UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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

Location: Rockville, Maryland

Date: Wednesday, March 29, 1995

Pages: 1 - 66

ANN RILEY & ASSOCIATES, LTD.
1250 I St., N.W., Suite 300
Washington, D.C. 20005
(202) 842-0034

DISCLAIMER

This is an unofficial transcript of a meeting of the United States Nuclear Regulatory Commission held on March 29, 1995 in the Commission's office at One White Flint North, Rockville, Maryland. The meeting was open to public attendance and observation. This transcript has not been reviewed, corrected or edited, and it may contain inaccuracies.

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

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

***

BRIEFING BY NATIONAL ACADEMY OF SCIENCES

ON STATUS OF INDEPENDENT REVIEW OF MEDICAL USE PROGRAM

***

PUBLIC MEETING

***

U.S. Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Wednesday, March 29, 1995

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

COMMISSIONERS PRESENT:

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

ANN RILEY & ASSOCIATES, LTD.
Court Reporters
1250 I Street, N.W., Suite 300
Washington, D.C. 20005
(202) 842-0034

STAFF AND PARTICIPANTS SEATED AT THE COMMISSION TABLE:

KAREN CYR, General Counsel

JOHN C. HOYLE, Acting Secretary

JAMES TAYLOR, Executive Director for Operations

KATE-LOUISE GOTTFRIED, IOM Study Director

CHARLES E. PUTMAN, Chairman

MICHAEL WEBER, NMSS Regulatory Issues Section Leader

FRANCIS X. CAMERON, Office of General Counsel

BILL MORRIS, Director, Division of Regulatory Applications, RES

FRANK CONSTANZI, Deputy Director, Division of Regulatory Applications

P R O C E E D I N G S

[10:00 a.m.]

COMMISSIONER ROGERS: Good morning, ladies and gentlemen. The Chairman's been delayed and he has asked me to start the meeting so we will proceed.

We are very pleased to welcome Dr. Charles Putman, Chair, and Ms. Kate Louise Gottfried, Study Director of the National Academy of Sciences Institute of Medicine Committee, that is conducting an independent review of NRC's program for the medical use of byproduct material.

The Commission has focused considerable attention on the medical use program over the past several years. Recently the Chairman and the other Commissioners have begun to believe that a part of NRC's program for regulating the medical use of byproduct material might be performed as effectively by other organizations that regulate the practice of medicine.

The Committee's review, begun in January of 1994, should provide the Commission with input on the need for or desirability of changes to the NRC's regulatory program.

We are well aware of the restrictions under which this Committee must operate including requirements for peer review. However, because of the emphasis currently being placed on the re-examination of all agency regulations by the Administration's National Performance Review, we hope

that the Committee is in a position to provide us with some insight on the results of their review to assist us in our re-examination.

Commissioner de Planque, do you have any comments?

COMMISSIONER DE PLANQUE: No.

COMMISSIONER ROGERS: Dr. Putman.

DR. PUTMAN: Thank you, Commissioner Rogers. Commissioner Rogers, Commissioner de Planque, it is a privilege to be here as Chairman of the Committee that you described and I am here as one member of 16 members of this Committee that has been working diligently since the inception of this study. I would like to emphasize a few points before I ask Kate to review with you current progress and deliberations.

This is obviously a fascinating subject matter that has tremendous importance to the public and importance to health care and importance to education, and importance in other arenas. Our Committee is truly an interdisciplinary committee representing all components of the discipline that would have to do with oversight and relationships to the regulation as well as individuals like myself who are practicing physicians.

I am pleased to tell you that we have made excellent progress and our report will be delivered on time. There is a time element here and I think that would be

important for you to know. I should also indicate to you that we are very pleased and compliment all of your staff that if provided information to us in a timely way we have gone through the initial charge to the Committee and have made some minor modifications, which again Kate will review with you, and this has been in concert and in harmony with your staff, so I would like to turn it over, if I could, to Kate now, and let her go through things, then we will be pleased to answer your questions. Thank you.

MS. GOTTFRIED: Thank you, Dr. Putman.

On behalf of the Committee I want to thank you for the opportunity today to speak with you about the progress of the Institute of Medicine's Committee to Review and Evaluate the Medical Use Program of the Nuclear Regulatory Commission.

Could we have the first slide, please?

[Slide.]

MS. GOTTFRIED: It's a pleasure to be here today and it is remarkable to me that we are already so far along in the process and actually only have about four months remaining until we submit the report for its initial review.

Next slide, please.

[Slide.]

MS. GOTTFRIED: This is a list of the Committee members. I am sure you are all fairly familiar with that.

I just want to bring to your attention that this is a committee that is comprised of approximately 16 people. It is an interdisciplinary group coming from a variety of disciplines, in particular radiology, radiation oncology, cardiology, nuclear medicine, medical health physics, regulation, federal-state relations, health law, risk assessment, quality of care measurements, statistics, patient advocacy, and consumer interests as well as ethics.

The Committee is a committee that is put together by the Institute of Medicine and requires the executive approval of the administration at the IOM. So it is a fairly rigorous process before a person becomes a member of the Committee. In addition to that, once a person is appointed, we have a bias or conflict of interest process that is conducted at the initial stage of the Committee formation. At that point in time anyone with a conflict of interest has to discuss what their concerns are, what their priorities are, and whether or not their conflict may or may not present a problem for conducting an objective review of whatever the issue is.

Biases are clear because people come from a variety of disciplines and in fact are expected and that is why the Committee has just a diverse composition, so in fact we can balance the different interests of the Committee members.

Next slide, please.

[Slide.]

MS. GOTTFRIED: Well, we all know that this study is sponsored by the Nuclear Regulatory Commission and that we have slightly over a million dollars to conduct the study and we are well underway with that.

Next slide, please.

[Slide.]

MS. GOTTFRIED: The Committee is in effect and is looking at the medical use program at the Nuclear Regulatory Commission, specifically the regulation of reactor generated radionuclides. The Division that this is in is in the Health Care Services Division of the Institute of Medicine and that was deemed to be the best Division within the Institute for this particular study.

How does the Division typically operate? The studies at the Institute of Medicine are often a combination of methodologies. In this particular instance we decided to go ahead and commission papers on subject areas that would relate to the study area to bring the Committee up to speed with respect to those areas various Committee members may not be conversant with.

In addition to that, we will hold six Committee meetings. To date we have held four and our fifth meeting is scheduled for May and our final meeting will be in July.

The report will be submitted for review in early August, so we are getting close to our deadline.

In addition to Committee meetings we have had a public meeting. We had a quality management technical panel and four site visits.

I am going to speak a little bit more about these later on, but I just want to run through quickly with respect to our commissioned papers, these are papers that we commissioned from experts in the field and request an outline and a contract with that potential author.

The papers that we commissioned for this particular study had to do with designing a new regulatory system, three regulatory case studies, a paper with respect to risk estimation of late injury from low level radiation exposure, radiation medicine, regulatory costs associated with the NRC's medical use program, radiation misadministrations, and perception of risk from radiation.

The public meeting was an opportunity for people with an interest in the area to give oral testimony as to their concerns, and that I will discuss further in my presentation.

The quality management technical panel was a panel that we put together because quality issues are clearly a concern in this area. Both have come under -- required a lot of attention by the NRC as well as the regulated

community and it was felt that it was important to really take a broad look at quality and understand what quality issues needed to be addressed.

Finally, and I will review this later on as well, site visits are standard with respect to IOM studies. The concern from the Institute of Medicine is that although these are typically an information collection process that is purely anecdotal it nonetheless gives us information, first-hand accounts from across the nation and in fact we covered the four regions of the country and I'll raise that as well.

It is important to also remember that once on these site visits the data collected, the information collected is kept in confidence and that assurance is given to those individuals whom we speak with.

The next slide, please.

[Slide.]

MS. GOTTFRIED: Well, what did we do once we were aware of what the NRC's request was? We went ahead and put together a statement of tasks. As you see before you, there are three major goals there.

The first goal is to examine the broad policy issues regarding regulation of radiation medicine. The second goal was to look at the risks associated with ionizing radiation in medicine comparing radiation medicine

to other medical modalities, particularly an assessment of the numbers of misadministrations and radiation medicine relative to the number of procedures performed.

In addition, we were to assess -- our third and final goal, to assess the existing regulatory system in order to determine whether or not this is the best approach for regulation of reactor generated byproduct material. As a caveat, I should say that the -- many of these -- the reprints that you have of the slides, they are not in order. A few people have new orders but we didn't want to go ahead and waste resources once we reordered them, so bear with me on that.

Next slide, please.

[Slide.]

MS. GOTTFRIED: The next slide is an expansion of our objective and recaps the charge and the methodology used to conduct the study. We looked at -- we are looking at an examination of the overall risks associated with the risks of ionizing radiation in medicine and specifically trying to achieve a comparative analysis of radiation medicine to other medical modalities as well as looking at the error rate, mortality and morbidity of misadministrations, compared to the total number of procedures in radiation medicine when properly carried out.

Next slide, please.

[Slide.]

MS. GOTTFRIED: With respect to the examination of the broad policy issues that underline regulation of radionuclides, the Committee has taken seriously the charge and is looking at the adequacy of the Commission's 1979 medical use policy statement as well as the extent of the NRC's responsibility to the patient involved in a misadministration as well as followup and notification requirements pursuant to the regulations.

The appropriate role for the NRC's medical consultant is another area that requires scrutiny and the composition of the staff at the NRC in the medical arena.

Finally, the NRC's regulatory policy and whether or not there is a better approach both from a policy perspective and a regulatory perspective as to ensuring regulation of medical use of radionuclides.

Next slide, please.

[Slide.]

MS. GOTTFRIED: Our examination of the broad policy issues regarding the regulation of radionuclides includes assessing -- sorry, I am repeating myself.

In response to this, the NRC has requested that we make recommendations on the following. A uniform national approach to the regulation of ionizing radiation in all medical applications and an attempt to look at an

appropriate criteria for measuring the effectiveness of the regulatory program needed to protect the public health and safety.

Next slide, please.

[Slide.]

MS. GOTTFRIED: Well, I am not going to review the medical policy statement, which I am sure everyone here is all conversant with. But to say that the Committee looked at the policy and is examining the policy in relation to the charge developed by the Committee in conjunction with the NRC.

Next slide, please.

[Slide.]

MS. GOTTFRIED: This is a vertical slide and so if you look to the end of -- for the commissioners it should be in the right order but for the rest of you, the end of your packet, there about five or so from the end is this representation.

The Committee having considered the charge needed to determine how to proceed and took it some time to think about a study paradigm from which to work from, we laid the foundation for the study and we sought to develop some sort of model that would depict the proper approach for the Committee. The Committee worked starting from what the -- you can't see from here but the scientific foundation and

looked at what underlies the regulation, what is the scientific foundation underlying the regulation of radiation, which means that we needed to talk about models of radiation therapy and how estimates of risk were evolved from these models.

Having established that scientific foundation, we needed to then look at the professional standards for control of these risks that come from the risk estimates. The scientific data is fairly fragile but it exists and, in fact, although controversial, there was data for us to look at.

Evolving from the scientific data is the regulatory framework that deals with the medical uses of byproduct materials. This is the existing -- this overall depiction is the existing depiction of the current system.

The NRC has asked us to deal with these issues and look at the regulatory framework both from a federal and a state perspective. The regulatory framework shapes the -- clearly shapes the -- what am I trying to tell you -- shapes the approach to be taken with respect to the professional standards as well.

There are -- when you see standards in the first instance when we are referring to professional standards and then standards above the regulatory framework applied to the governmental standards, there are a variety then of

pressures that exert influence on the enforcement program which would be societal, medical and political pressures. These pressures impinge on the enforcement program and, in fact, may not be in concert with the actual scientific data and foundation that has been laid previously.

That is what the Committee has attempted to emphasize and examine, whether or not the enforcement program and the standards that are an outgrowth of the various pressures have, in fact, are in fact in accord with the reality. This question of, are the risks associated with ionizing radiation in medicine commensurate with the existing regulatory framework.

CHAIRMAN SELIN: When you talk about the regulatory framework, are you talking about at all levels? Because we wish you to assume that everything else exists that exists today and the question is what does our regulation add to that as opposed to should it be us or state boards.

MS. GOTTFRIED: Yes.

DR. PUTMAN: Yes.

MS. GOTTFRIED: From Enforcement down really depicts the existing system.

CHAIRMAN SELIN: But at all levels?

MS. GOTTFRIED: At all levels, exactly. Federal and state. Yes.

CHAIRMAN SELIN: Health professional standards?

MS. GOTTFRIED: Yes.

DR. PUTMAN: I think that is a very important point about the health professional standards and is one of the reasons on this paradigm that there is distinction between the medical implication of standards, licensing, accreditation, consistency, retraining and we certainly have discovered considerable variability across the country in that.

CHAIRMAN SELIN: That's an interesting point. Let's not drop it at that point. Could you follow up on that a little bit, Dr. Putman?

DR. PUTMAN: Sure.

Certainly, the delivery of the radioisotope, for example, radioisotope for both diagnostic and therapeutic purposes, there is considerable differences in what perhaps states require for individuals that are labeled as paraprofessional support, technologists, level of formal education, level of board certification or where the subspecialty organizations may have a role, possibility for retraining or accreditation, moving from, say, a diagnostic area into a therapeutic area. And so there is considerable variability on coast to coast, small community, large community, et cetera.

CHAIRMAN SELIN: What role do the NRC standards

set, setting a minimum on this variability?

DR. PUTMAN: I think it would be our impression at this time that is not in the purview really of NRC. That is not, by and large --

CHAIRMAN SELIN: This is because you are talking about agreement states or is it true of states in which NRC is the nuclear regulator as well?

DR. PUTMAN: I would say that would be both. That is, that there may not be much difference between agreement and nonagreement in some of those categories. State licensing board and how the governance within that particular locale to requirements might be. There are some exceptions to that, I believe, relative to how the NRC would be evaluating those programs and asking those questions but, as far as oversight, are I think limited, really.

Is that a fair assessment?

MS. GOTTFRIED: Yes.

CHAIRMAN SELIN: That is interesting because we are supposed to be setting a floor on the variability on the licensing and qualifications of -- not of -- even of the physicians to some degree but especially the other professionals.

Thank you.

MS. GOTTFRIED: Just to sum up in terms of this paradigm, the enforcement -- the Committee was looking at

whether or not the enforcement program is really in synchrony with the underlying science and how in fact the program ought to be modified if, in fact, there is felt to be a disjuncture there. Looking at the scope, the purpose and the risks versus the reality and whether or not the enforcement -- what level is appropriate for enforcement, should it be wholly at the federal level or a combination of federal and state and the Committee views its responsibility as looking at making recommendations with respect to what the agency or mechanism ought to be for devising guidelines or regulations and imposing some sort of enforcement program, what modifications ought to be administered to the enforcement program and whether or not the scope of the existing regulation ought to be expanded.

Next slide, please.

[Slide.]

MS. GOTTFRIED: Well, regulation has clearly been one of the issues that is paramount in this study, although there are a variety of issues that we have undertaken. This particular slide just depicts the interconnection between the various aspects of regulation that the Committee is examining, what is the purpose of the regulation, what is the scope of the regulation and, in fact, what administrative or how many administrative agencies ought to be involved with respect to regulation of reactor-generated

radionuclides in particular and whether or not that scope ought to be expanded beyond reactor-generated radionuclides.

Next slide, please.

[Slide.]

MS. GOTTFRIED: This also is a vertical slide so it is cut off and it is toward the end of your packet there. It is simply a depiction of the sources of radiation and we -- the Committee has taken the broader charge of the NRC's to examine not only reactor-generated byproduct material but, in fact, to look at all of ionizing radiation in medicine.

The phrases here in yellow indicate those aspects of radiation that are regulated by the NRC, reactor-generated byproduct material, special nuclear material and reactors and the remainder being ionizing radiation but not reactor-generated radiation. Naturally occurring radiation, accelerator-generated radionuclides, machine-produced radiation, in particular X-ray machines and particle accelerators, those being the areas that are currently not regulated by the NRC.

Next slide, please.

CHAIRMAN SELIN: Before you get off this slide, I can't say much very good about the crazy quilt pattern of federal regulation but it does have the one benefit of giving us a control experiment to look at.

DR. PUTMAN: Yes, yes.

CHAIRMAN SELIN: Have you found any significant differences in health care delivery and safety and care between those materials and machines that the NRC regulates and those that we don't?

DR. PUTMAN: I am not sure we have, really. That is a very good question and it is data that we need to go back and look at because we have it. That is a very good question but I don't think we, certainly at this point, can make any significant comments.

CHAIRMAN SELIN: I would hope that would be something you would look at, you know, very soon because that sort of would tell us if we are even in the right ballpark or not. If the answer is no, it would be quite a burden for us to prove that we should even be in this business. If the answer is, yes, then the question comes, well, which parts of our programs are successful and which aren't and I would think that would be really the key question as you go about your study.

DR. PUTMAN: One of the issues is, of course, volume related. When we look at distribution of the X-ray machines, for example, for diagnostic purposes, are used more frequently and of course you have a distribution issue and it is a little hard to compare --

CHAIRMAN SELIN: Right. But we are more concerned

with the therapy than the diagnostic just because of the lethality of the material. It is not an absolute priority but that is where most of the attention has been put and at least the accelerators and reactor material, they are in the same order of magnitude even if there is a three-to-one or a four-to-one difference.

MS. GOTTFRIED: One of the fundamental questions that the Committee started with was what is the problem and, i.e., is there really a problem so that with respect to the risks associated and the level or the incidence of misadministrations, are we really dealing with a genuine problem or is it, in fact, minuscule relative to the total amount of administrations.

CHAIRMAN SELIN: That is one problem and then the second is, what about the differences between the NRC regulated and not regulated. If there were very little difference, then proponents of continued regulation would have to argue that our work raises both areas just by having an example to draw on and that is a much tougher argument to make than just look at how much safer byproduct material is in use than accelerated, than accelerator-generated radiation. So I would be very, very interested in your views on the answer to that question.

DR. PUTMAN: And there is a related question, of course, that is a little more difficult to deal with and

that is the one that has been raised by the medical community from time to time and that is whether the resources that are required under NRC regulation are in fact taken away from other more beneficial uses so that in the general scheme of things that, under NRC's regulations, this is an allegation. I am not supporting it one way or the other. That is what I would hope might come from your study but that the excessive demands of NRC regulation in fact, because resources are always limited, results in less -- a lower level of general health care than with another form of regulation which would not be so expensive or would provide opportunities for broader use of those resources, general health care.

CHAIRMAN SELIN: Let me summarize this a bit just so -- the first question, as I understand Ms. Gottfried, and I think it is a sensible one is, do we have a serious problem today that needs further regulation or do we have a situation which, all things being considered, is not unreasonable. If the answer is things are not unreasonable, then you get the more sophisticated question which is, would they continue to be not unreasonable if the regulation were let up.

You know, there are people in New York that have wolfsbane in their apartments. They say, see, it works, we have never had a wolf in our apartment.

You know, it is the old argument about deterrence, how important is deterrence. But clearly, I agree, that is a fundamental thing.

But then the second is, within the two main areas and probably concentrating on therapy because diagnostics is so many different things and some are dominantly byproduct and some are dominantly X-ray, et cetera. But within therapeutics, you do have an example of -- they are not exactly the same radiation, they are not exactly the same cancers but I am sure the statistics you have to deal with in your everyday life, these are close enough to being a universe that you could do the comparisons across.

That would be a fundamental question. If we find no significant differences between the two, then that would put quite a burden on the federal regulators to say that we contribute to both or that there is some mechanical or deterministic reason that byproduct material is intrinsicly more dangerous than accelerator material and therefore justifies a higher level of regulation. Then you can get into what works and what doesn't work.

I think those two fundamental questions would be of great interest and not to wait to the end of your report see what you believe the answers are.

MS. GOTTFRIED: No, we have been looking at that issue in terms of the intensity of regulation and whether or

not in fact it needs to be ratcheted up, if you will, or ratcheted down. I think in fact, with respect to nonreactor-generated radiation, there is a definite concern. The question is, if we are going to have an approach with respect to uniform regulation, how encompassing ought it be and at what level.

CHAIRMAN SELIN: Don't just look at first principles. You know, please look at the empirical data and see if today one could make the case that the people we regulate are on balance or at least the machines that we regulate are on balance any safer than the ones that we don't regulate, "we" being both NRC and the agreement states. That is yet a third question, is there any fundamental difference between the states that we regulate directly and agreement states. But that is not so germane to the central part of this.

DR. PUTMAN: I think one of the issues, and, of course, you're well aware of this, is the ability to assess in therapy what a -- let's call it a misadministration. An under-treatment is worse than over treatment, and one can have some general opinion that oftentimes in certain environments that that seems to be the direction that those providers tend to go. It is hard to weight that.

CHAIRMAN SELIN: It is safer for them.

DR. PUTMAN: Yes. It probably has a lot to do

with the volume, patients being treated.

CHAIRMAN SELIN: Does this take the form of a prescription that another medical practitioner would say was not aggressive enough? Because that is outside our field of regulation.

DR. PUTMAN: Yes. That is correct.

CHAIRMAN SELIN: The actual decision is not in our area.

DR. PUTMAN: That's right. That is the dilemma we have abed. Who can acquire a linear accelerator, for example, what are the guidelines. Of course, sure there are standard guidelines for health care practice. Very important, the health physicists, the dosymetrists. That is outside -- that is what we are struggling with to your question a bit: how do you look at the brachytherapy side versus --

CHAIRMAN SELIN: I just hope you give some attention to the heuristic as well as to the model.

DR. PUTMAN: We will. Absolutely.

CHAIRMAN SELIN: We have had trouble really making sense of the heuristic since it is not purely statistic. Dr. Polycove is terrific, but he can't do everything in the medical community all by itself.

MS. GOTTFRIED: It is an interesting point what Dr. Putman has said in terms of the under-prescribing for

radiation because, in fact, that escapes regulation completely, and when you talk to the experts they say that, in fact, is a major problem. That people, because of the concern of medical malpractice, that that is a greater issue, and yet, that is completely beyond the purview of what we are looking at.

Next slide please.

[Slide.]

MS. GOTTFRIED: This just simply represents one of the methodologies the committee decided to use which was to form subcommittees and look at some of the key areas, data risk issues of collection of data, which we've made some effort to do.

It is difficult collection data, as I know you all are extremely aware.

We've attempted to also get information with respect to non-reactor generated radiation from the FDA. That has been an interesting experience as well. So this committee --

CHAIRMAN SELIN: What does that remark mean?

MS. GOTTFRIED: It just means that collecting data from a large entity, a bureaucratic entity, and trying to get the kind of data you want, it is not always in the form that you wish it to be.

So that we may be looking for specific types of

data, and their data collection system may in fact be --

CHAIRMAN SELIN: They are not charged with keeping track of normal events having to do with non -- radiation devices the way we are, so I expect that it would be really tough to get even the quality of data we have, which is not so wonderful.

MS. GOTTFRIED: Right. It would simply represent a sample, but nonetheless, we wanted to try and see what they had on linear accelerators, for example.

CHAIRMAN SELIN: What did you find?

MS. GOTTFRIED: We are still in the process of looking through the data and collecting it, but, in fact, it wasn't very informative.

CHAIRMAN SELIN: It wasn't very informative.

MS. GOTTFRIED: The education and training is clearly a very important aspect of the study, and, in particular, if we are looking at looking at regulation and attempting to review regulation, and, in fact, minimize the extent of regulation.

It is believed that education and training are going to be key with respect to professionals, a variety of professionals, both physicians, technologists, physicists, nursing, et cetera, and that that education and training needs to, perhaps, be more uniform and we need to look at it at the state level.

Regulation was another key area that the committee has been spending a great deal of time on, and that committee has worked to look at and shape regulatory systems, alternative systems, and to think about what possibilities exist.

Quality management is another subcommittee taken very seriously by members of the committee. Again, the quality management rule has received a great deal of attention at the NRC, and by the regulated community as well, and so the committee felt that it was important to look seriously at quality issues.

CHAIRMAN SELIN: Are you going to be in the position to say something that you are comfortable with about quality management before the end of the study, or is that too hard to do until you've done the other pieces as well?

You know, we have lots of second thoughts about that quality management rule, and so the question comes whether you would be able to inform us on that along the way or is that something that --

MS. GOTTFRIED: The committee absolutely expects to make a recommendation with respect to quality management.

CHAIRMAN SELIN: When is what I am asking you.

MS. GOTTFRIED: In the final report.

CHAIRMAN SELIN: Are you going to have something

that would be useful for us before the final report on that topic, or is it just too hard to do that earlier?

MS. GOTTFRIED: It is probably too difficult. The report goes to review in early August, and I will get to that point when I talk about report review process.

CHAIRMAN SELIN: Okay.

MS. GOTTFRIED: But we are not allowed to vet the report prior to review.

CHAIRMAN SELIN: Okay.

MS. GOTTFRIED: Next slide please.

[Slide.]

MS. GOTTFRIED: One of the other methods of information, as I mentioned earlier, are site visits. the IOM fields it is very important to conduct site visits because we want to hear firsthand from the people who are effected by this particular area of inquiry.

We selected four states representing the four regions of the country, and selected two non-agreement states.

The states appear in the order in which we visited them, Georgia being an agreement state as well as California; Minnesota and Massachusetts, non-agreement states, and Massachusetts in the process, though -- a unique opportunity to look at Massachusetts since it is in the process of converting to an agreement state.

On the right-hand side of this slide indicates various organizations we visited: the state radiation offices, major medical universities, VAs, mid-sized hospitals, small hospitals, as many different people and institutions that we were able to get to in a two-day period.

COMMISSIONER DE PLANQUE: You went to the whole selection of facilities on the right-hand side in each of the states?

MS. GOTTFRIED: That is a good question. For the most part, yes. We only went to one pharmaceutical company. That happened to be in Georgia. We typically went to VAs, mid-sized, small and large hospitals. County departments of health were really only in California.

Next slide please.

[Slide.]

DR. PUTMAN: What we specifically tried to do was not restrict ourselves to a tertiary car center or major university medical center. That was always on our mind to really make sure we were sampling what is out there.

MS. GOTTFRIED: The spectrum, really.

We held a public meeting as I mentioned previously in order to allow those people both in the regulated community and in the general community at large to give us input with respect to this area.

We requested written testimony inviting letters -- sending letters inviting the testimony to, as you can see, about 124 professional associations and organizations, industries, and the 29 agreement states.

In that letter, we also requested that people forward the communication to anyone else who they thought might be interested, and so in response we received five unsolicited responses.

Overall, 38 responded who sent written testimony, and 15 of those 38 requested an opportunity to present at our public meeting.

I would like to also note that we invited specifically consumer groups, and got very little response to those groups, similar to -- I saw it in the task force report produced for the commission.

COMMISSIONER DE PLANQUE: Were most of the responses from the medical community?

MS. GOTTFRIED: Yes, very much. You will see in the next slide, please, that these are pretty much those who asked to actually present. They are actually in the order that they presented, but the typical associations that one would expect were interested in speaking, the American College of Radiology, the Radiological Society of North America, the Brachytherapy Society, the Society for Therapeutic Radiology and Oncology, the Roentgen Ray

Society, I was a little surprised by the American Association of Clinical Endocrinologists, but that was about the only surprise. The ACNP, SNM, et cetera.

CHAIRMAN SELIN: It was a surprise that the endocrinologists came aborad?

MS. GOTTFRIED: That requested an opportunity to speak.

CHAIRMAN SELIN: If you see my mail, it wouldn't have been a surprise.

[Laughter.]

CHAIRMAN SELIN: This is 2 percent of what we do; it costs us $5,000 a year. There is something crazy here. I should have said a few other things also. That is the essence, I'm sure, of what they have to say.

MS. GOTTFRIED: Next slide, please.

[Slide.]

MS. GOTTFRIED: As I discussed earlier, quality is certainly a focal point of this study, and not because we want to get bogged down in the symptoms of the problem per se. I think, to some extent, when you start looking at misadministrations and the quality management rule, et cetera, you are really looking at an outgrowth of a larger problem, and the problem is, you know, what is this illness that we are dealing with, what are we trying to diagnose, if you will, and what, in fact, is the cure.

I don't know that the cure is necessarily a prescriptive quality management program, although there may be some benefits to that.

The issue is what is for us in general, if we are going to attempt to ensure adequate protection of the public health and safety, what do we need to examine, and how does quality fit into that equation.

An Institution of Medicine Study actually devised this quality for you, and the definition that has been adopted nationwide, for the most part, it came out of a Medicare study. It is: quality of care is the degree to which health services for individuals and populations increase the likelihood of the desired health outcomes and are consistent with current professional knowledge.

In fact, that is what the committee is trying to assess: what is the current professional knowledge in this arena and are we ensuring the quality of care necessary for the public at large.

CHAIRMAN SELIN: This definition goes way beyond the NRC responsibility.

MS. GOTTFRIED: Absolutely.

CHAIRMAN SELIN: Ours has mostly to do with: are the services being delivered as prescribed, and are the health care workers and the public protected along the way? Not the basic 90 percent of this, which is, you know, are

you prescribing the correct care.

MS. GOTTFRIED: Absolutely. Some of the committee membership, having a broad-based background, has distinct interest in quality issues, and recognizes that the quality management rules as it is today, and the quality management program overall is a very narrow aspect of what quality really is, and wanted to look at quality in a broader context, and, in fact, determine whether or not quality issues should be dealt with and at what level they should be dealt with.

CHAIRMAN SELIN: It is like the Visigoth kingdom inviting the Moors in to settle an argument. I would be very careful with that if I were you.

MS. GOTTFRIED: Well, we are. The Institution of Medicine, in terms of quality issues, though, is very concerned about quality health care.

It is interesting because although the quality of management rule and aspects of quality, I can safely say, the committee feels need to be dealt with, but the question is: is it right now residing in the right place? Should quality issues really be dealt with at the state level or even in the professional societies, and who or what entity out to be involved in ensuring quality of care.

CHAIRMAN SELIN: There is also the reverse question in which there also is some interest, and that is

do the regulators, in particular the NRC, take actions which have the reverse effect of decreasing the quality of the medical?

In other words, are people afraid of something that we might do and, therefore, are not prescribing what they ought to prescribe. A question like that would be quite relevant.

We are not responsibility for quality in that sense, but if we have an inadvertent reverse effect on it, that would be of great interest.

COMMISSIONER DE PLANQUE: What did surprise me about the definition was the absence of something that alluded to decreasing the likelihood of unwanted effects. I don't know if that is intended to be included in desired health outcomes, but the absence of that kind of surprised me. There was a lack of balance to it.

Because, after all, that is what we are about, decreasing the likelihood of unwanted side effects. I would have expected to find something alluding to that in a general definition.

MS. GOTTFRIED: PLANQUE: That is a good point. This anti-dates me, but that is an interesting point and I will bring it to the attention of the people who work on that study.

COMMISSIONER DE PLANQUE: I was curious about the

source of that definition because I think, in general, that reflects the thinking in the medical community. That they don't often take into account negative side effects; they are looking only for the positive benefit, and don't often weight the two.

Next slide please.

COMMISSIONER ROGERS: It is a very loose kind of definition. If you really try to use it in some way, there is an awful lot of judgement that is involved there. Quality of care is the degree. How do you measure the degree? What is that?

For some of us that is a very, very loose construction. It may really be the best that can be done in general, but it certainly is very different from the approach that NRC takes in its regulation where we tried to find measurables that we can -- performance measurables that we can hold people accountable to in whatever we do.

That has been a big bone of contention here in how we regulate in this area. I can readily see that anybody who is used to operating under this definition of quality and feels very comfortable with it, would feel very uncomfortable with NRC's approach because it is a very loose definition and certainly subject to the interpretation of whoever wants to decide whether quality is being achieved, and what is the degree. What does "the degree" mean? How

do you compare that? What are the measurables in establishing "a degree"?

MS. GOTTFRIED: We asked our statistician that question also.

COMMISSIONER ROGERS: And? Gave up?

[Laughter.]

CHAIRMAN SELIN: I would like to take something out of each of my colleagues remarks. There are two different things we are saying. One is: we are uncomfortable with an unquantifiable measure. The second is: our job is not to get better outcomes, but avoid worse outcomes. We are regulators. We are not practitioners.

So when it applies to us, we just want to make sure that as you use the radiation you don't commit damage. Not "just." I mean, we also care about under-doses, but our main emphasis is that you don't commit inadvertent damage rather than that the patient is cured or what have you. That is just not central to the way regulators think.

You can say desired outcomes, positive as well as negative pieces, are there. But that is our frame of mind unfortunately or fortunately, so it is both the quantification and the "do no harm" aspect of it, rather than the "do as much good as possible."

MS. GOTTFRIED: That point is well taken.

Next slide please.

[Slide.]

MS. GOTTFRIED: Well, at this point, I just wanted to take some time to look at both our overview for the report, the forthcoming report, which is on schedule, and to talk about the report review process.

I can't, at this point, discuss recommendations and conclusions because they are in the process of being developed and, in fact, haven't been developed to date. The next meeting in May will focus on devising recommendations and conclusions during the report drafting process and once the committee has had an opportunity to review the initial drafts of the report, recommendations will then be developed, refined, and then reviewed again in July.

Well, what is the report going to look like, we all are eager to see it. I, myself, would love to have seen it written already. It is in process. The report is broken into three sections. We have divided it according to an overview, a background and policy section, and within those sections, you can see above, we have a summary which is a summary of the entire report, and it will run approximately 20 pages.

The front matters, the preface, acknowledgments, et cetera, committee membership, what-have-you, summary of the entire report, and then the introduction which sets the scene for the report and how the report evolved.

The second section is devoted to the background and the background really will be comprised of essential information for the general reader who wouldn't understand this area to begin with about radiation medicine, the risks of ionizing radiation in medicine, and the regulation of ionizing radiation in medicine.

Next slide, please.

[Slide.]

COMMISSIONER ROGERS: The first four and five, presumably those could be written any time, right? These are background, so you don't have to wait for the committee to agree with all that, do you?

MS. GOTTFRIED: The committee has to review all the different facets.

COMMISSIONER ROGERS: I mean, there is no big deliberations, I would think, on this.

MS. GOTTFRIED: No, it is just a question of agreeing on the language and the tone and the data.

The third section of the report, which is policy, really is the heart of the report, and will look at what the major issues and questions are that the committee confronted, whether or not the -- what the major alternatives are that the committee considered.

The committee has been working on devising a spectrum of alternatives and, based on those alternatives,

attempting to focus in on what one or more optimal systems might be, regulatory systems, and that section of the report will review the various alternatives, the pros and cons associated with each alternative, and then transition into the summary section, which is the conclusion, and a discussion of the preferred alternative.

COMMISSIONER DE PLANQUE: I am kind of curious. In your major issues and questions, we fully realize that you are not going to give us any hint as to where you are going. I think that has become clear, but could you at least tell us if you have identified any new issues or come up with any other questions that maybe we should have asked and didn't and that you are addressing, any issues that are on your plate other than what we might have been aware of?

MS. GOTTFRIED: I honestly don't think so. I think that, in fact, the charge was pretty well on target. There was a great concern about, you know, to what extent should we focus on exclusively reactor-generated byproduct material or expand it to all of ionizing radiation and medicine, not for lack of interest with respect to ionizing radiation in medicine but, in fact, because it is just so vast, and could we do justice to the field if, in fact, we expanded our scope. But the decision was to go ahead and expand and really build on the charge from the NRC with respect to ionizing radiation in medicine.

There haven't been any particular surprises in terms of areas that we didn't think about. The data issue in terms of collection of data has been a challenge, and the quality issue, which Chairman Selin had raised in terms of being way beyond the purview of what your quality area is, is an important and a valid point. I think that that will, in fact, be something that the committee just thinks should be further looked at because of the issue of, how do you adequately ensure the protection of the public health and safety which is, in fact, what the regulation is intended to do, so what is the purpose of the regulation, in fact, if you are not looking at some quality issues.

DR. PUTMAN: I think that probably on the education and training side, which one would say a study like this would always be included because you can't go wrong there, but the fact is, the committee itself, I think, if I may speak as an individual and not as chairman of the committee, I think the whole issue of radiation and what it is is a very, very confusing subject to informed people, much less, one might say, the only direct knowledge would be when they are referred by their doctor.

This is why the background information, I think, has been so important to us as it relates to an IOM study and the credibility of the entire report. We have tried to involve people that really have real knowledge and have the

credibility professionally with their peers to talk about issues of what radiation is all about.

Also, on the education and training, that is not clearly within the purview, but we believe that that is going go be important to the overall study, and probably has a lot to do with the quality. They are just absolutely linked, again not directly to the charge but ultimately, I think, affecting the credibility of how the overall study would be perceived, received, by peer groups and other people.

I was surprised when we invited participants, you know, individuals to come from organizations, et cetera. I made personally a real attempt to not just get the providers of these services but the referral, you know, the physician medical groups that are sending patients. It was discouraging, quite frankly, to see such a low level of interest. That wasn't just a letter, there were phone calls made, and personal, would you like to come and tell us what you think about these issues. They were not really informed.

The only group, I think, was the endocrinologists. Of course, I know why they were there. I mean they are obviously using both the diagnostic and therapeutic radioactive material, and they are concerned, obviously, about the licensing and it is a professional issue between

the radiologists and endocrinologists.

COMMISSIONER ROGERS: Is that the reason you think that the representation of the 15 presenters really virtually didn't include any people on the receiving end of nuclear medicine? I didn't see any organization there, there is a state organization representative, where that list is on your slides here, but at any rate in just going down that list of presenters, they are all, virtually all, organizations that represent the interests of people who are regulated by NRC, not people who might be the beneficiaries of some health benefits that come from regulation by anybody.

CHAIRMAN SELIN: Or even their representatives from starting positions.

COMMISSIONER ROGERS: I hadn't even though of that, but you mentioned that they weren't there.

For instance, just to pick something out of the blue, was AARP invited to come?

MS. GOTTFRIED: Yes, they were.

COMMISSIONER ROGERS: And they didn't show up?

DR. PUTMAN: That's right. Ivan, I am an internist and diagnostic radiologist, and I had the opportunity to talk with many of my internal medicine at national meetings and inviting them, actually, but they would not take advantage of that opportunity.

MS. GOTTFRIED: I personally contacted about six to ten of the groups that we thought would represent a different perspective, AARP being one of them, and they just didn't have -- either they didn't have the time, the interest, or the resources.

DR. PUTMAN: We did include two positions within one of our panels specifically, pediatrician, and I wanted a pediatrician there for obvious reasons, and also a general internist, so the committee did have that opportunity to hear that exchange, and the pediatrician was certainly well informed, I thought, about radiation and the use of it, the concerns about it. That is the only real -- except on some of the site visits there was a bit of exposure, too.

COMMISSIONER DE PLANQUE: And other consumer groups, were there many who just were invited?

MS. GOTTFRIED: Sid Wolf's group was contacted.

COMMISSIONER DE PLANQUE: No?

MS. GOTTFRIED: No.

COMMISSIONER DE PLANQUE: That's amazing.

MS. GOTTFRIED: It really was.

CHAIRMAN SELIN: As you know, we have something of that same experience ourselves when we ran our informal little survey.

MS. GOTTFRIED: We are definitely disappointed by the lack of response, but it just -- I think it is

important, though, because what it represents in my mind is that, in fact, radiation generally there is a perception of radiation but people don't distinguish between aspects of radiation and they don't understand the differences and, in fact, this is such a unique area because you are taking and people, who you tend to keep apart, and you are putting them together. I think when we talk to physicians generally and we ask them, are your patients fearful, how much do they question you, the response was, you know, the tend to believe and trust in the physician overall, and they are here because they are in a desperate situation and they need help. Certainly they have certain fears, and those fears are legitimate, but we attempt to inform them as best we can. The variability with respect to the information provided is interesting.

I think, though, just going back to your original question, nothing particular has surfaced as an area that we hadn't thought about or that you all hadn't requested us to look into, and I think that the focus really has now been on really, what is the big picture here. We can look at all these different facets of the issue, and we can appreciate that there are discrete sections that have to be addressed, but really overall is there a disconnect, is there a disjuncture between the scientific data and the extent of the existing regulation and, if so, let's fix it because it

is wasting resources if it is inappropriate and, in fact, if there is sufficient data to indicate that such a regulatory system is warranted, then let's demonstrate that.

COMMISSIONER DE PLANQUE: Do you think you are going to be able to answer those questions?

MS. GOTTFRIED: We certainly anticipate that, yes.

COMMISSIONER DE PLANQUE: You have posed them with such neutrality I can't tell which way you are going, it is frustrating.

MS. GOTTFRIED: That's all my legal training.

DR. PUTMAN: She's trying. This is my attorney here.

[Laughter.]

DR. PUTMAN: No, seriously, we are still -- that big picture, I think the committee has really a good handle on the whole issue, and that has been important, there has been a learning curve, and I think that with the information that has been collected, there is subjective data, there is objective data, there is a historical perspective, there are the state issues, the federal, I think the committee is now becoming pretty comfortable with where the big issues are, and will come forward with recommendations that are pretty solidly grounded.

Now people may disagree, but they will be pretty solidly grounded, I think.

COMMISSIONER DE PLANQUE: Well, I think that the big picture perspective is extremely important because that is one of the reasons we asked you to do the study. We don't have the resources to do that kind of big picture analysis, and that is important to the policy decisionmaking.

CHAIRMAN SELIN: The Commission does big picture things, but the analysis is what is missing when we do these.

COMMISSIONER DE PLANQUE: Yes, don't confuse us with the data.

CHAIRMAN SELIN: Yes.

DR. PUTMAN: Okay.

MS. GOTTFRIED: Could we have the next slide, please.

[Slide.]

MS. GOTTFRIED: Now I just want to take a few moments and look at the report review process. The National Research Council, which is the umbrella organization for the NAS and really administers the National Academy of Sciences, the National Academy of Engineering and the Institute of Medicine, is responsible for the overall report review process.

This is a process that is really taken quite seriously by the Academy and for good reason because I think

it really applies a certain level of rigor that would be absent otherwise from the ultimate report that is issued. The report will be issued in the name of the study as a whole, and the process itself can take anywhere from four to ten weeks, and so when I say we are on schedule, the committee is absolutely on schedule. The anticipated submission for the initial draft of the report is early August.

Where it is unpredictable is during this report review process which, in fact, can go anywhere from 4 to 12 weeks depending on the reviewers. What we are looking for during this process is a candid reaction by knowledgeable peers to the report.

At this point, the sponsor is not privy to the version submitted for review and that, again, is for a good reason, to ensure the integrity of the report and, in fact, to give the reviewers an opportunity to question anything that they may feel warrants further scrutiny.

Next slide, please.

[Slide.]

MS. GOTTFRIED: Well, the report review process starts off with a coordinator and a monitor. These are people who are appointed within the Academy and there is ont always a monitor appointed, but in this instance there will be a monitor. The monitor is there to ensure the integrity,

again -- further ensure the integrity of the process because there are expectations that there may be some requests to look at the legislation, repeal legislation, modify it, et cetera. That is another level that needs to be examined. So a monitor --

CHAIRMAN SELIN: Wait, don't go on. I didn't understand. I mean I understood each word you said, but I don't know what you said. What is the role of the monitor?

MS. GOTTFRIED: The monitor just --

CHAIRMAN SELIN: Legislation, what is it?

MS. GOTTFRIED: It is another layer in the review process, where typically there is a coordinator who coordinates the reviewers' comments.

CHAIRMAN SELIN: Right.

MS. GOTTFRIED: A monitor just oversees the coordinator, if you will, another senior person, to ensure --

CHAIRMAN SELIN: Somebody who is technically competent to understand the --

MS. GOTTFRIED: -- the recommendations.

CHAIRMAN SELIN: To make sure that what comes out is consistent with the recommendations that are made.

MS. GOTTFRIED: That's right.

CHAIRMAN SELIN: What does that have to do legislation?

MS. GOTTFRIED: Well, in reports where there is an issue with respect to legislation, I guess it's felt that it is important to have another perspective from the academy, somebody who is more conversant with making any sort of major recommendations and that is any report that has a regulatory component essentially or has any potential for making major, sweeping recommendations.

CHAIRMAN SELIN: Okay.

MS. GOTTFRIED: The review process typically involves six to 10 individuals and this review process will have closer to 10, perhaps even more. The expertise of these reviewers really parallels the expertise on the Committee but none of these individuals will have had involvement in the study itself and these people are also subject to executive administration review by the Academy.

What are they reviewing for? Well, they are looking for the following. They want to ensure that we, that the Committee itself has complied with the charge from the sponsor, in this case the Nuclear Regulatory Commission; whether or not the report is accurate and clear; whether or not the conclusions and recommendations that are made have a reasonable foundation; and that the reasoning and analysis that is the foundation for the recommendations can be subjected to considerable scrutiny by experts in the field.

The other point I want to make about these

reviewers is that they are anonymous to the Committee so the Committee has no idea -- I mean they know they are people in the disciplines but they don't know who the particular reviewers are and again that is to ensure the integrity of the review process.

COMMISSIONER DE PLANQUE: And they also undergo the conflict of interest scrutiny.

MS. GOTTFRIED: Yes. The mechanism for -- I mean all of this process is to strengthen the report review -- the report outcome, I should say, not the review.

Next slide, please.

[Slide.]

MS. GOTTFRIED: Once the reviewers' comments have been submitted to the Coordinator, the Coordinator then has to synthesize all of the reviewers' comments and indicates those points that the Committee has to address. I should say that in almost every instance every single comment submitted by every one of the reviewers must be officially addressed by the Committee and staff at the NAS. Only the absolute -- like "put a period here" -- is not actually responded to.

That is again to ensure the integrity of the report. It's doesn't necessarily mean that every comment has to be incorporated into the report, but if in fact we plan to refute some of the comments, those have to be

described and explained.

Once the staff and the Committee have responded to the satisfaction of the Coordinator, the Coordinator then gives his or her approval for the report to be released. Then at that point the report is released publicly with the NRC, and I am talking about the National Research Council in that instance, and the IOM imprimatur.

At that point the report would go for publication and ultimately dissemination.

The dissemination process varies from report to report depending on the level of interest, whether or not there would be an official press release. All of that is determined as the process unfolds later on, say early Fall.

We are submitting the initial draft for review in early August. If things go absolutely according to schedule I mean it is conceivable we would have the report completed by mid-September. The aim is by October 1 and then off to publication, which takes about eight weeks, six to eight weeks.

CHAIRMAN SELIN: We get the report around October 1st? Are we going to have to wait while somebody --

MS. GOTTFRIED: You get the report when it has been produced and published --

CHAIRMAN SELIN: You mean on October 1st when the report has been thoroughly peer reviewed we still don't get

to see it for six to eight weeks after that?

MS. GOTTFRIED: Not until there is an official release.

CHAIRMAN SELIN: Well, that's terrible. I mean that's really terrible. It's one thing to say that we can't get the report because it hasn't been peer reviewed, but to be held up for logistical purposes is really very, very questionable.

MS. GOTTFRIED: Well --

CHAIRMAN SELIN: We are desperate for this stuff. We are trying to act on it and because, you know, you don't have desktop printing or something like that we have to wait six weeks -- that's really unconscionable, if I have understood that correctly.

MS. GOTTFRIED: My understanding is that is the standard of the process. I can look into that and be happy to do so.

CHAIRMAN SELIN: If there is a review procedure, if somebody has to sign off, we can sort of impatiently tolerate that but the sponsor shouldn't get the report till the public does and it takes us six weeks to produce 10,000 copies, I think that would be unconscionable, I really do, and I may not understand the reasons for this delay, in which case I'll be glad to give you a contingent apology, but --

[Laughter.]

CHAIRMAN SELIN: -- but if that is the basis, nobody is going to want to wait. That's really not fair.

MS. GOTTFRIED: No, I appreciate that concern and I certainly will look into what the protocol is and if there is a problem with respect to standard protocol we can look into it further.

CHAIRMAN SELIN: Please.

DR. PUTMAN: I will also do the same and I was going to come back to some of the questions that you have asked.

CHAIRMAN SELIN: Right.

DR. PUTMAN: And I know timing is important to you.

CHAIRMAN SELIN: Right.

DR. PUTMAN: Kate, I don't know if I interrupted here.

MS. GOTTFRIED: No, no.

DR. PUTMAN: I have taken notes and I know that -- but I wanted to make sure and I don't have them in order but that if you have specific areas of concern and you have already some of them --

CHAIRMAN SELIN: And I am going to have four questions --

DR. PUTMAN: Please go ahead.

CHAIRMAN SELIN: -- and I would like them in some sort of a logical order.

The first question is -- I mean they are all things you have said or that have come up.

The first is the overall scope. Is there a serious problem in mortality and morbidity from radiation due to misadministrations as opposed to -- well, first of all, compared to just the intrinsic risk of using therapeutic radiation and then on top of that what the physicians do in the way of prescription?

DR. PUTMAN: Sure.

CHAIRMAN SELIN: So that is the first question.

DR. PUTMAN: Yes.

CHAIRMAN SELIN: The second question, within this overall question, is there some significant differential between those kinds of radiation that we regulate and those kinds that we don't, and "we" being byproduct. I am not looking to you for differences between agreement states and any insight on that would be --

DR. PUTMAN: We may have some of that.

CHAIRMAN SELIN: -- be welcome but it is not -- without that, the study can still be a success.

DR. PUTMAN: Yes.

CHAIRMAN SELIN: The third is sort of depending on the question. If you don't find a difference, is it because

we are not doing our job well or in other words what could we do better? We would hope -- I mean since there is an extra level of regulation for byproduct material compared to linear accelerators, it's not that we do byproduct material and FDA does exactly the same thing. Nobody, at least at the Federal level, does what we do for byproduct, so if you don't find that that extra level is producing measurable reductions in risk, is it because we are not doing our job well or is it intrinsic in the problem.

DR. PUTMAN: Yes.

CHAIRMAN SELIN: Conversely, if you do find some difference, what are we doing right and to what should we attribute that? The essence of our program is that we try to hone down to the essential point, so we are very interested in a tactical review of our program but it would be a different kind of our program but it would be a different kind of review depending on what you come out with on that basic answer, and I suspect you'll find that in some areas we make a difference and some areas we don't.

I don't expect just a yes or a no and also don't let me give you the impression that we are not interested in diagnostics. It's true that the therapeutic work really drives us, but things like radioactive iodine and some other questions are also very important.

DR. PUTMAN: Yes.

CHAIRMAN SELIN: And even the therapeutic work, the difference between palliatives and treatment is very important. If you kill somebody who is going to die anyway just a little bit later because you were very aggressive, that's one thing. If you have given somebody who is getting prophylactic treatment and that turned out to kill a person, that's -- and the reason I say that, some of our misadministrations we have got licensees who say look, these people were all terminal anyway, and we looked and they weren't terminal. They were sick, they were very sick, but they weren't terminal.

The fourth thing is please aware of costs in making your recommendations.

DR. PUTMAN: Yes, we will.

CHAIRMAN SELIN: We all would like to see statistics on correct administrations. We are greatly under-impressed that they'd be worth the cost of collecting and that is the most obvious one, but there are some other places where any reasonable scientist would say how can you do your job? You don't know what happens when things go correctly, but the implications of that are vast in financial and the licensees bear the costs of those implications, so please be careful about them.

MS. GOTTFRIED: Yes.

CHAIRMAN SELIN: Those are my only questions or

things that I would like to see answered.

DR. PUTMAN: Very good, and the other, of course, about the timetable.

CHAIRMAN SELIN: Oh, yes, yes. That's logistics. That's --

COMMISSIONER ROGERS: I think we all feel very strongly on that. I mean once the substance of the report has had the professional peer review and everybody agrees that this is it, this is what is going to be printed, we need to have that available.

DR. PUTMAN: I understand.

COMMISSIONER ROGERS: It's really critically important.

Well, there are a couple of other things that came out in your presentation that caught my attention.

One is you did mention in the training accreditation area that the different states, it's very different what's required.

Were there any implications of that observation with respect to your regulatory options? For example, if the states took over this area entirely from NRC, would we be handing over something to a patchwork quilt of agencies that would have very variable and significantly different capabilities of doing the job?

You know, one has to ask that question when you

make the observation that you did, that there's big differences out there. I think we have to know that. If you feel that there would be a significant problem, then it would have to be dealt with, not that it couldn't be dealt with but it would have to be addressed. One couldn't just simply hand over something and forget it, if that is the case.

I think if you could address that, that would be very helpful in your report.

The other one is sort of a big picture question, very big picture question, but you know, the lack of response here from the recipients of nuclear medicine as well as any of the public interest groups that are very concerned with respect to the existence of radiation in the environment is a matter of great concern to me here.

You know, this compartmentalized thinking that no radiation is good in the environment under any circumstances, which is basically the position of some organizations, none, and their absence of any interest in the nuclear medicine area where there are great benefits to be derived from the use, intelligent, careful use of radiation, and just ignoring that really poses a very serious problem in ever coming to a rational approach to how to recognize the existence of radiation as a part of our environment and to deal with it intelligently and

responsibly.

If there are organizations and significant organizations with lots of money and lots of clout that are simply dead set on focusing on everything except the beneficial uses of radiation, then it is going to be very, very difficult to every come to a rational position with those folks on any issue, and they really should be represented in these matters and express their views of concern and in fact be the recipients of the information which you are unearthing with respect to the beneficial uses.

It is a big picture question. I am not -- I don't think you can do a lot with it but you might be able to allude to it in some way in your report because it seems to me this is -- you know, we have two approaches here. One, the practitioners who are using nuclear materials for beneficial purposes who I am sure resent regulation by anybody -- we all do, it's only natural -- and have their own professionally arrived at standards that they consider adequate, but by themselves don't represent a checks and balances system by those who are outside of the profession itself and that does exist in the other areas of the use of nuclear materials or if we are talking about nuclear reactors, where, you know, everybody under the sun has a chance to say something about whether they think that

reactor ought to operate or not in their community and there is a great deal of public interest by private citizens and organized groups and so on and so forth.

Here, it is almost bizarre. There is no representation from those folks in this area where they ought to at least be listening, if not contributing, and it is very troublesome.

It is very troublesome in trying to think that we can ultimately as a broad community adopt a rational approach to the role of radiation in our environment. There are some good things about it and some bad things about it and one has to try to strike an adequate balance there and you are focusing on one aspect and in the other areas in which we work there is very much the -- I mean you pointed this out in the beginning, that this is a rather different approach to the control of nuclear materials in that here we are trying to expose people to radiation but we are trying to do it in a beneficial way, and it is a purposeful exposure whereas in virtually every other aspect of the regulation of radiation you want to stop the people from being exposed.

Somehow there is a very big gap between these two, an intellectual gap between these two, which really should be bridged. Any way that you can take a step towards trying to bridge that gap I think it would be in the national

interest to do so.

MS. GOTTFRIED: Well, it's really an understatement to say that it is a complex, an exceedingly complex, issue, but in fact the perception of risk by the public is something the Committee has been examining and trying to figure out how to integrate into the report.

It relates to education and training because one of the issue is how are you going to look at changing public perception and a lot of people are very cynical about the impact of education and educating the public about radiation and the numbers of dollars that would have to be thrown towards that and whether it would have any benefit whatsoever, and yet when you talk about perception, you could say it is a perception but that perception becomes the reality.

COMMISSIONER ROGERS: Oh, absolutely.

MS. GOTTFRIED: And in fact we have grappled with that a great deal and I don't want to get too philosophical but in fact that is a major concern amongst the Committee and how to base those perceptions in scientific reality and then see where it goes with respect to the public.

COMMISSIONER DE PLANQUE: May I introduce a thought on that issue? I recognize this was not in your initial charge but I, too, am struck by the lack of responsiveness from the consumer groups or the public in

general.

One of the issues that we at the Commission always grapple with is where is our role with respect to education or providing information and we are somewhat schizophrenic in trying to walk the fine line of where is education and where is promotion, which of course is verboten in our charge.

I would for one appreciate if you have any thoughts on the role of the regulator with respect to education or information in this regard. I think that would be most welcome.

DR. PUTMAN: The Committee has spent time, you know, at the end of a long day when you are trying to deal with data and then your questions are the ones that have come up.

We have been, as I have indicated, very disappointed, in fact we are kind of looking forward to more questions from the public or the individuals in the professions that are utilizing, and I don't think it was -- you know, maybe we didn't disseminate the information correctly. I don't think so. We really worked at that, so I think this has to be a part of the report and there is a difference of opinion as Kate indicated among the Committee right now, I think it is fair to say, on what does it mean when we talk about educating the public versus the education

and training as it relates to the professional groups, but it is -- I am confident there will be something there because it in itself is as critical as some of almost the specific charge, which I realize is more important in a temporal way but there's confusion, amazing, with the public and even the professionals.

The cardiologists did participate, I should tell you. They are both providers and referral physicians too but the cardiologists were actively involved from some of the societies.

COMMISSIONER DE PLANQUE: Are you finished?

DR. PUTMAN: Yes.

COMMISSIONER DE PLANQUE: I really had no further issues. I think most of them have been covered throughout the briefing but thank you very much for sharing your thoughts with us.

CHAIRMAN SELIN: Let me come back to one thing Commissioner Rogers said before we close. Don't get the impression that we believe it is necessary to educate the public that radiation is good for you. What we are saying is, in other areas, having a strong what you would call an environmentalist or consumer-oriented group has been very helpful for us because they have identified issues when it is just us and the licensees that care. That is a very one-sided kind of an adversarial process.

I have been disappointed. I am not proposing that we go out and educate the public but I really have been disappointed that we haven't gotten the benefit of the thinking of some people who are, you know, comparable to the antinuclear folks who bring up very good issues in the reactors area or some other similar areas as well. I too am perplexed by this.

MS. GOTTFRIED: Does it suggest to you that perhaps it is not perceived then as a problem --

CHAIRMAN SELIN: My wife is an ex-cancer patient. I'll tell you, she was a lot more nervous about chemotherapy than radiation. It is not just a disinterest in medicine. Somehow, radiation doesn't seem to have the same -- maybe it is unseen, maybe you don't see the symptoms of -- the effects of the treatment itself as much as you do in chemotherapy. But I don't think It is medicine in general; I really do think that somehow the medical perception of radiation isn't as serious as other areas.

That was the last thing I wanted to say. Not exactly that but when you look at performance or risks or what have you, I hope you will, as appropriate, take a look at other comparable medicines. Chemotherapy is a good basis. It is even more dissimilar than accelerator-produced versus byproduct material produced. But we do hope you, in making these overall -- is there a problem or isn't there a

problem, you look at, you know, stuff outside the radiation area but not just the statistics.

If you are taking a look at unevenness and training, how does that compare to other oncologists. If they are pretty uneven but it is true throughout oncology, then why do we single out radiation. If they are pretty uneven in radiation, then that is something to worry about.

COMMISSIONER DE PLANQUE: May I? It may be something that you are unaware of but recently there was a chemotherapy overdose.

MS. GOTTFRIED: I was just going to mention that.

COMMISSIONER DE PLANQUE: The part you may not realize is that our Region I apparently got several calls making some sort of connection or at least inquiring about radiation as a result of that chemotherapy death. One has to wonder what is going on here in the minds of the questioners to make that connection.

MS. GOTTFRIED: It will be very interesting to see if there is some sort of outcry from the public for regulation now in the area of chemotherapy.

CHAIRMAN SELIN: I think they just think we regulate the center as opposed to the use of the byproduct material. I think that is the simple -- there may be more to it but the simple answer is it is a radiation center, we are the NRC, we are responsible for everything that goes on.

This is terrific. Our rather intemperate reaction today, the idea that it will take even longer than I thought to get the report, you should interpret as a compliment to the work you are doing.

DR. PUTMAN: We do and we will work with you continually and your staff, again, have been great with us and for us.

MS. GOTTFRIED: We very much appreciate the time to talk with you today.

CHAIRMAN SELIN: Thank you very much.

[Whereupon, at 11:31 a.m., the above-entitled meeting was concluded.]

CERTIFICATE

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

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

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Wednesday, March 29, 1995

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

Transcriber: Corietta Israel

Reporter: Mark Mahoney

National Academy of Sciences
Institute of Medicine

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

Committee Members

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

Description of Study

Study:	Evaluation of the Medical Use Program of the United States Nuclear Regulatory Commission
Sponsor:	Nuclear Regulatory Commission
Budget:	$1.15 million
Study Chair:	Charles E. Putman, MD
Study Director:	Kate-Louise Gottfried, JD, MSPH

Description of Study
(continued)

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

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

Description of Study
(continued)

1 Examination of the overall risk associated with the use of ionizing radiation in medicine.

a) The frequency of errors and consequences associated with the use of licensed byproduct materials in relation to other medical procedures (such as chemotherapy, surgery, general anesthesia or administration of pharmaceuticals); and

b) Given the total use of licensed byproduct materials, the error rate, mortality and morbidity of misadministrations compared to administrations of licensed byproduct materials that are properly carried out.

Description of Study
(continued)

2 Examination of the broad policy issues that underlie the regulation of radionuclides.

a) Adequacy of the 1979 broad policy issues that underlie the regulation of radionuclides;

b) Extent of USNRC's responsibility to the patient involved in a misadministration, including notification and follow up;

c) The appropriate role for the USNRC medical consultant in the medical use program;

d) Whether the USNRC's regulatory policy could more effectively promote better patient care or safer medical uses of radionuclides.

Description of Study
(continued)

3 The USNRC seeks recommendations on:

a) A uniform national approach to the regulation of ionizing radiation in all medical applications, and

b) Appropriate criteria for measuring the effectiveness of the regulatory program(s) needed to protect public health and safety.

Medical Policy Statement

- The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

- The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

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

Statement of Task

Three major goals:

1 Examine the broad policy issues that underlie regulation of the medical uses of radionuclides;

2 Study the overall levels of risk associated with the use of ionizing radiation in medicine, comparing the errors and consequences of--

a) the use of byproduct materials to other medical interventions, and

b) the use of byproduct misadministrations to properly conducted administrations;

3 Assess the current statutory or regulatory framework for regulation of medical uses of byproduct materials.

Subcommittees

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

Site Visits

- Georgia
- Minnesota
- Massachusetts
- California

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

Public Meeting

Request for Written Testimony:

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

Public Meeting Presenters

Total Number: 15

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

Ionizing Radiation in Medicine

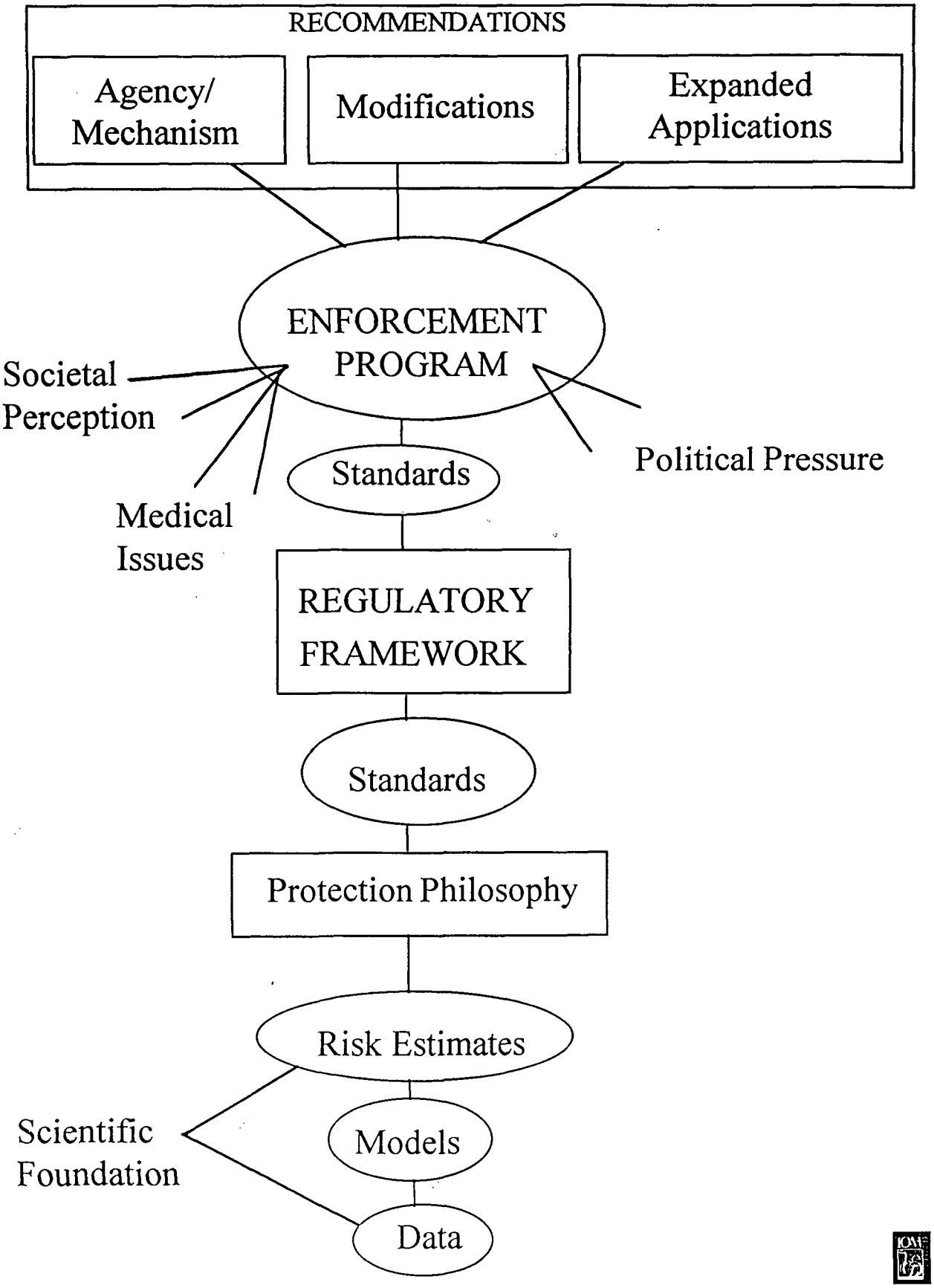
Radiation Source	Diagnostic	Therapeutic
RADIOACTIVE MATERIALS		
✧ **Reactor-Generated Byproduct Material**	**Radiopharmaceuticals***	**Radiopharmaceuticals*** **Teletherapy** **Bracytherapy (Interstitial, Intracavitary, Plesiotherapy)**
✧ **Special Nuclear Material (no medical applications)**		
✧ Naturally Occurring Radiation		Bracytherapy (Radium)
✧ Accelerator-Generated Radionuclides	Radiopharmaceuticals*	Radiopharmaceuticals,* Bracytherapy
MACHINE PRODUCED RADIATION**		
✧ X-Ray Machines	Plain film, Fluoroscopy, CT, Computed Radiography, Angiography, Dental x-rays	
✧ Particle Accelerators	Cyclotron	Linear Accelerator
✧ **Reactors**		**Boron Neutron Capture Therapy**

Sources indicated in yellow are subject to NRC regulation. All others are regulated at the state level.

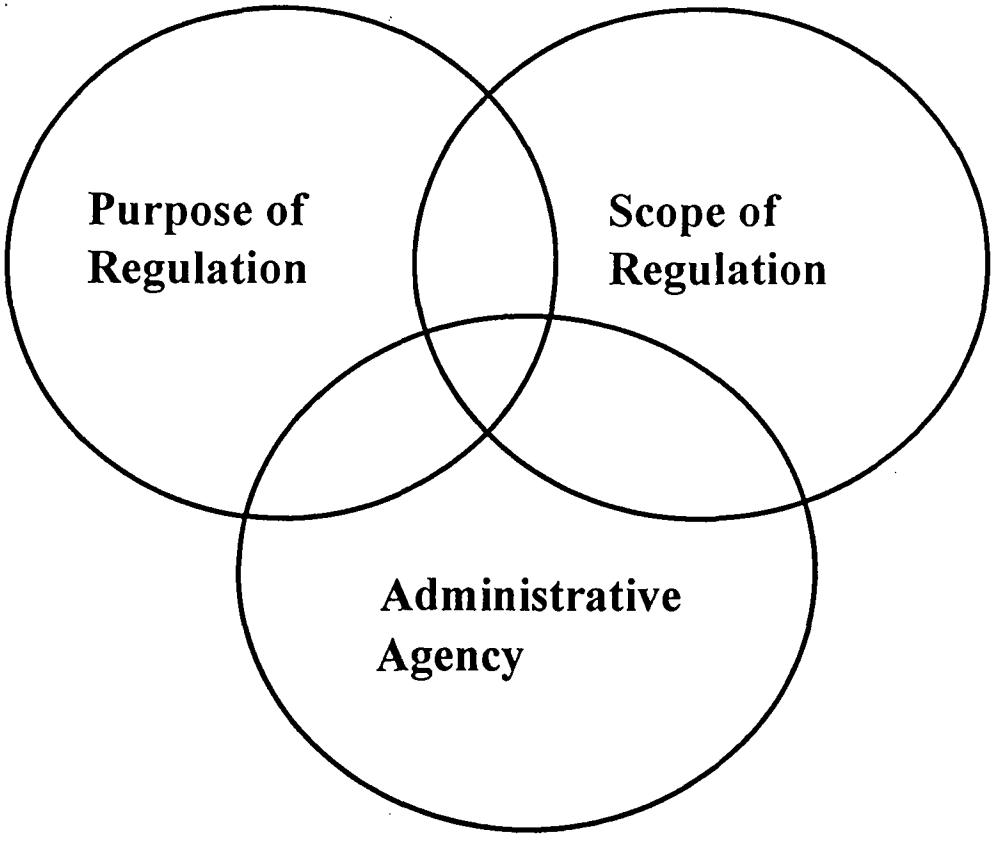
* Also subject to regulation by FDA's CDER and/or CBER

** All machinery is subject to regulation by the FDA's CDRH

Study Paradigm



Regulation


Purpose of Regulation
Scope of Regulation
Administrative Agency

Definition of Quality

Quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

General Outline

I. Front Matter

Part One: Overview

II. Summary

III. Introduction

Part Two: Background

IV. Radiation Medicine

V. The Risk of Ionizing Radiation in Medicine

VI. Regulation of Ionizing Radiation in Medicine

General Outline
(continued)

Part Three: Policy

VII. Major Issues and Questions

VIII. Major Alternative Regulatory Systems

IX. Summary of Committee Findings

X. End Matter

National Research Council Report Review

- Report issued in name of study committee
- Several week process
- Candid reaction to study by knowledgeable peers
- Sponsor is not privy to version submitted for review

Report Review Process

- Review coordinator and review monitor appointed
- Draft report reviewed by 6-10 individuals
  - Expertise similar to committee members
  - No involvement in the study
- Reviewers must be approved by executive office
- Reviewed for:
  - Compliance with charge
  - Accuracy and clarity
  - Reasoning underlying conclusions and recommendations

Report Review Process
(continued)

- Review coordinator summarizes reviewers' comments and indicates the points the committee must address

- Once staff/committee respond adequately -- approvals are given by review coordinator

- Report can be released publicly with the NRC/IOM imprimatur