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ON THEIR ACTIVITIES

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PUBLIC MEETING

Nuclear Regulatory Commission
One White Flint North
Rockville, Maryland

Tuesday, February 8, 1994

The Commission met in open session, pursuant to notice, at 2:00 p.m., Ivan Selin, Chairman, presiding.

COMMISSIONERS PRESENT:

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

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

SAMUEL J. CHILK, Secretary

WILLIAM C. PARLER, General Counsel

ROBERT R. KULIKOWSKI, Chair, Organization of Agreement States

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

2:00 p.m.

CHAIRMAN SELIN: Doctor Kulikowski, we welcome you here today. This is a topic of great interest to everybody in the audience, but especially to the Commission.

We welcome Doctor Kulikowski, the Chairperson of the Organization of Agreement States, to brief us on the status and activities of the organization.

I'd like to emphasize that the agreement states and the NRC are independent co-regulators. According to the Atomic Energy Act and the practice, when a state becomes an agreement state, the NRC terminates its regulatory activities over those entities that the agreement states will regulate. So, we are independent in one sense in assuring the health and safety of the public. On the other hand, it's very clear in law and in practice that ultimately it's the NRC that has to answer to the public for the health and safety of all American citizens as far as radiological hazards are concerned. So, we do have a responsibility even in the agreement states and the way of working out this delicate balance is one of the key issues that arises between the Organization of

Agreement States and the NRC.

In carrying out such a delicate division of responsibilities, it's absolutely imperative that effective communication and cooperation be achieved and that we and the agreement states have a full and clear ability to communicate our issues and our concerns to each other so that this joint responsibility can be properly executed.

This afternoon we look forward to hearing your views on issues such as compatibility, cost recovery and a number of these controversial issues which we're best off raising, addressing, solving them in what we hope will be a mutually satisfactory manner, and then going on to other business.

Commissioners?

Doctor Kulikowski?

DOCTOR KULIKOWSKI: Thank you, Mr. Chairman, members of the Commission.

I, first of all, apologize. Because of the weather, Wayne Kerr, the past Chair of the organization, was snowed in in Illinois and Richard Ratliff, the Chair-elect who will serve in this capacity next year, was detained in Texas because of a personal emergency.

In putting together the briefing today, I

think we all need to recognize that the states, each state has unique concerns and issues which are directly applicable to them and perhaps they share with other states as well as NRC regulated entities. Although in preparing this briefing I put together an outline which was shared with all the other agreement states for their comment and input, and I did receive a lot of comment on it, it's not intended to reflect all of the issues, but it is intended to reflect those major ones that are of predominant concern at this point. Hence, I will be speaking collectively for the agreement states, not as a representative of any single state and especially not the City of New York or the State of New York.

(Slide) I would wholeheartedly -- as the topics that we'll discuss are shown on the first slide, basically the status and how the states feel about the niche into which the agreement states belong; compatibility issues which have been topics of discussion over the past several years; the Integrated Materials Performance Evaluation Program, which is of particular concern at this point in time; the medical program and where that's going, especially in light of recent findings by Senator Glenn's committee; data collection, which we all recognize is a fundamental

necessity for us to run an effective nationwide program; and then touch on some other issues such as the cost recovery.

I wholeheartedly endorse, and I believe all the states do, that we are independent co-regulators. The plain language of the Atomic Energy Act says that you relinquish the authority to the states to regulate byproduct material. It should also be recognized that state programs run much bigger programs than just byproduct material programs. We regulate NARM in the same sense that we regulate byproduct material, and we also regulate machine-produced radiation. In our particular case, the machine-produced radiation aspect of the program is about twice the size of that of materials program.

Collectively, the states represent many years of experience. If you look at the existence of a national program under Atomic Energy Act, that's about 40 years old. The four oldest agreement states, of which New York is one, California, Kentucky and Mississippi are the other three, represents about 130 years of collective experience. So, when you deal with the states, you're not dealing with a young entity in that sense.

I would also reiterate the fact that

effective communication is absolutely essential. As I said to Commissioner de Planque earlier today, we're all in this boat together. We need to be focused in what our goals are. We need to ensure that we look forward, not just to next month or to what a particular entity wants from us, but to have an essentially integrated program where we talk to each other, meaning full disclosure on both sides so that surprises aren't brought up by one entity or the other, and so that we can effectively protect the public health and safety from radiological hazards in this country.

The states have noticed in the past, especially the past year when we've been working on some of these major projects like compatibility, that the Federal Advisory Committee Act has been an impediment to effective communication. It makes it very difficult when the state representatives can't sit on a federal advisory committee or if a committee is to be formed, it has to meet all the requirements of FACA.

CHAIRMAN SELIN: Could we stop there?

DOCTOR KULIKOWSKI: Oh, sure.

CHAIRMAN SELIN: To be frank, it's not clear to me why we can't just comply with the law and

still carry out our business. We've asked the General Counsel to do an analysis of the requirements of FACA and it doesn't seem that hard to charter a committee with broad enough responsibility so that we go through the one-time cost of both time and other resources of chartering the committee and then it could rotate some membership, et cetera, to carry out the business that we have, which would also -- actually, in my personal opinion, would actually have the benefit of providing on the one hand a unique opportunity for the agreement states because you're not licensees, you're not to be treated identically with the general public, but still in an open forum so that matters that affect many parties will be generally available to the general public as you discuss some early actions that NRC is considering.

But why don't we just do what the law tells us to do and set up an advisory committee which is built around the agreement states and comply with the law? Is there some hidden -- not hidden in that sense, but something we're missing about inconvenience, the serious inconveniences or impediments that FACA would cause?

DOCTOR KULIKOWSKI: No. I was just speaking historically at this point. I believe the

states are certainly willing to work cooperatively with the corporate NRC and explore any way we can have to effectively communicate with each other.

CHAIRMAN SELIN: Well, either the next time you meet or some other way, rather than -- I mean one thing we can't do is just treat FACA casually. That's certainly -- there are requirements and they do involve an investment. But if we took it as a hypothesis that we would set up an advisory committee under the Act and that it would be the agreement states advisory committee, why don't we actually just take a look and see what's involved in doing it and whether we shouldn't just sort of grit our teeth and say, "That's the world we live in," and see if we can't carry out your objectives and ours just within the spirit as well as the letter of the Act.

DOCTOR KULIKOWSKI: Sure. I think the states would be in agreement with that. I think one of the things that we need to do is we need to talk to each other a lot more.

COMMISSIONER de PLANQUE: Do you have anymore information on EPA's treatment of this, where they might be headed?

DOCTOR KULIKOWSKI: No, I don't at this point.

COMMISSIONER de PLANQUE: Okay. No late breaking news?

DOCTOR KULIKOWSKI: No late breaking news.

CHAIRMAN SELIN: Just a second, Doctor Kulikowski.

COMMISSIONER REMICK: Yes, Doctor Kulikowski. I had a question. Perhaps it's been answered, but I was going to ask you what is it that the agreement states wanted that was restricted or you felt prevented from FACA. Is it an advisory committee? I wasn't quite clear what it is the agreement states were looking for.

DOCTOR KULIKOWSKI: One notable example which happened to involve me personally was about a year ago when the compatibility working group was being set up. Several state representatives were asked to serve on that working group. All of a sudden it was changed that we could not serve on that working group unless we went through the entire FACA process and because of the priorities that was basically precluded. So, we were sort of telephone polled or ad hoc members, but not official members. That's just one example.

COMMISSIONER REMICK: So, it's participating in certain activities, might not be FACA

committees, actually structured committees. In other words, the question is, and I agree with what Chairman Selin has said about if it's an advisory committee we should certainly look at the feasibility of that. But is that what the agreement states are looking for or is it looking for something else?

DOCTOR KULIKOWSKI: I think an advisory committee, while it certainly is a very good idea and probably is an idea worth exploring at this point, however I think there are many opportunities where a less formal mechanism is necessary or would be convenient.

CHAIRMAN SELIN: What we should do, what I think we should do, is consider setting up an advisory committee. Then we could set up subcommittees ad hoc as necessary and I'll ask the General Counsel in a minute if there's any problem with this. But if the structure were in place, then it could be used as appropriate to handle specific topics that come up. That wouldn't preclude more informal discussions which would not be with the organization, but with individual people.

Mr. Parler, do you have a comment on the feasibility of setting up an advisory committee and then creating subcommittees under a committee set up

under FACA as topics arise?

MR. PARLER: No, Mr. Chairman, I do not, at least as a general proposition. You mentioned earlier that -- I think that you did, that I had provided at least a background analysis that covered a good bit of the territory with promises that things such as what other agencies might be doing. We would be pleased to follow up on it also, to work closely with the staff to respond to some of the requirements in this area that the Commission has earlier passed along to the staff.

In our analysis, in the memorandum of, I believe it's February 4th of this year, one of the examples that we point out that I think would be responsive to your question is the possibility of forming an umbrella committee, a broad-based committee that would be chartered under the Federal Advisory Committee Act and then from time to time subcommittees under that umbrella committee could be appointed and those subcommittees would not themselves have to be chartered.

CHAIRMAN SELIN: Why don't we look into this jointly as a mechanism and see, number one, if that makes sense and, number two, answering Commissioner Remick's question, take a look at some of

the specific instances where there were problems in the past and just see if this -- had this mechanism been in place, would it have answered the problems. We want to solve these problems. We want to do them fully and we want to do them openly and we'd like to comply, all else being equal, with federal law. So, why not?

DOCTOR KULIKOWSKI: As regulators, we certainly have the desire of having everyone in compliance with all the applicable regulations and laws. But I think this underscores the fact and I think this really needs to be recognized by both sides, that the agreement states are independent co-regulators. This sounds repetitive, but it's a very important point and one that the states believe is a very fundamental tenet in the relationship between the states and the --

CHAIRMAN SELIN: I should say this. There's no question about that. There's no question about your authority, but there's also no question that ultimately it's our responsibility that citizens in agreement states be at least as safe as citizens in NRC regulated states. So, to find a fine line that allows the authority to be executed in an efficient fashion, not only within byproduct radiation but your

broader health programs, while still realizing we're on the hook and we have to carry out our responsibilities, that's the ultimate task that faces the communications between the OAS and the NRC.

DOCTOR KULIKOWSKI: We certainly understand that.

COMMISSIONER de PLANQUE: Before you go on, I just want to make one more point on the FACA situation. It may be that by setting up a committee this will go a long way to solving some of the problems. There may still be instances where that is not really the best way to handle things and I think it would be useful for us to have those situations clearly delineated so we know whether or not we're -- by creating an advisory committee are we solving the problem or not and where are the gaps still and what are the options for filling those gaps?

DOCTOR KULIKOWSKI: Yes. As I understand, just prior to this briefing the states will also have a copy of the memorandum about FACA and we can certainly discuss this. One of the guiding principles of my stewardship of the organization this year is to make sure that all states are fully informed of what's going on. I mean obviously all 29 of us can't be here today to talk to you, although that would be a

desirable scenario. I fully intend to make sure that when the organization speaks, it speaks with the consensus opinion of the states or any dissenting opinions are clearly identified.

CHAIRMAN SELIN: While we're on this, we're not talking about replacing existing communication, but supplementing that. I still would expect the individual NRC officials to appear before you at your meetings to be able to discuss topics, et cetera.

DOCTOR KULIKOWSKI: Oh, definitely.

CHAIRMAN SELIN: We're not talking about replacing all of that with a FACA committee, but supplementing what we already have and building on that.

DOCTOR KULIKOWSKI: No. I think the more face to face communication that we have with each other, it's much better.

MR. PARLER: Mr. Chairman, may I comment briefly? The memorandum that I provided the Commission makes it quite clear that the subject that we're talking about, the advisory committee only applies in a fairly narrow situation where a group is established for the purpose of getting advice or recommendations from the group to the Commission.

There are all sorts of examples that I provided, free and open communications that are not within the constraints of the Federal Advisory Committee Act.

CHAIRMAN SELIN: Thank you, Mr. Parler.

DOCTOR KULIKOWSKI: Thank you.

(Slide) Perhaps the most -- I believe on slide number 3, entitled "Compatibility," this is probably one of the two topics that are of major concern to the states. Most of the states listened to the briefing that was held a couple of weeks ago and we think that the postponement of the February workshop was warranted. The reason for that was that we feel the whole compatibility issue has not been completely resolved. We don't want to cut off our noses to spite our faces at this point. As I mentioned earlier, we're in this together. We need to, as co-regulators, iron out this issue of compatibility. I don't disagree with you in the least that this should be done in an open forum. However, we are the regulators and we must be able to regulate effectively in the full light of the regulated community and the general public because it is their interest that we do have at heart.

So, I applaud the fact that the February workshop has been postponed to allow us more time to

get both NRC and the states more comfortable with the issues that have been discussed in the compatibility. I think there needs to be at least one more, at least one more NRC-agreement state interaction before we really take the dog and pony show on the road. This is another case, as I mentioned earlier, where FACA has been an obstacle.

CHAIRMAN SELIN: Before we get off that.

DOCTOR KULIKOWSKI: Sure.

CHAIRMAN SELIN: Agreeing with all that, it's my personal impression that although there are still some Ts to be crossed and Is to be dotted or whatever cliche one is pleased with, that we've made a lot of progress in separating out the concept of adequacy from compatibility and coming to a position which both serves the public and seems to meet many of the objectives that the organization or its individual members have espoused over the last year. Do you feel that also or do you --

DOCTOR KULIKOWSKI: Oh, definitely, Mr. Chairman. I feel we've come a long way with just addressing the issue of compatibility. It's an issue that the states have discussed for a number of years and have gone to the NRC in previous years with. There's been a compatibility working group among the

Organization of Agreement States before there was actually a formal organization of agreement states. So, it's an issue that we've wrestled with for quite some time. I think we've made great strides in the past year because there's been a real focused effort on it. However, my concern and the concern of many of my colleagues in the states is that not only do we have many Is dotted and Ts crossed, I think they all have to be dotted and they all have to be crossed and the grammar must be correct and the punctuation must be correct because basically the fear is, and we're all subject to scrutiny. The NRC has been scrutinized by both the Senate and the House of Representatives. Our agency has been looked at by various outside agencies and we're acutely aware of the fact that information which is less than perfect can be turned around and used against you very effectively for whatever reason for outside interest groups.

So, it's a major concern that the package be tied up in a very pretty package, an effective package and that there's a big red and gold bow on top so that when we go out to the public with it we can say, "This is really what we're happy with, what we're comfortable with, and we are convinced for the following reasons that we will protect public health

and safety and we'll have an effective program."

So, I think it's extremely important that we not have knee-jerk reactions to a variety of situations and just put something together quickly without thinking it through and looking at the far ranging consequences of what may happen and pursuing all the "what ifs" down the road.

COMMISSIONER de PLANQUE: Would you care to elaborate a little more on where you see this as being incomplete at this point?

DOCTOR KULIKOWSKI: I think that the -- I think a bunch of areas. We can really recognize that there are certain basic things such as the basic radiation protection principles, which must be identical in order for people to effectively communicate both nationally and internationally. There are other areas where compatibility, such as in the medical area, where the line is much grayer than that as to exactly what does it mean to be compatible. The medical area is of particular interest to me personally because our program is a large medical program and we see how physicians and other allied medical personnel are regulated from the non-radiation side, in very different ways and it doesn't really impact in a global sense in the sense that it impacts

nationwide.

So, I think we need to really go through and define and maybe just an informal working group of a couple of agreement state volunteers and a couple of NRC program people might just want to sit down and go through 10 CFR and say, "These are the things that form the fundamental core of regulations and what a compatible program means," because I think regulations are only one part of compatibility. There's the whole way in which the radiation control program, whether it's NRC or whether it's a state program, addresses their end product, that is the protection of public health and safety. I think the compatibility issue is tied up into all of those and there are a lot of interrelated things with adequacy that need to be sorted out.

So, I think while we've come maybe three or four giant steps, I think we have maybe one or two more to go to really nail it down, to make it unambiguous. When I talked to a number of the other state representatives, this is one of the concerns that they had, was that it's still nebulous, that it's not unambiguous, that it's open to interpretation and I think as good regulators and having, as an aside, just gone through an amendment to our health code, the

lawyers kept saying to me, "What does it mean?" And they said, "Make it as unambiguous as possible," and I think that's what we need to do because that will give us more credibility collectively with the regulated community and the general public and it won't be subject to interpretation or different applications depending on the entity being looked at.

CHAIRMAN SELIN: Well, as you know, when the Commission was briefed we were very pleased with the paper, but we also had some of these concerns. We expect that in the very near future there will be a somewhat revised version of that paper that will clear up some of these ambiguities.

DOCTOR KULIKOWSKI: The states will be very anxious to see that.

COMMISSIONER REMICK: Doctor Kulikowski, are you going to leave that slide by chance? There were two bullets on that last slide where you talk about concerns. I think I can infer what your concerns are. One is on the concerns about compatibility. The other is about the states being considered equal to the public, notified at the same time. I can infer what your concerns are, but it would be helpful if I knew for sure what those concerns are.

DOCTOR KULIKOWSKI: Okay. The concerns are -- the phone link that we had listening to the compatibility briefing was not the best at some point, so I'm not quite sure who said it, but I heard the opinion voiced that we should go with this to the states at the same time as we go to the public or the states shouldn't see it before the public. That gave me personally some pause. I think that that really could be interpreted to mean that the states are basically equivalent to members of the general public and I heartily disagree with that.

COMMISSIONER REMICK: But I guess I could argue on the other side that what is wrong as long as everybody knows at the same time? I'm not quite sure -- I can understand your arguments that the states aren't licensees and we're treating them perhaps like we would licensees in that specific case, but it's hard for me to argue that why shouldn't everybody know at the same time. Is there any reason why we should --

CHAIRMAN SELIN: If I might follow-up on that just a second. There are two separate questions and one is who knows what when and the second is what influence do you have on it. I really think they ought to be kept separate. We would be strongly

opposed to the idea of there being private meetings with the states where things are discussed that are not generally known to the general public. But it doesn't mean that the states don't have the first shot through perhaps a more formal mechanism of FACA to affect the staff's drafting, since you have to live with the regulations, before we open them up for general comment. We would be very uncomfortable with a situation where there was some private communication about what we were thinking to the agreement states that the public wasn't privy to. But it doesn't mean that you don't get a chance to comment or affect this until it goes out for general notice.

DOCTOR KULIKOWSKI: I appreciate that point of view and I think one of the things that I was thinking about is that it probably would lend a lot more credibility if you could do a news release and all the states could do a news release at the same time, for example, saying, "NRC and states release this particular policy on compatibility." I think it would lend a lot of strength to the compatibility issue as opposed to "NRC says." The states, after all, do regulate about two-thirds of the licensees in this country. And, if I'm not mistaken, the Atomic Energy Act says that both sides will work to be

compatible. I think it's really more of a spirit which I'll touch on as I sum up. It's a spirit of working together.

Several people have voiced to me and noticeably by their absence of comment during these past couple of weeks as I was putting this together, that there is some feeling of uneasiness that the relationship is changing and people aren't sure why and that perhaps there's some suspicions, probably on both sides. You know, I'm not going to make any value judgments about that, but I believe that there is -- whether it's because there is change, and I don't think that the agreement states in general are opposed to a change, but that there are -- because the relationship is changing, the underpinnings are a little less strong now than they were before. So, I think it's something that we all need to be conscious of and do our best to make sure that we enhance that trust in each other's collective agencies as opposed to eroding it.

CHAIRMAN SELIN: But I would suggest, number one, that in discussing this we separate information from comments because I think they're separate points. Our staff doesn't even communicate with the Commission except in public. Why should they

communicate with the states in private? So, the role of the states is clearly different from that of the regulated communities, et cetera. But it was probably my remarks you were referring to and I feel strongly that these communications should generally be open communications.

DOCTOR KULIKOWSKI: Philosophically I agree with you and it's the way I run my program at home, is we do everything in the full light of people. But there are times when my senior staff and I sit in the office and we make a decision before we go public. There's a sort of a natural break point from when you can discuss collegially among the regulators and then go public with it and say, "It's better to have our ducks in water before we go out and have people shoot at them."

(Slide) On the next slide, which I believe is slide 4, there's some bullets on the IMPEP, or the Integrated Materials Performance Evaluation Program.

CHAIRMAN SELIN: In the interest of full disclosure, I should tell you on my chart it's slide 5.

DOCTOR KULIKOWSKI: I'm sorry.

I remember a couple of years ago, Jack

Horner, who is the agreements officer in Region V, redid the evaluation for agreement states or the criteria for evaluation for agreement states. Jack and I talked on the phone at length about that and various things and the policy came out. I would like to go through that exercise again in the same way in that there was a lot more interaction between the states and the NRC. When I say NRC I'm talking NRC collectively. This, after all, is what's -- this is probably the most sensitive area when it comes to outside non-regulators looking at us collectively, looking at the NRC and the agreement states. It's important for the NRC because if the agreement states don't look good, the NRC doesn't look good. If the states don't look good, we have problems with our constituencies as well. But I think the NRC in particular has a dual role. You do, as you said and I don't disagree with you, that you have a role to ensure collectively the protection of the citizens of the United States. Therefore, if the Agreement State Program looks bad, you look bad as well.

In talking to various people, the Performance Evaluation Program, I think, at this point is still -- we're going off half cocked. We're not ready to really go out with this to the public because

if you collect data at this point in time you're going to be able -- one, you have to know what you're going to do with it. Two, you're going to have to pretty much know in advance what it's going to mean. And three, you're going to have to know how people can use it against you because that seems to be the scrutiny under which we fall at this particular time. There's a very high sensitivity to radiation-related issues, of which we are all keenly aware. To have not good data is probably worse than not having any data at all at this point. I'm not saying put it on a shelf and forget about it. I'm saying let's work on it and refine it so that we have again, like the compatibility issue, that we have a good product that we can all live with.

Comments were made to me that this needs to be an effective evaluation tool for both the NRC and the states and the basic measure is are the programs protecting public health and safety. I think one of the things that bristles the states most of all are the bean counts, how many misadministrations did you have or how many over exposures did you have. These probably don't tell you very much about the program per se. They tell you how well the reporting requirements are working, if you have reporting

requirements, and they tell you things that are not under the direct control of the program.

The important things are do you have the mechanisms in place to address areas where there may be public health and safety issues? Not only do you have those mechanisms in place to adequately protect, but do you have the wherewithal, both the technical expertise and the resources, to follow through to make sure that these are carried out?

COMMISSIONER REMICK: Doctor Kulikowski, if I could interrupt you.

DOCTOR KULIKOWSKI: Sure.

COMMISSIONER REMICK: I personally agree with you that they aren't necessarily indicators of performance. But do you agree that things like misadministration and over exposure is data that should be collected?

DOCTOR KULIKOWSKI: That's true. I definitely agree that it's data that should be collected.

COMMISSIONER REMICK: Well, I'm wondering, this is a thought that's going through my head, is there something about performance indicators that the terminology is wrong? We're talking about collecting data that we agree is needed to --

DOCTOR KULIKOWSKI: I definitely think we should address data collection as data collection.

COMMISSIONER REMICK: Yes. And I notice in your slides you talk about data. You don't talk about performance indicators.

DOCTOR KULIKOWSKI: That's correct, and that's because the performance is performance.

COMMISSIONER REMICK: Yes.

DOCTOR KULIKOWSKI: Is the bottom line are we having people injured because of radiological problems? That should be the bottom line measure. That's what we're all charged with, is protecting public health and safety. The states feel that the criteria must be ambiguous. I mean part of setting forth the Integrated Materials Performance Evaluation Program was so that there would be some measure of how well NRC is doing relative to the states and vice versa, and not just the regional inspection and licensing offices. But I think --

CHAIRMAN SELIN: That's a fair point.

DOCTOR KULIKOWSKI: It should be applied to all programs which are equivalent to state programs. For example, low-level waste, sealed source and device evaluations and the like.

CHAIRMAN SELIN: Let me say a couple of

things because of all the areas where communication is important, this is one where the communications, in my opinion, have been the least effective. Number one, we don't expect that there will be a common set of indicators, be they input indicators or output indicators for the NRC and for the states because the Commission's responsibility with respect to the NRC is different from ours with respect to the states. For instance, we need to evaluate the efficiency and timeliness of our own operations. We don't need to evaluate the efficiency and timeliness of your operations. That's not our business. It's the health and safety of people that are in your states that are our business.

So, there will be efficiency indicators that we need to collect on our own programs that we don't need to collect on the state programs. If it takes two years for somebody to get a license in a state, and unless that's construed as interfering with interstate commerce, that somebody who would be safe isn't operating is less of an issue for us than that somebody who isn't safe is operating. So, there are things that as managers of the public's resources we need to know about the NRC programs that we don't need to know about the state programs. That's the first

point.

Second, and perhaps the title, the Performance Evaluation Program, is at fault. We do not see that these indicators will then lead to a yes or a no depending on some arithmetic combination of them is greater than or less than a number. What we are talking about is establishing a database to which judgment will be applied. We see a three stage process whereas the agreement state comments more make it sound like a two stage process. You get these indicators and then you do some scrub on these indicators and you apply some tests and either the program is adequate or it's not. That's not what we had in mind. What we have in mind is there are certain data that should be relevant to comparative evaluations and to absolute evaluations and it would be very useful for those data to be collected systematically and on the table at arm's length from all the parties. But the judgments apply to those data. Therefore, how is the program doing require a lot of non-quantitative information and different people will come to different judgments.

We're not trying to reduce the decision making process to a mechanical process. Not only do those data have to be considered with judgment, but

there are other non-quantifiable -- I'll call them data, but other non-quantifiable information which also has to be taken into account. The idea is to have a relatively objective base which is both broad enough to give a fairly good picture about the programs, but still precise enough so that the numbers mean something that all parties can start from and then have other information brought to bear and judgments to be made. It's perfectly conceivable to me that we at a given state could agree on all the data for that state and still come to different conclusions as to how that program is doing.

The third point I'd like to make is that your statement that says we shouldn't just stick to the regional office, that may or may not be a good observation, depending on what we try to do with the data. We're not trying to evaluate NRC compared to the states. We're not even really trying to evaluate the states compared to each other in the narrow sense. What we're trying to do is answer two questions. One is broadly speaking are citizens in agreement states as well protected as citizens in NRC states? And secondly -- and for that you have to look at all 29 states, not because -- if for no other reason because an individual state is a very small sample. So, you

need to look at that and you need to look at trends there.

Secondly, do things stand out about a couple of states compared to their colleagues? For that you need to look at the sample over some length of time because one state in one year is a small sample.

But there's the impression that, number one, we're trying to set up a mechanical system to evaluate the states, and we're not, and number two, that this is all the information that's necessary to evaluate the states and that's not the intention either. So, my view, I should tell you, are three things. One is we haven't done a very good job communicating what we're trying to do. The second is what you said is very plausible, but I don't agree with it in one place. Until we see some data, it's hard to know what to do with this. It's hard to know what judgments we will do until we get a look at some of the data because we should be following a flexible decision making process that will be affected by what the data show, not trying to set up a bunch of decision rules in advance because the data are only a part of the decision and the desire to get out and start doing some pilot testing is to see where do we

get trivial answers and where is their interesting material that we should follow up on? Then the third point is that we're not trying to make the states look more like the NRC or vice versa. What we are trying to do is places where we have common problems, we ought to have a common approach. And places where we have different problems we ought to have a different approach.

So, there's a lot of work to be done and some of it is just communicating between us and the states because I was really quite shocked when I heard the states' strong negative reaction to the program, since to me it's obviously a good idea. So, therefore, we haven't communicated it correctly. Can't be that I'm wrong or the states are wrong. And the idea is to instead of trying to come out with a full fledged system is to do this thing in sections, get some data, see where we go, whether we have too many or too few indicators, but not have this decision process where you pour in the data and then out comes a grade. That's not at all the intention.

DOCTOR KULIKOWSKI: Okay. In a sense, I'm somewhat relieved by your remarks because very much the states have the feeling that this was a grading system.

CHAIRMAN SELIN: Absolutely not.

DOCTOR KULIKOWSKI: And I think this really speaks to the very issue that we do need to communicate about this particular topic much better, more effectively and spend some more time and, in fact, quite a bit more time before we go out and -- whether it's a matter of educating the states, maybe having a workshop particularly devoted to this, or addressing this at the program manager's workshop which is coming up in the late spring, to iron out and to make sure that everyone agrees because I don't think the states collectively disagree with the fact that there is going to be some sort of evaluation tool. The point has been made to me that the tool needs to be an effective one. In other words, it should get to the very meat of what you want. I think the states have viewed the mechanics of data collection as related to but not an integral part of what's been called the IMPEP Program.

I do reiterate, and I believe all the states' mandates are to protect public health and safety and that is really what you are in the broadest sense charged with under the Atomic Energy Act, is to make sure that that happens nationwide. Once you relinquish authority, you still have clauses that have

been added to the act that you will come in and do an evaluation of the program, and the states certainly don't disagree with that, I don't think. However, we do need to -- the concern, I believe, on the states' part is that everyone is treated equally and that everyone has the same level of protection, which is basically what you espoused earlier on today.

COMMISSIONER de PLANQUE: Let me --

CHAIRMAN SELIN: Just let me finish one point.

COMMISSIONER de PLANQUE: Go ahead.

CHAIRMAN SELIN: Remember, it's not like we're starting from scratch. We have 29 indicators today and they only cover about a third the area that these 13 or so cover. So, the idea is to make progress. It's not as if we're suddenly springing a bunch of -- we'd like to do fewer indicators than we do today. We'd like them to be less redundant than today's and we'd like them to be better understood.

Commissioner de Planque?

COMMISSIONER de PLANQUE: I have a problem in this area too and I think what essentially happens is people count the beans when they can't figure out how to quantitatively evaluate the soup. What we're really after here is what's the quality of the soup.

So, if we don't accumulate the data, somebody will. The data will be ferreted out somehow. I look at things like the bean counting items, like misadministrations and over exposures and contamination events and things like that and I say, "Yes, we need to look at these data." But I agree with you in the sense that we need to know how to look at those data and how to evaluate them in terms of the quality of the soup.

So, something like misadministrations, maybe you look at that as a rate. But when you get into things like over exposures, over exposures compared to what? I don't know the basis for comparison on some of these, either comparison from state to state, NRC to state, or within a state from time to time.

It seems to me what we're all struggling with here is how do you look at some of these measures and make sense out of them in terms of the overall quality of the soup. I think we have to face this collectively in terms of what do we do with these data when we get them. What's the bottom line? And I don't know that we've found the right answer yet.

DOCTOR KULIKOWSKI: Yes. I think, as you pointed out, that, depending on the category of data

that you're looking at, I think the rules will change. And I think that's what we're professionals in the health physics field for, because we have the expertise to do that.

I think the concern that I want to voice is that there not be sort of a transferral of how well a program is doing, i.e. the quality of the soup, to the number of beans in that soup. For example, a particular performance indicator, we probably have more diagnostic misadministrations in New York, but we also do five percent of the nuclear medicine procedures in this country every year. So, you really need to put the indicator, if you will, or the piece of data that you're looking at into its absolute context so that it cannot be used unambiguously and I think that's one of the concerns that we voice.

I think the discussion here today really points to the fact that we really need to go back and revisit this topic before we plunge headlong into it without realizing what the far-reaching consequences may be.

COMMISSIONER REMICK: And that's why I have a concern with calling these things indicators, because I'm not sure what they indicate.

Data we need. I think you go down, you

can justify that that data is needed by this agency to know in this country how many of this and how many of that, but as an indicator of an individual state program or NRC program, we're not sure. I would justify it as data, but I have trouble calling it performance indicators.

DOCTOR KULIKOWSKI: I definitely agree with you, Commissioner Remick. I know I've devoted a whole section to data, because my scientific training is as a research scientist and so I look at data and recognize it as a very essential portion of what we do in order for us to make a logical judgment on how to proceed in the future. If we find that data set A shows that there's not a problem in that area, we can certainly then shift our resources to addressing a problem which data set B shows there is a problem. I think that's what we need to do as managers. I do that all the time with the staff in the office.

If I have an inspection which is due, for example in a teletherapy unit, and I have an incident to respond to, a transportation incident in one of the airports, and this teletherapy licensee has got a good track record, I think I can put him off for a month without feeling that I'm going to jeopardize anybody's health and safety and I will go out and address the

situation which requires immediate attention. We need to be able to do that, and you do that by looking at the data.

COMMISSIONER REMICK: You give me an excuse to come back to a question I was going to ask. Earlier you said something about the fact that machine-produced radiation was twice as large, I assume in your state, than others. I was going to come back and ask you, how about the amount of effort required? I would assume that machine-produced you probably don't spend as much effort as you do with Atomic Energy Act materials.

DOCTOR KULIKOWSKI: We spend just about the same amount of effort for our particular program, about the same number of FTEs. We have about between 600 and 700 materials licensees, about 400 of which are medical, of which about 12 of those are medical broad scopes. We have in excess of 15,000 x-ray tubes of which only 53 are linear accelerators or therapy machines. And because of just the programmatic way of licensing and inspection, a materials facility is significantly different from the way a piece of equipment is inspected. We can run both programs with about the same amount of FTEs in each one, a little bit more on the x-ray side.

COMMISSIONER REMICK: I imagine your inspection frequency for x-ray machines is much less than you are for atomic energy material, Atomic Energy Act materials.

DOCTOR KULIKOWSKI: They're roughly equivalent.

COMMISSIONER REMICK: Are they?

DOCTOR KULIKOWSKI: Because we try to set our inspection frequencies -- and again this is just our program, not the agreement states collectively -- we try to set our inspection frequencies based on potential for risk and then track record of the licensee or the registrant so that, for example, our teletherapies we use the same inspection frequency as the NRC does, which is yearly, but we have the latitude that if it's a good facility we can extend it to every 18 months or we don't get so upset about it if it goes a little bit over a year. Other places we have -- you know, we're there, 365 days we're knocking on the door, and we do the same thing with the equipment.

COMMISSIONER REMICK: Okay. The reason I make that statement, I come from a background where the state was not an agreement state and therefore the NRC material inspections were far more frequent than

inspections by the state of x-ray machines, and yet I felt the research uses of x-ray machines in many cases was far more risky than the handling of Atomic Energy Act materials.

DOCTOR KULIKOWSKI: We try to assess the risk as well as you can by category, but none of our inspection frequencies exceed three years, so for everything we're three years or less with linear accelerators and cobalt-60 machines being annually inspected, comparable.

I'll just sum up the IMPEP -- I'll just use the acronym for now, recognizing that we really should do more talking on the subject -- by stating that the agreement state interaction is absolutely critical and it's essential if the program is to succeed. We're all in the same canoe paddling up the stream on this one. And again, it's someplace where people have felt that the FACA legislation has precluded the most effective communication between the two organizations.

COMMISSIONER REMICK: There's one bullet there where you said "resultant actions must be applied equally." I wasn't quite sure. Do we use the same firing squad or what was meant by that?

DOCTOR KULIKOWSKI: In several instances,

concerns were voiced that the reviewer when he reviews his own henhouse, if you will, for lack of a better word, may be applied differently because these are going to be -- I mean, there is a certain amount of subjectivity and there was concern that, if you find condition A in an NRC region and condition A in an agreement state and you want some remedial action because you feel that it's detrimental, that it should be applied fairly to everybody.

COMMISSIONER REMICK: I see.

DOCTOR KULIKOWSKI: (Slide) The medical program, on the next slide, has several bullets. And this is perhaps of more personal interest to me because of the large number of medical facilities that we regulate, but it certainly is an issue that I've been involved in over the past four or five years in various relationships with the NRC on the quality assurance and hence quality management rule as well as the medical issues associated with the Conference of Radiation Control Program Directors.

I think we all recognize that this is beginning to become a very rapidly changing field from when nuclear medicine started back in the late '50s and early '60s in force, and there have been -- I saw a response, and this was discussed at the managers

workshop at Hunt Valley last year and there was a response, and I've forgotten exactly who wrote the memo to whom, but it alluded to the fact that the medical area was being looked at and there would be changes anticipated in late 1997, which is almost three years from now, almost four years from now. That's probably much too long of a time frame and I think there was some discomfort on having gone through Part 20 over the last number of years, that the same problem should be avoided, that there are issues that we're dealing with that affect direct clinical care, that affect direct patient exposures, and they should be addressed and they should be addressed coordinately by the agreement states and the NRC.

Just as an example to support this, I had one of our licensees' representatives in our office last week who had come to pick up an amendment to use strontium-89, the new therapy agent to palliate the pain from bone metastases. She said to me, she said, "But Doctor so and so is not on the license," and I'm going, "Well, he doesn't meet the criteria published in our regulations which are exactly the same as those in Part 35," which was board certification in diagnostic radiology by the American Board of Radiology.

She said, "That's really strange because if you look up here, the same person who is board certified in radiology by the American Board of Radiology can use this material and this person probably has never injected any radioactive pharmaceutical in his life. He knows how to use an x-ray machine, he knows how to use a linear accelerator and maybe a cobalt unit."

But it's time that we really look at the whole medical area and this being just one example, do what we require of physician and other authorized users, is that training that we require of them? I'm not saying who provides the training, whether it's the board certification in ABR, but are the basic standards and the basic requirements for the types of things that they're trained in, are these adequate to adequately protect public health and safety? When you let someone who is boarded in diagnostic radiology who's been practicing for a number of years, who has maybe been certified in the early 1960s doesn't have a clue as to how to inject strontium-89 without causing some severe detriment to the patient.

So, I think that's just one example of concerns, looking at the whole medical program.

CHAIRMAN SELIN: Can I just come to --

DOCTOR KULIKOWSKI: Sure.

CHAIRMAN SELIN: This target date of late 1997, I don't know the reference, but the problem is that there's such delays built in the compatibility process that if we knew today exactly how we wanted to change the program to address the question that you brought up and related questions, it would take us a year to do a rule and then three years to propagate it through the agreement states. So, the point was not that we're dragging our feet, but the structure of the process has long delays built in it. I think what we're trying to get at is it would be very useful if thinking together one could come up with some reasonable interim solutions, either an ability to fast track certain regulations that have a high health and safety content or some voluntary way to get these adopted before compatibility requires them because these are just the structure of our doing the rule, which we need to figure out how to speed up where we know -- first of all, you've got to figure out what you want to do. But even after that, we have to do a rule and then the states have three years to adopt it, even if it's a question of strict compatibility, et cetera. The delays are too great.

DOCTOR KULIKOWSKI: Yes.

CHAIRMAN SELIN: We need to figure out what to do in these health and safety issues.

DOCTOR KULIKOWSKI: Right. I'm tossing this one on the table because I think it's a problem that we both need to look at and I think there's a lot of expertise in the agreement states both from a managerial aspect, maybe there are other ways to address this, as well as the technical expertise to say, "This is what's needed."

I guess basically the message is you don't have to go it alone and the states don't have to follow. We can be right up there or we may be proactive and take the lead on this. These are certainly options and say, "Look, this is the solution that we've come up with and what do you think of it?"

CHAIRMAN SELIN: Going not to the medical side but the procedural side, clearly the trend is to move agreement states and not fewer. The reasons are open to some speculation, but so long as that's the trend, this idea that NRC writes the regulations and then propagates them, there might be a better mechanism altogether to get the improvements into the field. This program was originally set up as if there were going to be an NRC program and a few agreement states and the balance of licensees is either already

shifted or is about to shift. The very structure of how long it takes to get things out and how they should be gotten out is --

DOCTOR KULIKOWSKI: Yes, I think this --

CHAIRMAN SELIN: -- something that your advice, your collective advice would be very helpful.

DOCTOR KULIKOWSKI: Yes. I certainly agree and I think the medical issue is just one example. But I think the entire managerial mechanism probably can do -- in this day of downsizing government, that's all I hear from our new mayor, is that we're going to downsize, we're going to downsize.

CHAIRMAN SELIN: While improving the performance.

DOCTOR KULIKOWSKI: Well, yes, and providing more services.

CHAIRMAN SELIN: He has prospects of becoming a governor or a president.

DOCTOR KULIKOWSKI: I guess. But the bottom line is that we really need to really work on this problem together. It provides an opportunity to come up with some innovative ways of doing it and not only protecting public health and safety, but making government more efficient at the same time. I'm sure that we realize that this is a reasonably complex

area. The agreement state organization chartered an ad hoc committee on medical use of -- of which Bob Quillin from Colorado is the chair and Bill Bassetti from Florida and myself are the other two members. We have collected an awful lot of data and one of the problems is that it's been some overwhelming because of the differences in material that we've found from state to state. It's not an uncomplicated area to regulate. I think this is one area that will be very fruitful for us to work very closely together on.

(Slide) Which brings me to the next to the last slide, I believe number 8, on data collection, reporting requirements and requests.

As a scientist, I know that when you collect data you've got to have a very high degree of confidence that the data is correct and that it's reliable if you want to make any decision based on it. That goes true for any regulatory decision as well. I think the views that I had from the states were that the development of the data sets must be by consensus. We need to sit down at a table and say, "This is what we want to collect and this is what we need to collect in order to make an informed decision about areas A, B, C and D," and that's not to say that these are cast in stone and can't change from time to time. But it

must be by consensus of NRC and the states. If we want to have a nationwide database on any particular topic, there will be much more likelihood of having a complete and accurate database if we all agree what we're going to collect and we can educate our licensees as to what we want to collect and the reason for collecting it and why it's important. I think that's part of the problem. When people are just asked, "Give me X, Y and Z," and you have no idea why, you tend to do something that is a higher priority than providing someone with a list of decontaminated sites, which were decontaminated 25 years ago, as an example.

Which brings me to the concern about knee-jerk reactions. Frequently the states feel that there are -- we're just asked for things for the sake of being asked for them. There are programs that we run which are integrated programs, as I said earlier, with both materials and machine produced radiation and there may be other responsibilities, radon, and we don't do just materials licensing and inspections. That sometimes puts unfair burdens on us.

For example, the most recent one I can remember is getting a request for experimental human studies not involving radiopharmaceutical development

that occurred before 1975 in our program and we'd like it within five business days. I just said, "I can't deal with this," and I just haven't even had a chance to write back a memo saying I can't deal with this right now. Just to get things out of our archives is longer than five business days.

So, I think we need to have some more maybe even informal communications saying, "Can you get stuff like this to us or what's the feasibility of it?" before we get an absolute request.

Talking about data collection in general, as I said earlier, we don't disagree with this. We think it's a very important part of running our collective program, to make sure that we have data so that we know if there's a problem area, we can identify it and we can identify solutions to correct it. In addition to the ad hoc medical community that the organization had, we had an ad hoc committee on reporting data, the report of which was transmitted I believe to Chairman Selin in August. We've not had a response at this point and we were wondering what was happening with a response.

I know AEOD has had a workshop which was sort of short notice and a lot of us couldn't get to, but we're still very much interested in the data

collection, making sure that it's a good database and that we can all share it and benefit from it.

CHAIRMAN SELIN: Let me make a couple points.

DOCTOR KULIKOWSKI: Sure.

CHAIRMAN SELIN: Commissioner Remick has pointed out the basic concept that if one has an indicator one should know what it's going to indicate and it's hard not to agree with that.

DOCTOR KULIKOWSKI: Sure.

CHAIRMAN SELIN: But the concept of indicator and the concept of data are somewhat different. When we're talking about indicators, which may not be the most felicitous phrase, we're talking about composite measures, whereas when you're talking about data you're talking about relatively raw -- I mean there are lots and lots of data that you need and lots and lots of data that we need. When we were talking about performance indicators, the idea was to reduce either by combining or smoothing down to a relatively few sets of time series that we were going to try to track. So, we weren't talking about data in the same sense that you're talking about here.

We do need to talk some about this because -- and our responsibility here is not

identical to that of the agreement states. We need to do an overall evaluation not only of individual agreement states, but of the Agreement State Program per se. There could be places where we think we need some data that the agreement states just don't agree with. We still will require those data if it comes down to that. Hopefully it wouldn't come down to that.

As far as your report, it deserves an answer and it should have had one. But the answer was there's a lot of material in there. We need to think about this in the context of the indicators and the context of what are we trying to do with the program. But the main point I'd like to make is that data collection here and the discussion of the performance indicators I really don't think are quite different.

DOCTOR KULIKOWSKI: Okay.

CHAIRMAN SELIN: I think they're different points. We don't expect out of the performance indicators as much as the states seem to think we had in mind. They are sort of intermediate composite factors. But here you're talking about basic data, knee-jerk. You're absolutely right, of course, about the old files. On the other hand, we do need more information than we get on at least therapeutic

misadministrations and a number of this other material.

DOCTOR KULIKOWSKI: But I think material data in the latter sense of numbers of events, for example, of what happens and I think that can be used both ways. There are -- for example, on therapeutic misadministrations, you may look at particular trends for a particular type of equipment that's going on to see whether people need more training and how to use it correctly. So, I think it needs to be done that way. I think to use data in the "performance indicator" sense requires a lot more care. As Commissioner de Planque pointed out, that's looking more at the quality of the soup. There are times when bean counting is very effective and it will show you something. There are other times when you've got to look at the more global picture.

I think this whole scenario really needs to be discussed with the states a lot more in depth because I don't think the states have this feeling, the same feeling that you've just presented. I know it was my personal opinion that they looked like two very different animals at this point. There was data gathering and then there were these list of things that we were going to be graded on, for lack of a

better word.

COMMISSIONER REMICK: To make sure I add to the confusion, your examples or several of the examples you used on data collection I agree were kind of short-term needs and so forth. What I was referring to before was some of the things that our staff is referring to as operational indicators I think are better classified as data.

DOCTOR KULIKOWSKI: Okay.

COMMISSIONER REMICK: Contamination events. I don't know if that's an indicator or not. Maybe it is, but it hasn't been justified as that. So, I was specific when -- my previous reference that I thought that data was a better use than operational indicators of things like medical misadministrations and over exposures, some of those might be justified, but as they are I see them as data that we need. As I say, I can justify that there's a need to know what that is nationally so we have some kind of a feeling and so forth, but I'm not sure I would call it an indicator.

DOCTOR KULIKOWSKI: I don't disagree with you. We need to sit down and talk about terminology --

COMMISSIONER REMICK: Sure. Sure.

DOCTOR KULIKOWSKI: -- and then say, "What you're calling data is what we're calling data." For example, misadministrations. They can be data in the sense that you look at them as beans and you say, "We're not seeing any iodine misadministrations anymore. We're only seeing strontium-89 misadministrations," what have you.

COMMISSIONER REMICK: Yes.

DOCTOR KULIKOWSKI: And that in and of itself tells you something.

COMMISSIONER REMICK: Sure, it's information.

DOCTOR KULIKOWSKI: However, putting those data in the context of the program is really looking at, as what Commissioner de Planque said, is the quality of the soup and that I think where we need to be extremely careful, that the number of events is used as some sort of indication of how the program is doing because that -- I think that's where the real thin ice is beneath the agreement states' feet at this point.

CHAIRMAN SELIN: Sure, but let's follow-up on that. First of all, we were talking about medical misadministrations. There are at least three things that we don't do now that we need to figure out. The

first is I'm convinced we're getting quite incomplete report of misadministrations, in spite of whoever signed the letter saying, "Why can't I believe that the states only have a third the misadministration rate that the NRC states do?" That's much less plausible than other hypotheses. I mean it's much more likely that the reporting is incomplete and that the NRC states are having three times as high a level of misadministrations as the agreement states.

But the second is maybe we don't have the definitions of misadministrations down very well.

But the third thing, most importantly, we don't know how to rationalize the denominator. We don't have data on the number of correct administrations. We don't know what we mean by a correct administration. We do need the data on misadministrations, but to do anything with it we need other things that we don't collect today and I don't think agreement states collect and that's the total number of events. Not the misevents, but the events. We don't even know whether we ought to be measuring a misadministration per sequence or per -- I mean there's a lot to talk about. It doesn't mean that we shouldn't collect the misadministration data, but we're very much handcuffed in what we do with that

until we figure out how to normalize that and how to get some surrogates for the normalization factors, even if we can figure out where to do it.

DOCTOR KULIKOWSKI: That was my point.

CHAIRMAN SELIN: So, there's a lot to do, but it doesn't mean that we shouldn't get better data on misadministrations, even though there's clearly no mechanical way of taking these data and say, "What should we include about these misadministrations?"

DOCTOR KULIKOWSKI: Right. I mean that was my point exactly, that you can gather a set of numbers or a set of discreet information points, whether they're numbers or more fine than that, and manipulate them. You can number crunch them and you can spread them out and you can do any number of things and add more data to them or put them into different contexts to give you different answers and different types of information, which I think is really the point that Commissioner de Planque was making, that you can look at numbers of events or you can look at numbers of events relative to the total number of events that are performed or you can put it into context of whether they're in agreement states or not agreement states and how many, what the proportion is. There may be more in non-agreement states because

there are a number of procedures performed in non-agreement states or that treatment modalities have changed, that there's a decrease. I mean we'll probably see more linear accelerator misadministrations in New York City than we will see cobalt units from now on because if you graph out the number of units, we see a steady decrease of cobalt units and a steady increase of linacs. So, just because they're in use more, we'll see more absolute numbers of events, but we may not see a greater ratio of events per total number of administrations or denominator.

CHAIRMAN SELIN: But I contend we start off by collecting better information on the misadministrations. As we see what the numbers are, then we can intelligently say -- I don't mean to crunch them and say, "Here are some factors," but say, "Where do we need to do more work to put these in context?"

DOCTOR KULIKOWSKI: Part of that could be what other data do we need to collect to supplement this. I think this is an ideal opportunity for the Commission and --

CHAIRMAN SELIN: But we don't hold off on collecting the misadministration because it's too hard

to collect the correct administrations.

DOCTOR KULIKOWSKI: I wasn't maintaining that. If I gave that impression, it was erroneous.

COMMISSIONER de PLANQUE: I think this is the point that you've been trying to make, and if we think it's difficult with misadministrations, what's the denominator on over exposures if you're looking at the over exposure rate? What's the denominator in contamination events if you're looking at the contamination event rate? I think these are the things that need to be worked out yet. What do you do with that? You can collect data on over exposures, you can collect data on contamination events, but again what does it tell us about the soup?

DOCTOR KULIKOWSKI: Sure. I agree with you. And just on over exposures, if it's 100 MR in a year, that's different from 100 MR in a week. We're looking at really moving targets here and I think the bottom line is that we need to be extraordinarily careful, collectively extraordinarily careful as to what we collect and how we use those data, data used in the most generic sense.

(Slide) I'd like to finish up by touching on a couple of other subjects that people commented to me about. On the next slide, on slide number 8, I'll

take the easy one first, the codification of agreement state requirements. Probably nothing else rankled more agreement states collectively than saying, "We will write regulations for the agreement states."

CHAIRMAN SELIN: But that's not what we said, or at least it's not what you should have heard. The intention was saying that if you look at it purely as an NRC problem, you can't go to any set of documents and say, "What do we today require of the agreement states? What's the basis for this? How do we run our operation?" The idea was not to set down a new statutory basis for the relationship between the federal government and the agreement states. The idea was to take a whole lot of stuff which is spread out in letters, memos for the record, memories of people not within the program and say, "What is the NRC program? What do we require of the states today? Not what should we require, but what's the description of our program?" and try to get it written down in one place.

Furthermore, there's so many changes going on in the program. We're not seriously considering trying to do this now or trying to get the program to settle down somewhat further. But it's not fair to anybody, it's not fair to our staff, it's not fair to

the agreement states, it's not fair to those who oversee our own program, to try to figure out what we're doing when you can't find out what our policies are about this or not. It's not a prescriptive program we're talking about, it's a question of putting in one place and putting somewhat clearer what the current situation is or what the current situation will be when it's been modified by some of these major changes that you've been describing.

DOCTOR KULIKOWSKI: Okay. Just two points. One, I agree, we'd need a set of groundrules to play by.

CHAIRMAN SELIN: Right.

DOCTOR KULIKOWSKI: And, you know, whatever the mechanism is, that's the bottom line, we need the set of groundrules. I think the second point is that it just points out to the fact that there was not effective communication between the NRC and the agreement states on this particular topic because there was a lot of misunderstanding by the agreement states relative to what you just said.

CHAIRMAN SELIN: It's conceivable that some of the miscommunications within organs of the NRC to other organs of the NRC.

DOCTOR KULIKOWSKI: You know, whatever.

I'm not here to dole out the blame to anybody. It's just an observation that this may be one topic that we need to talk about some more.

Lastly is the topic of cost recovery and pass throughs to agreement state licensees. I think this is an issue that needs to be really again looked at very carefully because there are a lot of issues which are not clear cut. The agreement states do provide regulatory input. They provide, in some instances, the initiative for regulations which is agreement states-staff time. We provide a lot of information to the Commission, the NRC as a corporate body and these are all things which we don't get compensated for that are compensated for on the local programs' time.

So, I think we need to really make sure that if there is -- we're probably at a good starting point and say, "These are the costs that we incur for running the agreement program relative to the requirements of the NRC and these are the cost elements that you incur by developing regulations which our licensees have to follow." I think we just need to again sit down and make a laundry list of where the various cost elements are. It certainly is an issue that I deal with everyday, is the cost of

running the program. I have to justify just about every penny that I spend.

So, with that, I would like to just --

CHAIRMAN SELIN: Before we get off of that one, Doctor Kulikowski, this is really a three sided discussion. I believe that the Commission's preferred solution is not to try to assess either the states or their licensees, but to have our appropriators clearly understand that it's just not fair that licensees in NRC states bear the additional costs of running the Agreement State Program. It's really up to the Congress to finally decide how this will be settled out. But we would just prefer that a portion of our cost of running the materials program which supports the agreement states not be put back into the base that we charge to the licensees, but other solutions might come out and some of them would have a deleterious effect on the finances of either the agreement states or their licensees. It's not so much that we should reach an agreement on how to distribute these costs, but we should have a clear understanding. You shouldn't be surprised and your views ought to be made known to your congressman as well when it's done. But the current situation is not stable and it's getting more unstable as the number of states go up.

DOCTOR KULIKOWSKI: I think any of us in government realize that fact and I think we all -- this may be a very fruitful area to discuss with the states because we've had to come up with creative ways of how we share our costs with our licensees as well. We go through this -- just about every two years we go through an exercise like this.

But I would like to just summarize that I think the most important thing is that we communicate the corporate bodies of the agreement states and the NRC, communicate effectively and openly with each other. We are in the same boat and we're paddling up the same stream in the same direction. If we sink, we're all going to sink together. I think that's the bottom line. The agreement states really need a commitment and I think from what I've heard from my colleagues on the agreement states that they feel rather tenuous about this. But they need a commitment from NRC that we are indeed viewed as co-regulators and that we collectively, the NRC and the states, implement a nationwide radiation protection program.

This really boils down to just an issue of mutual trust. We really need to really work on that issue. That may be more important than anything else that we do.

Just in conclusion, the Organization of Agreement States, and I think the agreement states collectively, look forward to developing an effective working partnership with NRC so that we can ensure our common goal. I personally look forward to working with the members of the Commission, the members of all the program staffs and the NRC and my colleagues in the agreement states during the coming year.

Thank you.

CHAIRMAN SELIN: Well, thank you very much.

I'd like to make a couple of comments. One is this is very helpful. Second is the NRC is much more interested in the Agreement State Program, not much less than we've been in the past. I wouldn't say we're more or less committed to it, we've always been committed to it. We think it's a good idea and, more importantly, the law says there shall be an Agreement States Program and our job is to make it work as well as possible.

One of the reasons perhaps that there's been so much disquiet is that things are changing. One reason that things are changing is that the Commission itself has gotten much more involved in the program rather than delegating it to an effective but

somewhat isolated office, and that's got good things and it's got bad things. You'll get to communicate with the decision makers a lot more directly that it's been in the past. But we also are worried about how the program should best be operated.

The fourth thing I have to say is that we have in some places been insufficiently sympathetic to the strong performers, but also insufficiently rigid with the weaker performers. We've put states into the Agreement State Program that clearly in retrospect weren't ready to come in at the time. We've carried states that should not have come in. We and the organization have got to deal with the strong performers where we all learn from them, but have tools that are appropriate to the people who aren't solving their jobs, whether it's from resources or what have you, so that we don't tar the whole group with the same brush, that we have approaches for states that have just not been compatible for years or don't have adequate resources. They're different from the ones that we have for the strong programs.

We are very strongly committed to this program. We see the Agreement States Program not only as a healthy program, but one that's going to expand rather than contract over the future and we're trying

to settle some hard issues that have gone unsettled for too long to provide a stronger foundation for growth. These issues are what is our role, what do we care about state resources, do we care about it or not, and the answer is sometimes we do and sometimes we don't. It depends on how the state program is doing. What do we mean by adequacy and compatibility? What is our responsibility for assuring the general public and the guys at the Congress, their elected representatives, that these are happening? What are we doing about our own materials program and how does that get reflected in the state program?

These are all weighty issues. We not only welcome, we need your help. You have 29 independent experiments on many of these same issues and we'd be very foolish not to learn from them. But it's going to be tough love in the sense that we need to learn with the good folks, but not tolerate such cavalier performance on the part of what's usually about a half a dozen states at a time at the other end. As this session has shown, I think it's shown there's a lot of room for further communication, so we have to spend some time on the modalities of improving these communications, the first topic that we discussed today.

We look forward to communicating with you probably more formally, but also much more frequently and in a much more, you know, straight -- here are our problems, how do we solve them together in a number of mechanisms.

Commissioner Remick?

COMMISSIONER REMICK: I have one question that I'd like to ask you, and, if you feel you would not like to answer it, I certainly understand, but I appreciate constructive criticism.

I have a sense that there's some dissatisfaction with our medical program, but I'm not sure what it is. From some of the things you've said, I could maybe -- is it a question of is it too stringent? Is it too inflexible? Is it not well thought out? Is it too prescriptive?

You've said before that you wanted things to be unambiguous, but I think sometimes unambiguous is the sister of being too prescriptive and sometimes we're trying to move more in the performance area and then things aren't so well-defined and are subject to interpretation.

But, am I correct that I have a sense that you're not happy with the NRC medical program and would you share with us, if I'm correct, any thoughts

you have along that line?

DOCTOR KULIKOWSKI: It's probably too strong to say that I'm not happy with it. I think it's just -- and I personally have more of a sense of it, because I regulate a large medical community. I think it's probably one of the more important programs in that it involves ensuring patient safety directly, and I'm not sure that I totally agree with Chairman Selin's characterization that a license that's not been issued for two years is protecting public health. I mean, there may be a worse detriment by not having those people treated than there is by having -- you know, we should really look at getting things out in a timely manner and ensure that they run safely. I think we need both components.

It just seems to me, and I've heard this because I have a number of friends in the biomedical community in our jurisdiction and having lived on that side of the fence for a number of years, that this is probably one area, and I'll be perfectly blunt, where the communication really does not exist as well as it could.

It seems to me that there's -- I've heard from colleagues or from people in our regulated community that there have been presentations by NRC at

Society of Nuclear Medicine meetings and the agreement states didn't even -- I mean, I called several colleagues of mine in the agreement states and said, "Did you know about this?" And they go, "No, what are you talking about," and they're talking about, you know, the future of the medical program, and I think that it's probably one of the areas where there's a little skittishness on how effective and trustworthy communication is between the two entities.

So, it's not so much with the regulations. I mean, I think it's been pointed out through several mechanisms that we probably need to go back collectively and look at several areas to make sure that they're up to date, given the changes in technology, but then it's more the philosophical approach to it that's caused not only myself but several other of my colleagues discomfort as well.

COMMISSIONER REMICK: That's very helpful.

I certainly welcome your comments today and greatly appreciate them. I came into the meeting with a little bit of concern that we -- we certainly have to move ahead on these things, but I am a little concerned we haven't thought these things out completely. I think we've made some big steps, but I must admit I'm a little concerned that we run off and

start pilot programs and so forth and we haven't thought out a lot of the things that we talked about, plus some others.

But I do appreciate your comments, your candidness, and thank you very much.

DOCTOR KULIKOWSKI: I thank you for the opportunity to be able to do this.

COMMISSIONER de PLANQUE: I have no further questions or comments, but I do want to express my appreciation too for your coming and sharing your thoughts with us and I hope we can do this more frequently.

DOCTOR KULIKOWSKI: Thank you very much.

CHAIRMAN SELIN: By the way, I'd just like to make one other small remark. There's a general feeling that, you know, you caught a little bit of some of this knee-jerk, that Congress beats on us and then we beat on the -- there's no congressman who gets reelected by beating up on the NRC. When a congressman or congressional committees express some interest, it's usually because there's a real problem there, not just a chance for a couple of easy -- there are always some easy points at our expense, but, you know, nobody gets a big benefit out of those.

DOCTOR KULIKOWSKI: No. I fully agree

with that. I mean, I've gone through similar exercises with our city council. Right before the agreement state meeting we had one of those.

CHAIRMAN SELIN: Fair enough.

Thank you very much, Doctor Kulikowski.

DOCTOR KULIKOWSKI: You're quite welcome.

CHAIRMAN SELIN: We look forward to frequent and varied communications.

(Whereupon, at 3:29 p.m., the above-entitled matter was adjourned.)

CERTIFICATE OF TRANSCRIBER

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

TITLE OF MEETING: BRIEFING BY AGREEMENT STATES ON THEIR ACTIVITIES

PLACE OF MEETING: ROCKVILLE, MARYLAND

DATE OF MEETING: FEBRUARY 8, 1994

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

Carol Lynch

Reporter's name: Peter Lynch

ORGANIZATION OF AGREEMENT STATES

AGREEMENT STATE ISSUES

Commission Briefing

February 8, 1994

Robert R. Kulikowski, Ph.D., Chairperson
G. Wayne Kerr, Past-Chairperson
Richard Ratliff, Chairperson-Elect

BRIEFING TOPICS

- *Introductory remarks*
- *Status of Agreement States*
- *Compatibility*
- *IMPEP*
- *Medical Program*
- *Data collection*
- *Other*

STATUS OF AGREEMENT STATES

- Independent co-regulators
- Not licensees; not general public
- Effective communication between NRC and states is essential
- Impediments to communication, such as FACA, must be addressed

COMPATIBILITY

- Major concern and interest to the agreement states
- Postponement of February workshop
- Concern about feeling that the states should not be involved before the regulated community and the public
- More NRC-State interaction is warranted
- FACA has been an obstacle

INTEGRATED MATERIALS PERFORMANCE EVALUATION PROGRAM

- Must be an effective evaluation tool for both NRC and the states
- Should include all programs
- Evaluation criteria must be unambiguous
  - > If criteria are not satisfied, resultant action must be clear
  - > Resultant actions must be applied equally
- NRC-State interaction is critical and essental for successful implementation

MEDICAL PROGRAM

- Length of time for evaluation and changes
  - > Target date of late 1997
- States have considerable experience and interest
- States must be involved
  - > Evaluation
  - > Development and implementation of changes
- FACA should not be an obstacle

DATA COLLECTION

REPORTING REQUIREMENTS AND REQUESTS

- Must be uniform and reliable
- Development of data sets must be by consensus of States and NRC
- Concerns about "knee-jerk" reactions
- *Ad hoc* Agreement State committee

OTHER

- Cost recovery
- Codification of agreement state requirements
  - > Agreement states are opposed to this concept

SUMMARY

- Effective communication is fundamental
- NRC commitment to State-NRC partnership
  - > Mutual trust and credibility