UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

Title: BRIEFING ON PROPOSED BASIC QA RULE WITH REPRESENTATIVES OF NRC ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES AND INDUSTRY SCIENTIFIC COMMITTEE

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D I S C L A I M E R

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REPRESENTATIVES OF NRC ADVISORY COMMITTEE

ON THE MEDICAL USES OF ISOTOPES AND

INDUSTRY SCIENTIFIC COMMITTEES

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[PUBLIC MEETING]

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Nuclear Regulatory Commission

Room 1130

1717 H Street, Northwest

Washington, D.C.

Thursday, April 7, 1988

The Commission met in open session, pursuant to notice, at 2:02 p.m., the Honorable LANDO W. ZECH, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

LANDO W. ZECH, Chairman of the Commission

THOMAS M. ROBERTS, Member of the Commission

FREDERICK M. BERNTHAL, Member of the Commission

KENNETH CARR, Member of the Commission

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

S. Chilk

W. Parler

J. Taylor

R. Bernero

C. Marcus

G. Tonnesen

O. Linton

F. Khan

R. Gross

V. Collins

M. Griem

D. Woodbury

P. Almond

AUDIENCE SPEAKERS:

N. McElroy

D. Cunningham

CHAIRMAN ZECH: Good afternoon, ladies and gentlemen. Commissioner Rogers will not be with us this afternoon. He is on foreign travel. Commissioner Bernthal will be joining us

shortly.

Before we proceed with the meeting today, I would like to point out that this is a historic occasion for more than one reason, first of all, our important guests with us today and they are all very welcome, but also it is an important occasion because this is very likely the last meeting that the Commission will have at "H" Street.

As most of you know, we on Monday move our headquarters office, the Commission offices, to the Rockville area in White Flint and so unless we have something scheduled tomorrow that is not scheduled now, this could well be the last meeting that the Nuclear Regulatory Commission will hold here at the "H" Street Headquarters.

The purpose of today's meeting is to discuss the rulemaking initiatives underway for quality assurance and the medical use of byproduct material. We will hear from the Nuclear Regulatory Commission Advisory Committee on the Medical Uses of Isotopes and representatives of the industry's scientific communities.

This is an information briefing this afternoon and the Commission is not expected to vote today on these issues. Many of you know that the Nuclear Regulatory Commission is proposing to amend its regulations concerning the medical use of byproduct material.

The proposed amendments would require medical

licensees to implement certain quality assurance steps. The intent is to reduce the chance of misadministrations and the Commission is also considering a more comprehensive program for quality assurance in medical use of radioactive material and a standard of care.

The Commission has great respect for the medical profession and does not want to interfere with the practice of medicine. We are also keenly aware of the value of the use of isotopes in both diagnosis and treatment.

However, the Commission has an important responsibility for public health and safety in the medical use of isotopes and we take this matter seriously and although we recognize that there are only a relatively small number of misadministrations, we believe that a quality assurance program would provide for improved patient safety by reducing the potential for and severity of misadministrations.

I would like to welcome the members of the Nuclear Regulatory Commission Advisory Committee and the representatives from the industry's scientific communities to the Nuclear Regulatory Commission. I appreciate your time and I want to thank you for being here especially on such short notice.

Before we begin today, do any of my fellow Commissioners have any opening comments they would like to make?

[No response.]

CHAIRMAN ZECH: If not, then Mr. Taylor, I would ask you to proceed, please.

MR. TAYLOR: Thank you, Mr. Chairman. You recall on the 22nd of March the staff briefed you on the proposed QA rule and as part of that briefing listed several alternatives on an approach to that rule but also recommended that the folks who are here today representing the medical community have an opportunity to present their views to the Commission.

So with that prelude, I will ask Mr. Bernero to introduce those who are currently here at the table and then I believe there will be a follow-up group, right?

MR. BERNERO: Yes. Thank you, Jim. Mr. Chairman and Commissioners, the people at the table now starting at Jim Taylor's left, first of all we have two physicians from community hospitals, Dr. Carol Marcus from the Los Angeles County Harbor-UCLA Medical Center and Dr. Glenn Tonnesen from Fairfax Hospital. I think you have met Dr. Tonnesen before when you visited Fairfax.

CHAIRMAN ZECH: Yes, I have.

MR. BERNERO: They use byproduct material for patient care and they will be able to speak authoritatively on these regulatory initiatives in quality assurance. Next to them are people representing organizations involved in medical care. Next to Dr. Tonnesen there is Otha Linton, the Executive

Director of the American College of Radiology and Dr. Faiz Khan of the American Association of Physicists in Medicine. These individuals should be able to speak on the voluntary quality assurance initiatives in the field, in the practice, and provide some useful comments on our rulemaking.

Lastly, over here in the federal enclave between Jim Taylor and me is Captain Richard Gross of the Food and Drug Administration, Center for Devices and Radiologic Health and he should be able to describe our sister agencies' practices that will be useful for this purpose. So if I could turn the floor over now to Dr. Marcus to start it off.

CHAIRMAN ZECH: Welcome again, Dr. Marcus, and you may proceed.

DR. MARCUS: Thank you, Mr. Chairman and Mr. Bernero. My name is Carol Marcus and I am the physician in charge of the nuclear medicine out patient clinic at Harbor-UCLA Medical Center in Los Angeles.

I discussed these proposed regulations at the January 26th meeting with the assistants to the Commissioners and it is a great pleasure for me to be here this afternoon to talk to you gentlemen directly.

Today I represent both the Society of Nuclear Medicine and the American College of Nuclear Physicians and that represents 12,000 people. At the January meeting I extensively discussed my attempts to implement the proposed

regulation as it appeared in the Federal Register of October 2nd and described in detail my extensive problems with the various prescriptive aspects of that regulation.

Those comments are on the record and I understand you gentlemen have read them and so I am not going to talk about that unless you want to ask me some questions.

Today instead I want to discuss briefly five and a half months of experience with a key element in the proposed regulations that did work that I didn't tell anybody about last time that I found to be so helpful in my practice that I am going to keep it in even if it ends up not being part of a quality assurance plan and I would just share with you the experience.

Then I am going to talk about an approach to the development of a nuclear medicine quality assurance program which would serve as a basis for our support of performance standards rather than prescriptive regulations.

For the past five and a half months, all administrations of sodium iodide in any form, I-123 or I-131, for therapy or diagnosis have been preceded by a prescription. Up until the time of the Federal Register article we only wrote prescriptions for therapy doses.

I had the feeling initially that this would cause some problems with holding up studies but, in fact, that did not happen at all. The endocrinologist knowing that I would be

reviewing all their cases before even a diagnostic dose was administered tend to give me better and more complete information and I think we actually improved slightly the general level of medical care.

It certainly went generally smoother and although some of them were miffed that they didn't have the power to just order a test, they got used to it. I told them it was probably going to be the law. They are just going to have to accept it and they did.

I am going to retain that. I think the lesson though is that prior evaluation of patients for I-131 therapy certainly is really a very helpful thing and as you have pointed out in the discussions of misadministrations that interposing the nuclear medicine physician between the patient and the dose might have stopped some misadministrations, I think probably there is some truth to that and I think that it is not unreasonable to expect the nuclear medicine physician to review cases ahead of time and that such a suggestion should be in the performance regulation.

After some six months now totally of considering these proposed regulations and the circumstances that led to them, I and the Society and the College am firmly convinced that performance standards rather than prescriptive regulations is the best approach to the misadministration issue.

Performance standards can be made practical and

appropriate to any nuclear medicine practice environment and many of them are really very different and this is so because each nuclear medicine physician really has the burden of defensible responsibility to do that. He knows his practice and he knows what he has to accomplish in the way of quality assurance.

If acceptable performance standards are not conceived by him or not adhered to, the NRC always has the power to suspend the institution's license or institute fines. At the present time, appropriate performance standards are required by the Joint Commission on the Accreditation of Health Organizations and their clout is hospital accreditation and reimbursement.

Performance standards can really work. On the other hand, as I have said before, I have found the suggested prescriptive regulations to be very impractical and generally unpromising as a generic approach to the solution of the problem at hand.

The Society of Nuclear Medicine and the American College of Nuclear Physicians therefore propose that we work with NRC to construct a guidance manual for nuclear medicine performance standards.

This manual would then be used as a basis for the development of specific quality assurance programs in individual hospitals and other health organizations. This

should result in a rather uniform national standard, the philosophy of which has been endorsed by NRC and hopefully a decrease in the already very low rate of misadministrations caused by performance deficiencies subject to improvement.

For those Commissioners and members of NRC who are interested in specifics, I have assembled portions of our nuclear medicine quality assurance program for you to read at your leisure. Some of you may not be aware of some of the aspects of quality assurance that are on the horizon or that are being incorporated by some of the larger institutions and i thought you ought to at least have a chance to see what some of the specific suggestions look like.

Melissa Brown pointed out to me that the performance standards manual that I was describing is very much like what the National Institutes of Health does with experimental animals.

They give you a manual of performance standards and you have to come up with a quality assurance program at your institution that satisfies them. So I brought a copy of that not because we consider our patients to be experimental animals but just as an example of a performance standard manual to look at.

There are several computer programs that have recently become available that I think you might like to see the printouts of. One of them controls everything in nuclear

medicine, radio pharmaceutical quality control, patient identification, the dose that was given, the lot number, everything you would want.

This is being sold at a decreased price or given away by DuPont if you buy some of your radio pharmaceuticals from them. There is a similar program for radiation safety officers that has been purchased by Medi+Physics and they are doing the same thing. If you buy some of their products, they will give it to you either cheap or free.

We had a recent inspection by the State of California and when the inspector saw the radio pharmaceutical printouts, he was most impressed with it and hoped that many organizations would have it.

The nice thing about it is that with a PC and a $139.00 program called "Carbon Copy" you can access our data from your office at the NRC directly and do your inspections from Washington, in fact. There are some very interesting possibilities for keeping track of things with it. So I am going to leave this with Mr. McElroy and he will make it available to any of you who would like to see it.

Thank you for the opportunity to speak and I thank you for your attention and consideration.

CHAIRMAN ZECH: Thank you very much. We appreciate it.

MR. BERNERO: Dr. Tonnesen.

DR. TONNESEN: Mr. Chairman and gentlemen, thank you for inviting me to come. As you heard, I am at a large community hospital in this area, Fairfax Hospital. My field is mostly teletherapy which for NRC practices beams cobalt machines although I do internal implants with encapsulated sources but unlike Dr. Marcus I essentially never give free radio pharmaceuticals to patients.

I have had the pleasure of giving Chairman Zech a tour of our facility and I have assisted some of the NRC staff in the early development of these rules and I, too, was at the January briefing and I will try not to be too redundant in repeating my comments there.

I had a grave concern over one small portion of the rule where it makes it the obligation of the licensed user to be sure that the patient has been referred for a therapeutic procedure. I would like to just comment on that again.

There is already a duty of the physician to assure that the benefits of a procedure out weigh the risks and the duty of the physician to inform the patient of the nature of the procedure and the risks and benefits and alternatives and obtain the patient's consent.

The failure to perform that duty is already either a criminal battery or a civil tort depending on the circumstances and there is plenty of precedent for what happens to people who don't perform that duty.

In the introduction to your proposed rules, the NRC policy is stated that the NRC will minimize intrusion into medical judgments. That portion is definitely an area of medical practice that does not need further regulation and I would like to see you drop that.

Moving on, the NRC has had a misadministration rule in effect since, I believe, 1980 and has now a lot of data on how frequent misadministrations are. Because of the power you have over licensure, I think you have a very good idea of how many misadministrations there are. I don't think you are missing in your sampling procedure very much.

The numbers that we have heard, about 27 misadministrations and so forth are already, I believe, down at the noise level, at the human error level, where reducing them further will be extremely difficult.

This is partly because of the clout that NRC has in licensing, partly because of the inherent measurability of radiation and partly because people who use radiation are already trained to use radiation and they are not doing it part time generally and also, through the ongoing quality assurance programs that already exist through the Joint Commission on Accreditation of Hospitals which as Dr. Marcus pointed out are performance based rather than prescriptive and are generally very effective.

Unlike your problems with nuclear power, for

instance, where the consequences of a mishap are so enormous that enormous expenses are needed to prevent them, I think we are at a level now where even very great expenses are not likely to further reduce the rate of errors at least not in a prescriptive sense.

The errors that are made may be minimized by better education and by better qualifications but not by making a more, what can I say, constrictive environment in which to use the products.

CHAIRMAN ZECH: But you are not saying, Doctor, that there is no room for improvement, are you?

DR. TONNESEN: There is very little room, sir. I think 27 misadministrations or a frequency of 0.01 percent is incredible.

CHAIRMAN ZECH: You don't think we can do any better than that? You think every misadministration was one that we should expect?

DR. TONNESEN: I am afraid that if you designed a program to prevent all the misadministrations of the past two years, we would find ways to make new misadministrations in the next two years.

CHAIRMAN ZECH: But that means, too, I mean, it is saying what I think you are saying is that there is room for improvement.

DR. TONNESEN: At a cost, yes, sir, but it would be

an enormous cost compared to the benefit.

COMMISSIONER BERNTHAL: I would just make the comment for the record here that I believe it is still a fair statement that in no case in the commercial use of nuclear power in nuclear power plants have we seen injuries that are comparable to the injuries that whether or not unavoidable, whether or not down in the noise, that are comparable to the injuries that have occurred because of certain misadministration events.

Now I am not speaking to frequency or any such argument but that should be well understood. We simply have had no comparable exposures.

DR. TONNESEN: And we are all very glad of that.

COMMISSIONER BERNTHAL: I am sure we are.

DR. TONNESEN: It is just that the medical field is different. You haven't as much control. I am sure you have already been plagued with all these numbers about the real accuracy of administering pharmaceuticals, aspirin tablets, and how very frequent it is that a patient who is supposed to get insulin really gets digitalis instead.

It is very difficult to regulate in hospitals and the fact that you have a very good idea of what is going on and that it is very, very good already means that you are going to have to spend a lot of money to make it a little bit better. There are always trade-offs.

There are only so many dollars to spend on medicine

and as a matter of fact, I have some ideas for how they might be spent better.

COMMISSIONER BERNTHAL: If I may, I don't want to interrupt too many times here, but we do have a requirement here of which we are acutely aware these days because the court has again made us acutely aware of it that we may not as a matter of our rules, we may not impose regulations that go beyond adequacy without finding adequate cost benefit justification for those regulations.

That is called the Commission's Backfit rule, a name obviously designed to fit with nuclear power plants but nevertheless applicable, I think, throughout our regulatory structure.

The Commission has not argued in this particular case, I believe, that we do not have adequacy of protection in this case nor have the staff argued that. The question is, as the Chairman suggests, can we improve and then the second question that we also have to answer for ourselves and the staff has to provide us with the justification is the issue you raise, whether the cost benefit calculation and it is a difficult one here because we are talking about human error. It is very difficult to calculate but at least at some point the staff will have to provide the Commission with an indication of whether we can make that justification.

So we will consider that. We have to consider that.

We are now required as a matter of law to consider whether the benefits justify the cost. I wanted you to understand that. I think you are aware of that.

DR. TONNESEN: Thank you. Later on, particularly in the advanced notice of the comprehensive rule you bring up a valid point about the qualifications and certification of the personnel who are dealing with these productions. These involve technologists, physicists, physicians but especially technologists.

Recently, the change in funding patterns has resulted in a curtailment of the training programs for these technologists. Basically, hospitals can no longer write off their overhead for training programs and expect to get paid by the federal government.

Therefore, since they have to make ends meet, they have curtailed the training programs and they no longer are qualified technologists coming out of training programs or not nearly enough. There never have been enough in my field and now there are even more not enough.

There is a desperate need to increase the quality and especially the quantity of these trained technologists and I don't know how you can do it because those decisions are made at very high levels about medicare.

But if you can somehow spend money more on generating good qualified people to handle these products rather than

making rules on how those who are already there are going to handle the products, you will be doing all of us a much greater favor.

COMMISSIONER BERNTHAL: Maybe we ought to do both.

CHAIRMAN ZECH: There are other branches of the government involved in this matter. We don't claim to be the only one but I would point out that our responsibilities are for public health and safety as it involves the use of nuclear materials and that is what we are trying to focus on, of course.

Training, we recognize, in all aspects of nuclear technology is crucial so we certainly would support that within the bounds that we have authority to do so but I do think that even though and we all like more training, but it seems to me that there is room for improvement in almost all aspects of human endeavor.

I certainly respect the fact that the misadministrations are very low. I would like to think though that perhaps they can be improved upon and what we are trying to do here is to ask for your assistance so we come up with something that really makes sense to you as well as to us and to the American public.

I appreciate Dr. Marcus' views as regards willingness to work with the NRC in developing performance based standards and so forth and Doctor, I know from visiting you and your

facility your initiative and your professional contributions in this area so what we are trying to do is to ask for your support and your assistance to make sure that anything that we might put out would actually improve even to a very small degree but certainly within the bounds of possibility, but we don't want to put out something that is going to intrude into the field of medicine or intrude certainly on public health and safety.

We are trying to improve it even if in a very small amount but my personal observation of things that have taken place even in the short time that I have been involved on the Commission have led me to believe that there are occasionally misadministrations although very, very few in number, I will certainly admit, but there are a few that seem to me that perhaps could have been prevented and I do think that if we can even only save a life or two in all this that we are doing that it may be well worth while.

So what we are trying to do is make improvement in an area that we recognize is being very well handled but we do the same thing in our other responsibilities as far as power plants are concerned. They also have a pretty good record of safety.

On the other hand, we keep trying to make them as Commissioner Bernthal points out above the adequacy level and that is what we are talking about here today, I think. We are not trying to say it is inadequate in any sense of the word but

we are trying to say is there a way you can help us to improve in this field that you are really the experts in and we need your assistance.

DR. TONNESEN: I hate to even begin to sound argumentative and please don't take it that way, it is just when you say "to save a life or two," we all want to do that and if you even say what is the value of a human life, we are all willing to put a very large number on that but if you want to save a life or two, you can do that in a lot of ways in the medical business because nobody has enough resources.

You can buy a few more ambulances for Washington, D.C. You can buy us a helicopter. You can fund a new operating room. In my own department I can come up with lots of ways that a million dollars a year could save a life or two.

CHAIRMAN ZECH: But we are talking about administration either diagnosis or therapy usually, I suppose, where it wasn't done right.

DR. TONNESEN: But see, I have to decide how to spend the money in my department and if you impose a rule that requires me to spend the money to satisfy that rule, it means I can't spend the money on something else and I am saying that the bang for the buck can satisfy a more stringent rule.

CHAIRMAN ZECH: We are only asking you, Doctor, as far as I can understand, we are only asking you in this narrow field that I am describing to you where misadministration did

take place, is there something that could have been done or should have been done that would have prevented it.

I recognize you can spend money for ambulances and all kinds of other things but in that particular instance, is there something that could have been done or should have been done that would have within our authority or your authority or your professional judgment, is there something that could have been done that would have prevented that from happening. That is all we are talking about, that very narrow field.

DR. TONNESEN: In fact, my hospital has never had a misadministration in my therapy department so no matter how much money I spent I couldn't have improved my track record any.

CHAIRMAN ZECH: But not everyone can say that.

DR. TONNESEN: That is true.

CHAIRMAN ZECH: We are talking about those who have had problems.

DR. TONNESEN: But if you pass the rule, I have to spend the money anyway.

CHAIRMAN ZECH: Well, not necessarily. If we pass the right kind of rule and you have a record of that kind of performance, if we write the performance standards like we are trying to talk about that Dr. Marcus has emphasized that we should do rather than be more prescriptive and we certainly would want to do that.

DR. TONNESEN: Exactly.

CHAIRMAN ZECH: But we need your help to do that. I would hope that then perhaps we would be helping or assisting perhaps those hospitals, those doctors, those physicians who have indeed had some kind of a problem and I think it is commendable that you have not and I hope that the good Lord will continue to give you that kind of a record.

DR. TONNESEN: Thank you.

CHAIRMAN ZECH: And I know you do, too, but perhaps there are others that have not been as fortunate and some of these things happen, I honestly believe, through certainly no malicious intent, it is just through perhaps a lack of training, perhaps a lack of understanding, perhaps some kind of carelessness that might have been preventable.

DR. TONNESEN: Now we are saying the same thing, that when performance is good, performance based standards will allow you to say, "Fine, we are doing a great job with the status quo." The problem is that the standards before us are not performance based, they are prescriptive.

CHAIRMAN ZECH: Well, we have interrupted you enough, Doctor, please proceed.

DR. TONNESEN: I am sorry, I have interrupted you, too, sir. Basically, I think I have said enough and I thank you for the opportunity to be here and I would be delighted to answer any questions if I may.

CHAIRMAN ZECH: Thank you.

COMMISSIONER BERNTHAL: I would just make the comment that as far as I know it is not a done deal yet, the kind of prescriptive rulemaking that staff has proposed.

COMMISSIONER CARR: That is why we are here.

COMMISSIONER BERNTHAL: Yes, I think somewhat at the behest of the Commission, I am not going to say that staff did all of this, the Commission observing the record and I have been here now longer than anyone except Commissioner Roberts who is two chairs over observing the record.

COMMISSIONER ROBERTS: You don't have to emphasize that, do you?

[Laughter.]

COMMISSIONER BERNTHAL: Where was I?

COMMISSIONER ROBERTS: I don't know.

COMMISSIONER BERNTHAL: Observing the record, we felt that something could be done and I think staff responded to that sensitive need. I do want to get back to the point though of cost benefit because you keep coming back at least implicitly to that point and I am looking at the staff briefing which they gave the Commission before we hear from you today where the staff indicated that the incremental cost per misadministration averted was $20,000.00.

That is Lord knows a difficult estimate to make and I am sure the error bars on that, the uncertainty bars rather are

substantial but it would not be difficult then to translate that $20,000.00 cost per misadministration averted into cost per man rem or thousand man rem, person rem, excuse me, averted which is a standard that unfortunately we do apply in this agency.

We do attach a certain value to human life if you will and to health effects. We have to do that. We have to have some standard. I guess I would ask staff at some point and maybe not right now in the midst of your presentation to remind us and respond again on the cost benefit question because it is a key point that you raise.

Would it really be better to spend the money in training? Is this simply not cost beneficial enough even within our regulatory authority? We don't have that much authority over the training that you are talking about but is this $20,000.00 incremental cost per misadministration averted, does that simply not justify the person rems avoided.

DR. TONNESEN: At the risk of wearing out my welcome, I am going to doubt that number.

COMMISSIONER BERNTHAL: All right.

DR. TONNESEN: If there are 27 misadministrations and $20,000.00 per, that is only a half a million dollars. I have no idea how many licensed users you have but if there are only 5,000 of them, you are only talking about a $100.00 per user. It would cost a lot more than that to satisfy this rule, a lot

more.

COMMISSIONER CARR: Is your data bank the same as mine?

DR. TONNESEN: I don't know.

COMMISSIONER CARR: Are you using our data bank?

DR. TONNESEN: No, sir, I don't know.

COMMISSIONER CARR: My brief sheet says that we have more than 50 misadministrations from 1984 to 1987 but even more worrisome is we don't even get all the reports before 1980 from 1976 to 1980, there was one misadministration that involved 400 patients. So I am not sure we are dealing with a good data bank that gives me a warm feeling that we know first how many are occurring and if we call one misadministration and it affects 400 patients, we may have a whole lot of people rather than just 27 people.

DR. TONNESEN: I am afraid I do not have your data bank, sir.

COMMISSIONER CARR: I am not sure it is worth having.

[Laughter.]

DR. TONNESEN: The number we have been throwing around at the January briefing was 27 misadministrations over I don't know what period, perhaps one of the staff could help me, but that was the number we were using to come up with the 0.01 percent misadministration rate.

MR. TAYLOR: I think we ought to share our data with

him.

COMMISSIONER CARR: It seems like we should, yes.

MR. TAYLOR: It is a first start anyhow.

COMMISSIONER BERNTHAL: Do you have some level, if I may turn to the staff for a moment, do you have some level of confidence in this $20,000.00 number and Jim, how did that translate into cost per thousand person rem or whatever.

MR. TAYLOR: I think a gentleman is here who has worked on it.

MR. BERNERO: Yes, Norm is here.

CHAIRMAN ZECH: Would you identify yourself for the reporter, please?

MR. McELROY: I am Norman McElroy from the Medical and Academic Section.

CHAIRMAN ZECH: Thank you.

MR. McELROY: Various individuals on the staff have a various degree of confidence in that calculation. I would have added another zero on the tail end and come up with about $200,000.00 per event averted.

I would also note that we typically do calculations with a healthy population when we look at cost per life saved and that is not the population that you are dealing with in a hospital. So the calculations very quickly become laden with very important societal considerations from policy considerations that I think are a little bit different than the

environment that you folks are used to working in.

COMMISSIONER BERNTHAL: Lest I be accused of being a physicist or something, I don't want to make too much a numerical exercise out of this but let's say it is $200,000.00 per misadministration, what is the average dose per misadministration? Does anybody know?

MR. McELROY: I hesitate to respond to that because is not typically a whole body dose which again is, I think, the kind of calculation you are used to working with in power plants. It is typically a very large dose to a very small portion of the body and the science is a little bit more difficult to use to predict the effect on the patient.

COMMISSIONER BERNTHAL: Maybe somebody can think about a reasonable guesstimate just to see if we are in the ballpark here but maybe we should go on.

CHAIRMAN ZECH: All right. Let's proceed. Did you finish, Doctor?

DR. TONNESEN: Yes.

MR. BERNERO: Otha Linton, would you make your remarks now?

MR. LINTON: Thank you, sir. Mr. Chairman, gentlemen, ladies and gentlemen, I feel like I am coming in the middle of this discussion but perhaps I will carry on. I am the Associate Executive Director of the American College of Radiology and about 8,500 of our 20,000 members are licensed

either by you or by a state to use byproduct material.

I also represent the American Society of Therapeutic Radiologists and Oncologists most of whose 3,000 members also belong to the College so I have Dr. Tonnesen twice, for example.

As a generalization the ACR has complimented the NRC and the Atomic Energy Commission on enlightened regulatory approaches over the years which have emphasized safety and have avoided intrusions into medical judgment and practice.

On the whole, your regulations have been practical and cost effective. In the opinion of our expert committees, the ones before us now don't meet your standards. Thus, our comments are not supportive of further regulations as a basis for improving safety and quality.

ACR, for example, has a long history of its own quality assurance programs applicable to the use of isotopes and those, too, have had a significant impact on the quality of practice that we now enjoy.

Those approaches include, of course, education, standard setting and credentialing those who can regulate, those who have to educate. So we are all coming from our points of view.

We have three points, sir, and essentially we are agreeing with what has been said here. The quality is amazingly good and certainly the Commission and its activities

deserve a very large share of the credit for achieving and maintaining that quality.

We fear in the sense of prescriptive regulations that we have passed de minimis and are approaching reductio ad absurdum and the best and tightest regulations won't keep somebody from making a mistake and hurting somebody. Maybe it will decrease this already small number but perfection is beyond all of us.

CHAIRMAN ZECH: If I may interrupt very briefly, we know the risk is not zero.

MR. LINTON: Right.

CHAIRMAN ZECH: We appreciate that. We are not asking for zero risk. We are just asking in your professional opinions, is there any way we can improve and if so, we want to listen to those.

MR. LINTON: I will come to that, sir.

CHAIRMAN ZECH: Thank you very much.

MR. LINTON: The second problem that we have had with this is the misadministration rule itself and I think the discussions that have just preceded us almost reflect that kind of problem.

As it was written several years ago, your answers are drafted by the institution's lawyers whose purpose is to avoid obligations and not as was the case prior to that to share with you the observations of physicians and physicists about what

went wrong and how can we keep it from happening anywhere else again.

The other thing, of course, is that the definition of a misadministration is such that while one misadministration harmed 400 people, many of those reported harmed no one. You ask about the average amount of misadministration. It could be a fraction of a rad in a diagnostic misadministration. It could be as little as 100 rads in a therapeutic administration because of the way the rule was not very well couched.

So we have urged you on many occasions and let me do it again in the context of this to define misadministration so that whatever efforts you devote to them are really getting at the actual problems and not making more work for the attorneys of the world.

If you were an attorney, I would not want to do you out of work otherwise, but here would be fine.

[Laughter.]

COMMISSIONER BERNTHAL: That's all right. You are welcome to advocate that.

MR. LINTON: My daughter the law student tells me to quit doing that.

CHAIRMAN ZECH: Well, let me defend our attorneys just very briefly.

[Laughter.]

CHAIRMAN ZECH: Because we make up the rules, we are

the policy makers are at the Commission level, and we rely on the attorneys to assist us. On the other hand, when we make the rule, they have to interpret them and apply them, too. So we at the Commission, I think, accept the responsibility. We try to make the best tactical decisions we have relying on our technical staff who I think are superb. We also rely on our legal people who I also think are superb. We are well served.

But if the mistakes are made, it is made by the Commission. It is our judgment and we accept that responsibility but we do think that we have some pretty fine legal people as well as some pretty fine technical people and I just want to make that point that this Commission is well served by our staff, legal and technical.

MR. LINTON: We have admired all of those levels over the years, sir, and think the problem is a difficult one. Actually, I was attacking the other lawyers who are trying to fight you back but still they may all be kin to one another for all I know.

CHAIRMAN ZECH: There are all kinds of lawyers all right, but we have some awful good ones is my point here and they do serve us well.

MR. LINTON: Let me try to recover from all of that then.

[Laughter.]

MR. LINTON: The third of our points before we get to

the good side of all of this is that you are a very vital part of a web of public and professional responsibility which goes into the creation and support of the standards that Dr. Tonnesen referred to and you will hear from Captain Gross and we might mention the Joint Commission on Accreditation of Health Care Organizations, the American Board of Radiology, the American Registry of Radiologic Technologists, the College, the Association of Physicists in Medicine and on and on.

The patterns of care study which the American College of Radiology has carried out for the National Cancer Institute has done more to define the state-of-the-art practice in cancer treatment than any other single activity and Dr. Tonnesen's organization participates in that, for example.

What it is to say is that there are a lot of people working toward the same aim and that certainly your responsibility is a very real and direct one but it is by no means the only thing going for what we are at. We, too, are concerned about costs.

We are particularly concerned right now in that the Medicare program will very shortly take about 20-cents of the hospital's dollar out of the way it ways for any radiology service including all of those in isotopic medicine, too. So that even a little more expenditure comes at a very painful moment unless there is a terribly good reason for it.

Now having rained on the parade up to now, sir, may I

offer some suggestions of where to go.

CHAIRMAN ZECH: We would appreciate that very much.

MR. LINTON: Well, the staff warned me, sir.

CHAIRMAN ZECH: Good.

[Laughter.]

CHAIRMAN ZECH: We are asking for help. We know we have problems. That is why we are all here.

COMMISSIONER CARR: If you help us, you help yourself.

MR. LINTON: Absolutely. sir.

CHAIRMAN ZECH: We are looking for assistance and we are grateful for your being here today and we are very anxious to hear your comments. Please, proceed.

MR. LINTON: I can hardly wait myself, sir.

CHAIRMAN ZECH: Good.

[Laughter.]

MR. LINTON: The first would be for the NRC to reaffirm its interest in safety and stay in that area. The intrusion into medicine is something that people bristle at.

CHAIRMAN ZECH: Don't let us do that. We don't want to do that.

MR. LINTON: All right, sir.

MR. PARLER: You can't do that.

CHAIRMAN ZECH: That's right. There is my lawyer speaking up, see.

[Laughter.]

MR. LINTON: He is one of the good ones.

CHAIRMAN ZECH: He is one of the good ones, that is right.

[Laughter.]

MR. LINTON: The second is as our committee talked over this thing and we listed all of the things I have cited and you have heard here, it occurs to us that perhaps all of together haven't really put it together to see if, in fact, there is a gap somewhere that either you or the FDA or somebody else might pick up on.

We think that correlating all of this, not just is the Commission doing its job, but together volunteers, other agencies and so forth, is there, in fact, a gap and we would urge you to take the lead in a correlative effort and in that respect discussions not only with you but meetings called for your staff, the other agencies, groups like the College, I think in a fairly short time could turn that up and tell us all the constructive ways to go.

We would like to urge that on you and we would like to offer on behalf of the College and I suspect the other groups to be part of that if we can go that route. So that is our pitch, sir. Thank you.

CHAIRMAN ZECH: Thank you very much. We appreciate it.

MR. BERNERO: Dr. Khan.

DR. KHAN: Mr. Chairman, ladies and gentlemen, I am professor of medical physics at the University of Minnesota and I am representing the American Association of Physicists in Medicine.

I thank the Commission for inviting the AAPM to present their views in this meeting. A formal item by item response to the proposed rules has already been submitted. At this meeting I would like to address the general issue of quality assurance and present my views on how a regulatory agency like the NRC should approach this problem.

It is well known that the standards of radiotherapy practice are not uniform across the country and that some facilities do provide sub-standard care to their patients. Patterns of Care Study under the American College of Radiology has demonstrated that standards of care do vary and that the quality of radiotherapy practice is definitely linked to the outcome of treatments.

Facilities that are ill-equipped and ill-staffed are the ones that operate without adequate quality assurance and, therefore,pose a threat not only to their patients' health but also to their employees and the general public.

It is obvious that the NRC is trying to upgrade the standards of practice by introducing regulations that cover some selected aspects of quality assurance. The idea is a

nobel one but the problem is that by identifying a few quality assurance procedures based on some isolated accidents is not, in my judgment, going to eliminate the possibility of more accidents or, more importantly, improve the standards of community practice.

On the other hand, it may encourage users to follow a few regulations simply to satisfy the NRC but still not improve their standards of practice. For example, there is no law that prohibits facilities to operate with inadequate equipment.

A cobalt unit that has poor beam geometry and poor depth dose can compromise the treatment of a cancer patient who needs better beam characteristics, accurate beam delivery, higher photon energy or electron beam.

A facility that treats all different types of cancer patients with an obsolete cobalt unit is symptomatic of a real lack of desire to upgrade its standards of practice and therefore is more likely to cut corners in quality assurance.

I strongly feel that the NRC instead of making rules based on isolated incidents should make it mandatory for the licensees to follow: (a) the staffing and equipment guidelines as recommended by an organization called ISCRO, and I would not like to spell it out because it is very difficult, but anyway, (b), the quality assurance guidelines published by the AAPM, my own organization. Actually, that document exists. Now it needs to be updated and I think we would like to work with the

NRC to update it and include some of the good points which were proposed in the rulemaking.

NRC inspectors could review institutions quality assurance procedures, for example, procedures and their frequency, log books, staffing, et cetera, in the light of the above reports. My point is that instead of legislating in response to accidents when or if they happen, the approach should be to have the QA programs in place in writing and the NRC review them and oversee implementation as well as minimize the type of accidents that the NRC is concerned about.

Another point I would like to make is that the NRC should not interfere in the conduct of therapeutic procedures, medical prescription or other decisions related to patient care and that is obvious that this meeting nobody disagrees with.

However, the NRC has every right to demand that the byproduct material is used safely and that proper quality assurance procedures are in place. The required quality assurance procedures for the radiotherapy equipment are available in the current AAPM document as I mentioned and the NRC can adopt this or an updated model of it.

These recommendations are based on well researched opinions of a task group on quality assurance of the AAPM and not a collection of rules and regulations which often hinder rather than facilitate optimal health care delivery.

Now I would like to summarize all of this by three

points that I have. First, the NRC should adopt a model quality assurance program in cooperation or in collaboration with the AAPM and the American College of Radiology and the licensees should be required to have this program in place and NRC inspectors should verify that it is being implemented.

Second point, the NRC should demand proper staffing to implement the program. Staffing means that the staff that takes care of the quality assurance is well trained, is, for example, board certification is one requirement that could be considered and they should have qualified physicians, qualified physicists and qualified technicians to do the quality assurance. The Blue Book by the ISCRO, it is called Blue Book because the color is blue, has staffing recommendations and that should also be considered when making recommendations on this issue.

Three, the NRC should leave the details of medical practice to the professionals involved. Organizations such as the Joint Commission on Hospital Accreditation can attend to more of these details than the NRC inspectors can. So these are my three points.

CHAIRMAN ZECH: Thank you very much. We appreciate it. Thank you.

MR. BERNERO: I would like to call on Captain Gross now, please.

CHAIRMAN ZECH: All right, thank you. You may

proceed.

MR. GROSS: Thank you, Mr. Chairman and Commissioners. I appreciate the opportunity to come here today and describe a medical quality assurance program that the Center for Devices and Radiologic Health has had in place for some time.

I am speaking today from the perspective of an organization with nearly 30 years of experience in the development and implementation of voluntary educational programs in cooperation with the states, manufacturers and medical professionals. Our more recent regulatory activities are directed primarily at manufacturers.

I would like to mention a few of the more recent examples of the impact of these efforts beginning with our efforts to encourage quality assurance programs in diagnostic radiology facilities.

While I will restrict my comments here to fit within the time allotted, I would encourage the NRC to conduct a separate meeting to discuss specifics in more detail. When our program was initiated, quality assurance programs were essentially unknown in medical facilities and measures of quality were basically left to the eye of the beholder.

The first step in changing this was to identify specific problems resulting in unproductive radiation exposure. Quality assurance solutions were then developed to correct

these specific problems.

Demonstration projects were conducted in medical facilities which showed the effectiveness of the solution strategies and helpful written manuals were published by the agency.

A comprehensive formal recommendation describing the organization of a quality assurance program was published in the Federal Register in 1979. Although the ten elements of the recommendation were discussed in relationship to a diagnostic radiology facility, the principles they outlined would be applicable in any medical area.

These recommendations and manuals continue to serve as a guide to individual facilities and the industry in the development of quality assurance programs. Our efforts to encourage the spread of good QA programs have been reinforced by cooperative projects with respective medical professions and appropriate segments of industry and the state radiation control programs.

The initial focus of these programs were the hospitals because of their high patient workload. Today nearly all hospitals and many non-hospital medical facilities have implemented quality assurance programs for diagnostic radiology. This does not mean that all of the technical problems that result in unproductive patient exposure are solved but the basis for their solutions are in place.

The situation with mammographic examinations provides a recent example of the process and the involvement of industry, the medical professionals and state radiation control program personnel. When NCI began its program to encourage the expansion of mammography capacity in the United States, FDA was concerned about the rather high exposures in that examination. Working with the radiology community we were able to determine what parameters were essential to proper mammography, good images with reasonable exposures.

In time, manufacturers were able to improve the equipment available for mammography and the essential exposure levels were reduced. The states were also provided with a program that was effective in identifying the problem areas and were able to demonstrate to the medical personnel how they could improve quality and reduce unnecessary exposure.

Recent studies in cooperation with the Conference of Radiation Control Program Directors have demonstrated that these voluntary programs have reduced mammography exposures about 50 percent over the last ten years. Recent cooperative efforts of FDA, the radiology community and the states have concentrated on further improvements in image quality.

In 1984, the FDA published separate quality assurance recommendations for nuclear medicine. While we have less information about the extent of their implementation, there has been strong professional organizational support for voluntary

quality assurance programs in nuclear medicine.

Even more recently and in a fairly short period of time, we have had similar impact in other areas of medicine, specifically, in anesthesiology and hemodialysis. In the case of anesthesia with no regulatory action a cooperative project with the anesthesia community has successfully reduced user errors that result in misadventures. This has resulted in the reduction of medical liability claims and this has in turn been reflected in reduced premiums.

This past Sunday the minister in our church made the observation that if the only tool we have is a hammer, then all our problems look like nails. Based on our experience, we would encourage the NRC to look for different tools especially educational tools that may be more appropriate for this particular set of problems than is the regulatory hammer.

Like regulatory solutions, educational solutions must be maintained. With educational solutions, however, much of the maintenance is provided by the professions involved. For example, FDA started workshops to encourage good QA programs in nuclear medicine. In a short time those workshops were taken over by the professional groups. The result, of course, is a reduced overall cost to the government.

The involvement of the professions in the problem definition and the solution strategy also tends to insure that the issues are clearly and fairly defined. The resulting

solutions are reasonable for medical facilities that are the target audience for these programs.

Doctors don't want to practice bad medicine and once problems are pointed out in a way that makes sense to them, our experience indicates that they will work hard to correct those problems. That is my five minutes. Thank you, sir.

CHAIRMAN ZECH: Thank you very much. We appreciate it. Does that complete the presentation?

MR. BERNERO: Yes. I would like to thank our guests here at the table and ask if we can change places here.

MR. PARLER: Mr. Chairman, while the folks are changing places, may I make a brief comment for clarify of the record?

CHAIRMAN ZECH: Certainly.

MR. PARLER: Some of the earlier discussion may have left the reader of the transcript with the impression that the Commission's Backfit rule applies legally in this area. Of course, the Commission's Backfit rule only applies to 10 CFR Part 50, nuclear reactors production and utilization facilities. However, generally speaking across-the-board in any of this agency's regulatory rulemaking endeavors, we do look at the thing from the standpoint of the cost effectiveness of the rule.

CHAIRMAN ZECH: Thank you very much. I appreciate that.

MR. BERNERO: Gentlemen, if you could join us, please.

CHAIRMAN ZECH: All right. Mr. Bernero, will you introduce our other guests, please?

MR. BERNERO: Yes. The gentlemen who have joined you now are all members of the formal committee, the Advisory Committee on the Medical Uses of Isotopes, and starting on the immediate left of Jim Taylor here we have Dr. Vincent Collins who is a radiation oncologist in private practice in Houston, Texas.

The next gentlemen is Dr. Melvin Griem, also a radiation oncologist at the University of Chicago. Next down the line is Dr. David Woodbury, a practitioner in nuclear medicine at the Westland Medical Center in Westland, Michigan and on the far end of the table is Dr. Peter Almond, a medical physicist at the University of Louisville.

As I said, these are all members of the Advisory Committee on the Medical Uses of Isotopes. They participated in the January meeting and they are available to discuss their comments with you. Perhaps I can turn to Dr. Collins first.

DR. COLLINS: My background is as a faculty member at Columbia University and then chairman at Baylor but for 15 years I have been in practice in a 200-bed hospital so I speak for the minor facility.

Now whether dealing with a breathing session or a

quality assurance program or that familiar classic course of mules, it is necessary to catch attention to start with. We have here a rule and there can be objection whatsoever to any of these. We can all be in favor of it, in favor of safety and quality assurance. The question is, is there any excuse whatsoever for a limitation to be placed upon this.

All of you here travel from home to get to the place today. You are fully aware that across the country there will be thousands of accidents and dozens of deaths on the public highway. We are not in favor of this. We are in favor of prevention. How many of you travel in a car equipped with a roll cage?

[No response.]

DR. COLLINS: Nobody?

CHAIRMAN ZECH: What kind of a cage?

DR. COLLINS: A roll cage. There may be some reason to restrict safety as far as driving a car is concerned, perhaps we are all not required to do that.

However, we come to our smaller institutions. These probably should be studied not so much for the purpose of policing as for assisting. Consider, for instance, Mrs. Billie Jo Brown, the double name is rather common throughout the South, and he is a truck driver is some remote place, say, 200 miles from Houston and mom has Hodgkin's disease, she has a carcinoma of the cervix, we are going to require treatment. It

is 200 miles to Houston, she won't be hospitalized for this, board, room, who is going to look after the kids, dad has to drive that truck to pay the bill, maybe we really ought to have a local facility for treating such things.

Now how do we do this? Well, for quite a few years my Department did operate a network, a treatment planning network, across the South from New Mexico through Texas to Louisiana where institutions, not institutions, but set-ups in small towns usually with a cobalt unit were performing the function of saving Mrs. Billie Jo from having to travel 200 miles, an impossible economic handicap.

Well, by telephone, by telecopier, by transportation the patient for consultation, by visits from our physicists, we did manage to operate these things.

Each of us have an opinion. We speak in light of our education, background or bias and we listen in a similar fashion. I am speaking from experience in this kind of thing and I don't think I share that with members of the Commission.

Now in these organizations out there we must consider what is the need for cancer care in a small community. Is that necessary? Well, my experience is one thing, yours may be another, the others in the audience may be still different. What is the need of such a small cancer clinic? What does it need to operate?

Certainly an appropriate quality assurance program

for each would be desirable and what they really need is a program of assistance to achieve an appropriate level of excellence and I might have started it by saying that everything I have to say has already been said. I am not saying something different. I am saying it differently perhaps.

Such programs should be encouraged and developed with a performance based quality assurance rule more appropriately and effectively than prescription based rule. We had the representatives here of the College of Radiology, the American Association of Physicists in Medicine, the American College of Medical Physics, the Health Physics Society, the Joint Commission on Accreditation of Hospitals, the Association of Community Cancer Centers, all are concerned with this. All have something to contribute. It is possible we could begin a collaboration.

So in line with what has been said, my suggestion is that we have talent available, we have programs in course. Have in mind that community facility out there that would really like to do better because the man who is relying upon a referral practice must have the approval of both the patient and the referring physician if he is going to survive. He wants excellence. He will assist, he will collaborate if we can provide a program for him, such things as the Blue Book, the other suggestions that have been made is what I am talking

about.

So in that case, I think that really sums up what I have to say and I can only add that my personal car does have a roll cage in it and if there is anyone here who feels that quality assurance should be subject to no limitation whatsoever and that they, therefore, would like to have a roll cage, I would be pleased and happy to provide a prescription for such a roll cage after this meeting is over.

[Laughter.]

CHAIRMAN ZECH: Thank you, Doctor.

COMMISSIONER CARR: Do you have an air bag, too?

[Laughter.]

DR. COLLINS: I don't need one with a roll cage!

CHAIRMAN ZECH: Dr. Griem, please proceed.

MR. BERNERO: Dr. Griem.

DR. GRIEM: I wish to thank you for inviting me to come. Let me introduce myself. I am Professor of Radiation oncology at the University of Chicago and I started my career at the Atomic Energy Commission Hospital there, the old Atomic Hospital, in 1954 and you people bent a twig in the direction of working in this field. Then I received a research career development award from the NIH and I have served on the Radiation Study Section for over eight years.

I have written a number of articles and I co-authored a text in this general area about two years ago in which we

invited about 30 people, Dr. Paliwal and I, to participate in a week long session on treatment planning.

Now none of the authors nor the editors receive any money from this and this is really although it is $20.00, the Radiological Society of North America subsidizes this as an educational effort. We sold over 2,000 copies of this.

In this book there are two chapters dealing with quality assurance, one from the physicist's point of view and one from the physician's point of view. There is also a chapter very relevant to brachytherapy written by Jim McGee from Decatur, Illinois, down where they grow corn and beans and he used brachytherapy in management of breast cancer and women from all over the southern part of Illinois come to him for that treatment.

He uses the Paris System, a manual system, of evaluating the dose and how this is to be done and he has an excellent outcome.

There is another chapter in here dealing with gynecologic treatment in which brachytherapy is essential and here again we attempted to educate on the appropriate use of sealed sources. This type of thing is available.

The second type of thing can be found in the Blue Book and I will leave that with you and this is a group of societies that have gotten together to specify what they think is essential for good care.

Now DeVita states in the book, "the radiation oncology community, succinctly presents the standards for clinical practice and the objectives for radiation oncology during the remainder of the 1980's."

Now in addition, there are a number of studies supported by the U.S. government which have reviewed the practice of Radiation Oncology, the methods used, the locations of facilities, types of hospitals, training experience, staffing and the many factors which affect outcome and that is the outcome in curing the patient and in avoiding complications.

The Patterns of Care and Outcome Analysis studies have been considered an outstanding example of how this process can serve and improve the quality of care in the United States. Now in fact, the say after the January 26 meeting of our advisory committee, I served as the chairman on a panel which approved a contract for continued support of the Patterns of Care and Outcome Analysis which deals with the broad scope of quality assurance as it impacts on cancer treatment in the United States.

Now they singled out three cancers, colon, prostate and breast; two of those use brachytherapy. The other thing they considered was fractionation and the last was quality assurance and how by improving quality assurance programs could they improve the quality of care.

Now it would seem to me that the U.S. Nuclear Regulatory Commission could more effectively improve the quality of radiation oncology in the United States and that is the use of teletherapy and brachytherapy by joining some of the excellent programs that are now in place.

In particular, I certainly would think that you might be wise to join together with a broad based government sponsored program on the Patterns of Care Study and its continued implementation which has a proven track record and then support this inter-society "Blue Book" which is referred to regularly by various administrations and it would be nice to have the Nuclear Regulatory Commission's name across the bottom.

CHAIRMAN ZECH: Thank you very much, Dr. Griem, we appreciate it.

MR. BERNERO: Dr. Woodbury.

DR. WOODBURY: Thank you, Mr. Chairman. I am David Woodbury, I am assistant professor of internal medicine at the University of Michigan, chairman of the department of nuclear medicine at the Westland medical Center, former employee of the Atomic Energy Commission at Oak Ridge, Tennessee.

I have been privileged to serve on the advisory committee for the NRC and when called to give comment relative to our January meeting, I was very pleased to do so until I was told that I only had five minutes.

So in order to try to get across the points I wanted to, I have taken the liberty of trying to outline what I have to say perhaps in a very cryptic and not very expansive form but certainly would be willing to answer any questions that you may have.

In a very simplistic mode, I have tried to outline three areas I would like to attend to, just a few seconds as I perceive the Commission's concerns, a minute or so on what I perceive as the concerns in nuclear medicine and I would like to spend most time on alternate proposals on how the NRC might be more effective in helping us determine quality assurance.

Ever since the Three Mile Island accident and Chernobyl the public has been increasingly concerned about radiation exposure and I am sure that this has heightened the concerns in the political arena and has raised concern about the Commissioners.

During this period of time, in fact, in 1979 and 1980 we had taken a look at quality assurance and misadministration and we thought that the incidence was sufficiently low that we need not deal with it no more but since that time, it has come up again.

In a four year survey, on the order of 27 misadministrations were found. So the commissioners concern is can we do better. One of the three things the commissioners thought were outlined in the misadministration reported,

problems might be inadequacy of training, lack of attention to detail and lack of redundancy.

I would like to digress 15 seconds to say something about the inadequacy of training because this is one area in which the NRC gives the medical community double information. For instance, during the same time the NRC is requiring greater detail in quality assurance, during the same period of time that there was some concern about decreasing the length of training for licensees. It gives a double message.

As a result of the problems of misadministration, the NRC has proposed ten separate new regulations to correct the problems. The nuclear medicine concerns relative to these proposed regulations, the nuclear medicine community in general approves of and has taken part in quality assurance. We have adopted the ALARA concept by subjecting patients, personnel and ourselves to as little radiation as is humanly possible.

We have attempted to abide by all the quality assurance guidelines by the Joint Commission as also by the state public health guidelines and we meet quarterly with our radiation safety committee who can review our activities on a quarterly basis to assure that we are in compliance.

The proposed regulation of 35-39B comes as close to the NRC intrusion into the actual practice of medical care as it ever has since changing from the AEC. This is a real concern to the medical community.

The community questions the rules as proposed as having any real effect on decreasing human error. The question is can we really legislate human error. There is a feeling that the rules were promulgated with limited impact on those specialists and organizations who are daily involved in the practice of nuclear medicine.

The cost effectiveness of the rules clearly have not been evaluated. One estimate is that it would cost the hospitals approximately five million dollars per year to decrease misadministrations and if that were half the record, the figures that we had is that it would cost $360,000.00 per misadministration, or $260,000.00 or $250,000.00, in that ballpark.

The feeling is that if the rules are placed in fact in force they may cause conflict with cost reduction regulations promulgated by HCFA and HHS by increasing, probably increasing the length of hospital stay.

As far as we now know, no studies to date have demonstrated deleterious clinical effects of radionuclide doses used for diagnostic purposes in animal studies or human studies. The lethal potential seems minuscule.

Lastly, resources that could be used for training or acquisition of better equipment and material might have to be used to keep up with the proposed rules.

How can we help NRC help us improve quality

assurance? If rules have to be made, any rule should be performance based rather than prescription based so as to best encompass the variety of practices that we have in nuclear medicine.

For instance, I doubt that the complexity of trying to review every chart, examine every patient sent for diagnosis was thought out. Ten years ago, 70 percent of nuclear medicine diagnostic procedures were done on in-house patients. That has reversed in the last three to four years and now 60 percent, in some practices, 60 percent of our procedures are done on an out-patient basis.

It would be very difficult to get all the charts from all these patients sent in from referring physicians and to examine each one after they have been examined by their own physician. There is a lack of practicality there.

If rules have to be made, we fully support the approach to doing pilot studies in these areas before the rule is made so that the financial, personal and administrative impact of the rules can be assessed before the study is done.

Dr. Marcus has already alluded to the problems that she had as she tried to do a pilot study on her own. Some benefit came out but there were a lot of headaches, some aspects that she just had to disband.

If this pilot study had been done before the regulations were promulgated, these effects, financial,

personal and administration, may have been forthcoming before the rule was proposed in the Register.

If rules have to be made, there should be a coordination of efforts with existing groups to have a synergistic effect on quality assurance. The American College of Nuclear Physicians has its fourth printing on its inspection manual and there are 25 pages that are dedicated to quality assurance, the back of which are about 15 pages on questions and answers so that when we inspect our nuclear medicine institutions, the institutions know what to look for. There is a check-off sheet plus there is a manual that tells them what we expect in quality assurance in nuclear medicine.

Lastly, I very strongly propose that the NRC and Commissioners improve communication with the nuclear medicine community and the medical community. Few physicians read the Federal Register. Many of us who get the Federal Register because the language is so obtuse will put it aside and say that we will get to it this weekend and sometimes we don't get to it.

Other organizations, the FDA and the Joint Commission have flyers on a quarterly basis that may highlight some aspect of quality assurance or some aspect of improvement in service. Other organizations have regional meetings, JCAH has regional meetings where they discuss some aspect of rules and regulation.

We propose the same type of thing might be generated through the NRC so that those practitioners who might not make the specialty meetings, who don't read the Federal Register, may have the opportunity to discuss the regulations as they impact on the practice of medicine.

We have also suggested that perhaps a national meeting could be held and this could be at little financial impact to the NRC because registration or tuition could be charged and I am sure that the hospitals would support sending their radiation safety officer to Washington or to a regional meeting where the quality assurance aspects and other aspects of delivery of medical care as it relates to radioisotopes could be discussed and the decisions could be implemented or at least explained and expanded.

These are areas that we think, the educational areas, would be very helpful so that the NRC comes across not as an adversary but as a colleague in assuring quality assurance. As we compare other organizations, other organizations say "This is what we expect" and when they inspect us at the end they sit down with us and say, "This is what we found right and this is what we found wrong and here are ways that we think you might improve. We will cite you in this area but we will give you time to correct what you are doing."

The NRC on the other hand says, "We are going to slip in unannounced, find out what you are doing wrong and they we

are going to fine you for it." So an adversarial relationship is set up that should not be. It should be an educational, a collegial experience where we are all going in the same direction for the improvement of quality assurance. Thank you, Mr. Chairman.

CHAIRMAN ZECH: Just one quick question, Doctor. I think you mentioned and if you could just tell us briefly, I think you mentioned that you thought that perhaps we were intruding into medicine.

DR. WOODBURY: Yes.

CHAIRMAN ZECH: Could you elaborate briefly on that, please? We don't want to do that, as I am sure you know.

DR. WOODBURY: The proposed rule 35-39B suggests that the user should examine every patient sent for a diagnostic procedure, should then contact every referring physician and this is a direct imposition into the practice of medicine because there are many ways that quality assurance can be promulgated without examining every patient particularly in a large institution where the patient has already been examined ten times by students, residents and interns.

CHAIRMAN ZECH: Is this the same point that Dr. Tonnesen was making?

DR. WOODBURY: Yes.

CHAIRMAN ZECH: Is he still here? Is that the same point, Doctor?

DR. TONNESEN: Yes, it is the same part of the regulation.

CHAIRMAN ZECH: Thank you. Thank you very much, Doctor.

COMMISSIONER BERNTHAL: I just want to make a comment. I am devastated to learn that along side the Gideon Bible there is not on every night stand a copy of the Federal Register.

[Laughter.]

COMMISSIONER BERNTHAL: You have made a very good point and it certainly fits in with my own long standing belief that we need to do a better job here in communications and that is a very useful suggestion you have made.

Exactly how that sort of in plain language communique could be distributed and should be distributed, I am not sure but perhaps our government and public affairs office could take a hard look at that suggestion. It is a good one and you have raised some other good points but I think maybe we should go on. Thank you very much.

CHAIRMAN ZECH: All right. Thank you very much. Please proceed.

MR. BERNERO: Dr. Almond.

DR. ALMOND: Mr. Chairman and Commissioners, thank you for this opportunity to speak to you. Mr. Chairman, you will appreciate that I believe that peoples whose last names

begin with "A" and "Z" occupy a special place in this world.

CHAIRMAN ZECH: Very special!

[Laughter.]

DR. ALMOND: The A's generally are asked to start off and the Z's generally to bring up the rear.

CHAIRMAN ZECH: That is the way it works.

[Laughter.]

DR. ALMOND: This is therefore an unusual position for me today being the last speaker.

CHAIRMAN ZECH: We trade places today.

DR. ALMOND: Thank you. I am a medical physicist with 30 years of experience with Cobalt-60 and brachytherapy in nuclear medicine. I have served as president of the American Association of Physicists in Medicine and as chairman of the Board of Chancellors of the American College of Medical Physics and I am vice chairman of ISCRO, the Inter-Society Council that produced this book so I have some experience in working with these.

All of these groups and others as you have heard are very actively involved in quality assurance programs. I do know that you were concerned somewhat that this committee seemed to be somewhat opposed to this rule when only 20 percent of the public respondees seemed to be opposed.

I can say having looked at a fair number of those organizations that did reply to you and those in particular

that I have mentioned and some of those I work with, we were rather like the man who was asked whether he had stopped beating his wife.

We obviously are for quality assurance and all stated that, however, if you look at the detailed comments by each of these organizations, I think they left no doubt in my mind that to be workable this rule would have to be drastically changed at least. There were just things that were not workable about it.

We are as you all heard very much concerned about quality assurance and the Commissioners, I think, are aware that the above mentioned organizations because it has been said many times today and many others have been from the very beginning active in setting standards and in developing quality assurance programs to ensure the safe use of radioisotopes in medicine. That has been one of their main concerns.

In fact, these, I think, everyone would agree have been very successful and as has been mentioned here today the extremely low misadministration rates for Cobalt-60 radiotherapy and brachytherapy, for example, with approximately one to two misadministrations in 10,000 treatments. So it is a very low number.

The Advisory Committee in its deliberations of January 26th of this year questioned whether it would be possible or cost effective to reduce this number any lower and

i would like to address that because it has come up today.

By the way and let me say about misadministration, I think to answer one question that came up, misadministration in this context means a dose different than ten percent from that prescribed and can be lower as well as higher.

So we may well be underdosing as well as overdosing the patient and, in fact, it is likely that the overall dose load to the population may be averaged out to very low but understand, it is just as bad in our situation to give a low dose as it is to give a high dose and there are misadministrations of those kinds reported.

You are all aware that radiotherapy is a complex form of treatment requiring an integrated team approach. There is the radiotherapist, the medial physicist, the radiotherapy technologist and very often a dosimetrist and this requires many links in the chain from the prescription to the treatment planning to the application and to record keeping.

How many links in the chain will depend very much upon the institution or the case being treated but there may be ten, 20 or 30 links in the chain. If only one of the links is broken, a misadministration may occur.

This actually is very clearly illustrated by the NRC's misadministration report in radiotherapy and here, I believe, we do have the same data bank. This report that was published in December of 1985, the case study report on the

therapy misadministration report to the NRC, is an excellent document and is really the only detailed account that we have of the types of misadministrations that occur.

During the three and a half years covered by that report there were some 300,000 patients or so treated on Cobalt units that entered into this report. It is interesting to note and I just deal with the radiotherapy external beam of which I think there were 16 reports, there were 11 different types of errors which occurred only once and that means on that chain, very randomly from wherever, from the prescription, the treatment planning or application, one chain broke here and one link another chain, it might have been another link and so on but they were not duplicated which indicates a very random distribution.

Only one error occurred twice, that is, the same link broke in both cases. There were three mathematical mistakes but that we do not know, it probably occurred somewhere within the whole total so there is, in fact, a very random nature here.

When you consider the hundreds of thousands or actually millions of parameters that were calculated, measured, set and recorded, this is a very remarkable record. I don't think it can be reduced and it is quite likely that if we repeated the study today, we would get a different set of errors. Different chains would be broken.

That is due to the very random nature of the errors and the very low frequency with which they occur. So it would not be possible in my opinion to base quality assurance upon a study like that trying to strengthen those links that did break because next time, another link might break.

So to try and write a comprehensive prescription quality assurance rule would result in a very big and largely unworkable document. If you tried and included all the links, the document gets very big.

The committee sort of having considered this felt the approach to quality assurance as you have heard today should be to require the licensee to submit their own quality assurance program as part of their license application for review by the NRC and which could be used as the basis for enforcement if they were not followed.

Now a large amount of assistance exists for the setting up and you have heard today about AAPM, this is their physical aspects of quality assurance in radiation therapy. It is a brief guideline, proceedings of a symposium on quality assurance of radiotherapy equipment, a symposium by the AAPM, The American College of Medical Physics has and this is one on quality assurance in radiation oncology and another in nuclear medicine. There are many of these such documents available.

COMMISSIONER CARR: If it is such a minor problem, why do you study it so much?

[Laughter.]

DR. ALMOND: Let me say the fact that these organizations have from the beginning studied and been involved in this has resulted in the very low misadministration rate.

COMMISSIONER CARR: We are coming in behind the problem.

DR. ALMOND: I would believe so. As you have heard, the NRC should consider working more closely with these scientific and professional organizations and assist in their educational programs where quality assurance is involved. If necessary, we need to get the word out there.

We have heard about the cost involved and that is a very difficult subject but we did hear testimony that between five million and ten million annually to implement this rule for an institution that has a single Cobalt unit but with good quality assurance already in place and physics support, the cost to that department might be $4,000.00 to $5,000.00. I can't disagree with these numbers.

They may be somewhat different but the numbers are fairly large and as pointed out, if that money is taken to do quality assurance, increased quality assurance, it has to come from somewhere and I do not see any recurring benefit to the patient.

We all, and I strongly believe that quality assurance in radiation oncology is a very important subject but that

adequate protocols and assistance exist through the various professional and scientific organizations as we have said and that the NRC should work with these groups to develop a performance based approach and you have heard that word from, I think, all of us rather than a prescriptive based approach to continue to ensure that radiation therapy is one of the safest forms of therapy.

Thank you very much.

CHAIRMAN ZECH: Thank you very much. We appreciate it.

MR. BERNERO: We have nothing else, Mr. Chairman. Thank you. Before we close the meeting i would like to remind the Commission in our briefing to you just a few weeks ago, we spoke of regulatory alternatives and one of them, alternative number two, was a performance based rule.

You have heard a number of exhortations and a number of offers of help today and the staff will dedicate substantial effort to developing a real performance based alternative for you to consider and in selecting the performance bases we will seek and I hope get the help of those who offered it.

I also would say that the staff will give special attention to the issue of the cost, the data base and the cost benefit analysis. It is a knotty one. I think we need to develop it better as a basis of decision.

CHAIRMAN ZECH: All right. Thank you very much.

Questions from my fellow Commissioners. Commissioner Roberts.

COMMISSIONER ROBERTS: No questions.

CHAIRMAN ZECH: Commissioner Bernthal.

COMMISSIONER BERNTHAL: Yes. I trust this point wasn't brought up early in the meeting. I was a bit late getting here but let me ask it if it was and maybe someone can repeat it.

In the staff's summary of public comments on the proposed rule, I noticed that among those supporting the proposed rule was the Commission on Radiation Therapy of the American College of Radiology which I understand is a subgroup or subset of the American College of Radiology as the name implies which opposed the rule and there was actually a middle ground which one could have taken.

Fifty-five percent suggested changes in the rule. It struck me as odd that in a subgroup of the American College of Radiology you would get support whereas the College itself opposed. Can somebody explain that to me?

CHAIRMAN ZECH: Yes, please.

COMMISSIONER BERNTHAL: Maybe the representative of the American College of Radiology would like to comment on that as well as the person who has been working with our staff, but go ahead.

MR. LINTON: Over a year ago some draft documents were circulated very informally and the Chairman of our

commission in writing what he admits is a personal letter to Mr. Miler of your staff agreed in part with some proposed changes relative only to misadministrations.

This letter somehow got entered into your record as supporting the whole current set of regulations and I believe that was an error, sir.

CHAIRMAN ZECH: Thank you very much.

COMMISSIONER BERNTHAL: Thank you.

CHAIRMAN ZECH: Norm, did you want add anything else?

COMMISSIONER BERNTHAL: Does that comport with your impression?

MR. McELROY: That is what I wanted to report. The committee had gotten hold of an early copy of the draft regulation, I believe, before it was formally submitted to the commission and they were responding to technical detail in that early draft. I don't believe they were supporting the entire initiative.

COMMISSIONER BERNTHAL: All right. Thank you very much. On the question again of cost benefit, I suppose that on the basis of the various numbers we have heard here today I could have and should have worked out the arithmetic here but maybe someone can tell me whether the staff has arrived at or one of the professional groups has arrived at another statistic here.

I don't know how many people receive diagnostic and

therapeutic administrations in a year or any other time for that matter. I have heard various numbers and suggestions for the overall cost to an operation or a hospital, I should use the term hospital, of such a program were it to be put in place.

Has anyone determined the estimated cost per administration or cost per patient and determined what percent of the bill so-to-speak for an administration this would amount to? In other words, suppose you implemented the rule as written and I doubt that we would do that but suppose, are we talking about one percent of the cost to the patient or are we talking about ten percent or a tenth of a percent, does anybody have any idea per administration?

DR. MARCUS: It depends whether you are talking about cost to satisfy the prescriptive regulations or cost to satisfy a performance based standard.

COMMISSIONER BERNTHAL: I really was referring to the prescriptive regulation in the proposed rule.

DR. MARCUS: All right. In my practice, it would cost and we don't have any misadministrations or radioiodine but to conform to the original regulations as written including overhead for personnel, personnel costs would be about $50,000.00 per year and we double the cost or a little more than double the cost of I-131 and I could go through the numbers because I have my total amounts and it would just me a

few minutes and those would be the major costs I think for my practice as an example.

But you are getting into something that is going to end up being between $50,000.00 and $100,000.00 per year for a department that had, I think it was about, 500 uptakes, about almost 400 scans a year and it was 58 I-131 treatments last year. That was the size of my operation so you are getting some idea.

COMMISSIONER BERNTHAL: So $50,000.00 to $100,000.00 per year.

DR. MARCUS: For a moderately large department.

COMMISSIONER BERNTHAL: Right, and it sounds like you are talking roughly about a 1,000 or so patients per year, is that what your summary was?

DR. MARCUS: Well, some of those patients are the same ones. You do an uptake on them and you do a scan.

COMMISSIONER BERNTHAL: All right, but nevertheless, per administration in effect.

DR. MARCUS: Yes, something like that.

COMMISSIONER BERNTHAL: So we are talking $50.00 to $100.00 per administration, is that the rough arithmetic here?

DR. MARCUS: I suppose but I will say this, that with what I would consider to be perfectly appropriate performance based standards, the costs would be practically nothing because basically the isotope costs would remain the same and I

wouldn't need new people, we simply do things a little differently.

COMMISSIONER BERNTHAL: Yes.

DR. MARCUS: I think that is a really important point to bear in mind.

COMMISSIONER BERNTHAL: All right. Thank you very much, Dr. Marcus. I should stress that I think that the Commission in other areas and I assume in this one has indicated some inclination toward performance based standards and I personally have not at all ruled that out as the path we might take here and if we can work with you to arrive at a sensible performance based regulations here, in my judgment that would be preferable.

A proposed rule is designed to do exactly what this one obviously has done. We have learned in what areas there may be flaws and will go on from here now I trust working with you to arrive at what I hope will be the best solution that we can possible devise.

That is, I believe, the summary of my comments for now. I want to thank you all for taking the time to come to Washington on a miserable day and present us with this information. I appreciate it.

CHAIRMAN ZECH: Commissioner Carr.

COMMISSIONER CARR: Would someone speak to the agreement states part of the problem and see if we are about to

get into a dual requirement, dual regulation area, or do you have some comments on that?

CHAIRMAN ZECH: Perhaps the staff could speak to that?

MR. CUNNINGHAM: Dick Cunningham. Mr. Chairman, we proceeded on the basis that the rule would be a matter of compatibility so that if it is adopted by the Commission it will have to be adopted by the agreement states.

CHAIRMAN ZECH: Thank you.

COMMISSIONER CARR: In the Minutes of the earlier meeting there was a comment about the quality of training and the fact that when we inspect, we don't ever look at training and never ask how good it is. Do you really want us to get into that area? We are very good at looking at training programs?

[Laughter.]

DR. WOODBURY: The question was, were you good at funding them?

[Laughter.]

COMMISSIONER CARR: No. I don't have to worry about funding them. That is somebody else's money but I would be more than happy to comment on the quality of your training programs if you want us to and I just wanted to follow up and see if that was one person speaking or if generally you would like us to put down some kind of requirements on your training

programs? I see some heads going this way and some going this way. Yes.

MR. LINTON: You deserve an answer, sir. There are many existing programs which we think more than serve the purpose and we would welcome your endorsement of those rather than inventing yet another one. Thank you.

COMMISSIONER CARR: Well, we don't always bless what we are looking at.

[Laughter.]

COMMISSIONER CARR: The other comment in that meeting was that one person said, "Your problem is you ought to put some teeth into the regulations you already have" referring to the rad safety officer who falsified the minutes for ten years before we caught up with him. Do you have any more comment? Would you like to amplify that statement about putting a little more teeth in the regs we have?

[No response.]

CHAIRMAN ZECH: No takers so far.

COMMISSIONER CARR: Silence reigns.

[Laughter.]

MR. TAYLOR: As the director of enforcement or ex director, I would take that to heart.

[Laughter.]

COMMISSIONER CARR: Well, it was in there so I thought I ought to mention it. I would certainly agree on two

points. One is the communications. We need to be able to get the word out not only to the major hospitals but to the little guy who is 200 miles from the local area that you were mentioning there.

We have to make sure that the word gets all the way down to the people doing the work and the other one is whatever we do, we have to run the pilot program. I appreciate Dr. Marcus' trying it out.

One of my precepts is how do you know it won't work if you haven't tried it. She has tried it and she knows it won't work. I believe that. So we want to make sure that whatever we do does work and I do appreciate your coming and meeting with us today. Thank you.

CHAIRMAN ZECH: Let me just make a couple of brief comments. First of all, I think somewhere earlier in the discussion the definition of misadministration in the rule was or perhaps in our regulations was brought up. If that isn't clear, it ought to be clear. It was brought up again recently here, I think.

Would anybody like to talk about that? Is that not clear?

MR. BERNERO: Excuse me, but I think the definition, most would agree the definition is clear. I think it is a matter of whether it is too broad. It defines by percentage, diagnostic or therapeutic dose but the question is, is you have

essentially harmful or harmless ones.

CHAIRMAN ZECH: Is it too broad? Should it be improved?

COMMISSIONER CARR: The question is whether it was clear or whether it was fair, I think.

COMMISSIONER BERNTHAL: Ten percent was the number that we heard.

CHAIRMAN ZECH: Plus or minus ten percent later and earlier I thought someone said that it should be defined more clearly and then the plus or minus ten percent so my question, I guess, really is, is there a problem with the way we have talked about misadministrations and should something be done about it? Yes, sir.

MR. LINTON: In the opinion of the expert committees of the American College of Radiology, that rule badly needs rewriting, sir. The way in which misadministrations are defined as a percentage of dose can be enormously misleading. Many of those which technically quality as misadministrations as I believe Dr. Almond said actually represent underdosing and not overdosing and all-in-all, what is a misadministration for Dr. Collins may be a totally different dose than Dr. Griem and his is good and his is bad and all-in-all, sir, half your problem is in how to figure out how to answer the misadministration rule.

CHAIRMAN ZECH: How to answer what again?

MR. LINTON: How to know when I have misadministered.

CHAIRMAN ZECH: How to define misadministration?

MR. LINTON: Yes, sir.

CHAIRMAN ZECH: This is what we need help on then so we are asking you to help us define it.

MR. LINTON: All right, sir. We have supplied that in writing several times. We would be glad to do it again or to expand now as you might wish.

CHAIRMAN ZECH: Let me hear from the staff briefly then regarding a definition of misadministration. We are hearing right now that it is not very well defined. I would like to know what your view is.

MR. McELROY: I would take a slightly different opinion from that expressed by Mr. Linton. The basic definition is clear. Where the staff has seen problems for gray cases or serious of events that have on occasion arisen and there is honest dispute within the staff and the medical community as to whether certain events have fallen within the definition of misadministration.

To respond to this problem, the staff is working with the Office of General Counsel on examining past events and other events that we can think of that might possibly be considered misadministrations and try to develop some additional guidance on when reporting is required but we share to some extent Mr. Linton's concern that perhaps the basic

definition should be reviewed.

COMMISSIONER CARR: There must be some degree of measurement that would be required. If we are going to have a performance based standard you have to measure performance somehow.

DR. COLLINS: I do think that some instruction or elaboration on the nature of dose would be entirely appropriate because the same number could have an entirely different result if it were delivered through a single field, through opposing fields, through a small field, through a large field, in a short time or a longer time. The number might be the same but the effect would be totally different and the very fact that dose is not a number.

Dose is a concept that for any given agent whether it be a biological one or a chemical one or an energy one, if the circumstance of delivery are precisely duplicated and if it is given to a precisely duplicable organic system then a predictable result will occur.

To the degree that we have not controlled the physical, chemical or biological agent offered or that we know precisely all the details of the organism or tissue to which it is being given, then the effect is chancy.

Dose is not a number. Dose is a prediction that you can produce a given effect with a given biological medicinal agent. One number may be entirely different as far as the

effect is concerned.

COMMISSIONER CARR: But our measurement would only control those things you can control.

DR. COLLINS: That doesn't control anything.

COMMISSIONER CARR: Well, you mentioned the things you could control and then you mentioned the things you were unable to control.

DR. COLLINS: Yes, but not in a number, not with a number.

COMMISSIONER CARR: You can certainly control the area, the distance, those kinds of things.

DR. COLLINS: But that is not recognized if you have a single number of dose and if you put in all the other numbers and then we begin to describe it.

COMMISSIONER CARR: So we should look at your computation rather than your answer? Is that what you are trying to tell me? I wanted to make sure I understood what you said and I am not sure I do.

DR. COLLINS: When we describe a misadministration in terms of a single number for dose or a percentage of that, that is a totally inadequate description of dose delivered.

COMMISSIONER CARR: Can there be an accurate description?

DR. COLLINS: If we describe all the features of the physical agent and describe the condition or volume or organ

being treated, then there is a chance we may predict what is going to happen. To the degree that you and I are in good rapport and we know exactly what we are talking about, I may say, "Let's give it 5,000" and you know I am talking about rads or another unit, you know I am talking about the distribution we are considering. You know the unit. We can communicate.

But if we do this without knowledge of what I imply and you infer, the result is very, very questionable.

CHAIRMAN ZECH: Dr. Almond.

DR. ALMOND: To some extent I think misadministration is an unfortunate term and I think we have alluded to the fact that in the performance type of rule, we would look at it as working as ALARA where you have action levels rather than misadministration levels.

So if the dose is different by ten percent from the prescribed dose and actually that does allow for differences between radiotherapists or cases, I mean, there is a prescription which is given but if it varies by a certain percentage from that, that is an action level to alert you that you better look and see that something needs to be done.

That actually in the report here worked fairly well. They found the doses were different by more than ten percent in these cases and took action on them. So I think perhaps if the word was changed a little bit and redefined, it does need redefining, but more in terms of an action level which then

requires some action to correct that and to make sure that things are put right.

CHAIRMAN ZECH: Mr. Cunningham, would you like to make a comment?

MR. CUNNINGHAM: Yes, Mr. Chairman. I think it would be well to just mention the genesis of the misadministration rule. Initially the misadministration rule was intended for the staff to analyze on a statistical basis generic things which we might correct through regulation.

The staff with our advisory committee has struggled with this definition over the years and we have modified it or adjusted it a little bit from time to time. The misadministration rule now is being used in a little bit different way. It is used to measure some degree of performance on the part of the licensee and it is getting closely connected with the quality assurance part.

So it is being used a little bit differently both by us and by the medical community. We are changing our thoughts on the misadministration rule including the definition or t he title of the rule and all this is being looked at in conjunction with the quality assurance procedure.

CHAIRMAN ZECH: All right. Thank you very much. I would also like to emphasize the importance of improving communications certainly with this group of professionals that has appeared before us today.

Certainly I think a performance based rule in this regard is something that ought to be given serious consideration. It seems to me that we ought to review, the staff should for us review what we have heard here today and perhaps come back and give us another briefing here sometime in the future.

I think what we have heard today has been very valuable. I would particularly like to thank all of our presenters who have come here today from all over the country and I apologize for restricting the time we have given you to talk to us.

I know many of you are very learned in your field and you have published documents and you have worked in this very professional field for many years but it was so important that we hear from you, that we, the Commission, hear from you briefly before we proceed any further in our progress on this rule and that is why we called you back here and we really are grateful for your appearance here today.

I think you have given us an awful lot of things to think about. The staff has briefed us in the past. We all have our own views and most of us feel that you do indeed do a remarkable job of practicing the field of medicine.

We do not want to intrude into the medical practice but we also recognize that from time to time even though there are a very small number of problems that if there is something

that we have responsibility for in nuclear materials we should be mindful of those responsibilities and so we have asked the staff to look at this very carefully to see what we could do to improve our performance and do a better job ourselves.

We relate with you on this because you are the ones that are practicing medicine and so you have a responsibility to your patients. We have a responsibility to the American public across-the-board for public health and safety and so we do come together in that regard.

I think we have a very common ground. We are trying to do something, I think, that is to benefit those who are the benefactors of the byproduct material that we are talking about and I think that together we can perhaps both improve our performances. I still think that there is that room for improvement although I recognize that it is going quite well across the board right now.

So I would like the staff to come back to us in a reasonably short period of time but I want you to have time enough to think about what we have heard here today and to feel like we are not rushing headlong into something that we have so many people here that deserve our attention and our respect, we want to listen to them. I want to listen to them and I know my colleagues do, too.

So we do want to take aboard what we have heard today and we would ask the staff then to come back to us and perhaps

give us their views. I think we should review the misadministration definition, take aboard other suggestions we have heard here today and see if we can't get a little closer with this community of professionals that not only is our advisors but others in the scientific community that we have listened to.

I think the staff frankly has done an excellent job in the past of trying to carry out the Commission's desires to make some improvement in this area but I frankly think today's discussion has been very valuable and very helpful and I would ask the staff to come back to us and give us their views after they have had a chance to review the very thoughtful things we have heard here today.

I particularly would like to thank all of you again who came here today and who have been working in this area and trying to help us for so many years. I am impressed not only with what you have said today but the things that I have reviewed prior to your coming here.

I agree that Dr. Marcus and her pilot program certainly, I like pilot programs, too, and she did it and it didn't seem to work very well. Well, perhaps we should learn from that and maybe we can design a better pilot program that is maybe more performance based.

I sensed in Dr. Marcus and in others here a willingness to try to come up with something that is a little

bit more reasonable, perhaps less prescriptive but something that gain is going to bring the results that I think we would both like to see and so I think some kind of further communications and further suggestions and recommendations from those of you who have as you leave here today and head back to your homes and your practices, perhaps if you have other thoughts that you think we should hear, why we would like to hear those thoughts, too.

So let's keep this open. Let's have the staff come back to us in a reasonable period of time and try to see where we should go from here. Are there any other comments from my fellow Commissioners?

[No response.]

CHAIRMAN ZECH: If not, thank you very much. We stand adjourned.

[Whereupon, the Commission meeting was adjourned at 4:05 o'clock p.m., to reconvene at the Call of the Chair.]

SCHEDULING NOTES

TITLE: BRIEFING ON PROPOSED BASIC QA RULE WITH REPRESENTATIVES OF NRC ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES AND INDUSTRY SCIENTIFIC COMMITTEES

SCHEDULED: 2:00 P.M., THURSDAY, APRIL 7, 1988 (OPEN)

DURATION: APPROX 1-1/2 HRS

PARTICIPANTS: (60 MIN.)

COMMUNITY HOSPITALS. THESE TWO PHYSICIANS USE BYPRODUCT MATERIAL FOR PATIENT CARE. THEY WILL SPEAK ON REGULATORY INITIATIVES AND QUALITY ASSURANCE.

CAROL S. MARCUS, PH.D., M.D. (NUCLEAR MEDICINE)	LOS ANGELES CO. HARBOR-UCLA MEDICAL CENTER (ALSO REPRESENTING THE SOCIETY OF NUCLEAR MEDICINE/ AMERICAN COLLEGE OF NUCLEAR PHYSICIANS)
GLENN L. TONNESEN, M.D. (RADIATION ONCOLOGY)	FAIRFAX HOSPITAL (NOTE: DR. TONNESEN GUIDED CHAIRMAN ZECH WHEN HE TOURED FAIRFAX HOSPITAL)

ORGANIZATIONS. THESE INDIVIDUALS WILL SPEAK ON VOLUNTARY QUALITY ASSURANCE INITIATIVES, AND PROVIDE LICENSEE COMMENTS ON THE RULEMAKINGS.

OTHA LINTON (RADIATION ONCOLOGY)	AMERICAN COLLEGE OF RADIOLOGY
FAIZ KHAN, PH.D. (MEDICAL PHYSICS)	AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE
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FOOD AND DRUG ADMINISTRATION (FDA) THIS INDIVIDUAL WILL DESCRIBE THE REGULATORY PROGRAMS AND VOLUNTARY INITIATIVES OF FDA'S CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

RICHARD E. GROSS (INTERGOVERNMENTAL PROGRAMS)	CENTER FOR DEVICES AND RADIOLOGIC HEALTH OF THE FDA

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES (ACMUI)

	THESE INDIVIDUALS WILL DISCUSS THE COMMENTS THEY MADE AT A RECENT ACMUI MEETING ON THE SUBJECT RULEMAKING
VINCENT P. COLLINS, M.D. (RADIATION ONCOLOGY)	PRIVATE PRACTITIONER, HOUSTON, TX
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