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NUCLEAR REGULATORY COMMISSION

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NUCLEAR REGULATORY COMMISSION

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BRIEFING ON OPTIONS FOR CHANGES TO REGULATION OF NUCLEAR MEDICINE

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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

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

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

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

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

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

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

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

Commissioners, are there --

COMMISSIONER de PLANQUE: No.

CHAIRMAN SELIN: Mr. Taylor, please.

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

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

MR. VOLLMER: Thank you.

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

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

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

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

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

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

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

We also receive strong support from the program offices.

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

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

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

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

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

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

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

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

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

manufacturer generally based on information from the user.

Finally, turning to slide 3 --

COMMISSIONER REMICK: Dick, a question on that.

MR. VOLLMER: Yes.

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

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

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

COMMISSIONER REMICK: Okay. I thank you.

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

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

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

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

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

MR. VOLLMER: Well --

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

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

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

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

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

COMMISSIONER ROGERS: Okay.

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

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

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

We didn't have the opportunity to do that.

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

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

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

Lloyd?

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

CHAIRMAN SELIN: In the agreement states?

MR. BOLLING: Yes.

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

board.

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

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

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

CHAIRMAN SELIN: Okay.

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

CHAIRMAN SELIN: Mr. Telford?

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

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

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

COMMISSIONER REMICK: Ohio.

CHAIRMAN SELIN: Yes.

MR. VOLLMER: Okay. Thank you.

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

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

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

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

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

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

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

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

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

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

MR. VOLLMER: Yes.

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

MR. VOLLMER: Thank you.

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

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

So, these are all listed in our appendix--

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

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

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

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

CHAIRMAN SELIN: Information groups or any such groups?

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

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

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

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

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

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

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

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

COMMISSIONER ROGERS: Yes.

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

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

COMMISSIONER ROGERS: Thank you.

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

MR. VOLLMER: Yes.

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

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

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

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

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

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

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

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

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

MR. BOLLING: I'm not familiar with those

groups.

CHAIRMAN SELIN: Commissioner de Planque?

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

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

MR. VOLLMER: It's the issues.

COMMISSIONER de PLANQUE: It's the issues.

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

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

at this point now.

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

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

Please continue.

MR. VOLLMER: Thank you.

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

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

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

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

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

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

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

MR. VOLLMER: Yes, sir.

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

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

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

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

CHAIRMAN SELIN: Misadministration reports?

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

malfunction but was determined later to be a user error.

CHAIRMAN SELIN: I see.

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

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

MR. HAMILTON: That's true.

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

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

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

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

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

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

CHAIRMAN SELIN: Okay.

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

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

CHAIRMAN SELIN: Okay. Fine.

MR. VOLLMER: And I think -- okay.

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

MR. VOLLMER: All right. Thank you.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MR. VOLLMER: Yes, sir.

CHAIRMAN SELIN: Okay.

MR. VOLLMER: Now our final principal

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

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

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

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

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

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

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

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

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

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

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

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

One is that of course there were other

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

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

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

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

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

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

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

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

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

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

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

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

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

Anybody else? I think that represents --

COMMISSIONER ROGERS: But you indicated that's just sort of one end of the spectrum of possibilities, not necessarily one that emerged from your studies.

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

COMMISSIONER ROGERS: Some people have espoused, right.

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

don't have that data.

CHAIRMAN SELIN: Okay. Please continue.

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

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

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

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

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

CHAIRMAN SELIN: Okay. Without saying who.

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

CHAIRMAN SELIN: Okay.

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

A variation of this could, for example,

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

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

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

Option 3 --

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

MR. VOLLMER: Yes?

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

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

COMMISSIONER ROGERS: Some oversight.

MR. VOLLMER: -- in setting compatibility

standards and things like that.

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

MR. VOLLMER: That's right.

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

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

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

COMMISSIONER ROGERS: Number 13.

COMMISSIONER de PLANQUE: Slide 13.

COMMISSIONER ROGERS: Slide 13.

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

perhaps even longer.

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

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

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

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

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

MR. VOLLMER: Yes.

COMMISSIONER REMICK: -- presumably would

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

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

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

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

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

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

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

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

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

therapeutic use and diagnostic use.

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

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

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

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

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

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

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

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

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

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

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

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

MR. VOLLMER: I think in a couple of areas

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

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

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

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

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

COMMISSIONER de PLANQUE: I would agree with that entirely.

MR. VOLLMER: Okay.

COMMISSIONER de PLANQUE: I'm just looking

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

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

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

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

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

MR. VOLLMER: Yes.

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

COMMISSIONER de PLANQUE: I would agree.

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

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

COMMISSIONER de PLANQUE: Yes.

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

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

MR. NORELIUS: Yes, that's correct.

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

We think that there could be some clever

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

That concludes the task force report.

Anybody else have anything to add right now?

Then, we can open it for questions.

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

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

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

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

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

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

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

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

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

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

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

In any event, those are my reactions to

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

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

MR. VOLLMER: Okay.

CHAIRMAN SELIN: Commissioner Rogers?

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

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

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

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

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

aspect of collection of adequate data.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

COMMISSIONER ROGERS: Yes.

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

COMMISSIONER REMICK: A couple comments and a couple questions.

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

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

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

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

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

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

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

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

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

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

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

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

MR. TAYLOR: On that subject? Okay.

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

CHAIRMAN SELIN: Commissioner de Planque?

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

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

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

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

MR. VOLLMER: No, we did not.

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

MR. VOLLMER: We talked about it sort of

qualitatively.

COMMISSIONER de PLANQUE: Yes.

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

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

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

COMMISSIONER de PLANQUE: Yes.

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

COMMISSIONER de PLANQUE: Exactly.

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

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

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

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

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

MR. VOLLMER: Thank you.

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

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

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

MR. TAYLOR: I would think the staff needs

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

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

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

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

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

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

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

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

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

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

MR. VOLLMER: No, sir.

CHAIRMAN SELIN: Commissioners, any other comments? Fine.

Thank you very much.

COMMISSIONER ROGERS: Thank you very much.

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

CERTIFICATE OF TRANSCRIBER

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

TITLE OF MEETING: BRIEFING ON INTERNAL MANAGEMENT REVIEW OF NRC PROGRAM FOR MEDICAL USE OF BYPRODUCT MATERIAL

PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: JULY 29, 1993

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

Carol Lynch

Reporter's name: Peter Lynch

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 (≈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