UNITED STATES NUCLEAR REGULATORY COMMISSION

PUBLIC MEETING

ON MEDICAL ISSUES PAPER AND OTHER

REGULATION ISSUES

Sheraton Baltimore North Hotel

903 Dulaney Valley Road

Towson, Maryland

October 29, 1992

8:04 a.m.

ANN RILEY & ASSOCIATES, Ltd.
Court Reporters
1612 K. Street, N.W., Suite 300
Washington, D. C. 20006
(202) 293-3950

A-4

I N D E X

PROCEEDINGS

CHAIRMAN MILLER: Good morning again. It seems that I was just here a few minutes ago. But this is our public meeting for today, and for the public I am Vandy Miller, the Assistant Director for the Agreement State Program in the Office of State Programs, U.S. Nuclear Regulatory Commission.

Now, today, our public meeting will probably last all day. What we have managed to do initially is to include the regulations that we want very early, early input into initially, and there will be several of them being discussed here this morning.

Then, about mid-morning we will have a break and then finish up on the regulations, and then the rest of the day will be spent on a special session lasting several hours, and will be devoted to the upcoming medical issues. We have several staff members from the U.S. Nuclear Regulatory Commission who are sitting out in the audience right now who will be handling that portion.

Now last evening, just before we ended up, I made a mistake in that I did not reccgnize -- well, I will take care of that later. Let's go on with the public meeting.

Now, we are going to have Dr. Donald Cool who spoke to you yesterday to come up, and he will take care of the first four items listed on your handout: one, 10 CFR

Part 20 clarification; two, 10 CFR Part 34 radiography; three, PRM 20 CFR Part 20 and 35, releases of patients; and four, 10 CFR Part 30, 40, and 70, timeliness of decommissioning.

After he finishes with those four, then we will call on Paul Lohaus, but first, let's hear from Dr. Donald Cool from the Office of Research.

DR. COOL: I wanted to spend just a few moments this morning to review where we are on several rule makings which have been of interest to you before, a couple of rulemakings which are very new and to get your early input on those.

As in times past, this is an opportunity for us to tell you some idea of what is going on and simultaneously to get your input with regard to the directions, comments that you may have.

As I go through each one of them, I will talk about the status of where the rulemaking is, where we are in that process, and what time constraints I may have in terms of getting input from you after this meeting.

You can go ahead and put on the next slide.

The first of the rulemakings deals with 10 CFR Part 20, and in particular some clarifications of requirements.

You are probably saying why in the world would Don

Cool be standing up here talking about a rulemaking on Part 20, that ought to be the last thing that Don Cool ought to be considering, given that the revision of Part 20 is not even mandatory yet, that most of you have not yet had an opportunity to put it into your state regulations, that the SSR really isn't finished up yet, and all those other things.

Well, there are a couple of reasons why craziness dictates that we might look at a couple of items. As we have gone around, developed the Regulatory Guides, done training sessions, held meetings like this all across the country in a w'de variety of settings, we have been asking people to give us input on how they perceive the Rule is going to work.

We have been trying to sort out exactly how it is going to be implemented, and there have been questions that have been raised. There have been situations that over the course of time it has been clear to us that despite all of our best efforts, some things maybe weren't as crystal clear and golden as you might otherwise want them to be, that when the reality of how it is going to work meets the little printed letters in the Federal Register, that there were some discrepancies.

Furthermore, just a couple of weeks ago, the Nuclear Regulatory Commission published a Policy on

Metrication, and I am going to deal with how that may impact Part 20 in just a minute.

The next slide.

The staff is at this moment considering -- and I say considering, it has not been initiated, it has not been an approved rulemaking activity by our executive director -- but we are considering whether or not to try and do a limited rulemaking, purpose to have a proposed rule on the street early in 1993, final by January 1, 1994, for obvious reasons, to correspond to the implementation date for the revised Part 20.

If we did such a thing, the changes would be only to those sections where there is sufficient rationale -- meaning there is sufficient unclarity, confusion, or otherwise to warrant trying to go in and surgically fix it.I am not talking about opening up a wholesale Part 20 bandwagon for you all to come and give me whatever you don't like. I know everybody has got their own favorite list of things that they would like to change in Part 20, and the list, if I had it on a computer paper and dropped it, it would crash to the floor and just sort of pile up there, because it is a very long list, everybody has got their own pet things they would like to do.

I have my own list of pet things that I would like to do. We are not talking about that. We are talking about

one, two, three, four particular items which, in order for this to really work well, an amendment to the regulation to improve the clarity, to improve the preciseness of what we are talking about, to eliminate questions would be useful.

This is the first step in trying to solicit Agreement State input into the process. It will not be the only step. We are looking at the potential of trying to get back together with you folks in another few months when we have gotten some idea of what we really want to do and have some proposals to talk about.

The other thing that I clearly recognize is that you are in the process at this moment of trying to put together your implementing state regs and that you have to do that by January 1, 1994, so one of the other things that the Office of Research will be developing the standard plan to do is to work with the State Programs people and you folks to try and come to some mechanism whereby if it looks like we really are going to go in and try to correct or clarify some requirements, that we have some sort of mechanism to try and build that into your process of putting your state regulations into place on the first pass.

I know that there is an incredible difficulty every time the NRC goes in and changes something just about the time you have managed to get it in the regulation and you have to go back through the process again.

I don't know exactly how that will work, but that is one of our goals, is to try and see if we can't help you to integrate some of those in, perhaps by allowing some flexibility on those particular items as we go through the first pass or some other mechanism to try and get them in.

The next slide.

What are the sorts of things we are talking about? This is one list. Maybe it is the right list, maybe it is the wrong list.

The first one, and the one that has sort of caused the most confusion, is the definition and use of a little term called "Controlled Area" that came into the revised Part 20.

This being an election year, my friends from Illinois have gone on the campaign trail. They have produced some buttons, which they gave me an honorary one.

Lloyd, why don't you put up that other one, just so everybody knows what this thing says. Okay. Take it back off.

[Laughter.]

DR. COOL: The question is whether or not to have that term, and if so, how it should be used. The Commission had originally put "Controlled Area" in to recognize the fact that a lot of licensees have areas that they control for some reason, not radiological, but they have got it

there because they want physical security in some cases, because they just don't want people wandering around, or whatever it happens to be.

Questions have arisen in times past, back in history with the other Part 20, which had only "Restricted Area" or "Unrestricted Areas." Licensees said, well, what do I about this place, I am controlling it, what applies.

So, in the infinite wisdom we thought, well, okay, we will call that a controlled area and we will try to make it clear what works and doesn't work there.

Well, now we get the flip side. What is this controlled area, what do I do with it, what applies? So, the same sort of questions have been coming back from the other side.

So, one of the items that we particularly believe may need a re-look is whether or not we continue to use the term and exactly how it should be applied.

Another one is where do the occupational dose limits apply, where do the public dose limits apply. In particular, we have had a lot of people who are very upset at the prospect that if you have a member of the public walk into a restricted area, under the regulation they would be subject to occupational doses. That is the way it is defined.

I don't think anybody in their right mind would

actually allow the school kids or the teachers association who are going through their local facility on the tour for the next hour to get anything measurable, let alone anything close to the public dose limit, let alone anything close to the occupational dose limit, but that is what the rule provides at this time.

So, that has raised some serious questions and hence, it is on our list as a potential thing to consider.

Another one: what is meant by dose from external sources? That seems like it ought to be relatively simple, but you would be amazed at the number of questions we have got as what is that 50 millirems sitting in there.

The next slide.

Another one that we have gotten an amazing number of questions on is at what point licensees can disregard some radionuclides that are in a mixture of radioactive materials in the air. 1204(g) has some words about that, and there has continued to be some confusion. That one is a little bit low on the priority list and may or may not need to be fixed.

The last one deals with the use of SI units. Now, some of you probably are shrinking in your seat at the thought that you might have to use sieverts and becquerels, but the Commission did publish a policy statement on October 7th in response to the Omnibus Trade bill of a couple of

years ago where federal agencies are supposed to do what they can do to encourage the use of metric units to foster international trade, and those sorts of things.

In response to that, the Commission's policy statement says that things that the Commission publishes are going to be in dual dimensions, with the SI units first, sieverts, becquerels, and grays -- as much as you may not like them -- followed by the special units, rads, rems, curies.

It says that those things are going to be in place on all future documents, that the Commission is going to go back and look at existing documents to determine whether changes are needed.

The one area that it would not apply to would be areas involving event reporting and emergency response communications. It was that exact reason, the emergency response communications, that Part 20, when it came out in final form, did not have a provision that would allow licensees to use SI units.

You will remember perhaps that the revision was dual dimensioned. We had special units first, SI in parentheses, but they are both in there. But the rule in 2102 says you have to use the special units on records and reports. So, effectively, you can only use rad, rem, curies.

That was because of the great concern what if somebody has something go wrong, and they report to the NRC, and they report to the state, and they report to the local authority, and something is happening, and they go one. One what?

Well, one sievert would be one thing, and that would be very bad. One millisievert would be something different, that wouldn't be quite so bad. One rem, that would be yet something different. One millirem would be something a whole lot different yet.

So, there would be a great confusion if people weren't being consistent in what they used, the State folks, particularly the local authorities, of the concept of a sievert or a millisievert or a microsievert or a millicentisievert or one of those terms, totally confusing. So, we wanted to limit the aggravation that that would cause and stay with the special uni' that everyone was used to.The proposal that is being considered as part of this revision would be to go back and to add some flexibility to allow licensees to use the SI units or the special units, so long as they were consistent. Don't give me microcuries and sieverts on the same report.

I mean you are either going to be SI or you are going to be special units with the exception that anything that is reported related to events or emergency response

would have to be in the special units.

One of the considerations is that if you are going to use SI, you have to have the special units in parentheses behind it. So, those are the sorts of things that we are particularly thinking about.

I am going to stop at that point just for a moment as I work my way through these rulemakings to allow for any questions on that particular topic before I move on to the next one.

[No response.]

Next slide.

DR. COOL: Part 34. We have talked to you, at least a couple of times I think, on doing a revision of Part 34. In fact, some folks from the Office of Nuclear Material Safety and Safeguards were talking to you the other day about a particular aspect of Part 34 dealing with certification.

This rulemaking activity is a broader rulemaking activity, to go back and look at the entire rule, contemplating a revision. There are a couple of things that are new on the status line here.

The first is last week we received a petition from the International Union of Operating Engineers saying we would like you to amend Part 34 to require two-man crews and we are going to wrap the response to that petition into this

rulemaking revision. That was one of the issues that was already very clearly on the table.

The second, for those of you who have not already made your reservations, and Vandy has not already sent the checks, there is a workshop scheduled the 16th and 18th of this next month.

Notifications went out on that quite awhile ago, to spend a couple days and talk particularly about the issue, about the approaches that are going to be taken, about how this might look and to get a more detailed input during that session.

If I could have the next slide. All I am going to do is give you a couple of really quick highlights.

The revision would be to attempt to bring Part 34 back up to speed, pull in the good stuff that the Agreement States have put in, long since NRC's rule just sort of sat there, some things the Canadians and other folks have done, to try and change the rule in that process, so that we are more consistent with things like Part 20, which have been revised since that time, and, as a basis for that, to consider the format and arrangement of the current 10 CFR Part 39 as the basis for that revision.

One of the things that we looked at as we started to go through 34, and we struggled with it and we looked at this long list that you folks have given us about all these

things you would really like to fix, we looked at all that and we said, you know, this really doesn't work very well in this format, how can we do this.

We sort of looked around a little bit, and somebody said, well, you know, a couple of these things relate to Part 39. So, somebody went off and looked at Part 39.

The more we got looking at Part 39 and the structure of that rule -- which is a lot more recent -- the more it appeared to us that going with the format and arrangement organization items that were in Part 39, modified, so that they are for radiography, not for well logging, would deal with, and it looks to be something on the order of 90 percent or more of the items that people had given us as ideas of things that needed to be fixed.

So, here is the heads-up, early warning of things that we are going to talk about during that workshop in a couple weeks. The staff is right now considering using the Part 39 format as the basis and then taking the specific big issues, like whether or not to use two-man crews, and to hang it on that new framework as the basis for the revision of the rule.

You can go ahead and put the next slide up. That ends what I am going to say on Part 34.

Are there any questions on that before we go on?

MR. GODWIN: Godwin, Arizona.

Relative to the two-man crew, we would support that. However, you might need to look at whether you want to have that for a requirement in fixed operations. It is probably real good for field operations, but for a fixed facility it might not be quite as necessary.

DR. COOL: Thank you.

Anybody else?

[No response.]

DR. COOL: Under Parts 20 and 35, on the release of patients, you may recall that the revision of Part 20 said that members of the public should have a dose limit or shall now have a dose limit, Total Effective Dose Equivalent not to exceed 1 millisievert, .1 of a rem.

It also had a provision to allow a licensee to apply for approval up to 5 millisieverts under certain specified conditions, program laid out, what they are going to make sure things are allowed, limited time frames, the variety of things that is in the rule.

Go ahead and have the next slide.

Part 35, as it currently exists, says that licensees are not allowed to authorize the release of patients from confinement until either the dose rate is less than 5 millirem per hour or the in the patient is less than 30 millicuries.

Given those things we had several petitions for rulemaking that were submitted over the last year or so.

Go ahead and put up the next slide.

Dr. Carol Marcus submitted a petition, which was docketed as PRM-20-20, and the American College of Nuclear Medicine submitted a couple of petitions. They actually came in as part of the comment process on Dr. Marcus' petition, docketed as PRM-35-10 and 35-10A.

If we can have the next slide.

PRM-20-20 requested that the NRC raise the dose limit for members of the public for patients receiving radiopharmaceuticals from 1 millisievert to 5 millisieverts, and that we look at amending Part 35 to, one, retain the 30 millicuries for I-131, but otherwise allow the maximum activity to vary around in accordance with the dose calculation based on the NCRP Report 37.

If I could have the next slide.

The American College of Nuclear Medicine's Petition 35-10 and 10-A asked us, first, to delete 35.75(a)(2), that is, delete 30 millicuries, just gone, and furthermore, to allow an outpatient option instead of mandating hospitalization.

They came in with an amended petition which clarified it, did not really change the basic request, but clarified it, saying we would like to have doses greater

than 30 millicuries in diagnostic types of activities, as well as the therapies, and allow them to be released, and getting a little more specific, we would like confinement to be something like remaining in the hospital or a private residence. Sort of an interesting concept.

The next slide.

There has been a lot of thinking. We had a workshop with a lot of you folks that are here today from the Agreement States in Atlanta, back in July. We spent a whole afternoon talking about that.

Last week we spent several hours with our Advisory Committee on Medical Uses of Isotopes. The proposal that you see here reflects ACMUI. Now it is a week later and you get your shot to comment on ACMUI and the medical community thinks they might like.

Coming out of that meeting the proposal would appear to be a two-pronged proposal. The second one, the second bullet basically leaves in place what is there now. It says, "Measured Dose Rates less than 5 millirem or activity less than 30 millicuries," one or the other of those.

Then, an "and" clause, go back up to the one above it, that irrespective of either one of those, the Total Effective Dose Equivalent to a maximum exposed individual, less than 5 millisievert or 500 millirem.

To go along with that proposal would be to amend Part 20.1301 to exclude the dose from patients that are released under the provisions of Part 35 from the requirements of the dose limit, so that the perception, which was the driving force behind the petitions that if patients were released in accordance with Part 35, the licensee would nevertheless be in violation of Part 20 would be removed.

The next slide.

This proposal would rely on a licensee calculation of dose to the individual likely to receive the greatest exposure, and would hopefully have built into it sufficient flexibility to account for biological elimination, the fact that the radionuclides decay -- a lot of the things in nuclear medicine decay very rapidly, as a matter of fact -- the occupancy, all of those things that could affect the actual dose to the individual, the significant other, wife, spouse, kids, whatever that may be, when the patient is released and goes back home, the basis behind that being Part 20 already contained a provision that would allow you to go to 500 on certain circumstances, so it is not a different number.

That number was based on the fact that the long-term dose rate ought not to exceed 100 millirem per year, but variations above that were acceptable in short

circumstances.

Here, you have got certainly a justification. You have got an individual who is not paying costs of staying in the hospital, is with family receiving that care and comfort which tends to be really beneficial for a patient's well-being, mental if not physical, so it would rely on that sort of calculation.

It would retain the two criterion that you had already, the 5 millirem and the 30 millicuries, for the practical ease of a nuclear medicine physician, knowing that he was able to release the patient on the basis of a measurement.

One of the things that the ACMUI came out very strongly on was if I just have it be this total dose rate, or I just use a dose rate 5 millirem or whatever it is, suppose I have got a patient whose uptake is a little bit different or who is thinner than the standard model, and so I run my standard protocol and it's an outpatient I am all ready to release, and I waive the meter, and whoops, now what do I do.

So, the medical folks argued that it would help them to retain those two criterion.

The third piece of that would be that the staff would propose probably some type of Regulatory Guide which would have some indication of some standard assumptions

which would be acceptable in terms of calculating the Total Effective Dose Equivalent to a maximally exposed individual.

For example, we could live if you are assuming occupancy, say, of a third or a quarter, some of those sorts of things. Licensees would always have the ability to look at the specifics of the case and do a specific calculation, but once again, that would allow you to generate sort of a standard set of numbers which would be relatively simple to use in the Regulatory Guide sort of format, the use of a Regulatory Guide rather than the rule in order to allow the licensees to continue to have that flexibility associated with the actual calculation.

That is where we are on that particular proposal. I will stop and see if you want to give me any feedback on that rule.

MS. McBURNEY: Ruth McBurney, Texas.

In your current rule, and you have confinement for medical care, is the intent of that hospitalized, and if so, why can't you just use the word "hospitalized," or does that mean in a clinical setting or what?

DR. COOL: Confinement -- and perhaps I am going to let John Glenn or some one of those folks answer the specific question -- the staff proposal at this point is not to change with regard to confinement.

The problem that we had with the proposal that

came out was if you allow confinement or something like that to mean someplace other than where you have control of the individual, then you really don't have control of the individual.

MS. McBURNEY: That is correct.

DR. COOL: And that really didn't fit with the ability to make this sort of calculation, know what sort of doses were out there. So, the staff's proposal at this point is not to change on that, hospitalization if they have to be hospitalized. If you have got some sort of particular clinic setting, where you have them in confinement and you have them in control, that might or might not be acceptable under the particular circumstances.

MS. McBURNEY: But you still mean controlled, in a controlled environment?

DR. COOL: A controlled environment where the licensee still has a handle on what they are doing.

MS. McBURNEY: That is correct. Thank you.

MR. KULIKOWSKI: Bob Kulikowski, New York City.

Just to follow up on what Ruth said, in our regs we do say "confinement," however, we also have a provision in our code that says it must be broadly interpreted.

We discussed this I think at the SR-6 committee meeting back in May. We really bandied around whether confinement indeed did mean hospitalization.

As far as our regs go, it would not mean solely hospitalization. We could confine someone anyplace as long as we were satisfied or the licensee could confine someone as long as they were satisfied that the control was maintained. It could be a private residence in some circumstances.

I just had a second question. That was I think also at the July meeting we talked about requesting NCRP to update Report No. 37. Do you have any update on that, Don?

DR. COOL: Two contracts have been issued. One is a relatively short-term grant to have NCRP provide us a commentary, a relatively quick updating which we expect within the year, hopefully next spring, and a second grant which says NCRP, go back and look at it top to bottom, inside-out, over the next two-year period to produce a revised report.

Those two things are both now issued and NCRP working on putting together the groups that are going to do that.

Steve?

MR. COLLINS: Steve Collins from Illinois.

A personal conversation with the original author of Part 35 indicated that Bob Kulikowski has the exact interpretation that he intended when he put the word "confinement" in the rule, that he did not intend it to be

limited to hospital, but as long as control was maintained, wherever.

Also, I want to point out that the view you expressed for the ACMUI was the majority view, but there was a minority view that indicated we should get rid of the 30 millicuries -- I am sorry -- that you should keep the 30 millicuries, but that also you should allow even more than that to the point of using strictly the basic statement in NCRP-37, that said that as long as any individual would not receive more than 500 millirem from the time of release until total decay of the nuclide, as calculated at a meter from that patient, that you could release, which in some cases would allow up to even 80 millicuries even for Item 131.

MR. MERGES: Paul Merges from New York State.

There are other issues other than consideration of the patient's needs when you talk about releasing a patient at 30 millicuries. In this country, we have seen a significant increase in instrumentation at the landfills and resource recovery facilities, and we are seeing a significant increase in the number of hits from people discarding their diapers and what have you.

You need to look at other issues beyond just the medical communities in the process of what you are going to release, also, how that would impact the release of a

patient who passes away and is going to be cremated.

You do need to look at those issues before you just decide on increasing that 30 millicurie level.

DR. COOL: I appreciate that. Thank you.

Any other questions or comments?

[No response.]

DR. COOL: If you do have thoughts afterwards -- I know I tend to once I get away from the meeting to, oh, I should have asked that question or that sort of thing -- in the next week or two, if you want to send me specific things, I think we can use them, but we are going to be moving fairly rapidly at this point to try and put together a proposal and get it out on the street.

One of our goals is to try and have this out, the proposed rule, roughly the end of the year or very early next year. Once again, the goal is to try and have this be a final prior to the January 1, 1994 absolute implementation date for Part 20 to avoid any potential difficulties with regard to that implementation.

The last one that I am going to deal with is timeliness of decommissioning. This gets back to what we were talking about yesterday, decommissioning always comes last. Here we go once again.

In this case, how long should it take for timeliness to come last, and how long should licensees be

given in order to effectively clean up their site.

This is a rule which has been kicking around in the staff for an untimely long time, a couple of years as a matter of fact. The rule in its second incarnation completed office concurrence just a week and a half or so ago. The rule had been sent to the Commission back in February of this year, the Commission had looked at it, sent it back to the staff, basically approving it, but asking a number of things to be done and for it to be resubmitted to the Commission for approval prior to publication.

That is now in process. It has not yet gone to the Commission. It has gone to our Executive Director for Operations. I expect it to go back to the Commission very, very shortly. In fact, it may make it to the Commission within the next couple of days. I don't know about the timing on that.

Once the Commission approves it and we get it published in the Federal Register, a comment period, and then onward to development of the final rule.

The next slide.

Applicability of the Proposal. I will emphasize once again this is a proposal which the Commission has not approved, so we are talking about things which are still subject to change without notice, that it would apply to all NCR licensees, that we are looking at a level 2 degree of

compatibility, something we think is important, but there is no reason why you guys can't be more stringent if you folks would like.

The Proposed Provisions. The first one, clarify what license expiration means. This isn't so much tied to timing, but rather some difficulties that we have had with licensees in times past about when their licenses actually expired and what it means if the Commission decides that they are not going to renew the license, or some of those sorts of things.

So, this is more a legal issue which is being carried along by this rule, but there are some clarifications to the expiration provisions.

A requirement for licensees to initiate the decommissioning process -- put that in quotes if you would like -- when notifying the Commission that it is ceasing its principal activities, it is no longer doing things at the entire site or in a particular building or outdoor area.

Now, the decommissioning process might be one of two things. It might be get on with cleaning it up if you have already got in place sufficient plans or if what you need to do really doesn't change the sorts of provisions that you need to live under, going ahead and doing that, or the process may be start the preparation of the plan if there are other procedures and activities which have to be

all planned out or if it is required by your license condition or one of those sorts of things.

The timing would be established for two separate things that I just mentioned. One, the end of the license, where the licensee is no longer doing anything, or the second one, what we are calling end of use, where you stop doing things in some particular area. These are mostly the very large sorts of facilities, sprawling buildings here and there, where they are no longer going to use that particular building on there.

That particular operation is no longer economically feasible, viable, whatever it is, and we are just not going to do that anymore. Well, if you are not gong to do it anymore, I believe you ought to go ahead and get it cleaned up.

Another one is to try and provide some clarification of an item which has been some source of confusion, which is a description of the conditions of the site when you submit the plan.

Logic tells you that if you are going to prepare a plan to clean up your site, you have got to know what you actually have on the site, where it is, how much of it you have, and those sorts of things, but there has never really been a requirement in the rule that says you have to know what it is you have got before you start planning for it.

This is going to clarify that, at the same time hopefully clarify that the final survey comes at the end. So, those goes hand and hand as a pair of provisions which hopefully will clarify the intent of that.

If I can have the next slide.

A couple of things related to Part 72, most of which you are not directly influenced by, but for ISFSI'S and some of those other facilities.

They already had some timing provisions in the regulations. They were patterned more after the timing that is in place for the reactors. Those will be changed with this proposal or at least we are proposing to change them to more model the pattern that is being used for the Part 30, 40, and 70's.

In particular, one of the things that is in this proposal at this moment is for those licensees to tell us two years before their expiration of their decision. Most of the time the renewal provisions say that on such and such a date you have to have submitted your request for a license renewal.

This is sort of the other hand. If you aren't going to renew it, we would like to know that, too, because that means we need to start the process of cleaning it up, so that when you actually get to the end of your license, you will be able to release the license, it will be cleaned

up.

If I could have the next slide.

The specific provisions with regard to the timing, a 24-month period allowed for cessation of the principal activities, 24 months after the time you stop doing something there to decide whether or not you are going to do something again to allow businesses the opportunity in varying economic cycles to decide if something really is or is not viable, whether they are going to start it up again, whether they are going to use it for some other purpose.

That allows the licensees flexibility, that the day they stop something, they don't immediately have to do things. A two-month period after that to provide for the notification and the initiation of the decommissioning process.

So, that means that from the time an activity actually stopped in this building or at this site until the time where something would have to be started, either the formal preparation of the plan or the actual starting to clean up would be 26 months.

There are provisions scattered all through the proposal which would allow for extensions for good cause - gee, I need a little longer to decide whether I am going to use it or not, I need longer to prepare the plan because this is really complex, I need really longer to clean it up

because I not in the compact and I haven't the foggiest idea of where I am going to send the wastes or some of those sorts of things.

A requirement for plans to be completed in 12 months if you have to prepare a plan, and finally, 18 months to actually do the work. That assumes that most licensees can probably complete the actual clean-up in 18 months. We recognize that may not be right in all circumstances and once again there are provisions built in to allow alternative times for whatever reason.

If I can put up the last slide, just in sort of a graphical form. These are little time lines with the dates and months, where zero is when the activity stops at the particular site. You can go 24 months before you have to think about much of anything and a couple of months to tell us, and then you have got one or two branches.

If you have to have a decommissioning plan, you have got 12 months to prepare that, and then 18 months to complete the work. If you didn't have to have a decommissioning plan, then you have got the 18 months to complete the work.

Now, the one thing that isn't on this time line, a wonderful little variable in there, is called how long it takes NRC or the state to act upon whatever request it was, particularly things like decommissioning plans or approvals.

So, this sort of represents the licensee's time blocks, but you can recognize that you can insert into there variable times for the amount of time it takes the regulatory agency to take action, and those would not be charged to the licensee. It doesn't seem particularly fair to say, licensee, you have got 18 months to clean up, but oops, it took NRC a number of months to decide that your plan was acceptable.

Are there comments or questions on the timeliness provisions? That completes the discussion that I had prepared.

MR. GODWIN: This is Godwin from Arizona again.

I believe that under your present provisions you have, what, 60 days for bankruptcies, to be notified and all of that kind of stuff, and I recognize that if one of your licensees declares bankruptcy, you may have a problem with this. The bankruptcy judge may not buy off on it.

Have you thought about any ways you can put either in a rule or what approaches we could use if this concept goes forward and deal with the bankruptcy? Although the federal law requires them to take into consideration health and safety, their interpretation of that is not always the same as you and I may interpret it.

DR. COOL: Yes, that is very true. As I had mentioned before, there are some things with regard to when

a license is expired. If you have got a circumstance like that, the way this proposal would work, you don't have that first 24 months, you are immediately into the process and those timing provisions kick in.

Whether or not that will work in a particular court case, we may have to wait and see what the lawyers say about that.

MR. FLETCHER: Roland Fletcher, State of Maryland.

Speaking of interpretation, on page 22, when you talk about, "Require those licensees that must prepare a decommissioning plan to include a description of the conditions of the site sufficient to evaluate the adequacy of the plan," there are a lot of very conditional words in there that I would interpret one way and a licensee might interpret another way.

I would suggest that perhaps some specifics on conditions that should be included in that plan might be added as subparagraphs to that.

DR. COOL: I appreciate that input. We deliberately wrote it in this form because this rule would apply to an incredible variety of licensees, and what would be an appropriate amount of information for a small licensee who had sealed sources, and those sorts of things, would be totally different from a large licensee, where there might be ground water contamination and some of those sorts of

things.

So, we had perceived it difficult, although I am always open to somebody giving me a new idea of how I could get around this problem, how I could write a list and know that I was right or know that I was wrong for a particular set of licensees.

MS. ALLEN: Kathy Allen from Illinois.

I used to work for a licensee, and analogous to this, we had a tank farm of chemicals. One process ended, we actually stabilized the tank rather than decommission the tank because of the expense involved. With the regulations and things like that, it was easier just to stabilize that particular tank a few years down the road than remove the entire tank farm.

Would you be willing to accept just financial reasons why they don't want to decommission a particular area of their site, because I noticed in the handout it said that the rulemaking is not expected to substantially affect licensee costs?

There may be some circumstances where it would be more expensive to decommission a particular area of a facility rather than waiting and decommissioning the entire facility at the same time, later down the road.

DR. COOL: I think that is certainly one of the things the Commission would look at. These would be looked

at on a case-by-case basis, and certainly those sorts of arguments would be an argument that you could put forward and we would look at, yes.

MS. ALLEN: Someone yesterday had mentioned if possible charge or repercussions for a facility that doesn't decommission within the proper time frame, would possibly require them to put money into a fund that would go towards the decommissioning.

No one indicated whether or not they would be allowed to reduce their surety amount by the amount that they put into that fund.

DR. COOL: I can't answer that question. I really don't know right now. What you are referring to in yesterday's discussion as part of the Site Decommissioning Management Plan, I would suspect that they would not because if they were allowed to decrease it, it would not then be any sort of penalty.

The thought that I believe Dr. Austin was talking about was rather than them paying it to us and effectively nothing getting done, trying to find financial mechanisms where we are hitting the licensee, but we have the money in a place where it can actually be used to do something about the condition simultaneously.

I think there is still a lot of things there that are going to have to be worked out as the staff continues to

move forward in experience with its sites on the Site Decommissioning Management Plan, so that may yet have to be worked out in court also.

MS. ALLEN: I just kind of think that some licensees may have some problems. That is the whole reason they put up their surety, and it is their facility, and they feel that as long as there is no threat to public health and safety, they may have a problem with this.

DR. COOL: Any other questions?

[No response.]

DR. COOL: If not, thank you very much.

CHAIRMAN MILLER: Let's give Don Cool a big hand.

[Applause.]

CHAIRMAN MILLER: I want to thank you, Don. By the way, he did have a handout in the back, and the next speaker, Paul Lohaus, does have a big handout back there, as well, so if you didn't pick up one when you came in, you can use this moment to do that.

Let me see if we have any members of the public here today. Are there members of the public here today, anybody? One, two. Well, you certainly can participate in these proceedings. If you have a question, you may move to the mike and ask it.

I also want to remind you now that Don did say to you that if you don't have any comments today, if you think

of some after the meeting is over, just jot them down and send them to Don Cool at Research of the Nuclear Regulatory Commission as soon as possible. I am sure that holds true for the other speakers to follow.

Now, we have the next three topics: Topic No. 5, 10 CFR Part 61, financial requirements for low-level waste disposal; Item No. 6, 10 CFR Part 21, notification requirements for defects in noncompliance; Item No. 7, 10 CFR Part 31, notification requests for generally license devices.

The individual who is to come up and discuss those with you is Paul Lohaus, who is on a rotation to Research at the moment, and he is the Branch Chief of the Regulations Development Branch of Research.

We will call on Paul Lohaus at this time.

MR. LOHAUS: Thank you very much, Vandy.

Given my long association with the Agreement States, I am pleased to have an opportunity to meet with you today and talk about three of our rulemaking actions.

Could I have the first viewgraph, Lloyd.

As Vandy mentioned, we would like to talk about some changes that we are considering to Part 61 dealing with the financial assurance requirements for the post-closure institutional control period for low level waste facilities.

The second is Part 21 relating to reporting

defects in equipment by materials licensees.

The third relates to a final rulemaking action. I want to talk to the status on where we are on the rulemaking action dealing with the 31.5 generally licensed devices.

I asked the project managers within Research to join me today, given the closeness of the meeting, and I would like to introduce them. If there are specific questions that you may have in the future, please feel free to contact them on these rulemaking actions.

With respect to Part 61, let me introduce Brian Rechter. Brian is project manager in the Regulations Development Branch and has responsibility for Part 61.

Mark Au. Mark has responsibility for Part 21.

Joe Mate. Joe has responsibility for the Part 31 and 32 rulemaking action.

May I have the next viewgraph, please.

In looking at the Part 61 rulemaking action, as you know, Part 61 does contain existing financial assurance requirements. At the time we developed Part 61, we went as far as we could in setting out a mechanism to try and ensure that there would be an adequate base of funding to cover the post-closure institutional control period.

We did not have a real hard statutory base for that requirement, and when we developed the requirement it was focused more on the lease or binding arrangement that

the operator might have with the landlord, and through that mechanism try and ensure that there would be an adequate base of funding.

With passage of Section 151 of the Nuclear Waste Policy Act, NRC was given a much harder statutory basis to establish a financial assurance requirement. So, in looking at the intent of this rulemaking, it is really to meet the statutory intent that we have within Section 151 and also to strengthen the financial assurety requirements we have within the existing rule to help provide a greater degree of assurance that there will be funds to cover the monitoring and surveillance and any requirement maintenance that is going to be necessary during the institutional control period.

Could I have the next slide, please.

Looking at the schedule, our next step in this process is to prepare what we call an initiation package. This basically lays out the concept for the rule, the draft rule language, the bases, and goes forward to senior management for review and approval to proceed.

We are looking to complete this package by the end of November, and in addition to any discussion today, if there are specific comments or specific points that you think we should address, should cover in this rulemaking action, it would be most helpful if we received them by the

end of November. That way we can focus and fold them into the initiation package for the rulemaking.

That completes my comments on Part 61. Let me stop at this point and see if there is any comments or points of discussion on this rulemaking action.

MR. BAILEY: Ed Bailey from California.

One of the things I think that has at least caused controversy and confusion and concern is that a state must own the property while the waste is being deposited. At least in California, that has been a major political issue.

If it could be clarified somehow that that waste or the title to the land could transfer to the state after close of operations, I think that would eliminate just one of the issues that is often raised by the anti's regarding the state accepting some unknown liability. That would really help I think in some cases.

MR. LOHAUS: Thank you, Ed.

MS. DICUS: Greta Dicus representing the State of Arkansas and also Chair of the Central Compact Commission.

I want to back up very strongly what Ed has said. In fact, we may want to push for a change in that particular part of Part 61.

MR. LOHAUS: Thank you, Greta.

MR. FRAZEE: Terry Frazee, State of Washington.

Just one point that our program manager wanted to

raise, and that was the parallel with the uranium mill requirements where there is apparently a cap, an upper limit, a financial limit. Ed is saying no?

MR. LOHAUS: Yes. There is for mills, yes.

MR. FRAZEE: Okay, for the mills. The point that our program manager wants to make is don't put any kind of financial lid on it, allow the states to require whatever total surety they want to see.

One of the things that I think Gary Robertson pointed out was that he would like to see included in the post-closure funding enough money to actually replace the entire cap in the event of a catastrophic failure of that cover.

MR. LOHAUS: That latter point is an important consideration in looking at the financial aspects and the question of maintenance, how far do you go and what kinds of contingencies should the applicant consider in looking at establishing a fund and the kinds of activities, do you go into contingencies, and if you do, what types of contingencies.

You can get into a lot of different scenarios that could occur, such as replacing the disposal unit cap or taking other types of remedial action. I guess given the focus of the requirements and given a lot of the focus on design and operations, and the post-closure observation of

maintenance period, we would hope that we would not have the situation develop.

You would have a high degree of confidence that you wouldn't have to go in and take major types of remedial action, but I think that is one of the issues that we will need to address in looking at the question of how much money should an applicant set aside.

Any other comments?

MR. MERGES: Paul Merges from New York State.

Third-party liability and financial assurance specs. You need to closely at that and look specifically at the issue of personal injury versus bodily injury in your definitions and make sure your attorneys agree with what you want to do with the regs there. Just an observation.

MR. LOHAUS: Thank you.

Okay. Let's move on to Part 21. This is a rulemaking action that I really did not have a lot of familiarity or understanding. It may be similar for some of you, but in looking at Part 21, it was originally issued in June of 1977 and was directed at implementing Section 206 of the Energy Reorganization Act.

In looking at the intent here, it was really to ensure that equipment defects, problems that would develop both from the standpoint of a licensee or a vendor that supplied equipment, that they would be evaluated and

reported to the NRC, such that their health and safety significance could be assessed, and also, if it seemed to be a generic issue, information could be provided to other licensees and vendors to ensure that it was addressed.

So, the focus seemed to be primarily on power reactor facilities, and the materials licensees, although when you look at the scope of the rule, materials licensees were encompassed within the scope of the rule, licensees were not clear and it really wasn't entirely clear in the staff in terms of the programs that were set up to deal with Part 21, how Part 21 should apply to materials licensees.

The Office of the Inspector General did conduct an audit in 1990 and looked at how the staff was implementing the provisions of Part 21. One of the conclusions that was reached was it is not clear whether Section 206 should apply to materials licensees.

That recommendation really had two parts. One is it asked that the Office of the General Counsel look at the legislative history and look at Section 206 to see if there was a clear statutory intent that it should apply to materials licensees, and second, that based on that determination and advice from counsel, that we proceed with a rulemaking action to either eliminate materials licensees from the scope of Part 21 or make it clear how Part 21 should apply to materials licensees.

Could I have the next slide, please.

What OGC determined is that Section 206 should apply both to reactors, as well as materials licensees, and the approach that staff is following in amending Part 21 is to really divide licensees into two categories.

The first category would be those that would have the capability and should have the knowledge to conduct reviews of equipment defects and to file reports with the NRC.

Licensees, all the major fuel cycle facilities, waste disposal, larger irradiators, the medical therapy device, radiography and spent fuel storage, those licensees under the proposal would be required to develop and implement procedures as a part of their license program to evaluate any defects that they identify in equipment and then to file reports with NRC.

Next viewgraph, please.

All other materials licensees would have the option to either develop procedures that they would apply within their program or they would have the option to notify the manufacturer or distributor of the device who, in turn, would be responsible for completing an evaluation and then reporting that evaluation to the NRC.

Basically, what we are trying to do -- if we can move on the next slide, please -- what we are trying to do

in terms of the rulemaking is to not only reduce the current level of uncertainty relative to the application of Part 21 to materials licensees, as I mentioned, but also to try and reduce the burden that would be faced by the smaller licensees who may not have the same degree of capability to conduct an evaluation and maybe properly place that burden on the manufacturer and distributor, where they would have a greater degree of knowledge and capability to do the evaluation.

If I may have the next slide, please.

One of the questions that really seems to jump out when you look at this -- again, I am not certain how many of you are really familiar with this or may have reflected Part 21 in your programs -- but the question of compatibility and the need for the states to adopt a similar requirement, I think comes into focus very quickly.

That is one of the issues that we will be looking at as a part of the rulemaking, as a part of the proposed rule. We will ask for comments on that issue.

In terms of, say, the next steps that we have in our process of preparation of the proposal rule, we are targeting mid-November to have the proposed rule package prepared and then to move that forward for management concurrence.

So, within the next two weeks, if you have

specific views or thoughts relative to the question of compatibility or the approach that we are planning to follow in developing Part 21, we would very much appreciate receiving that and give us a chance to factor that in at an early time.

Let me stop at this point on Part 21 and ask if there are any questions or comments.

MR. COLLINS: Steve Collins from Illinois.

What reasons did you have for putting radiography licensees in the first option as opposed to the second since a lot of these are very small companies where they obviously wouldn't have the capability to do those evaluations on their own, and which one of those options would well logging licensees fit into?

MR. LOHAUS: Let me answer the first question. Let me take back the question of well loggers, and we will take that under discussion and see where they would fit. I think given the fact that we have identified those specific categories, Steve, I would say they would fall in the latter category. They would be considered a small materials licensee and would have the option to report to the manufacturer/distributor.

You raise a good question relative to the industrial radiographers. Probably the larger companies should have capability to understand the equipment and

understand when there is a problem, take a look at it and do an evaluation.

For your smaller operations, though, they may not have the same degree of capability, and I guess the question would be how would we maybe split those.

Do you feel there is a clear preference from your standpoint of putting those into a category where they should have the option of reporting or doing the evaluation themselves as opposed to leaving them solely in the category of do the evaluation?

MR. COLLINS: Yes.

MR. LOHAUS: Okay. Good point.

MR. GODWIN: Godwin, Arizona.

I would support Steve's comments relative to radiographers. You might want to look at a division relative to a small entity. That might be one way you could look at that particular type division, if you wanted to approach that, but I would raise the same question relative to medical therapy device.

I suspect many of our smaller hospitals will also be unable to really carry out what would be an efficient investigation, particularly if you look at where some of these teletherapy units are. We saw some problems one time with a key, and nobody at the hospital had a metallurgical expert. We didn't have one either.

MR. LOHAUS: Good point.

MR. GODWIN: This is the kind of thing you need to look at. I would submit to you that you might want to consider asking gauge manufacturers to be placed in this first group, with the idea that the gauge user would be in the second group, because there have been on occasion some difficulties relative to gauges that have struck a cord of interest.

MR. LOHAUS: Okay. Thank you.

MS. ALLEN: Kathy Allen from Illinois.

I would think that you would want most of the manufacturers in the category one. There doesn't appear to be any requirement that the manufacturers develop and implement procedures for responding to the small entities.

How are we going to enforce the fact that these manufacturers get comments or problems from the field, but take two or three or four years to decide to investigate and possibly implement procedures to prevent recurrence?

My second part of that is what do you do about manufacturers from outside the country?

MR. LOHAUS: Very good points. On the first point I may not have been entirely clear. There will be a separate requirement as a part of the rulemaking that would apply to the manufacturers and distributors, that they would be responsible for completing the evaluation.

One other possible addition that we are considering is that when the smaller materials licensee would report to the manufacturer and distributor, that a copy of that report should also go to NRC.

That would give us an opportunity to be aware that there has been a defect identified and would provide an opportunity to us to follow up with the manufacturer and distributor if it did not appear that they were proceeding to complete an evaluation.

With respect to manufacturers and distributors outside the country, I don't have a clear answer for that, but I will certainly take that issue back, take a look at it, and see how we can address that as a part of the rulemaking action.

MR. GODWIN: Godwin of Arizona again.

It occurred to me that maybe one other area that may have some impact, but I am not sure, are you going to look at auxiliary-supplied equipment and materials that may affect the safety of the operations as part of this reporting equipment?

For example, software associated with operation of teletherapy units might be of some interest, electronic equipment that turns equipment on and off may be of some interest in gauging operations.

MR. LOHAUS: Good points. As I understand the

context of the rule, it does begin to move into areas such as that, particularly in some cases the material vendor suppliers or equipment suppliers, but that is a difficult area because once you open that, how far do you go down into the individuals that are involved up to the point where you have a completed gauge or a completed device.

MS. ALDRICH: Rita Aldrich, New York State Health.

Since FDA regulates the manufacturers of medical therapy devices, medical therapy devices seem to be the only group among these that are already regulated by another agency, isn't this either redundant or crossing regulatory lines of authority with FDA? How does FDA feel about this, are they involved in the rulemaking?

There is already a voluntary reporting program for therapy device defects through the U.S. Pharmacopoeia. It seems odd to have licensees use a voluntary program for the agency that has regulatory jurisdiction over the devices themselves and then impose a mandatory one under another jurisdiction, which to me is not at all clear.

MR. LOHAUS: A very good point. We will take a look at that and see what the relationship between FDA and NRC should be in this area.

Are there other comments or questions?

[No response.]

MR. LOHAUS: The next viewgraph, please.

The final rulemaking action that I wanted to talk about relates to changes to Parts 31 and 32. As you are aware, the proposed rule was published in the Federal Register December 27, 1991.

In principle, there is very good support for the changes that are reflected here. I know that you very actively participated in the development of this rulemaking package.

I have included as a part of the handout three viewgraphs at the end which go through the intent and the major changes that are proposed in this rulemaking action. I hadn't really planned to go through those in detail because I think you are all familiar with that.

What I really wanted to focus on was really the third bullet. We have the final rule prepared, and that is moving forward in our concurrence process, and we will be going to the Commission for their review and approval.

Relative to compatibility, the recommendation that is likely to go forward from the staff in this area is that this rulemaking action be a Division I matter of compatibility. I think there is a number of obvious reasons in looking at this.

Given the fact that there is need for some consistency across the nation relative to the manufacturers and distributors that are licensed both by NRC and the

Agreement States, the fact that this can help reduce some of the burden that the manufacturers face in filing reports and making sure that the general licensee gets a copy of the general license, and also in helping ensure that the general licensee has some clear guidance and clear instructions relative to the requirements that they must follow under their general license.

That is really the major point I wanted to make here and make it clear that as this package is going forward, it will likely contain a staff recommendation that it be a Division I matter of compatibility.

That completes discussion on Part 31 and Part 32.

Any comments?

MR. GODWIN: Godwin of Arizona.

I have a question relative to which way you are going relative to the final. I believe some comment was made relative to not authorizing the general license to be used on portable equipment and barges, and things like that, that you all are making a decision relative to that, particularly since you are asking for location as a part of it.

MR. LOHAUS: That is a question I don't have a clear answer on. Let me ask Joe Mate.

Joe, how will we handle that in the final package?

MR. MATE: Can I ask the gentleman to please

repeat the question, so that I understand it?

MR. GODWIN: There were some comments made at one of these hearings relative to not allowing the general license devices of this nature to be placed on portable devices, such as barges or installment trucks, and things like that.

I was wondering how you all finally handled it, because there is still a requirement to report the location, and if you report a location as a barge in Mobile Bay, it suddenly may end up in California.

MR. MATE: I am trying to remember that portion, and I don't believe that licensees would have the ability to use it on portable mechanisms.

MR. BAILEY: Bailey from California.

That brings up the question of would you do away with the existing general licenses for portable devices or have you -- well, it gets rid of my other question, if that, in fact, is true -- which was have you clarified the requirements for reciprocity using GL devices.

Secondly, I would encourage that not all aspects be a Division I item of compatibility since we intend to have different reporting requirements for limit of size and charge the manufacturer the registration fee rather than the user, and we really don't think it makes any difference, those kinds of aspects, on interstate commerce.

MR. LOHAUS: Thank you.

On the question of the location, I am not familiar with the details on that. I am going to check and we will give you a call and let you know how that is being handled. I just don't recall.

MS. McBURNEY: Ruth McBurney, Texas.

We had a discussion earlier in this meeting about generally licensed devices, and I would also like to echo Ed Bailey's last comment, in that there are several states that are already or are intending to require some sort of acknowledgement or registration of these devices in their states, and the amount of information that these states may require may vary.

So, please look at what parts of the rule might be Division I compatibility, because some states may want to require a little more information from those generally licensed devices.

MR. LOHAUS: Okay. Thank you.

MS. HADEN: Robin Haden, North Carolina.

We already have a general license program in effect, that has been in effect for a number of years. We have found that it's -- at least we believe it to be, and hope Dick does -- a pretty comprehensive program as far as general licensing goes.

So, a Division I compatibility may cause a

complete rule change for us in a program that is already very effective.

MR. LOHAUS: Okay. Thank you.

MR. FRAZEE: Terry Frazee, State of Washington.

This comment goes more to the specific licensees. We are developing a rule for the general licensees because there is concern for losing gauges, and you are going to require periodic reporting from the general licensee as a way of making sure that they still have the gauge.

With specific licensees, it is my understanding that NRC's approach is to issue the specific license, do initial inspection, and that is the last time they ever see the licensee unless there is a problem, which of course they would have to report.

Our experience has been in the State of Washington, even though we do periodic inspections of specific licensees on about a four-year cycle, we have in fact lost the gauge of company, management changes, ownership changes, and we come in four years later and the gauge is long gone.

Have you considered, particularly for NRC where you don't do periodic inspections, have you considered using the same approach for your specific licensees, sending out a notice, requiring them to report in on a certain frequency?

MR. KERR: Wayne Kerr from Illinois.

Paul, I can't let you get away. The discussion on compatibility I think highlights the problem of the application of compatibility and Division I. You know, these things indicate that you need to apply the rule of reason, is what the state proposes effectively the equivalent of what you have rather than identical in terms of some of the detailed provisions and wording.

MR. LOHAUS: Okay. Thank you.

Other comments or questions?

[No response.]

MR. LOHAUS: Thank you very much.

CHAIRMAN MILLER: Again, we want to give Paul Lohaus a big hand here for his contribution here this morning.

[Applause.]

CHAIRMAN MILLER: Again, if you come up with some additional comments, be sure to get them to him as soon as possible. He will be leaving Research at the end of December, going back to his old job as the Branch Chief of Low Level Waste Management Branch.

Now, we do have a couple more topics for this morning before we take a break. However, I don't see Janet Lambert in the room yet, and she was to talk a little bit about Part 61, above-ground disposer, and this is probably the first regulation that we mentioned under this early

involvement.

I think she has now brought it to closure. There is not a lot to say because this was discussed with you some two years ago, but if she comes in later, we will include this.

However, let's move on and have Mark Haisfield to come up quickly and talk about 10 CRF Parts 20 and 61, Uniform Manifest.

Mark.

MR. HAISFIELD: The first thing I just wanted to say is about Janet's rulemaking. It is with the Commission and I don't really know what is particularly in there, but it is supposed to come out final pretty soon. I don't think you will see any surprises there.

Could I have the slide.

This rulemaking, which is commonly referred to as the Uniform Manifest rulemaking, but that is the actual title that it goes by, so if you ever see that title in Uniform Manifest, it is really the same thing.

After this rule went out for comment, the commenters almost universally liked the idea of a uniform manifest, but an awful lot of them had problems with how the NRC was going to implement that concept.

One of the first big problems that we have to resolve is that our manifest would change how people are

filling out manifests right now for changing existing practice.

The reason we did that is because we were trying to meet DOT regulations as DOT explained it to us and as DOT said that we had to do it that way, and as DOT said that right now the manifests that are being done, are done improperly, and they just haven't gotten around to citing people.

They feel that the manifests that are currently being used are wrong. After reviewing a lot of the comments, however, we think the commenters made a really good point that the existing practice makes a lot of sense, and we are going back to DOT with those commenters' concerns and with our proposals to them to see if they might want to rethink it and if we can get some flexibility in how they interpret their regulations.

That is pretty much where we are right now in that rulemaking. We are just now going back to DOT. We have provided them our concerns, the comments. They have gotten back to us and wanted some additional information, and we have provided that.

We have also been requested by the Low Level Waste Forum to have a working public meeting about this rulemaking. We think that is a really good idea except until we can get things resolved with DOT, we think it is a

little premature.

So, we think it would be more effective if we wait until we get some resolution with DOT about how these forms are going to look like before we have that public meeting.

The last thing I wanted to mention is that DOT is also being caught up with the President's regulatory moratorium, and since our rule implements proposed rules of DOT, it is very unlikely that we are going go out with a final rule until they go out with their final rule.

At this point we haven't been able to get a very good story as far as how that moratorium is going to affect DOT. We know it is affecting them, but they seem to think that they may be able to push forward anyway, but they really can't commit to anything.

I think it would be very unlikely that we would go out with the final rule until they do. To sum it all up, basically, this rulemaking is going to be taking a step back or two until we get some of these issues resolved and we see where the moratorium is going. That is the status of this rulemaking.

If there are any questions or comments, I would be glad to help.

[No response.]

MR. HAISFIELD: Thank you.

CHAIRMAN MILLER: That gave us a good time for a

break now, and when we come back we will bring all of the medical staff up for the rest of the day.

Let's take about a 20-minute break.

[Recess from 9:28 a.m. to 9:50 a.m.]

CHAIRMAN MILLER: Now, this next topic is the Medical Issues Paper. It is a little bit different now. We are not going to talk specifically about changing the regulation at this time, but this is an all-encompassing topic. They are going to talk about a little of everything having to do with medical issues.

We have a distinguished panel that is going to do that. This panel is headed up by their division director, Dick Cunningham. Just raise your hand there, Dick, so everybody can see you. He is the Division Director of NMSS in the Office of Nuclear Material Safety and Safeguards.

Dick doesn't normally come to these, so I know there is going to be some important things to take place since we do have him in our audience this morning.

Now, we have also in the audience a member from OGC, Marjorie Rothschild. Anytime we are going to talk about medical issues, I expect to see her in the audience, and she is there this morning.

We also have a representative from Research, John Telford, who certainly would be helping out in the medical area whenever there is a need for a regulation, so we

certainly want to recognize him this morning.

Is there anyone else that is out in the audience that can add to this panel's discussion this morning? If so, I want you to raise your hand here because I don't want to skip anybody.

Okay. Seeing no others there, then let's talk quickly about the panel which you see here before you.

The branch chief, as you all well know, is John Glenn, Dr. John Glenn, who has been before you at least twice this week. He is the branch chief, and the other staff people you see here are members of his staff.

Everyone knows Larry Camper, who is the author of most of these things that get written in the medical area. He certainly has an able assistant in Dr. Patricia Holahan.

Then, we have a resident physician who works directly in Dick's division, and works very closely with the branch here that John Glenn heads up, and that is Dr. Pollycove. You will remember he was with us last year at the public meeting.

So, we have a very good panel here and I just want you to know now we are talking specifically about one specific regulation part of the medical issues. We are going to talk about a lot of medical issues here. How well it goes depends on how you contribute to this discussion here today because there are no set answers yet. We are

just seeking some dialogue.

To start this out we are going to call on Larry Camper at this time.

MR. CAMPER: Thank you, Vandy. Good morning.

Let me start off by saying that we have a lot of work to do today and knowing that this group is not shy, we are going to be getting a lot of input from you.

We don't have an ideal physical situation here. We wish that we had a round table where we could talk, and you all had microphones, and so forth. I know given the nature of the topics that we are going to cover today, you will have a lot to say.

So, I can only encourage you to stack up in line and let's get your comments on the record. We will try to make it work as well as we can. It will take several hours to go through what we are going to go through.

I would also like to just reemphasize something that Vandy was saying. That is, we are not here to discuss rulemaking; we are here to discuss the Medical Use Program, to a great degree in its entirety, if you will.

Each of you were provided a document identified as a "Medical Issues Paper." Dr. Holahan of my staff and Dr. Glenn's staff played a very large role as the primary author of that document. Dr. Myron Pollycove, our medical visiting fellow, one of two, was also very actively involved.

What I want to do is just kind of give you the backdrop, make a few introductory comments, and then Dr. Glenn will make a few comments about it.

What I would like to do is just share with you briefly a certain excerpt from a memorandum from Mr. Bernero, our office director, to Mr. James Taylor, of the EDO.

It says in part the following: At the Office of Nuclear Material Safety and Safeguards Management Conference held on August 3 and 4, 1992, it was decided to prepare a management plan for reassessment, guidance, and new initiatives in the Medical Use Program.

The issues associated with the regulation of the medical use and byproduct materials are complex, dynamic, and controversial. During the last two years, the Advisory Committee on the Medical Uses of Isotopes, the ACMUI, the medical community, and the Agreement States have taken strong exception to a number of aspects of our current regulatory program for the medical use area.

As a result, the staff has commenced a reassessment of the Medical Use Program and initiated a number of actions to address the more pressing problems. In a Commission paper identified as 92-175, the staff cited the medical community's increasing concern about the extent of the Nuclear Regulatory Commission's regulation and its

potential for interfering with the practices of medicine and radiopharmacy and described current activities, including rulemaking, to address some of those concerns.

The key component of the management plan which we are going to discuss today is a continuation of the staff's initiatives previously identified to senior management and the Commission, as well as others which have emerged as a result of continuing interaction with the regulated community.

The staff believes that these efforts will satisfactorily address many of the issues raised by the medical community while improving the overall effectiveness of the Medical Use Regulatory Program.

In addition to these initiatives, the staff has identified other program areas which should be reviewed to determine if substantial changes would improve the Medical Use Program and further address concerns expressed by the medical community.

Finally, there are likely to be other programmatic issues and alternative approaches to regulation, not yet identified by the staff, which should be evaluated and possibly changed.

The first slide.

So, what we are talking about today in conceptual terms is the development of a management plan for the

regulation of the medical uses of byproduct material. One of the things that you have often said to us has come to us early in the game, don't bring us a document that is essential a fait accompli and ask us to comment on it.

So, what we are doing today is in the earliest stage as possible, on a very aggressive time schedule, is getting your input conceptually.

The next slide.

The planned development includes the issues paper, which we will discuss at great length today, and you have had an opportunity to read at this point, public meetings with the Advisory Committee on the Medical Uses of Isotopes, which took place last Thursday and Friday.

We went through the exact same questions that we are going to go through with you today, the Agreement States, of course. We are going to meet next month, in November, with our regional counterparts to discuss the medical issues. Finally, we are tasked with producing a Commission paper in January of 1993.

With regard to the Medical Issues paper itself -- and I want to read this disclaimer for the record, so that it will be clear:

The Medical Issues paper raises a variety of issues in the NRC's Medical Use Program. The purpose of this paper is to stimulate discussion on these and possibly

other issues as part of the development of a proposed medical use management plan to be presented to the Commission. The discussion of issues within this paper does not necessarily represent official NRC policy.

The next slide.

The staff appreciates that there may not be an ultimate resolution of some of these issues, but recognizes a need to address them. Specific items that are beyond the scope of the staff's management plan for the medical use area have been excluded. Those were identified within the text of the issues paper.

With regards to the issues in the medical use area, we consider them to be four major categories. Under each of these categories there are a number of subsets, and then various questions within each subset.

The four major categories are: NRC's role in regulating the use of byproduct material in medicine -- and we are going to talk at great length about our medical policy statement; operational flexibility -- and by that we mean how on one hand can we have regulations that are specific and clear, easily understood by the licensed community, while on the other hand, providing flexibility for a very dynamic area, that being the medical use area, so that we don't restrict the practice of medicine and the practice of radiopharmacy; regulatory relationships -- you

will notice I am not using the "C" word. What we are going to be talking about, though, is the relationship that exists between you as state regulators, and us as federal regulators, and how we can take steps to work better together, to better communicate to the licensed community throughout the states to the extent that uniform criteria can exist, and things of that nature.

Finally, professional relationships. The other day I gave you an overview of the Quality Management Program. At that time I mentioned that we were going to be hearing from the American College of Nuclear Physicians regarding its audit program.

We want to explore some questions about the professional relationships and what we can do to enhance that audit function that industry does for itself.

Next slide.

The formulation of the long-term objectives and the umbrella policy. We will complete or reduce or perhaps redirect certain ongoing activities. We are going to continue to make assessments based upon periodic meetings once we submit the Commission paper to the Commission in January and receive direction from the Commission.

We do expect that in the future, we would continue to hold meetings and receive additional input from the Advisory Committee on the Medical Uses of Isotopes, from the

Agreement States, from organizations affected by the Quality Management rule, and the public, as well.

We would need to continue to identify, evaluate, and undertake new initiatives as a result of those periodic assessments.

With regard to the things that are going on currently, I want to take just a moment or two to go through them quickly because we do think there is a great deal of activity that is worthy of revisiting.

We won't discuss these very much today. Instead, we are going to be asking you a lot of philosophical questions, but just so you will be aware of the kinds of things that are going on now, because we do think this is an important part of improving the Medical Use Program.

The first is radiopharmacy rulemaking in response to a petition filed by the ACNP/SNM. We are going to propose to the Commission rather dramatic changes in the language within Part 35.

For those of you that took part in the meeting that we held with the Agreement States in Atlanta, I think you will recall that was a very productive meeting and many of the changes that were suggested during that meeting, we are going to suggest in the language change of Part 35.

The idea is to relax the procurement possibilities for obtaining radiopharmaceuticals in the practice of

medicine and to allow radiopharmacists to practice their profession.

The preparation of inspection enforcement guidance for the Quality Management rule. The other day I mentioned that we are heavily involved currently in the inspection guidance of performance-based inspections and that we are going to propose a rather significant modification to the enforcement policy for the QM rule. We will discuss that in great detail during our November 9 public meeting.

We are currently seeking bids for a contract to review the submitted QM programs, submitted to us by licensees. We have approached three of the National Labs and that process is currently underway.

We would hope to award a contract probably, hopefully, before the end of this year, this calendar year.

We did complete guidance for broad-scope licensees, including a standard review plan. There had been some confusion as a result of the 1987 change of Part 35 by some licensees as to what broad-scope licensees could and could not do.

That confusion grew out of some comments that were made in the statements of consideration, but the rule language itself was inconsistent to some degree with what the statements of consideration said.

So, we provided some guidance to our regions in

terms of a standard review plan to make sure that broad-scope licensees indeed have the flexibility that we intended for them to have and that they are licensed consistently throughout our five regions.

The next slide.

We are going to hold a public meeting with ACNP/SNM to explain the Quality Management rule, to seek their input. It will be a highly participatory meeting, as I explained the other day, and of course we are going to see the ACNP audit program presentation.

Truncation of recordkeeping requirements for the Interim Final Rule. You might recall that we had put in place an Interim Final Rule that was designed to address, at least in part, the petition that was filed by the ACNP/SNM.

The Interim Final Rule will allow physicians to make departures to the manufacturer's packaged instructions as long as they did certain recordkeeping requirements.

Well, on the 2nd of October we published a Federal Register Notice in which we truncated the recordkeeping requirements for those physician directed departures. They may now make those departures and not maintain the recordkeeping that was associated with the Interim Final Rule. That has been very well received we think by the medical community.

Review of modification of Abnormal Occurrence

Reporting Criteria for Medical Events. We believe, as a result of having developed the Quality Management rule, having made some fairly substantive changes in the thresholds for misadministrations, it is time to take a look at the reporting criteria for abnormal occurrences which get reported to the Congress.

So, we are currently underway to do that and we again think that we will propose some fairly dramatic changes to the Commission, so that we capture big-ticket items as opposed to the kinds of things we currently have in the AO criteria.

The next slide.

Rulemaking to cover administration of byproduct material to pregnant or breast-feeding women. We have discussed this with you before. We are currently working with Research to develop a rule whereby we would focus upon having licensees notify patients of the potential consequences of undergoing procedures in nuclear medicine when they might be pregnant, particularly therapeutic procedures, and to report incidents that involve unintended exposures to a fetus or a breast-feeding infant.

Finally, we are working on release criteria for patient undergoing nuclear medicine procedures, to make changes in 35.75.

So, those kinds of things are going on currently,

a lot of activity, and what we really want to do today is to explore and we want to ask you to think in broad philosophical terms, paint with a very broad brush, try not to the extent possible to get into specific things about Part 35 that you take exception to, because if we find ourselves debating the language in Part 35, we are not going to make a lot of progress.

We have no preconceived position on this matter. This is purely exploratory in nature. So, try to the extent possible to make your responses and your comments as general and as philosophical and conceptual in nature as possible.

With that, I would like to turn this over to Dr. Glenn. He has a few comments that he wants to make about the Management Plan.

DR. GLENN: Thank you, Larry.

I think for the rest of the presentation what we would like to do is have the discussion occur from the table, not be having formal presentations, try to overcome the barrier of the formal setup of the room as much as possible and invite an interactive discussion.

Based on some of the questions that were asked on Tuesday morning when I was here earlier, I think I should discuss a little bit about how these different meetings you have been hearing about were scheduled and also to impress upon you how much of an effort we are making to get you

involved as quickly as possible in this process.

We were tasked with the development of this management plan in August of this year, and we had to conceptually figure out, well, okay, how do we get the necessary input to develop the management plan, what time frames are reasonable, how can we both be responsive and make sure that we touch all the bases before we go forward.

The only way we could do that was to make use of existing mechanisms, meetings that already were scheduled, and use those opportunities to help us go forward. Fortunately, we had a string of meetings coming up in October and November that were already scheduled, that were kind of ideal for bringing up some of these ideas.

The first meeting we had was with the Advisory Committee on the Medical Use of Isotopes which had been scheduled for the 22nd of October, and so we did meet with them last week, covered the same paper with them that we are going to be covering with you today, have received some of their comments.

The next meeting that we saw that was on the agenda, and touched the groups that we feel we have to get involved early in terms of any of any of this process was the Agreement States meeting that we are at today, so we intended from the first to have this discussion.

The meeting with the ACNP/SNM and the other

professional groups is a slightly different meeting. That was scheduled mainly because of the problems associated with the QM rule, the OMB override, and the sense of both the staff and the Commission that a public meeting to discuss the information collection requirements of the rule to clarify misunderstandings that existed out there.

However, we also added onto that a discussion of the ACNP audit program since they about that same time wrote to the Commission wanting to discuss their program and how that could be incorporated into our regulatory scheme.

The public meeting on November 9th will not be specifically about this issues paper, and one thing I would appreciate your commenting on today, we will have met with the Advisory Group from the medical community, we will have met with our co-regulators in the Agreement States, and we will have discussed some specialized issues in an open forum with the professional societies, but one thing we are seeking is advice on whether before we proceed with the development of this management plan, whether we need to have a wider spectrum of public meetings where we try to solicit comments from people other than the government and the regulated community, and whether such groups actually exist that we could hold a productive dialogue.

Our objectives in this management plan are to develop the strategies to assure that we have the most

effective regulation of medical uses of radioactive materials that we possibly can.

I think that the plan probably will be as much about process as it is about content. The end product of the plan and the process may be rulemaking on particular issues, but we are really interested in how we arrive at good decisionmaking in terms of the regulation of the medical community.

One reason, of course, that we are working on this management plan is that many contentious issues have arisen in the last few years, and we have been criticized that we are over-regulating or that we are not regulating correctly, so we want to lay out a long-term plan strategy that will resolve issues in a timely manner, assuring that we neither over-regulate nor under-regulate, that the role of the government regulator is appropriate in this area of medical use of isotopes.

From this discussion we are not actually expecting you to give us the answers. I think we are anticipating that you are going to help us get the right questions, and then together we will work out what the right answers may be through this process.

Some of these, there is not going to a right answer, this tension between precise requirements, so that they are understood by everyone, so that the boundaries are

clear, and also that we have to allow the industry flexibility to change, to grow, to go down the area of new technologies, so we are always going to have that tension, that challenge.

We want to eliminate the possibility of anything going wrong, and yet, at the same time, we have to take the risk of something going right, as well, so getting that tension appropriately balanced in the way we do the regulations is very important.

With that, I would like to get into the first area of discussion. We have arranged the Issues Paper with sort of a general discussion and then going into five areas of particular concern.

Now, these were staff ideas from what we were hearing from you and from the regulated community about what some of the issues might be. The last appendix is Other Issues, and we certainly are open to the idea that in our brainstorming sessions, we may not have gotten to all of the issues or maybe even the most important issues. So, we are open to new ideas coming up.

But as the basis for the discussion, what we would like to do is go through these five areas, these five appendices to the paper, and have a discussion. We tried to build into the discussions, questions, so as part of this, we will pose these questions and invite your response.

If the consensus develops that in a particular area there is no issue, and that is your consensus, let us know early on, so we don't spend a lot of time discussing something that you don't think is too important.

Appendix A involves the Medical Policy Statement. In 1979, the Commission felt that it was important to make a statement to the public as to what the role of the NRC would be in the area of the regulation of the medical uses of radioisotopes.

I don't think I have to tell you, but I will just reiterate, that a policy statement of course in and of itself carries no force. It is not a regulation, it is not a law, it is a statement of intent. It is guidance that the staff should consider in terms of rulemaking initiatives.

There were three points to that policy statement. The first one was that the NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

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

Third, that the NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of

medicine.

Now, since this was published, we have had the proposed rules on Medical Quality Assurance, the final adopted rule on Quality Medical Management, and certainly the regulated community has claimed that we have exceeded the bounds of the policy statement and also there have been criticisms that the policy itself is incorrect, that the policy implies that the NRC should be more involved in the regulation of the medical community than is justified.

So, what we would like to do is open up a discussion in terms of the policy statement and whether it is adequate or not.

I will give you a little bit of insight into what the Advisory Committee told us last week. They essentially said that Policy Statement No. 1 was fine as it stood. It was their interpretation that that essentially referred to Part 20 types of radiation safety concerns having to do with workers and releases, they felt that the wording as it stood is appropriate.

With respect to both 2 and 3, they felt that the words might be okay, but that the way that staff had interpreted them in the past was perhaps not correct, and therefore, if we were to keep those, they proposed putting in strong adjectives and adverbs that would limit the involvement of the staff into certain areas, so it was to

limit the interpretation to make sure that the strength of the words would be that we would stay out of the area except where radiation safety was directly involved.

I would invite, at this point, comments from the States as to whether you feel there is any need to change the policy statement or if you have any specific recommendations with regard to the policy statement.

MR. WHATLEY: Kirk Whatley from Arizona.

[Laughter.]

MR. WHATLEY: I may get you in trouble here. Kirk Whatley from Alabama.

I would just like to comment directly on this, and I prepared my statement on this before I came to the meeting here.

It is very obvious that many people have different opinions on this matter. I think that may be an understatement of this meeting. But the question is why do we have different opinions, and I want to address one of the contributing factors or what I feel to be one of them, and that is a Medical Policy Statement.

The three statements of the Medical Policy are written in two terms that have come to be used every meeting I go to, performance and prescriptive. They are written in broad performance-based language.

They were even interpreted by the writer of this

document as that author viewed them, and that is not the problem, but the problem occurs when we all attempt to put our own words to what the Commission intended to mean by each of these policy statements, and that is exactly what was echoed by Dr. Glenn here.

Policy Statement 2 states, "The NRC will regulate the radiation safety of patients," and Policy 3 states, in part, that "The NRC will minimize intrusion into medical judgment affecting patients traditionally considered to be a part of medicine."

Is that the charge of NRC or is to protect public health and safety even if it does intrude into the sacred practice of medicine? There are differences of opinion on that.

The problem is that we disagree what each of these statements means. There is disagreements among NRC staff, among Agreement States, among the medical community, et cetera.

One question was asked, is it -- meaning the Medical Policy Statement -- sufficient to keep the Medical Use Program on track?

My answer to that is a resounding no because we don't know where the tracks are, we don't know where they are going, we don't know where they began, and sometimes a new set of tracks seems to just begin at the whim of some

statement that somebody makes or somebody's idea.

Sometimes it appears impossible to know which track the NRC is on, and the States also, and they do switch tracks in the middle of a journey wherever we are going, and depending on our own understanding, reasoning, and beliefs and experience, it appears lately that many of us are going in opposite ways, opposite directions on the same set of tracks.

This was also states in a document provided to us. These are not my words, but the authors of this document say the same thing, when it is stated, "However, different interpretations of the policy statement have led to conflicting opinions between members of the NRC staff, the Commission, and the medical community" -- and I would add Agreement States also.

A statement also appears in the Discussion section of Appendix A that was provided to us, that says, "A review of the Medical Policy Statement should focus on whether the prevailing rationale is different today."

I don't know what the prevailing rationale is today. It is certainly different every meeting I go to. I don't know what the prevailing rationale was back then. I am not sure anybody knows. I am not sure anybody in this room, here today, with the exception of a few, were even around when Part 35 was being developed originally at that

time.

In fact, the only forum in which it has been rationally discussed has been one in which each side was forced to defend his position in a hostile atmosphere, and to my knowledge, the Agreement States nor NRC staff have ever been asked their opinion on this subject before.

There are significant differences of opinion on medical licensing subjects and opposition is going to continue until they are resolved. I don't believe that all of Part 35 should be an item of compatibility in any way, form, or fashion. I have no problem with parts of it being.

Let me tell you why. The prevailing thoughts of NRC staff in the early 1980's, when this policy statement was in effect, that all medical licensing should be generally licensed, including therapy. Okay?

That is under the same policy statement that exists today. A few years ago, the statement was interpreted to mean that diagnostic nuclear medicine was so hazardous they would have had to have a misadministration rule for it under the same policy statement.

That is now being rescinded. It has been determined that diagnostic nuclear medicine is not so hazardous anymore, but all of a sudden, using the same policy statement has determined that it is, and that we are considering this to be an item of compatibility for all the

states.

Somebody used the word "waffling," and I think it may be appropriate from my standpoint. Using the same policy statement now it is my understanding that NRC wants this to be an item of compatibility. I don't know what the rationale for this is.

I don't want to leave the wrong impression. I go back to my original statement, and that being that we simply disagree on what the policy statement means and needs clarification.

DR. GLENN: I think, Kirk, I hear fairly clearly from you that in terms of that one question we asked, is the policy statement adequate to keep us on a steady course, you are giving us a resounding no on that one.

MR. WHATLEY: It has not kept us on anything.

MR. KERR: Wayne Kerr from Illinois.

The thrust of the policy statement as written now revolves around doctor-patient-NRC relationship. Since we are thinking today in broad terms, I would suggest that you consider making a statement on regulatory relationships in the policy statement, that is, what is the role of FDA, what is the role of NRC, the role of Agreement States, and state licensing boards, in particular.

It seems like if you would express that in the policy statement -- and I think that is an issue I know you

are going to get to later, and I am going to be gone by then -- but that is crying for a solution to state what those relationships are.

DR. GLENN: I think, in 2, there was an attempt to get at that, but I think again what I hear you saying is that it is a little too broad and not specific enough, doesn't really give guidance either to the staff or to others.

It does say where, you know, other standards are adequate that we won't regulate.

MR. FRAZEE: Terry Frazee from Washington.

With regard to the second statement, you might consider specifying what risk, what level of risk you are dealing with. That may be a little helpful to identify the distinction between diagnostic and therapeutic patients.

DR. GLENN: You bring up a good point. I guess one of the questions that we may want to discuss here, be it now or later, is what are good measures of risk for the NRC and for the Agreement States to consider in making these decisions.

MR. GODWIN: Godwin, Arizona, really.

[Laughter.]

MR. GODWIN: I think that I would more or less echo what Kirk said in that I think if you read out the policy statement and said how many can support it, probably

everybody would, but then when you ask what it meant, we would have the darndest fight you ever wanted to see.

It is a good policy statement as a general, broad scope of things, but standing on its own, it doesn't quite get there. It's the interpretations and defining where the track is or putting the fence up. There is an expression that good fences make good neighbors, and that is true. We really need to know where you are going to put that fence line down before we can really make an informed judgment of where you are going here.

I think that is probably the key item missing. You can either modify the statement or put out a supplemental interpretation section saying where it is. I am not really sure which way would be the best to go, but I it really needs a good, clear definition of what risk you are talking about, what do you mean by intrusion into the relationship.

I can give you my opinion all day long, and probably most everybody here would disagree. So, we really need to get down and try to build a consensus on where the fence is.

DR. GLENN: Any more comments on whether the principles are appropriate?

[No response.]

DR. GLENN: One of the next question was, is it

specific enough to keep the Medical Use Program on track while allowing accommodation of technological development?

I guess a corollary question to that, do you think that in fact -- Kirk pointed out that he has seen some lurches, go one way, then go the other way -- what is the sense of the group as to whether actions that have been taken in the last decade have been consistent with the policy statement as it is written?

[No response.]

DR. GLENN: Maybe a show of hands. How many feel that as you see the three principles, that there has been a consistent application of this in the last decade of regulation? How many say yes? How many say no? Okay. I have a consensus.

That gets us into the next area that we posed a question, and that is, in order to make that process more visible and perhaps as discipline to the NRC staff, should a line item be put into any rulemaking, into the statements of consideration, describing the relationship of this rule, whatever it happens to be, to the policy statement?

Could I have some statements on that?

MR. KERR: Wayne Kerr, Illinois.

Probably so. I think, if for nothing else, it would help you to explain, if you will, the kind of things that Kirk pointed out, you know, eight, 10 years down the

road there may still be some deviations, but at least it forces you to sit and say I have thought about it, and here is what we think today, and it is consistent presumably or else you wouldn't issue it.

MR. GODWIN: Godwin from Arizona.

I think what I would like to see is some way to know that whenever you decide that is time for a change, that a real informed decision is made by whatever group is going to make that decision -- and I think that may be a little vague depending on what decision you are making -- of at least looking at what had been said in the way of policy up to that point, and we have a clear switch-over to another track

I think what we see now is we come to a change point and the track suddenly disappears for a while, and then the cars end up somewhere else. This is what is a large part of the problem.

If we had a clear decision basis for the change and why we are changing, and all of that, I think it would help us ease our way through there.

For example, Part 35, I think the largest percent of it is all very good, but there are some places in there where we look like we have changed tracks and nobody knew there was a switch coming.

DR. GLENN: Again, I heard some comments there

that bring in this idea of measurement of risk. You are talking about having a clear decision basis. I think one of the problems that we have as a staff in developing regulations, in terms of the discussions with the Commissioners in developing new regulations, is a good measuring stick as to what the impact of what we are doing will be, what are the consequences and the costs.

I wonder if this is the right place to have some discussion about what kinds of measurements of effectiveness we might incorporate into our program.

MR. GODWIN: Godwin again from Arizona.

It appears that one of the things that you have not looked at -- but maybe you have, I am not real sure -- is that you would take the dose, for example, to do some risk estimate as far as diagnostic procedures, and you say, well, these are all not very risky.

That is fairly true when you look at the dose that is coming out. However, it is not clear that you said, well, okay, what about unnecessary exposure caused by, like I say, inappropriately trained persons ordering exams that are inappropriate for that diagnosis or that symptom group that is being presented.

You have these radiation doses being given and with no benefit to the patient, in fact. You can do a similar thing relative to x-ray, and as we see in

particularly mammography, that there is a great emphasis being made on making sure that the people who are reading and have the equipment and everything is being checked, so as to get the best optimal reading conditions for diagnosis, to prevent the doses.

Now, admittedly, the doses are somewhat higher in general for mammography, but we have a similar thing on the road to me regarding fluoroscopy, where you have had 5 percent of fluoroscopic units cannot identify a single phantom object.

You know when that gets going, you have a problem coming down there because effectively you are giving people exposure with no benefit to them.

I think you need to have some way of factoring that into your equation before you decide on some of your decisions not to have people necessarily trained.

DR. GLENN: Aubrey, you have raised some questions that get right on this nub of the dividing line between what the NRC should get into and what it shouldn't get into. I think you right, that the major danger to patients, probably in diagnostic procedures anyway, falls on the side of the adequacy of the procedure rather than on the radiation safety aspects of the risk, in other words, that more harm comes from a misdiagnosis or from many people receiving unnecessary exposure rather than from any

particular radiation risk.

I think, speaking for the staff, that the side we have been coming down on recently is that we will regulate the radiation safety aspects of that procedure, and not the medical quality assurance issues associated with that, but I would be interested in some comments from other states in terms of in going in that direction, are we going the right way.

MR. KULIKOWSKI: Bob Kulikowski, New York City.

First of all, I have a question for you, John, relative to your last comment. How can you really dissociate the two?

I think we are looking at a sheet of black on this side and a sheet of white on this side, and where the two pages meet, you would like to have this intersection of a black plane and a white plane, but you really have this fuzz, which we all can't get away from.

Just some other general comments. The States have the added responsibility of applying -- and I know at least in New York City -- we will have the added responsibility of applying similar type regulations to machine-produced radiation, as well.

Our administrative procedures people come down pretty hard on us when we say we are going to do this for one group, and a similar group that is doing something with

a similar risk we are going to do something different for.

New York State now has quality assurance for diagnostic radiology, so we are going to have to be involved in that, in nuclear medicine, as well.

The other comment that I want to make is the policy statement is all well and good. I don't believe, to the best of my knowledge, it is applicable to the Agreement States.

I mean I think we have different enabling legislation which may say things that are different than the Atomic Energy Act does for you people, and we are right in the middle of doing one of these right now, accelerated-produced facilities, as well, which require other special considerations.

So, I think basically, in summary, I think you probably do need a Medical Policy Statement. I think the questions that you need to ask are, one, not going to have any answers, any clear answers, and to make them applicable to the Agreement States, using the nasty "C" word, compatibility, I think it is just not possible.

It is not a question that we don't want to be compatible, but I have talked about, I am really disappointed that the Commission did not act on the compatibility paper in time for this meeting, because I think it was very important that this be done because it

seems to me that as we go forward and even discuss philosophically, these things are going to end up in rulemakings, and as we heard this morning, there are a bunch of rulemakings that are on the table now.

It seems rather absurd to me -- and I think that is the appropriate term -- to try to go ahead with these rulemakings without making a determination on the compatibility.

My recommendation would be that you stop all rulemakings, sit down and iron out the compatibility issue now, once and for all, and then go ahead, so that the rulemakings can be done in some semblance of sensibility.

Thanks.

DR. GLENN: I hear your thought there, I guess. One thing, if you read the paper, you did notice we sort of put a disclaimer in there that compatibility was not the issue of this management plan because it is such a bigger issue than this particular Issues paper.

MR. KULIKOWSKI: I know, but you can't really divorce it, just like you can't divorce misadministrations as part of radiation safety.

DR. GLENN: Again, all I can say is that my branch will not in fact be the group that will develop the plan that resolves the compatibility issues, but we hear you.

MS. ALDRICH: Rita Aldrich, New York State.

New York State, for information purposes, already has a regulatory requirement for quality assurance in both diagnostic x-ray and diagnostic nuclear medicine, and we hope by the end of November to have the same in place for radiation therapy.

There is a big difference in the focus. It is largely focused on optimization and radiation safety. I don't know that that is the jurisdiction of NRC, but it sort of reinforces what everyone else has been saying, that the risk to the patient has to be justified by the benefit. It is like a basic tenet of radiation protection.

The error prevention part of diagnostic, we consider to be rather low on the totem pole when you look at the importance of the diagnostic quality of the results of tests, especially with new cameras, complicated procedures coming along.

So, what we have done is say that traditionally what we have accepted in x-ray for ongoing oversight over whether errors are being made, whether the wrong person is getting a procedure -- and believe me, it happens are more often in x-ray than it does in nuclear medicine -- is that we have always accepted an ongoing analysis of retakes, repeats, misadministrations, which in x-ray is typically done by looking at your films on some kind of a regular basis and sorting them and just doing it statistically.

We are doing the same thing with nuclear medicine. We are treating it as the same sort of thing because it is the same kind of a risk. It is a statistical population exposure risk, it is not an individual risk item.

If anyone wanted a copy of the regulations that we have, we would be happy to provide them to you.

DR. GLENN: The last two commenters I think have raised a possible distinction between NRC and perhaps state regulations in this area. Let me just throw this out.

It is possible that the NRC should draw the line, and not get into medical quality assurance things, such as the reproducibility of films, the ability of the camera to detect artifacts, but that may in fact, by the nature of the way medicine is regulated in this country, be more of a state function.

Are there any comments on that?

MR. GODWIN: Godwin of Arizona.

I would draw the line at a different point perhaps from where you did. I think from my understanding of the Atomic Energy Act, that there are many areas that you would indeed want to be involved in quality assurance. I don't have that kind of difficulty.

But there are areas where probably you should not be dealing in, and perhaps even at the state level, many of our radiation programs should not be dealing in, and that is

where we deal directly in the physician-patient relationship, particularly individual patients, not so much as perhaps a group, but individual patients, I think that probably looking, for example, at dosages, a strong case could be made that you should not be looking so much at dosages while some of our State Programs may.

On the other hand, qualifications of people working might be an area that you would look at rather closely, and I am just giving my sort of personal opinions on this.

If there is a clear-cut function relative to the overall program, I think that the case could be made in some cases where you haven't a real function defined yet in your regulations.

Once a physician is determined to be competent to do the procedure, many of us probably need to step away and let that relationship run as a strictly medical malpractice relationship.

We cannot get into that kind of thing, the physician malpracticing after we have evaluated and determined he is a qualified individual prescribing it, that is probably the way it should be handled in our current regulatory process.

If he is determined to be malpracticing, we might want to think whether we need to continue to authorize him

as a user, but that is another issue, too.

So, I think there are a lot of places where you can look at that line and it is going to take some banging around to determine where it goes, but I do not think that we can interfere directly with the physician-patient relationship, nor should we once it is established that they are the qualified people.

MR. KULIKOWSKI: Kulikowski, New York City again.

Gee, John, has Carol Marcus gotten to you?

[Laughter.]

MR. KULIKOWSKI: Aubrey sort of said what I wanted to say, and it seems like talking about that line between black and white, it seems that that gray area becomes narrowest when you focus in on the physician-patient, you know, will the physician prescribe what he deems is best for his patient, whether indeed that departs from the package insert or what someone else may consider good medical practice. That I think is clearly on the one side that we don't have any authority to go into.

However, regardless of what the physician prescribes, once that medical determination is made, then it seems like we have the responsibility as the radiation safety regulators to ensure that the delivery of the prescription is done in an accurate fashion for the sake of radiation safety.

DR. GLENN: Is that an endorsement for the Quality Management rule?

[Laughter.]

MR. KULIKOWSKI: For the record, no, that was not.

[Laughter.]

DR. GLENN: That was a little bit facetious, but in fact that was certainly the intent of the NRC staff with the Quality Management rule was to just do exactly what you said there, to assure that the prescribed dose is delivered.

MR. COLLINS: Steve Collins from Illinois.

To give a specific answer, at least in my personal opinion, to the question you posed is I think where you draw the line, as you stated it for NRC, is the proper place for NRC to draw the line.

Some of us in our states have state statutes that allow us to draw the line a little bit differently, but even in those, we should realize, as health physicists, that we are not experts in the practice of medicine and a lot of times some of the things we have done should, instead of us imposing direct restrictions on medical practice, we should have provided our analysis of the situation to the proper board that gives licenses to physicians or pharmacists, for that matter, to do their practice and let them take the appropriate action.

DR. GLENN: Dr. Pollycove, would you like to make

any statements?

DR. POLLYCOVE: No, I would just concur with Steve Collins. I think that the matter of competence should be left to various bodies that are involved in competence, and this ranges from the residency review committees to the specialty certification boards, and also the state medical boards.

I think the groups that are primarily concerned with this are the ones that should deal with this, and the NRC's primary concern is with radiation safety, and I think that is its proper area.

DR. GLENN: Are there any more issues, questions people would like to raise about the policy statement?

[No response.]

DR. GLENN: If not, I will pass the baton over to Mr. Camper, and we will discuss the next topic.

MR. CAMPER: Next is Appendix B, which deals with Part 35.

You might recall in 1983, the staff had proposed a revision to Part 35, which was much more performance based than the final regulation. After publication of that proposed rule, the Commission directed the staff to redraft the rule with much more specific prescriptive requirements and to certainly a significant degree, that was at the urging of some Agreement States' representatives who felt

that the Part 35 needed to be more prescriptive-based at that time.

In doing this we tried to bring together a number of branch technical positions, certain information that was used in licensing guides, and so forth, to licensed medical licensees, and put it into one document.

Part 35 is both prescriptive based and performance based. These are relative terms. If you look at the recent Quality Management Rule, that is clearly a performance-based requirement, but yet we could go through a number of parts of Part 35 or components of Part 35 that are quite prescriptive, for example, leak test requirements, doing certain types of surveys, incoming packages, these types of things.

The question that come up then, the first question that we are asking you under the Part 35 category is, are there issues that should be incorporated into Part 35 or added to the current rule that you would like to comment on?When I say incorporated, I really don't necessarily mean added, we are saying added, or, you know, in the context of incorporated, we are saying perhaps modified, changed, or added to.

Any comments on that?

MR. COLLINS: Steve Collins from Illinois.

I don't know that I want you to slow down the

current rulemaking for it, but things that we have discussed in the Agreement State meeting that was completed yesterday, that should be looked into for possible inclusion in the future modification of the rule would be some standards for gamma stereotactic units, for mobile high-dose rate remote after-loaders, if in fact that application is allowed, and for mobile nuclear medicine services.

MR. CAMPER: We did, in fact, discuss those, as Steve will recall, at great length at the ACMUI meeting under this concept of emerging technologies that we felt needed to be addressed.

Those are the very ones, mobile nuclear medicine, the HDR's, in particular mobile HDR's. One of the things that the Advisory Committee said about this particular question is they felt that there really should be more emphasis upon performance standards.

Is there any general reaction to that?

MR. GODWIN: Godwin, Arizona.

As long as performance standards are something that are definitive enough that you can hang your hat on if you have to take an enforcement action. Unfortunately, many times we come out with this nice, wonderful performance standard, that whenever you get ready to do something, you find out that it is subject to 15,000 interpretations.

If there is an important radiation safety function

there, it needs to be clear enough that we can indeed do what we need to do to protect the public health and safety. That would apply really to all these things you are considering, not just this one subject.

Again, go back to our prior discussion. It is a wonderful performance standard, but everybody has got a different opinion on what it meant.

MR. CAMPER: That is a good point, Aubrey. I think all of us who have been out there in the field have seen, on one hand, there is merit to arguing in favor of requirements of Part 35 and performance-based standards as opposed to specific criteria, like we currently have in some parts of Part 35.

The problem that you get into, as a practical matter, is that in many cases licensees -- it certainly makes it easier for licensees if you have prescriptive requirements that are clearly black and white, very task-specific, I know exactly what I have to do as a licensee, and if I do those things, because you have made them very clear in your regulations what it is that I must do, and either as a physician, radiation safety officer, or through the use of a consultant, if I do those things, if I dot those i's and cross those t's, I can have a high degree of confidence that my program will pass an inspection.

Similarly, for inspectors, NRC inspectors or state

inspectors, if you know exactly what to expect of a licensee before you go in, it reduces to at least some degree the amount of on-site judgment that has to take place, and perhaps argues more for consistency amongst inspections.

So, while on one hand I think that performance-based criteria, as I said has merit, there is something to be said for prescriptive-based.

Now, what I would really like to find out from those of you from the States, is generally speaking, this idea of licensees finding it easier to deal with prescriptive requirements as opposed to having to develop performance-based standards, do you have observations on that or thoughts on that from your own inspection processes?

MR. KULIKOWSKI: Bob Kulikowski, New York City.

Yes, and I would sort of like to make an overall statement about the next three questions in Appendix B. Being a largely medical program, we have a fair amount of experience in this area.

First of all, I don't think it is possible to be exclusively performance based or exclusively prescriptive, and even within each category you are going to have them to various degrees.

I mean there are some things that we definitely want prescriptive - radiation safety officer, we want them to have specific training, not just to say training or

adequate training.

Experience from inspectors in the field, it depends, and we have medical facilities which range from nuclear med docs in private offices to major broad licenses, some of the largest in the country, and everything in between for the large non-broad scopes.

I don't think there is a consensus. I think it depends on the staff of the hospital, the radiation safety staff of the hospital, how they want to deal with things.For example, two very large hospitals may do things entirely differently, arrive at the same end point, and I think we need to -- and I am beginning to recognize this more and more -- the people that I send out in the field have to have the ability to make the judgment that not only is it something that is performance-based, but something that is prescriptive-based, as well, but be able to make the determination does the licensee indeed fulfill the radiation safety requirements, whether it is to the letter of the law or whether it is not to the letter of the law.

I mean, you know, go back to the Merchant of Venice, you know, can they take the pound of flesh, you know, what the licensee is doing may vary a little bit from what the regulation says in a very prescriptive sense, but does it get the job done adequately with no compromise to health and safety.

I don't think there is any answer to your question that there is any one right way for somebody to do something.

MR. CAMPER: Bob, if you had to come down either way, is Part 35 too prescriptive currently as it exists?

MR. KULIKOWSKI: I don't know. I can't give you a yes or no answer because for some of our licensees, yes, it is too prescriptive; for other ones, no, it is not too prescriptive.

MR. CAMPER: Any other thoughts?

MS. TEFFT: Diane Tefft, New Hampshire.

Just to say that regardless of what we think, there are states in their interpretation of their Administrative Procedures Act which are requiring very prescriptive regulations.

What is happening -- New Hampshire may be a good example -- is that when compatibility is an issue and we are going in and trying to take the existing regulations, say, NRC and the SSR's, and making them into prescriptive regulations because that is what the State is requiring, we in some cases are developing national policy in each of the individual states.

So, in answer to your question, I personally may not think that it is too prescriptive or not, but the State is going to say I know that Part 35, along with many other

parts, is nowhere near prescriptive enough.

MR. CAMPER: That is a good point.

Aubrey?

MR. GODWIN: I was just going to say that your question about is Part 35 too prescriptive or not, it is not a very fair question because parts of it I would say yes to both questions.

MR. CAMPER: Can you give me an example of what you think is overly prescriptive and perhaps an example of what you think is just about right?

MR. GODWIN: Well, trying to quickly from memory, I am not sure when you try to balance the training requirements for clinical use, and then you put in the training requirements for the radiation safety for the physicians, that a good balance has been struck there.

Will the radiation safety work be done by the physician or will it be done by somebody else, will that training be better placed somewhere else?

MR. CAMPER: We are going to explore that question at great length, probably this afternoon.

MR. GODWIN: I think there is an inadequacy and it doesn't clearly say what the authorized user is responsible for, yet, the physician is authorized user, but there is nothing that really says what is he supposed to be doing, you know, and there are other sections that I think would be

better. Some of the duties for the RSO, for example, are probably a better defined section than it had been in the past particularly.

I would just have to go through it article by article. I am just trying to do this off the top of my head.

MR. CAMPER: Yes, I understand.

DR. GLENN: I have an example of one where perhaps it is not that it is too prescriptive, but maybe it was wrong-headed. In Part 35, we require that the check source go with the instrument when it is sent to be calibrated. Should we get that prescriptive about how you determine that your instrument, when you check it, is working properly?

MR. FRAZEE: Terry Frazee from Washington.

Part 35 is a mixed bag, some are, some aren't. As far as enforceability of a performance-based rule, in fact we already went over one this morning earlier, talking about the patient release criteria.

I would say that at least part of that is performance-based, allowing the release of a patient if the Total Effective Dose Equivalent is less than 500 millirem in a year -- or 500 millirem. It doesn't tell you exactly how you have got to calculate that or figure it out, and that in fact could be the rule and just let it go at that.

Throwing in or leaving in the very prescriptive

part of it, saying 5 MR per hour, okay, that is very prescriptive. Some licensees could figure out a different way to do it.

So, I think that kind of a performance-based concept, that doesn't tell you all the individual steps on how to get there, but does give you something that is enforceable at the end, a goal, a well-defined goal, 500 millirem, I mean I think we would agree that that is something we could enforce to.

MR. CAMPER: Just to give you a comparison, generally speaking, we heard the ACMUI saying to us that Part 35 is overly prescriptive.

MS. ALLEN: Kathy Allen from Illinois.

I will give you an example of both.

MR. CAMPER: Good. Excellent.

MS. ALLEN: For brachytherapy, requiring a survey after sources are removed to verify that the sources have all been removed, I think is prescriptive and is very good. The requirement that you use iridium sources only for interstitial treatment of cancer is too prescriptive.

MR. CAMPER: We totally agree. We are trying to change that, in the very near future as a matter of fact.

MR. KERR: Wayne Kerr, Illinois.

Bob Kulikowski made a point that Part 35 is too prescriptive for some of his licensees, and not for others.

I think raises the question you probably have to regulate to the lowest common denominator. That is sort of a general philosophy. So, the good guys get hurt by it, and the regs are written for the ones that aren't so good.

MR. CAMPER: I think that is a very good point. One of the things that I constantly bring up in the advisory committee meetings is that clearly we have, you know, an excellent advisory committee that consists of physicians that I think most of us would agree are the creme de la creme, that come from very fine institutions.

They make suggestions. You can't help but make suggestions and offer ideas that divorce yourself from where you have been and what your own experiences are.

There are times when we do point out that believe it or not, the standards for radiation protection and radiation safety -- Dr. Pollycove is chuckling over there because I think in the last year or so he has had sort of an eye-opening experience -- there are some problems out there, and your point, Wayne, about regulating to the lowest common denominator is something I think that generally speaking, as regulators, we do have to do and it is the right thing to do.

I think, unfortunately, some people will look at that as, well, you have got the bad apple complex, whereas, we are really doing a great job over here and your rules are

inordinately overbearing, but we have to strike that balance somewhere.

I think what I am really hearing on this question is that the question on whether Part 35 is overly prescriptive or not prescriptive enough or performance-based, what I am hearing is you are saying it is really a mixed bag, you are saying that we perhaps should try to get to the lowest common denominator, and you are really saying there are instances where it needs to be prescriptive and there are instances where it needs to be performance-based.

MR. BAILEY: Ed Bailey from California.

Before you take that as a consensus opinion that we have to regulate to the lowest common denominator, I would suggest that there should be levels of regulation. There is absolutely no reason that I can see that a cardiologist, for instance, has to have the same set of rules that a board-certified nuclear medicine physician has to have.

MR. CAMPER: Are you speaking of training, Ed?

MR. BAILEY: No, I am talking all the way through.

MR. CAMPER: The radiation safety program across the board.

MR. BAILEY: Right. I mean they are totally different programs. Likewise, a radium quack or iridium

quack, whichever one you want them to be, there is no reason that I can see that they have to follow every single rule that a full-fledged nuclear medicine program has to follow, or maybe they have more rules, I am not coming down.

I don't think the rules have to be written, so that everybody has to do each one of these steps just because they fall under the guise of nuclear medicine.

MS. DICUS: Greta Dicus, State of Arkansas.

This is totally off the subject of the medical rule, but I have got to go and I won't be here, and I did want to make some general statements in order to have them part of the public record.

We are aware of the very large number of rules that are going through the system, and they impact every Agreement State. I think in the past year or two, somewhere between 25 to 30 rules are being worked on or currently considered. The impact on the States, both in terms of time and people and money, is significant.

The second point that I would like to make is that most, if not all, of these rules, decisions have been made on compatibility without in some cases consultation of the States. Particularly, I think Part 21 has gone from, let's see, from Division II to Division I. I don't know that we were consulted, and that does impact some of our programs.

Also, as has already been pointed out, there is

not a clear set of criteria to define how, who, what, when, and where the decisions on compatibility were made.

A third point, we are being required to implement rules that are flawed. The examples particularly are the decommissioning rule, Part 20, and the medical diagnostic misadministration rule.

We would like for these rules to be clear and to the point, and all the flaws in the rules corrected before we are required to implement them.

Again, I know I am off the subject, you do not have to comment, I just wanted it as part of the public record.

Thank you.

DR. GLENN: Greta, I will just mention I don't think it is off the topic because one thing we are talking about here is the process and long-term planning, and although I can't control all the regulations, certainly in the medical area one output of this strategy session may be that we say we are only going to have two rules a year or one rule a year at most, and get the maximum effectiveness out of that rulemaking.

MS. DICUS: Well, another point, again already made, but we regulate x-ray machines, we regulate non-byproduct material, we regulate accelerators, and here, when we are talking about the medical licenses per se, I

have got approximately 60 in my state, but I have 2,900 x-ray registrants.

When I have to implement a rule that has some risk-based option to it, particularly misadministration, I have got to implement it across the board, and I have to implement it for dentists, for chiropractors, and so forth.You have got to take that into consideration and the impact, because when we went to implement our diagnostic misadministration rule, we went to public hearing on it, and our people said, well, what about the dentists, what are you going to do about this, the people who came to our public hearing, and we said, well, we hadn't thought about that.

So, we had to go back, try to define a diagnostic misadministration on an x-ray machine, what is it, and what is going to be the impact, and where is the risk. So, it is important that that be considered when we have to implement these rules.

MR. CAMPER: Thank you for your comments.

Any other general comments about performance-based versus prescriptive?

[No response.]

MR. CAMPER: If not, then I would ask the question and perhaps just a show of hands is sufficient, and I think I know the answer, but it is should the rule be entirely performance-based, should Part 35 be entirely

performance-based? Let me see a show of hands that believe that it shcuild be.

[No response.]

MR. CAMPER: Let the record show that there are no hands. Okay.

What techniques should NRC use to identify potential new rulemaking endeavors? Let me just set that up a little bit for you. One of the things we have tried to do very clearly is to go to the Advisory Committee on the Medical Uses of Isotopes earlier and earlier in the process.

Similarly, we are trying to come to the Agreement States earlier and earlier in the process to talk to you about there is an issue or we believe that there is an issue and we think that something needs to be done about it.

Now, what needs to be done about it is something we have to work through and find out. It may or may not be a rulemaking. Other than the communication, the improvement of the communication technique, are there other things that we could do to identify potential new rulemaking endeavors?

MR. BAILEY: Ed Bailey from California.

I think there should be one basic tenet that should be put above everybody's desk, and that is, if it ain't broke, don't fix it.

I think there should be a clear procedure whereby a problem must be identified before you write a regulation.

I think what we have seen, not only in radiation, but in all areas of rulemaking, is that very bright people come up with a hell of a lot of "what-if's," and the way to solve or answer all those "what-if's" is to write a rule or regulation, so that you don't have a "what-if."

I very much support the concept of having rule-writing groups, I think as Ruth can attest to, but we must sort of remember that it shouldn't be anybody's job to write rules simply for the sake of writing rules.

This question about regulating medicine. The impression -- and it is not just my impression -- but it is things that are verbalized about a lot of people. There is a lot of M.D. envy, and we all make jokes about the M-deities, and there are at least one or two regulators who feel that, okay, we are going to get even with them now because I couldn't be a physician, for whatever reason, and I dare anyone to challenge me that that is not true.

I grew up I guess in a different atmosphere. I grew up in a hospital where my attitude was if I can't get a decent job, I can always be a doctor.

[Laughter.]

MR. BAILEY: There were some things I guess that would have prevented that. I think we have to try to really identify problems, and I think we can give some very good examples of where problems were identified and then rules

developed, and these really to some extent have come up from the States because, generally speaking, States have smaller staffs and have more interaction with people in their field.

I would point out the well logging regulations, the two-man rule in radiography, the testing of radiographers really to determine that they have been trained, not that they could pass a test.

I think when NRC decides to do rulemaking, the first thing up front should be here is the problem, and that problem should have to be related to radiation safety or the national defense, or whatever.

That is my idea.

MR. CAMPER: Any other thoughts or comments on ways to identify potential new rulemaking endeavors?

MS. ALDRICH: Rita Aldrich, New York State Health Department.

This is a little bit off the subject, but it is along the lines of what Ed was saying really. I don't think that NRC thinks in terms of the fact that states make rules on their own, they are not always simply adopting an NRC rule.

So, in addition to the burden of any rules you might think are good for us to adopt, states have -- and we have I think heard frequent mentions of it here today -- gone and done their own regulatory initiatives. NRC may

wish to look at those as possible models for some of the things they are doing or planning or thinking about.

Also, once we have done a major rulemaking, as we are doing with Part 16 and the sections that apply to medical use, we don't intend to touch that for quite a while, so we will have done what we are going to do before you come up with whatever it is you are thinking of doing to Part 35.

We are not going to go back and revisit that. We have got, as Greta said, Part 20 to work on. That is going to be a very intensive, not only rulemaking, but followed by information programs for licensees and working on interpretations. Shaking that all down is going to take an enormous amount of time and effort.

There is a financial assurance rule which I, at this point, don't know how we are going to adopt it given all of the holes that exist, but we need to do something. We need financial assurance, the waste crisis alone makes that critical.

Those are two major rules that could eat up enormous time. I mean even the New York State Health Department, we do not have a big licensing program. I have two full-time licensing staff plus me, and I do licensing in addition to whatever else, you know, wash windows, clean floors.

But I think that you should keep that in mind. I don't think you are looking at the fact that the states undertake rulemaking initiatives on their own, also address and solve problems in ways other than rulemakings on their own, and that having done that, not only do they not want to turn around and adopt something or change something just because NRC has decided that is a good idea, but the time and the resources are not there.

MR. CAMPER: I appreciate that. Just a comment or two about Part 35 again. We really don't have any plans to do anything to Part 35 at this point about this particular endeavor.

I mean we know that there are certain things in Part 35 that need to be cleaned up because there are inconsistencies between Part 35 and Reg Guide 10.8, and we know that those things need to be addressed at some point. We want to get to that sooner or later.

Assuming the Commission accepts the staff's recommendation on the radiopharmacy rulemaking, there will be a need there to make some adjustments in Part 35 because it is going to change things rather significantly, but other than that we have no preconceived idea at this point in time to make any changes in Part 35 other than administrative clean-up and what is necessary from rulemakings that are currently under consideration.

I mean it could well be when we go through this entire process and hold these meetings, and so forth, that the conclusion is that the things we currently have underway are sufficient at this point in time and that we should revisit this at some point in the future. So, really, we have no plan at this time.

MR. GODWIN: Godwin, Arizona again.

I am not sure it is on the record, but I think it should be on the record, that regarding professional qualifications of the physician, particularly in the clinical area, I feel that the professional boards and certification bodies of the physicians is probably one of your better sources for determining that, and I think we ought to support that strongly.

There may be a need to grandfather in those that are currently practicing, and there is probably a need to provide an alternate way for people to qualify, but I think we ought to lean strongly toward the professional boards, and even to the extent of where they adequately address radiation safety as far as operations, we might look at that, too, but I am not sure all of those boards currently do that.

On the other hand, regarding quality assurance, they probably set up good model programs, and they probably do a lot of work, but for the most part they are not as

independent as I would desire, and I think that we need to maintain our regulatory oversight and provide unannounced independent reviews of what is going on.

Certainly, they can supplement and may justify somewhat reduced inspection frequency, but I don't think you can walk away from it and say just because they have an independent quality review that you don't need to go in and make an independent assessment.

Certainly, we ought to encourage them to develop these things because I think their primary focus is something that may not always be our ability to direct. For example, I think they can do a much better job of improving patient care, which may not totally be a radiation safety issue, and I think that we ought to encourage that and, to the extent possible, encourage them to push that with their groups.

MR. KULIKOWSKI: Bob Kulikowski, New York City.

I would like to reiterate both what Aubrey and Rita said. I, too, do licensing at home, I only have two licensing people. Rulemaking is an onerous task for us. There are a number of things that are coming down tne pike that we have to do.

I realize the "C" word is not part of this discussion. However, just like Greta, I am going to sort of break the rules. That is what rules are usually for -- not

for licensees, of course.

Especially with respect to rules that, as Greta put them, are flawed, and we have to adopt them within the three-year time frame flawed or not, or we get a finding of perhaps adequate and not compatible, or a finding of compatibility is withheld upon the program review -- and this is a comment that I made in response to some Federal Register Notice about a year ago -- it seems very strange to me that you can find a program adequate but not compatible.

If the program is adequate, in my estimation everything is there, that is in place, that makes it compatible. I mean if you look at compatibility as being compatible with the Commission's goal of protecting public health and safety from radiation, if the program is found adequate, I don't think you can make a finding of not compatible.

MR. QUILLIN: Quillin, Colorado.

I have been around this business for 30-some years now and I think that when you ask about the need for rules, one of the observations I have to make is that sometimes I wonder what prioritization the NRC uses in picking the development of one rule over another.

Has the NRC ever gone through a process where they have tried to prioritize the problem areas and then tried to address their rulemaking process from that perspective?

DR. GLENN: I will just make a quick comment. We do -- you may not agree with it -- but, in fact, Research is required to submit to the Executive Director of Operations on a periodic basis a listing of all rulemakings, what the priorities are, which ones are being put off indefinitely, and there is a little rationale for every one of them.

So, in fact, there is such a process.

MR. CAMPER: Interestingly enough, you know, we go through a much similar process further down the scale, as well. We take a look at things that are under consideration, try to make some determination as to which of these things might require rulemaking and which can be handled in other ways.

Now, the two rulemakings that we are working on right now, one results from a petition filed by -- actually, there are three rulemakings -- two of them result from petitions filed and the third, dealing with pregnancy and breast-feeding, resulted from a number of incidents that were occurring that had some fairly significant consequences that we felt we needed to do something about.

Let us try to go back to focus on what we are doing here. The next question was: What level of research and analysis should be used to make the decision to forward with rulemaking?

Just to kind of set the stage for the question,

when we asked this question to the Advisory Committee, amongst the answers that we got was "the right amount." That is hard to argue with.

Of course, things such as scientifically credible arguments, trying to take a good look at risk, and comparing the risk to the population as a whole or to certain elements of the population.

Are there any other thoughts about what we can do in terms of research and analysis that we could bring to bear in decisionmaking as to whether or not to move forward with the rulemaking process?

MR. BAILEY: That is a different question.

MR. CAMPER: Yes, it is.

MR. BAILEY: Bailey from California.

The phraseology used in the question orally was different from what is written there. Do you want both of them answered? I think they are different.

MR. CAMPER: Right. What level of research analysis should be used to make the decision to forward with rulemaking? That is the question. What level of research and analysis?

MR. BAILEY: Well, certainly, there should the research that goes forward with the rulemaking, that provided the basis of your deciding to do a rulemaking. That is where I see the difference in the question.

You need to say why you decided to do this, what compelled you or what -- sometimes it is very simple, a new law passes, and we are told to write a rule, so that is a pretty compelling reason.

For other rulemakings, I think there needs to be a justification, and that may or may not involve research, but it will always involve an analysis.

MS. MAUPIN: I am going to digress here and try to respond to some of the issues concerning compatibility since I have been the project manager on that for I guess over the last three years now.

Basically, I know that without communication there can be no progress, and I don't want you to think that you are raising issues here on compatibility and no one is hearing you. I am hearing you, and we have heard you.

It is kind of complex to make a finding that a state is adequate and not compatible, but that happened over the history of the program because initially, there were basically three different types of findings: one, that a program was adequate, could be adequate, but they could also be compatible, but not in areas affecting public health and safety.

Then, there was the finding, yes, you can be inadequate, but compatible. So, I just want you to know that this is a complex issue. I know that right now

compatibility is only held in regard to regulations, and we know that there is concerns whether or not compatibility should address the overall program areas.

We did make some responses back to the Commission. As you know, we are awaiting their decision. There were some complicated scheduling concerning the Commissioners over the summer, and they were not able to respond back concerning this issue.

But I want you to know that your concerns have not fallen on deaf ears and that we are trying to respond, but as I said, now it is in the Commissioner's hands.

MR. CAMPER: Thank you, Cardelia. I think we all look forward to getting the compatibility question resolved.

Let me go to the next question on this particular issue. Are there other provisions of Part 35 that we have not discussed thus far, that interfere with effective regulation of the medical licensees?

At the ACMUI we heard that Part 35 was generally overly prescriptive. They felt that we perhaps should revisit the data for the 1987 rulemaking, the last time we implemented changes to Part 35.

They also felt that perhaps that there were industry standards in existence today that might allow some form of deregulation. Then, of course, I think the one that they felt most strongly about was the ability for medical

licensees to procure radiopharmaceuticals with much more flexibility than is currently allowed in the wording in Part 35.

We have, as I mentioned a while ago when giving you the overview, the staff proposes to make a fairly dramatic change, suggest a change in the language in Part 35, to open up and provide great flexibility to medical licensees as to where they may procure radiopharmaceuticals.

So, we think we are going to address that particular issue very thoroughly.

DR. GLENN: I don't mean to interrupt, but you have just given me a very good opportunity to make an announcement. That is, that John Telford has in fact brought along copies of the draft rule language to address the radiopharmacy petition, and those will be available for you to pick up today. I just couldn't pass that up.

MR. CAMPER: That is good news. I think when you read that language, you are going to see that it is (a) a tremendous simplification as compared to what we have discussed with you previously, and you are also going to find that it is all about suggestions that came out of the meeting in Atlanta with the Agreement States.

It was received very well by the Advisory Committee, even including Dr. Marcus, who was the primary author of the petition. So, we think it is constructive

changes in language, we think it does protect public health and safety while providing flexibility to medical licensees, and it does recognize the practice of radiopharmacy.

It has to undergo management review and concurrence, OGC review and concurrence, as well as Commission consideration, but the schedule for that is of submitting the rule in December.

So, setting aside for a moment this question of radiopharmaceutical procurement, the practice of radiopharmacy, and flexibility, as it currently exists in 35.100, 200, 300, and so forth, are there any other provisions of Part 35 that interfere with effective regulation of medical licensees, interfere with effective regulation of medical licensees?

[No response.]

MR. CAMPER: Seeing no expressions, hearing no comments, we will assume that there are none.

[Laughter.]

MR. GODWIN: I guess since I don't have all of the provisions of 35 that we have been trying to enforce, it makes it a little tough to answer your question, but as I recall, you all had certain flexibility relative to changing procedures by the licensee.

I would guess that probably has caused you all some problems relative to discussions between you and the

licensee as to whether the changes made by the licensee were within the scope of authority of the rule. I would guess that could be an impediment in some cases, but I don't know since I don't have that provision.

DR. GLENN: I will make one comment. I think probably the flexibility is not being exercised very much because the licensees are afraid that they will make a mistake and then we will cite them for it.

We haven't had too much of a problem with regard to after the fact interpreting administerial changes if they have been made, but my understanding in talking with certain members of licensees is that they are very cautious in terms of making administerial changes.

MR. CAMPER: Okay. The next question is one that you may or may not be able to offer much specific information on because it is not an item of compatibility yet in terms of implementation in the Agreement States.

The question is: Is there evidence that either the submittal of QM programs or the subsequent recordkeeping requirements have posed an undue burden on medical licensees?

It is still early in the game. It would be difficult for us to answer this question, as well. We just don't know yet. It is very early in the game. Clearly, for you it is an item of compatibility, but not for

implementation as of yet.

The Advisory Committee also agreed that it was still early in the game. They felt that perhaps some of the estimates for burden were somewhat underestimated, and they had some questions about the audit component itself.

But in the absence of evidence, given that it is not effective in your states yet, and it is still early in the game, are there any general thoughts that anyone would like to express about whether or not the Quality Management Program, the submittal of the Quality Management Program, or the recordkeeping requirements pose an undue burden?

I know we have heard a lot of criticism about the Quality Management rule -- I certain sat through a lot of that in its development -- but are there any additional comments?

MR. RATLIFF: Richard Ratliff of Texas.

I think the main problem I see on any of those recordkeeping requirements, you can relate back to radiography where you see direct threats, is that if you put too much emphasis on the records, the person makes records and there are records there available to look at, but whether they performed the survey or actually completed the radiation safety task with that in mind rather than keeping the record, I think you get derailed that way.

MS. HADEN: Robin Haden, North Carolina.

This is where I have to make one of those offhand comments. Our licensees are already required to do almost everything that is in the QM rule. They are already keeping the documents, so no, there won't be any great impact on them. They are already submitting the programs with their license applications, and they are already keeping the records.

However, the other side of that is we are still looking at a compatibility rule that is going to require a change to our regulations. It is a very intensive process that we are already doing something that is equivalent.

No one has talked to us about it to this point. No one has said if you have got something that is already effective -- our policy is already as effective as the QM rule in essence.

So, here we are getting around again to the "C" word that nobody really wants to discuss and talk about, but what some of the Agreement States are doing is already as good or better than the NRC, and we need to take that to task.

MR. KULIKOWSKI: Bob Kulikowski, New York City.

I just want to reiterate what Robin said, and I think one of the operative words is "equivalent," does compatibility -- again, we are going to beat this word to death -- because we need to know whether compatibility means

verbatim, word for word, or whether it means equivalent.

I mean you can have something which is equivalent to protect public health and safety, and it may not be a regulation, it may be a license condition because it affects only one of your licensees.

Just in the general tenor of regulation, I think this gets back to the analysis question that you brought up earlier, Larry. You know, rule-writing is not the panacea. You know, it is appropriate in certain situations, it is not appropriate in other situations to address an isolated instance or even a few isolated instances or incidents. There may be better ways to go about it.

I am not saying that a rule is not required, but I am saying that sometimes something happens in the regulated community does not warrant a rulemaking.

MS. ALDRICH: Rita Aldrich, New York State Health Department.

You are probably asking the wrong people about problems with Part 35, since I don't know about the other states, but we don't deal much with Part 35. You know, we haven't adopted much of it. You probably should be asking your licensees instead. I don't think you should take our silence for a statement that everything is okay. I just think you may be asking the wrong people.

But on the other subject, as I said, we are

requiring Quality Assurance Programs -- it is not quality management programs, quality assurance is a more extensive type of program -- we are not requiring them to be submitted any more than the other agencies within the State Health Department that require quality assurance, such as the Office of Health Systems Management, in the x-ray regulatory program, require them to be submitted. They are matters of inspection.

So, there again is an area where we have already done something that is different from what you are doing, but it certainly more than accomplishes the goal that you intend, because after all, the Quality Management rule has a very limited objective, to -- how should I put this -- to minimize the likelihood of random error, whereas, our quality assurance approach is, one, to optimize, and two, to minimize the likelihood of both random and systematic error.

MR. BAILEY: Bailey from California.

I think one thing you could put in NRC rules -- because when I look back at our agreement with AEC, the statement is, "The State will do its best to remain compatible," and the next sentence says, "and the Commission will do its best to remain compatible also."

I think the NRC should require in the Medical Section, that in states, number one, that the nuclear medicine physician be licensed to practice in that st[illegible]nd

because they do work on citizens of that state, and number two, if that state requires licensed nuclear med techs, that those people should have to be licensed by the state before they are allowed to work in an NRC-licensed facility.

MR. CAMPER: We are going to tackle that particular topic again this afternoon when we talk to this overall question of supervision, but I appreciate your comments.

I will move to the next question, then, and again this is a question that -- well, not this one, but the following question is one you may not have specific input on -- this particular question is: Is there evidence that the use of the term "misadministration" has had a negative impact on the practice of medicine or directly resulted in medical malpractice suits?

Is there evidence -- is there evidence that the term "misadministration" has had a negative impact or resulted in malpractice suits?

Ed is shaking his head in the affirmative.

MR. BAILEY: Yes. Ed from California.

MR. CAMPER: Do you have an example?

MR. BAILEY: Yes, HIV-positive patient. The hospital has settled out of court with the patient. She came back to the hospital with her lawyer because of misadministration.

Interestingly enough, according to NRC rules, it is not a misadministration.

DR. GLENN: Ed, I guess following up, is there any evidence that the word --

MR. BAILEY: Yes, yes.

DR. GLENN: If it had just been reported, there wouldn't have been the suit? That sounds like the one which was just ready for malpractice all the way.

MR. BAILEY: I don't know if you can separate the word from the action. I mean it implies you did something wrong.

DR. GLENN: Maybe to put this question a little more in context, I guess the reason we asked this question is people have told us that just the word itself is damaging because of the negative connotations and that what the NRC is really interested in is learning about significant events and evaluating them to see if there is something that needs to be done. But you are still saying yes.

MR. BAILEY: Yes, it is definitely a negative word. Now, I am not sure -- well, the interesting thing about misadministrations is they are not illegal, which I find weird, but you have to then be very careful on what you call a misadministration if you are in fact going to make them illegal.

On the other hand, if you deliver what the doctor

prescribed, it is not a misadministration. We have got a doctor now in California that is beating us about the head and shoulder. He said I made a mistake, I prescribed twice as much dose as I should have. I made a mistake. I want to report it.

We are saying it doesn't fit in the category. So, that kind of thing needs to be corrected, too, and I think that that doctor wanted people to have that information available to learn from what he did wrong, and he wanted it in the system to be counted, here is what is going wrong.

MR. CAMPER: Let me ask the question again. Just a show of hands.

You might recall that the staff at one point had suggested to the Commission that the term "reportable event" be used to define or describe these events that occur as opposed to the term "misadministration." In the final analysis, the Commission chose to stay with the word "misadministration."

Just by a show of hands, the word "reportable event" versus "misadministration," could I see a show of hands of the States' representatives that would favor the use of the term "reportable event" rather than "misadministration."

[No response.]

MR. CAMPER: Could I see a show of hands in favor

of the term "misadministration."

I see a couple of hands favoring "misadministration," and I see no hands favoring the term "reportable event," and I see a lot of abstentions. Okay.

MR. KULIKOWSKI: Bob Kulikowski, New York City.

Just to follow up on what Ed said, we actually had a misadministration event that turned out to have significant impact in that it caused regulatory changes from another aspect at the State Department of Health level with regard to blood banking.

That was we just didn't have a dirty needle used, we actually had an Indian 111 white blood cell labeling that was mixed up between an HIV-positive and an HIV-negative person. It was reported to us because it was the wrong patient.

However, the implication -- and I don't know what all the legal follow-up has been with the licensee -- but it is a severe -- it is a strange misadministration, if you will, because from a radiological health aspect, the fact that the person got -- he was going to get that much radiation anyway, so in that sense it was not a radiological misadministration, however, it certainly was a lethal misadministration, if you will.

You have almost got to do it on a case-by-case basis, it would seem. Obviously, there are some things that

are of relatively little significance in diagnostic. There are other things where the basic procedure which you would hope to have in place in the Quality Management-Quality Assurance, what have you program, to ensure the safe administration of that dosage, really probably would have prevented this. This happened a few years ago.

I don't know whether there is any clear-cut answer to your question, Larry. You are always going to find the exception.

DR. GLENN: Since Steve Collins I guess had to leave, I will mention I think, he raised at the Advisory Committee meeting the possibility that you get more reports if you don't call them misadministrations, that if it is called a reportable event, that you will get better compliance with the reporting requirement.

MR. CAMPER: Yes, and his comment was that you lose nothing by calling it reportable event versus misadministration, you get the very same data.

MR. KULIKOWSKI: Bob Kulikowski, New York City again.

We have always called it a misadministration, and don't seem to have any problems with our licensees. I have not had any negative -- I have not had people call me up screaming, saying I can't report it because it is a misadministration.

MR. GODWIN: Godwin, Arizona, but at the time I am fixing to talk about it was Alabama.

We had an event which was a misadministration or should have been a misadministration, and the hospital promptly turned it over to their risk management lawyer, who promptly claimed it was -- or started off going to claim it was a lawyer-client privilege and wasn't real gung ho to report it. We had to lean on him a little bit about that, but we thought we were going to have a real problem.

They came on through and reported it, but I wonder if that has interfered or become an issue relative to any of these rules.

DR. GLENN: I don't think there has been any legal challenge to our right to require reporting.

MS. ALDRICH: Rita Aldrich, New York State Health Department.

Again, in New York State, I believe that incident with the mix-up of the blood cells came in through this mechanism. The Office of Health Systems Management within the Health Department has an incident reporting program that is confidential. The initial reports are not subject to FOIA.

It was set up that way by the legislature. That encourages reporting, that the information won't be disclosed unless a finding of deficiency is made against the

institution. At that point it can be disclosed.

The terminology appears to be unimportant. Once it is reportable, it doesn't seem to matter what you call it. It is the reportability that drives things. So, most of the medical community we have talked to doesn't think it matters, whatever term you use eventually become pejorative because the connotation is it is a reportable error, therefore, it is important and it is going to get us in trouble from a legal perspective.

MS. ROTHSCHILD: Marjorie Rothschild from NRC, Office of General Counsel.

John, I just wanted to make sure, did I hear you right, you said there has been no legal challenge to our right to require reporting?

DR. GLENN: Right, and I guess in the narrow sense that it is a violation of doctor-patient relationships. I know the QM rule was challenged in court, but that wasn't the basis for it.

MS. ROTHSCHILD: Right. That is what I just wanted the record to reflect, that the NRC was sued on the QM rule, and I believe that included a challenge to the revised misadministration reporting requirements in the rule, and NRC's position on the rule was upheld completely by the D.C. Circuit, and the suit was, in effect, thrown out.

So, to that extent we were challenged and upheld.

MR. CAMPER: Okay. The final question in this particular part is -- and again this is a question you probably can't give much specific evidence of at this point because it is early in the game, but again perhaps a general comment about your thoughts on it -- the question is: Are there any examples that the QM rule is an encroachment on the practice of medicine? Any thoughts on that?

[No response.]

MR. CAMPER: Okay. I see no comments.

We are at a point, Vandy, where we could break for lunch in terms of what we are doing. We will come back. The next section that Dr. Glenn will cover is Inspection and Enforcement. Also, Jim Lieberman, the Office Director for Enforcement, will be here in case we have any tough questions.

Then, we will be talking later on, after that, about medical supervision including related training and experience issues. That should be lively.

CHAIRMAN MILLER: Yes. I just want to emphasize that we really need to get back promptly at 1 o'clock because we must be out of this room by 4:00, not in the room at 4:00, but out of it by 4:00, so we will need all the time we can muster for the afternoon session.

We certainly want to give the panel this morning a

big hand for the morning session.

[Applause.]

[Luncheon recess taken at 11:51 a.m.]

AFTERNOON SESSION

[1:00 p.m.]

CHAIRMAN MILLER: We will ask that you give us your attention now as we kick off the afternoon portion of the Medical Issues Paper discussion.

In speaking with John Glenn, he feels that we are pretty much on schedule, and that means then that we will be able to clear this room by 4:00, and we continue to seek your spirited discussion on the issues that we are going to be laying out here for you.

Now, to kick it off for the afternoon, we have Dr. John Glenn, who will kick it off.

DR. GLENN: The next topic that is contained in the issues paper has to do with inspection and enforcement, and of course, I think that is sort of where the rubber meets the road with respect to the regulatory program.

I think a lot of the comments that were made in terms of the regulations relate to the fact that you want the regulations to be prescriptive enough that you can have an effective inspection and an enforcement program to achieve the objectives.

Certainly, we feel that the objectives of our inspection program are to be able to identify licensees who are not running safe programs, not complying with the radiation safety regulations, and the purpose of the

enforcement program is to assure corrective action is taken and is hopefully lasting. We want to fix it now and keep it fixed.

We are going to be exploring some questions about how we do inspection and enforcement, seeking comments on ways that they could be done differently, better, other alternative methods to achieve our objectives, assuring that there are safe programs being conducted out there.

I think one criticism we frequently hear from the regulated community is that our inspectors focus in on the nits, piling up violations, not looking really for safety, but for the small items.

My experience has been that I think NRC and Agreement States have very similar programs. So, I pose the question: Do our current inspections focus on those aspects of programs that are most important to radiation safety? Is there any legitimate criticism that we focus too much on records, paper, those kinds of compliance issues?

MR. FRAZEE: Terry Frazee from Washington.

I think it might be worthwhile if NRC did do an audit of their inspectors and just take a look at what percentage of time they do spend looking at records versus observing operations, interviewing employees, and making actual measurements.

A test case of one. One of my inspectors did

accompany an NRC inspector recently, and my inspector came back fuming because there was too much time spent on the records, and that is something that in my program and in my opinion, you know, records are way, way down on the list. I mean we do them in many cases because the NRC says we have to.

My own philosophy is, you know, get out there and like a politician, press the flesh, talk to people, find out what is going on, you know, how are things happening, watch what they are doing, yes, look at some records to make sure that it looks like they following through on that end of it, but that is not a high priority with me.

I think what I would like to see would be the amount of time that you save by not doing inspection of records, not reviewing records becomes time saved that can be invested in doing additional inspections, and in fact, coming back more often.

It is the frequency of visits that needs to be improved even at the risk of doing something less on the inspections. That increased frequency, you know, name familiarity, you know them, they know you, there is communication that is increased, the communications in a sense of also being instructors.

Just talking with somebody you are instructing them as to what you think ought to be going on in their

program, and I think that is a valuable tool in terms of gaining compliance.

DR. GLENN: I certainly agree with you on the audits. I guess one thing we do, in fact, make it sort of a performance requirement on our supervisors in the regional offices, that they do accompaniments of inspectors and actually do some field audits of inspectors.

But we have never instituted any sort of measurement process, some sort of objective measure to see how the inspections are actually conducted, get feedback on whether, in an objective manner, we can determine that indeed the time is going where we want it, observing actual operations, determining that people understand the requirements, records to the point that they verify that what somebody is doing when they know you are there is also what they do when you are not there.

Let me just ask the question. In the Agreement States, do any of you have an especially good way of auditing inspector performance that we can maybe consider as a good model?

MS. ALDRICH: Rita Aldrich, New York State.

We do annual accompaniments of each inspector. We have a field supervisor who tries to ensure consistency among inspectors. It is one of the biggest problems you have with the regionalized program.

Everybody has their own personal approach to this. We have at least one inspector who, left alone, would look through records until she just got kicked out, you know, and it is not terribly productive is our finding.

Also, from your original question, we sent out to all of our licensees last year an audit form, and we said they could use this or something of their own. Actually, what we did was we took it out of that ALARA Medical Institutions new reg. We took that and modified it to suit ourselves.

Essentially, what we did was make a deal. We sent it out with a notice to licensees that if they would do these audits on a regular basis -- we suggested it quarterly, but smaller licensees, you know, we told the inspectors, encouraged them to call us if they want to make it a longer interval because that is kind of frequent -- but if they would audit their own records, when we come for inspection, we will just spot-check. If the spot-check is okay, we won't go any further.

We also modified our inspection form. We divided it up into modules. Along the lines of what Terry was saying, we have decided that the important thing is to get there, and times are tight, money and staffing are problems, we are going to get there. If we have to abbreviate the inspection, we will.

So, we divided the form up into modules, ranked them in order. The first one is waste management because it is kind of important right now. Those first few have to be done. After that, it is up to the discretion of the inspector.

Our inspectors are very well trained, very professional. We trust them to make those judgments based on the past history of the licensee. We find that licensees appreciate this. They don't like being hassled all the time about records, and then get a letter that says we found one day out of the last 365, we didn't do a moly breakthrough. It is not productive, and I think the licensees decide in many cases that we will make the record instead of doing the action because we know that is not going to get us in trouble. That is exactly where you don't want to go.

DR. GLENN: And you found that that has worked rather well, people actually document they are doing the audits?

MS. ALDRICH: Yes, it is working well. We wanted them to be more familiar with their own program, not to use us as an auditing function. I think a lot of what we do for our licensees is giving them free health physics services that we shouldn't be doing. I would rather have them do it.

Also, Ed Wright from Oregon -- I get the Wrights mixed up -- whichever one works for Oregon, at the Atlanta

meeting this summer, mentioned a form designed for hospitals, that one of their licensees was using. I asked him to send me a copy of that.

We are modifying that. The other form could be used. We have modified it, so you could use it in any kind of a program. But this one is specifically directed towards medical, and it includes a lot of QA, Joint Commission oriented, which is what we have put in our regulations, and might be more useful to them.

We have had one broad licensee submit their own form that was excellent. We have also circulated that to our licensees, and we did do one other thing. I don't know, about a year or a year and a half ago, in the Health Physics Journal, there was an article by an RSO at a large academic institution.

It was about outside audits. I approve of outside audits, everyone should have one. What they were doing was he would have an RSO from a similar institution come in every year and audit his program, and he would return the favor. This was a good article on how his program worked.

We sent that out to all of our broad licensees and our other larger licensees and suggested to them that they could really improve their programs if they did this. So, we are waiting to see whether or not they implement that one.

MR. WHATLEY: Kirk Whatley from Alabama.

I think it is important, the attitude a licensee takes towards an inspection and following rules is vital to all of us. They need to want to follow rules, and they don't need to follow them simply because they have to.

That is an attitude that we have tried to get our licensees to use over the years. I think we contribute to those attitudes the licensees have. Let me give you an example.

A few weeks ago, we got a new employee in our office, that has actually been working in public health for an excess of 20 years, but he has switched over to our department. He accompanied one of our inspectors.

They went out and did a long inspection of a pretty good-sized hospital. In the closeout interview, the inspector sat down with the administrator, and literally bragged on the program about all the good things that were going on and what a good program they had.

But there was one little, small item on noncompliance, and we came back. The inspector drafted his letter, and it was reviewed by this new employee. He came into my office, and he said, "Is this the way we write our letters?"

I took a look at it, and I really hadn't looked at it before, and basically what it said was your program is in

bad shape, you know, you have got one item of noncompliance. It never reflected all the good things that had gone on.

It said you have got to post this thing on your wall, you have got to reply within 30 days, and all of this stuff. You know, we are going to change that. I went back and asked our inspectors where that came from, and they said that is the way NRC said do it in our inspection course.

I don't whether that is right or not. I am just telling you what was said. I think we need to emphasize some good things people do, too, and not just dwell on one little, small bad area sometimes. I think we can contribute to improving things by changing some things, such as that.

MR. CAMPER: Just to follow Rita or Terry or Kirk, for that matter, I hear you saying that you use an audit function, a sampling, if you will, of records, and you place a review of records per se, for the sake of reviewing records, sort of down the list of priorities in your inspection.

I assume that in each of your states, your licensees commit, they send in a program, they say they are going to do certain things, they are going to keep certain records, they give you examples of those records, and so forth.

But then when your inspectors go out, you are looking at your regulatory requirements and you are also

looking at the commitments the licensees make.

Now, in the process of looking at the commitments the licensees make, you sample some records. I guess what I would like to know is at what point -- let's say, for example, you are sampling and you find two or three dose-calibrator constancy checks that were not done on certain days, what do you do then?

Do you then delve more deeply into the records? Do you simply say that, well, we observed that there were two or three things that were not recorded, but we chose not to go any further? Do you cite them when you uncover through your random process that this hasn't been done?

I guess I am trying to understand what is your threshold for determining that there is a need to look more closely at the records, perhaps cite for having not done these things or at least not recording them.

How does that work for you, generally speaking? As you answer, how much discretion do your inspectors have in the field versus what management -- in other words, management can set the tone for your inspectors.

You can let them have a great deal of discretion or you can set up a scenario where inspectors feel like if they miss anything, they are in trouble, or if some inspector follows them later, it is going to be viewed badly if they overlook something. Just generally, how do you

handle that?

MR. FRAZEE: Terry Frazee from Washington.

You asked too many questions. I can't handle them all at the same time.

As far as records are concerned, we do the sampling of records in cross-check with other similar records or interrelated records, sort of get a feel for what was happening during a period of time.

If the inspector starts to see gaps in the records, they will start -- a couple of options -- they can start looking even further and making a big case, if you will, because they missed records or they can just say, hey, look, based on some sampling it appears that you are not doing such a good job on keeping up with records.

It depends on whether it is current history or ancient history. You know, you go back and you sample, and you may pick out 10 months ago and pull it, and, you know, so there are a few that they are missing back then. I mean that is not as significant as if, when you walk in today, and yesterday's records are not complete.

To jump into one of your later questions, it is quite a bit inspector judgment, you know, how does this inspector feel about this licensee based upon his observations and interviews with the licensee.

That will have a great influence upon whether he

really starts digging and creating a big case, and sending out the letter that Kirk was talking about, or whether it is a little bit more low key.

You still cite them, but there is different approaches, how big is the stick you are going to hit him with, you know, what are you trying to accomplish here. We are trying to accomplish compliance, and we are trying to accomplish the attitude on the licensee's part that, you know, we want to comply, we want to get on with doing business here. They don't feel good when you beat them over the head.

MS. ALDRICH: Rita Aldrich, New York State Health.

First of all, they look to see have the internal audits been done. They will check some of the records that were checked during those audits. If they don't check out, we obviously have a problem.

Now, the first problem is you said you audited this, I am looking at the same records. Is it falsification or you just don't know what you are doing, you know, is this an education problem, is this a training problem?

The inspectors have a great deal of discretion. As I said, they are very well trained. They are good health physicists. The inspection form, the summary part of it we realized a few years ago we had just sort of left a blank space summary, let the inspector write a summary.

That turned out to be largely editorializing, in some cases slander. So, we decided that these things were all fallible, and especially when incidents come up, medical misadministrations or low level waste incidents, people all of a sudden calling from newspapers and want every inspection done in that area at a large generator, and this inspection report says something slanderous about the RSO.

We took NRC's indicators that you came up with for slides and program performance, and used those instead, and parenthetically, we also listed prompts for the inspector of things that they might wish to cover, so they are very specific.

One of the problems that we found, that again you have to keep prodding people to correct, is the tendency to look at the trees, and not the forest, and count nits, and look at records, records, records, and not notice that the person, you know, who is doing the dose calibrator check doesn't know what the actual limit is and can't convert from CPM to DPM. It is much more important to concentrate on those things.

One of the other problems that we found -- I can't remember, maybe it will come back -- but we found that it was very important to go out with them periodically and actually watch what they were doing.

That, I think is really critical. If you don't

know what your inspectors are doing in the field, you have got a problem.

We also ask for feedback from the licensees, and we found that having regional meetings, we encourage them to invite us to meetings. Mallinkrodt has put on a couple of regional meetings for us.

One was precipitated by an enforcement action. Everybody in the particular region got panicked. NRC had taken an enforcement action of a VA hospital in the same area, and they sort of thought there was something going on.

We brought everybody. I brought my licensing staff and our field supervisor, and they got to ask all the questions they wanted. It was a big meeting. We had about 55 people there. We actually got physicians, which is very unusual at an evening meeting.

What they wanted to know is what we wanted to demonstrate compliance. We had another one recently in the Buffalo region. We had the Long Island Society of Nuclear Medicine Technologists. I went to their annual meeting last year.

It is very important to communicate to them what it is your inspectors are going to want to see when they come, and it is also important to encourage them to give you feedback in case the inspectors come in and do something other than what they were led to believe they were going to

do, but a lot depends on the quality of your inspectors.

MR. CAMPER: Rita, do you cite them? Let's say, for example, you are doing a random sampling. Let's pick dose calibrator linearity, for example. Let's say you find that it is not done twice. Would you cite that?

MS. ALDRICH: Yes. Again, we would look and see, did you check this record. You know, it is among the things that we had on here to be checked. If you did check this record, didn't you notice it wasn't there. It kind of flows, it is kind of obviously really.

We don't find that much of a problem with people making records of things that are fictitious, but what we do see is a tendency to focus on making the record, and not seeing the implication of what you are writing down. You are not comparing it to the action level. That is one of the biggest problems that we see.

MR. LEVIN: Stuart Levin, Pennsylvania.

We are a non-Agreement State, but we do actively license norm and do all the inspections and everything.

In response to your question about how good your inspections are, of course, we get all your correspondence, and I have it all on the mainframe computer, so I can always go and check your statistics if I want.

However, it is a matter of philosophy in one way. When I came to work in Pennsylvania, the first thing I was

told I was I am a health physicist, and not a policeman. If your inspectors go out and act like policemen, you are going to have a hard time because once you leave the place, and your back is turned, if you haven't sold them on radiation protection, they are not going to do it.

So, we use the health physics philosophy. The regulations we consider as minimal health physics protection type activities, and hopefully leave them with a good feeling, help them a little if they need it, cite them when they are supposed to be cited.

One of the problems that you have, and we have, and probably everybody has, is part of the effectiveness of that inspector is on how much experience he has.Prescriptive regulations are not only good for licensees, but they seem to work well for brand-new inspectors, because they can read it and get a yes or a no, but the more experience the guy gets or the woman gets, the more they can pick out what is important and what isn't.

Our experienced people will not cite if they forgot to post a notice to employees. If that was the only thing that was missing, they get a nice letter from us, and they put the notice up while we are there, and that takes care of the problem.

MR. FRAZEE: Terry Frazee from Washington.

Back to differences in inspectors, I have got, for

instance, two inspectors. One acts like a new inspector. I mean looks at lots of details, goes over records, I mean really is thorough, and at the same time I am fairly confident he does a good health and safety inspection.

I have another inspector who is more typical of the old hat. He walks in the door, records aren't that important -- records are important, I don't mean to say that -- but that is not his focus.

I mean he is talking to people, he is concentrating on health and safety issues. I tend to see a whole lot more citations out of the "newer" inspector than I do out of the older inspector, which is fine.

From my perspective as the manager, that is okay. I take advantage of that in rotating him through licensees, through the same licensee basically.

Occasionally, I get comments back from the licensees, but both of those inspectors, as part of their spiel, talk about the other inspector, saying, hey, look, you know, I am looking at a certain set of things, my eyes are different than the next guy's eyes, and the whole purpose here is to make sure that the whole program is improved with time.

Dr. Glenn, you asked an earlier question which sort of led this off, and I think I interpreted your question as being how would we audit our own inspectors with

reference to records.

What I have been doing is it is kind of like timing them, you know, get out the stop-watch, and how much time do you spend looking at records versus interviewing people versus measurements.

That is difficult to do because most of my inspectors are just going 50 million miles in different directions all at the same time, so you have got to sort of make some judgment on my part as to how much time they are spending.

But I use that as a rough handle on are they spending too much time on records or versus some other category. It is not that there is a goal in mind or, you know, if you spend more than 25 percent of your time, that is a gig, I am not doing that, but it is a point that in closing with that inspector, I can say, gee, you spent a lot of time on records here, you know, why did you do that, was there some reason for it.

Sometimes there is. If they were finding something and looking for something specific, that is probably okay. But I think that is kind of a tool that you might consider, you know, clocking them, how much time is being spent.

MR. GODWIN: Godwin, Arizona.

In looking at the record situation, it is going to

be focusing primarily on the nuclear medicine. I would expect an inspector to go in and sort of look at the size of the program and pull a representative sample of records.

If they look all right, he would probably pass on to some more records. He would look pretty much in depth at things like exposure records, and things of that nature, because having x-ray, as well as this, we would like to know about over-exposures either place.

If he found a single record not complete, I would expect him to look a little more in depth and try to establish is that a single violation, if you will, or is that a pattern, and I expect him to look particularly at such things as weekends.

Over time, particularly while I was in Alabama, we discovered that technicians for some reason don't associate quality control with weekend work. I have never quite understood that, but we look for the weekend records, and match, you know, did they do a patient, did they do the quality control, that kind of stuff.

In looking at the overall program, if he goes through and finds a single record or an occasional leak test that is one or two days late, that would lower our evaluation as to how serious the violation is. It will still be cited, but it will be a Category 5 rather than a 4, something like that.

On the other hand, if there is an indication that it is a well-established pattern at the facility, reflective of management lack of interest, then it would go up in categories, as well as perhaps bring on more serious considerations of management meetings. So, we use it that way.

In evaluating our inspectors, I try to discuss, not all, but a lot of our inspections with the inspector before I sign off a determination of a violation. My key reason for discussing it with the inspector is to determine does he understand what they are doing, does he really understand the problems that are at that institution.

If he does, and the report reflects it, obviously, I have a better feel for the violations and their significance and can determine what category they should fall into.

If he doesn't, I may not accept his violations until we have documented it a little more clearly and we understand really what they are doing there. If they didn't have records, yes, they get cited, but you really need to know how significant that relates to the overall program operation to determine the category of significance.

That is really important, and I see that as something that a lot of the Society inspectional operations are not in a position to do.

DR. GLENN: We have sort of moved into a topic that comes up a little bit later, and I think maybe I will skip over and come back to another question.

One thing that we have been doing in the last few years in the NRC is to try to encourage licensee self-identification, you know, correcting their actions, and this sort of thing, is by saying, hey, there is going to be a category of violations that we are going to call non-cited violations, and basically, either it is of low significance, rare occurrence, and the licensee agrees to take corrective action right on the spot, or it is something where they, in fact, in an audit program identified it themselves, took corrective action, and appeared to have fixed the problem.

We are encouraging our inspectors to treat those as yes, you were in violation, however, we are not going to cite it. We do -- and I think our inspectors get a little mad at us in Management -- because we do require them to document all those, but again I think that is part of the feedback process, so that we know what our inspectors are finding, what kind of judgments they are exercising.

I that is probably a plus, you know, on the side of eliminating unnecessary paperwork, review, and sending the right message to licensees. One thing it does do, though, is say that NRC inspectors can now exercise this discretion in the field prior to coming back and exiting

with their supervisor.

I was just wondering, any comments on that particular way of dealing with this question of proper focus priorities?

[No response.]

DR. GLENN: Does anybody think it is a bad idea?

[No response.]

DR. GLENN: Okay. I will go back to the question I skipped, then. The NRC a couple of years ago changed their unannounced inspection policy for reactor licensees, and now most of the regional-based inspections at reactors are, in fact, announced inspections.

One reason that the NRC felt they could do that, of course, is that they have resident inspectors at reactor sites, so essentially you have got unannounced inspections going on continuously as the resident happens to wander around the facility.

We get complaints from licensees that the unannounced inspection policy is disruptive to them and unfair. I was just wondering, what are your comments about the policy for materials licensees which the NRC still has, unless there is a reason not to announce it, all inspections are unannounced?

MR. LEVIN: Stuart Levin, Pennsylvania.

I used to accompany NRC inspectors when I was

doing those inspections. As a matter of fact, I even accompanied them when they used to be called AEC inspectors.

We find in our state experience that for large facilities, it is more economical to make an appointment. You are spending a lot of time there. Especially if you are traveling a long distance, if they are not there, you have really wasted time.

On the other hand, on our x-ray program, for instance, when you have got a load of dentists and chiropractors, and whatever, we never make appointments with them unless they have some unusual hours. You can usually walk in their office unannounced, get the thing done, go on to the next one.

There were times I accompanied NRC inspectors, we got in the car and rode for two hours, got down to the site, and they weren't doing radiography that day. He didn't have an alternative place to inspect sometimes. When you are flying out of the regional office, this is all time and money.

We have found that for the most part when we have made appointments, we have still found items of noncompliance, which kind of suggested that even though they knew we were coming, they didn't seem to do anything extraordinary to see if they had anything wrong.

I just realized while I was sitting here, in the

old days, occasionally I would accompany an NRC inspector, and we would sit in the little outer office of whoever we had to go and see in the plant for an hour cooling our heels. I realize now they were probably running around in the plant trying to get something fixed up in a hurry.

MS. ALDRICH: Rita Aldrich, New York State Health.

When I first took my present position, we were announcing inspections. We found that with a couple of consultants we had some problems when inspections were announced with any kind of lead time, that committee minutes would appear all written in the same hand, in the same ink color, so we switched over to an unannounced.

Since that time, we have been having to have inspectors in one region in the state do inspection in other regions, for various reasons, short staffing, also there is an ethics law in New York State that makes us try to rotate inspectors, so you don't have the same person going to the same place. Also, it improves the quality of the inspections and it is better for the licensees because they don't get personally regulated by an individual forever.

But those inspections are announced a few days in advance to make sure there is going to be somebody there, if it is a place like a private office.

A hospital, there is always going to be somebody around, and besides, you want to get there when they are not

expecting you, because we all know what goes on in hospitals. We have a physician also and a tech, and if there is nobody there minding the shop, and they are still doing nuclear medicine, you want to see what happens in the absence of the person you have on record as RSO.

Universities, you are going to have to have the RSO to be able to function, so you had better announce those. So, I think logic and common sense really dictate.

We also don't want the licensees to spend two weeks getting ready for us. That is counterproductive. I wish NRC would do our reviews unannounced.

[Laughter.]

MR. KULIKOWSKI: Bob Kulikowski, New York City.

A couple of things. I think what Rita has said, and what other people have said, are that inspections, just to summarize, you need to do everything on a case-by-case basis because what works in one situation isn't going to work in the next.

We have had a little experience with announced versus unannounced inspections. Now, we don't have the geographical problems that most places have because I can get somebody out on five minutes' notice basically.

However, the past couple of program reviews, we have been beaten over the head -- not so much this past one, but the one before especially -- that we weren't doing

unannounced inspections because of an historical reason. One of our former Commissioners about 10 years ago made a pact with the Greater New York Hospital Association especially with respect to x-ray facilities, that they would do announced inspections.

I agree with Rita that hospitals are not really that much of a problem because if you miss the administrator on the entrance meeting, it is not such a big deal. You can go and see what they are doing, catch them for a few minutes, the entrance is not that big a deal. Usually, you are there a day or two, so you catch the administrator on the exit, which we always do.

It is a problem sometimes for small offices to do an unannounced inspection because you may have a radiologist who has a small nuclear medicine practice and a radiology practice, and he has got, you know 30 women lined up to do mammographies that day, and you come in and you say, well, we need the machine, and you know, what is he supposed to do, so that does present a logistical problem.

We have facilities that are sort of targeted, that we know that we don't want to give th -- if we do announce and make an appointment, we don't giv' them a lot of lead time. There are other ones that we know that have a good inspection history, that we can say, okay, we are coming next month and things won't really change very much.

So, I think, not only how you perform the inspection, but whether you announce it or not has really got to be pretty much on a case-by-case basis, depending on how well you know your licensees.

MR. BAILEY: Ed Bailey from California.

We hold the right to do unannounced inspections, and I think that that is maybe a key to it. I would agree with most of what people have said except that I think the impact on smaller facilities is often bigger than on the large ones, so I would agree with Bob.

For the most part, our medical inspections are announced, and by "announced," that means usually the day before or two days before they are given a call. It doesn't mean that they are told weeks in advance.

Now, if we have people traveling to Northern California, say, to do x-ray inspections, they may be scheduled a week or two in advance because you are going to hit a bunch of small towns or something.

HCFA, on the other hand, for mammography, is being pretty insistent that those inspections be totally unannounced, and at this point we have got agreement from them that we can announce them two days in advance.

I think the concept of unannounced inspections is very important. We recently had a doctor complain that in 27 years of being inspected he had never been treated like

the Gestapo coming in unannounced to inspect his program. So, I think it is important that everybody realize that, you have the right to do that, and I think periodically you need to do it, you need to work it into the system.

I would comment, too, on rotating the inspectors. I think for the most part the managers know which inspectors are not the good inspectors. I can remember one time when we exchanged a regional inspector who always came up with two or three or less violations, and a new inspector went to the region, and everybody was getting 12 or 14.

So, I think you need to rotate the inspectors, and you need to look at, not only accompanying them each year, but then taking a sampling of their inspections and trying to confirm what they did, so that you don't get a high percentage of wind chill inspections.

I mean you can do an inspection if you have got a good file without ever going to the facility. You can fill out a form well.

MR. GODWIN: Godwin, Arizona.

Arizona, I think is operating pretty much like we did in Alabama. It looks like it from what I can tell so far. Virtually all are unannounced. Occasionally, you run into a situation where somebody is not there, let's face it. If you have an extra folder with you, you can do another unannounced. Fortunately, in Arizona, most of our

inspections are in Phoenix, too. That is another little easy thing, somewhat like New York City in that regard.

But generally speaking, I found in Alabama, and it looks like it is working the same way in Phoenix, that unannounced inspections are not that unproductive. You go in there and you know some things that you just will have to do.

For medical, in particular, you have got to understand when you make the inspection that the patient is going to come first, and anybody who is an inspector that doesn't understand that, trying to do medicals, is in deep trouble right off the bat.

It is just a matter of when you get there, indeed, if they are too busy to be inspected at that time, I would have someone leave, then come back later, but that doesn't happen very often, they don't have to wait terribly long to get in for the most part. Occasionally, you will have to wait an hour, but generally it is less than that.

Know that when you go into a hospital, you are better to go in the afternoon, for example. Most nuclear medicines and most radiology departments are busy as heck in the morning. If you go in the afternoon, you have a lot better luck. Get there at late lunch, a good time to hit. Those kind of tricks do a whole lot of good.

Approach it with the idea of learning what they

are doing. It really works out quite well.

Industrial radiography is another ball game, trying to find where they are working is real tricky, but that is not what we are here for. Get a good microammeter and ride around the industrial area is where you will find them.

MS. ALLEN: Kathy Allen, Illinois.

Illinois does mostly unannounced inspections. In a previous life, I worked for a broad-scope licensee, and we had been inspected by NRC and Illinois, and most of our inspections were announced, some were unannounced.

We didn't really see a problem from a licensee standpoint either way. If we knew the day before, we usually stayed to make sure that all the records were actually put in the proper files and whatever, and if they just showed up that day and said we were being inspected, then we would have to say, well, here is our file and here is a bunch of stuff that hasn't filed yet, and here you go.

We didn't mind it either way. It seemed like it was just a snapshot of what you do. If we had a problem, for example, if you couldn't keep up with the backlog of wipe tests or something like that, it was almost better unannounced because then it showed management what the true situation was in health physics, not necessarily staying up all night to put all the documents in order, but this is the

way it is, guys, and that is why we need the help.

DR. GLENN: I think there is a little bit of variety in opinion, but it sounds like everybody agrees that the right to unannounced inspections is important, some percentage should be unannounced.

What that percentage is and which licensees is perhaps somewhat variable, but an appropriate mix of announced and unannounced is what I hear, some of you leaning towards most of them being unannounced and some would say most being announced.

Another issue that frequently comes up -- and I have talked before about how we could take low severity level violations that are identified and corrected by the licensee and make them non-cited violations or on-the-spot simply giving what we call a 591 form -- I think many of the enforcement cases that the NRC has had in the last 10 years have involved situations where we have had multiple severity level 4, maybe even some 5 violations.

What we do is to sometimes aggregate, say if we see a problem in this part of your program, we see another problem over here, it indicates to us that your program isn't working. So, although any individual problem that we found is not very significant, looking at the thing as a whole, we think that it constitutes a management breakdown, which we will classify as a severity level 3.

So, many of our enforcement conferences at medical facilities involve that kind of conclusion. I would say most of the events that I have seen that result in enforcement conferences in medical are either what we call program breakdown, aggregation of smaller items, or else events that involved a serious misadministration. Those tend to be the kinds of things that bring us into the strong enforcement category.

Any comments on this system of aggregating minor violations and calling them a serious problem in aggregate?

[No response.]

DR. GLENN: Everybody thinks that is the appropriate way to do it. Okay. Good.

One question has to do with are programs being effective in identifying and correcting safety concerns, and, if so, what aspects are most effective in identifying and correcting safety concerns.

We have fairly frequent civil penalties within the NRC, and so I think maybe throw that out as one tool we have to trying to assure that people focus on problems.

MR. FRAZEE: Terry Frazee from Washington.

Actually, before we get too far away from the unannounced inspection, it occurred to me that unannounced inspections are extremely important if you are concentrating on records. Announced inspections, the worst thing that an

announced inspection is going to do without respect to records is that the licensee is going to scurry around, getting his act together, training his workers, making sure that they know the right answers, and so we walk in and they have got the right answers, then we walk out, and we are happy, they have been trained.

So, from that perspective, you know, maybe unannounced inspections aren't really that critical, but then again, there is the radiographer, so --

[Laughter.]

MR. FRAZEE: The last issue was civil penalties, and we don't have civil penalties. We seem to be getting pretty good compliance without them. We do carry the ultimate big stick, which is you just jerk the license, and so I think that is an important tool that is there for threatening them.

As far as aspects of the inspection enforcement program that is most effective, again, I am going to go back to it is the observations, it is the interviews, talking to these people, training them.

DR. GLENN: So, mere regulatory presence by an intelligent inspector is your most effective tool.

MR. FRAZEE: Yes.

MR. KULIKOWSKI: Bob Kulikowski, New York City.

Yes, I agree a lot with what Terry said. We don't

issue a lot of monetary penalties. We have found that enforcement conferences are very effective.

As far as the one thing that I have had the most positive feedback on with respect to the actual inspection protocol itself, is the exit interview where we insist that management be present.

What we do is usually have a technical closeout with the RSO or somebody from the radiation safety staff before we go in, so the radiation safety staff doesn't get any punches pulled on them, and present it in a positive light to be constructive for the health physics people, and telling the management that this is really, you know, it is either a good program, it is a bad program, and if it is bad, where can you patch it up, fix it, make it better, and give the radiation safety people adequate support.

MR. TEDFORD: Tedford, Alaska.

There are a couple of observation points that I have made over a period of years. One, that the attitude of the upper level management in a hospital is directly proportional to the quality of the program that you are going to see.

I think that is true also with reactors and any other field that you are in. If upper level management desires that there be a good program, and the attitude is correct, that is going to be reflected all the way down

through the program.

Now, upper level management needs to know what the program is. I think several states have conducted excellent forums in this area. Texas has had meetings with their licensees and told them what the problems are.

I think there are other mechanisms that we have had available. In my case, where I had medical newsletters available to me -- and I have always had those available -- I have told the licensees what the main problems are, and they are pretty uniform throughout the NRC and the states.

The number one problem with regard to medical licensees is the Medical Isotope Committee or the Radiation Safety Committee, as the case may be, and not meeting and not governing and not looking at the program.

On the other hand, you can flip over to X-ray, and its non-beam alignment, half-value layers, film batches in some instances, but if you tell the people what their principal problems are and the ones that need to be corrected, if you have any good administrators or good management, they will look at that, they will see, and they will correct it.

So, I think it is an approach and telling people what the problems are, and being up front about it before you go to inspect them.

MR. GODWIN: Again, Godwin from Arizona.

I think it is imperative that the inspector understand what is going on at that facility, and not asking leading questions when he learns what is going on. The typical example that we see with a new inspector is, you know, you take wipes. Well, what is a good answer? You have told him the answer.

But if you ask him for his wipe records first, and he has got them, then you can say show me how you do the wipes, well, he doesn't have a clue, and you have got a pretty good idea of whether he really knows and is serious about the program.

You have to go through and talk their language. One of the most difficult problems we have is getting the inspector to ask the question in a language they understand.Some of the records in radiography are not -- you ask them for a utilization log, and in a lot of places you are going to get "what," but you ask them for show me how you keep records of where this thing is located, "oh, yes, I got that one right there."

So, you have to talk their language, but you also have to understand how they do it without leading them to the answers. The last part of it is, as you go through, find out if they understand why that is important, not because it is a rule, but that it represents something to protect them or their patients or some interest that they

have. That keeps them motivated to keep doing it.

MS. HADEN: Haden from North Carolina.

Going back for quality programs, I think Rita's idea of internal audits is a very good idea. North Carolina does cite noncompliance items even if they are discovered by the radiation protection staff, but we use almost a non-cited approach by removing them from noncompliance as a result of whatever action was taken.

Aubrey made some very good points about speaking somebody's language. We do mostly announced inspections based on our budgetary crisis right now. If you find out how to talk to a technologist and you start out with tell me what you do during a normal day, they will tell you honestly and openly what they have been trained to do, and you can solve those problems.

But what we have started with our licensees now is we hand-deliver new licenses as much as possible. You get upper management involved, you get the radiation safety officer involved, you get the authorized users involved, explain to them up front what their license conditions mean, what our expectations are, and particularly in cases where they have consultant-prepared applications, make sure they understand what they have committed to.

We have found that the first inspections following those deliveries are better than they would have been before

they were delivered, they are not operating for a year, six months or a year or two years without any oversight. That has been very effective.

Oh, industrial radiography. In North Carolina, they have to report all temporary job sites to us.

DR. GLENN: Just a quick follow-up question. Does the hand delivery of new licenses, does that cause you any scheduling problems in terms of usually when people are getting a new license, they are eager to get it as quickly as possible?

MS. HADEN: Generally not. What we do is if it is far enough away in the state -- we have one office centrally located, and the farthest point takes about five hours to get there -- we may send them their copy in the mail and schedule a week or two later a follow-up if we have got somebody in the area, but we prioritize at least within the first six months that they must be reviewed initially to do that management review of a new license.

MR. MARSHALL: Stan Marshall of Nevada. She stole a little of my thunder, so I will just expand on her comment about hand delivery of licenses.

Really, the inspection enforcement loop begins with that first communication to the licensee. We have found that, yes, that hand delivery and that 30-minute discussion with the licensee management saves at least that

30 minutes to a half a day on that first inspection, plus you have cultivated some continuity in that licensee's impression toward you as a licensing agency.

We have found this to work well. We only began hand delivery of major licenses in the last couple of years, so I can give you a comparison, a recent comparison.

It works for new licenses, and yes, you have got the problem in Nevada where some of our people are 400 miles from either of our inspection offices, but that scheduled hand delivery sets the stage for the unannounced first inspection.

It also works for renewals or the circumstances where you have a private physician at a hospital who moves to Montana, and the hospital suddenly recognizes they now have no program and must get an institutional license. You have set the stage for hand delivery and a better first inspection for them.

MR. TRUMP: Carl Trump from Maryland.

We have recently adopted the new frequency or the frequency schedule of the NRC, whereby the gauges have been kicked from a 5 priority to a 4, and likewise up the scale.

I think on initial visits to such as a gauge program, we find that in most cases everything under the sun is wrong with these programs, anywhere from the licensee not having the regulations, to posting, labeling, what is

required, what is going on.

I know I maybe stepped on some toes, but I have talked it over with our management and also Charlie Flynn in Licensing here, that I think that it is really crucial that somehow we would increase -- not only giving licenses out, maybe on a new license -- but the pre-licensing visits, not only for the 1's or 2's, but sometimes down to 5's.

I think if only one visit were to be made to those programs out there, they wouldn't be in the sad state of affairs they would be in when we get to them. Then, obviously, we always call it the initial discussion, this is kind of your trial run, so to speak, and you don't do too much to them other than they have got to respond in a compliance letter within 20 days.

But the second time around -- and they may be put on what we call the hit list -- maybe a year later, and they have got the same problems wrong, and it is centering around management control, then we are likely to take a severe action, such as a conference and/or civil penalties, and we do have a lot of civil penalties.

We do travel across the state, and you know Maryland is quite wide. It is about 175 to 200 miles across. So, when even our reciprocity friends come in, because a lot of our radiographers, we have more radiographers come from out of state than we have in state,

and we do r iire that they notify us tnree days in advance of the pers nel they have, cameras, vehicle, and everything, and any changes that occur, they have to notify us, plus the fact they notify us of the times, so that when we are riding out to Western Maryland, we are not going to take a ride in the sun when they finish up early or they don't work that day.

So, we put that in, and all these go out in a letter form prior to reciprocity even being started.

DR. GLENN: I will ask a question. How many of the states have something like this hand delivery of licenses?

[No response.]

DR. GLENN: Do all of those people feel that it is an effective way to get the program started?

[No response.]

DR. GLENN: I will ask a slightly different question on the enforcement options and then move into what may be a fairly long discussion on voluntary programs.

Do any of you find that you lack the tools you need in order to correct certain kinds of problems? Is there any lack of having enforcement tools available in order to solve problems?

MR. BAILEY: Ed Bailey from California.

Yes, I think that administrative penalties, as we

would call them, the lack of having them is detrimental to our program.

DR. GLENN: Your administrative penalties are similar to our, what we call civil penalties?

MR. BAILEY: Right.

DR. GLENN: The agency itself without involving the legal system.

MR. BAILEY: Right, without involving the court system. The court system just takes too long, at least in California, to get a case from the time something occurs. Number one, you have got to get either the Attorney General or the District Attorney to think that it is important enough to do in the face of murders and other cases.

So, we tried this past session to get administrative penalties, and the California Medical Association was successful in getting that struck out, so we will be going back again sometime, but right now our department is saying they don't want to fight the medical association until we correct some things, many of which are related to the Medical Guide. So, we will do that.

I had one question that I wanted to ask about the previous topic. Of those states that deliver their licenses, do you deliver them by licensing personnel or inspection personnel, or both?

MR. GODWIN: Godwin of Arizona. There seems to be

a great mass of people coming up to answer that question. In the interim, we would like to mention one little quirk regarding enforcement. You all broached on it I guess it was yesterday or the day before.

If you are using self-inspectors that are coming in, you may have difficulty using their inspections as an enforcement action. You should be very cautious of that. Again, I am well aware that these people, when they go through and impose these programs on the State Programs, they announce it to the legislature as third-party inspections, but they are actually hired and paid for by the institution that is being inspected, and that makes it self-inspection in my book.

But you need to be aware that you may have trouble taking enrorcement actions even if it is found that they are doing all sorts of weird things.

MR. FRAZEE: Terry Frazee from Washington.

In our case, it is the license reviewer that is hand-delivering the license. I should also point that the license reviewer is also responsible for doing compliance inspections, alternating with our compliance program, so they have got a first-hand feel for what is going on out in the field.

The reason I came up, though, we don't have civil penalties, but we do have something that is perhaps a little

innovative. It is called the fee for additional service.

We have defined follow-up inspections and when we crank in follow-up inspections, then we can charge them an hourly rate for our time on site. So, they don't want us to come in a second time.

MR. MARSHALL: Stan Marshall, Nevada.

To answer Ed's question, I will qualify it because we all recognize there is a world of difference between Nevada and California, so I will set up the scenario.

We have got a licensee in Nevada who is getting a license, and I have got staff in Carson City and Las Vegas that are involved with both activities. Who do I send? I am more likely to send a primary inspector who may or may not have had any element of license review activity because it helps to put a face with a name of the first one in the door to do the inspection.

The guys in our ivory tower who might only do 5 percent of their time in inspections anywhere, may not handle those administrative questions, especially if they line up their techs and everyone who is familiar with the process.

MR. TEDFORD: Tedford, Alaska.

I would just like to make a comment about what Ed Bailey stated earlier. I have functioned in both states, have enjoyed the advantages and disadvantages of both

systems. One is the Medical Department system where, like Ed said, you have to kill somebody to get an action taken, and the other is where you have administrative penalties or you have civil penalties. There is day and night difference between the two.

Where I used to write letters until I was blue in the face, in the state that had the Medical Department situation, and when I then was able to operate under civil or administrative penalties, I never had to look for them. They got the answer back once there was money associated with it.

MS. HADEN: Robin Haden, North Carolina.

We don't have civil penalties, so we just use our administrative conferences or follow-up enforcement conferences where we bring the licensee into our office to discuss what we consider to be the bottom-line problem with their program, and that is generally pretty effective so far.

To answer Ed's question as far as license delivery goes, the license delivery is performed by one of our license reviewers that happens to also be my inspection compliance staff, and we don't make any rules as to whether it was the initial license reviewer or not. If it is not, all the better, it gets one more good read-through to make sure that it is complete and accurate before it goes out.

MR. GODWIN: Godwin, Arizona.

Just a suggestion to our good friends with NRC, whenever you increase your inspection frequency because of a weak history, shall we say, that increased frequency might should be considered a non-routine inspection because it is not at the routine interval.

I don't think it makes that much difference in the medical end, but it sure does in the radiography end. We did this for a while in Alabama until we discovered you all weren't doing it, and since we were trying to track you all, we had to drop off doing that, but you would be amazed about how you get there and you have to pay for an extra inspection every six months in radiography, particularly when it jumps up about 25 percent, that tends to get their attention.

MR. BAILEY: Bailey from California.

We use the enforcement conferences. One of the things that we quite often negotiate in the enforcement conference is an outside review, and we try to be very careful that it is not a brother-in-law review.

I think you have to insist on who that reviewer is going to be. You don't get the guy that came and looked at your program last year, who is across the street. You find somebody that you know has a good program or does a good review of a facility, and you get them to come in.

We found that that has been pretty darn effective, particularly in medical facilities where the administration, and rightfully so, will tend to support the medical staff against the regulators, and then they get somebody to come in and say, well, your medical staff is not doing it the same way we would do it at our facility. It lends a little more credibility to it.

DR. GLENN: I will make one observation. I have found that quite often the threat of a civil penalty is a very effective tool for getting corrective action. Sometimes when you actually impose it, then they dig in their heels and start fighting and some of the costs associated with the hearing process begin to make you wonder whether it was worth it or not, but many times the threat of the penalty is an extremely effect ve tool.

MR. TRUMP: Trump from Maryland.

We have both the administrative penalty and civil penalties in our statute. These can result from inspections or investigations where they licensee has definitely fouled up either procedurally, the safety system, or personal monitoring, things of that nature they were not wearing it.

We choose mostly to call them in for an enforcement conference, management conference, and at the time we think we are going to be pursuing a penalty, administrative penalty, we will tell them at the time we are

still going to pursue a penalty after all the corrective actions have been discussed at the table and what measures they are going to take in the future, and any other material that we need to be sent to us to determine that they are going to be in compliance.

A letter will usually go out within probably 10 days to two weeks following that of our decision. Now, we can charge up to $1,000 a day up to $50,000 for administrative penalties without going to court. We don't have to go to court.

Over 10,000 of the civil penalty, we can only seek it through the court system. So, therefore, our Attorney General's Office has advised us to go the admin way and, say, take half a loaf and swim with it and move on rather than seek higher penalties, but that is not to say that we can't pursue that. In fact, we have got one case now that is coming up I guess with Neutron Products.

But the thing is that with these type of penalties, they do have the appeal period in which to appeal this, and of course, it is with the ability to pay, and so forth.

DR. GLENN: I would like to move to -- and Aubrey has already brought it up a couple of times -- to the next subject for discussion in terms of inspection and enforcement.

That relates to the fact that we did receive a request from the American College of Nuclear Physicians during the period when the Commission was considering the override of the Office of Management and Budget's denial of the information collection part of our rule.

That letter said we have a voluntary program that inspects for quality assurance in nuclear medicine. We would like to meet with you, Commission, and see if there are some aspects of our program that match up with your program and whether you could give some sort of recognition to our program.

We had an informational meeting with the ACNP in September. They described their audit program to us. It is clear from that discussion that what they are looking for is what they called "deemed status," which would essentially mean if someone voluntarily participates in this program, then some aspect of the NRC's program would be waived for that part of the radiation safety program.

Now, this is something that we have not done before. Certainly, we recognize credentialing by the boards in medicine as far as training is concerned. We are in the process of the radiography certification program, recognizing again training certification by an independent body.

We have never recognized the audit in lieu of

inspection aspect before, but we certainly are going to approach this with an open mind and discuss it with them, but we would like your input on what we should be looking for.

Aubrey has already pointed out, can we use the finding of a voluntary audit program for enforcement purposes. Something we have to explore with them is whether they are willing to have sufficient disclosure for us to feel comfortable that if a problem is identified, that we will learn about it and be able to independently judge the corrective action.

But at this point there are several programs out there that could be recognized. Certainly, the ACNP is the only one who has approached us, but in developing the Quality Management rule, a lot of consideration was given to whether the JCHO audits could cover the inspection of the Quality Assurance Program.

But, anyway, should the NRC recognize voluntary programs, and if so, what aspects?

MR. GODWIN: Godwin, Arizona.

Having broached it, I will charge forward. If you recall my comments relative to industrial radiography, ditto. The problems, as I see it, first of all, there might be a small administrative problem with you all, but since you charge fees based upon, in part, services rendered, ala

the inspection, well, obviously, if you are not doing the inspections, you need to reduce your manpower and reduce your fees, so that is just sort of one of the administrative things that will be kicking along.

It seems to me the first question of can you use the inspections for enforcement is an issue that you would want to address, and how are you assured that their inspections are addressing the same issues that you have identified as a radiation safety issue, and how will they take their enforcement action, what kind of sanctions will they do.

For example, I could see a real problem if they said they walked into a facility, Dr. Jones' office, and announced that we are here to do our deemed inspection, and said, "Nope," so we will decertify you, and they walk out and don't tell anybody, you are stuck with a facility you haven't inspected, nobody has inspected, and how long will that condition before you find out.

Interpretive matters relative to the regulations might be an issue that you need to look at, and how will they ensure that their inspection interpretations will be consistent with yours, will the inspections be unannounced, will a certain portion of them be unannounced.

Again, suppose they sanction someone who you would have revoked the license, will they allow that information

to be circulated to other jurisdictions, so that we may not want that individual or organization, whichever it may be -- a person I guess would be the best way to describe it -- operating in our jurisdiction.

Falsification of records being submitted as part of the inspection might be an item of interest. What happens with complaints, who is going to be responsible for investigating complaints, particularly employee complaints, and the list sort of goes on and on. I think that will do for a start.

MR. KULIKOWSKI: Bob Kulikowski, New York City again.

A couple of comments, and these have to do with our machine radiation programs. The American College of Radiology has a Mammography Certification Program. We have on several instances gone to "certified" facilities and they have not only had violations, they have been issued stop orders because they are in such bad compliance.

I personally would be very hesitant to substitute a voluntary protocol for something that we normally have the authority and right to inspect. We are also under extreme pressure from our mayor's tennis partner's lobbying firm to have third-party inspections of dental facilities.

We have run into a lot of the same questions that Aubrey has brought up about if someone goes out and does an

inspection, and one, if they find a severe violation, how do they communicate that to us; two, can we use their inspection documents to proceed with escalated enforcement, and the questions go on and on from there.

I, for one, am very uncomfortable with this sort of thing.

DR. GLENN: Bob, one follow-up. In terms of this mammography inspection, were these in areas where what you looked at overlap? What I am trying to figure out is that they covered the same thing, but they didn't see the problem, or was it you were just looking at different things?

MR. KULIKOWSKI: No, it was things that are covered by the ACR in the QA certification, and actually what we are doing is exploring right now with the ACR and our lawyers whether we can indeed legally notify the ACR when one of their accredited facilities is not able to pass one of our inspections.

MR. FRAZEE: Frazee from Washington.

Voluntary audits should not be the basis for a compliance action on our part. Another one of your questions deals with whether we would reduce or change our inspection frequency, and the answer is no, if we are going to do anything, we ought to increase the inspection frequency, certainly never decrease it.

If we are aware of the audit findings, that is fine. Their goal should be basically looking at the same goal or end point that would be looking at, and we can make that assessment ourselves, and we don't have to base it upon their findings, and certainly would not want to do so. It should be something that we find, we see ourselves.

MR. GODWIN: Now, to present perhaps another part of the thing. I feel that, particularly in the medical field, that the professional certifications and all are very important.

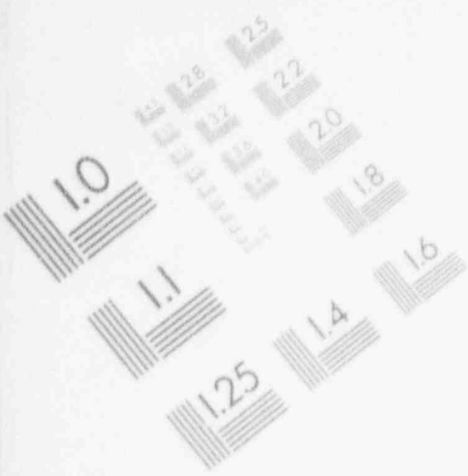
There are areas that are being addressed that are vital to our overall interest, that are not something we perhaps should get ourselves into. For example, the training, they are probably in a much better position to evaluate someone's training.

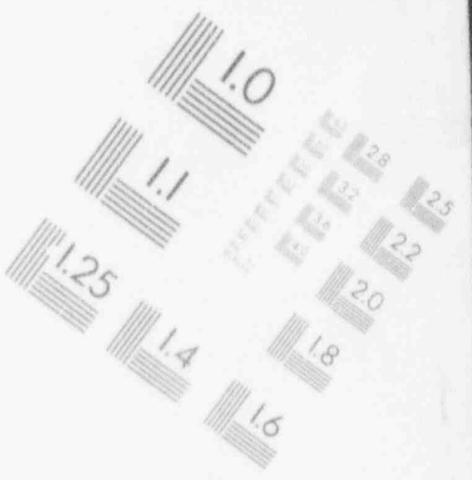
They are in a much better position to look at the overall end product quality of the work. We are interested in that. I would like to see us do that, but I think they would be in a much better position to say this particular patient was really treated well, and we really don't have any business to get individual patients.

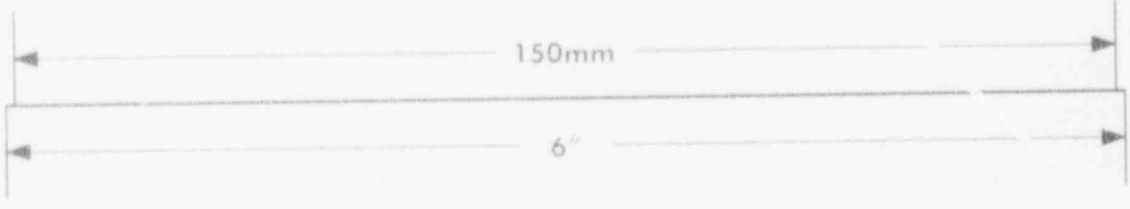
They have that unique ability that is important and should be taken care of. I think we need to encourage the professional groups to get in and work. They can make our jobs so much easier, and they can really help.

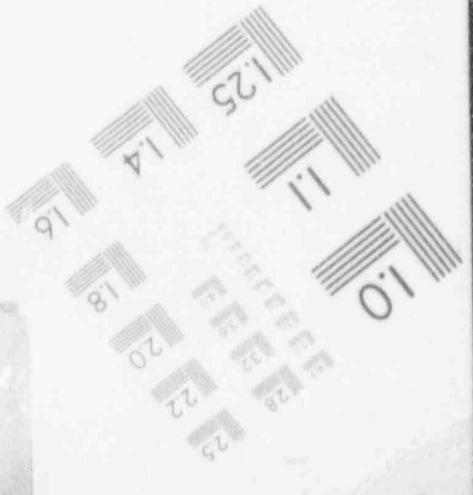
1

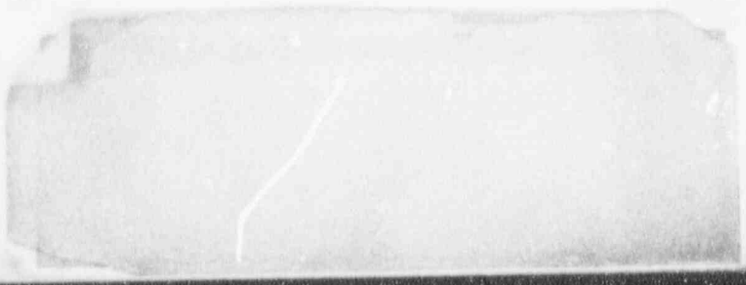
IMAGE EVALUATION TEST TARGET (MT-3)





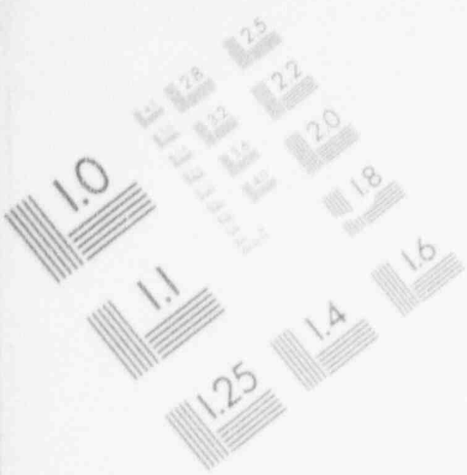


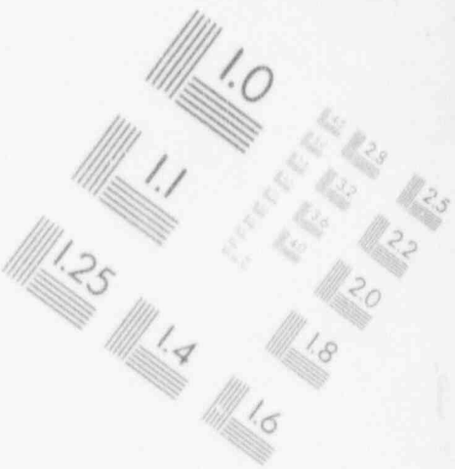


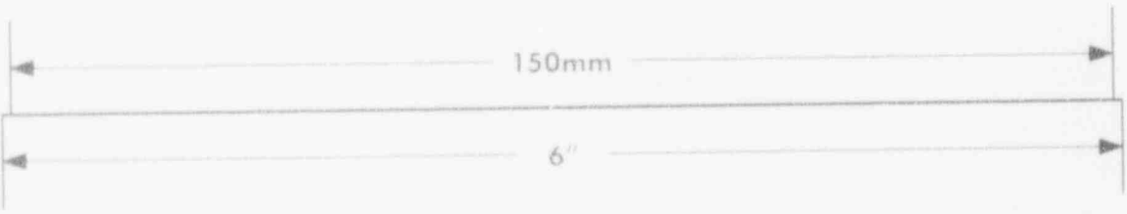


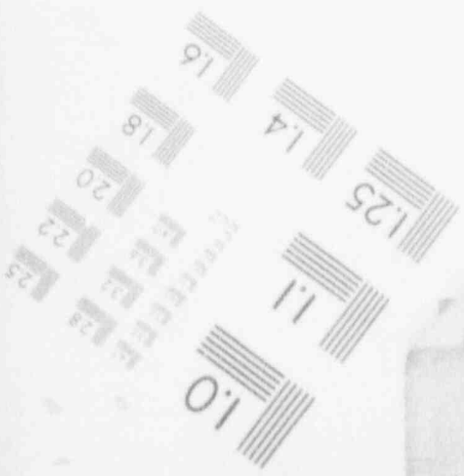
1

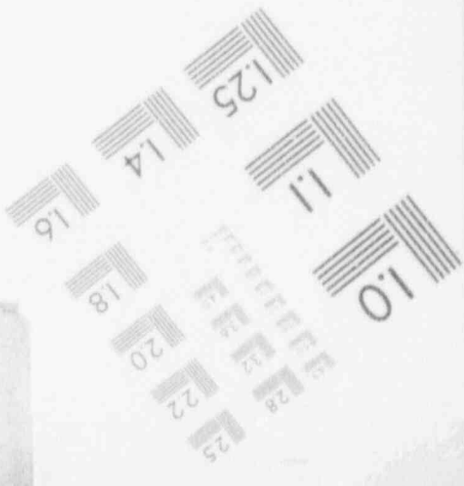
IMAGE EVALUATION TEST TARGET (MT-3)





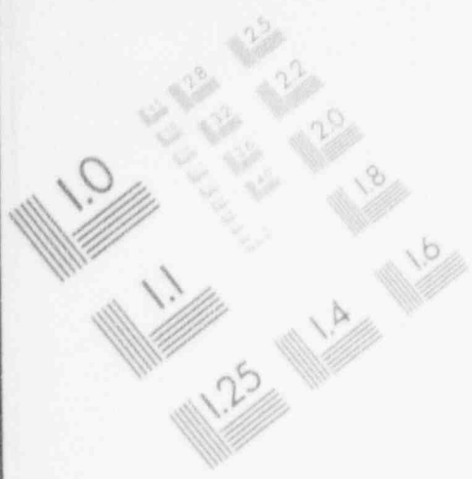


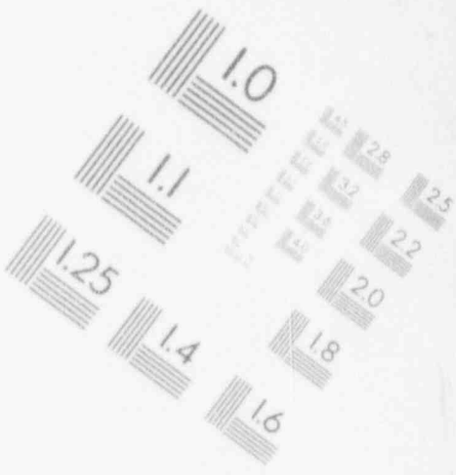


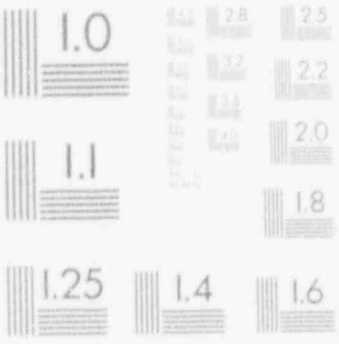


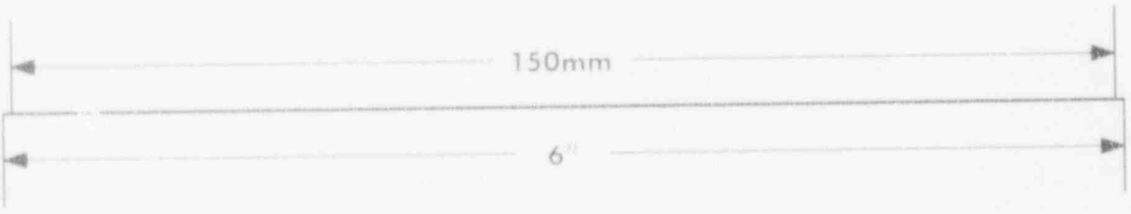
1

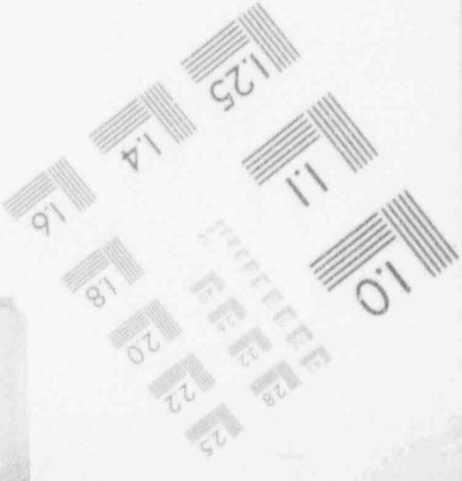
IMAGE EVALUATION
TEST TARGET (MT-3)












1
IMAGE EVALUATION
TEST TARGET (MT-3)
1.0
1.1
1.25
1.4
1.6
1.8
2.0
2.2
2.5
2.8
3.2
3.6
4.0
4.5
5.0
5.6
6.3
7.1
8.0
9.0
10.0
11.0
12.5
14.0
16.0
18.0
20.0
22.0
25.0
150mm
6"

So, I think we need to do something to encourage the professional associations to participate and work with us as partners rather than an adversarial relationship. I think it is very important that we bring them on-board.

DR. GLENN: I guess a follow-up. Do you see some area where we could actually give them something back in return? I agree, I have drawn VENN diagrams of ACNP's Quality Assurance Program and our Quality Management Program, and theirs is a much bigger program. However, it doesn't really overlap that much with ours.

But when it gets into is the patient getting good treatment, their program answers that question a lot better than the NRC's inspection program does.

MR. GODWIN: I think there are aspects that we can give them credit. Obviously, I would think that we could give them credit for the training review. If someone is certified by an appropriate organization, we can give them credit for that, assuming -- well, if it is a valid certification, let's put it that way.

Where they have established an example or some sort of quality control program overall, that encompasses all or part of what we would need, I would think that we could make our inspection only touch briefly on those areas, just enough to spot-check to make sure that the facility is indeed following the program that they have committed to.

We wouldn't have to go into depth.

You could touch on things and shorten up your inspection to the degree that maybe you only look at their reports where their people have come in for certain aspects of it.

I don't think we can totally duck the issue of doing unannounced inspections at some frequency. If we have a facility that had some decent inspection history, and was using that, I personally feel we ought to recognize their program and lengthen the inspection interval.

I disagree with my colleague from Washington to some degree, and that is all right, too. I mean, you know, you have got to look at it. But I think there are things that we can do that would give them credit, and since the NRC is charging fees for their inspections, lengthening the interval translates into saving money.

MS. ALLEN: Allen, Illinois.

I am not really clear whether or not -- I understand third-party inspection -- but I am not really clear whether or not you would accept a licensee's statement that they will participate in a JCHO type of QM program in lieu of submitting another program for us to evaluate for licensing purposes.

DR. GLENN: That is the question, should we. If we have established that it achieves the same objectives as

our program, would we recognize. They would perhaps not have to submit a program, and perhaps we would at least waive some part of the inspection.

MS. ALLEN: But I can see where they would be independent of each other, yes, we will accept your QM program, but we are still going to inspect you according to our regulations to see if you still meet those requirements without even looking at the inspection, even just a statement saying that we were inspected annually or whatever, because licensees may have a problem with you looking at actual inspection reports, but a statement signed by management may be acceptable enough.

The question is -- and I think you are going to address it at your November meeting -- which one of these programs meets the requirements of the QM rule, and is there going to be some sort of list where licensees can say we are going to do this one and therefore we don't need to submit it.

MS. ALDRICH: Rita Aldrich, New York State Health.

I think I can give you one parallel for the kind of thing you are looking for. What we are proposing for the therapy QA requirements, which we hope to get adopted, as I said, by the end of November, is our inspectors will inspect for the presence of a QA program.

We are requiring outside audits to look at the

efficacy of the program. We have on our Medical Advisory Committee a member of the ACR's practice accreditation review for therapy, and he keeps telling me that they don't look for QA programs when they go in to do these reviews.The data that they get from these reviews are used in the -- good heavens, what is the name of the program that the American College of Radiology runs -- Patterns of Care Study, which they go back, all that information feeds into establishing parameters for particular types of cancer treatment, particular sites, upper and lower dose levels, and other things that seem to, in their effectiveness, increase the likelihood of control of the tumor.

He keeps telling me this, we don't look. In fact, he says he is not even sure it is a question, do you have a QA program. They don't care. What they care is what is the quality, not what you have on paper, but what do you have in reality.

They look at five treatment sites in the practice accreditation review, and they look at the patient treatment data and the follow-up on the patient, how the patient does, and that is what they are looking at, the effectiveness of the Quality Assurance program.

So, what we are saying is that our inspectors will inspect for the presence of a QA program, but we want outside audits to look at the effectiveness of the program.

Again, it is one of those things, as I said before, that there are things that we can't and shouldn't do for our licensees, but that they do need to do for themselves to close the loop on quality assurance.

I don't know about the importance of these kinds of things for diagnostic, but we have used a requirement for an outside audit for diagnostic programs where we had severe problems.

Partly that is because we are in the Health Department, we have another part of the Health Department that is the Office of Health Systems Management. They will sometimes go in and do a review and find clinical problems, and then we might take a joint enforcement action, and this has in the past included a practice accreditation review by the American College of Nuclear Physicians.

I agree with you that their inspection report -- I have a copy, and it is far more detailed and much better suited to evaluation of a quality assurance program for diagnostic than anything that we could ever do.

I don't know about requiring it. I think if you looked at it the same way, that you would look for the presence of a QA program, that we have in our regulations specified certain minimums -- which essentially are the Joint Commission's requirements, we are not trying to invent anything -- and then look for something like this to close

the loop and fill in the rest of it, because our inspectors are not going to be able to look at treatment plans for patients and find errors.

DR. GLENN: I guess one thing we did already mention to the ACNP is that, as currently constituted, their audit program does not include the use of written directives, and without that definition being in there, there is almost no overlap with the NRC's Quality Management Program.

So, there would be some things clearly that they would have to change about their program before we could see any comparability at all.

One thing I heard is that there is a possibility, not so much of waiving inspection programs, but of waiving certain aspects of the inspection program. In other words, the regulatory agency would be responsible to see that a program exists, that a program has been implemented, that audits are performed, but in terms of whether the program is working, that could be judged by an independent authority, at least in some cases.

I believe it is 2:30. My understanding is that at 2:30 we have coffee service.

Why don't we take a 15-minute break.

[Recess taken from 2:34 p.m. to 2:55 p.m.]

DR. GLENN: There was another paragraph of

questions relating to inspection and enforcement. In looking those over, I think we pretty well covered all the topics, and so I think the next area is another very large and important area.

I would like to move on and Mr. Camper will lead the discussion having to do with Training and Supervision.

MR. CAMPER: In the interest of time, I am going to try to just hit some of the high points, Appendix D in your Medical Issues Paper.

What it is really saying is that Medical Use licensees are somewhat unique in the sense that the justification for the use of radioactive materials in the practice of medicine must be done at the direction of a physician, and that historically, physician-authorized users have occupied a very unique place in our licensing scenario.

If one goes back to the early days of AEC and the development of nuclear medicine, the authorized user I think most of us would agree meant something. They were typically at the forefront of developing radiopharmaceuticals.

They were the most knowledgeable individuals to deal with, not only medicine and the practice of medicine in terms of using radioactive materials in the practice of medicine, but also in terms of radiation safety requirements, handling procedures, and so forth.

Well, over time some other specialties have come

along, other individuals who know a lot about radiopharmaceuticals and how radiation safety programs should be conducted.

We have nuclear med techs, we have radiation therapy technologists, we have radiopharmacists, and we have other physicians that have come along that want to use radioactive materials in the practice of medicine.

Now, if you use that as a backdrop, and you also consider that the day-to-day supervision of the actual handling and use of materials in many facilities is being done by someone than an authorized user, there are literally scenarios which exist where the authorized user is not on site for some prolonged periods of time.

When we revised Part 35 in 1987, we did try to set up specifically some flexibility on this question of supervision. You might recall historically, there was a time when we wanted to see authorized users being available within 15 minutes, and then it was an hour, but then in 1987, we realized that it really is case-by-case specific and the need for the degree of supervision was left in the hands of the authorized user.

Similarly, the question of training and experience, what is the adequate amount of training and experience for a physician that wants to use radioactive materials in the practice of medicine.

I think most of us would agree that board certifications, of course, are a very good standard, but there is also this "or" category. We can't rely strictly upon board certifications. That would be restraint of trade. So, we have the "or" category that says a physician may come in, and as you know, if you demonstrate 200 hours of didactic training, 500 hours of types and quantity, 500 hours of clinical -- those two may be done concurrently -- in some minimum time frame you can match the "or" category.

Well, this question of training and experience, you know, tends to bubble to the surface periodically. It has been there recently. Dr. Myron Pollycove has been leading a task force to take a look at some training and experience criteria for us to see what might be done to change that.

So, with that as sort of a backdrop, what you find in Appendix D is a series of questions that is designed to say that, look, if we were to take a look at this question of the authorized user and what he or she is or is not in terms of today's practice, some interesting questions and concepts come to mind.

For example, the first question is should training and experience requirements be general or should they be more specific to the user's intended use of licensed material.

As you know, right now, on one hand, we look for 200 hours of didactic training. We are looking for instrumentation and physics, radiochemistry, mathematics, and so forth, of a general nature, radiation safety across of the board of a general nature.

Is that appropriate or should there be some adjustments in that level of training or the content of the training or the breakdown in training for, say, cardiologists as compared to somebody who wants to do a broader spectrum of nuclear medicine?

Should it remain general in nature or should it be more specific to the practice intended? That is the first question.

MR. FRAZEE: Frazee from Washington.

In my opinion, the training and experience requirements for radiation safety handling should be put on the radiation safety officer and that responsibility. The list of authorized users does not need to have that listing in there for a couple of reasons.

MR. CAMPER: You are saying authorized users, physicians would not necessarily need to be listed?

MR. FRAZEE: Right, the list of authorized -- you can cite it better than I can -- but the different categories of use that are listed in the back of Part 35, whether it is diagnostic or therapy or whatever.

There are two reasons for that, for not bothering to put that in there. One, in terms of Aubrey's question the other day about what is the function, what is the purpose of having an authorized user on the list or on the license.

I interpret the authorized user as being that individual who is responsible for directing the application of radioactive materials to humans. That is the responsibility end of it there.

It would be through many of the things that are already listed in there, you know, establishing the criteria for patient acceptance, writing a clinical procedures manual for the diagnostic realm, writing the actual order that causes an application of radioactivity to be administered to a patient, but that is their function, that is their role. They have the professional competence to do that sort of thing.

With all due respect to your comments about interfering with free trade or whatever, you know, I would be happy to just say if you wan to be an authorized user, you have to be board certified, that's it. I mean that is your professional group has determined that you have a level of competence that we will accept that allows you to apply radioactive materials to humans.

MR. CAMPER: You have an "or" category currently

in the State of Washington.

MR. FRAZEE: Oh, sure. The outcome would have to be some sort of a grandfathering of people that are already there, but by a date certain, you know, two years, three years in the future, it is like that is it, you would have to have board certification to be "the authorized user."

The flip side is that the radiation safety aspect, which we are all saying, I mean that is what our role is, to ensure radiation safety, well, it is the handling of the materials, and the first thing to do would be to beef up the training and experience requirements for radiation safety officer.

What does it mean to be a radiation safety officer? You know, the list starts out with certified health physicist. All right. So, you have got some high-powered individual who has a lot of specific radiation safety training.

Then, it goes through and it lists some "or" categories, and that would be an appropriate place to stick in the training and experience types of considerations that you would want to have for an authorized user who is authorized to administer or cause the administration of materials to patients, to at that point define, if you want to be the radiation safety officer, which the license would have to have one, you would have to have such-and-such

training

Now, it may be the stuff that you have just pulled out of the individual areas, but the emphasis is the radiation safety officer is that person who is responsible for making sure that radiation safety is handled appropriately and that anyone working under that license, tech, janitor, whatever, has appropriate training.

That is already in the list of duties of radiation safety officer. So, a lot of the things that we would be concerned about are actually covered in other areas.

MR. CAMPER: Terry, let just interrupt you there. You are answering a lot of questions.

MR. FRAZEE: Yes, I know.

MR. CAMPER: But with regard to this question about general training versus training that is specific to the intended use by that particular applicant, which way do you tend to come down on that?

DR. GLENN: Make it more specific, a person who does one organ imaging, does he require the same amount of certified training as someone who does imaging --

MR. FRAZEE: If there is the distinction in the handling of the material, then yes, it should be appropriate, the radiation safety training should be appropriate to the type of handling of the material that you handle. Iodine is different than technetium, but if you

just dealing with a bunch of different technetium isotopes, I mean it is all the same, whether it is cardiologist or nuclear medicine clinic where they are only doing technetium. It doesn't matter. I mean it is the same thing that is going on. You are dealing with spills, you are dealing with some exposure.

Therapy, of course, you have got larger dose rates, so you have got to have maybe a little bit more emphasis on shielding, and so forth. So, yes, there would be some specific additional training, but it would be for the handling of the material, nothing to do with the clinical aspects or anything like that.

DR. GLENN: Where I am having a little difficulty with this concept is if we went to board certification, but let's say that a cardiologist is board-certified in internal medicine, would that qualify them to direct the application of radioactive material to a human being?

MR. FRAZEE: Right, it depends on what is in the board certification, but I guess from my perspective that is not my problem, that is the medical community's problem.

DR. GLENN: But if we have a regulation that requires a certification, how do I determine which certifications to put on that, that is my question.

MR. CAMPER: It is our problem because we are the ones who grant the authorization to possess and use

radioactive materials, so it is our problem.

MR. GODWIN: Godwin, Arizona.

I am going to approach pretty much the same thing and see if the two of us can't get together on our answer here. I tend to think that particularly for the clinical part of it, it should be the boards. The boards ought to be the ones primarily doing it.

Legally, we may have to have an "or" in there, but I would hope in actual fact the boards are primarily the ones that are doing it. I would have no problem, say, if there is a board of cardiology, as a part of that board they required a certain amount of nuclear safety -- or clinical work I should say. That makes sense.

To the extent that they may have to use or deal with leaking connections and things in the administration of the material to the patient, there should be enough information in that certification to handle that part of the issue, or as sort of an alternative we may have to have like a 40- or 50-hour training course as opposed to the 200 that we are talking about now.

Certainly, the physician would have a lot less unless he is going to be the radiation safety officer. If the physician is the radiation safety officer, he would need an appreciable amount. He needs to learn all the regs, know what all is going on.

It seems to me that we may want to put on the licenses the radiation safety officer as a separate unit, and we may want to redefine away from authorized user and go more to prescribing physicians, list a radiation safety officer, and list the technicians more as authorized users with regard to preparing and handling individual doses.

He would be an authorized user to the extent that he is drawing up the doses into needles and perhaps actually injecting into the patient, but not the authorized user as far as a prescription.

That would be strictly a function of the prescribing physicians, and those physicians who are charged with that responsibility are the ones we have got the training records on, not every physician who happens to refer somebody down there. They would have some responsibility to look it over to make sure that it is appropriate.

I think that will address most of the questions you have looked at, in that we are looking at board certification to generally qualify the prescribing physicians, perhaps with a supplemental training of somewhat of a minimal nature, with a rather extended course for the radiation safety officers, and that could either be the physician or an appropriately trained technician could serve as a radiation safety officer, and then have our

technicians, who would have the appropriate board certification for them.

I think it is important that they would be appropriately board-certified to be the practicing technician.

DR. GLENN: I think maybe it is appropriate at this point, so that we can weigh the two solutions, let me try to describe for you what the ACMUI recommended to us.

What they recommended was that a physician should have clinical experience with patients that have radioactive material in them, and that there should be some sort of preceptoring process, somewhat similar to what we have now, but this preceptorship would serve as a ticket to an examination.

Now, this examination could be part of the board certifications that we already recognize or it could be an independent exam, and they informed us that we could have the Board of Medical Examiners develop a test that we approve.

So essentially, they were suggesting what we do is have a requirement about how much training a person has to go through, what topics, and that someone signs off that this person is ready to treat humans with isotopes, and that then is their ticket to take this exam. If they pass the exam, then they are qualified as a prescribing physician.

MR. GODWIN: I had envisioned perhaps a little less government involvement. I would have the certification, I would have successful completion and have the preceptor sign off that they successfully completed it.

It sounds like a modification of the Texas radiography type situation. Quite frankly, you know, philosophically, you may have a tough time dealing with the fact that we are requiring people to have an elaborate training program and pass an exam before they can expose radiation to p pe, but we don't do the same thing for humans. So, there is some thought there you need to think about.

MR. TEDFORD: Tedford, Alaska.

I would just like to share some experiences with you and past visitations in the field. Most of the nuclear medicine physicians trained in this country today, initially were trained at the National Naval Medical Center at Bethesda, the key individuals who have resulted in people who are now board-certified nuclear physicians, if you will.This went on over a number of years. I don't know whether the course is still ongoing now, but the course encompassed four weeks, and in the course they were taught mathematics because they had a very poor understanding of mathematics initially when they came in.

They were taught radiobiology, they were taught

biophysics, they were taught dosimetry, they were taught safety, they were taught shielding, they were taught all the general aspects, and they also are required to have a preceptorship, a preceptorship for the particular types of patients that they desire to be involved in afterward, and that preceptorship had to be under an individual who had done these tests and who had been accepted by the boards in paths qualified to do so.

So what you have is a melange or a mixture, if you will, of the general aspects that you have spoken to and the specific training that is involved. You have four specialties involved in this field principally. You have cardiologists who have come in recently. Initially, you had radiologists, you had pathologists, and you had internists.

The radiologist started off in the field initially. They brought the internists in because of their diagnostic capability, and there have been boards that have been established all the way down this line.

What Aubrey said is to the heart of the matter, let the people who are in the specialties tell you what it is that they need to know, because regardless of what you sit on the boards, they are going to ask these radiation safety questions, they are going to ask about dosimetry, they are going to ascertain that these physicians know what they are doing.

It is this other side group that you are looking at that you are going to bring in. and the final judgment in this case, in all cases, is a group of physicians who can sit and look at the qualifications of individuals you have questions on, and they will tell you the truth, believe me.

The qualifications for the pathologists were not nearly as great or as restrictive because they were dealing mainly in in-vitro type situations, and so they had a much reduced schema.

In summation, they need to know the whole field to a certain extent because the boards are going to ask these questions of them.

MR. GODWIN: Godwin again to expand a little bit on my answer.

When you look at therapy, you will have to have a much closer coordination to make sure that they do get all of the brachytherapy, teletherapy, and radiopharmaceutical therapies appropriate in their internship or whatever to qualify for the boards and make sure that is either to get a full certification, you know, for everything, that is one thing, to get a limited -- we might have to recognize some sort of limited certification, for example, where they are using strontium-90 for eye for the ophthalmologists.

Those kind of certifications we can probably get with the boards and get them out, but I think it would be

best if we can work through a board in some way.

MR. CAMPER: The next question was very much of a related question, but yet somewhat different, and that is, are the current criteria necessary, that being -- let's focus upon the "or," the 200 to 500, and the 500, given that board certification I think most of us would agree is very positive and good.

Are the current criteria necessary if the physician does not bear the primary responsibility for radiation safety? If needed, could the training and experience requirements for a physician user not seeking authorization to supervise radiation safety programs be less than the current criteria?

In other words, if you want to be an authorized physician user, but you don't want to be the radiation safety officer or to be responsible for the radiation safety supervision, could the training criteria be less, could the 200 to 500, and the 500 be less under that scenario?

MR. FRAZEE: Is that for a certified?

MR. CAMPER: No, no.

MR. FRAZEE: A non-boarded individual?

MR. CAMPER: Right, non-boarded, may be boarded in something other that nuclear medicine or one of the board certifications currently listed in Part 35, could be board-certified in cardiology, for example, or neurology,

but the point is they want to be an authorized user, but they are not going to be responsible for radiation safety supervision.

Could the training be less than the current criteria?

MR. BAILEY: Yes.

MR. CAMPER: There is a firm answer.

MR. BAILEY: I will give you the example of a guy who is a certified health physicist, who didn't have that criteria, who went back to medical school, and I would hope to heck that he could be an RSO when he got out of medical school at a small hospital.

I am agreeing with the people that say that the RSO duties probably should be looked at separately from the clinical duties. I think most of our problems with hospital health physics programs have been where the physician was the RSO and the program was a little bit too big for him to manage, and not big enough to have a professional health physics staff, if it is a small program, yes.

But honest to gosh, it is really a waste of talent in my opinion to have a board-certified nuclear medicine physician doing film batch reports and all this other stuff. I mean you can hire us a lot cheaper, and probably we are more interested in it than the physician.

I mean they like people, some of them, and let's

get them to doing what they have spent most of their lives trying to learn how to do, and that is be a doctor, and concentrate on putting requirements for the RSO, and if they come together, fine, if they don't, fine.

MR. FRAZEE: Frazee again.

If the State Board of Medicine in their judgment allows a physician to do nuclear medicine activities, then far be it from me to tell them that he can't.

DR. GLENN: Okay. That's any physician.

MR. FRAZEE: Okay, but this is the State Board of Medicine.

MR. CAMPER: But they license them to practice medicine, Terry, they don't license them to practice nuclear medicine.

MR. BAILEY: Bailey from California.

I think this may be the crux of why we are having problems. We are licensing them to possess and use radioactive materials. Now, they have to get a license from us to do that. That is in addition to whatever medical license. It is not unlike their whatchamacallit license -- narcotics license. There is a separate license for that. It is a hazardous material sort of and so is this.

I can't agree that we just let them go.

DR. GLENN: I think the real question is for a person who is going to direct the application of radioactive

material to a human being, is there some minimum amount of radiation training they need. I see Ed saying yes.

MR. FRAZEE: That sounds pretty good. I guess back to the philosophical aspect of this whole thing, we have issued a license to an institution, and they have got a qualified radiation safety officer, and this authorized user that we are now talking about isn't going to touch radioactive materials, not going to handle it at all.

The only thing he is going to do is select the patient, prescribe, direct that radioactive materials be administered to a human, and I am not sure that that is not so far out of line.

MS. MILLER: And interpret the scans.

MR. FRAZEE: Oh, yes, and interpret the scans. I mean, okay, he does all those great things that we say they do.

DR. GLENN: I think it focuses better if you think about a brachytherapy program.

MR. GODWIN: It seems to me that indeed, as I discussed earlier, that we do have a certain responsibility ala the patient for the patient's radiation safety, and there is a little glitch relative to comparing it with other sources of radiation where there is no one that has that direct responsibility at the federal level.

Because of that, yes, I would say that NRC had

some responsibility to assure that there is some reasonable degree that the material is given at the proper time, at the proper set of conditions, which implies that, yes, they need some minimal training to determine what those are.

There may be some procedures in the future that use such a very minimal dose that you may say that that is such a minimal risk that you might want to go back to a general license, so that any physician can do it, as you had with this other general license that you ended up with nobody producing the drugs for.

Therefore, I would not want to be on the record that from now on that you would have to be board-certified in something, but I do think that it might be appropriate to at least have the concept available that at some point, where the dose is below some level, perhaps you would want to consult with FDA on what an appropriate level is, or EPA, or somebody like that, that you might make procedures of that type open to any physician.

But, in general, from what I know about the doses currently, the procedures currently, I would say board certification would be the appropriate way to go.

MR. BAILEY: Ed Bailey from California.

We do test doctors and certify doctors to use x-ray equipment. You must have a permit from the state if you are an M.D. to operate or supervise the operation of an

x-ray machine, and that involves a safety test which they just take on radiation safety and the regulations.

The only people that sort of duck out of that are board-certified radiologists. So, you can always set up some system that addresses the problem, and if you get the board to handle the questions, then you don't have a problem.

MR. CAMPER: Let me ask a question, then, and respond by a show of hands.

If an authorized physician user is not going to have responsibility for radiation safety supervision, how many of you, by a show of hands, would agree that the training could be less than our current requirements?

MR. GODWIN: What part of the current training?

MR. CAMPER: Two hundred, 500, and 500 in no less than six months.

MR. GODWIN: The 200 could be less, but I am not sure about the others.

[A show of hands.]

MR. CAMPER: I am seeing eight hands.

How many feel the current training is sufficient, it is appropriate?

[A show of hands.]

MR. CAMPER: Four hands.

MS. ALDRICH: Rita Aldrich, New York State.

One of the things upcoming is the changes to the pharmacy type regulations. Now, as I understand it, you are going to be allowing deviations from the package insert.

MR. CAMPER: Yes.

MS. ALDRICH: That to me seems that we need to go in the direction of more training, not less. I don't care whether this person is a radiation safety officer or not, to make judgments in that area, they certainly need some minimal amount of training in the physics concepts. If they change the route of administration, they can't rely on the package insert for dosimetry.

The other thing that seems to be complicating this is the RSO function. In hospitals that don't have health physics staff, only techs and doctors, we require that it has to be an M.D. who is the RSO. It is a question of authority. A technician can't tell a doctor what to do.

The doctor can delegate everything, but remains responsible for seeing that these things get done. The main problem we see with small programs that are not effective is they don't purchase enough consulting physics support, and I really think that that is where the problem is.

One of the things we have done with hospitals where performance is really bad is require them to get a consultant in to set up their program for them -- we are not going to do it -- and then to maintain an adequate level of

consultant support after that.

We don't do that alone, of course, because the Joint Commission requires the same thing, so again there is more than one agency pushing toward the same goal.

MR. CAMPER: I think we have done as much as we can do on that one.

The next one is, is the training and experience of an authorized user physician sufficient to qualify him or her to be an RSO? Again, we are talking about the "or" category, the 200 to 500, and 500.

Is it sufficient to qualify them as an RSO? Any thoughts on that?

MR. GODWIN: Godwin, Arizona.

I think the question there turns upon the quality of the 200 hours. Two hundred hours spent somewhere going and playing golf is a lot different than 200 hours in laboratory class, classroom work, and things like that.

I think the real crux of our problem is I don't know of anyone who really knows what they get for sure in the 200 hours or where good, approved courses are. So, with that in mind, I think we need to look at the quality and subjects covered before we can make an informed decision.

DR. GLENN: Again, one of the suggestions of the ACMUI was the exam, which sort of says, okay, we can't be there every time they give the course, but if the course

included these topics and these people say they took the course work and they can pass the exam, that is sufficient.

MR. GODWIN: Well, I prefer the exam over existing for a year or two and then taking over.

MR. CAMPER: They also suggested to us that we might look at existing licenses and status of the RSO's to determine whether or not there really is a problem.

MR. GODWIN: Getting out or approving courses may be another way, and have a required exam, and then occasionally having someone sit in on that might be a good way to do it. There are all sorts of alternatives to this system that may not be quite as expensive as giving an exam and proctoring exams.

MR. CAMPER: Right. You have led us right into the next question. It has your footprints all over it, Aubrey.

Should NRC become involved in monitoring the adequacy of consultant radiation safety courses, these 200-hour programs, residency programs, and board certification courses as they relate to radiation safety? Should we monitor them or, in fact, with regards to the 200-hour courses, should we put in place some approval mechanism for them?

Any thoughts on that? I think we know where Aubrey stands on that. Any other opinions or thoughts on

that?

[No response.]

MR. CAMPER: We often hear of these 200-hour programs, particularly the ones provided by consultants. There are a number of people who criticize them.

I think they raise questions like do they really spend 50 hours in a weekend doing this, what is the quality and caliber of the instructors, is there any feedback mechanism in place to determine that the physicians, in fact, completed the course satisfactorily, is there testing, for example.

We have some of the same kinds of concerns, and we have had some thoughts about going out and perhaps monitoring some of these courses, and we would probably also monitor some of the residency programs by using Dr. Pollycove in particular to help us with that.

Any other thoughts other than what Aubrey has already expressed about this?

MR. FRAZEE: It is kind of like the bottom line is, you know, is it working, is there really a problem, how are all the physicians doing once they are really out in the field as far as whether or not their training has been adequate or not.

If you do get into monitoring -- and I agree that would probably be a nice thing to do -- you need to have

some way to get it into a national database, so we would all have access to it and perhaps other states could monitor programs in our own states and add to that database.

It would certainly avoid some duplication of effort and streamline the evaluation process by the license reviewer, wouldn't have to go through line-by-line their training experience if there was this database.

I am not firmly convinced that we have to monitor these programs, but if we do, provide the information because we probably could make use of it.

MS. ALLEN: Allen, Illinois.

Isn't there an STIS database already for training?

DR. GLENN: That is correct. We have been very careful, though, to always say that that is not an approval process, in other words, that that means at one point in time a reviewer has reviewed the course syllabus and the method that the teaching group uses to ascertain the effectiveness, and has found that acceptable for licensing purposes, but there is no warranty that that program has remained the same, there is no periodic checking, so I would not call it an approval process.

MS. ALLEN: Well, we have been inundated with requests from consultants with videotapes and disks that expire on a certain date, and all kinds of things, looking for approval for these training courses, for everyone from

hospital security to physicians. Maybe we need some sort of uniform guidance document.

DR. GLENN: That is why we are asking these questions. I think technology is going to say that if you don't require that the training be received in a residency program and through board certification, the number of different ways that people are going to be able to get training is going to be immense.

MS. ALLEN: Well, maybe it can be patterned after like the sealed source and device evaluation. There is uniform guides for evaluating whether or not they are any good, they go on a database, they can pay -- I don't know -- some annual fee or some sort of an annual review, whether or not they have been changed or updated.

They can be charged a fee for our evaluation time.

DR. GLENN: I have to admit my bias. My bias is towards this exam because it gets us out of that business, and I would rather say that there is an examining organization, I know the quality of the exam they give, and I don't have to worry about the quality of everybody who trains someone to take that exam. It is easier.

MR. CAMPER: We have some more questions about physician training and experience, but I think, in view of our time, we will jump to another area of training to try to get some of this on the record, as well.

Since technologists perform the majority of isotope handling, should there be a minimum level of training and experience requirement for technologists who use byproduct material for diagnostic and/or therapeutic procedures? Your thoughts, please.

MR. BAILEY: Yes, sir. There should be a certified nuclear med tech licensed by the state.

MR. CAMPER: Let's say they are not -- now, we are the regulators -- what would be that minimum level of training that they should have, that we would require them to have?

MR. BAILEY: Equivalent training to that.

MR. CAMPER: Equivalent training to that. Other thoughts?

DR. GLENN: Again, I will mention that the ACMUI advised. It was very similar. They said state registration or certification. However, in a state that does not register technologists, they told us to keep out of it.

MR. CAMPER: Right, they did.

MS. ALDRICH: Rita Aldrich, New York State Health.

A few years ago we amended our code because we knew all the nuclear med techs were out there injecting, and we had always said they couldn't. State Education said they couldn't, but State Education didn't want to license them.

So, we amended the code to say that only techs

with certain qualifications could inject because that was sort of an end run to beef-up their qualifications, and it is board certification -- well, yes, it is called board certification -- the AART or the NMTCB, or completion of a CAHEA-approved program, which really boils down to completing a program licensed by the New York State Education Department.

They need not necessarily take boards, but they are foolish if they don't, but either one of those mechanisms allow them to inject.

What we are doing now is expanding that in licensing to say if you have a generator, you are not going to use unit doses, also has to be a certified tech, and if you are going to use PET pharmaceuticals, things that are of greater hazard, in the licensing process we are requiring that those same qualifications apply.

MR. CAMPER: As I understand it, there are some states that require that there be a certified technologist licensed by the state in the states that do do licensing, or if they have an individual that has not met that criteria, that training has to be considered on a case-by-case basis.

Are there other states that have that requirement, in other words, either you must be a certified and licensed technologist, and if you do not meet that criteria, then you must have some training and experience which is reviewed by

the state? There are other states, I understand, Arizona or Alabama?

MR. GODWIN: Arizona.

MR. CAMPER: Arizona. Okay. Any others?

MR. FRAZEE: State of Washington. We have a voluntary certification for technologists, so therefore, no, we don't have a requirement for registered techs.

I am going back to what I think I was proposing earlier. The emphasis should be on the radiation safety officer and Part 19. You have to provide adequate training for your workers.

Now, what constitutes adequate training may come into play here, but again, that is why it is important to have really adequate training for the radiation safety officer, one of which should be how to train his technologists.

MR. CAMPER: During our meeting in Atlanta there was a fair amount of talk, and there were some suggestions that perhaps this idea of having an authorized user listed on the license and being only a physician is something we should consider abandoning, and that perhaps we should have physician-authorized users, as well as other authorized users, for example, technologists, if you will, who are handling the materials as a matter of routine.

In answering these questions, what are your

thoughts about that, as well, in terms of listing the authorized user under a certain category, physician user, and/or listing technologists as yet a distinct and different category of authorized user?

MR. TEDFORD: Tedford, Alaska.

I wasn't going to speak to that question, but as long as I am up here, I will.

MR. CAMPER: Okay.

MR. TEDFORD: I think, if you look, authorized user has to be a physician.

MR. CAMPER: That is correct.

MR. TEDFORD: You might get into the problem of practicing medicine in particular states, the way they may interpret the law. That is my comment on it, for what it is worth.

I would like to digress for a moment on these courses that are given for qualification of individuals who are not board-certified to practice nuclear medicine, if you will, and some of the courses are given across the country.

Some of these programs in various states who certify x-ray technicians, nuclear medicine technicians, look at qualifications, et cetera, also have other categories of qualified individuals, like practical technologists.

To do that, they must establish a course or a

criteria for that course, a certain number of hours that the subjects will be given, et cetera. They usually will send their people from a board to go out and to visit and to check on these schools to see what they are actually giving and that they do meet these criteria.

I think that is what is needed in the case of your people who are nuclear medicine, as well. Some sort of check should be performed to ascertain the quality, the quantity, and what is actually being given in some sort of an established criteria course.

MR. BAILEY: Bailey from California.

I would suggest exploring the use condition that says by or under the supervision of Dr. so-and-so, or I would say in our case, by or under the supervision of Dr. so-and-so, users under the supervision must be certified technologists, or whatever, very similar to what you do in some of the broad-scale licenses or big licenses that are not true broad licenses with 3 to 83, and all that, where you allow people to work under the supervision of somebody. Otherwise, you are going to be adding names all the time.

MR. GODWIN: Godwin from Arizona.

I made a suggestion a while ago, I would stick by it. It is not unanimously agreed to by the states around, but I think it is one approach.

An alternative may be to put the criteria in the

regulations and say that people who meet those criteria are indeed authorized users, so you wouldn't have to put names on the license, and the inspector would simply have to check to see if everybody meets that qualification.

However, then you run into the little problem of what happens if they have lost their certification or what happens if they have malpractice, and all those kinds of ramifications. There are several approaches to it.

But I think it would be good to clearly have the radiation safety officer spelled out on the license. I personally like the idea of the physicians being listed as a prescribing physician -- I think that is more in line with what he actually does -- and the technologist listed as a user, authorized user, preparing user, or whatever you want to call it, because that is more in line with what they do.

The comment could be made if you go that route that, well, you have taken away the responsibility of the physician for the overall operation of a radiation safety program in the hospital.

There are a fair number of hospitals where the physician is technically an independent contractor, is not an employee of the hospital, and really has no legal association with the employees except by whatever the hospital assigns to him, so hospitals are responsible anyway, so I don't see where that would make a whole lot of

difference.

If it is a private physician operation, he will be the named licensee, and the licensee is responsible. So, I think you can at least explore that some. I am sure there are some other legal questions that should be raised about that.

MS. ALLEN: I have a bunch of answers for you.

MR. CAMPER: Great.

MS. ALLEN: First of all is yes. Second, we have technologist accreditation in our state. If you don't keep your accreditation up to date, you are fined.

DR. GLENN: A clarification on that. You have it in your state. If NRC licenses users in a state that does not do that, should we assume that function?

MS. ALLEN: Okay. The problem is what you should do is contact other states that do have technologist accreditation rules, see what they are, see if there is any common ground, see if you can come up with a commonality before you delve into that, because I don't know if every state would want to do what we do, because we cover both x-ray and materials, and you guys of course don't believe in x-ray -- I mean recognize x-ray, sorry.

If you have someone other than a physician as an authorized user, I have to bring up Rita's point again. You are already going to potentially authorize deviations from

the package insert with approval by an authorized user. Does the technologist at that point have the experience to be able to deviate?

DR. GLENN: We would be sure not to do that. I mean if we changed definition of authorized user, then we wouldn't allow authorized users to prepare or compound or whatever you want to call it. We have to make sure we are consistent there.

MS. ALLEN: And something to keep in the back of your mind, not all RSO's live at the hospital. Some are consultant RSO's that travel across many miles, some are just a physician or so that share between many hospitals, and some of the things that I have heard don't really jibe with consultant RSO's or physician RSO's shared among many facilities.

MR. CAMPER: Let me see if I can try to wrap this particular one up. What I think I am hearing is something like the following. I think most of us would agree that certified technologists is optimal, licensure by states is optimal, but in those cases, from a public health and safety standpoints, as regulators charged with protecting public health and safety from the use of radiation, we would tend to agree that there should be some minimum level of training and experience, absent licensure or certification by the state, for technologists that are handling radioactive

materials for diagnostic or therapeutic uses.

Is that fair, yes?

[A show of hands.]

MR. CAMPER: I see a few hands. Okay. Does anyone disagree with that? Rita?

MS. ALDRICH: What I said before is we are tying it to the function. What do you mean by handling? If you have a private office where you have nothing but unit doses, and the physician does the injections, and you have a tech, but the tech doesn't do very much, maybe calibrates, there aren't enough of these people to go around. There aren't enough certified techs to do this.

We thought about trying to factor this in, and we decided we would start with generators because nobody should be handling a 2-curie generator without some demonstrated training and experience that has been tested. I think certification is the only way to go on that.

I don't think there is anything much else besides certification that we would want to do on a state level. We already have basic requirements, as was said before, for training of employees. I think you can get into a lot of trouble about just what it is this person does that requires some level of training and experience.

The reason the State Education Department hasn't licensed nuclear medicine technologists is the fear that

there would not be enough people to go around. What we are encouraging those techs to do is to get certified, you know, cross-trained x-ray techs that are licensed. New York State does license x-ray techs, get certified, you know, be prepared, because it is in essence rationing, but there has got to be a point at which you would say no, this person doesn't need it, you know, I mean what exactly are they doing. You use unit doses, I mean what is this person involved in.

MR. TELFORD: Telford, NRC.

I would just to provide a clarification for the record. In the draft rule language that we gave out at noontime today, under 35.100, 35.200, and 35.300, for those persons that would either be doing or authorize a departure from the package inserts, as Kathy and Rita alluded to, would be two types of persons.

One would be the authorized nuclear pharmacist, and the second would be a physician who is an authorized user, who also meets the training requirements of 35.920. That is the requirements that Larry has been talking about today, of the 200, 500, and 500 hours.

It is only that physician, not the physician that qualifies under 35.100 or 35.300 -- I am sorry -- 35.910, 35.930. Only the physician that qualifies under or meets the requirements of 35.920 would be allowed to make the

departures or direct the departures.

Therefore, as Dr. Glenn has pointed out, if we make a change in definition of authorized user, we would be sure to carry that through.

MR. CAMPER: Thank you, John.

A little bit different type of question. Should the NRC require the physical presence of a qualified radiation supervisor, that being a physician, a physicist, a pharmacist, or a technician or a technologist, at all times when byproduct material is being used?

I see Aubrey nodding in the affirmative. I think Ed is nodding in the affirmative. Any other thoughts or feelings about it?

DR. GLENN: Any negatives?

MR. GODWIN: I think you need to stress that any one of those present would be adequate. I do not see a need for necessarily a physician to always be present, and I would limit the definition of use, that after a patient has received a dose by injection, that going back to the room would not be part of it, spending the night, for example, and things like that, would be under normal hospital care or with special instructions if it is a therapeutic dose.

MR. BAILEY: I would agree with what Aubrey said with one exception, that physician, user physician, authorized physician should be present in the room when

therapeutic doses of liquid iodine or therapeutic doses of iodine are administered orally, over 30 millicuries.

MR. CAMPER: Any other thoughts? Rita, did you have a thought?

MS. ALDRICH: I am not sure I understand the question directly. Are we talking about supervision from a radiation safety standpoint, RSO-type functions? We made a change to our regulations last fall that defined radiation safety officer qualifications for both x-ray and nuclear medicine, because they hadn't been really clear before.

We put in there a requirement that for radioactive materials programs, the radiation safety officer has to be present 50 percent of the time when materials are in use, but the way we are interpreting that is in nuclear medicine, during the period, the time of the day when doses are being prepared and/or administered, because under -- I digress -- but under our allowance for technicians to inject, there is a supervision requirement.

It is under the supervision of the physician on the premises, doesn't have to be in the room, but has to be on the premises.

With the rising problems, we have blood-borne disease transmission, we are falling back on that more and more. The physician has to be present anyway, so if it is a one-man office, you know, we have pretty much tied him to

the premises if the technician is injecting, at least while the technician is injecting.

If we are only talking about the radiation safety officer, whether that is the physician or it isn't, the person has to be present 50 percent of the time when materials are in use, because our approach is that if that person is responsible for radiation safety during handling, they have to be there when the handling is going on or they are not going to know whether or not people are complying with procedures.

DR. GLENN: I think this question was probably more generated by what I will call the circuit-rider syndrome, where in a fairly remote area there will be a group of physicians and maybe actual presence at the facility by the physician is one day a week, and the question would be, well, it is unreasonable to say the physician has to be physically present, but should we have some person, be it an RSO or a technologist who has received a certain amount of training, always present whenever material is being used with the qualifiers that Aubrey has suggested.

MR. CAMPER: We have very little time left. As Vandy pointed out, we need to be out of here by 4 o'clock, so let me ask just one more question. I am sorry.

MR. GODWIN: If I could expand just a little bit.

MR. CAMPER: Absolutely.

MR. GODWIN: There is a corollary question that wasn't asked, do you want to require the nuclear medicine physician or the authorized user physician to be within some travel time from the hospital or wherever it is being administered.

We had at one time physicians in Texas prescribing in Alabama. They were legitimate licensed Alabama physicians, but they lived in Texas. That did cause us a little problem.

It seems to me you would want them within an hour or so of the facility in the event something happened, some sort of reaction happened where the other physician could probably take care of the reaction, but you would like for them to work with any radiation-related problems.

However, if they are not the radiation safety officer, you maybe can get away from that, so you ought to consider that as part of your work-up.

MR. CAMPER: Assuming the medical institutions were following the criteria in Part 35 for physician training and experience, should NRC rely upon medical institutions to review the training and experience of physician, authorized user, or applicants, and make that determination without notifying NRC?

In other words, we know that currently broad-scope

licensees can in fact review the training and experience credentials of physicians, applicants who want to be authorized users, and they maintain records that they have conducted this review process within the Radiation Safety Committee minutes, or something of the sort.

Should limited specific licensees, medical institutions be able to do the same thing?

MR. GODWIN: Godwin of Arizona.

I can give you Alabama's answer. The Medical Advisory Committee in Alabama said no, they want to review the first time a physician came in to practice in Alabama, after that, then the hospitals could review the limited scope, but absolutely the first time they got licensed in Alabama, they had to be reviewed by the medical committee.

MR. CAMPER: I see Vandy moving around back there, and I know we are getting close to the time, so I think I will stop asking questions, but I would like to make just one more question of a general nature.

Is there some issue that we have not discussed thus far or that you thought of in looking through the Medical Issues Paper that you would like to put on the floor, that you view as being very important, so we can consider it further? Yes, sir.

MR. KASYK: George Kasyk, Department of Labor.

This is not only for medical, but for all the

other applications. If we require somebody to be present, it does not necessarily mean he will see the application. I think it should be clarified that he should witness the operation, not just be present. He can be in another room for a whole year, and never see anything.

MR. CAMPER: Okay. Any other general thoughts about issues of importance?

MR. ZALOUDEK: Yes. David Zaloudek with Louisiana.

I was wanting to make sure we are filling in all the gaps, if there are any. You all may be familiar with the task force on RSO's, and I was wondering if you could give us a status report on where that stands for medical facilities.

DR. GLENN: We plan to initiate that. It has, unfortunately, been put on hold simply because the resources of the Medical Section, Mr. Camper's section, have been overstressed to the breaking point this fall.

We hope in the spring to actually activate that task force and get that moving. The end product we hope will be a new reg that will help answer some of those questions that institutions are always asking us, well, how many people should we have the radiation staff, how should a radiation safety committee function.

We hope to do a rather in-depth look at that.

MR. CAMPER: Yes. I would only agree that we think that is very important, and the new reg, when we ultimately develop it, we think will answer a lot of the questions about resources and duties and responsibilities, and we are going to get back to that, we really are.

I do want to say one more thing, Vandy, if I may. I think all of you know that Steve Collins has been serving on our Advisory Committee for the Medical Uses of Isotopes as the States' representative.

The staff recommended, and the Commission agreed, that we should rotate Steve from the ACMUI, so as to allow maximum participation by as many Agreement States as possible, and the Commission agreed with that.

Consequently, we have out currently, published on the 16th of October, a Federal Register Notice calling for nominations of new members to the Advisory Committee on the Medical Uses of Isotopes. It is calling for a States' representative, a regulator, or someone with a states' perspective on regulation.

I would encourage you, if any of you are interested, to self-nominate or through your organizations, to nominate individuals, so we may consider them for participation on the ACMUI.

Steve has done an excellent job, giving us the States' perspective, but we do really feel, and the

Commission feels, that we should try to get maximum participation, so please bear that in mind, that the nominations are open right now. I have extra copies of the FRN if anyone would like to see it.

CHAIRMAN MILLER: It is now time for us to draw this public meeting to a close. I had one program director say to me that he has been in a program in one of our states for over 30 years, and this is the first time NRC has ever asked him for his opinion on something.

So, I certainly think we ought to salute Dr. Glenn and his fine staff here today in this public meeting for asking your opinions on a lot of different subject matters today, and you certainly have given them some good input, and you have not heard the end of any of these topics, I will assure you, because I was just watching them writing down these fabulous notes, but we have a good court recorder over here to my right, so if they missed something, they certainly can get it out of the record, and I am sure that they are going to take all of your comments to heart.

I do want to further say, though, that this has been a rather long week and some of the States have departed already, so whenever you are getting these counts, just remember that we did not have all 29 States raising their hands on each of your questions. Keep that in mind.

Of course, we had some usual ones every time, and,

Aubrey, I certainly want to thank you for being right in on everything that was asked here today.

[Laughter.]

CHAIRMAN MILLER: And your colleague, Ed Bailey, Terry Frazee. I can depend on you all. I told them that you all would definitely stay to the end, and you certainly have done that, and I want to salute you for being able to do that.

Now, I do have a couple of other comments to make. During this week, we received a letter from the State of Oklahoma, from the Governor, saying that they would like to seek Agreement States status, and that is the kind of thing we like to hear.

In fact, Oklahoma was here this week, at this All Agreement States meeting, and we normally try to invite those non-Agreement States to the meetings who have shown some interest in becoming an Agreement State.

So, we found out that this is happening this week. The letter is on the way.

There is also an announcement concerning the FFE3 meeting that was scheduled. That is the full-field exercise. That has been canceled. You can appreciate all the problems that FEMA is being faced with at this time, such as the steel problems with the hurricane out of Miami, Florida, et cetera, so they have their hands full, and they

didn't say when this is going to be rescheduled, but right now it is off.

Now, I want to take this time to thank the various program officials of NRC, especially NMSS and Research, for their contributions to this public meeting today and for their contributions in the two and a-half day All Agreement States meeting, because without the other program offices' support, this meeting would not have been as successful as it was.

Certainly, I can't say enough about the Agreements States themselves who really made a tremendous contribution to the All Agreement States meeting, and you certainly added immensely to this public meeting today.

I opened the meeting up this morning saying I made a little boo-boo yesterday, and that was because I did not mention Wayne Kerr as the new Chair for the Organization of Agreement States. This morning I was trying to find him in the audience, and he slipped my vision, and I didn't get a chance to focus on him, so I said I would just deal with this later.

So, that is what I really wanted to tell you, but I certainly did not mean to slight Wayne Kerr yesterday when I was talking about the relationship with the Agreement States organization and talking about Dr. Mary Clark coming in as the new Chair-Elect, but we have got a Chair already

that has got to perform for at least one year before she moves in for her year. She is still here with us right now, too, by the way.

I also want to again thank the State of Maryland, Roland Fletcher, and his in-house staff. He is the only one that is not here, but I see all of his staff members still here. We are just delighted about that.

You certainly have been a great host for us for this week, starting out on Monday and going right through to the final hour of Thursday, and we thank the State for hosting the annual meeting and this public meeting.

I would be remiss if I didn't say a few kind remarks about the hotel, because the Sheraton of North Baltimore here has really put on a good professional atmosphere for us here at this hotel.

I can't think of anything that we can complain about. The rooms were very nice, the people that are on the staff did everything they could to make your stay very wholesome, and we certainly want to commend this hotel for making our week very successful.

Then, too, we have had two recorders, two court recorders here this week, and you know, they work the hardest because they must document everything that takes place, and certainly I would like to thank the young lady here to my right, and she can also pass that on to her

colleague who she replaced in the middle of the week. I just want to say one word to them, we will certainly be looking forward to the final report.

I think now that I have covered about everything that I really wanted to cover, and the report of these proceedings, both the All Agreements States meeting and the public meeting today, will be placed in the U.S. Nuclear Regulatory Commission public docket room for public access.

Now, before I close, there is always somebody that needs to say one last word.

Is there someone that would like to say the last word?

[No response.]

CHAIRMAN MILLER: If not, then, again let's give this distinguished panel a big hand.

[Applause.]

CHAIRMAN MILLER: We call the public meeting to a close at this time. It is now four minutes after 4:00.

[Whereupon, the Public meeting concluded at 4:04 p.m.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

In the Matter of:

NAME OF PROCEEDING: Medical Issues Paper and Other Regulation Issues

DOCKET NUMBER:

PLACE OF PROCEEDING: Towson, Maryland

were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

Debbie Tallman

Official Reporter
Ann Riley & Associates, Ltd.