena.
17 So, they're comparable.

18 CHAIRMAN SELIN: Misadministration
19 reports?

20 MR. HAMILTON: Misadministrations is a
21 difficult term and Mr. Vollmer will point out a little
22 later we're trying between FDA and NRC to coordinate
23 that kind of definition. We get reports when the
24 device malfunctions or when a manufacturer would give
25 us a report that might have been reported to him as a

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1 malfunction but was determined later to be a user
2 error.

3 CHAIRMAN SELIN: I see.

4 MR. HAMILTON: We do not see
5 misadministrations that are directly user errors.

6 CHAIRMAN SELIN: So the user errors,
7 unless somebody would kill through a user error, you
8 might hear that.

9 MR. HAMILTON: That's true.

10 CHAIRMAN SELIN: Okay. But that point I'm
11 trying to make is that this second set shouldn't be
12 read that the NRC regulated radiation cannot be
13 subjected to a health and safety finding. You're
14 talking about comparisons among the different types of
15 radiation if there's an overall health and safety
16 problem that requires a major change in regulatory
17 jurisdiction?

18 MR. VOLLMER: I'm sorry, the second --

19 CHAIRMAN SELIN: Yes, the statement says,
20 "Information are currently available for definitive
21 health and safety findings." Well, of course,
22 definitive is such a strong word. But if we took out
23 the definitive -- I understand the emphasis of your
24 observation to be that you're not doing a reevaluation
25 of the health and safety of NRC regulated medicine,

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1 but a look overall and say there's not a clear need in
2 terms of a lesser quality of health and safety in the
3 non-NRC regulated area to call for an extension there.

4 MR. VOLLMER: (Slide) Would you put slide
5 8 up?

6 Mr. Chairman, I think unfortunately you
7 have -- there was one change made in that, if you
8 could look at that.

9 CHAIRMAN SELIN: Okay.

10 MR. VOLLMER: We've characterized it a
11 little differently. Actually we've written what's --
12 thank you, sir.

13 We've written what was in our finding and
14 we've articulated it a little differently in this
15 slide, which is more appropriate, and that is the
16 information is not currently available to determine if
17 there's a health and safety problem.

18 CHAIRMAN SELIN: Okay. Fine.

19 MR. VOLLMER: And I think -- okay.

20 COMMISSIONER ROGERS: I'd like to come to
21 the point in your report on page 4 about the look to
22 the states to see the need for additional data, but
23 this may not be the right place to do that. But I
24 would like to hear a little bit more on your views of
25 that.

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1 MR. VOLLMER: All right. Thank you.

2 The next principal finding is that which
3 you mentioned, Mr. Chairman, and that is that there's
4 not sufficient information currently available for all
5 uses of ionizing radiation to determine if there's a
6 health and safety problem, the magnitude of the
7 problem if one exists, and the need to reallocate
8 regulatory responsibilities. We think this is sort of
9 a key issue since it gets to the heart of the question
10 we were asked.

11 It seems to us that an evaluation of the
12 health and safety significance of the problem is
13 warranted. As I indicated before, it's not clear from
14 our limited study that the expense of establishing a
15 very comprehensive database as described in Appendix
16 B is warranted, but I think some look at what's out
17 there in terms of data and how that could be evaluated
18 and analyzed to get a sense of whether not there is a
19 health and safety problem is what we should do.

20 Now, from a regulator's perspective, we
21 respond as we should to any significant health and
22 safety problem we see on an individual basis, but we
23 just don't have the wherewithal to put that together
24 in terms of, if you will, a safety goal for medical
25 radiation or how that safety goal might compare. I'm

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1 just using a general term here without any
2 quantification, or a safety goal for medical radiation
3 if one compares that to other medical treatments,
4 either modalities in radiation or broadly speaking.

5 So, and I'll get to it later, this, as we
6 understand it, is something that the National Academy
7 will be looking at and we think it's appropriate.

8 But again, the greater problem seems to be
9 one of uniform reporting from all sources to assure
10 awareness of the events. That would help just in the
11 database itself because one could make judgments on
12 the denominator and come up with factors. If you had
13 similar reporting across the nation, you could come up
14 with a sense of whether or not one type of regulation,
15 i.e. the NRC type versus the non-agreement state types
16 that don't have or may not be applying our licensee
17 type requirements to their licensees or certification
18 holders, if there are any differences in the real
19 health and safety impact of that.

20 CHAIRMAN SELIN: But there's nothing even
21 remotely underway that would produce mistakes in the
22 use of non-NRC, non-AEA ionizing radiation, is there?
23 We talked about devices, but as far as --

24 MR. VOLLMER: Well, except for what they
25 might get on the user level. Again, I guess it could

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1 be anecdotal but there's certainly no requirements of
2 that.

3 CHAIRMAN SELIN: There's nothing, no
4 survey or nothing that would have the effect for the
5 non-AEA material that Part 35 is supposed to do to
6 the --

7 MR. VOLLMER: Not that we're aware of.

8 COMMISSIONER ROGERS: Just before you turn
9 from that I wonder if Mr. Hamilton could give me just
10 a little bit better understanding of how FDA
11 approaches its analysis of devices from a standpoint
12 of the possibility of an accident. In other words,
13 how would you characterize the examination that FDA
14 does of a medical device in its approval, that
15 involves radioactive material? What would be the
16 kinds of things that FDA would want to look at there?

17 MR. HAMILTON: Devices would go to market
18 in one of two ways within FDA. The process which we
19 call the premarket approval, which would be -- in
20 fact, do not at this time contain any devices that
21 contain radioactive sources that I'm aware of. The
22 primary way is what we call our 510(k) process or our
23 notification that a manufacturer has a product that is
24 substantially equivalent to a product that is
25 currently on the market. Our Office of Device

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1 Evaluation then would look at the manufacturer's
2 application that would show detailed information about
3 how that device is equivalent to the device that is
4 currently marketed. We would then look at a number of
5 factors as to how it's produced and the labeling of it
6 and things like this. We do not do anything specific
7 relative to the radiation properties of it other than
8 to make sure that there is basically no public health
9 or safety hazard involved with it.

10 COMMISSIONER ROGERS: Well, I guess what
11 I was trying to get at is -- it sounds to me as if
12 your focus is on the medical efficacy of the device,
13 if it's to substitute for something else, but what
14 about questions of its vulnerability to failure. I'm
15 thinking of the brachytherapy device where the wire
16 failed and resulted in the source being left inside a
17 patient.

18 Would you be looking at matters such as
19 that, namely possibilities of failure of the device
20 that could lead to an accident, a misadministration of
21 some sort?

22 MR. HAMILTON: I believe that we do. I
23 think that that process is going to improve with the
24 implementation of the memorandum of understanding
25 between the two agencies because the NRC, at least in

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1 the AEA products, has a good source integrity type
2 program and I think communication between the two
3 agencies in that area will improve that operation.

4 COMMISSIONER ROGERS: Well, what about
5 those areas where NRC is not involved in other kinds
6 of devices that NRC wouldn't be involved with?

7 MR. HAMILTON: I think that our people in
8 the device evaluation group would use the same kind of
9 criteria in their examination of the product, just a
10 transfer of the technology from non-AEA to AEA within
11 house.

12 COMMISSIONER ROGERS: Do you have any
13 particular in-house directives to require that?
14 Sometimes the right hand doesn't know what the left
15 hand is doing, you know.

16 MR. HAMILTON: We have what we call --
17 within the Office of Device Evaluation, there are
18 review guidances that are set up for the review
19 officers that look at specific kinds of products. I'm
20 not that closely familiar with which guidance would be
21 done for radiation therapy products that were non-AEA,
22 though.

23 CHAIRMAN SELIN: Could I just follow-up,
24 Mr. Hamilton? Today, you know, without the MOU,
25 without future -- do you, does the FDA through

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1 information gleaned from our misadministration
2 reportings get insights in reviewing the AEA type
3 devices that you don't have for the non-AEA
4 radiological devices?

5 MR. HAMILTON: I think that's true, yes.

6 MR. VOLLMER: (Slide) On slide 9, the
7 next slide, we indicate that improvements could be
8 made within the existing regulatory framework. We
9 believe that ongoing activities within the NRC, such
10 as the management review of the medical management
11 plan and lessons from the recent incident
12 investigation team report, will improve NRC's
13 regulation of the medical use of radiation.

14 At the FDA, their new requirements for
15 facility user reporting of adverse events, as Don
16 indicated, there's enhanced manufacturer reporting,
17 enhanced state and FDA cooperation and information
18 exchange. These things were indicated, I think, by
19 Doctor Burlington in his previous testimony.

20 In addition, the NRC/FDA memorandum of
21 understanding we think will lead to better knowledge
22 of the systems and the problems on both sides. And
23 again, that's basically I think what Don was saying.

24 And finally, the National Academy of
25 Sciences study will deal with a number of areas that

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1 we believe need study to answer the question of
2 whether to change the regulatory framework, such as
3 the risk of treatment by ionizing radiation compared
4 to other modalities and recommendations for a national
5 approach to the regulation of medical radiation.

6 So a lot of these things are germs that
7 are in what we think need to be done and I think what
8 we're saying is a lot of them are apparently underway.
9 We think they'll be fruitful, so that's why we've
10 included the things that are going on in our option 1,
11 because we think it would be sort of a stark option if
12 it didn't include the fact that a lot is going on and
13 a lot is going --

14 CHAIRMAN SELIN: Your status quo ante is
15 not just the current system, but the current system as
16 it might be improved so that --

17 MR. VOLLMER: The current system, sort of
18 betting on the calm, that the things that are going on
19 now, most of these are going on --

20 CHAIRMAN SELIN: You have to try to
21 separate out benefits from changes of jurisdiction
22 versus benefits just from better management?

23 MR. VOLLMER: Yes, sir.

24 CHAIRMAN SELIN: Okay.

25 MR. VOLLMER: Now our final principal

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1 finding was we found that, despite the lack of
2 definitive risk data and recognition that there are
3 opportunities for improvement, it's not clear that the
4 current regulatory framework does not adequately
5 protect the public health and safety.

6 Federal and state programs already in
7 effect combined with professional medical practices
8 and voluntary professional standards appear to have
9 served the public health and safety and we, in the
10 look that we did, we couldn't articulate it any
11 differently. We think that a lot that is going on is
12 done well.

13 There are inconsistencies. It is a
14 patchwork quilt, if you will, as I think was indicated
15 by the Senator, but we couldn't -- it wasn't clear to
16 us that we're not adequately protecting the public
17 health and safety. To find one way or the other, we
18 would need more data and better consistency in how
19 that data is articulated.

20 (Slide) Moving on to slide 10, it is
21 simply our characterization of the problem as we see
22 it. As we see it, it's a lack of a fully coordinated
23 regulatory effort as well as a lack of sufficient data
24 to evaluate the effectiveness of the effort, so it's
25 a two-handed thing. It's not just that the effort is

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1 a bit inconsistent and patchwork, but we really can't
2 tell how well it's serving the public because of the
3 lack of data to evaluate it across federal and state
4 agencies to achieve the national goal of adequate
5 protection of the public health and safety. That's
6 how we have characterized the problem.

7 COMMISSIONER ROGERS: Just before you
8 leave that, Dick, what would -- it may sound trivial,
9 but what do you really mean by "effectiveness"? I
10 mean, for example, one could simply mean that really
11 there is with more data a clearer demonstration that
12 the public health and safety is protected. Get more
13 and more and more data, you get more and more
14 confidence, but nevertheless there's nothing changed
15 in terms of the bottom line conclusion.

16 On the other hand, effectiveness very
17 often also combines not only results but the use of
18 resources required to achieve those results and we
19 might have a very effective program from the
20 standpoint of protecting public health and safety but
21 an ineffective program from the standpoint of the
22 resources that it eats up that might in fact be used
23 for other public health and safety benefits.

24 So do you have in mind that combination of
25 effectiveness really encompassing the notion that it's

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1 an efficient system as well as delivering, not only
2 does it deliver a result but it does it in a
3 reasonable way?

4 MR. VOLLMER: Yes. That's my feeling for
5 what's in mind here and when we get to the options
6 you'll see more of that. But we would agree that one
7 could lay on a tremendous amount of regulatory
8 trappings here which may improve or may decrease the
9 incidences that happen and things like that, but the
10 cost effectiveness is I think what I meant there. If
11 anybody cares to comment otherwise -- but I think
12 that's it.

13 The effectiveness in one area, one would
14 have to -- for example, the application of NRC
15 requirements, how effective that is from a cost
16 benefit point of view as opposed to what agreement
17 states do in other areas or even non-agreement states
18 do for a NARM machine is an answer we don't know, but
19 it's the effectiveness in the broad sense that we're
20 talking about.

21 (Slide) Moving on to slide 11, we're
22 getting into the options here. Before we deal with
23 the options, I'd like to indicate a couple of
24 comments.

25 One is that of course there were other

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1 options that had advantages that were attractive and
2 had support from respondents. The ones that we've
3 identified you'll probably see why we did it from a
4 consistency point of view and so on, but I'll get to
5 that in a minute.

6 But, for example, if uniformity was the
7 keystone that we were looking for here, then one could
8 argue for a full federal control or setting of
9 regulations and their implementation without an
10 agreement state program. For example, we would set
11 the regulations and we'd be responsible for licensing
12 and inspection and enforcement, which is what I mean
13 when I say "implementation" in this sense. Keeping in
14 mind that our definition of implementation means that,
15 one would -- there would be a burgeoning amount of
16 federal resources required if we took on that role,
17 but, again, it might be the most -- the best way to
18 take care of uniformity if that were the keystone
19 problem.

20 On the other hand, one could argue that
21 the federal government should be responsible only for
22 basic radiation safety, as in Part 20, and not set any
23 requirements for impinging on the delivery of
24 radiation to the patient. There was certainly outside
25 support for this.

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1 So these two examples would represent an
2 end of a spectrum which had attractiveness either to
3 meet an identified problem or had attractiveness to
4 some of the people who are very intimate with the
5 delivery of this to patients. Either could be found
6 to be attractive depending on the outcome of a better
7 evaluation. We wouldn't count those out, but the
8 important question that we tried to address was to try
9 to get a set that we thought met a number of the
10 issues, could solve a number of the issues, and we
11 didn't want to preclude other options by defining a
12 preliminary set here that might be well considered for
13 other reasons.

14 Getting on with the preliminary options
15 themselves, this number one option is sort of the
16 status quo with recognition of the planned and
17 potential improvements from those activities that I
18 had mentioned earlier in the findings. We think it's
19 important to make these improvements, as I indicated
20 in part of the option, but I personally believe that
21 it would still be the option of choice at this point
22 in time, even if there weren't such a broad spectrum
23 of improvements that might lie on the horizon, because
24 again I don't think we've been able to tell that there
25 is a health and safety problem anyway.

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1 CHAIRMAN SELIN: You weren't asked to
2 choose an option. You were asked to --

3 MR. VOLLMER: No. No, sir. I wasn't
4 trying to do that.

5 CHAIRMAN SELIN: Right. But can I go back
6 to something you just said before you put the options
7 up? In reading the report, I was struck -- given the
8 people you talked to, I wouldn't expect many people
9 calling for more regulation, but I would have expected
10 some kind of a sentiment to ask us to cut back not
11 just on how we do the misadministration but that
12 there'd be a powerful group out there that would say,
13 "Why don't you just do sources and keep out of the
14 medical use of radiation?" I didn't see that in the
15 report.

16 The impression I got was a comfort with
17 the status quo, even among people who you would think
18 would have an interest in lightening the federal hand
19 of regulation. Did I misread your results?

20 MR. VOLLMER: Well, I'll comment and open
21 it to anybody else who would like to comment.

22 I don't think you did. For example, I
23 think the states in many cases at the meeting we had
24 on May 20th would indicate that they would like the
25 federal standards set. Now they didn't suggest

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1 backing off from some of the other requirements. I
2 think there was more of a set of uniform standards
3 that they'd like to be able to deal with. I think
4 they were perhaps comfortable with the current
5 situation.

6 In my recollection of the input we
7 received, there was not a strong -- there were some,
8 but not a strong emphasis on backing off to the extent
9 you suggested, although what I just discussed a minute
10 ago would imply that, that we would set the standards
11 and not deal with the user level.

12 Anybody else? I think that represents --
13 COMMISSIONER ROGERS: But you indicated
14 that's just sort of one end of the spectrum of
15 possibilities, not necessarily one that emerged from
16 your studies.

17 MR. VOLLMER: That's right. It didn't
18 emerge from ours, but it's certainly one that --

19 COMMISSIONER ROGERS: Some people have
20 espoused, right.

21 MR. VOLLMER: -- might very well be
22 attractive. And if we had the data to show that, for
23 example, our regulation at the user level didn't
24 really help a heck of a lot, then you could argue that
25 maybe that would be a good approach to pursue. We

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1 don't have that data.

2 CHAIRMAN SELIN: Okay. Please continue.

3 MR. VOLLMER: Okay. We've just listed
4 sort of the pros and cons briefly. We discuss them
5 much more in the report. For one, of course, the
6 agencies were considered in their current roles. We
7 talked about the initiatives, but it doesn't address
8 the fragmentation and inconsistencies that we talked
9 about before which may or may not be problems when it
10 comes to the bottom line, protection of the public
11 health and safety. We just don't know.

12 (Slide) The next slide, slide 12, shows
13 an option where the federal government develops the
14 requirements and implements them in an agreement
15 state-like program for all sources of ionizing
16 radiation used in medical therapy. So this option,
17 you could argue, sort of spreads the NRC model to all
18 sources of radiation across the board and would
19 utilize an agreement state-like program to --

20 CHAIRMAN SELIN: This means that, assuming
21 that this change didn't change the desire for states,
22 the agreement states, that in 21 states we would
23 inspect and regulate for all sources of ionizing
24 radiation used in medical therapy; and the other 29
25 states, the agreement states, would continue to do

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1 what they're doing but they would have to do it
2 against our standards and our regulations, for the so
3 far nonexistent standards and regulations for linear
4 accelerators?

5 MR. VOLLMER: I would agree with what you
6 said, except where you use the word "we" and "our."
7 We're talking about a federal somebody.

8 CHAIRMAN SELIN: Okay. Without saying
9 who.

10 MR. VOLLMER: Yes, but at the federal
11 level exactly as you articulated. That would be this
12 option, yes, sir.

13 CHAIRMAN SELIN: Okay.

14 MR. VOLLMER: We think this would have a
15 fairly substantial impact on federal resources
16 relative to some of the other options but would
17 provide perhaps the best level of uniformity, and of
18 course this particular option is for therapeutic
19 application only and would not cover diagnostic. So,
20 again, the task force had in mind for this option
21 regulations similar to those currently in effect for
22 byproduct material by the NRC extended to all sources,
23 therefore this would be an NRC-like program for all
24 sources.

25 A variation of this could, for example,

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1 have the requirements extend only to the point of user
2 application or some other point in the delivery system
3 and so you could set the standard of how far the
4 system went down. In other words, Part 20 all the way
5 down to Part 35 one could set where you want to -- if
6 you knew enough about it, where you wanted to set the
7 discriminator for regulation and use a consistent
8 system across the board in an agreement state program.
9 That's sort of the option that we have in mind here.
10 We just don't know enough to even suggest where that
11 discriminator would best be set, again because the
12 information is not available.

13 The pros and cons of that we've tried --
14 you'll find a number of these things, pros and cons,
15 reduction of state authority, requires legislation,
16 increased federal cost. I think I probably should
17 have ranked these a little bit more definitively, but
18 we ran out of the words here to modify some of these
19 options. But clearly, since this one would have the
20 federal government develop and implement regulations
21 for all sources, it would be the most costly from the
22 federal government's point of view and it would
23 probably decrease the states' authority to the largest
24 extent possible in addition to that. But on the other
25 hand, it might be the most uniform in terms of

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1 application, so, you know, you get one thing but you
2 lose something else.

3 Option 3 --

4 COMMISSIONER ROGERS: Excuse me. Before
5 you go to option 3 --

6 MR. VOLLMER: Yes?

7 COMMISSIONER ROGERS: -- it isn't so clear
8 to me that there would be a long-term increase in
9 federal cost under that program. Since it is an
10 agreement state-like program where the
11 responsibilities are taken up by the states, there
12 would be some increase in cost in the beginning in
13 developing the regulations and so on and so forth.
14 But once it's handed over to the states, why would it
15 necessarily involve increased federal costs?

16 MR. VOLLMER: If all states became
17 agreement states, that would be true and then you
18 would be going into option 5. But in this case,
19 basically we're talking about implementation by the
20 federal government in an agreement state-like program.
21 So where you didn't have the agreement state we would
22 have the responsibility, where you did we would have
23 responsibility for certain oversight --

24 COMMISSIONER ROGERS: Some oversight.

25 MR. VOLLMER: -- in setting compatibility

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1 standards and things like that.

2 CHAIRMAN SELIN: But in 21 of the states
3 as of today, we would have -- "we" the federal
4 government --

5 MR. VOLLMER: That's right.

6 CHAIRMAN SELIN: -- to take an expansive
7 view, would have to do the actual licensing and
8 inspection.

9 MR. VOLLMER: Theoretically, it could be
10 that, if states became agreement states, then we would
11 only have the compatibility burden and the setting of
12 regulation burden, yes.

13 (Slide) Next slide. I can tell which one
14 it is, then. Option 3.

15 COMMISSIONER ROGERS: Number 13.

16 COMMISSIONER de PLANQUE: Slide 13.

17 COMMISSIONER ROGERS: Slide 13.

18 MR. VOLLMER: Okay. I was unfortunately
19 speaking a little bit to that just a minute ago, but
20 that includes diagnostic as well as therapeutic, in
21 other words extending the NRC-like program to all
22 sources in both diagnostic and therapeutic with an
23 agreement state-like program for all sources. If I
24 misstated before, this is the one I meant would be the
25 highest federal cost certainly in the short-term and

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1 perhaps even longer.

2 CHAIRMAN SELIN: This would basically pick
3 up -- option 2 picks up linear accelerators and option
4 3 picks up x-ray machines, basically?

5 MR. VOLLMER: That's right. That's right.
6 That's correct.

7 MR. NORELIUS: And other diagnostic uses
8 of radioactive materials, say thallium use, which is
9 a big one.

10 COMMISSIONER REMICK: I assume that if we
11 did something like this where we picked up the
12 responsibility, being "we" the federal government, for
13 non-AEA materials in devices like x-rays, it would not
14 only be limited to the medical uses, be x-rays used in
15 research also, presumably.

16 Once you get into that game, there are
17 some pretty hairy uses of x-ray machines in research
18 which are much more complicated perhaps than in
19 medical because the devices are modified and so forth
20 for special research applications. Although we're
21 talking about medical here and we talk about getting
22 into these other areas, there would be other uses than
23 medical that --

24 MR. VOLLMER: Yes.

25 COMMISSIONER REMICK: -- presumably would

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1 come under and I can see there would be increased
2 costs.

3 MR. VOLLMER: Yes, sir. I agree, and we
4 talk about that on the top of page 8 and say,
5 basically, if we allocate regulatory responsibility in
6 this way, that it would be beneficial to consider all
7 similar use of radioactive material, industrial,
8 academic, research, and medical. So we think that's
9 true, yes, sir.

10 COMMISSIONER REMICK: That's what I had in
11 mind. Thank you.

12 MR. VOLLMER: Okay. Option 4, I think,
13 gets into a little different slant. The two options
14 that preceded were parallel in the sense that they
15 would extend NRC-like application to both therapeutic
16 or all uses with the agreement state type of process.
17 These, option 4 and 5, are also parallel in the sense
18 that the first, number 4 here, applies to therapy and
19 number 5 will apply to diagnosis and therapy.

20 Now both of these would have the federal
21 government set the regulations and the states would be
22 fully responsible for implementation as they now are
23 for NARM machines, so we would basically be providing
24 the standards. In this one we weren't thinking of the
25 state program. We were thinking of the federal

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1 government really pulling out of even the requirement
2 for implementation in the non-agreement states as well
3 as the assurance of compatibility and oversight in the
4 agreement states, so this is backing off a little bit
5 further.

6 We think that uniformity would be lessened
7 by this, but on the other hand one could argue,
8 perhaps rightly so, that the states could set up
9 something like the conference of radiation control
10 program directors or something which, if the states
11 really joined in, that or some other organization
12 could provide implementation standards and perhaps
13 implementation assistance. So you might end up with
14 a fairly effective system in that way with the federal
15 government providing the oversight, the uniformity in
16 terms of regulations.

17 And again, as before, those regulations
18 could be discriminative or could be set at whatever
19 level. We were thinking broadly sort of at the user
20 level, but you could back off all the way up to
21 wherever you wanted to back off to so that you
22 wouldn't impact the user level or the patient delivery
23 level.

24 (Slide) And finally, as I indicated, the
25 next slide is simply the same as 4 only it deals with

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1 therapeutic use and diagnostic use.

2 CHAIRMAN SELIN: It seems to me that
3 there's another real option that hasn't been looked
4 at, and that is to treat all medical use of radiation
5 the way we now treat linear accelerators, in other
6 words where the federal government just backed out of
7 the medical use material and we just said we will
8 regulate the sources just as we do any other sources.
9 You have to have alarms and you have to follow the
10 rules in handling the cobalt, but as far as the
11 medical applications to just back off.

12 My original view is that we're in an
13 unstable situation at this point where we have a large
14 degree of regulation in one kind of radiation and very
15 low in another and it's illogical.

16 Now one set of things says in different
17 ways we should extend the federal domain to the non-
18 AEA sources to varying degrees. Another would say
19 that the linear accelerators are no less safe than the
20 cobalt devices, "why not back off and let the states
21 regulate the cobalt devices the way they regulate the
22 linear accelerators?" and I think it's important that
23 such an option be considered. Now you could consider
24 that as the limit for option 4, but I think it's
25 really a fundamentally different option where it just

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1 says we will do less. The federal government doesn't
2 often look at that and I'm not saying that's what we
3 would do, but I think that's a real option.

4 MR. VOLLMER: Yes. I think it is. We
5 talked about that. It would be a variation of 4, I
6 think, with a discriminator set pretty far back in
7 terms of federal interaction, but certainly that is
8 one that we didn't investigate in detail, nor did we
9 investigate a lot of these in detail, but it's
10 certainly one that would be a viable thing to look at.

11 CHAIRMAN SELIN: All of the options except
12 the status quo have the federal government getting
13 more involved in non-AEA devices. I think there
14 should be an option which says, you know, if you
15 looked at the data and you could find no difference in
16 health effects between the AEA and the non-AEA
17 options, one conclusion would be that we could back
18 off the AEA options without expecting any detrimental
19 impact on health and safety. Although logically you
20 could say that's the limit to option 4 or option 5, in
21 fact it's really a different option in my own view.

22 MR. VOLLMER: I think it is a different
23 option and I've got to go back to what I had said
24 earlier, that we tried to develop the options to deal
25 with the problems as best we could determine them here

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1 and admittedly we didn't have enough and we don't have
2 enough information to tell, for example, if uniformity
3 of application at the user level is a real problem.
4 If it weren't, then that type of an option would be
5 very attractive for a lot of reasons.

6 COMMISSIONER de PLANQUE: Just more or
7 less on that point, one of the reasons we're here and
8 we're dealing with this is, is there a problem to
9 begin with in terms of public health and safety, and
10 one of your original conclusions was we don't have
11 enough data to definitively say there is not, if I can
12 characterize it that way.

13 If you look at the options that you've
14 presented here or even some additional options, how
15 would the problem of having enough data to show the
16 effectiveness of the program be addressed in any of
17 those options? Or would you wind up with a worse
18 situation?

19 MR. VOLLMER: If I understand your
20 question, Commissioner --

21 COMMISSIONER de PLANQUE: We're where we
22 are because we're not sure we have enough data to say
23 definitively we've got programs that protect the
24 public health and safety.

25 MR. VOLLMER: I think in a couple of areas

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1 we've said that we are gathering additional
2 information that will be helpful. We're doing a
3 number of things that will be helpful and I think
4 we're --

5 COMMISSIONER de PLANQUE: That's not my
6 question. If you went to any of the other options, do
7 you then produce again the same problem of not being
8 able to gather enough data to definitively say that
9 those options are effective?

10 MR. VOLLMER: Well, if we went to option
11 2 or 3, Josie is pointing out that in the conclusion
12 section -- where are we?

13 COMMISSIONER de PLANQUE: Unless you get
14 involved with reporting requirements, then you're left
15 with the same fundamental problem. You don't have any
16 information to evaluate the system. Is that a
17 reasonable interpretation?

18 MR. VOLLMER: I think what we were trying
19 to say is that there should be independent -- I mean,
20 before you go to any of the options -- data collected.
21 That's clear.

22 COMMISSIONER de PLANQUE: I would agree
23 with that entirely.

24 MR. VOLLMER: Okay.

25 COMMISSIONER de PLANQUE: I'm just looking

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1 further down the road. If you were to even entertain
2 the possibility of these options, have you done
3 anything to solve that initial problem? Would you --

4 MR. VOLLMER: I don't think we --

5 COMMISSIONER de PLANQUE: -- if you made
6 any of those options the new system?

7 MR. VOLLMER: Well, all of these options,
8 I think, could specify that you would be collecting
9 information as you went along and as part of the
10 requirements set by the federal government or whoever
11 sets them that you would get this information. So
12 from that point of view it would, but in advance you
13 wouldn't necessarily have that information available.

14 COMMISSIONER de PLANQUE: Correct, but in
15 order to answer the same question we're trying to
16 answer now you would indeed have to do that sort of
17 thing.

18 MR. VOLLMER: Yes.

19 MR. NORELIUS: I might just add a thought
20 that it may not be necessary to establish a full
21 database to answer the question.

22 COMMISSIONER de PLANQUE: I would agree.

23 MR. NORELIUS: There might be other
24 studies that you could do that would be statistical or
25 limited in nature which would give you sufficient

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1 information so that you may not come to the conclusion
2 that you need a full database.

3 COMMISSIONER de PLANQUE: Yes.

4 MR. NORELIUS: Although the regulations
5 could provide that in any of these other options.

6 COMMISSIONER de PLANQUE: Well, this is
7 also connected with Commissioner Rogers' questioning
8 earlier. If you're looking at effectiveness in the
9 full sense of the word, it doesn't necessarily make
10 sense to spend a lot of resources so that you have 100
11 percent of the data. You can make conclusions with a
12 lesser amount.

13 MR. NORELIUS: Yes, that's correct.

14 MR. VOLLMER: (Slide) Okay. Finally we,
15 on the last slide, slide 16, conclude that the
16 framework currently in effect should be maintained
17 until current initiatives produce results and more
18 definitive data on the magnitude of the problem, until
19 that data is available, data on the magnitude of the
20 problem. Again, as Chuck had indicated, when we talk
21 about it in the report we don't necessarily think it
22 is cost effective to barge into a tremendous data
23 gathering mode, particularly since there's no real
24 mechanism to get it anyway at this point in time.

25 We think that there could be some clever

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1 and very careful but fairly scientific ways of
2 collecting good data to give you a good sense of if
3 there are areas in this overall scheme of regulation
4 that are weak in terms of weak in the sense that
5 they're affecting the public health and safety and
6 then you could focus your attention on that. Perhaps
7 you won't be able to identify it, but I think you
8 would get a sense of what it might be from a careful
9 selection of data.

10 That concludes the task force report.

11 Anybody else have anything to add right
12 now?

13 Then, we can open it for questions.

14 CHAIRMAN SELIN: I'd like to respond to
15 the material. My overall conclusion is we don't have
16 as much information as we need at this point to even
17 have laid out what the options are and what has to be
18 done and I'll sort of tell you what I think are the
19 holes, might have a little discussion. It's not
20 guidance. It's more of a round table at this point.

21 First of all, the interviews that you
22 conducted turn out to be much more interesting than I
23 would have expected a couple of months ago, but that
24 sharpens the need to have a broader set of interviews.
25 You put more weight on them. You're effectively

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1 asking us to put more weight on them than I would have
2 expected and so I do believe we need a more balanced
3 set of interviews which I'm afraid that even the
4 Federal Register would be hard to do in a reasonable
5 amount of time, but it might even be a short way of
6 getting notice. But in any effect, there are
7 organizations and there are consumer advocates within
8 states. Almost every state government we deal with
9 has another side that we could do.

10 So without saying how to do it, I believe,
11 mostly because you've shown how productive those
12 interviews can be, that we need a broader set of
13 interviews. On behalf of the Commission, I think it's
14 clear the Commission did not encourage you or did not
15 give you either the time or the tools to get those,
16 but in retrospect I think we need those.

17 The second is I think you have to sharpen
18 the options. To me there are three options and they
19 all have some variations, but most of the attention so
20 far has been on extending therapy. So unless evidence
21 shows up that says that we ought to talk about
22 extending diagnostics, I don't think that should be --
23 you know, logically it's in there, but I think we
24 ought to concentrate on things that we have some
25 reason to believe ought to be done.

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1 The three options are to cut back, to stay
2 where we are, or to go to a full approach. Now maybe
3 there's a fourth one which would be to extend the
4 standard setting so that all therapeutic radiation was
5 treated the same but at a lower level of federal
6 inspection than we have today. We may have to think
7 about that.

8 But you've talked to enough people. I
9 don't think you should be constrained by just saying
10 we have a logically complete set. I think you really
11 have to make some judgements as to which are possible
12 and which not. And I wouldn't put too much stress on
13 the options because you've pointed out the data
14 problem, but as I go through the argument you'll see
15 why I think it's necessary to have the options.

16 The third is to pick up the point that all
17 Commissioners have really made but to go a step
18 further. It's not enough just to say the data aren't
19 there. I think you have to say what data do we have
20 now and furthermore, to follow-up on Commissioner de
21 Planque's point, what data do you need in order to
22 decide on whether an option is a good idea. Instead
23 of saying let's collect all the data in the world and
24 go back and see what we have, you have to do a little
25 bit of backward experimentation. If such and such is

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1 the option, what data would we need to decide if
2 that's a good option or not? You can't collect it in
3 this time.

4 And the fourth comment I'll make is that
5 I think it's more in the phrasing, you know, in the
6 deference that you've paid to the Commission, but the
7 language is too passive. I mean, there aren't going
8 to be more data unless we go out to get them, so to
9 talk as if we should sit back until more data are
10 available really begs the question. The question is,
11 what do you think the Commission ought to do in the
12 way of going out and collecting the data? Do you
13 think it's worth -- I mean, you can't answer this yet,
14 but, when you start addressing what data are needed,
15 I think you ought to be saying do you think it's worth
16 collecting all this data. Are there steps that can be
17 done that are intermediate?

18 I just think that there has to be a little
19 more of an action-oriented -- well, first of all,
20 there has to be a broader representation of the
21 opinions. The second is, I think the options have to
22 be sharper. And then the third is, I think there has
23 to be some more action-oriented so we know what to do
24 with the work.

25 In any event, those are my reactions to

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1 what's there now. They're really put on the table to
2 discuss so that when the Commission decides what to
3 instruct you to do we can have some feedback from you
4 rather than -- this is not a first guess as to what
5 we'll ask you to do, but my personal reactions are we
6 need some information in this way. How hard would it
7 be? Does it make sense to try to do?

8 But I think it may be useful to go around
9 and see what each of the Commissioners have to say and
10 then try to react to whatever they say.

11 MR. VOLLMER: Okay.

12 CHAIRMAN SELIN: Commissioner Rogers?

13 COMMISSIONER ROGERS: Well, it seems to me
14 that the reason we got into this was a request from
15 Senator Glenn that we give him some thoughts. And the
16 thoughts, it seems to me, are thoughts for the nation,
17 not just thoughts for NRC. And while you have dodged
18 the question, when you say federal authority you
19 haven't said who it is. We've sort of automatically
20 thought you were talking about NRC until you corrected
21 that and made sure that it wasn't necessarily NRC.
22 The breadth of your considerations came out a little
23 bit more clearly.

24 But my point is that if we were just
25 talking about NRC I think there's one point of view we

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1 might take. But if we're talking about a set of
2 recommendations to be offered to Senator Glenn or not
3 even recommendations but just a perception of options,
4 let's put it that way. I think that's probably a
5 better way to put it. I don't know that we should
6 make a recommendation. I think what we ought to be
7 doing is providing some, through our own expertise and
8 efforts what seem to be options, without necessarily
9 any specific recommendation of a particular option
10 other than perhaps an observation that there's not
11 enough data available to really make a good choice at
12 this point. That might be a consideration.

13 But in addressing the data question, first
14 I was a little bit concerned about the statement in
15 your report that the states in general, as well as
16 some respondents from other sectors did not see the
17 need for collecting additional data and making health
18 and safety comparisons and so on, to what the rest of
19 the sentence is in the report.

20 It seems to me that the basis for their
21 believing that no more data is necessary is that they
22 feel that public health and safety is being adequately
23 protected in the use of radiation. I think there's
24 some questions about whether adequate data really
25 exists to convince everybody of that, but that's one

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1 aspect of collection of adequate data.

2 It seems to me the other one though comes
3 to this question of effective program. That concerns
4 the use of resources. We could be spending enormous
5 amount of time, effort and money to protect public
6 health and safety in a very inefficient way and public
7 health and safety gets demonstrated that it is indeed
8 being protected. But that, it would seem to me, is
9 not the only question and therefore the central
10 question -- I think I might differ slightly with the
11 Chairman on the central question being as you've
12 stated it, whether public health and safety is being
13 adequately protected. That was on slide 5. It seems
14 to me that the question of with a reasonable
15 expenditure of resources is an issue and that in the
16 collection of data I would like to see a suggestion
17 that data be collected on precisely that aspect of
18 this. Are resources being used effectively in
19 ensuring public health and safety where it is being
20 ensured? If it isn't being ensured, what would be the
21 required additional resources that might be needed?

22 But it seems to me to take a kind of
23 prophylactic view of this from the standpoint of
24 economics is a mistake, that resources are very
25 determinative of what we do always. The notion that

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1 resources are irrelevant to this question is having
2 tunnel vision. Resources are fundamental to what one
3 can accomplish and perhaps NRC's concerns are not
4 primarily with resources, but if we're making a
5 recommendation as to what one ought to focus on here
6 for somebody else's consideration, then I certainly
7 would opt for including in that the use of resources,
8 data on the use of resources. We've heard about that
9 from our own ACMUI at great length of how regulations
10 and regulatory practice impacts on their ability to do
11 their jobs because the regulation eats up resources.
12 I don't know that I necessarily agree with them, but
13 it's certainly an issue and I would expect that it's
14 an issue in other areas as well.

15 So, my point here is that I don't think
16 the central question is solely adequate protection.
17 I think there is this effectiveness question that we
18 talked about a little bit earlier that also ought to
19 be in there when one talks about collecting data. I
20 would hope that that is something that we include in
21 our elucidation of the kinds of data that need to be
22 collected.

23 MR. VOLLMER: Well, without making
24 excuses, I think perhaps the report might have come
25 out somewhat stilted in some of these areas, but I can

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1 assure you that the task force has that in mind and to
2 think about that because --

3 COMMISSIONER ROGERS: I think it needs to
4 be clearly obvious in --

5 MR. VOLLMER: -- we recognize, for
6 example, in talking to others that -- some would argue
7 that radiation medicine is the safest thing you can do
8 in the hospital environment and maybe that's right.
9 I personally don't know one way or the other. But I
10 think it's been made clear to us that the treatment
11 modalities and different -- when you look at the
12 spectrum of things, what you focus on is how much you
13 have to apply to get adequate protection.

14 Now, I personally from the after side sort
15 of build that in when I look at adequate protection,
16 I look at cost beneficial if you made it a basic
17 requirement of safety. I'm not trying to do that to
18 get the rest of the task force involved in that.

19 COMMISSIONER ROGERS: I would say that I
20 don't think that comes through clearly enough in the
21 report.

22 MR. VOLLMER: But we do agree with that as
23 being an important aspect.

24 COMMISSIONER ROGERS: The objection to
25 collecting more data seems to be that you don't need

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1 it to demonstrate that adequate health and safety is
2 being assured. It seems to me there's another reason
3 for collecting data, that it's being effectively
4 assured.

5 The other point that I'd make is that I
6 agree with the Chairman that it seems to me there are
7 other options here that perhaps need to be identified
8 a little bit. I was looking for them beyond what was
9 here and I didn't see them. But I think that the
10 discussion today has in my mind clarified a little bit
11 what your thinking was in back of these options. In
12 your description, Dick, of what was being involved,
13 because I'd focus on your introduction of the notion
14 of the discriminator setting, it seems to me that's a
15 very important aspect of what's involved in your
16 thinking here that within each of these options where
17 you set the discriminator determines really a
18 qualitative difference in some ways as to how one of
19 those options would actually work out.

20 I think perhaps casting your observations
21 in a way that includes the notion of the discriminator
22 setting in terms that a non-nuclear physicist would
23 appreciate, the significance of that, because I think
24 that to me it strikes home. I know exactly what you
25 mean when you say set the discriminator. I'm not sure

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1 that the full import of that is obvious to all. I
2 think it is an important part of your presentation
3 today as far as I'm concerned.

4 MR. VOLLMER: It's a thing we did talk
5 about but couldn't deal with in terms of the time to
6 produce this thing.

7 COMMISSIONER ROGERS: Yes. But somehow
8 the flavor of that I think is important.

9 MR. VOLLMER: But it is something we did
10 talk about and how far should we go. We talk about it
11 in terms of Part 20, Part 35 and other parts of the
12 regulations, where should you set it.

13 COMMISSIONER ROGERS: Yes.

14 MR. VOLLMER: But I must say the basic
15 discriminator we set here was at the user level. We
16 just couldn't parse it out any better than that right
17 now.

18 COMMISSIONER REMICK: A couple comments
19 and a couple questions.

20 I think the Commission gave you a very
21 difficult if not impossible task because of the time
22 limit, but it was something that needed to be done and
23 I think you've done a good job of identifying some of
24 the options. I agree with some of the comments made
25 earlier that there are probably other options. The

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1 one the Chairman identified I think is one. I don't
2 think that's so important at this time. We have a
3 number of efforts going on here. We had a need for
4 this because of a commitment made to Senator Glenn,
5 but we have a number of other things going on in
6 parallel and I don't want to take the thunder of what
7 I think Commissioner de Planque might be thinking
8 about because she keeps reminding us of getting a
9 coordinated effort in these various things that we're
10 doing.

11 But I really look -- I might be wrong, but
12 I'm looking to the National Academy of Sciences to
13 look at the various options and come up with some
14 strong recommendations on which ones from their
15 perspective they think we should follow. So, I think
16 it's premature at this time to be thinking about which
17 one of these we go. We have a number of things we're
18 doing and in my mind a very important one is that
19 independent National Academy of Science which will
20 look at various options and might come up with ones we
21 haven't even thought of that we'll have to consider.

22 The goes along with the Chairman's
23 comment. I agree we need more input from different
24 groups, but I'm not sure when we do that. It might be
25 premature now because once we have the National

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1 Academy of Science's recommendations and if we decide
2 to follow one of those or some other course, then I
3 think is the time we need very broad input on the path
4 that we might have picked out to proceed on. I'm not
5 against getting the public input before, but I think
6 it's going to be necessary and very important at that
7 stage.

8 A couple questions. I should know this
9 one. Perhaps I'm embarrassed to even ask it on the
10 question of pacemakers. What role does the NRC play
11 in regulating materials in pacemakers?

12 MR. NORELIUS: We have evaluated those
13 devices in the past for radiological safety purposes,
14 issued licenses authorizing their implantation and
15 follow-up of patients and inspected them as we do
16 other items.

17 COMMISSIONER REMICK: Okay. I'm thinking
18 more of the FDA/NRC MOU right now because there are
19 materials other than byproduct material involved.
20 Most of that NRC/FDA MOU talks about byproduct
21 material.

22 Another interesting question comes to
23 mind. If we look to boron neutron capture therapy, is
24 the reactor a device in that case? The neutrons are
25 non-ionizing radiation. So, we talk about only

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1 ionizing radiation. Boron is not a byproduct
2 material. Have you thought about that in the wording
3 of the MOU? That's not our discussion today. I'm
4 throwing this out. I've asked for a staff briefing
5 tomorrow to explore some of those. But when we think
6 about that MOU, I think we're thinking just about
7 byproduct material now and maybe we have to be
8 thinking just a little bit more broadly.

9 MR. TAYLOR: That's a good point, sir.
10 Let me look at that.

11 COMMISSIONER REMICK: I've asked for a
12 staff discussion tomorrow on that very subject.

13 MR. TAYLOR: On that subject? Okay.

14 COMMISSIONER REMICK: That's all I have,
15 Mr. Chairman.

16 CHAIRMAN SELIN: Commissioner de Planque?

17 COMMISSIONER de PLANQUE: Yes. I want to
18 congratulate you on the job that you did. I agree it
19 was somewhat of an impossible job and you had to
20 navigate through many alligators in the river to get
21 from there to here. So, I think you did an excellent
22 job and certainly within the time that you had I think
23 the product is very good.

24 MR. VOLLMER: Well, thank you. You're
25 looking at the folks who did it. We appreciate it.

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1 COMMISSIONER de PLANQUE: I guess one of
2 my basic philosophies is if it ain't broke don't fix
3 it. So, I get back to the original problem of is it
4 broke, which brings me back to the discussion of the
5 database. You've clearly said here that we don't have
6 enough data to definitively say we're not negatively
7 impacting the health and safety. I still have an
8 uneasy feeling that we don't have a handle yet on what
9 the uncertainty is in the data that we already have.
10 You certainly don't need 100 percent data in order to
11 be able to make an assessment. Statisticians have
12 made a career out of using less than 100 percent of
13 the data, but at assessing the uncertainty or how much
14 better you're likely to get the data and how much more
15 improvement will you have if you do get closer to 100
16 percent of the data.

17 I would assume in the time given that you
18 really didn't have a chance to look at this, or did
19 you?

20 MR. VOLLMER: No, we did not.

21 COMMISSIONER de PLANQUE: Okay. To me
22 it's still somewhat of a critical issue because we're
23 not sure yet how much data would you really need to be
24 more comfortable in your statement.

25 MR. VOLLMER: We talked about it sort of

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1 qualitatively.

2 COMMISSIONER de PLANQUE: Yes.

3 MR. VOLLMER: Certain areas we're
4 comfortable in and certain areas we weren't and we
5 recognize that we didn't have to collect all the data
6 we had identified in the appendix by a large margin.
7 It was the types of data we felt might be needed, but
8 not necessarily a full collection. But I agree with
9 you that we could go a good step if we set our mind to
10 that as a task and we have not done that.

11 COMMISSIONER de PLANQUE: Yes. And you
12 certainly can take data and say, "Well, how uncertain
13 is it? How much of an error might we be making
14 looking at what we already have?"

15 MR. TELFORD: I would like to note that in
16 the list of issues that we sent out, this is in
17 Appendix B to the report --

18 COMMISSIONER de PLANQUE: Yes.

19 MR. TELFORD: -- in the area of data and
20 health effects. I believe for each of these items
21 you'll see at the end, "And the uncertainty on each
22 estimate."

23 COMMISSIONER de PLANQUE: Exactly.

24 MR. TELFORD: So, the task force
25 identified that and agrees with you.

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1 COMMISSIONER de PLANQUE: Yes. Yes.
2 Okay. And for me it's hard to even entertain
3 particular options until you really have a feel for is
4 it broke because if you know it's broke, then you have
5 to figure out why it's broke and then see if any of
6 the options you've suggested will address that
7 particular problem.

8 Just one additional comment on
9 Commissioner Rogers' resources and effectiveness. I
10 see that we addressed data collection in many areas
11 and a lot of it to me looks at indirect measures of
12 what we're really looking for and in this case we're
13 looking for is the public health and safety in
14 jeopardy in any way. We do a lot of indirect measures
15 like numbers of backlog on licenses, numbers of people
16 and that sort of thing and maybe not enough on the
17 other side of the coin, what's the real harm, what's
18 the real issue here. So, that's clearly part and
19 parcel.

20 MR. VOLLMER: Even misadministrations has
21 not necessarily direct corollary with harm and that's
22 another issue that we just couldn't really address.

23 COMMISSIONER de PLANQUE: No. Okay.
24 That's all I have, but I do congratulate you on an
25 excellent job in a short period of time.

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1 MR. VOLLMER: Thank you.

2 CHAIRMAN SELIN: Mr. Vollmer, did you want
3 to add anything now that you've heard some of this
4 discussion?

5 MR. VOLLMER: Well, I think the issue on
6 the recommendations, I guess we perhaps took a very
7 narrow view of trying to focus on what the Commission
8 wanted in that area. We recognize that none of the
9 options that we could think of except the going
10 forward and getting a better handle on the problem
11 were really viable at this time. So, perhaps we've
12 been better served just to talk about the one and not
13 list the other. But we did put the others down just
14 as ways that we felt could solve some of the perceived
15 issues that are out there and we just don't know if
16 they're real issues or not yet.

17 But I think the comments the Commission
18 made we appreciate. I think we've found this a
19 challenging and interesting job and some of the things
20 you've brought up were questions that we felt were
21 important to address and should be addressed to reach
22 a conclusion on this for yourselves and for anybody
23 else that's interested in this field. So, we
24 appreciate the feedback.

25 MR. TAYLOR: I would think the staff needs

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1 to understand whether you would like this task force
2 to continue, delve into the availability of data, such
3 as it is, even to and including linear accelerator
4 applications at the user end, if it's available, and
5 pursue some of the issues that have been outlined
6 here. I presume from the comments that it's the
7 intent of the Commission that we continue.

8 CHAIRMAN SELIN: Don't assume that. The
9 Commission has got to discuss that. But let me just
10 go back to the history because I think the history has
11 been miscast here a little bit.

12 Number one, we had intended, we the
13 Commission, to look at these issues before we
14 testified to Senator Glenn. He asked for an interim
15 report but this is part of the Commission's business,
16 not just to meet a one shot requirement. It has many
17 objectives and that's one of them and that still
18 remains valid.

19 The second is it was never intended that
20 you make a preliminary recommendation on the options.
21 The whole idea was to do a meta analysis to lay out
22 what would have to be known and what is known today
23 for another group, perhaps the National Academy group,
24 to come to some conclusion. So, we never asked you to
25 choose and the whole reason for defining options which

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1 may or may not have been well conceived was that
2 before we asked you things like are the data adequate,
3 you'd have to say, "To decide what?"

4 So, this is not a substitute for the
5 National Academy group or any other group. It was
6 more to get at the work. In fact, I think you've
7 proved that useful because if in fact the data are not
8 adequate to support such an analysis, then convening
9 a big group and having them come in two years later
10 and say the data are not adequate to support the
11 analysis would probably be a situation we'd like to
12 avoid.

13 So, the Commission's deliberations on
14 whether to continue the task force will not be can you
15 do what the National Academy group could do two years
16 in advance, but by having the task force continue
17 could we get some things out of the way so that the
18 other groups could prosper? I think that's the key
19 question.

20 I also would like, of course, to support
21 Commissioner Rogers' point about resources. I didn't
22 mean to leave that out. We could have a program --
23 you know, the Department of Health in New York City
24 might order every apartment to buy a plant, the
25 wolfsbane plant and then two years later prove that

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1 nobody had been attacked in an apartment by a wolf and
2 therefore they have an effective program. So, that's
3 clearly not the kind of thing that we're looking for.

4 We need to talk among ourselves and the
5 real question I had for you, is there anything else
6 that you thought would be useful for our deliberations
7 before the Commission comes back together to tell you
8 what we'd like you to do next?

9 MR. VOLLMER: No, sir.

10 CHAIRMAN SELIN: Commissioners, any other
11 comments? Fine.

12 Thank you very much.

13 COMMISSIONER ROGERS: Thank you very much.

14 (Whereupon, at 11:43 a.m., the above-
15 entitled matter was concluded.)

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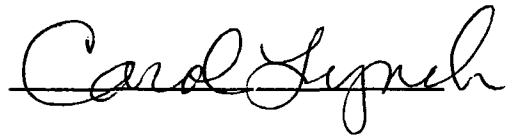
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PROGRAM FOR MEDICAL USE OF BYPRODUCT MATERIAL
PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: JULY 29, 1993

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**TASK FORCE REPORT ON
MEDICAL RADIATION PROTECTION
OPP-93-04
Revision 1
COMMISSION BRIEFING
JULY 29, 1993**

7/29/93

BACKGROUND

- **SENATE GOVERNMENTAL AFFAIRS COMMITTEE HEARING ON MAY 6, 1993**
- **REQUEST FOR PRELIMINARY REPORT**
- **TASK FORCE GUIDANCE FROM EDO ON MAY 17**
- **MAY 20 CRCPD MEETING**
- **COMMISSION GUIDANCE PROVIDED ON JUNE 10**

CURRENT REGULATORY FRAMEWORK

- **NRC CONTROL LIMITED TO BYPRODUCT MATERIAL
(\approx 25% OF THERAPY)**
 - **REPORTS REQUIRED OF MISADMINISTRATION BY
USER**
- **FDA CONTROL COVERS ALL DEVICES AND DRUGS
AT MANUFACTURER**
 - **REPORTS REQUIRED OF DEATH OR SERIOUS
INJURY**

CURRENT REGULATORY FRAMEWORK

- STATES HAVE BROAD PUBLIC HEALTH RESPONSIBILITIES BUT IMPLEMENTATION FOR MEDICAL RADIATION VARIES WIDELY
 - NRC AGREEMENT STATES HAVE COMPATIBLE PROGRAMS BUT IMPLEMENTATION LAGS NRC LICENSEES
 - MOST AGREEMENT STATES EXERCISE SIMILAR CONTROLS OVER NON-BYPRODUCT MATERIALS
 - PROGRAMS IN NON-AGREEMENT STATES VARY

APPROACH AND DEVELOPMENT OF ISSUES

- **DEVELOPMENT OF CENTRAL QUESTION**
- **RELATED ISSUES**
- **OBTAIN INPUT FROM STAKEHOLDERS**
- **PRINCIPAL FINDINGS**
- **CHARACTERIZATION OF PROBLEM**
- **PRELIMINARY OPTIONS**

CENTRAL QUESTION

DOES THE CURRENT ALLOCATION OF AUTHORITY AND RESPONSIBILITY AMONG FEDERAL AND STATE REGULATORY BODIES MEET THE NATIONWIDE GOAL OF ENSURING ADEQUATE PROTECTION OF THE RADIOLOGICAL HEALTH AND SAFETY OF THE PUBLIC, INCLUDING PATIENTS AND HEALTH CARE WORKERS, FROM ALL SOURCES OF IONIZING RADIATION USED IN MEDICINE?

CATEGORIZATION OF RELATED ISSUES

- **UNIFORMITY OF REQUIREMENTS AND REGULATORY OVERSIGHT**
- **DATABASE AND HEALTH AND SAFETY IMPLICATIONS**
- **TRAINING AND EXPERIENCE CRITERIA**
- **COMMUNICATION AMONG FEDERAL AND STATE AGENCIES**

CONTACT LIST

- STATES
- NRC ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
- FEDERAL REGULATORY AGENCIES
- FEDERAL MEDICAL LICENSEES
- PROFESSIONAL SOCIETIES
- MEDICAL EQUIPMENT AND
RADIOPHARMACEUTICAL MANUFACTURERS
- VOLUNTARY HEALTH ORGANIZATION

PRINCIPAL FINDINGS

- **CURRENT REGULATORY FRAMEWORK
INCONSISTENCIES**
 - **POTENTIAL TO ADVERSELY AFFECT ADEQUACY
OF RADIATION PROTECTION**
- **INFORMATION NOT CURRENTLY AVAILABLE FOR
ALL USES OF IONIZING RADIATION TO DETERMINE
IF THERE IS A HEALTH AND SAFETY PROBLEM**

PRINCIPAL FINDINGS

- **IMPROVEMENTS COULD BE MADE WITHIN EXISTING REGULATORY FRAMEWORK**
 - **INTERNAL AGENCY STUDIES**
 - **NRC/FDA MEMORANDUM OF UNDERSTANDING**
 - **NATIONAL ACADEMY OF SCIENCES STUDY**
- **DESPITE LACK OF DATA, NOT CLEAR THAT HEALTH AND SAFETY NOT ADEQUATELY PROTECTED**

CHARACTERIZATION OF THE PROBLEM

A LACK OF A FULLY COORDINATED REGULATORY EFFORT AS WELL AS A LACK OF SUFFICIENT DATA TO EVALUATE THE EFFECTIVENESS OF THE EFFORT, ACROSS FEDERAL AND STATE AGENCIES, TO ENSURE ADEQUATE PROTECTION

PRELIMINARY OPTIONS

1. MAINTAIN THE CURRENT FRAMEWORK FOR THE REGULATION OF MEDICAL IONIZING RADIATION, WITH RECOGNITION OF THE PLANNED AND POTENTIAL IMPROVEMENTS
 - AGENCIES CONTINUE IN CURRENT ROLES
 - ACCOMMODATES ONGOING INITIATIVES TO IMPROVE REGULATORY OVERSIGHT
 - DOES NOT ADDRESS FRAGMENTATION AND INCONSISTENCIES FOR NON-AEA MATERIAL AT STATE LEVEL

PRELIMINARY OPTIONS

2. THE FEDERAL GOVERNMENT DEVELOPS AND IMPLEMENTS REGULATIONS THROUGH AN AGREEMENT STATE-LIKE PROGRAM FOR ALL SOURCES OF IONIZING RADIATION USED IN MEDICAL THERAPY
 - PROVIDES UNIFORMITY, CONSISTENCY, AND AVOIDS GAPS IN RADIATION THERAPY
 - ACCOMMODATES AN AGREEMENT STATE PROGRAM
 - REQUIRES LEGISLATION AND INCREASES FEDERAL COST
 - REDUCES STATE AUTHORITY

PRELIMINARY OPTIONS

- 3. THE FEDERAL GOVERNMENT DEVELOPS AND IMPLEMENTS REGULATIONS, THROUGH AN AGREEMENT STATE-LIKE PROGRAM, FOR ALL SOURCES OF MEDICAL IONIZING RADIATION**
 - PROVIDES UNIFORMITY, CONSISTENCY, AND AVOIDS GAPS IN RADIATION MEDICINE**
 - ACCOMMODATES AN AGREEMENT STATE PROGRAM**
 - REQUIRES LEGISLATION AND MARKEDLY INCREASES FEDERAL COST**
 - SIGNIFICANTLY REDUCES STATE AUTHORITY**

PRELIMINARY OPTIONS

- 4. THE FEDERAL GOVERNMENT DEVELOPS REGULATIONS FOR ALL SOURCES OF IONIZING RADIATION USED IN THERAPY WITH STATES RESPONSIBLE FOR IMPLEMENTATION**
 - PROVIDES UNIFORMITY, CONSISTENCY, AND AVOIDS GAPS IN THERAPY REGULATIONS**
 - STATE FLEXIBILITY IN IMPLEMENTATION**
 - REQUIRES LEGISLATION AND STATE FUNDING**
 - DIFFERENCES IN PROGRAM IMPLEMENTATION**
 - REDUCES STATE AUTHORITY**

PRELIMINARY OPTIONS

5. THE FEDERAL GOVERNMENT DEVELOPS REGULATIONS FOR ALL SOURCES OF MEDICAL IONIZING RADIATION WITH STATES RESPONSIBLE FOR IMPLEMENTATION

- PROVIDES UNIFORMITY, CONSISTENCY, AND
AVOIDS GAPS IN REGULATIONS FOR RADIATION
MEDICINE**
- STATE FLEXIBILITY IN IMPLEMENTATION**
- REQUIRES LEGISLATION & INCREASES FEDERAL
& STATE COST**
- DIFFERENCES IN PROGRAM IMPLEMENTATION**
- REDUCES STATE AUTHORITY**

CONCLUSION

THEREFORE, WE CONCLUDE THAT THE REGULATORY FRAMEWORK CURRENTLY IN EFFECT FOR IONIZING MEDICAL RADIATION SHOULD BE MAINTAINED UNTIL CURRENT INITIATIVES PRODUCE RESULTS AND MORE DEFINITIVE DATA ON THE MAGNITUDE OF THE PROBLEM ARE AVAILABLE