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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

(ACMUI)

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THURSDAY

FEBRUARY 22, 1996

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ROCKVILLE, MARYLAND

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The advisory Committee met at the Nuclear Regulatory Commission, Two White Flint North, T2B3, 11545 Rockville Pike, at 8:30 a.m., Barry A. Siegel, Chairman, presiding.

COMMITTEE MEMBERS:

BARRY A. SIEGEL	Chairman
DANIEL S. BERMAN	Member
JUDITH I. BROWN	Member
DANIEL F. FLYNN	Member
ROBERT M. QUILLIN	Member
JUDITH ANNE STITT	Member
DENNIS P. SWANSON	Member
LOUIS K. WAGNER	Member
THERESA WALKUP	Member
JEFFREY F. WILLIAMSON	Member
A. ERIC JONES	Member

ACMUI STAFF MEMBERS:

LARRY CAMPER

PATRICIA HOLAHAN

TORRE TAYLOR

ALSO PRESENT:

MARJORIE ROTHSCHILD

JOHN GLENN

CYNTHIA JONES

A G E N D A

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

(8:39 a.m.)

CHAIRMAN SIEGEL: We are back on the record and ready to resume the morning session.

Our business is to continue working our way through the questions about the NIS/IOM report and then, when we get around it, to talk about the issues with internal contamination events and security of radioactive material a little bit later in the day.

Where we left off yesterday, and I am unaware, before we go, of any requests for public statements this morning, so we will just charge into our own business.

Where we left off yesterday was essentially a conclusion that this committee was uncomfortable with D as articulated by the committee and felt that a slightly stronger version of D or bordering on E was closer to where we would have put ourselves, thereby indicating that we believe that some federal authority was appropriate and that some centralization of policy making was appropriate and some need to insure that the states would not go off in a laissez faire way, needed to be built into the regulatory system lest there be fifty different versions of Part 20 and some states that regulated medical safety issues and others that didn't touch them whatsoever.

So, that approach, though a little bit different from the NIS approach, still holds to the basic principle of wanting uniform regulation of all sources of ionizing radiation and also believing that regulatory oversight should rest with an agency whose primary focus is health rather than radiation, per se.

Okay. So that is where we were.

Professor Wagner?

MEMBER WAGNER: I'd like to comment and add one thing.

I think we also reviewed the idea that the entire rule-making and regulatory process needs to be examined.

CHAIRMAN SIEGEL: Correct.

MEMBER WAGNER: To find the fault with what we did in the past in order to devise a new regulatory system that would be more effective int he future.

CHAIRMAN SIEGEL: Right. I forgot to include that we recommended that basically Part 35 would be rebuilt or whatever its replacement set of regulations would be.

MR. CAMPER: Question. Lou, do you have any ideas about how such a review should be conducted?

MEMBER WAGNER: No. I was hoping for that from the IOM, like I said. But I think at this time it is the time to start thinking about how that should be done.

My first step would be to look at how we did things in the past, why do we come to the conclusions and the regulations that we have? Why do we have the enforcement agency we have? Why do we feel that the enforcement has too much authority and is a little bit out of control? Why is this and what got us to this point and how do we avoid this in the future?

I think that is what needs to be investigated and looked at.

CHAIRMAN SIEGEL: So, do we want to continue working through Part 35 or would you rather have us just charge into question 2?

DR. HOLAHAN: Well, actually then I think we got into the IOM. Perhaps if we focus ont he IOM report and get into number 2 and them move into --

CHAIRMAN SIEGEL: Okay. That's fine.

We want to talk briefly about the rationale used in Mr. Adler's dissenting opinion and our thoughts on whether he is no standard deviations from the mean or three standard deviations from the mean.

Anyone wish to begin.

MEMBER STITT: I reviewed this again yesterday and you were talking about the minority report, right?

CHAIRMAN SIEGEL: Correct.

MEMBER STITT: And I remarked upon the similarity between what we had discussed at the end of the day yesterday and some of the points that he made.

In the very last paragraph, his concern, "I object to the uniformity envisioned in the report, to wit, a repeal of all federal authority over its medical uses."

He then goes on to say, "I favor re-examination of risks and appropriate restructuring of regulatory approaches," which is sort of amusing because that is the part we discussed yesterday.

I think we have actually more in common with that segment of the report than with the body of the report.

CHAIRMAN SIEGEL: Yeah, I think that we are somewhere in between the two extremes. He makes the point that he is uncomfortable with just assuming that the states will take it up and we made this same point.

He made the point that tearing down the operating, established federal authority and just starting from scratch with the states didn't make sense and we made, essentially, the same point. We thought there still needed to be some central authority.

He made the point that the principles of the Quality Management Rule weren't what's wrong, it was the way that the Quality Management Rule was implemented and enforced and we complete agreed.

So, I think in the final analysis we are not in wild disagreement with Mr. Adler's dissenting opinion, but neither are we in wild disagreement with the majority NIS report. We are somewhere in between.

He makes valid points and we don't think his arguments should be just thrown out with the bathwater.

MEMBER FLYNN: Also, he has a footnote on page 264 and I am sure it is hard to go through this and read every single footnote carefully. But his footnote, number 15 on page 264 refers back to one of the strong arguments made for alternative D which is that -- and this seemed to be emphasized several times.

That, "The NRC and its Agreement States would continue to regulate the manufacture of byproduct material. The manufacturers would not be able to distribute radioactive byproduct material to users unless they were licensed by the states.

Consequently, this requirement provides an inducement to the states to expand and revise their existing control programs to include the byproducts."

He brings up a good point that -- if you look at that footnote, I can find that section.

"The proposal establishes no criteria for the NRC to apply in order to determine whether a state's regulatory program meets some type of standard."

How would the NRC decide whether the states simply have appropriately included byproducts in their program or not? Who is actually overlooking this process? There is no one.

I think a lot of confidence is put in the states and I think that the thing that is missing is that I don't see any comprehensive analysis of current state programs.

I see people who have asked for states to supply documents and many states have not supplied any documents and you assume that these documents exist. But maybe they don't exist. Or maybe they exist and they can't find them.

CHAIRMAN SIEGEL: I suspect the latter, maybe.

MEMBER FLYNN: I don't think that some states really look into these, some very small states really -- it may be a laissez faire sort of program whereby if a major program occurs, then call us, but we have no really active program.

I am suspecting that that could be the case in some states. I'm talking about some of the smaller states. Do you have any other information to suggest otherwise?

CHAIRMAN SIEGEL: No, I don't have other information, but by the same token one could take a counter argument approach of where are the bodies?

So, if you have a state where the practitioners are largely self-regulated and there is a very open approach

and the state does little more than say register -- and there are some states that don't do much more than that. Then it means that the practitioners are functioning essentially in a self-regulated mode with, potentially, the state having the authority come in if a disaster occurs.

In the process -- one of the things that we have gotten into -- and we talked about it yesterday, is our desire to have federal authority because we want uniformity and we want to make sure that the states have some level of involvement.

But I think we should not get into the trap of starting to overemphasize the risks of what we are talking about here.

We all agree that high dose brachytherapy done incompetently has the potential to be dangerous, not only to patients but to members of the general public.

On the other hand, I think this committee is long on record as saying that diagnostic nuclear medicine has to really get bad to start hurting patients or members of the general public.

Even when you look at the abuses, even when you look at the things that the NRC has found to be so egregious like technologist that, on their own accord, decide to double the administered doses of radiopharmaceuticals because that makes the day go faster.

If you actually try to say, based on the scientific evidence what harm has been done to those patients, you are very hard pressed to find scientific evidence that those individuals have been harmed.

Do we think it is the right way to practice medicine? No. But is it an imminent danger to the public health and safety? It is neither that either.

So, I would say we need to be a little bit careful that we don't find ourselves all of a sudden saying that what we do for a living in incredibly dangerous, because it is not more dangerous than the rest of medicine but with a few exceptions at the extreme end of what is involved with radiation medicine.

Jeff?

MEMBER WILLIAMSON: Well, I guess just to follow up on that. In reading appendix L, I think he somewhat exaggerates the risks and exaggerates the importance of the existing regulatory system in promoting quality.

I think the fact that there aren't noticeable numbers of bodies, as you put it, floating around in the 90 per cent of radiation medicine that is not regulated federally, indicates that largely what maintains quality and holds the radiation enterprise together is its sort of internal quality assurance and practices and practice patterns.

I find that he is really arguing in this that federal regulation is an essential tool. I think that although he points out the need for restructuring regulations, I think that he imagines something very similar to the current system is what is needed.

MEMBER FLYNN: Or he imagines that there may be some greater degree of uniformity that we should strive for that we shouldn't have one state that has one set of regulations and another state in Texas or Illinois have a ten fold or hundred fold increase in the requirements.

And I don't think you need to see bodies. I think the problem is that the trend looked at general principles and some of the ones that you spoke about yesterday in terms of ALARA principles.

Well, if people are getting higher doses than they need to, they may not have any scientific evidence of harm, but I don't think it is a good thing to do. And I don't think we should promote states to have ten and a hundred fold variations in their programs.

And you don't see bodies if you don't follow ALARA principles.

CHAIRMAN SIEGEL: Correct. Lou? Larry, go ahead.

MR. CAMPER: I want to make an observation about your comments. It really gets back to Lou's concern that I have heard him say several times now.

Why are things the way that they are?

Your point, and I think it is a valid point, is you are talking in terms of risk. What is the risk here and what are the consequences of some of these events?

I believe, based on my own experience, if we developed regulations and enforcement programs that were purely based on risk only, we would have a totally different regulatory posture.

I think this agency would; I think a lot of other agencies would as well.

Part of the thing that causes the problem that you have raised several times, Lou, is that there are many expectations of regulators by different segments of the population. The practitioners have a view and risk is something that you are familiar with very much in your day-to-day way of doing business and therefore you form a set of expectations of how regulators should behave and treat you as practitioners.

The public has a different set of expectations. Some segments of the population have yet an even more extreme set of expectations. Congress has a set of expectations.

And there is no question that certainly this agency has reacted to even singular event which have in turn been put in place a rigid and vigorous regulatory approach.

And what happens is, over the years, if you react to singular events, at some point when you pause and look at the aggregate you find what arguably some people would call even a draconian approach.

But you get there because of all these different expectations of the system.

So, just an observation from a regulator's standpoint. And of course bodies is not the level at which regulators would be expected to react. The threshold for reaction should be much, much lower than that.

Now, some people that mis-administrations is far too low and I understand why they do. But it is not harm and it is not bodies either.

One other point on Dr. Flynn's comment here on this footnote number 15. The last sentence of that footnote is the one that I found the most interesting and I have thought about this a number of times as I have read this model as proposed.

It says, "Whether or how the NRC would have such authority if all the agency's medical use program, is unexplained." I think it is important to note that under the model as proposed, we would be out of the game. Either

Congress would take us out of the game or we would take ourselves out of the game. We would no longer have an involvement in medical use.

Sooner or later, it is not clear to me, what that means to the existing Agreement State agreements. Because those Agreement States agreements, we had authority for byproduct material at the time.

I don't pretend for one moment to be an attorney and I don't see anyone here from the Agreement States program, but I have to believe that some review would have to take place of the existing agreements and perhaps new agreements put in place or something, with modifications or some sort of codicil to that effect.

But the bottom line is, I think that last sentence is most profound because under the model as proposed we are out of the game, totally.

MEMBER WILLIAMSON: I don't think that report suggests precipitously jumping out of the game. They talk about a transition period I'm sure to address those issues.

MR. CAMPER: Well, I am referring to his particular concern that there be some federal presence and some qualifier for how state's programs are adequate.

And we simply, at some point, would no longer be involved.

MEMBER SWANSON: A thought I've had is a consideration. One way it seems that you could attack this issue fairly rapidly and insure interim regulation would be to take the NRC medical use program, including within that its advisory committee activities and its Agreement State program and transfer that program from the NRC to basically reporting in the DHHS structure.

Along with that transfer, the existing budget would then cover the budget issues that go along with that.

What that allows you to do then is basically insure that you have continued regulation during the period of transition. You can expand on your Agreement State program to basically focus your attention on the non-Agreement States now to begin to bring them up to assume responsibility for their own programs which would seem to go along with this report.

And, also at the same time, you can rewrite the Part 35 regulations within that structure. So that would give you a way to develop a set of "uniform regulations" that the states could operate under.

MR. CAMPER: It's a different model, of course, than the one proposed, and it has a lot of -- it would require legislation.

MEMBER SWANSON: If it is going to require legislation, I think that you would also want to look at a structure in that where if you did do that and that was your

agency and say you called it a commission on the medical use of isotopes, I think you would want to have leadership of the commission that would represent both the medical community and probably the leadership from the existing NRC structure also.

So, you might have like two commissioners of that, one representing each side of the situation which then gives you a system of checks and balances on it.

CHAIRMAN SIEGEL: I don't know how the federal feels about commissions these days, given that organizations that require multiple people to get together to make decisions may be ultimately less efficient than those that have a single administrator.

No offense intended to anyone in this building.

Lou?

MEMBER WAGNER: I think it is important that we understand. And you made the comment, Barry, and I wish to expand on it just a little bit.

What we are recommending really must, must, must have a tempered control to it. The facts are that we are really recommending that we go from a 10 per cent regulatory status to a 100 per cent regulatory status.

We run the very severe risk that at the federal level, the regulatory process will get out of control again and start emphasizing very low levels of risk with very tight

restrictions and make it a far more miserable situation than it currently is.

That risk is there and it is real. And I think it is very important that the recommendations of this committee emphasize that the regulation that is needed is the regulation to protect workers and the public. And that a very strong revolution in how the regulators control the practice of medicine needs to be examined so that we don't get into the over-prescriptive problems that we have had in the past.

I can give you fine examples of how states over-prescribed and make hay-day out of very small risks. I have fine examples of that use of gonad shields in CT, for one. Things like that where silly ideas are brought forth as important regulations. Nonsense. And we have to make sure that this kind of thing doesn't occur in the future.

We run a very sever risk with this kind of a recommendation and it must accompanied by a big precautionary note of precaution in regulating the practice of medicine.

CHAIRMAN SIEGEL: I agree. I think, in part, that is one of the overriding reasons to see this housed in DHHS rather than in the NRC because of the fact that we have reasonable confidence in the fact that the DHHS will look at a regulatory scheme in the light of the overall risks of medicine, the overall resource allocation in medicine and can get a better handle on it.

And I think past experience with DHHS suggests that. They are a federal agency. They have just the propensity to over-regulate based on the last bad experience as does any other federal agency.

On the other hand, I think my experience leads me to believe that the large number of physicians within DHHS, the much greater overall understanding of the health care system, tempers their approach because of the experience that the people that work at that agency have as distinct from the people who work at this agency.

And that is not meant to be an attack; that is just an observation.

You have worked at DHHS in a variety of capacities for a long time now. Do you agree with the statement that I just made?

MEMBER JONES: I think there is the sense of progress that is built in to it. But we are really a data-driven organization and that is something that helps guide us in what we are doing. It is not just our own practice.

CHAIRMAN SIEGEL: FDA is data-driven.

MEMBER JONES: Exactly.

CHAIRMAN SIEGEL: I'm not sure HCFA is data-driven.

MEMBER JONES: No, but I think they try to be.

CHAIRMAN SIEGEL: They try to be. But lacking data, then they just simply decide not to pay for it until we have the data. And that is okay too. I can understand their motive.

Jeff?

MEMBER WILLIAMSON: Following Lou, I just wanted to suggest we not sort of appear to be endorsing the full content of the dissenting opinion because he makes a number of claims here.

One, that the level of risks are much higher than the apparent or no misadministration rates would suggest. He argues that it is not true. That current regulatory enforcement practices are unnecessarily burdensome and intrusive. And, moreover, that regulatory authorities indeed have the right if not the obligation to intrude in the practice of medicine.

That is how I am reading this. He has defenses in this appendix of all those views.

CHAIRMAN SIEGEL: Right. I do not think that we were suggesting that we agree with all his statements , but simply that we agree with some of his concepts about not moving as far away from the federal government as alternative D suggested.

Judith?

MEMBER BROWN: Before we leave it, I just feel it incumbent upon me to make some kind of statement in agreement with the dissenting opinion here.

I guess in the context of Newt Gingrich being Speaker of the House and Pat Buchanan possibly being a presidential candidate and the attempts to dismantle the consumer agencies we have had like EPA, OSHA, CPSC and even FDA, I am concerned about the political climate emerges from.

I guess what I would like to do is agree strongly with Robert Adler in his writing and read the part that I found particularly compelling into the record so that it appears in our minutes, not only in the kind of obscure appendix L of the IOM report.

On page 264 he says, "That so objectionable is federal authority to the committee members that they specifically issue even a minuscule dollop of residual federal regulatory authority. I find this unacceptable.

Regrettably, my experience with state authorities and professional medical societies does not leave me sanguine about their ability to deal with radiation hazards in a completely acceptable fashion.

Not only do state authorities often have limited resources and expertise, they often find it more difficult than would federal authorities to resist political pressure from those they regulate."

I just wanted to second that statement.

CHAIRMAN SIEGEL: Lou?

MEMBER WILLIAMSON: Judy, I agree with you completely, but from a slightly different point of view and that is the opposite can occur.

The state regulators can be so overburdensome that they can interfere with the practice of medicine and actually end of being counter-productive to their charge to protect people by hand cuffing practitioners with higher expenses, higher regulation and attention to detail that is just simply unnecessary.

So, I agree with that view, but I think we have to look at it from many different perspectives.

And I read Mr. Adler's statement and many points in there I agreed with. But I have to tell you I purposely did not look at his profession before I read it. I wanted to see what he had to say.

And as I read it, one thing was very obvious to me: This man has never been directly regulated by the NRC. He has never felt the burden of na investigation. He has never felt the burden of an inspection. He doesn't know what it is like and how the simple principles can be carried to such an extreme that it just gets out of hand.

And that I think is the problem with the regulatory process. I agree with his principles. There is nothing wrong with the principles.

I don't fear the federal authority as much perhaps as the rest of the committee members who perhaps are reflecting upon one all their experience with one aspect of government which was the NRC and the way that it was regulating them.

MEMBER BROWN: I appreciate your comments on that. The part that bothers me -- I don't think anyone is arguing for the status quo here. I think we are all seeing the need to change and the kind of punitive and as you say criminalizing kinds of things that the NRC has done to those that they regulate. At least they made them feel like criminals you are saying.

But the part that Mr. Adler talks about is that the mood of the committee was such that they wouldn't, as he says, "accept even a minuscule dollop of residual federal regulatory authority". That is the other end of the pendulum and I don't want to go there.

CHAIRMAN SIEGEL: Neither do we.

MEMBER BROWN: Right. I am not suggesting that the committee does, but I am just speaking for myself.

CHAIRMAN SIEGEL: Bob?

MEMBER QUILLIN: I want to comment on several things that have been discussed yesterday and today.

One item there has been comments about what state programs have or don't have, who looks at them and who doesn't look at them.

Unfortunately, in this discussion it has never been clear whether we are talking about the current situation or the situation as would be envisioned under one of these options.

But I can tell you what the current situations is for an Agreement State. On an average of two and four years, we have a complete review by personnel from the commission.

Now, under the new program called the IMPEP program, there is state representation on the review team and also the team that reviews the documents, once it comes to headquarters.

So, there is a regular review of Agreement State programs. Now there is not a regular review of any other type programs such as an x-ray program. That is not done by DHHS.

Program directors on request will do a complete review of all activities, but that is only on request.

At the present time there is an oversight, there is a way of looking at whether the Agreement State program was doing a competent job. What its strengths and weaknesses are.

MEMBER SWANSON: Bob, do you find that an onerous process or a --

MEMBER QUILLIN: Well it is a challenging process but I think it is necessary because it is very easy to get in a situation where you overlook something or somebody else is doing is a better way. I think it is a valuable process. I've gone through these kinds of reviews throughout my entire career so I don't think it is an onerous process.

Another issue our authority to be an Agreement State comes out of the Atomic Energy Act and relates to the fact that the NRC has the authority and the NRC gives up this authority, there is some question of what authority we would have then. Especially if another agency didn't get legislative authority to do this.

It is very possible that if the NRC unilaterally gave up authority, nobody would be regulating this area. Especially if HHS didn't get the resources or authority to do it.

So, that is a distinct possibility.

I would also like to comment about a statement that was made yesterday by representatives of the study about their data requests to the states.

We received two separate requests from the IOM. The first, if I remember was just a generalized question. Then there were some specific questions that I think were

shown here in the appendix. I don't remember them asking for a copy of the regulations, but if they did ask for a copy of the regulations, I am sure that we sent them one.

But a copy of our regulations, which consists of everything from protection from radiation to uranium mill tailing regulations is about twice this thickness. And if they asked for it, that's what they got.

And every state does their regulations in a format that follows whatever the state model is, the state numbering system is and they don't follow the NRC numbering system.

So, I am sure that the Institute of Medicine, if they got these regulations, threw up their arms and said we don't know what to do with them now that we've got them because we have all this paper and we just don't have time to look at them. So they just stuck them aside and that was it.

We didn't highlight what they were looking for and we didn't go anything beyond just furnishing the regulations which is what we typically do when people ask for our regulations.

A comment on Adler's dissenting opinion. I have to agree with two things that he said. One is, on page 259 he says, "One simply cannot draw meaningful quantitative conclusions from data drawn from such disparate sources."

And I think one of my problems with the Institute of Medicine report is the data just is not there to support the finding.

But I also agree with another statement. He says, "I repeat my general support for transferring the medical use program to an agency like the FDA," on page 263.

I think that although he has concerns about how this decision was reached and some of the conclusions that were made, he came to the same basic decision that the committee did yesterday when we voted on how we would like to see this program go.

CHAIRMAN SIEGEL: The conclusion that the data are not there is an easy position to take if what you want is the data in a well-digested, uniformly acquired form that came from a single, comprehensive study of byproduct material risks versus non-byproduct material ionizing radiation risks, versus surgery, versus chemotherapy.

Unfortunately, nobody has ever done the study and we are actually on the record as a committee recommending to the commission several years ago, and I remember Commissioner Rogers saying to me why would the NRC have any interest in funding such a study. I recall we recommended that the NRC should actually figure out a way to fund such a scientific study because medicine needed the data. And I agree it might not be in NRC's overall interest to fund the study.

But if you look at the composite information in the literature about the risks of various forms of medical practice, and admittedly you have to do a little assumption generation, but we all know that risk assessment done by federal agencies involves a fair amount of assumption and often times the conservative approach is the one that is taken.

So, even using conservative assumptions, if you couple the analysis of the literature with the experience of medical practitioners who obviously have some axes to grind but are not necessarily intrinsically evil people, you will find that the risks in this realm are not greater than the risks in the rest of medicine.

I absolutely stand on that, and I think that Adler is just one more person that doesn't understand radiation risks has made the statement that he has made.

We are never going to overcome this problem in medicine, the NRC is never going to overcome this problem, the fact that the public at large is simply not capable of dealing with stochastic risk. It is just too complicated for the average member of the general public to understand. They just can't deal with it.

MEMBER FLYNN: And you think the states are?

CHAIRMAN SIEGEL: No, I don't.

MEMBER FLYNN: See, I think you probably misunderstood what I said yesterday. I think there should be some comprehensive analysis of all state programs. And this group of radiation protection program directors should be on that committee. But so should nuclear medicine and radiation oncology physicians and medical physicists.

Because I keep on hearing from you that you are worrying about the state regulators. I think that if we did such a comprehensive analysis between programs, we are not going to recommend more regulations for the states, but we would take away such things as gonadal shields for CAT scanners.

And I think such a comprehensive program would make things easier in Texas, but it might also put at least some minimal regulations that physicians and medical physicists could agree to in states that have nothing.

MEMBER WILLIAMSON: Well, another way to say what you just said is there aren't so many talented thinkers about these problems that we should feel confident that 50 states will install 50 sets of staffs who will be enlightened thinkers about the problem. I think the chances that you can get a credible scientific analysis of risks versus benefits is greater if it sits with a central federal authority than if it sits with 50 individual states.

I mean there are some states that wouldn't even be able to field an advisory committee based on the number of people in the state who have enough real, genuine scientific expertise in these areas.

I don't mean just an average radiologist who finished the residency program and thinks he knows something about radiation risk, but someone who spends a reasonable part of their life thinking about this problem and tries to understand the frame work of risk assessment as opposed to shooting from the hip.

That is why I disagree with the IOM and really think that some central federal authority at some level in the process is absolutely essential, because I think we get a better product if it comes from the best minds collected together, even in this town.

(Laughter)

MEMBER WILLIAMSON: I think probably everybody in their own way has said this on the committee. Just to underscore, just speaking for myself, I think we are also say it should be a different agency. It should not be an agency that is exclusively occupied with safety issues and is in the mode of zero tolerance.

In the hope that we are getting more progressive and not only more effective but also less burdensome set of

regulations for those physicians are practicing according to the standards of practice.

I was talking during one of the breaks and one of the NRC staffers said that the real problem is that the standard deviation on the low end is about 10 per cent of the practitioners that are really bad that kind of drive the regulations.

As a result of the way that we do things, we try to force those the people on the tail to come into the standard deviation, and as a result, we burden all of the 90 per cent.

So, I think some kind of performance-based standard that lets whatever the new regulatory structure effectively get at and motivate that 10 per cent of really sub-standard practitioners without unnecessarily hand cuffing and harassing the vast majority of radiation medicine practitioners that are doing a very good job. Not a perfect job, because a perfect job cannot be done without infinite resources.

CHAIRMAN SIEGEL: Maybe we should make as a recommendation that this new agency, whatever it is, install all regulations with a sunset provision that forces them to be periodically re-evaluated to avoid the kind of ratcheting problem that we acknowledge that has led to current Part 35.

The government by yo-yo problem that simply is not going to go away. As long as we continue to live in a democracy that is structured the way that this one is we will continue to have government by yo-yo. And I don't see any way around it.

Every time there is an event, some congressman is going to say that it is their job to make sure that this kind of event doesn't happen again. He or she will be well-meaning, hold a public hearing, the right people will get exorcised about the problem, legislation will get introduced, our pressure will come to bear on the federal agency that is responsible and there will be another regulation.

The only way around it is a sunset, so that as people tend to forget the thing that precipitated the problem, you at least have the opportunity to look back and say it really wasn't a problem, it was an aberrant single event and we really didn't need this regulation.

That could be one thing you could try to build into a new agency, because you only have to watch the *Washington Post* once a week to get a feel that this is unfortunately the way that this government works.

MEMBER WILLIAMSON: I think maybe another way of putting it is that some sore of risk assessment criteria should be systematically built in to the mandate the regulatory structure.

CHAIRMAN SIEGEL: Well, all regulations have risk assessment, but they are still subject to the political pressure that the yo-yo effect brings to the process. We just have to be realistic that that is the way the government works.

A fresh opportunity to rebuild the system does at least have the option to build in sunsetting provisions into the regulations as something that the system could incorporate at the front end.

MEMBER JONES: I'm asking. Are you saying the yo-yo effect comes about from the regulatory agencies?

CHAIRMAN SIEGEL: I don't think there is any doubt that it comes about from a mixture of public outcry, congressional outcry and then the regulatory agencies sometimes initiate, but often times respond.

As was clearly articulated in this report, it is hard for the NRC to know what line to walk, when on the one hand, we sit here as an advisory committee and the community at large says trust a doctor. There really isn't a problem. There's really nothing to regulate. You've blown this all out of proportion.

And on the other hand you've got the Cleveland Plain Dealer saying how incompetent the NRC has been in protecting the public, and you've got Senator Glenn's committee saying, "You guys didn't do your job." And you've

got the GAO saying, "Look at the chaos in radiation safety protection criteria across the United States and the world." And so the NRC says, we've got to chart a course through this somehow, and let's find something that's somewhere in the middle that doesn't have the regulated community tying us up in court all day long and can least get the senators off our back.

MEMBER JONES: I don't think you're going to get rid of the yo yo effect because I perceive a good deal of it comes from Cleveland Plain Dealer sort of situation.

CHAIRMAN SIEGEL: I agree you can't get rid of it, but an agency can built into its procedure an ability to periodically redo its risk assessments. And risk assessments of a regulation that was created in haste in response to the last yo yo, Nader, had the potential to be rescinded when people have had five years to reflect on the reality of the data.

I mean it's a highly reasoned approach that's highly unlikely to occur, but it never hurts to be a wishful thinker.

MEMBER STITT: Barry, you recommended to us maybe a couple of years ago, "Breaking the Vicious Cycle", and yo yo is such a catchy phrase, but that's what it's about, the knee jerk responses to public outcry, and Congress people that are trying to get their name in front of their constituents to

keep their visibility high. But that's a very interesting discussion.

CHAIRMAN SIEGEL: Steven Bryer was right on target on this.

There's the other book. Did I send you all an e-mail about that science and nonsense, or whatever? That book by Stephen Milloy? Because that is an amazing book. It's a book about how the science of risk assessment can be twisted to make it conclude almost anything you wish it to conclude. The case control study is an interesting scientific methodology. And if you haven't read this book, it's 50 pages. It's free. And those of you who want it, I'll send out another e-mail message after this meeting telling you how to get it, because it's both entertaining and damnably true.

MEMBER QUILLEN: You can also order it by e-mail too.

CHAIRMAN SIEGEL: You can order it by e-mail. It's a wonderful book.

I think we've addressed Question 2, while continuing to address a big picture along the way.

Question 3 is an interesting one, just to read it.

"On what scientific basis might NRC make a finding that there's no unreasonable risk to the health and safety of the public, and thereby pursue withdrawal per

recommendation." B2, which says, that the NRC should initiate formal steps under the Administrative Procedures Act, to revoke Part 35 in its entirety, if Congress fails to act within two years in response to the A1 and A2 recommendations to Congress.

The question goes on to say,

"With the lack of data cited in the report how could NRC make the findings necessary in Section 81 of the Atomic Energy Act, if current congressional action was not taken. Would this data not be essential to determining the effectiveness of a regulatory program, or are there other bases upon which action could be taken? How could NRC do a regulatory analysis to determine the cost benefit of rulemaking?"

One way of interpreting these complicated questions that Trish posed to us is, on what basis could NRC decide to overturn its existing medical policy statement? That is in part another way of rephrasing it. And, in addition to on what basis they would just throw out Part 35 and stop regulating medicine. And let me start with a partial answer by saying, I think that what we've set up to now suggest that we are sufficiently locked into the concept that, if Congress doesn't act many of the other IOM recommendations become moot, and in a way we're not sure we could tell you a clear scientific basis for just throwing all of Part 35. We

might help you if you loop back to where we would have been without the IOM report. We would have planned on helping you rebuild Part 35 from scratch, based on an item by item risk assessment; what's really necessary in the year 2000; what level of patient protection is really required versus what can we document as being provided by self regulation in the medical community. What level of environmental protection is really necessary. Are assays really necessary with year 2000 generators? And we could have done that, but I think I personally am uncomfortable that we could sit right here right now and quote for you the scientific literature that would say, if Congress doesn't act you should just send Part 34 because the IOM tells you to do it.

Now I'd be curious to see what the rest of you think.

MEMBER SWANSON: I think the question this raises in my mind is, who do you have to justify this finding to? If you need to justify it to the public -- going back to earlier comments -- I'm not sure that any scientific data is going to take away the public's concern about radiation risk, no matter how much you collect. If you have to justify it to Congress, again, I think you're facing the same problem. If you have to justify it to yourself, well maybe that's a different issue. But my sense is that you're going to have to justify it to the public.

MR. CAMPER: Well, Marjorie is here, the Office of the General Counsel. Perhaps she could discuss the procedure and mechanics of that particular component of the Act much better than I, but I would invigor from my perspective that if the Commission were to decided for example to change its medical policy statement, and to address the rationale called for in the cited section, they would certainly have to subject that to public scrutiny. I would envision published the policy change, and it would be subject to comment. There would probably be public commission briefings, etc., etc.

So I think the answer is, in layman's terms, the Commission would have to explain its move to its constituency; that being, the regulated community, the public and the Congress.

Marjorie, you want to comment on that?

MS. ROTHCHILD: Certainly. Could you just repeat the question?

CHAIRMAN SIEGEL: I can repeat it. The question is, if NRC were to decide that it was going to just assume Part 35, the NRC would have to make a regulatory analysis. The things that put Part 35 in place in the first place, which was its judgment that the public health and safety was being protected by these regulations, that it now had scientific evidence that it didn't need these regulations anymore. And

that's really the question. So who would have to be satisfied?

My answer to the question would have been, that the people who have to be satisfied, is the NRC has to build the legal arguments that its statutory responsibilities given to it by Congress have been fulfilled based on this scientific analysis.

MS. ROTHCHILD: Well, I guess I would approach it maybe from a different point of view. I would say that Section 81, which is cited there, the Atomic Energy Act, which is cited in the questions. That has provisions at the end that state that NRC can, if it makes the necessary findings, exempt certain classes or quantities of use from the requirement for a license. So I would assume that that's one basis upon which the Commission, if it wanted to, could either rescind Part 35 in its entirety -- If we're talking about make other major changes that's a basis for doing so.

So I think Section 81 is a place where one might look first if you're assuming that Congress doesn't act and the Commission wanted on its own to say exempt all medical use of byproduct material for the requirement for a license.

So I agree with them, the entity that would have to be satisfied would be the NRC. In other words, if it's going that route, the Section 81 route, that states it can

exempt these uses or quantities provided it makes certain findings.

So, does that answer you question?

MS. ROTHCHILD: I think so.

So further comment on this question?

Jeff?

MEMBER WILLIAMSON: I'm not sure I know if this literature, but I guess before we leave the topic it would be interesting to know if there is any body of literature in the different branches of radiation medicine documenting various sorts. I suppose we could classify things into different -- but probably treatment delivery areas would be the most likely thing the literature would address of one kind or another.

In other words, is there other data besides the collected misadministration statistics, which seems such a tiny number as to make these comparisons like they're 10 more misadministrations this year than last year, like totally statistically meaningless. Where their other data in the professional literature, if anyone knows about that, could be useful in addressing the issue.

CHAIRMAN SIEGEL: That may be handling the question in not quite the right direction on that. This is kind of a tough question. What do we recommend that the NRC just unilaterally withdraw from medical licensure, and

basically -- From the materials end what does that mean if you were to do that? It means that our party material could be shipped in interstate commerce and received by who?

MR. CAMPER: Well if you look at the wording it says, "Exempt certain classes, quantities, or users of byproduct material from the requirements of a license." What that means to me is, is that the Commission can make a determination that based upon some body of evidence that it is not necessary any longer to regulate the medical use of byproducts material, and therefore not have the necessity of issuing licenses for such use of byproduct material.

Now if we assume for sake of discussion that the Commission made that determination, it then does raise a litany of questions such as the one you just posed. And that becomes, what is the basis by which institutions can possess and use radioactive material?

Would the states, despite a departure by a federal agency, which had regulated this area, believe that in the interest of its citizenry and to protect public health and safety, it would be necessary for medical institutions to have a license to possess and use byproduct material? Now obviously I don't know the answer to that, but it raises those kinds of questions.

But, based on my own experience, it is difficult for me to conceive a scenario in which the public would want

the possession and use of radioactive material absent a license to do so by some authority. It's difficult to envision that. But the fundamental thrust of this question is, is that, if one looks at our regulation, Section 81, as Marjorie has said, there is a vehicle available to the Commission to allow such a relaxation. The question would have to be, on what basis could the Commission reach that finding? And you've stated it so very well, Barry. There's just not a body of scientific information that has the right kind of pedigree and credibility that the Commission can turn to and say, this is what we can base this decision to depart upon. And that's what we're searching for, because we like you know, it's not an easy thing to come up with.

It particularly becomes compounded when -- As I was having a conversation with Barry, we were off the record. It becomes vertical when you have a situation where in fact, albeit a few, there had been deaths involved, with the use of ionizing, radiation and medicine. And how does that factor into the overall body of knowledge. Again, bearing in mind that there is a constituency to satisfy; that is, a complex constituency.

CHAIRMAN SIEGEL: There have been deaths, but there have been deaths from antibiotics too, and the only license you need to receive antibiotics is a license to practice medicine.

MR. CAMPER: Right, and what that argues for is that the wrong standard of performance being applied to ionizing radiation.

MEMBER WILLIAMSON: There's also deaths with non-byproduct material generated radiation as well.

MEMBER JONES: This is raising a question in my mind, about Section 81 talks about certain classes and quantities. Do we really want to have the therapeutic part given up by the agency? Perhaps only the diagnostic levels should be turned over to the states or freed up. We're looking at things like alphaemitters coming along. I'm not sure that our agency has that capability or where that's going to come from.

CHAIRMAN SIEGEL: Well, because that's really not what we're saying. What we're saying is there still should be some federal policymaking authority and some federal authority, but with programs that are administered by the states. We are not recommending that this just be turned over to the states, lock, stock and barrel.

MR. CAMPER: Let me just draw a distinction here. But if you focus on Question 3, which is Recommendation B(2). Recommendation B(2) says, NRC, if Congress does not pursue this within two years then you do it. In terms of the contents of the recommendation it's not clear who would assume.

CHAIRMAN SIEGEL: But I think one way to answer that is in a way this is getting concatenated, we've sort of given a vote of no confidence that the states on their own and medical professional societies on their own will do the job adequately. And consequently we are sort of inexorably linked to Congress doing something and failing that. Then what we would help you do is carefully rebuild Part 35, and that might in fact result in exempting some of the things that are currently covered under Part 35. For example, it's possible that the things that are currently -- pollution and excretion, we might say that there's no reason in the world that you need a license to do any of those kind of studies anymore. We might also say, there's no reason in the world that you need a license to use diagnostic radio pharmaceuticals, as long as we were going to be stuck with a system that still discriminated byproduct from non-byproduct material, and byproduct material from other forms of ionizing radiation. But on the other hand we seem to be so strongly on record of being in favor of a uniform consistent approach to the regulation of all ionizing radiation that we would I guess conclude that we really don't support Recommendation B(2) is the final analysis. Because failing congressional action to make it uniform, we're very dissatisfied with the outcome altogether and then we're just back to square one, and we'll help you rebuild Part 35.

MEMBER WILLIAMSON: I just have a question. I'm not too clear in my own mind what the regulatory consequences would be if Part 35 is gone, but all the other various parts of the Code of Federal Regulations that impact on the users, not necessarily medical, byproduct material would have. So, if Part 35 were gone how would the other remaining sections of the Code of Federal Regulations impact a hospital?

MR. CAMPER: Well, a removal of Part 35 would create a domino review effect, if you will. In other words, we would have to take a look at the other parts of the regulations and what those implications might be for medical facilities. If a Part 35, then the question becomes what happens to licensure as we now know it.

MEMBER SWANSON: What happens to patient release criteria?

MR. CAMPER: Well it depends upon what model you look at. If you look at the model as envisioned by the Academy Part 35 goes away in its entirety. Well with that goes the good and the bad in its entirety. Their model supposes that the states would rise to the occasion, would regulate byproduct material, and there would be some guidance provided. But it's not clear at all about what currently exists in Part 35, what would happen to it. I don't think that's clear at all. Frankly I think different states would do it differently.

But getting back to Jeffrey's question, their model calls for Part 35. It also calls for those parts of Part 20 which deal with medical use. Just things as occupational workers and medicine which are effected by Part 20. So if you take strictly their model, what it calls for as Part 35 goes away in its entirety. That raises questions about licensure. They believe the states will pick that up, and the hoop will be that their licensees can't receive material once they in fact have licenses. Maybe that will happen to 81, I don't know.

So the simplest answer is, I think if Part 35 went away we'd have to look at, what other regulations apply to medicine that apply to all other users of byproduct material and determine what that impact would be.

DR. HOLAHAN: I'd just like to add something to that though, as medical use licensees the license is issued pursuant to Part 30, so there is still a license in terms of Part 30, and as Larry said, there may still be a license, and then they need to comply with other parts of the regulations. So it could be that Part 35 would go away, they would still have a license for the possession and use of the material.

CHAIRMAN SIEGEL: Right. And in theory.

MR. CAMPER: That's difficult to envision, because that is correct with Part 30, but if one looks at Part 30, we also issue license to Part 34, to industrial

radiography, Part 35, to medical, Part 36, to radiators, Part 39 to well-logging. I mean specific parts have been created to implement a very general licensure requirement. It's not clear to me that if you remove Part 35 why you would still need to have a license given how we have implemented licensure. I mean it raises a difficult question.

CHAIRMAN SIEGEL: Well if except that if you believe that the principle objective of continuing licensure is control of environmental general public and occupational exposure. If the NRC weren't controlling occupational exposure to radiation OSHA would be doing it, as they're doing it for non-ionizing radiation, or the states would be doing it. Or if you happen to have a Department of Energy funded cyclotron the DOE takes over that responsibility for you. So the protection requirements are there, and you could I think imagine a paradigm where basically you get a license under Part 30 and your responsibility is to ensure that the license material is handled such that Part 20 is complied with; that the members of the general public don't get in excess of 100 milligram per year, and occupational workers don't get in excess of 5 grams per year, and you add one thing which says, members of the general public can get up to 500 milligrams per year from patients released pursuant to medical therapy. And then what you do, you leave it up to licensees to devise the systems that ensure that Part 20 is complied with.

Now, the problem with that of course is that we're right back to square one, which is, whether the licensees are doing an adequate job is in the eyes of the beholder and the beholder in this case is the NRC, and we end up having a series of license conditions, and we're no better off than we were when we started. We might be better off on the first day, but within six months we'll be in much worse shape.

MR. CAMPER: Two thoughts on that. They have models that one can envision to deal with this. The Academy has come back with a particular model. Under their model it calls for the Congress to do certain things and for this agency to do certain things. Their's is an extreme model, if you will, but there's any number of other ways you can tackle this.

The other problem you have in all this, getting back to the model that Barry was just talking about, is you have 40 or 50 years or regulatory history now, and regulatory history like law which is built on precedent, it becomes difficult to depart from, unless you have very strong rationale and can defend that rationale in the eyes of the public. It's just a very difficult thing to do.

But I did want to comment on one thing that Barry had said, with regard to Section 81 and a revision to Part 35, if you look carefully at the word that's in Section 81 it does

talk about exempt certain classes, quantities or users of byproduct material. I would imagine that there's several approaches the Commission would have available to it under that section. In other words, we talked a few minutes ago about the idea that you simply exempt medical use in toto. But I can envision a more workable scenario, an easier scenario to tackle in terms of this committee, if in the final analysis the Commission decides to stay in and we modify Part 35, and you can look specifically at the issue of exempting certain classes of licensees under Part 35 or certain quantities of material, or certain types of users.

The most readily available example that comes to mind is the limited diagnostic application, or diagnostic applications for example. That becomes a little bit easier as a model to work with for this committee.

CHAIRMAN SIEGEL: Until we start talking about the turf issues.

MR. CAMPER: Right, that's true. As opposed to what is the scientific basis for complete and total withdrawal.

MEMBER QUILLEN: Barry, I'd just like to make a comment about something you said which is the OSHA issue. And OSHA in non-agreement states retain authority to look at radiation issues. And if you've ever been to an OSHA

inspection you think that the NRC inspections are easy, because the OSHA inspections are even more onerous.

CHAIRMAN SIEGEL: Correct. No, I'm not disagreeing. We have OSHA come and inspect us for our non-byproduct radiation exposure. It's quite entertaining.

We've more or less answered Question 3.

How much is it worth continuing with 4, in terms of continuing walk through Part 35 or is it premature? We started yesterday.

My concern with walking through Part 35 is I hate to shoot from the hip. It seems to me like that's the subject of a 10 day meeting.

CHAIRMAN SIEGEL: I agree. Clearly if the Commission decides to take the approach that, okay, after consideration either in terms of what they now know or in terms of what they might gain over the next several months or what have you, that we're going to stay in the game. Then clearly at some point there would be a definitive working session of this committee, in which we would carefully dissect Part 35 in painful detail, and determine whether this should go or it should stay, or it should be modified, or how that might be. And I think that's something we would ask you do early on in the game before we went into any type of proposal making or even an ANPR to discuss the issue. So there would

be the opportunity to go through that; it would be an absolute necessity.

I guess the thing that would be interesting at this point in time, rather than getting into some of that detail we were headed down yesterday, just philosophical observations about Part 35, general observations about Part 35, may have some utility at this point. But I don't feel even strongly about that.

MR. CAMPER: Mr. Ayres reminded me yesterday that we hadn't talked about training and experience.

CHAIRMAN SIEGEL: Your favorite topic.

MR. CAMPER: My favorite topic. And so a meeting without training and experience would not be a meeting. It's reasonably clear that one of the things we'd want to see changed in Part 35 is a whole approach to training and experience validation. At least in theory, the paradigm we've suggested in the past is the paradigm we would try to build on, which is one of minimalist radiation safety training and documentation via examination or some deemed organization taking on that function, as opposed to the current system which is artificial.

The alternative approach, just to put the other side of the paradigm, is to raise the bar substantially and make the individuals who are trained at the highest possible level, which runs into potential restraint of trade problems,

but then you can throw out all the rest of the regulations. That's one of Carol Marcus's favorite models, which is, just make sure the absolutely best people are doing the job and then you really don't need the Part 35. Well trained people plus Part 20 is all you need. That would be an interesting topic for debate, but not something we can do in the next ten minutes.

CHAIRMAN SIEGEL: Well what's going on today in health care in efforts to reduce costs and maximum utilization of personnel, cross training of personnel, so forth and so on, complicates that issue even further, and you're right, it would take a long time to get through it.

MEMBER WAGNER: Would it be appropriate for this committee at this time to take on the recommendations that we did give the NRC yesterday, and look for a consensus amongst the committee? And I believe the recommendations yesterday were, that the QM rule should be rescinded. I think the second recommendation was that ALARA as a regulation be removed, but as a concept be promoted. And I'd like to see if on those two points whether or not it would be appropriate for this committee to form a consensus or see if there is a consensus on this at this meeting and make it a formal consensus for recommendation to the Commission.

CHAIRMAN SIEGEL: I actually think we'd reached that already.

MEMBER WILLIAMSON: There was also some discussion about modifying the reporting criteria, and disassociating it from the requirement --

CHAIRMAN SIEGEL: That was part of the discussion that we had, and I've actually been reasonably comfortable that we've reached a consensus on those issues.

MR. CAMPER: Actually you identified three or four key points as a rationale for rapid departure from the QM rule.

MEMBER FLYNN: Let me just comment on something that Bob had pointed out. I suspected that what you had said was true, because states, the way they put together their programs would put them together in vastly different methods, and so to get all this documentation with the states would be very difficult to go through to compare paragraph to paragraph and chapter to chapter. And I'm also assuming that with the 22, or if it's a 21 now, non-agreement states, that because you are used to responding to the NRC because you are being overlooked by them, you are probably more accustomed to getting requests for your documents and having your documents at least cover certain areas for them to review them. But the 22 non-agreement states may not be accustomed to outside entities asking for their programs.

When you talk about rebuilding Part 35, instead of rebuilding Part 35 in terms of actually rewriting it, I

suggest that you consider coming up with minimum core areas in Part 35, and taking these core areas, and actually investigating as a study to see how well each of the 50 states can -- how are they covering these just very basic core areas for the non-byproduct material. And that would be quite a study, but it would be probably very important to do, before you would jump to transferring all of the authority to the states.

I'd be less worried about your state because you are used to having outside scrutiny, than I would be for the 22 states that are non-agreement states.

MR. CAMPER: I would envision that if we ended up going the rewrite Part 35 route, and I think that as part of that process we would want to go back to basics and have this committee work this closely. And actually, Dr. Williamson proposed an interesting model early on in some of his comments yesterday that I think we would want to look at any rethinking of the regulation where you talked about, there are certain things that a general practice is applicable to all forms of radiation. There are certain specific properties of radioactive material that need to be looked at, and of course the question of medical use, and what's the proper role of regulation with regards to medical use. But under a model or something similar to that, a basic review of the very foundation of Part 35 would have to take place before any

rewriting. That would be just an adjustment, a band-aid. What you really need to do is go back to basics and create a new Part 35.

CHAIRMAN SIEGEL: Dan.

MEMBER BERMAN: Just for the record, since you brought up the training requirements issue, I think that the general tenor of the discussions has been that there is for diagnostic nuclear medicine a very low level of risk. And when you look at Part 35 you see rather excessive language dealing with the rate of radiopharmaceuticals, and the handling of radiopharmaceuticals, and then the delivery of the radiopharmaceuticals requiring a very broad training of the user. Pursuant to what you had mentioned before, you had seen certainly in the spirit of recommendations that, if there isn't a rather rapid migration towards the recommendations of the Academy, that any rewriting Part 35 would be appropriate to be majorly reducing the requirements for this limited use of radiopharmaceuticals for diagnostic purposes.

CHAIRMAN SIEGEL: I don't disagree with you. I think many of the requirements related to diagnostic uses don't need to be there. Rechecking in a dose calibrator, a dose that was dispensed by a commercial pharmacy, it's a nice check, but when you get something from the hospital pharmacy already loaded in a syringe you don't send it for chemical assay to ascertain the pharmacist has put the correct material

in the syringe. You trust the pharmacist's professional practice to believe that you're getting the right material. The wipe testing that occurs in most diagnostic nuclear medicine facilities, yes, there is technician present on the floors and door handles of nuclear medicine facilities, but no, the public is not being harmed by that technician, and it will be gone in the morning.

So many of those things could be reexamined on a case by case, detailed basis, and I think they would be. My sense is that we've hit the big picture items in Part 35 in terms of your thinking and talking to the Commission.

We're do for a break. My sense of what we have left to talk about on this stuff is that it's going to be under an hour.

Don't you think?

DR. HOLAHAN: I think so.

CHAIRMAN SIEGEL: Substantially. And therefore I would ask that while we're breaking we see if we can get the folks who want to talk to us about the P-32 related stuff sooner rather than later, and whenever they get here we'll stop and divert to them, and then we'll go back to whatever's left with this and wrap up our business. I'd just soon get them on the docket this morning if we can.

Anybody disagree with that? I'm assuming it's doable?

MR. CAMPER: We'll try to do that, Barry. They're on for 1:00 at this point. We'll pulse them and see what we can do.

CHAIRMAN SIEGEL: Yes. I mean if we can we can; if not, we'll take a long lunch I guess.

All right. Let's take a break.

(Whereupon, the proceedings went off the record at 10:04 a.m. and resumed at 10:30 a.m.)

CHAIRMAN SIEGEL: We are back on the record.

I've had a request from our transcriptionist friend that people not speak directly into the microphone because it's breaking his eardrums. So these are very sensitive microphones and, if you work at about this distance, you'll be just fine.

Okay, we do not have a definite word on when John Glenn and Cindy Jones are coming to talk to us. We're hoping they'll appear sometime in the next 25 minutes, but it's only a hope. So let's keep trucking with the questions and we'll see what happens. If not, we may end up taking an early lunch break.

We are to question four I think. Never mind, we did question four. Emilie Latella says never mind.

Six, if NRC statutory authority for medical use were deleted, it requires the subjunctive, in it's entirely and the states were to assume this authority, what action

should be taken and by whom to assure that there are no regulatory gaps in the national medical use regulatory program during the transition?

So Dennis already put a suggestion on the table. This is going to go fast. I think in a way we are so concatenated with congressional action that to assume that all of a sudden there would just be a vacuum is, we think, unrealistic and not consistent with our recommendation. But maybe I'm not --

DR. HOLAHAN: I think the other point thought that we were trying to get at in that question is even if congressional action goes forth, things are going to happen, I mean it's not going to be, okay, today you don't regulate and today you do. There needs to be some fort of transition, and I guess the question is more how do we go through that smoothly if that were to happen.

DESIGNATED FEDERAL OFFICER CAMPER: Let me just add that I think Bob has pointed out very well some of the encumbrances the states face in terms of going through creating statutes and so forth. My best guess is, if Congress were to enact the NAS recommendation as proposed, it would probably take five to seven years, and that's just my personal guess, for all states to put in place legislation and statutes and so forth to conduct their own programs. I say that based

on my experience in watching states move from non agreement to agreement state status.

It takes several years. In some cases as much as several years. Then you have a situation, bear in mind, that you have some states today that have little or no program, and they would have to move from little or no program to a byproduct materials program of some reasonable magnitude. The question is during that transition period of some duration, what kind of steps and actions should be taken to insure that there are no regulatory gaps. You're looking just at going into the states area, but coming back into the federal side of it over to the Department of DHHS. I'm not sure -- they're not comfortable with taking this on.

I would that -- I was accused yesterday of being somewhat sanguine about this ever coming about. I have a feeling that there's going to be a lot of reluctance at least to see this change. And what the committee needs to do is work with this more rather than trying to pass it off to another agency. I'm not sure exactly that it's going to be acceptable to try and make this change that the IOM has suggested, particularly since it's an opinionated report without much data backing it up to help us make a decision to support that decision.

CHAIRMAN SIEGEL: I'm not totally sure I follow our point, Eric. I mean the principles that this committee

has espoused which are similar to many of the principals espoused by the IOM committee where this desire for uniformity and regulation of ionizing radiation coupled with that being done by an agency whose primary mission is health. And yes I agree the Department of Health and Human Services, if simply handed this today by some magical transfer mechanism without appropriate enabling legislation from Congress, appropriate funding and the proper direction, would probably say no we can't do this job given our current budget constraints and with the people we have, but that's equally unrealistic.

I mean I think the whole set of recommendations is built on the assumption that Congress is willing to act, that Congress believes that some uniform approach to regulation of ionizing radiation with central federal responsibility at some level and distributed administrative responsibility to the states is an appropriate thing to do.

If Congress does not choose to do that, then I don't see any easy way out of the current situation. I think we're then basically stuck with NRC continuing to do byproduct material, and we can help the NRC restructure its medical byproduct material program and hope that the states will follow suit with respect to their non byproduct material programs following NRC's lead. But short of that I don't see, if Congress doesn't act, I don't see how we're going to make this uniform.

Just one thing, seeing Al Lohrman out in the audience made me think about, and that is the potential of a Tenth Amendment issue here, whether Congress will view that it has the right to create uniform national regulations or uniform national statute relating to things that are not currently covered by the Atomic Energy Act. They might say that the Constitution didn't vive us the right to do this and therefore we probably should steer clear of it.

I just throw that out. It's just food for thought. I haven't got a clue. I'm sure there's a way around it. I'm sure there's a way to tie it all to health care reimbursement under HCFA that makes it not sound like it's related to getting into a new area of governance that was formerly left to the states.

DESIGNATED FEDERAL OFFICER CAMPER: Let me explain why we asked this question. The question supposed that our authority has been deleted in its entirety. And the states are assuming this authority. We say what action should be taken and by whom to insure that there are no regulatory gaps. The thrust is from a practitioner's standpoint, some of you function in agreement states, some of you function in NRC jurisdiction. Obviously this question is a question that we will have to wrestle with at great length as we go through any decoupling process. But it's an early pulsing question as to what types of problems do you envision as you think about it

at this point. And it really is from the standpoint of being practitioners. Some of you involved with states, some of you involved in jurisdiction, NRC jurisdiction, can you see early problems that we should be thinking about as regulators as we try to go about some orderly decoupling process.

CHAIRMAN SIEGEL: Say that again?

DR. HOLAHAN: But including the involvement with DHHS. I mean to make that part also a smooth transition, if DHHS -- if Congress did include DHHS in the legislation. And again there is a gap in terms of the transition, if it did go from NRC to DHHS.

CHAIRMAN SIEGEL: Why does there have to be a gap?

DR. HOLAHAN: Well, will there be maybe the question is and how do you insure that there isn't, both as the states pick it up and DHHS develops their program n accordance with recommendation --

CHAIRMAN SIEGEL: Perhaps a solution in a way is perhaps a simplistic one, but it's a solution that gets right to the heart of it. You would basically just transfer -- you know, one day there was an Atomic Energy Commission and the next day there was ERTA and the AEC -- and NRC, excuse me, and I'm sure that that dismantling took a fair amount of transition but it was accomplished. The responsibilities were split and it occurred.

And a similar sort of thing, if one day the medical use program of MNSS all of a sudden all the employees were DHHS employees in some new part of the FDA or some new branch of DHSS, it could be done. I mean that's an administrative problem.

DR. HOLAHAN: Okay.

CHAIRMAN SIEGEL: And it doesn't necessarily imply that there is a regulatory gap and that the public health and safety will go down the drain during the period while people are running around like chickens with their heads cut off trying to figure out what to do because I can't conceive that our government is going to let that happen. I mean there will be a well-ordered transition plan worked out now matter how the authority is shifted, if it's shifted within the federal government. It won't go according to clockwork, but there will be a plan.

MEMBER SWANSON: I also think, you know, and part of the reason why I made that suggestion is I think, if we're going to do this practically, you've got to build on the agreement state program which is -- I mean you're going down the line towards where this wants to go anyway with your agreement state program, so it would be foolish not to build on that existing program to get where this report wants to go. I mean to just drop it and say we're going to start over from scratch doesn't make a lot of practical sense to me, okay.

CHAIRMAN SIEGEL: And I can't envision Congress doing that.

MEMBER SWANSON: I can't either.

CHAIRMAN SIEGEL: I just can't see Congress saying as of this date the NRC stops, as of this date a new federal agency that has to start from scratch begins to process. It just seems illogical that they would do it that way. They occasionally do things that are illogical, but this thing is even more illogical than usual.

Jeff?

MEMBER WILLIAMSON: It seems that, you know, there is an existing process by which non agreement states can get converted into agreement states. And if an congressional action is going to take five to seven years, surely the transition would be a lot easier if in that interval a lot of hard work through existing mechanisms were focused on transforming non agreement states into agreement states. What are the means currently at NRC's disposal for affecting such transitions?

DESIGNATED FEDERAL OFFICER CAMPER: To agreement states you mean?

MEMBER WILLIAMSON: Yes, to induce non agreement states to become agreement states.

DESIGNATED FEDERAL OFFICER CAMPER: I think that's the operative word right there is "inducement." I mean

you have a situation today where a number of agreement states have chosen to become such, 29 I believe it is, there are a number of others that are in the process, Oklahoma, Pennsylvania, Massachusetts to mention a few, but my observations have been that for what reason that process takes a long time.

And it's as much -- I mean a state has to go through a number of steps to become an agreement state. And typically what slows it down is the state itself. I mean when we receive the applications from the states and then when you go through a regulation review, a process review, we look at their resources, there's a number of hoops they have to jump through to become an agreement state. But I think we go through that part of it fairly fast, but the states pursue at different speeds for a whole lot of different reasons. Some of which are politics, some of which they have to plant the idea with a particular legislator or governor and then see it ferment over time, there are a number of reasons.

But I think the problem is, and what you just said, and that is what wasn't addressed by the committee, and I now know why based upon John Rappaport's answer yesterday, and that is because the idea of exploring the expansion of the agreement state program, because it encompasses all materials, wasn't an option that the committee felt was appropriate to even consider because it was beyond the scope of the study.

But the issue of what do you do to entice those states, that have not yet chosen to become agreement states, to become so is a very interesting question.

I would envision that things could be done, and certainly the easy parts are providing technical assistance, taking steps to have them work through some type of cooperative arrangement from a learning standpoint with those states which are currently agreement states and so forth and so on are the fairly easy part of it.

The difficult part of it is, is for whatever reason a number of states have simply chosen not to become agreement states. Some of that is politically motivated, some of it is resources, some of it is low population density and therefore they don't feel like they're going to need such a program. I mean we have some of the states in the west like Wyoming and Montana that have no interest, at least thus far. We had Idaho, which was an agreement state that gave the agreement back. The governor chose to give the agreement back.

So I what you'd have to do is try to find a mechanism, and I don't really know what that is honestly, to stimulate those governors of those states which have thus far opted not to become agreement states to do so. There had to be some carrot in there that made it worthwhile for them to pursue it.

CHAIRMAN SIEGEL: You could announce that you're going to increase your fees by a factor of 100 five years hence --

MEMBER WILLIAMSON: And all the NRCs would be up in arms.

CHAIRMAN SIEGEL: -- and that would be an enticement for people to become agreement states.

MEMBER JONES: How much complaints do you have with those agreement states, are they really agreement states or is that just a euthanistic term?

DESIGNATED FEDERAL OFFICER CAMPER: Well, actually the agreement state program I think is working very well. In fact I thought Bob did a very eloquent job of making some comments about the agreement state program. And I'm only going to add to what he said, the agreement states go through a very rigorous process to become agreement states. They go through a very scrutinise review by our agency in terms of the regulations. We, much to their chagrin, we impose upon them compatibility. And we view them as co-regulators working together to insure public health and safety. They don't like the compatibility word, but we impose upon them adequacy of regulations and compatibility. Adequacy is almost never an issue. Compatibility can be an issue.

The impact review that Bob referred to is a rigorous review of their program. We provide training to the

agreement states. We interface with their management through working groups. And I think by and large the program works very well.

By contract, those states that are not agreement states, we have minimal interaction with the regulators. We do interface with the CRCPD. We do review suggested state regulations. But it's much more aggressive and formal on the agreement state side than on the non agreement.

MEMBER SWANSON: Could you foresee a scenario where you could have like agreement state compacts or there could be cooperative agreements between states to have one state regulate for another state, for example to cover your problems with Montana and Wyoming?

DESIGNATED FEDERAL OFFICER CAMPER: Well, I don't know. Anything is possible I guess, but personally I doubt it because I think again you get into, you know, parochialism and territoriality and preferences within particular state borders for how to do things. And, you know, we have a model that's worked with varying degrees of success, the compacts created by the Low Level Radioactive Waste Policy Act. We're now 16 years or so into that thing. This has varying degrees of success.

MEMBER SWANSON: I think it's a very different issue that we're talking about.

DESIGNATED FEDERAL OFFICER CAMPER: Oh, it is a very different issue. But I'm saying there is a model that has some different degrees of success. But I guess it's possible, but I think there is a lot of things to overcome to achieve that particular model.

CHAIRMAN SIEGEL: We could privatize it.

DESIGNATED FEDERAL OFFICER CAMPER: We could do that too.

CHAIRMAN SIEGEL: That's another approach. I mean I mentioned yesterday, you know, just kind of jokingly, Colorado taking over and doing the job for Wyoming, but I mean taken to an extreme that argument could be that you could privatize the business of nuclear regulation or ionizing radiation regulation. I'm not quite sure the United States is ready for that concept yet, but.

DESIGNATED FEDERAL OFFICER CAMPER: Well, even in the academy's model, at one point they talk about this idea of states forming consortiums to assist each other in providing the regulatory services that are needed to carry out a viable program. I guess that's certainly possible. I mean I wouldn't rule them out. I know that there was a great deal of preference from state to state within its boundaries as to how it wants to regulate materials uses, but it's certainly possible.

CHAIRMAN SIEGEL: Eric, you had a comment?

MEMBER JONES: Well, I'm not sure I should say this, but I was thinking back a few years ago when I was on the outside and not working with the federal agency and the entire radiopharmaceutical program was shifted from the NRC to the FDA, I'm not sure that my colleagues out n the community are entirely happy with what we were doing with the regulation of drugs. And I just wonder, if we did the same thing with shifting the radiation control over, whether we'd be any happier with that as a community.

In other words I guess I feel very cautious about the IOM suggestion of moving this NRC. And I'm not clear in my mind how much control NRC would retain, how much responsibility would be moved into DHHS.

CHAIRMAN SIEGEL: Right. I mean I agree with that concern. And particularly the issue of how you separate one part of the materials program from another part of the materials program. It's still a little bit, more than a little bit, it's unclear to me exactly how that occurs. And although I suppose it's possible that all material uses in medical institutions could come under the purview of this new organization and the states, it seems awkward that there would be parallel tracks for well-logging on the one hand regulated by the NRC in 21 states and for medical uses now regulated by the state with DHHS.

So, you know, all the states becoming agreement states coupled with oversight of the medical stuff in a health related agency is kind of the cleanest way to deal with the whole thing simultaneously.

The mechanics are still not clear to me, but I think that although I agree with you, Eric, that the community is not overwhelmingly pleased with all the things that the Food & Drug Administration has done for the furtherance of nuclear medicine, I think that comparing pre-1975 with post-1975 behavior is potentially dangerous because the character of drug development changed. A lot of things changed that would have made the old Atomic Energy Commission approach more awkward.

And so, could the FDA have done better? Sure, the FDA could have done better. But let's assume that the NRC had decided that it all of a sudden wanted to tighten up its approach to letter radiopharmaceuticals out on to the market place under the old Atomic Energy Commission Authority, I think we would have had a far, far more difficult time convincing five NRC commissioners that there was a drug lag related to radiopharmaceuticals that needed to be dealt with. Then we would have been talking to physicians in the position of commissioner and the Food and Drug Administration, and the Assistant Secretary for Health or whatever level we chose to target.

So I don't think the mere fact that it moved to FDA is intrinsically a mistake. And my personal belief is that I would rather be discussing this whole regulatory schema with an agency that deals with overall health issues rather than with an agency that deals with just radiation issues and is worrying about zero tolerance reactors as 98 percent of what it does for a living. Just the mind set I'd rather be focused on. Personal preference.

And you might prove to be right, but it will only be because it just didn't evolve the right way, not because the FDA was intrinsically the wrong place for it to go, in my opinion.

Others?

So did we answer this question or not really?

DESIGNATED FEDERAL OFFICER CAMPER: One of the things we look forward to, getting back to Jeffrey's point, as Trish Holahan mentioned early on, we have sent this report out to all the governors of the 50 states and have asked for feedback in terms of their impressions of the recommendation, what the impact would be upon their states, how long would it take to affect such a change, so forth and so on. I don't know to what degree that in and of itself will stimulate further dialogue or interest in those governors with the agreement state programs, but it may have some impact in that

regard. But it's premature yet to be able to say, I just don't know.

CHAIRMAN SIEGEL: Any more comments on item six?

MEMBER FLYNN: Just one more comment.

CHAIRMAN SIEGEL: Yes.

MEMBER FLYNN: I was just looking at some of the list of non agreement states, and the non agreement states these are some of them, Alaska, Idaho, Montana, West Virginia, Wyoming, Delaware, Vermont, and Washington, D.C. is a non agreement state. And I think that some of these will, like Alaska for example, very sparse population, very disbursed. In Alaska, and I just had to go through this recently, there are three radiation oncologist in the state of Alaska, so we're talking about some areas with very sparse resources, and maybe not a lot of people who can put a lot of their time into trying to devise a program.

So I think it's really important that when you dismantle Part 35, again my suggestion would be to come up with some very minimal, not highly regulated, very minimal core values I guess to see how these states, or how is Washington, D.C. for example, looking at non byproduct material, are they? I mean how are x-ray machines in Washington, D.C. handled? How are they handled in Alaska? Just to gather the information, not to encourage them to

regulate more, but just see what are they doing right now. I mean I don't know.

CHAIRMAN SIEGEL: I think the conclusion to six is, is that any precipitous deletion of NRC authority simply doesn't make sense. And I suppose it's good to be prepared for it, I just can't imagine it happening. I agree with you this is going to occur by an orderly transition of some sort assuming Congress decides to act on this. And there will be confusion during the period of transition because there will be some dual regulation for a while, but that's the only way we're going to get to a better circumstance because there's no magical solution to this unfortunately.

So anything else or have we pretty much done this?

Seven, I don't think we explicitly did seven, but I think we've addressed seven about how to insure uniform protection of patients in the light of potential differences in state priorities, industry pressure and consumer interest. We basically addressed seven by saying we voted for D with teeth, right, or E?

And we've already dealt with 10 and 11. So where do we stand?

MEMBER BERMAN: Barry?

CHAIRMAN SIEGEL: Yes.

MEMBER BERMAN: Just if we're going to skip seven, one thing that Dennis brought out yesterday in questioning the people from the IOM was that I think we're uncertain as to who makes up the CRCPD. And it seems as though the CRCPD was a convenient group, a mechanism for the IOM to turn to to help generate some kind of a uniform standards. And it's not really very well, it probably isn't as a group, as well developed as it would have to be in order to really function well if the NRC were to disappear from their activity.

And I think it would be good of us to be considering that strengthening the CRCPD would be an important part of this new approach, if it were to come into effect.

CHAIRMAN SIEGEL: Actually I think we were even stronger than that because we were essentially saying that some central federal authority still needed to be present. And that won't make the CRCPD superfluous, but if the standards get developed by the central federal authority, then the standard state regulations of the CRCPD will in fact follow what the federal authority has done.

Do you have a comment?

MEMBER QUILLIN: The Conference on Radiation Control Program Directors is an organization whose membership is basically the 50 states and the Territories also. The voting membership or the program directors and I am a voting

member for an example, there is an executive office in Frankfurt, Kentucky and the work of the conference goes on through a number of different committees.

Dick Gross mentioned yesterday the committee that looks at the suggested state regulations, but there are committees that look at other issues too. And they are also liaisons to various professional groups. For example I am a liaison to the American National Standards Institute for the conference, and I follow the ANSI activities and make a report periodically on that .

The fundamental activity that the conference does that relates to this report is the suggested state regulations. And that activity has changed somewhat in the past few years to try to expedite the regulatory process, the development of regulations, and to get them out in a much earlier form.

Just to reiterate what Dick said yesterday, those regulations are developed by a committee which consists of state and federal participation and also outside participation by interested parties. Representatives of the American College of Radiology for example frequently work with the committee on medical issues. And non medically you'll see industry representives depending upon what industry is being affected for example.

So it's an organization which I think has been very effective over the years. The challenge it faces, as alluded to in these two IOM reports is the fact that it's federally funded. The vast majority of its funds come from the federal agencies. And as the federal agencies' funding has been cut back, the CRCPD's funding is likewise threatened with reduction. So the question is, you know, how are they going to be funded in the future to continue their activities.

CHAIRMAN SIEGEL: Lou?

MEMBER WAGNER: Within the CRCPD I guess the regulations are made and the voting members come up with some consensus. Would you give me some idea how many of the voting members are actually practicing medical people, MDs, medical physicists, people who actually are practicing?

MEMBER QUILLIN: None of them are because we're talking about the people in the conference are basically the state radiation control program directors and their staffs. These are not people who practice medicine on the side.

MEMBER WAGNER: And my criticism I guess by handing this over and making them such an authority is that you're going to have the same problem we've got now. Because within the NRC one of the biggest criticisms is the lack of medical input, and it's the same darn problem. And I guess, if I wanted to give advice to the NRC is how to change their program to be more effective, it would be to incorporate more

medical professionals into the regulatory making and enforcement process. And to figure out a way to get that to go.

This committee, look at the composition of this committee, and look at the recommendations we have given you in the past, and look at our record in terms of what we've done, how you've gone against it and then what's come back to you.

I mean I think that there is a lot of lessons to be learned here. I don't wish to have those who are regulating completely dominate the whole thing, but I think you need a stronger hand as to when the people who are going to be regulating it to get a stronger hand about the input on how this regulation is going to affect the practice. And I think this committee has been very effective at being extremely concerned about protection of people, about professionally performing the duties correctly, and doing the right thing for the people of this country. And that's what we need as better input in the regulatory process.

DESIGNATED FEDERAL OFFICER CAMPER: Just a comment on that, Lou. I believe that this committee has increasingly done the very thing that you're alluding to. I've watched this committee certainly grow in the last six years in terms of its involvement. And it's gone from what was pre-1990, arguably a fairly modest technical advisory

committee, into a committee that has increasingly affected policy not only in terms of specific rulemakings, but has increasingly affected policy in terms of which way the agency should go with its medical use program.

I mean I think, and I've heard Barry comment, that we've certainly, you know, bring things to us sooner. Not only when you have a consensual model that now is embodied within proposed regulatory language, and we've done that. Now, the QM Rule was debated by this committee, but the QM Rule, the development of it also predated the changes in this committee which occurred in 1990. But if you look at the patient release rule for example, I think this committee had a profound impact upon the patient release rule.

And I think that all of us agree that this committee has increasingly worked the way that we wanted to work and has impacted policy. And I think it's healthy, alive and doing well. And I agree that it's essential that that occur.

In addition to that the Commission started its Medical Visiting Fellows Program. We have Dr. Pollycove who has been on the staff with us now for several years, and of course Dr. Rotman, the radiopharmacist was there. So I think in fairness to the Commission it has made a number of changes to be receptive to the medical community and to try to get more input. I mean the idea that the committee is chaired by

one of the member of the committee and so forth, it was a change. So I think they've been receptive.

Now, could we go further? Perhaps. One of the -- we have in the agency is the idea of full time physicians on the staff. Frankly I don't think there's a lot for them to do on a full time ongoing basis. Therefore, now Dr. Pollycove has been very effective and useful to us in terms of reviewing. For example, he played an active role in doing the radiopharmacy guide which is currently under development and about to be published for comment.

But keeping a full time position busy in an ongoing fashion is something that you have to ask the merits of that. By the same token, I think the approach the Commission has taken thus far to get that active input is working well. Can we do more? Probably so. But I think it's working pretty well.

So I agree with you in terms of the input, and I think that the committee can help us make the revision to Part 35. And if we're to stay in the game, I think that this committee will play an active role in getting a revision of Part 35, and we'll probably end up with a lot more reasonable regulation as a result thereof.

CHAIRMAN SIEGEL: Yes.

MEMBER WAGNER: Just one other issue and that is that not only in the rulemaking process, and I really

appreciate the changes that have occurred, they clearly have made an impact. But also in the enforcement area, that's another issue. More medical professionals should be involved in that enforcement process and the decisions about how to enforce what is on the books.

And I think that the onerous issues have been brought to the attention of the past and they have been somewhat ignored in terms of the enforcement. We need a cooperative effort from the agency with the medical regulated community to exchange information and to perform enforcement in such a way that it encourages the exchange of information about how things go wrong so that we can better improve these things in the future.

Right now it's the onerous task of enforcement. I think there is a lot of regulated people out there who would rather keep shut about any problems, keep their mouth shut about it and not bring it up to the attention of people simply because they fear what can happen with regard to the enforcement issues.

MEMBER WILLIAMSON: Well, I think it would be helpful, maybe, to have some sort of a basic sense of what is the sort of breakdown of professional qualifications in FDA and in NRC. So I'll ask, in your reactor regulation division which, as I understand, is your largest focus, what percentage of the professional enforcement and rulemaking people are ex-

reactor professionals, health physicists and nuclear engineers. And in the medical program how many medical physicists and ex-medical practitioners are represented.

I think that both sides of the house have within its ranks ex -- for example, on the reactor side you're dealing primarily with nuclear engineers, other types of engineers, health physicists, and a very large percent, and I don't know exactly what it is, but a very large percent have field experience within the reactor power industry. Some are with nuclear Navy, some are with the various utilities. But I would say there is a very high percentage.

Now, I could speak more specifically to the medical program because I have more familiarity with the backgrounds of all the individuals that we have. There with perhaps the exception of one or two people, every member of the medical program staff comes from either an engineering or physics background associated with medical u se of ionizing radiation and has field experience, every one of them.

A number of us have been RSOs or assistant RSOs, or consultants in the private industry. We have no physicians on the staff with the exception of Dr. Pollycove, but we do have staff that has an active understanding of therapeutic applications of ionizing radiation, research applications of ionizing radiation. Most of us, as I say, I can only really think of one or perhaps two that have not actually had

extensive dealings with it -- for example radiation oncology, medical physics and health physics, and medical research.

DESIGNATED FEDERAL OFFICER CAMPER: Even I can distinguish between health physics and practicing radiation oncology physics or nuclear --

MEMBER WILLIAMSON: Oh, so would I. I'm aware of the distinction.

CHAIRMAN SIEGEL: Any other comments on this general issue that we're on?

All right, failing that I think we've actually reached --

MEMBER BERMAN: Barry, I guess just one more. Bob Quillin earlier today made I think a very thought-out comment about what he thought would be the impact of the change if the Institute of Medicine report is enacted. And I thought that his comments actually were good background to our suggestions. What I'm saying is that I thought that Bob Quillin's earlier comments were potentially important background to the rationale behind our suggestion as a new alternative to be considered. Because I thought that they took into account the potential several changes that would be potentially -- several aspects of the program that's currently in place that might be lost with a new system, if the Institute of Medicine plans to simply enact it as is.

For example the comment about the periodic inspections of the relationship between agreement states and the NRC, acting as kind of like a JCHO review, it improves the quality of what the agreement states are doing, but that might be lost.

So my suggestion was that in some way that those comments could be highlighted in relationship to our proposal.

CHAIRMAN SIEGEL: Okay.

Any other comments?

Jeff?

MEMBER WILLIAMSON: Is there a sense that another recommendation of the Institute of Medicine report is being disagreed with, namely that the Council of Radiation Program Directors, you know, be the responsible entity for drafting a more uniform set of regulations?

CHAIRMAN SIEGEL: I think that was built in with D with teeth.

MEMBER WILLIAMSON: Yes.

CHAIRMAN SIEGEL: And for E. They seemed, I'm not saying they're throwing the baby out with the bath water completely, but it seems to me that we believe that the way to get uniformity is through some central authority that has the ability to impose that level of uniformity.

And I mean the problem with the CRCPD, unless -- state regulations is the word "suggested," and they either can

or cannot be adopted and they run the risk of 50 different versions of Part 20. And that's just not acceptable, at least in my way of thinking.

All right, I think we've beat this baby to death. And we have reached the end of this discussion. Unfortunately neither Cindy Jones or John Glenn are presently available. We have reason to believe that John Glenn might be finished with a meeting in a few minutes, but we don't know that for a fact.

DR. HOLAHAN: No, not until noon.

CHAIRMAN SIEGEL: No, not until noon. Will he be available at noon, do we know that?

DR. HOLAHAN: We don't know.

CHAIRMAN SIEGEL: So we're still in limbo. Well, the problem is I don't want to break for lunch until 1:00 o'clock. Any change we can get better data if we took another ten minute break to find out what's going on or are we likely to have the best data we're going to get at the moment?

Let's just scratch for five minutes and see if we can just get a better sense whether these folks might be available.

(Whereupon, at 11:13 a.m., off the record until 11:30 a.m.)

CHAIRMAN SIEGEL: We cannot locate any of the folks that were supposed to speak to us originally at 2:00

o'clock and are now planning on speaking to us at 1:00 o'clock.

We do have a few administrative issues that we can deal with. And what we're going to do is break for lunch now and be reconvened at 12:30 with the hope that they will have shown up, and maybe we'll have reached them by 12:30 and, if not, we'll deal with the administrative issues between 12:30 and 1:00, and then we'll be back at the planned revised 1:00 o'clock time and we'll get out of here.

So lunch.

(Whereupon, at 11:30 a.m., the proceedings in the above-entitled matter were adjourned to reconvene this same day at 12:30 p.m.)

A-F-T-E-R-N-O-O-N P-R-O-C-E-E-D-I-N-G-S

(12:39 p.m.)

CHAIRMAN SIEGEL: We're back on the record. Hope everyone enjoyed lunch. We expect to get onto our next topic at around 10 till 1:00 or so, so we can deal with a few administrative matters before we do.

First is the issue of whether or not we need to have the currently scheduled, at least tentatively, meeting in April. I think the dates April 22 and 23. Does that -- 23rd and 24th is what we had previously blocked out based on calendar review. Whether or not we would need that meeting depended on in part what we accomplished at this meeting, and depending on whether other burning issues of the day remained to be resolved.

So I think the way we need to answer the question is just first for me to ask Larry and Trish whether there are operational type issues that you need ACMUI input on or rules in progress that would come up as early as the April time frame.

MR. CAMPER: To a large degree, that would depend upon what action the Commission decides to take on the next 30 days. I think that there are a number of technical issues that we could explore with the committee as we normally do.

For example, an agenda item that's not on the agenda today would be some type of updating or status report

on the patient relief rule, for example. Certainly as always there's a number -- we can certainly put together an effective and meaningful technical agenda for a one-day meeting. However, having said that, again though I think that a major determinant is what the commission decides to do in the near-term future.

CHAIRMAN SIEGEL: Okay. Having heard that, are there specific items that any of us have in mind that even barring that, you would think would warrant an April meeting?

MEMBER FLYNN: If we didn't have an April meeting, when would the next meeting be, in the fall?

CHAIRMAN SIEGEL: Either in the fall or depending on the next part of the administrative discussion. If we have a commission briefing then we would almost certainly need a pre-meeting to make certain that what we were going to do at the commission briefing made sense, and that we're all in agreement on it.

If we do it that way, then we would potentially have the opportunity to do some business in addition to getting ready for the commission briefing as part of our meeting prior to the commission briefing.

But otherwise, the next meeting would be the regularly scheduled fall meeting, which hasn't been scheduled yet, but it would be Judy's meeting. You would shoot for the October time frame presumably. Dan.

MEMBER SWANSON: At our last meeting, we had discussed the possibility of having a Friday session following this one, that was going to deal with specifically looking at limited diagnostic -- requirements for limited diagnostic use.

What happened with that discussion?

MR. CAMPER: Well, it's still alive as far as we are concerned. This meeting of course was a special meeting to deal with the NAS report exclusively. We did add on two additional items at the request of the chairman.

But from our vantage point, if the committee wanted to focus on the T&E issue or more specifically, what type of training should be in place for limited uses of materials, I mean that's certainly something we could work with you on if you feel it's important to talk about it, a timely subject.

MEMBER BERMAN: I guess the only consideration is if the Institute of Medicine Report is enacted, then I think that whole discussion would become meaningless, redundant. So I think we probably should wait to see what the outcome is of the Commission determination on how to handle the report.

MR. CAMPER: There's two ways to look at a potential April meeting. You can have an April meeting where an agenda would be created along the more classical lines that would have different issues. Or you can have a meeting where the agenda would focus upon what the agency is doing at that

time as a result of any decision the Commission might have made.

CHAIRMAN SIEGEL: But if we do that, I think April may be a little premature.

MR. CAMPER: Possibly.

CHAIRMAN SIEGEL: That just seems like not enough will have happened yet, is my gut feeling.

My inclination is to say that we ought to keep the April dates on the book, but recognize that there's better than even chance that we're not going to have that meeting. Let's wait and see what the Commission says. If it looks like there really is a strong reason for us to go forward with an April meeting based on what this commission does with its initial reaction to the NAS report.

Like if the commission says we don't think any of this is going to fly, but rebuild part 35, then we ought to have a meeting that attacks training and experience as a major component.

MR. CAMPER: Or for that matter, again as I said, we have submitted a plan to the Commission. I'm not at liberty to discuss publicly the details of that plan at this moment in time. But the staff has submitted a plan to the Commission for its consideration as to how to process and to proceed with the NAS report that we have.

Even though I'm not at liberty to discuss the plan, I would say the following. If in fact the Commission decides to go with the staff plan, then a committee meeting would be of value to discuss the plan, how we're going to proceed, some of the plan elements of that overall plan, and so forth and so on. That could be of utility. I can readily see why that would be useful.

But again, I won't know until we get feedback from the Commission.

CHAIRMAN SIEGEL: So we'll just leave those dates open for right now.

The second item was, as you heard earlier today, we've had a request from Chairman Jackson to provide a commission review. We haven't done one -- it's been a couple of years now. She was asking for something around May.

My initial reaction was uggh. That's U-G-G-H for the transcriptionist, because of the fact that my next three months are awful to say the least. I'm out of the country for 12 of the days in May and have some requirement to actually earn my living the normal way some of the months -- some of the days that I am in town.

What the commissioners apparently wish to hear about is our thoughts about the NAS IOM report. Obviously we've done a lot of work over the last day and a quarter or day in a half crystallizing our thinking. I'm still a little

bit reticent to suggest that this committee has done all of its homework with respect to the NAS IOM report.

We punched some holes in the report, and it's an appropriate form of peer review. The individuals who have expertise in the same matters that they reviewed, and we gave our impressions and we have our preferences and our concepts.

But to say that we have constructed the equivalent of that report and have come up with a carefully considered detailed plan for getting from point A to point D with teeth, no pun intended, I think would be unfair. We've talked about it and we've talked at length, but I don't think we'd be prepared to sit down and draft a document that is the minority report repaired by the ACMUI in supplement to the NAS IOM report.

So one concern that I have about giving our recommendations to the Commission as early as May is that I think that -- we're going to concatenate a little bit here, I think that we depend on hearing what the staff is being directed to do and which the direction the Commission is leaning, to know whether we can then give our advice about those particular leanings.

So if we knew all of that by May, then I could conceivably squeeze a May commission briefing in with a committee meeting the day before. My gut feeling is is that

it's going to get delayed into June or something like that. That is just my sense.

I think the best we can do is ask you to please pass that information back through the EDO to the commissioners for us and say that we weren't sure we were going to be ready to meet with them in May.

MR. CAMPER: Okay. We can do that.

CHAIRMAN SIEGEL: Do any of you wish to substantially disagree with that? I'm not sure that jumping in in May buys us very much, until we're a little bit clearer what the agency's response is to the NAS report. Bob.

MEMBER QUILLIN: Do you have any idea what the time lines are in assessing this report from the agency?

MR. CAMPER: Well yes and no. I know the time line suggested in staff's plan to the Commission for how to proceed with the NAS report. What I don't know is how promptly the commission will get back to the staff on the plan.

At the outset of this meeting, Dr. Cool pointed out several possibilities. You know, the commission could look at the staff's plan and say, yes, that's what we think we should do, please go do that. Or they might say, go do that with this modification. Or they might opt to roll it into the strategic assessment initiative that is underway currently, which has a timeline along the summer months.

It's just, it's difficult to say at this moment until I get more feedback from where the Commission is going.

Now having said this though, again though I can readily see again that if the Commission were to opt to go with the staff's plan, that an April meeting for further deliberation by this committee on the NAS report, and perhaps a more clear articulation of the alternative what you think is your choice, might be useful.

But again, I can't say too much about that at this point, until I get feedback from the Commission as to whether or not they want to endorse our plan. That is all I can say about the timing of this plan.

CHAIRMAN SIEGEL: Jeff, you had a comment?

MEMBER WILLIAMSON: I was just wondering what role any briefing this committee would make to the Commission would sort of -- what role that would play in their deliberations, both over your staff implementation --

MR. CAMPER: I think it's extremely valuable. I mean various chairmen can speak from his own experience. But my observation about the importance the commission has placed upon this committee in how it does its business and the role it plays has increased substantially.

I know the briefings that I have seen, I mean there was an active viable briefing I thought.

MEMBER WILLIAMSON: I guess I was asking a more specific question. Do they want some immediate input from us in the course of making some decision about your proposal before them currently?

CHAIRMAN SIEGEL: They'll get some input by way of the minutes of this meeting, which pass to Don Cool, and then from Don Cool to the EDO. From the EDO, to the Commission. This is not a committee that reports directly to the commission. It reports to the director of -- actually Carl.

MR. CAMPER: No. It's actually Don, regional director of --

CHAIRMAN SIEGEL: It's Don, okay.

MEMBER WILLIAMSON: What is EDO, by the way?

MR. CAMPER: Executive Director of Operations.

MEMBER FLYNN: I remember that two years ago, that some of the commissioners actually read the transcripts and had prepared questions. They were well prepared two years ago to our committee. They wanted to get a second opinion and also ask specific questions.

CHAIRMAN SIEGEL: I agree with what Larry said. When there have been substantive issues to discuss, the eyeball to eyeball meetings with the commissioners have been I think quite effective. We've had an opportunity to get our medical viewpoint laid in front of them quite clearly and the

interchange has been useful. We've had a chance to understand their viewpoint. It has been very worthwhile.

My only point of being a little bit hedgy about all this is as worthwhile as it is, it is a moderate amount of work for the chairman of this committee to prepare for a Commission briefing. Consequently, I want to make sure that any time I still have to do a Commission briefing, and I think I can probably speak for Judith, that we have important issues to take to the Commission, so we don't just prepare some slides that have fluffy things on them and kind of smile at each other across the table in the other building.

MR. CAMPER: Well, two points. One on Jeffrey's comment. What we understand at this point, Jeffrey, is that the chairman has expressed an interest in knowing what this committee's reaction to the IOM report was.

Secondly, --

MEMBER WILLIAMSON: Is this a timing question then? I mean June or July, should we suggest a June or July?

CHAIRMAN SIEGEL: Why don't we defray the answer to that question until I get the chance to look at my calendar and let Torre know what it looks like.

I think May is -- I'm anticipating particularly tricky. But June or July might be better. But I want to look at my calendar since I intentionally don't carry it with me so I never have to commit while I'm on the road.

MEMBER BERMAN: In terms of timing for substitute input to the commissioners, I wouldn't think there would be a more important time than this one, where the whole nature of the NRC's involvement in medicine is now being brought into question. This is a committee that they've worked with in the past. They have an outside blue ribbon panel making a suggestion as to how things should be changed. I would think that input from their own advisory committee might be very important.

CHAIRMAN SIEGEL: I don't disagree, but I just want to reiterate the point I made that one of the things we criticized about the NAS report in terms of some of the things they recommended was that they didn't seem to have the data that would support all their recommendations.

For us to go forward with our recommended alteration without necessarily having the clear data to support our alternative recommendation puts us in just as awkward a position I think.

So that's why I am being cagey. I just -- I agree that it's important. I'm not saying we should put it off indefinitely. I'm just not sure that May is the right time, and that we'll know enough about the process.

I think that today -- yesterday and today's input will reach the commissioners.

MR. CAMPER: The commission will be provided with a copy of the transcript and of the minutes.

MEMBER STITT: And how would a meeting with them -- it would be different, I understand how, but would we be trying to accomplish something different when we meet with them than having them read the transcript?

CHAIRMAN SIEGEL: It is just more effective to talk to people face to face and have them ask questions about why -- I mean, just like we did with John Villforth and Kate Louise yesterday. How did you reach that conclusion and try to probe a little bit, rather than just reading the written minutes, which will by their very nature be telegraphic.

MEMBER STITT: There are a couple of other questions. If that's the nature of what the meeting would be, is June or July a reasonable time? Is that distant? I think part of the problem is I don't understand what the next steps would be. It may be that no one knows what the next step would be.

CHAIRMAN SIEGEL: That is what I am really suggesting is, is that we sit tight until we see what the next step is. If it looks like the Commission reacts to this staff's suggestions in a way that suggests that all this is on a very fast track, then I will just reconsider everything I said and we'll come here in April and we'll talk about this

more, and we'll plan a Commission briefing some time in May. That's what we'll do.

I'm saying we just need to maintain our flexibility now.

MR. CAMPER: What I was going to do was to -- we'll provide them with the transcript and the minutes as promptly as we can. We'll also share with them the timeline feedback that we've had thus far.

We'll also ask the EDO to pulse the Commission as to whether or not they feel there is a sense of urgency to have a briefing by the ACMUI or the chairman of the ACMUI as part of their deliberative process.

If we get a signal back that we really do want to see it now, because it's important to decisionmaking now, we'd try to figure out a way to make it happen.

CHAIRMAN SIEGEL: Jeff.

MEMBER WILLIAMSON: What data collection do we need to undergo? I guess you mentioned that we're lacking data to support our preferred suggestion. Clearly data is lacking for all sorts of positions one might take on this issue, but I guess that raises the question what could we do to sort of improve the knowledge base?

CHAIRMAN SIEGEL: I don't think there's much that this particular committee can do in terms of gathering the data. That's a good question.

I mean our biggest concern was what level of state's willingness was to accept all this responsibility that would be ensured.

You may be right, Jeff. I don't know the answer. I think we just need to let this one percolate for a couple of weeks and see what happens. Then I know how to reach nearly all of you by E-mail, a few of you by Fax.

MEMBER WAGNER: Will the minutes of this meeting reach the Commission before the briefing by the IOM?

CHAIRMAN SIEGEL: The transcript could, minutes not a chance.

MS. JONES: The transcript can, but it probably won't.

MR. CAMPER: When will the transcript be ready, Torre?

MS. JONES: I'll have one copy tomorrow, and I'll have today's copy on Monday. So we can hand carry them and bypass all the --

CHAIRMAN SIEGEL: There is a strategy that we have never used in the past that we could. I am willing to do it with your help.

MS. JONES: The only problem is, we have to have a way to do this and provide the copies.

CHAIRMAN SIEGEL: But there is a strategy, which is that we could prepare pre-minutes that would be if Larry,

Trish, and Torre put their heads together and just quickly and with my help, we drafted out a summary of the key items of our recommendation, not the full minutes, Torre, but literally outline form. It wouldn't contain all the reasoning, but it would at least have the key elements and our key answers to the questions. Then we could get that as a first round document.

We've talked about that as an option in the past. We have actually talked about it with the commissioners, but have chosen to follow this approach of the more formal minutes, which take typically about 30 days to produce after we have the transcript.

There is nothing, I believe, that would prevent me from drafting a memo to Dr. Cool that says the ACMUI made the following major recommendations at its meeting last week, and full minutes will follow.

MR. CAMPER: That would be fine. It would be our preference that we get something to the Commission depicting the committee's viewpoints on the IOM report before they are briefed by the Academy. I think that is very important.

MEMBER WAGNER: I think it's very important that those points also include the committee's perceptions of weaknesses within the IOM report itself. I think it's very important that it contain the perceptions of the weaknesses within the IOM report, as perceived by the committee.

CHAIRMAN SIEGEL: Let's see what we can capture in a page and a half worth of bullets. I think being realistic about my time constraints, it's not going to be the usual 20 page minutes.

Okay. So we've dealt with our administrative issues, and now we're right on schedule.

So we're going to talk about proposed rulemaking, reporting requirements for unauthorized use of licensed radioactive material. Cindy Jones from Operations Branch is here to discuss that with us.

MS. JONES: I took the liberty of three-hole punching your overheads today.

CHAIRMAN SIEGEL: You have missed our discussion for the last day and a half.

MS. JONES: Yes.

CHAIRMAN SIEGEL: One of the terms we have talked about a lot in the last day and a half is the term that we have labelled government by yo-yo.

MS. JONES: Did I miss much?

CHAIRMAN SIEGEL: Do you understand that concept?

MS. JONES: Yes.

Well welcome, everyone. I'm sure you have had a busy time the last day and a half or so. What my aim this afternoon is, and then John Glenn who you are all probably familiar with after me, will be discussing some of the outcome

of the recent incident investigation team report, which was on the ingestion of phosphorous 32 at the Massachusetts Institute of Technology in Cambridge, Massachusetts.

John Glenn went as the team leader of that report, and of course as was in the Indiana, Pennsylvania incident which occurred, which Dr. Glenn and I were involved with as others, outcomes -- a fairly substantial report. This one contains quite a bit of information on internal dosimetry of this individual that was contaminated, very good reading.

It also contains a response from MIT in regards to how they responded to this report. So what I'll be going over is after we have these incident investigation teams, the team is responsible for putting together the findings, both findings about the licensee, and also findings about what NRC's regulations or regulatory framework provides.

There were a couple of very interesting findings in this one as well. Just to bring you up to speed on this incident as well as the incident at the National Institutes of Health, which is still ongoing, they were most likely the result of a deliberate act by a knowledgeable person. Much more beyond that, we're not at liberty to discuss at this point, since there still is an ongoing investigation at both MIT and at NIH.

There also was an issue about security and control of radioactive materials at both facilities, in that

the team felt, in particular the IIT, which again is the Incident Investigation Team that looked into the Massachusetts incident, were weak. I'll go over that in a few minutes.

Management oversight of the radiation protection program was weak as well. In addition, one unique aspect of an incident investigation team is that we're given no holds barred, so to speak, to look at the NRC regulations. In this case, the team found that the regulatory standards as well as guidance regarding security control of byproduct material were inconsistent. We'll go over some of those as well.

MIT licensee overall response was very good. The licensee did do a very good job as far as the internal dosimetry and counting analysis of the individual for some months after the event and the intake occurred.

Also, NRC reporting requirements are not specific regarding intentional contamination or by use of deliberate acts. That primarily is the discussion that John Glenn will go into after my discussion this afternoon.

There were six major concerns that the IIT came up with regarding what improvements could be made to either licensed activities or to regulations. The first one was security and control of radioactive materials.

The team felt that MIT's program for security and control was not effective to deter or detect diversion of byproduct material. That's a question that the commission is

dealing with and the staff was dealing with as we look into both of these investigations.

Part of the recommendation from the Executive Director to the staff was that the staff needs to evaluate the existing regulations regarding security and control, and also regarding accounting for an inventory of radioactive material.

Current regulations for both limited and broadscope licenses do not address the level of detail to which accounting for radioactive material is required. As a result, there was a concern regarding 10 CFR 20.2201 which requires licensees to report theft or loss of material which are greater than 10 times the quantity listed in appendix C, but it's not clear if this regulation is intended to require that licensees perform inventories to determine if that level of material is there or if there was discrepancy noted in their inventory.

So there may be a requirement or a proposal for a requirement in a regulation which were requirements.

One of the things that we need to look at rather immediately, and we proposed to our management, is that we issue what is called a policy and guidance directive to both materials and inspection staff, licensing and inspection staff in the regions as well as headquarters on what security and control of radioactive material is.

A number of these incidences were escalated enforcement resulting in severe level three violations. We need to be clear, both in our guidance to licensees as well as internally consistent so that we have a clear direction on security and control.

The second recommendation made by the incident investigation team was that there were a number of precursor events which the team felt could have given either the licensees in this country or the NRC some information about perhaps this was a problem waiting to happen. Therefore, they wanted to look at how the information was collected by the Office of Evaluation and Operation -- let's see, Analysis and Operational Data, AEOD, more acronyms for you to learn -- and to see how that information can be disseminated to both inspection staff, licensing staff, and licensees.

The other thing that they found is there was a number of information and events that were reported in agreement states, and how can we get that information to licensees about precursor events. Again, John Glenn will go over what kind of events these were.

But the agreement states are under a voluntary participation program regarding how they get their information on events to our data base. That process is becoming automated and it is getting better. There is some effort to improve it. But from when the information comes in to how

fast it gets out to the people that need it is what needs to be worked on more.

We'll also look at the need for international nuclear material events, probably through IAEA, International Atomic Energy Agency, and we'll develop and work with international programs as appropriate, to get that kind of information again to the people that need it.

One of the other recommendations was for reporting requirements. In this case, the team found that the reporting requirements were unclear for intake. Specifically it was regarding this regulation in part 20, which is 2202 regarding licensee's requirement to notify the NRC in the event involving loss of control of licensed material that may have caused or threatens to cause a total effect of dose equivalent of greater than five rem in a period of 24 hours.

There was some difference of opinion as to how that would be interpreted. MIT, as well as some NRC staff interpreted this to mean that even though the intake may deliver a total effective dose equivalent of over five rems, it will not do so in 24 hours, and therefore, it was not a reportable incident.

This was how MIT felt. That was the reason why they did not report the incident until almost two months after it occurred.

So what the staff is proposing to do is to issue an information notice which will go out to all licensees clarifying the requirements and just to make the statements a consideration that were in part 20 a little bit more explainable.

Again, it's the intake of radioactive material in 24 hours and that the committed effective dose that is received by an individual during a 50 year period following the intake.

It didn't seem to be too confusing afterwards, but when you are in the middle of an event --

CHAIRMAN SIEGEL: What does that paragraph in part 20 say now?

MS. JONES: This is what it says. I didn't bring a copy of the regulations. But this is what it says.

CHAIRMAN SIEGEL: That's the current language?

MS. JONES: Yes.

CHAIRMAN SIEGEL: So why were they confused, just out of curiosity.

MS. JONES: They felt that the total, and perhaps John can tell me exactly --

DR. GLENN: I don't think this is the wording, because the word intake doesn't appear I don't think. Due to an intake maybe, but it's not actually the intake in a 24 hour

period that occurs in the regulations. If it were, I don't think it would be a problem.

MS. JONES: Yes.

MEMBER WAGNER: What is the regulatory section?

MS. JONES: 2202.

CHAIRMAN SIEGEL: It's not in there. We have an incomplete part 20.

MS. JONES: What I can do is give you a copy of that in the correct language.

The current NRC guidance regarding the assignment of dose requires that the internal dose be assigned to the calendar year in which the intake occurred. But MIT and a number of other NRC staff felt that it could be confusing. So we are issuing an informational notice which basically restates what the regulations already have. 2202-B. Part 20.2202.

MEMBER WILLIAMSON: So it was interpreted that no reporting had to be done because they felt that five rem or whatever hadn't been given in 24 hours?

DR. GLENN: That's correct. To be fair to MIT, let me clarify it a little bit.

They essentially had two factors that they were taking into account. One is the dose turned out to be two percent below five rem. The IIT did conclude that they had reason to believe that it threatened to cause an exposure in

excess of five rem early on. Some of the data indicated it was over five rem. Some didn't indicate it was over five rem.

So the team did conclude they had reason to consider reporting it on the basis of a threatened to cause an exposure above five rem.

MS. JONES: And the words threaten to cause are in the regulations.

DR. GLENN: Right. They never concluded that it had in fact exceeded five rem. In fact, we concluded that they came in slightly under five rem at the end.

However, the author did raise this issue that the reporting requirement was for the dose received in 24 hours. They interpreted that to be actual energy deposited in tissue over a 24 hour period.

MEMBER WAGNER: Yes. The wording is quite clear. Twenty four hour notification. Each licensee shall within 24 hours of discovering the event, report any event involved in loss of control of licensed material possessed by the licensee that may have caused or threatens to cause any of the following conditions. Number one, an individual to receive in a period of 24 hours an annual effective dose equivalent exceeding five rem.

So it's quite clear that it says in a 24 hour period. That is the interpretation. It wasn't within a 24

hour period. It occurred over a longer period because of the decay.

CHAIRMAN SIEGEL: The more interesting question is, is how can you receive an annual effective dose equivalent in 24 hours.

MEMBER WAGNER: It says the total.

CHAIRMAN SIEGEL: Thank you. Okay.

MS. JONES: So you will be seeing probably a newsletter article on that, as well as an information notice.

Another concern that the IIT had was regarding management oversight. I think the report shows the staff at this licensee facility, as well as a radiation safety officer, really did a very good job at assessing the dose to the individual. But there were a number of concerns regarding management oversight regarding broad scope licensed programs with respect to the RSO radiation safety officer, radiation safety committee and authorized user and supervisor.

One of the things that the staff is planning to do of course, we had already recognized the need that this was a concern. Last year we issued a new reg 1516 which was entitled, "Management of Radioactive Material Safety Programs at Medical Facilities." That was developed and issued last January, 1995, to help licensees in developing a sound program for adequate management of their radioactive material program.

One of the things that we are tossing around the idea of, and I've actually drafted some language, is for an advance notice of proposed rule making. Part 35 of course is very good at being able to explain the roles of radiation safety officer, radiation safety committee, authorized user and supervisor. The intent would be to strengthen part 33 to be more similar to that.

ANPR, if you are not familiar with that process, is putting together draft language. In this case, would also have some questions for people to answer. You know, do you think this is a good idea, is this not such a good idea. What proposal would you have for strengthening these kinds of roles at licensing facility. It would be for usually an extended period of time for comment, four or six months.

Then the staff looks at all the comments that they get back. Sometimes we get good advice on how we can improve the language. Sometimes we get changes that indicate the rule is really not needed, this rule change and so forth.

So we go out with an ANPR which would clarify these rules and we would add also or propose a requirement for inventories of unsealed byproduct materials, since the incident investigation team, as well as other team inspections around broad scope facilities has found that inventory control or requirements for inventories is a concern and can lead to loss of control of radioactive material.

CHAIRMAN SIEGEL: Can you give me a hint about what you are thinking about in terms of inventory requirements, inventory frequency, what discrepancies you would allow between inventory and what you expect to have?

MS. JONES: It hasn't even really gotten that far. It may be just a question in the rule. Currently I don't have it written in the proposed ruling.

CHAIRMAN SIEGEL: Okay.

MS. JONES: It just says inventory would be required. It may be up to the licensee to determine how that program is established.

A number of licensees have computer programs that they run their inventory requirements off of. A licensee could choose how to do that. I don't think we would prescribe what exactly they need to do.

MEMBER WAGNER: This is an interesting point, because I think the IOM's recommendations were for medical institutions. It clearly impacts now on different parts of the regulations if you take broad scope licenses to medical institutions. There's my further implication here.

MS. JONES: One of the other things is you are probably aware of, is there is a draft regulatory guide out which is DG-0005. This was a revision to the reg guide 810.5. We were thinking that this perhaps may need to be put on hold until we either issued the NPR or decided what to do with part

33, because of course it does talk about how a program would apply for and what kind of package they would put together for broad scope programs.

Of course if part 33 is significantly changed, then that regulatory guide on how to put together your package for your program would also need to change. So that may be put on hold pending incorporation of this.

All these items that I am talking about today are currently with the executive director for operation. They will be reviewed and then approved, and then a time line is put forward. But it is a fairly quick timeline as far as ANPR would expect that if it is approved by the executive director that we could imagine seeing it out on the street in May or June timeframe.

MEMBER WILLIAMSON: May I ask what is part 30 and what is part 33 in their functions?

MS. JONES: I don't have the exact title. Part 33 is for licenses of broad scope. I should have brought part, my regulations with me.

MR. CAMPER: Part 30 is the broad administrative chapter that deals with licensing. Part 33 is specifically licenses of broad scope.

MS. JONES: Adequacy of NRC's guidance and procedures for event response. This is more for the NRC to look at and to improve.

As I mentioned before the Office of Evaluation and Operational Data, the AEOD, is responsible for putting together internal procedures on how we put together elevated response teams for incident investigation.

At the highest level of course is the incident investigation team. AIT, a lower level than is called augmented inspection team.

MIT's incident investigation team -- why do we have three acronyms here. MIT had an incident investigation team. NIH was an augmented inspection team. One of the things that we're looking at is we need to correct and probably clarify how an AIT becomes upgraded to an IIT, and what kinds of factors should be strengthened in how an AIT is conducted, exit and entrance interviews, use of transcribed interviews.

The NIH inspection team did not used transcribed interviews. They were not aware of the fact that that could have been available. Part of what we can do in the future is better training of those individuals that are on the team, so that they are aware of what is available, and use transcribed interviews when we need to.

Media coverage was really pretty well, but the exchange of information between individuals, between licensee, between the NRC, and then in NIH's case, it involved a Federal investigation as well. So we have a number of different

people that are involved with this investigation, and a better procedure needs to be made so that we can mesh together and better coordinate.

We'll also look at the adequacy of guidance for how we charter or how we start these AITs and IITs as well, which involve deliberate acts which were not covered before under the current guidance.

The last issue that the IIT came up with was regarding the adequacy of NRC's guidance for licensee response to intakes. This had a number of different components. Analyzing the intake itself of radioactive material. In NIH's case, analyzing the fetal dose.

When licensees seek outside medical expertise, should we be perhaps giving them some guidance on who they can contact, how they can contact facilities like REATs and so forth.

Then also for NRC staff, in particular inspections staff who monitor licensee evaluation of intake, what types of training and also procedures are available regarding the inspection staff on how to better analyze and monitor that.

One thing that has come out of the Office of Research or will be shortly is a new reg which is called Contribution of Maternal Radionuclide Burdens to Prenatal

Radiation Doses. Dr. Shlomo Daniff has been working on that in that with a contractor. That will be issued in May, 1996.

In addition, the large new reg that we use, which is about three inches thick on interpretation of bioassay measurements, I don't believe will need to be revised, but there may need to be a supplement issued so that we can better clarify for licensees how and when to collect, for example, urine samples, how to store them, when to collect them, what a 24 hour period means.

As you read in the new reg on the Massachusetts incident, it's just not as simple as collecting 24 hour urine specimen. In order to provide some clarification and guidance to licensees, we're going to probably issue a supplement to that or additional guidance probably in IN or a newsletter article.

Let's see. In summary then, we do have a number of ongoing actions which are on a fairly brisk timeline. There is a proposed rule out for public comment regarding required reporting for deliberate mis-use of radioactive material. John will be talking about that. The comment period was for a period of 30 days. He'll also be mentioning that.

Evaluation and security and control regulations and guidance, we'll be beefing that up, and explaining a little bit more to licensees, as well as to our inspections

staff, what we can do in the interim until perhaps a rulemaking change is made.

We'll determine the need to develop requirements for inventory and accounting. As I mentioned before, it may be as a question in the ANPR for part 33, or it may be just a separate section, and get comments back from the licensee community.

One thing I should mention about the ANPR is that the state of Illinois has drafted this language and has been working on beefing up their "part 33 regulations" in the past year and a half or so. They shared with us their part 33 rule language so that all I really had to do was take that and then convert it to our language, and then take the incidents and lessons learned from these two events as well as some others, to put it in there. So that we do have a lot of input from the agreement state area already in this issue.

We'll evaluate the current regulations and guidance regarding restricted, unrestricted, and controlled areas. As you may recall, there was a rulemaking effort underway about a year and a half ago regarding controlled areas. For those of us on the non-reactor side of the house, we wanted to eliminate controlled areas for material licensees. That went out as a proposed rule. That rule was retained. The controlled area in fact still is in part 20.

It raised some questions, which I really won't go into detail right now. It's in the report from Massachusetts. But there was quite a bit of confusion regarding controlled areas. When you cite controlled areas, when you cite restricted areas. We'll be putting together some guidance for licensees on when to clarify, and what areas should be cited as restricted, controlled, or unrestricted. Apparently there really isn't guidance in that area.

Then as we go through each of these tasks from the incident investigation team, where we see the need to provide or put in regulations, the proposed regulations, we'll do so. In some cases, regulations will not be changed. They just need to be clarified through an information notice and/or a newsletter article.

So, any questions?

CHAIRMAN SIEGEL: Probably several. First of all, it seems fairly obvious that several of these issues are potential agenda items for whenever it is we have the next meeting. So I would like to just get that out on the record. Because I think there's some real important implications for these activities for academic medical institutions. So the ACMUI, as we requested at the last meeting, would certainly like to have some input into the practical effects with these things.

Maybe I need to ask John this, but I can start with you. How are you going to do your cost-benefit analysis in terms of deciding where to set the bar in terms of security of byproduct material at academic institutions?

MS. JONES: Good question.

DR. GLENN: Actually, I think it even goes beyond cost-benefit. It gets into technical feasibility as well. I think that's one of the hard things we're going to have to struggle with, because the immediate thing might be to say well to a tenth of an ALIs. That would be the thing to have control to this sort of thing.

But if you are talking about discrepancies for a therapeutic shipment of iodine 131 of 150 millicuries, you are never going to see an ALI, 10 ALIs, or whatever if that happens to be missing from that shipment. So there's a lot of analysis that you need to go into in terms of technical feasibility as well as cost benefit.

CHAIRMAN SIEGEL: Because as you obviously know, the culture in most academic institutions is a lot different than the culture in a power plant. The kinds of security that universities which are kind of free places are likely to impose on their staff from an institutional point of view, and then the kind of security requirements that the staff are likely to be willing to live with.

I mean part of being a university professor and having tenure is that you don't have to pay attention to anybody. That's part of the culture of the job, is that you can say or behave any way you wish, and you can't be fired because you have tenure.

It's just that kind of culture that imposing exceedingly stringent security requirements for relatively small amounts of radioactive material in most instances, has a potential to really really disrupt academic institutions in a serious way, and to appear unwarranted, and this is akin to the discussion we've been having for the last day and a half, when there's hazardous chemicals that are not so regulated and hazardous biological materials, some of which are regulated but many of which are not in those same laboratories.

So it's again, how far do you let the Atomic Energy Act push through the culture in an institution when it's only one of the potential hazards that have to be dealt with in that institution.

MS. JONES: Well, I don't think we'll go so far as to make it unreasonable. I mean a number of us have been licensees, and certainly can recognize that.

The concern that we had is we did have guidance that was out on the street in the form of a health physics position. That contradicts the regulations. So that's our

responsibility to be able to correct that guidance, and correct it in a way that is reasonable for licensees.

One way we can do that is through the comment period.

DR. GLENN: Let me add a little bit to that since I was on the team and made some of these recommendations.

I think if you read the report, you'll find that what the team raised most was the fact that we had a regulation that really restricted down to zero. We had guidance that said well, it's at least up to appendix E quantities and it could be even more than appendix E quantities that you don't have to secure.

That is the situation we say really has to be fixed. We can't have that contradictory regulations and guidance like that.

CHAIRMAN SIEGEL: I don't disagree with that. I hope you don't go to zero though, because it ain't possible. It just can't happen. Besides, don't forget all that missing plutonium that you can't account for.

MEMBER WAGNER: What's going to be our procedure here? Are we going to go through this summary report that we received in our pre-packets for this meeting? Is John going to give a report or what are we going to do here?

CHAIRMAN SIEGEL: Well, John is going to tell us about the proposed rule.

MS. JONES: If there are specific questions on the staff action items that you had, probably John or I could --

MEMBER WAGNER: Well, there's a lot of findings here, like on security control of radioactive materials in laboratories and things. I ran through what you found and I've read the words. I have no idea what they mean and why they are findings. I'd like you to elaborate on them because I don't understand them.

Crowded laboratory areas and benches limited the line of sight of workers to visitors and to areas in which radioactive material was used or stored. It's very inspecific and probably needs to be, because you are trying to summarize things, but I can't get a picture of what we're talking about here.

Are we talking about laboratory benches that had stuff piled up so high on them that people couldn't see what they are getting around? I mean it says it's crowded conditions. What does that mean?

DR. GLENN: Let me comment on that. It's sort of all of the above. I guess the most striking thing when you went into this particular suite of laboratories was that it was not laid out in hallways and labs that run off of the hallways. Instead, this complex was laid out like a maze. So

to get from one laboratory to another, you might have to go through two other people's laboratories.

This is also a laboratory where there is a lot of competition to work for the director of the laboratory. So it was crowded. There was equipment and stuff piled all over.

In particular, the area where the radioactive material was stored was sort of in a middle laboratory which if there happened to be someone whose lab bench was right next to the refrigerator, it could be seen. Otherwise, people could wander in from outside the suite of laboratories or from another laboratory into this area where the material was stored, open the refrigerator, take whatever they wanted, leave. No one would have ever detected it.

In fact, the team members in late on Friday evening or on Saturday morning were able to walk in and have access to the storage area. So the whole picture was one of there was material that was supposed to be secure. Anyone -- well, that's a little far, but there was no effective means for the people in that laboratory to control access to it.

MEMBER WAGNER: Were there radioactive materials signs around appropriately? Were things appropriately labeled?

DR. GLENN: The signs were very prominent. There was no problem with the signing.

MEMBER WAGNER: So what you are saying is that with the signing, that unknowledgeable person at least would be able to read the signs, and they wouldn't go into a refrigerator and store their food necessarily in the refrigerator?

DR. GLENN: I think one thing you have to realize, this II team was not looking at the incidental intruder. We were talking about someone who came in to take material.

MEMBER WAGNER: Okay. But it's very difficult to access some of this.

MEMBER SWANSON: I have a disconnect there though. This is an intended -- if somebody intends to do this, who is to say that that's not somebody that is authorized to be in that lab to begin with?

DR. GLENN: One thing that I think if you read the full report you'll find out. The IIT did not conclude that the cause of this incident was security. It's just that it was one of the contributing causes, because good security would narrow down the number of people who could have perpetrated the act.

MEMBER WAGNER: I can tell you I know in our laboratories in our facilities, if there was somebody on the inside who wants to get at radioactive material in our labs,

short of putting a security guard outside, I don't see how we're going to stop them.

In intentional acts, willfully taking material from some of the labs, when you're talking about small --

CHAIRMAN SIEGEL: That's what John just said. At least that limits it to employees who can get into the building, as opposed to --

MEMBER WAGNER: Somebody from outside.

CHAIRMAN SIEGEL: Just walking in off the street.

MEMBER WAGNER: Some anti-nuclear person or something, who comes in and wants to try to sabotage things.

MS. JONES: A number of our laboratories -- excuse me, licensees have requirements for either securing radioactive material either by closing the door to the lab, or being in attendance.

In many cases, usually around lunch hour, you can go in and the laboratory is unlocked, and there's quite a bit of material around. So we're just trying to instill that there's a sense of security and control that licensees need to take account when we find that there have been these deliberate acts that have taken place.

DR. GLENN: Let me just add a little bit of what MIT did in this particular laboratory to address the issue. That was, they put a lock on the refrigerator, and they made it so that there were four custodians of the refrigerator.

Now does that eliminate the possibility that one of those four custodians will take material out and do something with it? No, it doesn't. But we certainly would have a much better idea of where to look and where to begin the investigation to find out what happened, who did it, and how, under the current situation than in the situation that existed prior to the event.

MEMBER WILLIAMSON: So I guess in summary, if you feel the existing regulations on security of radioactive materials in laboratories are adequate and sufficiently clear but they simply weren't following established practices?

MS. JONES: Actually, I don't think they are sufficiently clear. That's the problem.

DR. GLENN: Yes. What we said is they may be, but there is conflicting guidance out there. That needs to be straightened out.

MS. JONES: Yes. The regulations clearly state zero. The health physics Qs and As and the health physics positions say appendix E quantities or possibly higher, which is a number greater than zero. So we need to clarify that.

CHAIRMAN SIEGEL: You're confused, Lou?

MEMBER WAGNER: I'm still confused. I'm trying to week all this out. First of all, could you explain to me that difference. Could you state just one more time, because I am very slow, could you please --

CHAIRMAN SIEGEL: He's from Texas. That's why he's slow.

(Laughter.)

MEMBER WAGNER: Where is this conflict in the regulations that things are confusing that you are trying to clear up. That's what I'd really like --

CHAIRMAN SIEGEL: Well part of the problem is we only got in our books a small executive summary. What you needed was the whole book to be able to find some of this stuff. We can --

MS. JONES: I found it really quickly. We can send you a copy of this. It's on page 5-3 of the report. But there's a section that was called Regulations for Security and Control. It reiterates what's in 20.1801 about storage and control.

It says, licensee shall secure from unauthorized removal or accessed license materials that are stored and controlled in unrestricted area. The licensee shall control and maintain constant surveillance of licensed material that is in controlled or unrestricted area and that is not in storage.

However, the Qs and As that I mentioned, which were part of the health physics positions as well, had question set, and these were published back in 1992, which inquired if the regulations in those parts, parts 20.1801 and

1802 would impose on one on all quantities of radioactive material however small, to which the NRC responded no.

On two, on quantities that are exempt from labelling in accordance with 20.1905, which we also corresponded no. So clearly, we were giving mixed signals. That is part of the findings. The licensee certainly was using the guidance as many licensees have done. We have found a mistake that we need to correct and clarify for licensees.

MEMBER WAGNER: I guess part of the problem though becomes to what level of security. It's rather vague in that it says you must secure against unauthorized removal. Clearly if a crook goes in there and breaks the lock and takes it out, by definition it's not secured from unauthorized removal. So now you've got to go to another level of security.

Where in the guidance does the user know to what level security this must be maintained in order to meet the regulatory standard?

MS. JONES: That is what we'll have to work on.

DR. GLENN: And Lou, I think you jumped way ahead of the regulation and even considered regulation when you said that we would require security beyond a lock. I think a lock in most circumstances is going to be considered adequate security.

MEMBER WAGNER: I'm asking that question because it's -- I mean we don't always have locks on all our refrigerator doors, but we have locks on all the rooms.

CHAIRMAN SIEGEL: But Lou, I'll bet you if you walk up and down the halls of the labs in most of your medical center at lunch time or at the end of the day when people would be ideally locking their labs so that their computers don't get stolen, you will find that many of the labs are in fact unlocked because people left for the end of the day, and they just forgot to lock the labs.

It turns out that with a little bit of attention, helped by events like this, that institutions that are willing to take a little time and effort to think through the problem can actually make dramatic changes in very short periods of time in the security level and the level of security awareness in the institution.

At Washington University, and I won't say for a moment that we're perfect, having seen NRC announcements of various forums on the Internet and also aided by the fact that I was aware of these things, our radiation safety committee has sat down and talked about this. We have now security in three hospitals, plus the university main campus, plus the medical school.

Basically, when they do their walk-throughs at night, they are checking to make sure that all labs are

locked. When labs are not locked, they are doing two things. They are leaving a notice on the lab that they lock and say why it was locked. These are labs that are posted for containing radioactive materials. And then notifying the Radiation Safety Committee.

Second offenders are going to lose their privileges until they indicate to us how they are going to establish a system of ensuring security in the laboratory so that we can make an effort to bring ourselves more in compliance with the spirit, if not the letter, of part 20.

We are big and a very complicated institution. I think other institutions can make similar sorts of efforts.

MEMBER WAGNER: I think one of our problems that we've noted is the fact that all the cleaning people at night tend to go down the halls and open up all the doors.

CHAIRMAN SIEGEL: They need to learn not to do that. That is a common problem. They simply need to be instructed.

MS. JONES: What we used to do at UCLA was put the garbage cans outside the door.

MEMBER WAGNER: Some of the things that I saw in here that I started asking questions about, and that is looking at the security of the building. Was this a building solely dedicated to research and to such use of radioactive materials, or is this a multi-use building where you have

classrooms and other things inside the building along with other laboratories and things like that?

DR. GLENN: This building was mainly for research. I don't believe there were any classrooms in it. But it wasn't restricted to radioactive research. I mean there were other activities in the building.

MEMBER WAGNER: The point that I guess I'm making is that I know with our building, if we look at our security outside, yes, we have a card entrance type of security to get in, but I know when I get to my building and I have forgotten my card, I just wait for a student to come around. The student goes and I just follow him right on in.

DR. GLENN: That's exactly what the IIT found.

MEMBER WAGNER: Of course. Short of increasing your costs for security, I'd want to make sure there was real need to increase the costs of security in these circumstances. That's a simple one, and I don't know how you really get around that other than you simply only have one entrance and you've got to go through a guard to get in.

CHAIRMAN SIEGEL: I think the point you are making is that this has to be thought through very very carefully, because there is the potential to wreak major cultural havoc and potentially for risks that don't warrant major cultural havoc.

Even if you look at the precursor events and the considered history of the total amount of use that occurs, we're still not talking about large numbers of events. We're not talking about a major problem. So remember that the yo-yo should stay up rather than necessarily going to the full extent of its excursion.

John, we were talking about government by yo-yo earlier before you were here.

Jeff.

MEMBER WILLIAMSON: Where do you intend to set this lower level, I guess, below which you don't have any concern whether the materials inventoried/secure whatever. Are you going to leave it at zero as the current regulation says or go with what seems more practical and reasonable guidance?

MS. JONES: I can't predict what the future will hold, but we clearly -- having had a hand in writing the questions and answers, our intent was appendix E quantities. That that was a reasonable -- that those are quantities that we talked with National Energy Institute. NEI worked on those Qs and As with us.

They were the liaison for the materials community, and felt that that was a reasonable amount. It may be that in the interim guidance, we can say okay this is the

level we're using. We'll reiterate what was in the Qs and As and then work on rulemaking to fix that.

But as Dr. Siegel mentioned, we will have to put forward the risk basis for that cost benefit analysis. That's some work that we have yet to do in research.

MEMBER WAGNER: I still have got a few more questions here. If you had done that, if you set it at that level, would it have changed anything in regard to these events potentially occurring?

MS. JONES: I can speak for the National Institutes of Health. There was a security and control issue at that facility.

MEMBER WAGNER: Was it at those levels?

MS. JONES: It was above those levels.

DR. GLENN: It was above those levels at MIT also. The intake was approximately 10 times the Appendix C limits. So clearly, there was more in that refrigerator than was discussed as not needing security in the Qs and As.

MEMBER WAGNER: I can see a lot of problems coming in with this inventory, because how frequently would you have to take this inventory and monitor. You are talking about materials that have a 14 day half-life here. So they are going to be decreasing in their activity rather rapidly. They might not be used as frequently. They might be used only intermittently or whatever.

How frequently would somebody have to take an inventory and to look at their materials in order to make this effective?

MS. JONES: Well, we would propose that licensees determine what frequency that inventory would be at. I don't think -- you know, we're not in the process of establishing very prescriptive regulations. We typically have or are in the process of providing regulations where we allow the licensee to come in with a proposal and establish that frequency and basis for that.

MEMBER WAGNER: I think that's a very difficult issue though, because when you are using these low levels of radioactive material that emit only beta particles and trying to take an inventory of the routine basis where you would pick up on that, and then making that an effective means by which to protect people within the department, I think that has to be scrutinized very carefully, because it's a great idea, but is it a practical matter that you can really do to get an effective result.

I would say there's a lot of questions as to whether or not you can with some of these activities.

MS. JONES: I would say that MIT was an excellent example of how they were able to have an inventory and come up with how much of it they lost, which coincidently was exactly the amount that ended up in this person.

MEMBER WAGNER: Is the purpose of the inventory to try to prevent incidents or is the purpose of the inventory simply to say if an incident occurs, to figure out how much is gone?

DR. GLENN: Both. Certainly the prospective kind of protection would involve large quantities. I mean when you have a big discrepancy can you pick that up.

CHAIRMAN SIEGEL: Any other questions for Cindy? If not, John.

MS. JONES: Thank you.

CHAIRMAN SIEGEL: Keep us posted.

DR. GLENN: What I'm going to discuss is the first piece of any rulemaking that came out of the IIT, and it had to do with the fact that we didn't have a clear requirement that, when wrongdoing is associated with the use of radioactive materials, that the NRC be notified and have some chance to assess it, and investigate, at an earlier stage.

As Cindy's already mentioned, the two events that we're talking about are the NIH at Bethesda and the M.I.T. event in Cambridge, Massachusetts.

At NIH, the eventual dose estimates were above our regulatory limits. And I don't have it on the slide here, but, of course, it was also the embryo fetus that was exposed as well.

Also, there were a significant number of people involved in either a separate or a secondary contamination event at NIH, so that a total of 27 people had measurable intakes or uptakes of P-32.

MEMBER WAGNER: How many of those got the dose, of eight to 12 rem?

DR. GLENN: The one got that. The fetus got approximately that much, in the same range, slightly smaller. The others, significantly less. An order of magnitude less.

Again, I missed the first part of Cindy's, but one thing is that there was a water cooler at NIH that was found contaminated, and that may have been a source for many of the 27 people who were contaminated.

MEMBER WAGNER: How did -- do we know how the person who was pregnant got contaminated?

DR. GLENN: That's an ongoing investigation.

MEMBER WAGNER: Okay.

DR. GLENN: One thing the IIT found out, in looking at -- you know, what was stated that an investigation team looked at if there was a precursor. Should we have known that something like this could happen, should we have had some preparation for this? Some regulatory, mechanism, authority in place.

And I was actually surprised at the number of similar events that we were able to identify, by going through

historical notices, by asking the agreement states for information.

And these are the ones that were most significant. There were some other ones was well, but with either smaller quantities, or of a different nature.

I might mention that the one at the University of California, in 1978, was probably the most significant one of all. It involved three people.

One individual had an uptake estimated at three to four millicuries, and there was external contamination as well. And there were actual radiation burns found on the skin of the most exposed individual.

The IIT did try, actually, to find out why we did not react more at that time, because the NRC was aware of that. We were able to review the reports of the event.

And I can only speculate. But this report came in in February of 1979, and it could be the Commission was distracted by other things that happened in March of 1979. So, but, we could not nail down why more wasn't done at that time.

An event that I had been aware of was Brown University, in February of 1982. But I just realized, in the slide, that we said agreement states. It was at that time, too. Okay, so that is correct.

In Rhode Island, very similar situation to the ones that we had in the two more recent events. In that it was found in the sink, and so many of the same features that we saw in these other two.

Washington University, in the early eighties. This was a deliberate intake by the person found with contamination. And this is the one that was pretty well wrapped up.

Most of these, who did it is still kind of an open question, but this is one where the technician, who had access to the materials, eventually they had self-administered material.

We had an event with iodine-125, at a research laboratory in the VA in the Bronx in `84. We have Albert Einstein, Duke University. Again, this one, potentially, could have been very significant.

We didn't have enough details to know whether that 5.96 is real or not. I think it's kind of an upper bound of what it might have been.

But you will see at six millicuries, we're talking about some pretty hefty doses, to the exposed individual. And, again, that was unresolved as to whether it was self-administered, or whether someone else did it.

University of California, we had an iodine-125 uptake in `91. And we found one in Toronto, Canada, but this one we learned of by a little bit of happenstance.

It was an agreements -- all agreement states meeting, and we were discussing the, all the people were discussing the IIT, and the representative from Canada mentioned that they had had a similar event a couple of years before.

This one was interesting because they, in fact, got a confession, and the individual went to jail. That individual is now out. Now that he's out, he's saying that he really didn't do it, he was advised incorrectly by his lawyer to confess.

But, as in this case, it was not self-inflicted. It was a roommate gave the material to his roommate, so it was kind of an interesting case.

CHAIRMAN SIEGEL: John, I'm actually surprised that you're surprised at the number of events. I'm surprised it's as small as it is.

DR. GLENN: It could be that there are quite a few more. This is what we were able to surface, that was documented either by the NRC or the agreement states, but no one had ever pulled it all together, and so there could be quite a few more.

MEMBER SWANSON: I'm not sure I agree with that statement. I mean, these are deliberate incidents, where people are deliberately doing this, okay, I mean.

I don't -- I think there's lots of instances of contamination out there, but I really don't think that there are a lot of people out there deliberately putting radioactive materials in other people's sandwiches, okay. Come on. I'd like to think that, in the society we live in, there's better than that.

MEMBER WAGNER: I don't know what the situation is, but there's two different kinds of situations. Number one, if it is an intentional act and they're using radioactive material, it seems to me they'd want that to be found, because that's a material which you can find, and you can say, "oh, I'm contaminated."

You can't do that with other things, with other substances. So it seems to me like they want it to be found, as a prank or joke, or whatever, and it's intentional for that reason.

Others, it's just simply stupid people who really have no concept of radioactive material, and think it's a joke to go do these things, and then it accidently ends up as somebody imbibing radioactive material.

Those are your two circumstances. I'm frankly as little surprised that it was such a small number, but I'm glad it is.

DR. GLENN: One of the striking things about the NIH and M.I.T. events to is note how close the eventual doses were to the limit. And you wondered whether that was part of the initial event.

One thing that we try to do, in mounting an Incident Investigation Team, is to come up with the root cause.

This team was not able to come up with a root cause, because we couldn't identify who and we couldn't identify why. Therefore, it makes it kind of difficult to say what is the root cause, of what the event was.

We did know what were some contributing causes. One, as we discussed a little bit earlier, M.I.T.'s program for controls and accounting for radioactive material was not effective.

And the team chose to deter or detect deliberate diversion of radioactive material. So we were taking note that that's not the cause, but it contributed in that, if it had been better, it might have been deterred, or it might have been detected and resolved a little bit faster.

The one that brings us to the rule-making is that NRC did not have reporting requirements, in place, to collect

information about deliberate acts, in order to assess the frequency. So we do not know how often these kinds of things occur.

And third, NRC did not disseminate information about known precursor events, and did not inform licensees of the NIH event until four months after its report.

So, again, do we have a purpose for gathering this information? Yes, that's to share it with licensees, and to integrate it into our regulatory program.

Okay. What do we consider doing? With respect to the middle one, the fact that we don't have the information, we can take no action. Essentially, just count on getting the same type of reports we get today.

We could go in and amend the licenses to require people to report these things, or we can amend the regulations.

The first alternative, to do nothing, we rejected, because we wouldn't learn anything about these potentially deliberate activities. We wouldn't be able to take necessary follow-up actions, or to conduct investigations in a timely manner.

I can't say that we would have had a better chance of finding out the root cause, if we had been there earlier, but think, certainly, by the time you get there, two months after the event has occurred, the trail is cold.

People have told their stories so many times that you're not likely to gain much information that is going to change as you ask more people, and follow up on the investigation.

So the timeliness of response, I think, is a very important aspect for the NRC. And I'm not saying that we're willing to have an official investigation for every report.

That's one of the fears of licensees, is that, if you report this, every time there's going to be an AIT or an IIT.

I can assure you that the resource demands upon the agency are such that, for that self-correcting error, in fact, is the way it would be going. But we do need to know about it to have some ability to assess early on.

The second alternative, to do it by licensing wasn't chosen, because that's -- it would cost too much money, it's not effective, and it wouldn't work.

And, of course, we chose the rule-making, because it answers all the problems we have with doing nothing.

We get prompt reporting, we can confer with the licensee, taking appropriate action to assess the consequences of the situation, and to reduce the likelihood of further exposures.

Now, this is one I didn't mention before, but I think this is an important aspect. If there is something

going on, if someone has crossed this boundary, where they're trying to harm people with radioactive material, it's important that that be clearly detected, and the person removed from doing that, or that there at least be some deterrents put up.

The upswing is that the rule-making process is an open process. It does allow public participation. It provides the NRC the opportunity to hear from the public, including licensees, in terms of instrumentation powers.

MEMBER WAGNER: Why aren't there other alternatives? Like the NRC issuing an advisory to licensees, delineating what they are required to do by the rules.

And, also, delineating the need that, if there is a subversive event, that it needs to be reported in order that the NRC can make proper investigation.

Under these circumstances, why is it necessary to make it a rule that now will punish not the guy who committed the act, but, actually, the licensee, if they somehow are found to be in violation of the rule by some interpretation.

I don't know why we have to threaten the licensee with punishment, or violation of a rule, in order to try to elicit important information like this from them.

DR. GLENN: There are kind of two aspects to your question. Let me take -- the first one is, from impact on the

public, and having to go out and get clearances in order to do this.

If we ask licensees to voluntarily report, we have to go through some sort of process. But that gets to your next question. And that is why is it that we would want to be able to force that request.

And that's judgment on our part, that this is something that's important enough for us to know about that it should be a requirement, and not a voluntary process.

MEMBER WAGNER: I guess I have to take that. I disagree with that attitude, because I think it is that kind of attitude that creates derision amongst those who are licensed.

And they then tend to be less willing to come up with information, and are more likely to take a posture of trying to cover up situations, rather than to be cooperative.

Because now they're made criminals, if certain situations -- not really criminals, but they're criminalized in they're eyes, and they're very reluctant to do that. I think there's a better approach --

DR. GLENN: You're only criminalized if you willfully don't report what's required to be reported.

MEMBER WAGNER: Sure. But then there's going to be an investigation. People are going to come in, you're going to have a lot of public exposure, you're going to have a

lot of publicity exposed with these things, that create problems in a rule-making situation.

If you can elicit information from these people, freely, and have a more friendly face with them, to show that you're there to help them. That yes, they have a problem, and "yes, we can help you solve this problem and take care of this issue," it's a totally different response.

And I'm very concerned about this mindset, that we have to make it a rule, and have to punish them if they don't. These are acts that have to get under control, but I'm not sure you're using the right psychological approach.

DR. GLENN: Okay. I will mention, and I guess, if we don't make it a requirement, then people are going to say "well, I don't want to report anything unless I have to, because I'm going to get in trouble with my institution if I go to the RSO about this, and it's not a requirement." And we do see that problem in particular.

MEMBER WILLIAMSON: Excuse me. Don't you already have rules on folks, to protect people in the whistle-blower capacity, like that, from their institutions? Who voluntarily communicate?

DR. GLENN: Yes.

MEMBER WILLIAMSON: Aren't there rules that cover that already?

DR. GLENN: It does protect the whistle-blower. It doesn't protect the NRC from the mindset of the institution, and all the people at the institution, that they don't want to have the headaches that come with letting the NRC know about it.

MEMBER WAGNER: Yes. But my experience is that, if somebody thinks that they've been contaminated by radiation or anything, and they think they're a victim of something, they're concerned about that. And it's going to be hard to keep that from getting out, getting to the public, and getting back to other people.

I mean, it's the RSO who's the person who's going to have to take the lead, and decide what to do, and hopefully to be responsible about those things, but.

And I think there's two different approaches, and I don't think that you've given a lot of consideration to the alternate approach, because I don't even see it as an option that you listed.

DR. GLENN: Well, essentially, the option is voluntary reporting, and I admit, we didn't discuss that.

MEMBER WAGNER: Well, it isn't always voluntary, though. I mean, it's a matter that there are rules, already in effect, that say that, if the exposures get above certain levels, you've got to report those.

And what you're now saying is that you're making more of a rule for lesser contaminations, in situations which now takes it one -- you're ratcheting it up.

DR. GLENN: What we're saying here is, in fact, deliberate acts -- the idea that there is someone who is going to use licensed material in order to harm another person, is a substantial interest of the NRC.

MEMBER WAGNER: Yes.

DR. GLENN: That is the position.

MEMBER WAGNER: I agree with that position.

CHAIRMAN SIEGEL: Then, if you agree with that position, how is the NRC going to get the information if it isn't reported?

MEMBER WAGNER: It's the same way that the FDA says that it's very important for them to know about any injury to a patient from a device that produces x-rays, you know.

CHAIRMAN SIEGEL: That's mandatory reporting, currently.

MEMBER WAGNER: Yes, that's correct. That's right.

CHAIRMAN SIEGEL: It used to be voluntary, but, under the most recent device amendments, that requirement is now mandatory.

MEMBER WAGNER: That's correct. That is a matter that -- and that also involves a clear injury to someone, too. That's correct.

I guess you have drug, pharmaceutical things which are voluntary, or drug reactions, or things of that nature, which are voluntary. I don't know what the measure of success is for those things.

But those are also various areas where it's voluntary reporting. So there are several precedents. And the fact that I didn't see it as an alternative, I guess, is what's really bothering me.

MEMBER BROWN: I'm curious. Do you think what they're asking would be unduly onerous, in your institution?

MEMBER WAGNER: No. I don't look at that as being unduly onerous. No, I don't. What I guess is the problem that I have is I look at the victim, and I look at the perpetrator.

And the person who's really guilty here is the perpetrator. That's really the guy who we'd like to get after, that's the one we want to catch.

But the people who are using these things, they're the victims, and now we're making rules, which now make them, make the victims, the people who break the regulations, and are in violation, if they don't do something, because of what some other criminal did to them.

MEMBER BROWN: But it's intended to protect those victims from the criminals.

MEMBER WAGNER: Yes, I understand the intent. I don't have any problem with the intent. The intent's great. No problem. We do have to get the information.

MEMBER BROWN: I guess I just struggle with my knee-jerk reaction, when I come to consumer advocacy, and I'm wondering if you were having a similar knee-jerk reaction concerning the regulation.

MEMBER WAGNER: No. What I'm, saying is I didn't see any other alternative up there, as to how to get the information, and how to solicit the information.

I didn't see it listed as an alternative, which tells me there's a mindset that that alternative doesn't even exist. We saw other alternatives. We didn't see that one.

And I think that there are precedents, in other industries, where the other alternative is a viable alternative to try to get that information, without making the victim somehow a person who can violate the law by the fact that there's some interpretation that hey, this might have occurred.

CHAIRMAN SIEGEL: Look, I think -- why don't -- you made your point. We're through talking about.

DR. GLENN: Your comments have been precisely made.

MEMBER WAGNER: Okay.

CHAIRMAN SIEGEL: Let's talk about this first part first, and then deal with it. And then we can go on to the second part.

DR. GLENN: Yes. Okay. And I put up the proposed rule languages that was published in the Federal Register.

And what it proposes is the licensee shall notify the NRC Operations Center by telephone, as soon as possible, but not later than 24 hours after discovering one, licensed radioactive material was used for a purpose not authorized by the applicable license or regulation.

So that's the first test, in order to be reportable, is that it's outside the licensed activity. Some things might be, if your use is authorized by the license, that would be an activity not authorized.

But, if General Motors started giving radioactive materials to people, their license doesn't permit that. So that would be not authorized by the license.

In terms of medical institutions, it might be if the radioactive material is being given to patients, but not under the supervision of an authorized use. Someone else is authorizing the use of material.

So, somehow we've gotten outside the bounds of what the license itself authorizes. And, in that case, we're

really outside medical use, even though it's a medical institution as is defined in Part 35.

Second test. Such use cause, or has the potential to cause an exposure to an individual, regardless of whether or not it exceeds the regulatory exposure limit, as identified in 10 C.F.R 20.2202, which is the microrem threshold.

So, a purpose not authorized by the license, but which does not result in -- or would not result in exposure, is not captured by this either. The only thing I can come up with, and I'm not sure this is a good example, would be falsifying records.

Clearly, the license doesn't allow you to -- doesn't want you creating false records, but that would not fall under this reporting requirement, because it doesn't have the intent of causing anyone to be exposed.

And, finally, such use must -- was intentional, or the licensee receives information that the use was allegedly intentional. So there's two things. One, either you know it was intentional, or someone has alleged that it was intentional. If it passes all three of those tests, then you have to report it to the NRC.

CHAIRMAN SIEGEL: Let me talk about an extreme example here for a moment, and see how you would react to it. An educational institution -- this doesn't work.

If I take a non-exempt quantity of a radioactive material into a classroom that wasn't authorized to have radioactive material in it, then I've done something that wasn't authorized by the license.

I did it intentionally. I'm a teacher. And the exposure to people in the class could be measured in microrems. Does that fit this?

DR. GLENN: I think it probably does. If teaching was not one of the uses listed in the license, then -- most educational institutions include teaching as one of the uses of radioactive material, but if --

CHAIRMAN SIEGEL: Is that what you want to capture, those kind of events?

DR. GLENN: Not particularly, but we might.

MEMBER WILLIAMSON: I think the intent of personal harm or injury.

DR. GLENN: Yes, but now you're going inside somebody's head. We're trying to make a test that doesn't require that you actually get inside somebody's head.

MEMBER WAGNER: I think the use that I see, at some places in Texas, is where radioactive material is taken to the pharmacy to go to an x-ray room, to see if the healing's faster.

They never take it out of the bottle or anything. They just carry it on over there. It's in transport, and they can look and see whether the shielding is adequate.

Now, the intent there is quite good, because the intent is to make sure that you're going to be reducing exposure to members of the public.

But that very use, in itself, will cause a few of the x-rays to get through the shielding material, and possibly expose somebody on that other side of that wall.

DR. GLENN: I guess the question is is that out of the bounds of the license?

MEMBER WAGNER: And that's exactly right. That's the point here. And I'm not sure that that use by that technician might not meet that definition.

DR. GLENN: I'll give you an example, which we would consider would trigger that. This is an example that -- something very close to this happened anyway.

Let's say that you're expecting an emergency drill, and you decide to put radioactive material that can easily be moved on people's skin. But you've never gotten approval on your license to do that.

That would be an activity not authorized by the license, it results in exposure to individuals, and was intentional. And that would be reportable.

MEMBER WILLIAMSON: Do you want to know those kind of things?

DR. GLENN: Yes.

MEMBER WILLIAMSON: What things do you -- what is it that you really want to know? It sounds like you want to know incidents where the radioactivity is used almost in a criminal way to injure somebody. And that implies intent to harm, doesn't it?

DR. GLENN: I agree with you. The intent to harm is there. But I don't know -- can you give us a regulatory test for intent to harm?

MEMBER WILLIAMSON: Allegedly intentional, is that what you mean? Come on.

MEMBER SWANSON: You could do the opposite. You could say, under two, such use listed in one, about causes, it has the potential to cause a non-beneficial exposure to the individual.

DR. GLENN: That would even be -- that would be more dangerous, I think.

MEMBER SWANSON: I don't think so. The potential --

DR. GLENN: Unless it's medical exposure.

MEMBER SWANSON: Testing the room's equipment is beneficial exposure.

DR. GLENN: Yes.

MEMBER SWANSON: Putting it in someone's sandwich is not beneficial exposure, okay.

DR. GLENN: Hopefully, there is not routine violation of condition one. I guess what we're hearing is that there may be a lot of circumstances that are -- which are violations of condition one. Those can be fixed. I mean, a simple license amendment would fix those.

MR. CAMPER: The authorization to encompass things, like Lou's example.

CHAIRMAN SIEGEL: I'm more concerned about interpretation of condition one. Unfortunately, the copy of Part 35 we have here is an old one. We don't have one that's been updated with the radiopharmacy changes.

And I'm just -- I'm trying to just think if there's anything, in terms of the use of by-product material in medicine that could be viewed, that we would view as a routine practice, but that you could somehow interpret as not authorized by the applicable license.

I don't think there is. I mean, if we can afford the radiopharmaceutical, then give me a therapeutic pharmaceutical for something that I'm labelling, would it fit this reporting requirement?

I think the radiopharmacy rule has fixed this completely. My question is is there anything in brachytherapy or teletherapy regulations which could -- that we would

consider a routine practice, would be captured as condition one. Jack, do you have an answer to that, or?

MEMBER WILLIAMSON: Well, some questions at least. I'm -- it's never been clear to me, for example, that the authorized use really addresses, for example, quality assurance, dosimetry measurements, and other things like that. Which we need to do, but, you know, I'm not really aware that our license addresses it in general. It certainly does for radiopharmaceuticals. I know I've inserted it in some of the amendments I've written recently, just to cover myself.

CHAIRMAN SIEGEL: Check sources and [Inaudible word] sources.

MEMBER WILLIAMSON: Yes. So what if I take a source out to do some measure strength, and maybe a student is observing, okay. Would this be covered as an occupational [Inaudible word]?

It's intentional. This person gets a microsievert of a radiation. Do I have to report that to you? That I allowed a student to watch me calibrate sert?

DR. GLENN: I think that's certainly within the intent of what we think we're operating on, on most broad scope licenses, but I won't swear that you couldn't find licenses written in such a way that it wasn't permitted.

MEMBER WILLIAMSON: Or Louis' example, where, you know, he's moved the radiopharmaceutical to a room, to test the shielding integrity.

DR. GLENN: I don't know. Do you know the definition of research and development? Because almost all of these broad scope license, to do these kinds of things, have research and development as one of the activities. That would be 30-something P, I think.

CHAIRMAN SIEGEL: I have it. Research and development means "theoretical analysis, exploration or experimentation." That's good.

Or "to the extension of investigative frames, materials of a scientific or technical nature into practical applications or for experimental or demonstration purposes, including experimental production or testing of models, devices, materials, and processes."

"Research and development, as used in this part and in Parts 31 through 35, does not include the internal ingestion or administration of by-product material, or the radiation therefrom to human beings."

DR. GLENN: I think that that would cover almost all of the activities that people have mentioned so far.

MR. CAMPER: One observation here, in terms of what's being raised. When somebody tells us that, when we

develop studies under the rules, if it goes that way. But we need to be clear about these points.

DR. GLENN: Yes.

MEMBER WILLIAMSON: I just would hazard a general opinion, having discussed a few examples. That you would just -- even though the criterion may not be absolutely clear, you put it in there, what you really want.

You want these things to be reported to you that involve isotopes used with the intent as a weapon, more or less. That's really what you'd like to know.

DR. GLENN: We certainly want to catch that, and we might want to catch a little more than that. But I'm afraid that --

MR. CAMPER: Let me give you another example, where it's not a weapon, it's not designed to harm, it's when the technologist decides that it's going to image the other technologist's scanners [Inaudible words]. Not a weapon, not [Inaudible word], but it's not authorized.

DR. GLENN: And I've seen that happen.

MEMBER WILLIAMSON: That's happened a lot. Sure, I have, absolutely.

MEMBER WAGNER: I had a technologist once, who wanted to prove that they weren't screwing up on the imaging. They injected themselves to help prove it.

CHAIRMAN SIEGEL: Ever since they took those fluoroscope machines out of shoe stores.

(Laughter.)

DR. GLENN: Certainly, if you have suggestions on better ways to word it to get at the intent.

MEMBER WAGNER: John, my biggest problem is that a lot of these regulations -- it's matter that it's very difficult to interpret them correctly.

And the intent of the regulation gets somehow buried in the legalistic wording and the precise wording of these things. And I think that's where a lot of the anxiety is created, between the licensee and the NRC.

And we really need to have a better communication somehow. I don't know how to do it, but we really need a better communication of why are we doing it, what is our intent.

And, you know, if you do it this way. The examples we brought up. We already showed that, at the beginning, we're struggling with what exactly is the meaning.

It makes RSO's and other people -- it gives them anxiety, in looking at these things. They're inclined to say "well, gee, does that fall under this rule?"

It's just like the same problem you had at M.I.T., looking at the 24 hour situation and the

interpretation. It gives us anxiety all the time to know "well, gee, are we within, or are we not within these bounds?"

DR. GLENN: We'll accept help, in terms of sharpening that up. Now, the thing is should it be a regulation? I guess you can comment on that, too. But, if it's going to be a regulation, is there a better way to say it? We certainly need your help.

MEMBER FLYNN: If you have a regulation, will you have a regulatory guide also, that could be two or three pages long, maybe four or five examples for the RSO's to understand the intent of the regulation?

DR. GLENN: We hadn't been planning on that, but that's certainly -- it wouldn't have to be a long regulation. I think three or four pages long, giving the four or five examples that you're thinking about.

MEMBER WILLIAMSON: If the concern of it being a regulation and being sort of broad like this is that -- I know if something slips by, you know it doesn't fit your intent.

If you find out that you slip up, even though it's a totally trivial violation, it's a very -- it's a level three, they're going to come after us, and harass us unmercifully.

We've had this happen with the administration criteria, where I'm sure tens of thousands of dollars were spent over what was essentially an administrative,

misadministration. There never was an issue of harm to patient. There was no, not even a blip in the treatment.

So I'm concerned that, when it's written as a regulation like this, the punishment's attached, and the intent is not spelled out in a very clear way, and could capture a lot of innocent things that could be used as clubs to beat institutions unfairly.

CHAIRMAN SIEGEL: The issue here is prevention.

DR. GLENN: That's the point. I mean, that's the whole point.

CHAIRMAN SIEGEL: Okay. I actually think that you two guys are overreacting to this a little bit. I, having explored now some of the thinking a little bit, with John, if you realize that we've got three fairly explicit conditions that have to be met.

First of all, that it wasn't something that was authorized by the license. That, at least in the case of most broad licenses, institutions -- most of the things we've suggested that we might be worried about are, in fact, captured by the license.

Two, and the second is that it was intentional or has been alleged to be intentional. And those are pretty uncommon intersections of two conditions, to do it.

One thing that might soften it, and I'm sure you've all talked about it, is, instead of saying no limit,

did you consider the possibility that you might set a lower threshold for reporting than the M.P.D.'s?

As a way of capturing more events, but not necessarily capturing the sublimely ridiculous sort of microsievert exposure, because someone carried this, I guess, from room A to room B, and that wasn't authorized by the license.

DR. GLENN: Yes. I guess it -- I'm sure it's been considered, but the problem is, that the sense, the intent that we're trying to get at -- what's the threshold for intent, I guess, maybe. Yes, we're trying to get into heads again.

MEMBER WILLIAMSON: When you say intent, you're trying to get in, you've already done that, the [Inaudible words].

DR. GLENN: Well, maybe we'll put the next one up, because we sort of go a little further. So that you don't feel that you have to stretch your imagination too much, in terms of the intent. And that is that, if you're in doubt, report.

That's essentially what Section B says. "The licensee shall notify the NRC Operation Center, by telephone, as soon as practical, but not later than 48 hours after discovering that provisions (a)(1) and (a)(2)_ occurred, and

that the licensee cannot rule out that the use was intentional."

So, if you have -- it was not permitted by the license, it had the potential to expose the person, and you can't rule out the use was intentional, report it.

CHAIRMAN SIEGEL: John, every time a technologist undergoes a thyroid bioassay, and the thyroid counts are elevated, you have to say to yourself, "oh my God, now that could have happened because that technologist did therapy yesterday.

But, wait a minute. Couldn't someone have intentionally given that person iodine-131 in their coffee, and oh my God, it could be intentional? I have 24 hours to launch an intensive investigation. And, depending on what I find, I have to call the NRC." In all fairness, this --

DR. GLENN: Maybe that's why we need a threshold, because, you know, if the person could have gotten an exposure as part of their routine activities, and whatever you find is within the bounds, that could happen in that routine activity, maybe that -- the presumption should be that it was part of the routine activity.

CHAIRMAN SIEGEL: And cannot rule out. So anything I find, there's no way I can rule out that it was intentional.

MEMBER SWANSON: Can't you reword that to say that, you know, it's either -- that the fact that it was intentional was either known, or suspected.

CHAIRMAN SIEGEL: Well, that's what it says, in the first one.

MEMBER SWANSON: Yes. It needs to end right there.

CHAIRMAN SIEGEL: I think it's just major, major --

MEMBER WILLIAMSON: Wait a second, Barry. It does say 1(a) has to be true, (a)(1) has to be true. And that means there would have to be a documentative, non-authorized use.

CHAIRMAN SIEGEL: No.

MEMBER WILLIAMSON: Yes.

CHAIRMAN SIEGEL: Go backwards. Let me see.

DR. GLENN: I think what we intended -- What you're saying -- I think what Barry's saying, there could always be one of those acts as well as what the person is authorized to do.

CHAIRMAN SIEGEL: You can't ever rule out (a)(1). If you find that a human being has activity in them, you can't ever exclude that didn't occur, because it wasn't by way of (a)(1). How can you exclude it?

And I'm assuming that no license authorizes someone to divert radioactive material into someone's coffee. No license assume that. Anytime there's internal intake, that always was a possibility, and, therefore, condition (a)(1) is instantaneously satisfied.

DR. GLENN: And I see what you're saying. Take, for example, the M.I.T. exposure. The person found it doing a survey first. The person did work with P-32, it was possible that they could have had contamination.

What made us determine that it was a deliberate act was that it was ten times whatever he worked with, at any one time.

As the idea that a person continually contaminates himself with small amounts of P-32, gets up to that large a quantity, it would stretch credulity quite a bit. It seems like it had to have been --

MEMBER WAGNER: What you have is an internal conflict, with what you have up there, because (a)(10 makes it sound like you know that it was used for a purpose not authorized.

But, then, when you go to this B over here, it says "and the licensee cannot rule out the use was intentional." Well, if you know (a)(1) -- after discovering that provision (a)(1) has occurred.

Once you know (a)(1), you don't need (b), "and the licensee cannot rule out," because, by virtue of the fact that it occurred under (a)(1), it had to be intentional, for that. It was not authorized, and you determined that it was not authorized.

MEMBER SWANSON: You could change that by saying that the provisions of (a)(1), (a)(2), and (a)(3) have to be met. And that it was allegedly intentional, and you can't prove it otherwise.

MEMBER WILLIAMSON: I think that that's true. Maybe (b) should just be strengthened, because you can -- you've written it in such a way that, if you don't have proof that it was unintentional, it was intentional.

Act as if it were intentional, rather than what you probably mean is there's some prima facie evidence that it was intentional.

DR. GLENN: Well, you certainly don't want to hear about every possible violation.

CHAIRMAN SIEGEL: That's one way to keep you from sending out teams to investigate.

(Laughter.)

MEMBER WAGNER: What you really want to know about is --

CHAIRMAN SIEGEL: Operators are standing by.

(Laughter.)

MEMBER WAGNER: What you really want to know is if there was some subversive action. And that's really what you want to know. You want to make it clear to the licensee that he must have reason to suspect that this was a subversive action. You want to communicate that.

DR. GLENN: And, if they have any suspicion, we want them to err on the side of reporting it rather than not reporting it. That's really what this is saying, err on the side of reporting.

MEMBER WAGNER: That's right, but the way it's worded, it's clearly got some internal conflicts that aren't getting that message across appropriately. Maybe you need the word subversive. Maybe that word subversive.

DR. GLENN: Then we get into an argument about what subversive means.

MEMBER WILLIAMSON: We know that. Now, you've got the argument of suspicion. You have to prove a state of suspicion, so.

CHAIRMAN SIEGEL: One person at a time. The House Committee on Un-American Activities.

(Laughter.)

DR. GLENN: C, I don't think it has judicious, telling you who to report it to.

MEMBER STITT: I don't understand. There are so many conditions, and so many subcategories. And there's a 24 and there's a 48.

And, you know, it's easy to look back at things, but various points, probably a very common one. And how to you know, if you're looking at a tech's readings?

DR. GLENN: Well, you think it's not -- well, the 48 hours essentially gives you time to do some investigation, and, at the end of that time, if you haven't reached a conclusion, report it.

MEMBER STITT: So you're required to do a 24 hour report, and then a 48 hour report, depending on what criteria? I think we need more staff to work these.

MEMBER WAGNER: You've got to do this in 24 hours. You've got a busy day. You've got other obligations you've got to do. There are obligations to patients, and things you've got to carry out. You're supposed to stop everything, because there might have been a minuscule exposure that was intentioned?

DR. GLENN: It's not our intent to capture those.

CHAIRMAN SIEGEL: I think, if what we're looking for really occurs, you do want to take some time out, and look into it. But I think I've heard the message about B.

DR. GLENN: One fix could be to just quit with A. We'll consider that. D just points out that, if you make a

report because it's an overexposure, that takes care of the reporting requirement.

CHAIRMAN SIEGEL: I see. So you don't have to report it twice?

DR. GLENN: You don't have to report it twice.

CHAIRMAN SIEGEL: That's true for al reporting requirements, isn't it? I mean, if something has --

DR. GLENN: I think so. Unless, I guess, if there's something you don't disclose about the event. If you just report that there's been an event, and there's another reporting requirement that really should disclose something else about it, then that might be.

In this case, we're being very clear. If you told us that it's an overexposure, we're probably going to investigate it, so we don't need to know anything more.

CHAIRMAN SIEGEL: Just, for the record. Is there a consensus of the Committee, B is overkilled? Judy, do you agree with that, too?

MEMBER BROWN: If you [Inaudible words].

CHAIRMAN SIEGEL: We have consensus on that.

DR. GLENN: Okay, just the cost analysis, as it was presented in the Federal Register notice. We were estimating that there could be up to 20 of these per year.

That's a guess. We know about about one per year, so this is assuming that we're only getting about five percent, through current methods.

We estimate 20 hours, in determining the cause of the event, preparing the report, complete management review of it, and call to the NRC Operations Center.

We have not included in there if the NRC decides to send an IIT. How much time that's going to take, in terms of the staff time.

But that's really under our emergency response and enforcement, and that sort of thing. It's already been accounted for, in other regulations. So, any comment on that?

CHAIRMAN SIEGEL: John, when you send an IIT out to an institution, do you bill the institution for the cost of the?

DR. GLENN: No, we don't. No institution could probably bear the cost.

CHAIRMAN SIEGEL: Because that would certainly be a disincentive to report it.

DR. GLENN: Yes.

MEMBER WAGNER: Not even the NIH?

CHAIRMAN SIEGEL: Any comment about the cost analysis?

MEMBER SWANSON: Do we have any idea of a cost benefit analysis? We're spending 46,400 dollars. What's the

benefit accrued from that? I mean, if you take these two events we looked at, what did the NRC involvement change in how the patients were taken care of?

DR. GLENN: I think we we're saying that this is really an adequate protection kind of thing. That, if there are deliberate acts occurring out there, that that's a sufficient threat that we really don't have to do the normal cost-benefit, 2,000 dollars per person analysis.

Though, again, at 46,000 dollars it would only be 23 rem would justify the cost. So, if someone reported four of them, about five rem, you know, and we could have in some way deterred those, the cost would be covered.

MEMBER SWANSON: I don't think that's a cost-benefit analysis. What I'm saying is you're going to get this information.

What have you seen that, by you having this information, has changed how this -- I can't say the patient in this case, the victim of this event has been treated?

Because you pointed out, clearly, in M.I.T. that, you know, the actions of the institution were appropriate in taking care of the individuals involved. So what's the ultimate benefit of this to the public, the public member?

CHAIRMAN SIEGEL: That's actually not the purpose. I mean, that's not the principal purpose. The

principal purpose is not to ameliorate injury to the potentially injured parties.

The principal purpose is to gather the information, to determine if there is any trend that warrants intervention.

So that -- I mean, if in fact M.I.T. and NIH really are the first two events in what is a unidoser, as opposed to the Unabomber, the NRC having access to that information is the best way to become aware of it.

MR. CAMPER: Intervention may be informing.

CHAIRMAN SIEGEL: I mean, at least in theory, that is the one public reason for the information to come to a central clearinghouse.

MEMBER SWANSON: But, in practicality, if somebody set out to deviate, to do this, they're going to do it.

They're going to find a way to do this. So I'll go on record saying I really don't think that there's going to be much benefit derived from this, okay.

MEMBER FLYNN: I think a person who does this once, though, may do it more than once, and may move from lab to lab. And, if they can get their hands on, instead of a half a millicurie, can get their hands on 50 millicuries, then you could have some have some deaths with [Inaudible words] in about three weeks.

But the couple of the accidental exposures, where they did get 50 millicuries, I mean, their white counts dropped to zero basically. Those were accidental exposures in cancer patients.

So I think what would concern me is one or two individuals, who have some psychotic problem, if they do this once, and they're working in a laboratory environment, and they move from one institution to another. I'd be concerned that they could do this a second time or a third time.

MR. CAMPER: Or copycatting by someone else.

DR. GLENN: One of the reasons why M.I.T. was an iodine case was there's a possibility that there was copycatting, I mean.

MEMBER WAGNER: I just had another observation. I'm very concerned about the fact that there's no threshold for reporting in terms of doses.

And the issue that I have here is that you do want everything to be reported, even down to very low levels.

The exposure results, in less than a millirem, for example, the person's still going to be reporting. And I'm not sure that that, not having some kind of a threshold, isn't appropriate for this.

How much consideration have you given to that idea, of a zero versus some other more reasonable threshold,

like maybe one-tenth of the MPD, or something like that, as a reporting threshold, for this kind of event?

DR. GLENN: We can certainly re-look at it. If you really pass all three of those tests with flying colors, it's hard to have a threshold.

I mean, if it's clear it was not authorized -- well, I guess, what you're saying is two is only conditionally met before, for a very small exposure. That they have to expose an individual.

MEMBER WAGNER: Yes. That's right.

MR. CAMPER: These are intentional, or allegedly intentional events. It shouldn't be driven by thresholds. We want an awareness.

MEMBER WAGNER: It's something to think about. I'm not sure about it. I haven't given it a lot of thought.

There's an issue, I think, with regard to how -- the thing, I guess, I'm worrying most about is how are the users going to interpret this, and how much anxiety is it going to cause them?

What are they going -- are they going to be able to use this, in a practical sense, without much burden, or is it going to cause a lot of anxiety, when you get down to these really small amounts?

DR. GLENN: Yes.

MEMBER WAGNER: And that's what I have a problem with.

DR. GLENN: I think one of the things that we're concerned about is, if you do put in a threshold, then you have people measuring to see how close to the threshold -- once you draw a line, then people work to that line, and make calls.

They may make a bad call, whether to report it or not, because they think they're going to be under, but then they turn out to be over the line and that sort of thing. But.

MEMBER WAGNER: Yes. And I agree with your point that it's quite uncanny that the exposures in both cases were just marginally at the limits.

It's almost as if the person who did it thought that, if he worked under the limits, it would never be reported. That it would be a ha-ha, at the institution.

And either that person is sitting around laughing, and saying "gosh, look how I got the NRC involved." Or else that person's sitting around, saying "oh my God, I really screwed up. I got them involved, and I didn't want to." I mean.

DR. GLENN: The opposite possibility is also there. That, if somebody wanted to do something to get a lot of attention, it wouldn't really be that harmful.

MEMBER WAGNER: Yes.

CHAIRMAN SIEGEL: John, what was that radioactive material getting into the [Inaudible word] waste stream? So --

DR. GLENN: Deliberately. I think it had to be deliberately.

CHAIRMAN SIEGEL: You can't -- that's where you really get into problems.

DR. GLENN: I see. So you're saying that --

CHAIRMAN SIEGEL: A vial of -- ten microcuries of P-32 gets thrown into the regular trash. The researcher says "I can't be bothered with it." Maybe it was intentional, but there's no way to know.

It gets thrown into the regular trash. It has the potential to cause exposure to an individual. And that potential to cause exposure really now gives you a huge amount of latitude, in terms of what you would define as being captured by item two. And it could have been intentional.

So, it wasn't authorized under the license, it has the potential, and it could have been intentional. It's got to be reported. Here, boy, is this going -- even A is going too far.

MEMBER WAGNER: You're finally coming around to seeing my point of view.

CHAIRMAN SIEGEL: No, I absolutely understand the NRC point of view, in terms of wanting to capture willful acts of subversion. I like the term. But I just don't think you want to catch these little events --

DR. GLENN: Well, that's what I'm saying --

CHAIRMAN SIEGEL: -- that might have been intentional.

DR. GLENN: Remember, we're not after the might have beens. You know, where there's an explanation for it but we can't rule out that it was deliberate.

CHAIRMAN SIEGEL: But B clearly has to go, then. But even A still has potential problems.

MEMBER FLYNN: In this four page reg guide, if the intention is that there may be between one and 20 -- between one case and 20 cases a year that may be reported, and give three or four examples, it's going to really clear as to what the intention is. If you're expecting --

DR. GLENN: Examples may be the best way to do it.

MEMBER FLYNN: Examples, because you're saying we expect maybe one case a year, maybe up to as high as 20, and these are the kinds of cases that we are focussing on.

MR. CAMPER: But, again we need to be in statements of consideration space. We need to draw these clear distinctions as examples, perhaps, in the SOC.

MEMBER WAGNER: Some of this wording. You're using this word intentional, and why is it difficult to put into number two, (a)(2), where you say "has the potential to cause an exposure to an individual."

Why can't you make it more qualified, in that it is an act that appears, at least has the appearance or the intention of exposing an individual? If it has the intention of exposing an individual, that's really what you're trying to capture.

DR. GLENN: We think the way we put one, two, and three together, I mean, we've already done that.

MEMBER WAGNER: Yes, but it's not clear, because, if you read it in the order that it's in, that doesn't come out, to me. But the intention to expose an individual is what the point is.

And that clears up Barry's point about throwing it into a trash can. That clearly was not intended, because it was in the trash.

CHAIRMAN SIEGEL: I stored a sealed source in an unshielded cabinet, because it was more convenient for me. But I wasn't intending to expose other people.

It has the potential to cause exposure, it was a willful act, it wasn't authorized by the license, but I wasn't really trying to harm people. I was just being a little stupid. Report it?

MEMBER WAGNER: That's got to be taken care of internally. That's an internal consideration.

CHAIRMAN SIEGEL: I mean, I don't see an instantaneous fix, at the moment, in my own head, but I do see problems with this, and I suspect --

DR. GLENN: What I'm hearing consistently is the boundaries aren't clear.

MEMBER WAGNER: It's very true.

CHAIRMAN SIEGEL: The language captures too much.

DR. GLENN: And I can tell you that I know that the staff struggled with the language. We thought we'd done a pretty good job, but you're telling us that we haven't done well enough.

MEMBER STITT: Well, I'm not sure you can ever get the product you wanted. Even though you've got some good examples in here, as I read them through, I nodded my head yes and no.

But, you know, I could be involved in something, and decide it doesn't fit, and then you could come back later and say it certainly did. I can understand why you would have interpreted it this way.

I mean, so you're always going to lose, without some sort of boundaries. But we actually don't want any boundaries, any levels, any minimums.

DR. GLENN: Well, you want a boundary on the wrongness of it. We don't want a boundary on the significance of the individual event, because we were saying that the significance can go beyond the actual exposure in the event.

MEMBER WAGNER: I think intentional exposure of individuals is a very critical aspect. That the RSO, or the person in charge must determine that there was an intentional effort to expose someone.

MEMBER WILLIAMSON: Or evidence thereof, some reason.

MEMBER WAGNER: Yes. And then I think, if you transferred a little more authority to the RSO -- I know you're suspicious of them a lot of times. But you've got to give them a little bit of leeway to make that interpretation, so they feel comfortable with what they did.

If it's a matter that -- I think they have to be given a little more of that authority, because it's something that simply has to be turned over. They have to determine whether or not there was an intent to expose somebody.

And that's something, you know, that's always going to be controversial, because the RSO inspector is going to say "well, we think it was intentional." "Well, we didn't." And there's always going to be a reason for one side or the other.

But, when there's clear cases, then I think that it's evident. I mean, if the water cooler is contaminated, there's clear indication that this was an intent to expose.

DR. GLENN: And I think, in most of the cases we're interested in getting reported, it will be fairly clear, but -- and you're telling me we need to define the boundaries.

To finish up here. We did ask for public comment, and your comments will be taken into account. But, if you want to make more comments, you're welcome to do it.

One thing I will mention is there was a 30 day comment period. We have had several requests for an extension of the comment period, and we will be doing something shortly on that. There will be more time to comment.

CHAIRMAN SIEGEL: Why did you elect only 30 days on this one?

DR. GLENN: Because we felt that it was important enough that it needed to get out in a hurry. But given the fact that people were telling us that they don't have enough time to make appropriate comments, we're going to expand the comment period.

MEMBER WAGNER: The other comment I guess I'd make, John, is that, in terms of citing people and violations, if an RSO intentionally covers up something, or intentionally withholds information that should have been reported, that's a serious violation. That is quite clear.

But, a lot of times, these rules and regulations get so convoluted and difficult to interpret, that RSO's spend a good amount of time just trying to figure them out.

And they become victim to the convolution of the regulation. And that, I think, they live in fear of, which is part of our problem here.

You know, I sympathize with the fact that yes, if somebody tries to really cover up information, or willfully does not report something that should be reported, that's wrongdoing. But.

DR. GLENN: Again, the one thing people are going to report. But what you're saying is it's not going to be easy to determine when.

MEMBER WILLIAMSON: What I was suggesting was just say in clear, everyday English this is the category of cases you want captured.

DR. GLENN: If you've got the clear, everyday English, send it to us.

MEMBER WILLIAMSON: Cases where somebody tries to, intends to injure another person via the mechanism of radiation exposure. That's what you want, but you get kind of very legalistic definition of that. That doesn't make it exactly clear what you intended.

CHAIRMAN SIEGEL: But that means that a prank wouldn't be captured.

MEMBER WILLIAMSON: Yes. It should be refined to include pranks, too, I think.

DR. GLENN: Send your language.

CHAIRMAN SIEGEL: Good. Any other comments on this?

(No response.)

Thanks, John. We appreciate your making the time to tell us about this, and we're glad we got a chance to express our concerns about it.

MEMBER FLYNN: Just one other point. That, at Oak Ridge, at REACTS, they do have an international registry of radiation accidents, and I'm not sure if it includes some of these European exposures, too.

CHAIRMAN SIEGEL: All right. Anything for us, that's relevant to us? No.

MEMBER WAGNER: I have your e-mail here that states "I just finished reading Science Without Sense, by Steven Milloy," M-I-L-L-O-Y. This is your e-mail.

CHAIRMAN SIEGEL: Oh, good.

MEMBER WAGNER: And --

CHAIRMAN SIEGEL: You're really a pack rat, aren't you?

(Laughter.)

MEMBER WAGNER: I have too much -- I just want you to tell me what I have got to do to get that, off of here, off of the e-mail.

CHAIRMAN SIEGEL: Send it over. Put it on the record so everybody in the United States can know about this.

MEMBER WAGNER: That was the problem with the e-mail, I think, because it said to get it, but I didn't see how I was going to get it.

CHAIRMAN SIEGEL: Yes, it's the Cato Institute, and I thought this e-mail message contained Milloy's address. No, but there's actually an e-mail address you can order it from, and I was going to give it to you. It doesn't. I'll get it for you.

MEMBER WAGNER: Okay.

CHAIRMAN SIEGEL: Okay. All right. Is there any other business left undone? If not, as far as I'm concerned, we can adjourn, and that means Larry can do it officially.

MR. CAMPER: I would like to make just two comments in closing. I would like to thank the members, again, for the deliberation on the NAS report, and on these regulations. Again, we thank you. I appreciate your efforts.

And I'd also like to thank, on the record, the representatives of the National Academy, Kate Louise Gotfried and John Villforth.

They, yesterday, had to present a report, obviously, that's somewhat controversial. They had to defend those findings. And I commend them for doing the best job they could. Thank you. That's -- and I declare the meeting closed.

(Whereupon, the foregoing meeting of the Advisory Committee on the Medical Uses of Isotopes went off the record at 2:56 p.m.)