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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the matter of:

COMMISSION MEETING — Docket No.

BRIEFING ON SECY 83-62, PROPOSED REVISION TO 10 CFR PART 35, "HUMAN USE OF BYPRODUCT MATERIAL"

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NUCLEAR REGULATORY COMMISSION

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BRIEFING ON SECY-83-62 - PROPOSED REVISION TO

10 CFR PART 35 "HUMAN USE OF BYPRODUCT MATERIAL"

- - -

PUBLIC MEETING

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Nuclear Regulatory Commission
Commissioners' Conference Room
11th Floor
1717 "H" Street, N.W.
Washington, D. C.

Tuesday, April 19, 1983

The Commission met in open session, pursuant to notice, at 10:03 o'clock a.m., NUNZIO J. PALLADINO, Chairman of the Commission, presiding.

COMMISSIONERS PRESENT:

NUNZIO J. PALLADINO, Chairman of the Commission
VICTOR GILINSKY, Member of the Commission
JOHN F. AHEARNE, Member of the Commission
THOMAS ROBERTS, Member of the Commission
JAMES K. ASSELSTINE, Member of the Commission

STAFF AND PRESENTERS SEATED AT COMMISSION TABLE:

S. CHILK
J. MALSCH
J. ZERBE
J. DAVIS
R. CUNNINGHAM
W. WALKER
B. OLMSTEAD
W. SPELL
R. ROBINSON
O. LINTON
K. WHATLEY
J. DELMEDICO
P. VACCA

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P R O C E E D I N G S

CHAIRMAN PALLADINO: Good morning, ladies and gentlemen. The Commission has before it consideration and action by notation vote a proposed rule-making that would significantly alter the licensing processing for medical use in byproduct materials.

The purpose of this morning's meeting is to learn from the staff what the proposed revision entails and some of the rationale behind the changes that are being suggested, and also to hear from representatives of several groups who would be directly affected by the proposed revision.

With us this morning in addition to the staff are Mr. William Spell who will comment from the viewpoint of the Agreement States, Dr. Ralph Robinson, President of the American College of Nuclear Physicians representing the views of that organization and the Society of Nuclear Medicine, and Mr. Otha W. Linton who will speak on behalf of the American College of Radiologists.

I understand that there are differences of opinion both within the NRC staff and among the organizations represented this morning with regard to some features of the proposed revision. One of the purposes of this meeting is to identify and discuss these issues. I would invite the speakers to comment on them at the appropriate time. Unless other Commissioners have opening comments, I would turn the

meeting over to Mr. Davis.

COMMISSIONER AHEARNE: Could I ask one question? Since many of the questions that we might have of NMSS may be addressed by the following speakers, will we be able to get back to questioning NMSS after the other three speakers, in which case I would hold most of my questions until then?

CHAIRMAN PALLADINO: I would expect that we would be able to do so, sure.

COMMISSIONER AHEARNE: Fine.

CHAIRMAN PALLADINO: Are there any other comments?

(No response.)

CHAIRMAN PALLADINO: We will try to allow the presentations to go as smoothly as possible so we have time to return to questions.

MR. DAVIS: Thank you, Mr. Chairman. First as you say, we are here today to talk about a proposed rule-making to Part 35 of the "Human Use of Byproduct Material." Byproduct material licensing as I am sure you know is one of the oldest of the regulated activities by NRC. It has been regulated by NRC and its preceding agency, AEC, for about 35 years.

At one time it was the principal licensing activity of the AEC.

COMMISSIONER GILINSKY: In the good old days.

MR. DAVIS: In the good old days. Medical licensing, of course, is a subpart of this byproduct material licensing

and constitutes a major use of radioactive material.

Currently under NRC jurisdiction, there are about 2,500 hospitals and physicians that are licensed and about an equal number, perhaps a few more, by the Agreement States. These administer about 15 to 20 million medical procedures per year using radioactive materials.

In turn, we have a fairly large workload of applications associated with the handling and regulation of these licenses. We get about 2,500 applications per year for some either new license, modification to a license or a renewal of medical license. So it is a fairly large flow of work.

Over the years the licensing program has been modified principally on an ad hoc basis. About 18 months ago, we began a systematic look at medical licenses and what you see today is a result of that systematic look.

Dr. William J. Walker, Jr., who handles the medical and academic licensing section in our division of Fuel Cycle Material Licensing will be our principal speaker.

COMMISSIONER GILINSKY: Does "doctor" mean medical doctor?

MR. DAVIS: No. He would make more money outside. In any event, he will be handling it. We have a briefing prepared which will speak to why we think the change is needed in doing the re-look, what our goals were and in general terms

what the changes are that we are proposing.

Basically the changes which Dr. Walker will go into in some detail are two, a change to the rules and then a change to the processing internally of applications. So there are two approaches which are contemplated.

Now there are other staff members here in the audience, two of whom wrote the Commission expressing some concern about the approach being proposed and both of them are here to answer any questions you may desire to place to them.

COMMISSIONER GILINSKY: I hope we will be able to hear briefly from them at the conclusion of the presentation.

MR. DAVIS: However you desire to interface with them, is fine. I will turn this now over to Dick Cunningham who heads the division under which this is done.

MR. CUNNINGHAM: Mr. Chairman, I think just to expand a little bit on what John said and why we changed this rule, if you look back over the last 30 years in nuclear medicine, it has been marked up until about five years ago with rapid growth in technologies. New technologies were developed quite rapidly.

Over past five years though, nuclear medicine has pretty well stabilized in the development of technologies although new radiopharmaceuticals are being added to the list of drugs used for patient management. But the technology

involving procedures, safety procedures, and so forth have fairly well stabilized and we have what is now a rather large and mature nuclear medicine industry. The consequence though of this growth in technology over the last couple of decades has resulted in regulations not keeping up to date with -- complete integrated regulations not keeping up to date with these changes.

Our licensing procedures are scattered through regulations, guides, license conditions, staff technical positions and so forth. The consequence of this proliferation of bits and pieces of rules and requirements has been that we get poor applications often and the license reviewers must spend a lot of time reviewing the details of the application to be sure that everything is in place.

Given the resources we have and the pressure to act on these applications quickly as quickly as we can for good reason because they affect the ability of hospitals and physicians to manage patients, the staff has had little time to concentrate on the major issues of safety significance.

Just as an example, a few years ago, we were advised by our medical advisory committee as well as some other organizations that we ought to substantially increase the training requirements for physicians practicing a broad range of nuclear medicine. The staff action on that was delayed almost a year simply because of the need and the pressure to

review applications. It was about that time that we decided a major overhaul was needed in these regulations so that we could streamline what was required from applicants, consolidate it, integrate it, and put it in one place so that we could use our resources addressing the major safety issues, training, for example.

No matter how detailed we would look at procedures in nuclear medicine practice, the quality of the program ultimately rests on the training of the physician. If you have been in nuclear medicine laboratories and see the movement of patients and the volume of traffic through these, you know that in the final analysis what you are really looking for are well-qualified practioneers.

It is these kinds of issues that we should be addressing. That resulted in forming the task force which Bill Walker headed to try to streamline and integrate these regulations and get them in one place to the extent possible and allow the staff to concentrate its resources on those matters which are of more importance to safety significance.

With that supplement to what John said, I will turn it over to Bill to explain what we did and why we did it.

MR. WALKER: Thank you, Mr. Cunningham. Mr. Chairman and Mr. Commissioners, I have slides prepared and I think each of you has a copy of these and I will speak from these if I may, please, I think it is important to point out that

the task force that actually worked on the revision of the rules and the procedures was composed of representatives from all the major offices of NRC, NMSS, Research, ELD, The Office of Administration, Inspection and Enforcement including representatives from each of the regional offices, the Office of State Programs and two representatives were appointed from the Agreement States to sit on the task force.

The major drafting committee, as it were, was composed of representatives from NMSS, Research and from ELD.

The first thing that I think we need to address is why we wanted to change this. The current requirements as they are imposed on nuclear medicine are patchwork. The current Part 35 was put together in 1967. It has been amended quite frequently since then. I counted this morning something on the order of about 26 or 27 amendments to those regulations. Many of these were added in what was or appeared to be appropriate fashion, but makes it very difficult to read.

It is now confusing not only to the applicants but to the NRC staff that must impose the regulations. The regulation, however, is supplemented with requirements from numerous other sources, guides, individual policies, standard conditions which have been developed over the years by the staff.

The need to support such a cumbersome set of requirements means that the licensing process itself must be

cumbersome. So we need to look at overhauling the licensing process itself because the current process is neither efficient nor effective. I think we can point to the fact that frequently questions are asked from this Commission about our backlog. I think Mr. Davis and Mr. Cunningham have shown that that was part of our problem.

COMMISSIONER AHEARNE: Could you just give me a feeling for how big a backlog there is?

MR. WALKER: I have some figures. I thought we might have a question on that one. The backlog if you count actions over 30 days that are pending at this particular point and these are 30 calendar days in-house, total actions, there are 189 of them right now.

COMMISSIONER AHEARNE: Did John say you have about 2,500 per year?

MR. WALKER: Oh, no.

COMMISSIONER AHEARNE: How many do you have per year?

MR. WALKER: Total actions per year, we are projecting 6,700 total actions per year.

COMMISSIONER AHEARNE: All right, 6,700 per year and you have 189 that are over 30 days.

MR. WALKER: Correct. In house at the current time, we have all actions of any age approximately 1,200 of them right now.

COMMISSIONER AHEARNE: What is the average time

it takes to get this process in action?

COMMISSIONER GILINSKY: Did you say there were only sixty some-odd that have been here over 30 days?

COMMISSIONER AHEARNE: One hundred eighty-nine, which is a pretty small number.

COMMISSIONER GILINSKY: That is what I thought.

MR. WALKER: But these are over 30 days and there are a number of those that have been here a considerable length of time beyond that.

COMMISSIONER AHEARNE: What is the average length it takes you for an action?

MR. WALKER: I have some figures on that, too. It depends on the action itself.

COMMISSIONER AHEARNE: Obviously there is wide variety.

MR. WALKER: The processing time on medical applications for March in 1983, it was 77 days and 219 actions. So that gives you some idea of where we are right now.

COMMISSIONER ASSELSTINE: Bill, when you say 219 actions for medical applications, I take it that includes new applications, renewals and modifications.

MR. WALKER: And amendments. Correct.

COMMISSIONER ASSELSTINE: Does most of the effort basically go to new applications?

MR. WALKER: Our priority system calls for us to

process a new application first.

COMMISSIONER ASSELSTINE: I gather the renewals, you don't go through and check everything all over again. It is the responsibility of the applicant to identify the areas where they are changing.

MR. WALKER: That is correct.

COMMISSIONER ASSELSTINE: How many new applications do you get per year?

MR. WALKER: We are expecting receipts for new applications projected for the year of 700. This is just not medical. These are all applications. I didn't break all of these down. The processing time, however, that I gave you was for medical applications.

COMMISSIONER ASSELSTINE: Could you give me a general idea of new applications for medical? A number.

MR. WALKER: I would say probably in the order of 45 to 60 days.

COMMISSIONER ASSELSTINE: Number in a year.

MR. WALKER: Number in a year, the '83 receipts for new medicals was 128.

COMMISSIONER GILINSKY: These licenses are for what now?

MR. WALKER: The greatest majority of them are for nuclear medicine services diagnostic type implementation.

COMMISSIONER GILINSKY: They permit what? Use of

radioactive isotopes for some period of time or what?

MR. WALKER: The license is issued for a period of five years and is renewed after that five years.

COMMISSIONER GILINSKY: So presumably people can send in an application well in advance of the end of the five year period? It doesn't sound like a couple of months is a great burden.

MR. WALKER: We send out reminder notices at 90 days before the expiration date. We include in the packet various information that they need for renewal. So we are talking -- but the times I am giving you are the times from the time we receive the renewal application.

COMMISSIONER GILINSKY: I understand that. I guess the situation was more under control that I thought.

MR. MALSCH: Actually for renewals, if they submit a timely application, the license is continued automatically in effect until the staff acts on it.

MR. DAVIS: There are three different types of applications here. One is for new, and by new we mean an institution or a physician who has not previously used the material. Those are the ones which run the opportunity if we delay of interfering with the practice of medicine.

COMMISSIONER GILINSKY: Except that one doesn't just go into nuclear medicine all of a sudden. There is a long planning period no doubt.

MR. DAVIS: I would hope so.

COMMISSIONER GILINSKY: And part of that planning period is planning to get a license.

MR. DAVIS: The second are amendments which are, of course, are authorizations to change what they are doing on a pre-existing license. That is the largest flow of applications. We get about 2,000 of those per year.

COMMISSIONER GILINSKY: Can you just give me one example of what we are talking about here?

MR. DAVIS: How about the example of extending the use to a different use?

COMMISSIONER GILINSKY: Add additional isotopes to the list?

MR. WALKER: Add additional isotopes to the list or add a new user or change a radiation safety officer, something like that.

CHAIRMAN PALLADINO: Do they involve a change in procedures?

MR. DAVIS: They may or may not.

CHAIRMAN PALLADINO: I meant, included among them may be some that involve a change in the procedures.

MR. DAVIS: Yes, it could be.

CHAIRMAN PALLADINO: It could be other procedures in the license?

MR. DAVIS: Yes. The third category is the renewals

and that is the one where the timely application would apply. These are the ones that get the lower priority and we get about -- we are projecting about 550 of those.

CHAIRMAN PALLADINO: I was going to say, aside from the timing and workload problem, if there is confusion among the regulations, I think --

COMMISSIONER AHEARNE: I was just trying to get an understanding. They mentioned that they were trying to make it more efficient and talked about the backlog, so I wanted to get a handle on that.

You also said that you want to make it more effective. Do you have some indication that the current approach is not effective?

MR. WALKER: It is not effective in soliciting the submissions that we want from the licensee simply because the licensee frequently does not understand these.

COMMISSIONER AHEARNE: I made the assumption that effectiveness was that there was adequate protection of the public health and safety.

COMMISSIONER GILINSKY: Are patients protected?

MR. WALKER: I think patients are well protected.

COMMISSIONER AHEARNE: As far as that type of effectiveness is concerned, the fundamental mission of the NRC of providing adequate protection of public health and safety through the regulated use of radioactive materials, you are

not raising into question effectiveness of that, are you?

MR. WALKER: No. I am talking about the effectiveness, I think, of the process itself that we are looking at.

COMMISSIONER ASSELSTINE: If, as you said before, that the present jumble of guidance whether it is in the regulations or in various other guidance documents is confusing and the licensees or applicants don't understand or may not understand all of those requirements, it seems to me that does have an implication on public health and safety.

COMMISSIONER AHEARNE: Jim, I can see that that could have a potential for it but I was trying to draw a contrast between in the 1970's there were really real charges of the effectiveness with the public being adequately protected. I wondered whether that was the issue here.

COMMISSIONER ASSELSTINE: All right.

MR. CUNNINGHAM: If I may expand on this a little bit, as Commissioner said we don't get that many receipts of new applications simply because most hospitals have nuclear medicine services.

By far the bulk of our work is in the license amendments. Those license amendments are rather important because many of them involve adding a new drug to the procedure or a new physician that is allowed to use or work under the license and so forth.

When it gets to effectiveness, there are several ways to look at it. Certainly if effectiveness means efficiency, then the consolidated procedures help. There is as Commissioner Asselstine pointed cut, effectiveness in the people who use these things fully understanding what they are required to do and why they are required to do it.

There is another part of effectiveness. To the extent that the system is inherently inefficient, the delays in issuing those amendments means that certain types of drugs in that period are not available for patient management. That affects public health and safety in a way that is somewhat different than we normally consider it but it is there.

COMMISSIONER GILINSKY: You are talking about something like a two month period, is that it? Does this 77 days characterize the time for amendments?

COMMISSIONER AHEARNE: If I understood your numbers correctly, it would be over 200 actions and a total of 77 days, is that correct?

MR. WALKER: Yes.

COMMISSIONER GILINSKY: Earlier, it sounded like it would be less than that.

COMMISSIONER AHEARNE: Less than three days per action.

COMMISSIONER GILINSKY: I see.

COMMISSIONER ASSELSTINE: Yes, that is right.

COMMISSIONER GILINSKY: I guess I didn't follow that.

COMMISSIONER AHEARNE: When I asked you what was the average time, you gave me, you said here is the number of actions and here is the number of days.

MR. WALKER: That is correct.

COMMISSIONER AHEARNE: My interpretation of what you meant was that the sum total of all of the days that were taken for all of those actions.

COMMISSIONER GILINSKY: It is like a third of it.

COMMISSIONER AHEARNE: So, do I divide the number of actions by the number of days to get the average days per action?

MR. WALKER: No. These are the average days per action.

COMMISSIONER AHEARNE: Seventy-seven days.

COMMISSIONER GILINSKY: No. It is 77 days before the thing gets out. People aren't working on it for 77 days.

MR. WALKER: They may have started working on it the first day it came in but from the time it comes in to our door the first time until we sign the license and send it out is averaging 77 days.

COMMISSIONER GILINSKY: How many man-days or woman-days per action?

MR. DAVIS: You are talking, how much time does it take to issue a license. Is that your question?

COMMISSIONER AHEARNE: Yes.

MR. DAVIS: How much applied staff time?

COMMISSIONER AHEARNE: Yes.

MR. DAVIS: We will have to get you that information.

COMMISSIONER GILINSKY: Do you have any idea?

MR. DAVIS: It varies greatly.

MR. WALKER: We do have work factors that we calculated.

CHAIRMAN PALLADINO: However, I would caution against jumping to saying it takes so many staff hours to do something because sometimes to make a telephone call for me takes three days.

(Laughter.)

CHAIRMAN PALLADINO: Because I try to call and I don't get somebody and they have to call back. You all have had the same thing happen. Then when I get the person, they have to check the information and accumulate it to respond to questions. So I caution.

COMMISSIONER GILINSKY: But this is the way we plan our work.

MR. DAVIS: What I can prepare you which we don't have with us, we can give you the work factor for new applications, amendment applications and renewal applications.

COMMISSIONER AHEARNE: Fine, which would be your planning factor.

MR. DAVIS: That is what we use in the budget.

COMMISSIONER AHEARNE: You had said that you have about 6,700 actions per year. Is that right?

MR WALKER: That was for all materials.

COMMISSIONER AHEARNE: You also said that you have about 189 which are over 30 days at the present time.

MR. WALKER: That is correct.

MR. DAVIS: Is that just medicals or all of them? We may be operating off of two bases here.

COMMISSIONER GILINSKY: I thought he said 1,200 less than 30 days and 189 over 30 days.

MR. WALKER: I have two lists. One of them is for all actions in house pending at this time. I have another list --

COMMISSIONER GILINSKY: We are not talking about medical licenses?

MR. WALKER: These are all materials licenses.

CHAIRMAN PALLADINO: Can we concentrate on medical?

COMMISSIONER GILINSKY: Why are we talking about the others?

COMMISSIONER AHEARNE: Because they are under this rule.

COMMISSIONER GILINSKY: I thought they were not

covered by this rule.

MR. WALKER: The medical days do not change very much as far as looking at a license at the industrial side and the medical.

COMMISSIONER AHEARNE: Just looking at the actions covered by this rule, strictly by this rule, can you tell us how many you expect per year? How many did you get last year?

MR. WALKER: In 1983, our expected receipts for new licenses are 128. We expect 1,972 amendments and 556 renewals.

COMMISSIONER AHEARNE: About 2,700 total actions.

MR. WALKER: Approximately, yes, sir.

COMMISSIONER AHEARNE: Covered by this Part 35.

MR. WALKER: Yes, sir.

COMMISSIONER AHEARNE: Can you then go on to talk about how long it takes you to handle these?

MR. WALKER: Yes. In March of 1983, we handled 219 medical applications.

COMMISSIONER AHEARNE: That includes what?

MR. WALKER: News, renewals and amendments. The average length of time for those was 77 days.

MR. DAVIS: That is dwelling time inside.

COMMISSIONER GILINSKY: How large a staff works on these? How many persons would work on these 2,700?

MR. WALKER: Currently there are five in my section

working on these right now. There is a regional office in Region I and in Region II. There are three people in Region III at this time and I believe there are three, also, full-time reviewers in Region I.

Now they don't work just on medical licenses in the regions. It is a little difficult to say how their time is split up because they will be working on several types of licenses.

COMMISSIONER AHEARNE: When you talked about the 2,700 though and the 219 and the 77 days, did that include the regions?

MR. WALKER: That included the regional totals as well.

CHAIRMAN PALLADINO: We are spending quite a bit of time on this aspect and if that is what the Commissioners wish, fine, but we do have a lot of other material to cover and I would suggest that we proceed.

COMMISSIONER GILINSKY: It looks like about one man day per application.

MR. WALKER: I would have to go back and work out some sort of a ratio of the number of actions they are doing in the region that are medical versus the other ones. If you are talking about per medical application, I don't believe that is true.

MR. DAVIS: But, again, we have the work factors

which we developed for the budget which we will be glad to get down to you.

MR. WALKER: But we are keeping track of a large number of numbers and I think it would be best if we went back and gave you these from the work factors.

CHAIRMAN PALLADINO: Why don't you submit those separately.

COMMISSIONER GILINSKY: I thought these 2,700 that John added up were the medical ones.

MR. WALKER: Yes, these are medical.

COMMISSIONER GILINSKY: You have 2,700 and you have about ten people working them, so each one does about 270.

MR. WALKER: For the regional participants, we don't have the fraction of their time right now that they are spending working on medical.

COMMISSIONER GILINSKY: I assumed that five-sixths of them were working on the medical ones.

COMMISSIONER AHEARNE: At most, it could be off by a factor of two.

COMMISSIONER ASSELSTINE: That is right. It would be downward in any event.

COMMISSIONER GILINSKY: If you assume that every single one of them is working on the medical licenses completely, you get the same number within an hour, a man-hour.

MR. WALKER: We will generate some more numbers to

verify that. I think that would be best.

To continue, our next reason was to improve the standardization and consistency in licensing.

The system requires many individual judgments on the part of the technical staff. The only way you can achieve a uniform application review or uniform application of these regulatory controls is if you are working from a well-defined base of requirements.

COMMISSIONER GILINSKY: Let me ask you. Is there some NRC publication which is a guide to getting a license or an applicants' kit or regulatory guide that brings all of this together for people?

MR. DAVIS: There is information that we send to applicants that describe how to fill out the application.

COMMISSIONER AHEARNE: There is a reg guide 10.8 which is called Guide for the Preparation of Applications for Medical Programs.

COMMISSIONER ASSELSTINE: That is really keyed in to the application as well.

COMMISSIONER GILINSKY: Is the process still confusing with this guide?

MR. WALKER: The guide makes it easier. With our form and with our guide and we say that if you come back and tell us you are going to everything in the guide, then we will give you a license.

COMMISSIONER GILINSKY: What was the reference earlier to poor applications? You said something about getting a lot of poor applications and that this was a problem? That worried me a little bit.

MR. CUNNINGHAM: It is a problem that it leads to inefficiencies. We have to write back deficiency letters. The applicant doesn't know where all of the requirements are and where to look for information and so on and so forth.

COMMISSIONER GILINSKY: Doesn't a poor application reflect on the applicant?

MR. CUNNINGHAM: Not necessarily. It reflects on his ability to know where to go and exactly what the license reviewer is going to think is necessary for him to meet to get a license.

COMMISSIONER GILINSKY: Will this guide tell him how to prepare an application in a satisfactory way? We are dealing with pretty intelligent people.

MR. WALKER: Most of the things that we ask questions about are for the most part omissions. We don't usually make them or the majority of them aren't you did it absolutely wrong, go back and redo the whole thing. It is that you didn't know what to submit to us on your application and come back and tell us that you, in fact, are going to do that.

COMMISSIONER GILINSKY: Can you give me an example?

MR. WALKER: I think as an example, he may submit to

us a long lengthy procedure and in that procedure he may not include in that that he is going to keep people from putting their lunch in the refrigerator with isotopes. He doesn't intend to let his people do that.

COMMISSIONER GILINSKY: How do you know that?

MR. WALKER: Well, I --

COMMISSIONER GILINSKY: Have we had any cases like that?

MR. WALKER: Oh, yes, we have had cases like that, but most of those cases have been cases where the guy has already said that he wasn't going to do that and so submitted it to us.

It is not a matter of really his intent but the matter of whether or not he is going to do it or not.

These are very few and far between. We do get cases like that but they are very few and far between.

CHAIRMAN PALLADINO: I wonder if we are spending our time on the most important aspects of this. From what I have read, there are reasons for making changes. I would like to hear a little bit more about some of the changes that are proposed. For example, I gather the license now has procedures in them which is different from what I believe we do in reactors and those are the sources of many of the problems and how you are going to handle it under the new situation would be of something of interest to me.

COMMISSIONER GILINSKY: Tech specs are a part of the license.

MR. DAVIS: But they are not procedures.

MR. WALKER: They are not procedures.

COMMISSIONER GILINSKY: I wonder if the tech specs aren't more analogous to the procedures you are talking about here. But in any case, why don't we go on.

CHAIRMAN PALLADINO: The tech specs do not include the volumes of procedures that are on the shelf that they refer to. I do think that we ought to discuss at least some of the aspects of their writing procedures and whether or not there are guidelines that are percedures and whether they comply with them. Those are some of the things that I think are open questions.

COMMISSIONER GILINSKY: For myself, I was trying to understand what the question was to which this is the answer.

MR. WALKER: Let me go just a little bit further. I think once I get into the changes that we are proposing specifically, I think that you will see. I am going over some of they why at this particular point.

I think the last and final thing is that we were really responding also to the Commission's policy and program guidance when the Commission, itself, said that we should make our regulations reflect the reality of nuclear technology. That the regulatory process, particularly the licensing

program should be efficient and effective and finally that regulatory decisions should be reached without unwarranted delays.

Our goals in everything we did were number one, to maintain safety. This is not to say that everything that had been put down before and had been considered by somebody as an important safety item was not relooked at. We wanted to make sure that when we changed or when we included an item of safety, that it was realistically an item of safety and consider its true impact on the overall safety of the operation.

I have also ready mentioned, I think, enough --

COMMISSIONER GILINSKY: What sort of assumptions go in to assuming that when you drop various requirements that you maintain safety, which isn't to say that there may not be good reasons for dropping the requirements, but how did you go about concluding that the dropping did not involve any reduction in safety?

CHAIRMAN PALLADINO: That is what I want to get to.

MR. WALKER: I think it is a process whereby the staff individuals look at an item and decide and I am talking about people who are well trained and experienced in the area of implementing these various safety aspects, look at these things and realistically evaluate what the implications are.

We also did such things as look at the regulations

to see if the regulations already provided for something which we were duplicating in Part 35.

COMMISSIONER GILINSKY: Are you going to go into detail?

MR. WALKER: Yes. I would like to continue right on to that. Our proposed changes took place in two ways. We consolidated all of the requirements and updated these requirements.

The second part is we looked at the process and saw how to upgrade that process so that we could develop the most effective and efficient process of licensing consistent with our need to make a finding of safety on the part of the licensee.

Let's go right to the major changes. This was in the first sheet you have here, to consolidate and update the requirements. Currently, we place these requirements in licenses on the licensees through regulation, branch policies, standard conditions of licenses and guidance protocols.

The applicants frequently do not understand the difference between a requirement and good practice and they are confused as to what to submit to us. So we propose to consolidate all of the essential safety requirements into consise and coherent regulations.

COMMISSIONER AHEARNE: No one can argue with that obviously.

MR. DAVIS: I would hope not.

COMMISSIONER AHEARNE: The only issue clearly is going to be whether the word "essential" is agreed to.

COMMISSIONER ASSELSTINE: That's right.

MR. WALKER: That blows part of my presentation. I think when you say that you put the requirements -- when you have looked at the safety requirements very carefully and then you incorporate all of these into a single document that can be used as a source for both the licensee, for the licensing staff and for other staff members such as Inspection and Enforcement.

COMMISSIONER AHEARNE: I don't think any of us are going to argue with that as a sound goal to strive for. It sounds great. The question is, are all of the essential requirements in there?

COMMISSIONER GILINSKY: The Chairman had earlier made reference to changes in the way the procedures are going to be handled. That and one other item was among --

COMMISSIONER ASSELSTINE: Training qualifications.

COMMISSIONER GILINSKY: -- training qualifications, were among those raised by some of the members of your staff. I don't see either of those covered by any of these bullets. I wonder if you could touch on those since you are talking about all essential safety requirements consolidated in concise and coherent regulations. Could you just hit those

two points? The different way that you would be treating procedures and what the significance of all that is and what we are doing now and how it will be done --

CHAIRMAN PALLADINO: I think he has that. It is on the second page. "Change in a licensee's procedure requires a license amendment," as an example on the next page.

COMMISSIONER GILINSKY: It says, "amendment required only for significant changes." If you want to wait until then, fine.

CHAIRMAN PALLADINO: I was urging us to let him go through these.

COMMISSIONER ASSELSTINE: I think it is more than just on amendments though. It is new applications as well.

COMMISSIONER GILINSKY: This is at such a level of generality as John points out, one can hardly with but at the same time, we are not coming to grips with the regulations.

COMMISSIONER AHEARNE: Realistically, one of the big issues is right now they have to put down procedures and in your proposal they are not going to have to put down all those procedures. I think that is a major change and you ought to address it and tell us about it. That is obviously one of the issues that have been raised, that does not maintain safety, so please tell us why you think it would be a good idea.

MR. WALKER: I think that when we set out to restructure the regulation, we set out to look at all of the requirements and to put into the regulation those things from fairly standardized procedures which had been developed and which are included in 10.8, those things which were essential for the licensee to comply with.

If he complies with the regulation, then those requirements are included in the regulation.

COMMISSIONER GILINSKY: Are you saying that you have a model set of procedures in the regulations?

MR. WALKER: Models which don't include all of the detail that a licensee would put into a written procedure but include the key elements. For instance, on survey meters, we state to what level they should be calibrated. We state essentially items of the calibration procedure which we think are essential to having a calibrated instrument. How he puts those together into a specific procedure to say that I am going to use the source and put it ten feet away and calibrate my instrument and this sort of thing, those parts of the procedures are required.

It is required for him to develop a written procedure that will incorporate these things in the regulation.

COMMISSIONER GILINSKY: How do we know if the procedures make any sense?

MR. WALKER: I think we rely on several things.

Number one, if you will look at the new training and experience requirements that are now incorporated into the regulation, this is where we, in fact, say that the physician's qualification or the user's qualifications are now adequate to insure that he has had training to know how to do these things.

If it doesn't make sense, then we haven't done a very good job of developing the training and experience qualifications for these users. We put this into the regulation specifically to meet that need. There have been a number of actions --

COMMISSIONER GILINSKY: What are these training requirements?

MR. WALKER: They are included back in the back here and I think probably an example, the most frequent one, the training for imaging and localization studies. On the application, the user himself states what he is applying for in terms of use and states that he meets one of three sets of qualifications. One, he has appropriate board certifications. These have been looked at very carefully to see the requirements of the board, the training that is required before the individual meets the board plus the areas --

COMMISSIONER GILINSKY: Does he send in a copy of a board certification?

MR. WALKER: Not at this point, he doesn't. At this

point it is very easy for us if he says what his name is and that he is board certified by ABR for us to go to the ABR certification list and find out whether he, in fact, is certified.

COMMISSIONER GILINSKY: Do we do that?

MR. WALKER: We do that now. I have one staff member, a licensing assistant, who checks the qualifications as they come in against the requirement. The requirement now is in the guide. It is not in the regulation. There is frequent confusion on the part of both the administration of hospitals and physicians themselves as to whether or not that is just guidance or whether it is a real requirement. When it placed in the regulation, there will be no doubt that that is a requirement.

We have put in here, I think our paragraph 35.920 which is a training requirement for imaging and localization sgudies, we go through this.

CHAIRMAN PALLADINO: Are you talking reg guide or regulation?

MR. WALKER: This is the regulation now.

COMMISSIONER GILINSKY: Then what? You said that there were three alternatives.

MR. WALKER: The board certification is the first alternative and we list the boards in 35.920. We then say that he has training -- the second alternative is to have

training and experience as specified in 10 CFR. We say that he should have completed 200 hours of instruction, 500 hours of supervised work experience, 500 hours of supervised clinical experience in basic radioisotopes handling techniques applicable to the use of prepared radiopharmaceuticals, generators and reagent kits. Then we go further to break this down and to hours of radiation physics, radiation protection.

COMMISSIONER GILINSKY: This is the requirement?

MR. WALKER: This is a requirement in the new regulation.

COMMISSIONER GILINSKY: How does he deal with that possibility? What sort of question do you ask him?

MR. WALKER: We ask him, does he meet this requirement. Then he has to state that he does, in fact, meet this requirement.

COMMISSIONER GILINSKY: Did you run a check on that of any sort?

MR. WALKER: There will be a check on that at the first inspection.

COMMISSIONER ASSELSTINE: Which may not be fore several years after the license is issued.

MR. WALKER: Right now, IE visit each new licensee approximately within the first six months of operation, medical licensees.

CHAIRMAN PALLADINO: Coming back to procedures, I think we can take some lessons from the reactor business. One, the procedures do not necessarily have to be a part of the regulation but they should be called for -- there should be a call for compliance with them which is one of the things that I think is missing in here, that if we prepare the regulation, there is no requirement that they comply with them.

I am not sure that there is any review of them made.

MR. WALKER: Yes, sir. I believe there is.

COMMISSIONER GILINSKY: In the reactor case, we do review them very carefully.

CHAIRMAN PALLADINO: That's right. And we do a lot of pretesting. We observe. We inspect. If we want to borrow taking the procedures out of the regulations from the reactor business, then I think we ought to also borrow or consider whether we want to borrow the preinspection. We go inspect before we grant the license or as part of the granting of the license.

These are some of the things that I was wondering about that we might discuss at least in connection with procedures.

COMMISSIONER ASSELSTINE: At least under the present process, you have a review of the procedures because they are

submitted as part of the application and you also have enforceability because they are part of the license under the present process. Isn't that right?

Before anyone gets a license, you all will have reviewed and approved the procedures and the procedures are spelled out as part of the license application so they are also enforcing it.

CHAIRMAN PALLADINO: Having it spelled out as part of a license application might be something that is worthwhile taking out of the license, but somewhere the procedures ought to be reviewed and approved.

COMMISSIONER AHEARNE: I think that one fundamental difference though at least in my understanding of the past has been whereas in the reactor business, we have a lot of people doing inspections so we go to plants. We go through those.

CHAIRMAN PALLADINO: I am saying we ought to do similar things.

COMMISSIONER GILINSKY: As a practical matter, it is very difficult to go out to 2,700 locations.

COMMISSIONER AHEARNE: The argument has been that in this area what you do is you send the material in and we review it and what seems the anamoly here is because of the workload, we are going to propose dropping that knowing full well, we know the difficulty we have had in getting more

people to do regional inspections and we aren't even going to have those additional people out there.

COMMISSIONER ASSELSTINE: That's right.

CHAIRMAN PALLADINO: We have 128 new ones per year.

COMMISSIONER ASSELSTINE: But you have 2,600 existing ones though.

CHAIRMAN PALLADINO: I am thinking if a new applicationcomes in, I think the procedures somewhere ought to be examined, approved and a pre-license inspection be made.

COMMISSIONER GILINSKY: How big a package are we talking about here when we talk about procedures? What is involved? When we talk about reactors, we have books full of procedures, but what are we talking about here?

MR. WALKER: You are talking about what you see in 10.8. And 10.8 includes model procedures. That is about --

COMMISSIONER GILINSKY: How many pages are we talking about roughtly?

COMMISSIONER ASSELSTINE: It is in one of these attachments.

MR. WALKER: Fifty or sixty pages.

COMMISSIONER ASSELSTINE: It is 62 pages.

COMMISSIONER GILINSKY: That is a typical procedure that you would expect and we are talking about the current rules or future rules, you would expect that good practice requires procedures of this sort be developed before nuclear

medicine is practiced. Is that right?

COMMISSIONER ASSELSTINE: In fact, an applicant can simply reference those, can't he?

MR. DAVIS: That is one of the purposes. If he will follow these procedures, then you don't have to do an individual review of procedures. If he does not follow these procedures --

COMMISSIONER ASSELSTINE: He can propose an alternative.

MR. DAVIS -- he can propose some other method of meeting the requirements.

What we have tried to do is bring the requirements together out of a variety of documents and I use requirements in a less precise term than reactors because some of our requirements have been expressed almost exclusively in positions and reg guides, and bring those into a document where you don't have to reference seven or eight things to find out what the requirements are, propose to him a standard procedure to meet these requirements and then you go by that and we proceed with the processing of the application.

If he doesn't like those procedures for some particular reason and he wants to do it another way, he can submit his own custom way of meeting those requirements at which time, as I understand it, these would be reviewed.

COMMISSIONER GILINSKY: I understood under the new rules, he would not have to submit another set of procedures.

COMMISSIONER ASSELSTINE: That's right.

MR. WALKER: This would have to meet those requirements that are in the regulation and those requirements again that we --

COMMISSIONER GILINSKY: Suppose he wants to depart from these model procedures that you have written, does he have to submit changes to you under your new proposed regulations?

MR. WALKER: Only if he was departing from one of those essential items that we have incorporated into the regulation such as to calibrate your instrument to plus or minus 10 percent.

COMMISSIONER GILINSKY: Not merely if he is departing from your model procedures?

MR. WALKER: Not merely if he is departing from the model procedures, yes.

CHAIRMAN PALLADINO: Is there any procedure with which he must comply even though he had written them? It is not clear that there is a compliance called for in these procedures.

MR. WALKER: Under the new regulation, under 35.33.

COMMISSIONER AHEARNE: Do you have a page number?

MR. WALKER: Page 54 of Enclosure 1. We have

administrative requirements for the licensee and the Radiation Safety Committee and the Radiation Safety Officer. We make the licensee responsible for not only establishing but assuring implementation of his written procedures which should cover emergency actions, periodic radiation surveys, periodic inventory of byproduct materials, safety during the use of byproduct material.

CHAIRMAN PALLADINO: Where are you reading this?

COMMISSIONER AHEARNE: Section 35.33.

MR. WALKER: At the bottom of page 54, paragraph (b), (i), (ii) and (iii).

COMMISSIONER ASSELSTINE: But if you also look at page four of the paper that you all sent up, you say, "In its inspection and enforcement role the NRC would be concerned with whether or not the requirements in the regulation are being met and not with the details of the procedures used to meet them." I took that to mean that if it is not in the regulations, you don't worry about it. It is just now what you codified into the proposed rule and the other elements of the procedures that the applicant or the licensee would use to satisfy the regulations may not even look at those as part of the inspection program.

MR. WALKER: That statement may be somewhat misleading. I think that the full intent of this was that the licensee develop and implement his own procedures. If he

has written procedures and he is not following his procedures, then I am sure, that that wouldn't --

COMMISSIONER GILINSKY: What check do you have on his written procedures? How do you know other than the fact that he says he has procedures that he has them or that they are any good?

MR. CUNNINGHAM: For certain types of procedures and Bill mentioned them, we will not review the procedures. There is a requirement that he has procedures, that these procedures be written and that his staff is trained to follow these procedures.

The details of the procedures are not ones which we would review. This really boils down to a fundamental question of what we are trying to accomplish. The things that we have considered and which as best we can determine are the major safety related issues are well identified and will be examined.

We have training requirements on physicians that probably exceed when you consider the typical way these physicians develop in a four-year residency program or something like that, probably exceed other training requirements.

What we are heavily dependent on are the ability of these physicians to operate safely. Remember what we are talking about mainly is occupational public safety not how they manage their patients.

COMMISSIONER GILINSKY: But we don't check on the training in advance of granting them a license. They simply check a box.

MR. CUNNINGHAM: We confirm that they have the training.

COMMISSIONER GILINSKY: How do you do that?

MR. CUNNINGHAM: Checking the list of residency boards.

MR. WALKER: They send us the same sort of thing in these days. I discussed this just to make sure my perception hadn't changed since the last time I looked at one with the individual on my staff that is now looking at training and experience requirements being submitted by physicians. If she comes with problems, she will escallate it to the senior reviewer, but for the most part she sees these things. When they don't meet the current criteria which has been published in the reg guide, she will go back and frequently query them just on the information that they have submitted.

COMMISSIONER GILINSKY: What do they submit?

MR. WALKER: They submit a record of the number of hours that they have spent in the various types of training, radiation protection instruction.

COMMISSIONER GILINSKY: It sounds like they would no longer have to do that?

MR. WALKER: There is no certification on here at all. This is simply their own statement of how they perceive the training they have received. The only one that there is a certification on is the clinical part where they have had to deal with the clinical use in patients. In that one, that must be signed by the preceptor.

The other form which they now submit is nothing more than their own evaluation of their requirements which is not drastically different than what we are asking here except that we are making them certify here whereby we don't make them certify on the current one.

MR. CUNNINGHAM: Part of the problem in the training requirements is that there was a fair amount of confusion among the physicians as to what the training requirements actually were.

The rule clarifies that. If somebody is going to falsify an application, there isn't too much we can do about that. If they understand what the requirements are and they certify that they have these requirements, we won't go much further than that except picking it up in at inspection time and checking boards and things like that.

We really can't prevent on this scale and it isnot imaginable that there would be any wide scale falsification of meeting the requirements for training.

COMMISSIONER GILINSKY: But there could be a

different interpretation about the degree to which a particular training is relevant and so on.

MR. WALKER: That is the purpose of the regulation.

COMMISSIONER GILINSKY: It is a little easier to check to box than to submit evidence of such training.

MR. CUNNINGHAM: It is not greatly different from what we are doing except that we tried to make the training requirements more specific and put them in a rule.

I want to go back again to the training versus procedures. We do have extensive training requirements on these people. We have identified those elements related to safety that we feel are important.

If you will look at what we are trying to accomplish and really recognize what goes on in a nuclear medicine laboratory where the record would indicate that occupational exposures are running well below ten percent of the limits. There are ALARA requirements that they have to follow in these rules, also, a procedure for ALARA.

Then you have to raise the question how much time should we be spending and utilizing our resources on the important safety elements considering what these doses are generally running and the operating experience and how much time we should be looking at these detailed procedures as to where somebody wears a lab coat or doesn't wear a lab coat which doesn't make a lot of difference in general safety

requiements.

That is the kind of thing we are dealing with in trying to trade off here.

COMMISSIONER AHEARNE: Although I have been helping slow the pace down, we have at least another 30 minutes of other people.

CHAIRMAN PALLADINO: I was going to suggest that maybe we see if you have any other significant points that you want to bring out. I think we ought to hear the visitors. I would make a comment that my general reaction was that this is a very good step forward except for a few key questions such as procedures and how we are going to make sure that they are complied with and that they are reviewed.

But I think that many other features of the proposal have merit.

Do you have any other points?

MR. DAVIS: I guess you are going to get another shot at us after you listen to the rest of the staff and maybe the points will come out during that.

CHAIRMAN PALLADINO: All right. We have had the people come in and I think it is encumbent upon us to listen to them. I wonder if we might have Mr. Spell, Dr. Robinson and Mr. Linton come to the table and have them make their presentations and then we can raise questions either with the staff or with other members of the staff.

I was going to suggest that we take them in the order that I have on my piece of paper. Mr. Spell, then Dr. Robinson, then Mr. Linton.

MR. SPELL: Chairman Palladino and Commissioners, my name is William H. Spell. I am Administrator of the Nuclear Energy Division for the Office of Environmental Affairs, Department of Natural Resources of the State of Louisiana.

I am appearing before you today as Chairman of a rather loosely knit organization which I have chosen to call the Association of Agreement States. It is not a formal grouping but it is a group that meets once a year to discuss problems of mutual interest with the NRC.

I won't go into the history of the Agreement States and, why we are interested in this particular aspect, I think that has been adequately brought out.

I would like to point out, also, that I have been asked to represent the Conference of Radiation Control Program Directors because this group has representation in all 50 states and is composed of some states which are licensing states where they license naturally occurring and accelerator for juiced isotopes.

On my right is Mr. Kirk Whatley, Chief of the Radioactive Material Licensing, for the State of Alabama, Department of Health. Mr. Whatley has served on an ad hoc

committee appointed by the Conference of Radiation Control Program Directors to review the salient features of 10 CFR 35 in this particular revision. He alont with Mrs. Mary Lou Blazek of the state of Oregon have been intimately involved in that. They did meet at one time with the NRC task force. However, I believe, Dr. Walker was absent at that particular meeting.

They have been in contact mostly by mail and telephone, I believe. Mr. Whatley is very intimately involved with the proposed changes to 10 CFR Part 35. I am indebted to Mr. Whatley and others in the Agreement States who have provided information to me in the preparation of these comments.

At the last Agreement States meeting in Gaithersburg this past September, there was enough concern over the proposed changes to 10 CFR 35 to prompt a resolution to be passed that requested that the Agreement States be afforded an opportunity to testify before the Commissioners prior the rule-making, and for this, we do express our appreciation.

We do comment the efforts of Commission staff in incorporating the various loosely woven requirements, the license conditions, the things that are contained in the Regulatory Guides and getting these all into a single consise, hopefully consise document. We have no criticism. In fact, we do commend this particular action.

The thing that we are primarily concerned on is the

method of implementing these proposed changes and in doing so continuing, we hope, to protect the public health and safety.

We don't know, at least I don't know, the answer to why is it necessary to change the method of implementation. I have asked a few questions here.

One, is it necessary because of the Commission's commitment to decentralization? Is it because there is a backlog of licensing actions? Is it because we see very little evidence of injury to the general public and therefore we feel like we can lighten up on the requirements? Is it because of the Commission's commitment to charge fees and if it were to require additional staff, would the Commission be able to raise sufficient fees to cover the cost without causing a furor and that might not be the right word?

COMMISSIONER GILINSKY: Pardon me for interrupting you, but I wonder if you could just along the way explain what you mean by the method of implementation?

CHAIRMAN PALLADINO: Thank you. I had the same question.

MR. SPELL: The method of implementation that I am talking about is primarily the lack of the pre-licensing review that you have been discussing. That is the key issue there, I think, that the Agreement States are concerned about.

COMMISSIONER GILINSKY: Good.

MR. SPELL: As I indicated, I don't have the answers

to these questions and I just want to point out some things that I feel like may occur as a result of changing this.

For example, in the decentralization process, there are some features there that we like very much. We like to be able to deal with the regional offices and the people there and they have been extremely helpful to us.

We feel perhaps that if the licensing process is carried on in the regional offices, it perhaps may cause some uniformity to be lost that has previously been in effect. I am not sure that will be the case, but it is possible.

In talking about the backlog of licenses, I checked with the State of Texas. They have approximately 600 medical licenses. I am told that it takes two reviewers and these are experienced reviewers and about half of a supervisor's time to oversee this. They have about a two-week turnaround time for the licenses.

In my own state, we have about 300 medical licenses and we have about two and one-half man-years or person-years of effort in both the licensing and the inspection part of it. So I only bring these figures to your attention to show that it can be done in less than 77 days.

One of the questions that I would raise with regard to the 77 days is, there must be some reason that it takes 77 days and I would propose that possibly part of the reason at least is that there may be problems with these applications

changing the method of doing it may not reveal all of these problems prior to issuing the license.

That is one thing that I think does need to be addressed.

I feel that a backlog of license applications and requests for amendments or renewals should not be the sole basis for changing a regulation or a method of doing business. On the other hand, if we have improvement, significant improvements in health and safety, that in itself is significant reason for changing the regulations.

As I have indicated, probably, the greatest concern of the States to the entire proposal is the lack of a pre-licensing review of radiation safety procedures and physician qualifications.

We have had various estimates given as to the number of deficient applications, somewhere in the 40 percent range, and perhaps the number of physicians who at least thought they were qualified but apparently were not based on someone's review, were about 15 percent. I don't claim these figures to be accurate.

COMMISSIONER AHEARNE: Where are those?

MR. SPELL: I really cannot remember who told me the 15 percent figure. It may have been Mr. Whatley. It may have been Commission staff. I really don't know where that came from.

COMMISSIONER AHEARNE: What about the 40 percent number?

MR. SPELL: The 40 percent, I believe, is a Commission figure. I believe I heard that figure this morning already. If I did not, I apologize.

COMMISSIONER AHEARNE: So that is the basis of your "40" and the "15" you are not sure of?

MR. SPELL: That is correct.

I think the point I was trying to make here is that you are not going to have 100 percent of the people who advance the proposal that they are qualified who actually are.

The problem then is if we do not look at these questions, a set of procedures could be implemented or an unqualified physician could be allowed to practice for a period of time before these deficiencies are noted. Then the question is, what would happen if this takes place and is this good health physics practice in allowing this.

The question of compatibility, I don't think needs to be addressed at this point except to say that even though it is not a matter of compatibility, the Agreement States do license about twice as many medical licenses as the Commission does. For this reason we perhaps have a very significant interest in it because we feel that there may be pressure on the states to adopt similar if not identical regulations.

We also have a possible problem with suppliers of radioactive drugs who may have difficulty if we don't maintain some degree of uniformity in knowing exactly what the procedures are in each of the states. We have already given them their share of headaches, I think.

Philosophically, maybe we ought to consider whether or not abandoing the reviews of procedures for medical applications sets a precedent to do the same thing in other areas that we regulate.

In my own state, we certainly would not want to lighten up on the things that we require for industrial radiography and some research applications need a greater review of the procedures that are being proposed.

I have given you some figures for the period January 1, 1982 through June 30, 1982, the last data that I have available and it does show that the NRD administered 2,622 medical by-product material licenses while the States collectively administered 4,691. It is not quite two-to-one, but it is close.

The inspection data is, I think, also significant. The NRC would, I believe, need to have a greater commitment in the inspection effort if they were to go the way that it has been proposed. Presently the number of medical license inspections for the NRC for that period of time that I just mentioned was 51 broad licenses, some of which were medical,

and 314 other medical license inspections. For the same period of time the Agreement States performed 54 broad license inspections and 1,001 other medical license inspections. Not necessarily the same priority system was used in each case.

We support the concept that a good review of an application for a medical license can prevent a complete misunderstanding later on. It may be one in which the licensing agency can be perceived to be guilty of contributory negligence.

I would propose this as a question to be considered. I am not a lawyer and I don't pretend to know the answer to it but if we do not do an adequate job of protecting the public health and safety, then I think anyone could at any time they thought they had been injured bring such charges against the agency. It has happened in some cases, I think,

In order for this proposed change to work, there has to be an exceptional commitment on the part of NRC to do more at the regional level particularly with regard to inspections.

An inspector at a medical institution is someone who is not there necessarily by invitation. He is probably marginally welcome if at all. He is invited to do his job and get out as fast as he can and he does have some pressure not to interfere with the practice of medicine.

This is understandable. There are patients there.

I believe firmly in my own mind that the actual review process can be done at someone's office rather than in the actual inspection setting.

I don't think this particular aspect has really been addressed and there is no indication that the Value/ Impact Statement has addressed the actual impact on the regional offices. That is something that I think should be done.

One of the things that I would like to bring out is that I am not sure that all of the states have had the opportunity to review the draft that is before you.

COMMISSIONER AHEARNE: I would say it a little more strongly.

MR. SPELL: Not all of the states have had an opportunity to review the draft that is before you. For this reason, to make the statement that the Agreement States are in favor of the total document is without basis. I would not want my state to have its name as being in favor of it and I think most of the others would not also.

I have not chosen to go into some of the very small items that obviously have to be worked out but there are many health and safety deficiencies in there.

I have asked Mr. Whatley if he would be prepared to comment on a few of the significant ones that he saw outstanding in the document and if you would like to hear them,

I think he can give you several examples of significant health and safety items which either need to be smoothed over or actually changed in order to be good practices.

CHAIRMAN PALLADINO: We have used up more than ten minutes although it has been a very, very helpful presentation.

COMMISSIONER GILINSKY: I wonder if we could just hear a word on the procedures issue before we go on to another speaker.

CHAIRMAN PALLADINO: I was going to go on to another speaker.

COMMISSIONER GILINSKY: Could we just take 60 seconds to get your view on that?

Is that acceptable?

CHAIRMAN PALLADINO: Sixty seconds -- I will yield.

MR. WHATLEY: In my personal opinion, I feel that there are numerous sections in this regulation which in my opinion do not reflect an adequate health physics safety program. For instance, the leak test procedures. It requires a test sample be taken from a source. It leaves it up to the interpretation of the licensee what is a test sample.

Someone in my office says he would take a chisel and a hammer and take a test sample. Then an inspector goes out and he is forced to be make an evaluation on that. There is no requirement that a standard source be used for converting counts per minute into microcuries to determine whether the

source is leaking or not.

Survey measures are required to be calibrated to a ten percent accuracy with a source of estimated activity. I don't understand that.

In my opinion again, there are problems with survey requirements, when to survey, the type of survey measures to use, procedures for doing the survey.

CHAIRMAN PALLADINO: Could we get some of these submitted to us?

MR. SPELL: They have been submitted, Mr. Chairman. They have been submitted in writing by various members of the states and, of course, any other version that comes out will be commented on likewise, sir.

MR. WHATLEY: I have served on the task force, sir, and many of these comments have been submitted before to the task force. Those are some. I could go on.

CHAIRMAN PALLADINO: But in the interests of letting the others speak, maybe that is far enough for the moment.

MR. SPELL: I will be happy to conclude. It will take about 30 seconds. I would like to commend the Office of State Programs' staff for keeping us involved in this process and to offer the services of the Agreement States in developing a set of regulations that we can all live with. We recognize that we all have a stake in this effort and we will do what we can to assist.

Thank you very much, Mr. Chairman.

CHAIRMAN PALLADINO: Thank you very much. We will go to Dr. Robinson.

MR. ROBINSON: Chairman Palladino, Members of the Commission, I am Ralph G. Robinson, Head of the Division of Nuclear Medicine at Kansas University Medical Center and President of the American College of Nuclear Physicians which is an organization of approximately 1,200 physicians actively engaged in the practice of nuclear medicine.

These comments are presented on behalf of the College and also represent the views of the Socity of Nuclear Medicine, a professional organization of over 10,000 scientists, physicists, pharmacists, physicians, technologists and other professionals involved in nuclear medicine. The combined membership of tehse organizations represent the nuclear medicine community in the United States.

The College and the Society are grateful for this opportunity to appear before you and present our views on the proposed revision of the Nuclear Regulatory Commission's regulations for Human Use of Byproduct Materials, 10 CFR 35. We urge the Commission to act favorably and move the proposal forward for publication in the Federal Register.

No set of regulations affects the day-to-day practice of nuclear medicine more directly than 10 CFR Part 35. The licenses issued by NRC under these regulations define the

perameters under which the use of byproduct radioactive materials for diagnostic and therapeutic medical purposes occurs. Therefore, the proposed revisions under consideration today are of the utmost importance to the membership of the College and the Society.

Mr. Chairman and members of the Commission, we would like tocompliment you and your staff for their initiative to consolidate and streamline the requirements of 10 CFR 35. For a number of years the nuclear medicine community has operated under requirements scattered amont several documents, including Inspection and Enforcement orders, regulatory guides, technical reports and various conditions attached to individual licenses.

This has often resulted in confusion and unnecessary and/or duplicative paper work. It is, we believe, to the advantage of all affected partiesincluding NRC, the nuclear physician and most importantly the patient that regulatory requirements be developed as succinctly and clearly as possible. The proposed revision of 10 CFR 35 will accomplish much of that objective and we strongly urge you to support this effort.

Existing licensing review procedures relating to the Human Use of Byproduct Materials are cumbersome and unnecessarily lengthy. In our view, the informational requirements currently required to complicate the licensing process by

forcing applicants to include detailed copies of procedures to be used in complying with the regulatory requirements in addition to the necessary information relating to radiation safety.

The volume of information currently required often results in the need for more information from the reviewer's perspective. Frequently this need for additional information does not concern matters of radiation safety, which are of primary concern to the College, the Society and the Commission, but rather involve minor procedural issues. This often results in "Deficiency Letters" which greatly increase the time required to complete a license review and creates a prolonged paper shuffling exercise.

I might add to my statement that you have before you, just to second some of the staff comments made earlier that many of the problems arise in license amendments which may be minor changes in procedures but require a formal license amendment and add to the 2,000 submissions annually to the Commission and may slow the introduction of new diagnostic procedures in the medical practice.

The modifications proposed in this draft will help eliminate some of the unnecessary paper requirements, produce more timely decisions and better reflect the sophistication of today's nuclear medicine practice, thereby enabling the medical community and NRC to more appropriately focus their

resources.

We understand that information relating to procedures and other requirements must still be developed and maintained by the licensee. Thus, the substantive details needed by NRC for judging the adequacy of a licensee will be maintained and readily available for inspection.

We also concur with the recommendations contained in the draft to eliminate the general license. In view of the advances in thepractice of nuclear medicine, the general license approach in effect creates a dual licensing system. The use of specific licenses and specific licenses of broad scope obviates the need for a general license category.

Mr. Chairman and members of the Commission, while we are in general agreement with and strongly support the thrust of the proposed revisions, there are some specific requirements in the current draft that we feel should be modified.

However, it is our intent to address these issues through official comments from our respective organizations once the proposed revisions appear in the Federal Register. We will provide a detailed analysis once the full text of the proposed revision is published.

In summary, let me reiterate our general support for the proposed revisions, and assure the members of the Commission that the nuclear medicine community shares your

commitment to provide for the safe and effective delivery of nuclear medicine patient care, ranging from mobile service to the most sophisticiated hospital setting.

The College and the Society have had a long-standing and continuing interest in maintaining quality health care and probably have more quality assurance efforts underway than any other medical specialty. We believe that the proposed revisions will serve to enhance the objectives of the Commission and of the nuclear medicine practitioner.

Thank you again for this opportunity to appear before you and I would be happy to answer any questions now or later if you would like to go on to the next speaker.

Thank you.

CHAIRMAN PALLADINO: Any questions?

COMMISSIONER GILINSKY: Yes. You seem to be saying that it is a great bother to be sending copies of procedures to the NRC. Since these procedures have to be developed any way, I understand you to be saying that the equivalent procedures would get developed no matter what. What is the difficulty about sending them in?

Let me add another point here. I sense that you are saying that reviewers are being unreasonable in the way they review these procedures and nit-pick them with the things that are really vital. Is that a correct understanding of what you are saying?

MR. ROBINSON: We are not saying that any one is nit-picking. We are saying that if we send in 50 or 60 pages of detailed procedures, it is quite likely that there may be a minor error somewhere which will result in a Deficiency Letter and stop the whole process for two or three months.

If in our view the detailed procedures are not that important to the operation of a facility which is judged on its overall merits in terms of its ability to safely handle, store and receive, the staffing of that facility as detailed in an application and the training and experience requirements which have been strengthened in the past year and added to the rewrite but, in fact, are already in place, that a minor change in procedure or the need to include 40 or 50 pages of procedures themselves, we think are unnecessary.

We have to keep them. We do keep them. They are available for inspection. If there is a minor problem with one procedure that is found on an inspection, then it would be noted and corrected. But I don't think that should impede the entire licensing process.

COMMISSIONER GILINSKY: But, as has been mentioned here earlier, we can't inspect these licenses in the way we inspect reactors, for example, where we have resident inspectors and teams coming out regularly and procedures really get quite a scrubbing. At least they will in the future. That is not possible here and really pretty much the

only check you get is this review at the time of application. Clearly one can't go through 50 pages in detail, but I would assume that the reviewers are trying to hit the important points. If they were being unreasonable, that is a separate management problem.

CHAIRMAN PALLADINO: I wouldn't necessarily take it as given that we can't inspect the new applications if the number is on the order of 120 in a year.

COMMISSIONER GILINSKY: That is a separate issue that I think we need to take a look at. I am not as familiar with hospitals as I am with reactors, but certainly procedures are vital. I don't think you would argue otherwise.

MR. ROBINSON: No, and all of our procedures are written down and we are inspected not just by the Nuclear Regulatory Commission or the Agreement States, but we have joint Commission on Accreditation Rules. We have a variety of rules. We have many procedures in place. I am not sure they all have to be part of the application document.

Here, we are simply agreeing with an opinion that is developed by NRC staff.

COMMISSIONER AhEARNE: On page four, you mention some specific requirements with which you disagree. What is your position on the qualification requirements section?

MR. ROBINSON: We are fully supportive of the qualification requirements with one very minor exception which

I know Mr. Linton is going to address and that is the 1,000 hour training requirement which is listed in the proposed revision as I think arbitrarily defined and divided in half, 500 clinical and 500 laboratory.

You have already specified the number of hours of actual instruction in each sub area that must be included. We would support the concept that requiring 1,000 hours of supervised training without further subdividing that and leaving that up to the training director would be a legitimate thing to do.

COMMISSIONER ASSELSTINE: Dr. Robinson, I wonder if I could ask you to comment on the point by Mr. Spell and that is, would you agree that it might be easier to resolve the questions about the procedures or about compliance with elements of the regulation during a licensing review process rather than when an inspector visits and is actually in the setting where you are trying to provide services as well?

There are additional complications if we are swinging the burden now to the inspection part when our inspectors actually come to visit you or your institutions.

MR. ROBINSON: Well, they are visiting my institution today, but I said that I would be here instead. Backing up for a moment, that is a bit of a complicated question. I will try to be brief. It was brought out earlier and I appreciate the comment about our intelligence earlier that

between the regulatory guide 10.8 and the really rather several pages of forms that must be sent in as well as procedures and all of this, I have been through those guides and I find them confusing. I think the proposed document in general certainly greatly simplifies and brings together in one place many of the things that are necessary for the license application.

I think the applicant and the reviewer and the field inspection people will all benefit by having this brought into one place.

We have problems on inspections. The field guides for inspection have taken on the aura of regulations. The staff here has recognized that. I think that if we could bring all this in under Part 35 and spell it out as it has been proposed, it would be simpler for everybody and still adequately protect the health and safety of the public.

COMMISSIONER GILINSKY: I don't think there is a lot of argument about bringing things together and having clearer regulations. The real question is the content and the way we are going to go about carrying out our responsibilities. You are basically arguing for a little less of a look than is being taken at the present time and I guess there are mixed views on that.

MR. ROBINSON: I am speaking first to nuclear medicine. I am not speaking to radiation therapy and Mr.

Spell's problems with leak testing sources and some of the things that he has mentioned. I am also a preceptor. I write those preceptor letters that were referred to earlier. I, and I think most people like myself, take that as a rather serious obligation and that is part of the process of application of license.

For each resident as he begins to finish his training, we sit down and review exactly what he did do in nuclear medicine, actually how many days he spent. We figure out the number of hours by going over his exact schedule. We look at the classes that he took and how many hours. We look at the exact number and type of procedures, clinical procedures, that he participated in and we develop a separate letter for each and every one of them and it reflects that training and the fact that I have verified it.

I would simply say and there has been a little bit perhaps of an attitude that a lot of people are going to be licensed who shouldn't, that are going to take advantage of this, and I would say that in medicine, one, we are concerned when people violate rules of any sort. The first thing that happens if someone gets a violation or a citation from NRC is that his medical staff is going to wonder why and he may lose his staff privileges and without his staff privileges, he is out of business in a practical sense. He can no longer receive the radioactive materials. He has no place for them

to be shipped. He has no license.

Even if he has his own license, he is out of a facility.

I think that physicians will take these very seriously and will do a better job of compliance if they are easier to understand.

COMMISSIONER GILINSKY: If I understood the earlier presentation correctly, the sort of letter that you were talking about, would no longer be required?

MR. ROBINSON: I am going to continue to provide them myself as documentation of experience. You have in this draft a requirement for 1,000 hours and certain number of hours of lecture. Your experience requirements are quite detailed and lengthy and I see that there would be no charge in that.

COMMISSIONER GILINSKY: If I understood correctly, it was really up to the doctor to check that he did, in fact, comply with the requirements.

MR. ROBINSON: He checks off that he has a residency or is board-certified.

CHAIRMAN PALLADINO: We are going to run out of time soon. This is a very valuable dialogue and I appreciate it, but I do want to give Mr. Linton a chance to make his presentation and I hope still to get back to some of the staff

members that had some differing views.

Mr. Linton, please proceed.

MR. LINTON: Thank you, Mr. Chairman. Gentlemen, my name is Otha W. Linton. I am director of government relations for the Aermican College of Radiology. Many of the members are licensees of the Commission or the Agreement States.

My comments here represent the opinions of two of the college's commissions where most of the members have had an opportunity to discuss the concept and in some cases review the text.

We think, Mr. Chairman, that proposed Part 35 should be completed, submitted for public review and adopted by the Commission. As nearly as a document can be judged in advance, it should meet most of the goals it sets for itself in alrity, consistency, economy and efficiency for all concerned. We found it easy to read and follow. Applicants for licensure should find their tasks made substantially simpler.

In previous testimony, the College has suggested that the paternalistic anachronism of federal control of medical uses of byproduct material has largely been succeeded by the medical mechanisms of specialty training and credentialing boards.

COMMISSIONER AHEARNE: Could you tell me when in a time frame, when did the credentialing boards come into

existence?

MR. LINTON: The American Board of Radiology which predated the whole atomic age began offering a medallion for special competence in nuclear medicine at the end of the 1950's. The American Board of Nuclear Medicine dates to, I believe, 1964. Dr. Robinson?

MR. ROBINSON: Final approval, 1972.

MR. LINTON: All right. It had been in motion.

COMMISSIONER AHEARNE: So anything that we might have seen since 1972 has occured since the credentialing boards existence?

MR. LINTON: Yes, sir. You have a proud paternalism there.

COMMISSIONER AHEARNE: Another way of looking at it can be that if any problems have occurred, major problems have occurred since then, then it says that the credentialing boards didn't solve all of the problems.

COMMISSIONER GILINSKY: You had some pretty dreadful ones.

MR. LINTON: If the Commissioner would infer from my comments that we have solved all of the problems, I owe you an apology.

COMMISSIONER AHEARNE: All right.

COMMISSIONER GILINSKY: I must say that I have to add a comment. To have a representative of the medical

profession accusing anyone of taking paternalistic attitude is, I think, a little bit much.

(Laughter.)

MR. LINTON: All right, sir. You have concluded that you have a presence here and so our comments are directed toward the shape of that presence. We do note that you recognize the professional credentials and, of course, we are grateful for the chance to have one document which would tell us all we need to know and respond to.

We are concerned, Mr. Chairman, because a recent study such as the one by the Hospital Association of New York State suggested that as much as 25 percent of the hospital dollar is spent in complying with regulatory requirements of all kinds from federal, state and local agencies. Any reduction in such requirements in the cost of responding to them can only be applauded in these days of soaring health costs and dramatic efforts to reduce them.

COMMISSIONER AHEARNE: You say that 25 percent of the dollars were spent in complying with regulatory requirements. Is the implication that those were requirements that need not be complied with so this 25 percent was wasted?

MR. LINTON: Not entirely, sir. The question of how overlapping and duplicative and redundant adds to it in great cost.

COMMISSIONER AHEARNE: I am sure. We are familiar

in our other side of the world in regulatory requirements on licensing reactors and there is also an issue that often comes up and this is a regulatory burden and it is a requirement and some of the requirements are there for essential safety. I just wanted to make that clear.

MR. LINTON: The requirement, let's say, for fire code is not one that any of us quarrel with or clean food or so forth. But the costs are substantial.

CHAIRMAN PALLADINO: Nevertheless, might you not have independently imposed some of these same requirements on yourselves. This is what makes it difficult to evaluate a statement like that.

MR. LINTON: Yes, indeed, sir. In the state of Maryland, something like 120 agencies impose some kind of requirement on hospitals. Are we are suggesting is that any streamlini , would be to the benefit of all of us.

CHAIRMAN PALLADINO: I could understand the benefit of streamlining but these numbers are hard to interpret and they do give imlications that sometimes I don't think are necessarily correct.

MR. LINTON: Very good, sir. As a matter of fact, in the nuclear medicine department, the figure was slightly lower than the overall 25 pcercent.

We do make three suggestions, Mr. Chairman, for possible changes in those. One of them, Dr. Robinson has

already discussed. One of them relates to a requirement of Part 35.75 relating to the institutional stay of patients in which we suggest essentially a two-tiered approach, one, where the amount of radioactivity is significant and one, where our committees felt that it is not significant.

The third point which we suggest is the dropping of Part 35.37, the so-called "misadministration rule." As we understand it, sir, this would require an action by the Commission to reverse a recent vote and it is a request which we are considering submitting in a petition.

CHAIRMAN PALLADINO: What is 35.37 again?

MR. LINTON: Misadministration rule. The earlier material available from the staff indicated that a violation rate of less than 0.01 percent which we suggest makes it a bother rather than a benefit to anyone concerned.

COMMISSIONER GILINSKY: It isn't like everybody is filling these things out and we are only getting one-hundredth of one percent significant reports. It is only reported if there has been a misadministration.

MR. LINTON: That is correct, sir.

COMMISSIONER GILINSKY: So you can turn this right around and say that as long as the number of misadministrations is low, it should be no bother for physicians. I don't understand your point at all.

MR. LINTON: My point is that it was regarded as a

bother, sir, and one which we think is unproductive.

We also were somewhat concerned about the legal point of self-incrimination because early in the drafts, the information was provided not only to the Commission to which there was no objection but also to other parties.

COMMISSIONER GILINSKY: It seems to me that people have a reasonable right to know how many of these misadministrations there are and I think we have to be able to keep track of the nature of these misadministrations to make sure that we are carrying out our responsibilities and also to make sure that everyone can benefit and learn the lesson from them.

MR. LINTON: The Commission obviously took that position in its recent vote, sir.

COMMISSIONER GILINSKY: We would very much like to hear an opposite view explained. If what I am suggesting is wrong, then by all means, I would like to have it corrected.

MR. LINTON: If the Chairman wishes to take the time, sir, we would be glad to enlarge on this.

CHAIRMAN PALLADINO: Enlarge two minutes worth.

MR. LINTON: Dr. Robinson would like to give me help here.

MR. ROBINSON: We understand that this particular question is the subject of a separate review and we did not address that in our formal comments. However, from the

physician's perspective, I would like to just comment that several studies have been done on therapeutic drugs. These are drugs which were taken in high dose multiple times per day for periods of time up through days or years in some cases.

It is a fact and perhaps an unfortunate fact that about 30 percent of therapeutic drugs in this country are misadministered either by the doctor, by the pharmacist, by the nurse on the floor or finally, by the patient who just didn't understand the directions. But we don't go around filling out forms about that and we are trying to improve that and the patient package insert has come along and things like that to try to improve the compliance in taking the drug. They take too big a dose, too little a dose, wrong time of day -- all those things are misadministrations.

So we practice in a climate where it is very difficult to get therapeutic drugs properly administered. Then we turn to the diagnostic level where they are radioactive but they are given in small quantities and in micrograms of drug, usually only once, and we are required to report what we consider to be minor problems.

Of the hundreds of misadministrations, they probably occurred out of five or ten million administrations or whatever the numbers work out to be -- it is a very small

number. But then we find this sort of headline in every major newspaper in the country as a result of your staff study which added up that 800 people got misadministrations so the headline goes out over the wire service and was developed from a story written in Science Trends and they only picked up, of course, the first part, that 800 people got the wrong dose of radioactivity and this is really a major problem.

We get a very black eye with the public. That is absolutely impossible to recant that sort of bad press.

That is just one example.

COMMISSIONER GILINSKY: When you referred to the earlier figure as 30 percent, those were non radioactive?

MR. ROBINSON: Yes, sir, and those were therapeutic levels of drug.

COMMISSIONER GILINSKY: It may well be that when --

MR. ROBINSON: That sounds large, but that is the climate that the physician views the problem. That is his perspective. I say that that other problem is a problem and yet it is one that is very difficult to approach. Meanwhile probably 98 percent of the misadministrations we consider to be of a minor nature but they are required to be reported.

MR. LINTON: That was really the basis of our earlier point.

COMMISSIONER AHEARNE: That is a distinction, I

think, and there were two problems that I think you identified. One is perhaps a problem of the level at which reporting should be done and the second is the difficulty in getting a fair press treatment in the area of nuclear activity. We can help you with the first, but the second is beyond our control.

MR. ROBINSON: Yes. We understand that.

CHAIRMAN PALLADINO: Perhaps you can help us find a way to deal with that.

(Laughter.)

MR. LINTON: Mr. Chairman, this was our only chance to bring that point to the attention of the Commission. However, we would not like it to detract from our basic support of Part 35 and our petition to you to adopt it and move it forward.

Thank you, sir.

CHAIRMAN PALLADINO: Thank you. Any other questions? We want to allow time for exploring the differing opinions by the staff.

COMMISSIONER AHEARNE: I have one question that I want to ask Mr. Spell. On the general license elimination, you didn't address that?

MR. SPELL: I do have a personal feeling on that. We never did go to the general license and if that is an indication to you, we feel like we have a better handle.

COMMISSIONER AHEARNE: So eliminating it?

MR. SPELL: Would not affect us in our state. I think Mr. Whatley may wish to comment.

COMMISSIONER AHEARNE: Mr. Whatley.

MR. WHATLEY: No. I agree with what Mr. Spell said.

COMMISSIONER AHEARNE: Would it be correct that the Agreement States as a group never really specifically addressed that to your knowledge?

MR. SPELL: I can't comment. I don't know. But I have a feeling that you may find it somewhere maybe evenly split, maybe 30 to 50 percent split, on the ones that did and didn't.

CHAIRMAN PALLADINO: Gentlemen, thank you very much for being with us and for your enlightened comments.

MR. SPELL: Thank you.

MR. WHATLEY: Thank you.

MR. ROBINSON: Thank you.

MR. LINTON: Thank you.

CHAIRMAN PALLADINO: I would ask the Commission how they would want to proceed at the moment. My suggestion would be to see if we have Patricia Vacca and Joe DelMedico here.

MR. DELMEDICO: Yes, we are here.

CHAIRMAN PALLADINO: How about joining us at the table. We would like to hear the thrust of your comments on the proposed rule.

MR. DELMEDICO: Mr. Chairman, I am Joe DelMedico.

I am a member of the Medical and Academic staff. As you know from previous correspondence, I perceive two major problems. The first is that there will be no pre-licensing review of the applicant's procedures and controls as they relate to radiation safety.

I would have less concern if the new regulations spelled out the same operating procedures that we presently require in the license application. However, it does not. Attached to your copy of this statement which I will provide in a moment, you will find a table that I prepared after I reviewed the proposed regulation.

Among other things, the table identifies a number of specific operating procedures and safety instructions that we presently require in the license application. In the proposed regulation, these are replaced by vague requirements to implement "safety procedures," "patient control instructions," and "contamination control instructions," all of unspecified nature.

My understanding is that an inspector could issue a notice of violation only in the case where no procedures had been implemented. If some procedures have been implemented but they are inadequate or inaccurate, NRC would have no recourse.

This remains true regardless of what may or may not be written in the companion regulatory guide. The problem

stems from the fact that the new regulation does not dictate the specific content of the required procedures. The same holds true for the required instructions. My second major concern is that there will be no pre-licensing review of the physician's training.

CHAIRMAN PALLADINO: If they were approved, if we went through the process of approval of a procedure, then I presume an inspector would have a way of measuring against?

MR. DELMEDICO: Yes, sir. After they are approved they are added to what we call the "tie-down" condition in the license. It is a condition that says that you shall operate in accordance with the statements that you made in letters dated thus and so date.

CHAIRMAN PALLADINO: All right.

MR. DELMEDICO: My second major concern is that there will be no pre-licensing review of the physician's training and here I mean physicians who are not board-certified because as you have heard, that is very easy to check. We presently conduct this review to determine that the training is sufficient to avoid unwarranted radiation exposure to the physician, medical workers and to the public including patients.

COMMISSIONER AHEARNE: Do you have a rough idea of how many physicians who have the licenses are board-certified versus how many aren't, what percentage is the split?

MR. DELMEDICO: Let me answer you in a different way. When an applicant comes in, all they have to do is write that they are board certified and a date. A licensing assistant checks this information in the reference book that we have and the amendment is put out immediately.

The ones who are the problems as you might expect are the ones who are not board-certified, the ones who might be more marginally qualified.

COMMISSIONER AHEARNE: I was just trying to get a feeling for the percentage of the problem. Is it one percent who aren't board-certified or 50 percent?

MR. DELMEDICO: I would say just roughly from my experience, 40 percent are board-certified, 40 percent of the applications that we get are board-certified and 60 percent are not.

The proposed rule instead requires that the licensee keep a brief description of this training on file for review by inspectors. However, inspectors may decide that they will not routinely review this information to determine whether or not the physician is qualified.

As we all know, an inspection is not a review of a program in its totality. It is merely an audit. I can certainly understand the basis for such a decision.

It is a bit late to be checking a man's credentials after he has already held an NRC license for six months and

has used that license to perform 1,000 or more nuclear medicine procedures.

Review of physician qualifications has traditionally been a licensing not an inspection function. Such determinations would range from difficult to down right confrontational if they had to be made on the spot in front of the physician. From my own experience, I know that these reviews can take weeks while the physician gathers additional documentation.

In addition, such reviews may require consultation with NRC's advisory committee on the medical uses of isotopes or contacts with the directors of training programs and so on.

You can well imagine the uncomfortable decisions that an inspector would have to make. Is this physician not qualified or is his documentation merely inadequate? Should the nuclear medicine department be shut down until this can be determined? Should patients awaiting vital nuclear medicine procedures be sent back to their rooms undone?

At the present time, we in licensing pay attention to the quality of the physician's training not just the quantity.

This distinction would be lost under the proposed rule. Let's suppose that the physician received his hours of training from an equipment manufacturer who stands to make a $200,000.00 sale of nuclear medicine equipment. It is rather

unlikely that any physician would fail such a course even if he never bothered to show up.

The licensing staff discovered that one such program included an eight-hour tour of the City of Milwaukee as part of the core curriculum.

(Laughter.)

CHAIRMAN PALLADINO: Wouldn't the preceptor have to step in there?

MR. DELMEDICO: There are two parts to a physician's training. One is hours, more or less classroom hours, in basic radioisotope handling techniques. The physician documents these himself on what we call Supplement "A". The second is a preceptor form which discusses the various numbers of cases that a physician has actually performed under a preceptor position.

In the optimal cases such as Dr. Robinson's these programs are integrated. But this is not a requirement. It is not a requirement now and it is not a requirement in the proposed rule. A physician can take the basic radioisotope handling hours from one place and serve a preceptorship which generally means not handling material and learning how to handle material, but rather how to sit behind a viewbox in interpret studies at another institution.

The Commission's experience with serious medical misadministrations seems to indicate that they are caused by

human error and due to lack of attention to detail. It appears as though these errors cannot be reduced through further regulation. One thing is for certain. This problem will still be with us in the future.

If we discontinue our pre-licensing review of physician training, sooner or later we are bound to have a serious therapeutic misadministration linked to an unqualified physician.

Media interest at that point would result in a public relations disaster.

In closing, let me emphasize that my concerns are not so much with the new regulation but rather with the proposed method of implementation. Unfortunately, this SECY paper does not separate the two so that they can be voted on individually. The proposed regulation would work rather well if we kept our current level of pre-licensing review. Any deficiencies could then be made up by license conditions.

Alternatively, the proposed regulation could be changed to dictate specific equipment, procedures and instructions similar to ones that we currently require in the license applications.

In any event, I believe that there should also be a pre-licensing review of the physician's training and experience.

Thank you.

CHAIRMAN PALLADINO: Joe, do you have specific places where you would make suggested changes to Part 35 in line with your comments?

MR. DELMEDICO: Certainly the first and most important change that I would make is for NRC to retain the pre-licensing review of the physician's training and experience.

CHAIRMAN PALLADINO: Suppose I were to believe what you say and I wanted to make a recommendation that we go this way. I don't feel that I am smart enough to know what part I should put it in there and I was wondering if you had some thoughts along those directions or could develop them?

MR. DELMEDICO: I prepared a listing of the major differences between the current regulation and the proposed regulation.

COMMISSIONER GILINSKY: I think what the Chairman is suggesting if I understood correctly, is a marked-up copy of the regulation incorporating those changes that you would like to see in there.

CHAIRMAN PALLADINO: Specifically, those two points you raised.

MR. DELMEDICO: I certainly could do that. I have not done that.

CHAIRMAN PALLADINO: I would find that helpful.

MR. DELMEDICO: It would require someone to give me

permission to spend the hours to do that.

(Laughter.)

CHAIRMAN PALLADINO: I think we can work that out.

COMMISSIONER ASSELSTINE: Perhaps we ought to hear from Pat as well.

CHAIRMAN PALLADINO: Oh, yes. I certainly want to hear from Pat.

MS. VACCA: Mr. Chairman and Mr. Commissioners, thank you for giving me the opportunity to speak to you today on this matter. My name is Patricia Vacca. I, too, am with the Material Licensing Branch in the Medical and Academic Licensing Section.

As Joe has indicated, we both have given you previous documents indicating what our principal concerns are about this document. I would like to give you three pieces of background information. In view of the fact that most of the issues that come before you are reactor oriented, you are probably not super familiar with all of the things that go on in the materials area.

I took the opportunity to look at NUREG-0714 and I believe you have some copies of handouts on this matter. That document has occupational radiation exposures for 1979, the most recent year that is available, and shows that medical licensees are second only to power reactors in the number of personnel overexposures reported in 1979. Reactors reported

27 overexposures while medical licensees reported 13. In total occupational collective dose, reactors showed an estimated 39,759 person-rems while medical licensees were something just over 9,200 person-rems.

It should be noted that not all of the medical exposures are from NRC licensed materials. They can be from NRC materials, from X-ray uses and other things that are not licensed by NRC or from some combination. It is not clear exactly what extent of that total occupational exposure is due to things that come under NRC's purview.

It is interesting to note that in the NUREG document they mention that the doses incurred by medical workers are of particular interest because the majority of workers are young women and that estimates by EPA indicate that 20 to 24-year old females in the medical field comprise one-fourth of all the women workers in the United States radiation work force and since some of these people could be in the earlier stages of pregnancy, the total occupational dose could result in somewhat greater semantic risk than you might first thing from the numbers.

The second point I would like to bring to your attention is the types of licensees that are principally affected by Part 35. We are not talking about the broad type A licenses that are university-based medical centers. We are not talking about NIH, so don't keep NIH in mind as

the typical example. These are broad licenses or places that do not only the well-established diagnostic and therapeutic studies, but they are the folks who develop the new diagnostic studies, the new therapy procedures. They do research on humans, normal volunteers, on patients. They do laborabory research, animal research, et cetera.

These are not the kinds of licensees that are principally affected by this change. The broad licensees have well trained staff, excellent facilities, equipment and they operate with the decisions being made on a day-to-day basis by their own in-house radiation committee using criteria that have been approved by the licensing staff.

The people who are really affected by this regulation are the group medical licensees, the small community hospitals, physicians in their private offices and if they have one or maybe a few trained physicians they are in good shape and they may have a few technologists and a technologist or a physician is the person who doubles as the Radiation Safety Officer.

If you can just keep in mind the kind of licensee we are talking about, and one that I have in mind is a licensee that I have had frequent communication with. It is an 85-bed hospital in a small town on Interstate 80, west of Laramie, Wyoming. They don't have the same capabilities as an NIH.

Also, the people who are representing the major organizations in many cases are people from large institutions that have broad licenses that have the greater resources than our broad licensees do and they may not keep in mind or have in mind clearly all the problems that a smaller licensee have.

As has been indicated before by you, I certainly am not opposed to the idea of putting all our requirements in one place and improving the efficiency of the licensing process. My concerns are on the two issues that Joe mentioned, our review of physician's qualifications as well as our review of the applicant's radiation safety procedures.

With regard to physician qualifications, I think that it is important that we make a determination before the license is issued that the proposed user is qualified by training and experience to use the radioactive material safely.

On that application form that you have heard about, the proposed new application form, there are three boxes that could be checked. One has to do with the board certification. If a physician checks that box, as has been indicated already, that is easy enough for us to double check and review and make sure that the person truly is board-certified by the appropriate board. One other box that the person can check says I request an exemption from the requirements and the form says that the documentation is attached.

Again, in that case we would be looking at the physician's qualifications, his training, experience as we do in the present case.

What I am concerned about is if the physician, the non-board-certified physician checks off the box that says "training and experience as specified in 10 CFR Subsection J," experience has shown that most of the board-certified physicians and these are the people who are likely to check off that last box do not now provide NRC on the first go around with adequate documentation of their training and experience.

We usually have to go through any where from one to three rounds of correspondence to get the additional information we seek or for the licensee or applicant to come to the conclusion that he wants to withdraw the request because the physician needs some additional training.

The training and experience criteria that we are using today is essentially the same as that proposed in the SECY paper. I think in all probability we can expect that most non-board-certified physicians will not have sufficient documentation in their files to show that they meet the training and experience criteria or requirements that would be in a new Part 35.

COMMISSIONER AHEARNE: Could you make a rough estimate? In the group that you say you go through the one

to three rounds of questions, what fraction ends up withdrawing versus what fraction ends up getting approved after all this?

MS. VACCA: I think after all is said and done, a very large percentage eventually have shown enough information either for the staff in our branch to make a determination or if we have some qualms to go to our advisory committee.

You are correct that in many, many cases whether it be 90 percent of those cases, we eventually wind up coming to the conclusion that the person does have adequate training and experience.

COMMISSIONER AHEARNE: I am not correct or incorrect. I am just asking the question.

MS. VACCA: But there is a large percentage where you come to the conclusion that a person after all of this has adequate training and experience. In perhaps 10 or 15 percent of the cases, the application is withdrawn.

COMMISSIONER GILINSKY: That is pretty high, isn't it?

MS. VACCA: These are numbers off the top of my head. I do not have any statistics on that. I am not sure that it is easily available. It is not a large percentage in any event.

My concern would be offset, as I believe Joe has indicated, by NRC continuing to obtain and review before the

license is issued documentation on the training and experience of these non-board-certified physicians.

The other principal concern I had has to do with the radiation safety procedures. Today as you probably know, one of three things that an applicant or a licensee might be sending to us.

He could send us copies of the various procedures that he has that he is going to use, that he has either developed or has had developed for him by a consultant. Secondly, he might commit to following a certain set of procedures that is in the regulatory guide, 10.8. Or it might be some combination of those. He likes some of the procedures in the regulatory guide but he doesn't like others so he develops his own.

In the current version of Part 35 that you have before you in this SECY paper, I know there are some examples of instances where procedures are mentioned and some detail is gone into, for example, the calibration of survey meters.

I am concerned about those instances in the SECY paper where Part 35 does not mention certain kinds of radiation safety procedures that I believe are important to health and safety.

For example, I do not see in there procedures that would insure accountability of sealed sources that are used for therapy. We have had a lot of instances where the

sources have been lost, patients sent home with the sources in them, various and sundry other problems associated with those sealed sources. One of the things that we have tried to do to offset those problems has been to request licensees to have better accountability procedures.

I don't see that particular requirement in this version of Part 35.

I am also concerned because certain procedures are mentioned but without sufficient detail that you could have a clear understanding of exactly what it is that the agency expects is going to be included in those procedures.

I take as an example the requirement to have some procedures with regard to contamination control for iodine therapy patients. I have certain ideas about what that might contain. Joe may have others. Each of you may have other ideas. But it is not clearly specified in the regulation as far as I am concerned what those minimal criteria actually are.

It seems to me that there are several different options that the Commission could take with regard to the procedures. One obviously would be to continue the current practice of reviewing the applicant's radiation safety procedures just as we are now.

A second option would be to incorporate into Part 35 procedures equivalent to or very similar to those found in the various appendices to reg guide 10.8.

A third point might be that the regulation in all instances say that licensees shall have thus and so kind of procedures. The licensee must follow the procedures they have in place and that the procedures contain certain specified minimum features.

Lastly, I suppose there is the option of revising the application form so that the licensee says, yes, I have so-and-so kind of procedures, I will follow those procedures and as a minimum, my procedures contain X, Y and Z factors whatever they are that might be identified by NRC either in terms of a licensing guide or perhaps on the application form.

These are just four options that I thought about. I, of course, have not discussed these with ELD. I don't know to what extent each is viable.

I think the SECY paper only outlines one option and I think that the most key factor in my concerns about Part 35 are how it would be implemented and some of these other options might be things that could be considered.

If we continue to review an applicant's procedures before issuing a license, then it is not so important, I don't think, that Part 35 is specific with regard to content of certain types of procedures or if the regulation doesn't specifically mention a certain set of procedures because this is something that could be resolved in the licensing

process.

On the other hand, if the staff does not review the procedures in the licensing process, then I think some major changes would need to be made in Part 35 and if those changes are not made, then I think we would expect that licensees could be operating for some period of time before they are inspected either with no procedures in place or using inadequate procedures. It is not clear to me the exact extent to which NRC inspectors will have the time to devote to the reviewing in detail the various procedures and also the adequacy of those procedures will come into question when the inspector appears on the scene.

In general, I think, adequacy of the procedures established now during a licensing process and the inspector only has to be concerned with whether or not the procedures are being followed. That is a general statement. It is not true in every single case, but I think it is fairly true.

Those are the principal things I wanted to bring to your attention. Thank you.

CHAIRMAN PALLADINO: Thank you. Any questions?

COMMISSIONER ASSELSTINE: I have just a couple, Pat. You mentioned the 85-bed hospital near Laramie, Wyoming and it sort of struck a responsive chord.

(Laughter.)

COMMISSIONER ASSELSTINE: I guess one of the

questions I wanted to ask you was how burdensome are the application requirements that we have for a small hospital like that and to the extent that you think that they are burdensome, are there ways of reducing that burden while at the same time preserving the pre-licensing review of such things as training and procedures?

I guess the same thing would also apply to smaller users than that.

MS. VACCA: In the case of the 85-bed hospital, their heart is in the right place or at least their words are in the right place. They are telling us that they are very anxious to keep on our good side and do everything according to the rules and regulations and our expectations as is probably true with most of our licensees.

I would think that for the licensee who finds the procedures in the regulatory guide acceptable, that he would not have a great amount of trouble filling out the application form nor complying with the procedures. The procedures were developed originally, those procedures in the various appendices in the reg guide, were developed originally with some help from the committee of the American Association of Physicists in Medicine. They have been modified during the public comment period on the reg guide. They have also been modified through staff experience. There may be some points in there that are perhaps overly conservative and that one

could look at with a fresh view and perhaps take some of those out.

I don't really think that the current licensing process is all that burdensome. I appreciate the fact that licensees have to come to us and make some changes in the procedures and perhaps there are some things in the options that I mentioned that might offset some of those amendments.

Perhaps we could go to a procedure where we would say, we must have procedures for whatever the subject matter package opening and as a minimum, your procedures must incorporate factors A, B and C without telling them, "Put your gloves on first. Now walk four steps over there and pick up this thing in your right hand; et cetera.

Some of the procedures are perceived as being that prescriptive. I disagree. I don't think they are that bad. But there is some room for improvement in them.

COMMISSIONER ASSELSTINE: So by in large, you wouldn't view even the present approach as a limiting or restricting the ability of small hospitals and doctors to provide these kinds of services in rural areas, for example?

MS. VACCA: No. I have two licensees in Wyoming that are having trouble. Their principal problem is recruiting physicians.

CHAIRMAN PALLADINO: Pat, could I pick up a follow-up question. Suppose the procedures were not part of the

license but they were approved. That would cause you no problem, would it, if there was a process for approval?

MS. VACCA: I am not too sure. I didn't quite follow that discussion earlier.

COMMISSIONER GILINSKY: Are they, in fact, part of the license?

CHAIRMAN PALLADINO: Yes, and one of the problems is that every time you want to make a little change in procedure, it takes a licensing amendment. Let's assume that it was taken out of the license but there was still an approval?

COMMISSIONER GILINSKY: This sort of tie-down that you were talking about earlier.

MS. VACCA: This tie-down condition?

CHAIRMAN PALLADINO: That would give you no problem or would it?

MR. DELMEDICO: It might provide some problems to the inspector because he looks to that tie-down condition to issue citations.

COMMISSIONER GILINSKY: The Chairman is asking if there were such a tie-down, but I don't know that there is really an important difference in it.

CHAIRMAN PALLADINO: Following somewhat the way we do with reactors. That is what I was getting at.

COMMISSIONER AHEARNE: In reactors, we will approve

the procedures.

COMMISSIONER GILINSKY: Having reviewed them.

COMMISSIONER AHEARNE: We will review them and approve them and then if they deviate from them, they can be cited. The procedures aren't a specific piece of the license. It is a question of the formality they have to go through to change it. That is the issue. But it still has the pre-approval and in your term a tie-down is there.

CHAIRMAN PALLADINO: Any further questions, Jim?

COMMISSIONER ASSELSTINE: I have one further question.

Pat, you have mentioned a few substantive concerns about the provisions in the revised version of Part 35 and I know we heard some of those from the Agreement States representatives as well, both you and Joe.

Is your feeling basically that the proposed revision to Part 35 that we have before us could be cleaned up fairly quickly and easily from that standpoing or are the problems such that it really needs a fresh look before we act on it?

Is it something that in essence should be sent back to the staff to be worked on setting aside for the moment this issue of the review of procedures and training as part of the license application process?

MR. DELMEDICO: That would be my recommendation. I

have personally a great problem, myself, as an NRC employee making comments during the public comment period, for example.

COMMISSIONER AHEARNE: I have had the same difficulty.

MR. DELMEDICO: If we have concerns as employees, I think we need to reach the Commission in advance of that point and by the same token, I think when a rule goes out for public comment, it should be in fine shape.

CHAIRMAN PALLADINO: Also, if you make comment that results in a change and that hadn't been a substantive issue for the public to comment on, you have to go out for comments again.

COMMISSIONER AHEARNE: That still doesn't get to the question.

COMMISSIONER ASSELSTINE: My question was, is it in good enough shape that the kinds of problems that exist now can be corrected fairly quickly and easily or is this something that really needs to go back to the staff for a fresh look in terms of what is in this revised Part 35?

COMMISSIONER AHEARNE: As a working assumption, if there were some provision incorporated that picked up the pre-licensing review of procedures and qualifications.

COMMISSIONER ASSELSTINE: That's right.

CHAIRMAN PALLADINO: Incidentally, I was waiting to get the staff back to ask them the same question.

MR. DELMEDICO: In the past year and a half that the rule has been in the process of being written, I have perceived that these are major philosophical differences.

COMMISSIONER AHEARNE: Yes.

MR. DELMEDICO: I haven't been able to make a dent in them as you can well imagine.

Certainly if agreement were reached that we do need to review physician qualifications and we do have to have hospitals and physicians tied to some rather specific procedures, yes, I suppose that the basic package could be cleaned up rather quickly

COMMISSIONER AHEARNE: In other words, the rest of it, the pulling together in one place, those aspects of it are all right.

COMMISSIONER ASSELSTINE: That is really the question. Setting aside the question of the pre-licensing review of training and procedures, does Part 35 do what it was intended to do, that is, to pull together in one place virtually all of these essential elements so that you had in one place all of those elements that you wanted to impose as requirements or are there enough problems there that it really needs to go back for a major rework?

MR. DELMEDICO: No. I don't believe that there are problems there. I had to use the SECY paper a great deal in preparing my original letter to you and also in this

discussion. I found it rather easy to use and well organized.

COMMISSIONER ASSELSTINE: All right. Good.

CHAIRMAN PALLADINO: I wanted to give the staff a few minutes to make comments. We will try to adjourn in the next five minutes.

Thank you both very much for your comments. We appreciate it very much.

John, I thought it would be appropriate to give you a chance to comment particularly on the two points that have been raised having to do with the pre-licensing review of procedures and training.

MR. DAVIS: We should have tracked you though more of this than we thought you would want to be tracked through. But we have Bill and he is going to track you in just a few minutes into what we would do with the new rules having to do with procedure.

I think it has been rightly characterized. There is a difference in philosophy, but I am not sure that the difference in philosophy is a wide difference in philosophy.

Basically what we had hoped to do in this new procedure with regard to the procedures themselves is to come to some degree of standardization. Secondly, while the rule, itself, would require, that they meet certain standards and then not get so involved with the detail of how each specific hospital meets that standard. So that when for some reason

they feel they have to change the details, they have to come back to us for an amendment to the license.

CHAIRMAN PALLADINO: You would perceive approving the procedures?

MR. DAVIS: I would say that the licensees, if they meet the basic requirements, should have some flexibility in how they meet those requirements and the option to change those detailed procedures without having to come to us for pre-review. When we talk about procedures, as I understand these procedures, they vary from somewhat general to extremely specific.

I think the thing to do is to let Bill walk through this as to what we had in mind so you will have at least a better understanding of what, I guess, is now a minority view.

(Laughter.)

CHAIRMAN PALLADINO: We can characterize views as minority or majority.

MR. DAVIS: The view of how we thought we were guaranteeing safety and how we did not see this rule as a dramatic walk back from safety but merely a cleaning up of the way to get there. Bill, why don't you pick it up?

MR. WALKER: Since we are working with the training and experience, the pre-review of physician training and experience and procedures, I would like to start with the

physicians.

CHAIRMAN PALLADINO: With what?

MR. WALKER: The physician's training and experience, how we propose to do it and why we don't feel that it will be drastically different enough to give us any less assurance than we are getting right now.

As I pointed out, there is already a new requirement for the physicians to actually sign his name that he does, in fact, meet these with a very specific reference to the place where the requirements are contained in the regulations. There is another requirement that the highest management of the licensee sign the application and the statements are made that the people who have said that they have this training, in fact, do comply with the regulation.

The last point it mentions that he may be subject to such civil and criminal penalties as provided by law if he makes a statement in here that is not true. This is a warning to that man who is very atuned t malpractice and everything else, that he is, in fact, making a very sound statement.

COMMISSIONER AHEARNE: What page was that on?

MR. WALKER: Sir, that is at the very end of enclosure 1 and it is on the application form, itself. That should be the last page before the first green page that you have there.

COMMISSIONER ASSELSTINE: So you say block 25 is signed by the supervisor, not by the physician.

MR. WALKER: By the hospital administrator or the hospital director.

COMMISSIONER GILINSKY: What is your estimate of the number of applications that are withdrawn now? We talked about that earlier.

MR. WALKER: I would say less than five percent. I think we ought to go back and get you a figure on that but it is very rare that they are withdrawn.

COMMISSIONER GILINSKY: That is one out of twenty. Let's assume that everyone was acting in good faith and thought they were qualified and turns out not be qualified.

MR. WALKER: Less than five percent. I don't know quite how much less than five percent. It may be considerably more. Most of the physicians do, in fact, have the training. There may be in a couple of instances, and we are working with one right now where the individual had the training required to do this but it is older than five years.

This is one which he may or may not have been clear on from the current format of the requirements and under the new regulation, we make it quite clear that this five years of uninterrupted or somewhere in there, he has received some continuing education. This is the principle that all of the physician specialities follow. It is this principle of

continuing education.

Here is a matter that we will probably have this guy withdraw his application because although he has all this training, he didn't have it five years ago.

But this is one of very few. Most of the time when it is something like this he can come back and this one may also be able to do this and document that, in fact, the only reason that he didn't come in the first time was that the documentation was fairly complete except for one small point. He is roll qualified. Even those occasionally that miss meeting the full qualifications have had very extensive training that includes a large amount of radiation safety and although they may not meet our formal requirements, I don't think that they are so ill-informed or so ignorant of radiation safety principles as to present much of a hazard.

I think that is an important point.

COMMISSIONER GILINSKY: Let's turn this whole thing around. Why have any requirements at all? Why don't we just leave it to the medical profession? I suspect that that would be something that they would favor.

MR. WALKER: Maybe we go back to the same sort of a thing, a philosophy that has sort of crept into licensing and that is, if there aren't enough --

MR. OLMSTEAD: The answer to that is very simple. You are required by law to have requirements.

COMMISSIONER AHEARNE: But here we have a proposed rule. We can also have a proposed piece of legislation.

MR. OLMSTEAD: There are many options.

COMMISSIONER AHEARNE: I think Commissioner Gilinsky is addressing fundamental health and safety questions and philosophy.

COMMISSIONER GILINSKY: We also have tremendous latitude in setting standards.

MR. CUNNINGHAM: This question has been raised a number of times and there is a substantive question of the need to regulate this. I think from what we have seen years ago when we put the general license into effect and continued it just from the comments we hear today about what is perceived as a lessening of regulation, you can see the difficulty it runs into.

We haven't reduced the safety requirements. But the perception of it raises a hornet's nest. I think if one were to try to abandon regulatory requirements on physicians and hospitals all together, it would be unsuccessful.

COMMISSIONER GILINSKY: But you are saying that you would run into public relations problems. What are the health and safety problems? Are we doing something that needs to be done or are we just doing something that people expect that really doesn't need to be done?

MR. CUNNINGHAM: You always have to ask the question,

compared to what?

COMMISSIONER GILINSKY: Compared to having doctors basically regulate themselves.

MR. CUNNINGHAM: Certainly, these radioactive drugs if mishandled can cause safety problems. There is no question about that. Now if you compare it to other risks that are available in the hospital which are largely unregulated, I think they are somewhat comparable. Fluoroscopy machines, all kinds of therapeutic drugs, all of these present risks to patients and they are available without the degree of regulation we have.

But if you compare it to risks in the nuclear industry which we regulate, then it is a different question.

MR. WALKER: There is an important difference in the use of radioisotopes in a medical situation and the use of therapeutic drugs or surgery or anything else. The risk is to the patient in these other specialties. In our case, the risk is not only to the patient but to the people using the radiopharmaceuticals and to the other people employed in the hospital as well as the public.

Therefore, it is a different situation and requires different regulations to govern it.

COMMISSIONER GILINSKY: I guess I am not sure where you come out on this. We were talking about training qualifications and you set a certain standard that I guess you

think it is very important to be maintained, but you say that even if it is not met, those people are really qualified. It sounds like we have the wrong standard.

MR. WALKER: No. What I am saying is that the relative risk is not as great as it would be as if you had a completely untrained individual in charge of this, someone who wasn't at least striving to meet some sort of the standard.

COMMISSIONER GILINSKY: Is it important for NRC to set these standards? Would they not be maintained otherwise?

MR. WALKER: It is important for us to determine the qualifications of the individual.

COMMISSIONER GILINSKY: Why is it important for us to do that? Would not the doctors do that themselves or the hospitals?

MR. WALKER: The staff is following the medical policy statement which the Commission has --

COMMISSIONER GILINSKY: I am trying to understand what your view is so we can understand whether we are doing the right thing or we aren't?

MR. CUNNINGHAM: I think the answer is that to the best of our knowledge, we are doing the right thing and we have the training qualifications set at a level which appears to be appropriate. We have done this with the advice of our medical advisory committee. It is our best estimate what

those training qualifications should be.

CHAIRMAN PALLADINO: Bill, you were trying to make a point or two. Have you made your points?

MR. WALKER: Only that this training is well documented now in the regulations.

CHAIRMAN PALLADINO: How about this part where you just certify? I can understand saying I certify that I am certified.

COMMISSIONER GILINSKY: Board-certified.

CHAIRMAN PALLADINO: Board-certified. I certify that I have the 500 hours of training in this area and whatever is required, but when you get to that other category that says that I certify that I did this and so under item J.

COMMISSIONER AHEARNE: That is the 500 hours.

CHAIRMAN PALLADINO: Is that what the 500 hours is? Where is the uncertainty that was described earlier?

COMMISSIONER AHEARNE: The uncertainty that was described earlier is that the person doesn't have to show where they got that 500 hours. They just certify that they have met that requirement.

COMMISSIONER ROBERTS: Under threat of civil and criminal penalties.

MR. DAVIS: And they must maintain the records, of course, on file.

CHAIRMAN PALLADINO: They what?

MR. DAVIS: They must maintain on file the records that serves as a basis for that statement but they don't submit it to us for pre-review.

CHAIRMAN PALLADINO: I gather that right now they do submit it to you under the present rules?

MR. WALKER: They do, but it is only as it is in this case, a personal certification that they have received it. It is nothing more.

CHAIRMAN PALLADINO: Do you review what comes in?

MR. WALKER: We look at it to see if it, in fact, meets what we have set as a standard.

COMMISSIONER AHEARNE: And if you have questions?

MR. WALKER: If we have questions, then we will go back.

CHAIRMAN PALLADINO: So that is the one philosophical difference at least on this point.

MR. WALKER: Yes, but I don't think it is a very wide one.

MR. OLMSTEAD: To just give you a little practical experience, what happens when the certification is falsified is we issued an enforcement order and it went out and the Justice Department was informed and the doctor acceded to the revocation of his license on the grounds that the Justice Department wouldn't prosecute him. That is what actually happened.

COMMISSIONER AHEARNE: How did we know it was falsified?

MR. OLMSTEAD: We had an informer in the particular case that I am aware of.

CHAIRMAN PALLADINO: As you said earlier, when a person is intent upon falsifying, he will do it but sometimes you think you are in compliance but you aren't because you can't interpret the rules, is there some harm in having this supporting information sent to you to review it?

MR. WALKER: The only harm is that once an individual is identified as a user, if it takes several months for us to negotiate placing him on the license, he is essentially in a professional limbo. He may have already made a move from his previous location to the new location.

COMMISSIONER GILINSKY: Wouldn't the new hospital or practice or whatever have expected to get the sort of documentation that would make clear that he would qualify for a license? Wouldn't they review that before he moved and they accepted him and new arrangements were made? And what is the difficulty about xeroxing that and sending it to the NRC?

CHAIRMAN PALLADINO: At review time.

COMMISSIONER AHEARNE: I gather the problem comes when the documentation is not complete.

MR. WALKER: That is true.

COMMISSIONER GILINSKY: Which means that they may not have been very careful. The more I listen to this, it seems to me that it adds an element of discipline into the process.

COMMISSIONER AHEARNE: Could you answer the question that was raised by the other staff members? John mentioned that the information has to be kept on file under your proposal. Would you expect the inspector in doing this inspection to look at that documentation and then reach the same kind of a conclusion that your reviewer would? What does the inspector then do? The information is adequate, what would you under your proposal have the inspector do at that stage?

MR. WALKER: I would think that it would be appropriate for him to look at it.

COMMISSIONER AHEARNE: He looks at it and it is inadequate. What does the inspector now do? Does he cancel the license?

MR. DAVIS: I would anticipate that he would go into an inspection mode and give the individual the opportunity to develop the information which is missing.

COMMISSIONER GILINSKY: Suppose it takes a week to get it and the guy is there for that afternoon?

MR. DAVIS: It would be submitted to him as part of the enforcement action.

CHAIRMAN PALLADINO: In the interest of time, I think

you sense an interest on the part of the Commission to get that loop closed on this training certification.

COMMISSIONER ASSELSTINE: And procedures.

CHAIRMAN PALLADINO: I don't know how many people but I think I can count at least three or four.

(Laughter.)

CHAIRMAN PALLADINO: And go into the procedures and here it gets a little trickier perhaps at least in ascertaining where people stand, where the Commission stands. Again, I thought the model that you were trying to follow was going to the reactor model where the procedures are taken out of the licenses themselves, so that you don't have license amendments involved.

Then if we follow the reactor model, you would still have approval of a procedures.

COMMISSIONER GILINSKY: Initially.

MR. DAVIS: Here again, I will have to talk to DeYoung. Is it correct that all of the procedures at a reactor are approved by the NRC?

COMMISSIONER GILINSKY: No.

COMMISSIONER AHEARNE: We have changed since TMI.

(Laughter.)

MR. DAVIS: Are you certain?

COMMISSIONER AHEARNE: On this side of the table, we

are never certain.

COMMISSIONER GILINSKY: For a reactor, you are really talking about emergency procedures.

MR DAVIS: Let me interject one thing here though. I think if you look at the rule and here again believe it or not are astute enough to recognize that you do have some concerns about it, but if you look at the rule what we attempted to do in the rule as I understand it is to focus attention on those matters which the staff believes is important to safety.

Obviously, there are some differences of opinion as to the level of safety associated with each of the elements within the procedure. So consequently, it was an attempt to focus, an attempt to get the attention of the staff on those things which were important to safety more than the details of all of the procedures which may come in and I don't know whether we didn't get the message across or we missed the mark, but in any event, we do recognize that you do have concern about our not prereviewing every procedure and prechecking every amendment to a procedure before the licensee can begin to use the material for which he is asked.

CHAIRMAN PALLADINO: I don't really know enough about the process even on reactors.

COMMISSIONER GILINSKY: On reactors, it is the

emergency procedures.

CHAIRMAN PALLADINO: What I am not sure about in the reactors is what procedures we looked at, what we prove and what we don't.

MR. DAVIS: I am told that it has to do with the importance to safety.

COMMISSIONER AHEARNE: Yes.

MR. DAVIS: Which is what we thought we were doing in this one.

CHAIRMAN PALLADINO: Maybe you are, but I was anticipating that this process would involve review of, let me say, major important or otherwise similarly characterized procedures.

MR. OLMSTEAD: I would like to mention something because I think there has been a misimpression created about the enforceability of the procedures. This rule does have the features in it that the reactor rules do for procedures that don't have to be part of the license in that if the inspector goes in and the procedures are not there, that is a citable violation.

COMMISSIONER GILINSKY: Not there at all.

MR. OLMSTEAD: Not there at all or if they fail to implement the provision of the rule that requires procedures to do specific things. They might have a procedure that covers three out of four things and not the fourth. That would

still be a citation, a violation.

If you take the procedures out of the license which is what we do in the reactor area, then there is normally a mechanism to change the procedures by something like a radiation safety review committee and that feature is in this rule, too.

The only differentiation is that they haven't identified critical procedures that have to be submitted.

COMMISSIONER GILINSKY: The difference is that we are in very close contact with the reactor licensee.

MR. OLMSTEAD: I understand that there are some major policy questions for you, but I didn't want you to have the impression that they weren't enforceable.

CHAIRMAN PALLADINO: That was one of my questions. I wasn't sure whether they were enforceable.

MR. DAVIS: They are enforceable.

COMMISSIONER GILINSKY: To the extent that you are dealing with parts of the regulations as they would be codified in this part.

MR. OLMSTEAD: But failing to have procedures could not occur under this regulation and be in compliance with the regulation.

COMMISSIONER GILINSKY: Failing to have the procedures entirely.

MR. OLMSTEAD: Failing to have a procedure called

for by the regulations and it specifically calls forth those types of procedures that are required.

MR. DAVIS: It calls for certain subjects which is what the staff believed to be important to safety.

CHAIRMAN PAL'ADINO: Let me make a suggestion. I do have to adjourn pretty soon, but rather than try to jump to a conclusion even though I have developed a little bias, I would like to explore my bias a little more and maybe others want to, I think on this point it might be well for the Commissioners to indicate any guidance they would like to offer on the procedures rather than try to do it hurriedly right now.

COMMISSIONER ASSELSTINE: I am inclined to agree with that. I think the procedure and the substance tends to be mixed up a little bit, too, in the way the rule is done.

COMMISSIONER AHEARNE: What I would like to do is to follow up on your earlier suggestion to see an alternative and since there are at least two elements of staff who felt very strongly about an alternative approach, at least I would like to see that alternative approach.

CHAIRMAN PALLADINO: You mean what I had asked Joe DelMedico?

COMMISSIONER AHEARNE: Yes.

CHAIRMAN PALLADINO: I was not envisioning what I had asked Joe DelMedico to be a major undertaking, but rather

where in the rules he would implement a suggestion.

COMMISSIONER GILINSKY: The two principal suggestions.

COMMISSIONER ASSELSTINE: Yes. I would agree with that.

COMMISSIONER AHEARNE: That would help, I think.

CHAIRMAN PALLADINO: This has been a very valuable meeting. Incidentally, I do find great merit in a number of aspects of your rule.

MR. DAVIS: I wish we could have a list of those.

(Laughter.)

COMMISSIONER AHEARNE: I would like to make two comments. First, I will take another look at the threshold for this Administration, a point that was raised. I would like to thank Mr. Spell, Mr. Whatley, Mr. DelMedico and Ms. Vacca.

I guess my point is that one of the difficulties that I know I have as a Commissioner is understanding when there are serious issues and they, I believe, in this particular case enabled me to understand that there was a serious issue here which I would never have gotten from the staff paper. I think that is just unacceptable.

I am not saying I fault where the staff came out. That is not the issue. Staff, seems to me, have good reasons in their judgment for the position that they have ended up

with and senior management then concludes that is where the staff's position is, that is what senior management was supposed to do. I in no way fault that you have reached this conclusion.

What I find unacceptable is that coming up to the Commission for this kind of a major policy decision just the almost total absence of the seriousness of this other side. It did take the Spell, Whatley, DelMedico and Vacca to bring that forward. I thank them very much for it.

I am not sure where I come out on the issue. I am not saying that I agree with them. But it is just that our role is principally trying to decide on policy and we have to understand what the serious issues are.

COMMISSIONER GILINSKY: I must say that I agree entirely with John.

CHAIRMAN PALLADINO: Any other comments?

(No response.)

CHAIRMAN PALLADINO: I want to thank our outside visitors also for their participation.

COMMISSIONER GILINSKY: Yes, it was very good.

CHAIRMAN PALLADINO: We stand adjourned.

(Whereupon, at 12:47 o'clock p.m., the Commission meeting was adjourned, to reconvene at the Call of the Chair.)

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NUCLEAR REGULATORY COMMISSION

This is to certify that the attached proceedings before the

Nuclear Regulatory Commission

in the matter of: Briefing on SECY-83-62 - Proposed Revision to 10 CFR Part 35 "Human Use of Byproduct Material"

Date of Proceeding: Tuesday, April 19, 1983

Docket Number:

Place of Proceeding: Room 1130, 1717 H St., N.W.
Washington, D.C.

were held as herein appears, and that this is the original transcript thereof for the files of the Commission.

Marilynn M. Nations
Official Reporter (Typed)

Official Reporter (Signature)

APRIL 18, 1983

SCHEDULING NOTES

TITLE: BRIEFING ON SECY-83-62 - PROPOSED REVISION TO 10 CFR PART 35 "HUMAN USE OF BYPRODUCT MATERIAL"

SCHEDULED: 10:00 A.M., TUESDAY, APRIL 19, 1983

DURATION: 1-1/2 HRS

PURPOSE: TO DISCUSS PROPOSED REVISIONS TO PART 35

SPEAKERS:

1. (20 MIN)
   BILL WALKER, NMSS

2. (10 MIN)
   WILLIAM SPELL/REP. OF AGREEMENT STATES

3. (10 MIN)
   DR. RALPH ROBINSON, PRESIDENT
   THE AMERICAN COLLEGE OF NUCLEAR PHYSICIANS
   (ALSO REPRESENTING THE SOCIETY OF
   NUCLEAR MEDICINE)

4. (10 MIN)
   OTHA W. LINTON, DIRECTOR OF GOVERNMENTAL RELATIONS
   AMERICAN COLLEGE OF RADIOLOGISTS

DOCUMENTS: SECY-83-62
OTHER DOCUMENTS TO BE DETERMINED

PROPOSED RULEMAKING

10 CFR PART 35

"HUMAN USE OF BYPRODUCT MATERIAL"

WHY CHANGE?

- CURRENT REQUIREMENTS ARE PATCHWORK
- LICENSING PROCESS NEEDS OVERHAUL
- STANDARDIZATION AND CONSISTENCY NEEDS IMPROVEMENT
- RESPOND TO COMMISSION POLICY AND PROGRAM GUIDANCE

GOALS

- MAINTAIN SAFETY
- IMPROVE EFFICIENCY

PROPOSED CHANGES

- CONSOLIDATE AND UPDATE REQUIREMENTS
- UPGRADE THE PROCESS

MAJOR CHANGES
CONSOLIDATE AND UPDATE REQUIREMENTS

CURRENT	PROPOSED
• REQUIREMENTS ARE PLACED ON LICENSEES THROUGH REGULATIONS, BRANCH POLICIES, STANDARD CONDITIONS OF LICENSES AND GUIDANCE PROTOCOLS	• ALL ESSENTIAL SAFETY REQUIREMENTS CONSOLIDATED INTO CONCISE AND COHERENT REGULATIONS
• LICENSING DECISIONS ARE MADE WITH LIMITED UNIFORMITY ON DETAILED REQUIREMENTS	• REQUIREMENTS FOR LICENSING STANDARDIZED
• TECHNICAL REQUIREMENTS HAVE BEEN ADDED TO REGULATION IN A HAPHAZARD FASHION AS PROBLEMS WERE IDENTIFIED	• REGULATION INTEGRATES CURRENT TECHNICAL DEVELOPMENTS AND PROCEDURES
• HAPHAZARD AMENDMENTS MAKE REGULATION DIFFICULT TO READ AND INTERPRET	• REGULATION RESTRUCTURED FOR CLARITY AND CONSISTENCY

MAJOR CHANGES
UPGRADE THE PROCESS

CURRENT	PROPOSED
• APPLICATION INCLUDES EXTENSIVE, DETAILED DESCRIPTIONS OF APPLICANT'S OPERATION FOR NRC REVIEW	• APPLICATION FOCUSES ON KEY SAFETY ISSUES WITHOUT SUBMISSION OF UNNECESSARY DETAILS
• LARGE STAFF COMMITMENT TO REVIEW OF APPLICATIONS	• FOCUS STAFF RESOURCES ON OTHER ISSUES, INCLUDING DEVELOPMENT OF NEW TECHNOLOGY AND SAFETY RELATED ISSUES
• STANDARDIZATION OF APPLICATION REVIEWS DIFFICULT BECAUSE OF DIFFUSION OF LICENSING REQUIREMENTS	• SIMPLIFICATION AND STANDARDIZATION OF PROCESS PROVIDES NECESSARY UNIFORMITY AND CONSISTENCY
• CHANGE IN A LICENSEE'S PROCEDURE REQUIRES A LICENSE AMENDMENT	• AMENDMENT REQUIRED ONLY FOR SIGNIFICANT CHANGES

MAJOR CHANGES
UPGRADE THE PROCESS
(CONT'D)

CURRENT	PROPOSED
• LIMITED COMPUTER USE POSSIBLE IN LICENSING PROCESS	• EXPANDED USE OF COMPUTER POSSIBLE
• LICENSING DELAYS AND BACKLOGGED APPLICATIONS	• ROUTINE APPLICATIONS PROCESSED WITHIN TWO WEEKS AND EVENTUAL ELIMINATION OF BACKLOG

ACHIEVE GOALS

- MAINTAIN SAFETY
  - RECOGNIZE LICENSEE EMPHASIS ON SAFETY
  - FOCUS ON IMPORTANT ISSUES
  - FOCUS OF NRC SKILLS

ACHIEVE GOALS

- IMPROVE EFFICIENCY
  - CONSOLIDATE REQUIREMENTS
  - IMPROVE STANDARDIZATION
  - IMPROVE QUALITY ASSURANCE
  - REDUCE PAPER FLOW
  - REDUCE PROCESSING TIME

NUREG-0714 (VOL. 1) SHOWS THAT MEDICAL LICENSEES ARE SECOND ONLY TO POWER REACTORS IN:

- NUMBER OF PERSONNEL OVEREXPOSURES REPORTED IN 1979

  REACTORS: 27 OVEREXPOSURES

  MEDICAL : 13 OVEREXPOSURES

- TOTAL OCCUPATIONAL COLLECTIVE DOSE

  REACTORS: 39,759 PERSON-REMS

  MEDICAL: 9, 230 PERSON-REMS

TYPES OF LICENSES

1. TYPE A LICENSES OF BROAD SCOPE

   - LARGE INSTITUTIONS (E.G., NIH, WALTER REED, NNMC)
   - DO RESEARCH, DIAGNOSIS AND THERAPY
   - LARGE WELL-TRAINED STAFF
   - EXCELLENT FACILITIES AND EQUIPMENT
   - DAY-TO-DAY DECISIONS BY LICENSEE'S RADIATION COMMITTEE USING CRITERIA APPROVED BY NRC

2. GROUP MEDICAL LICENSEES

   - COMMUNITY HOSPITALS; USE IN DOCTOR'S OFFICE
   - WELL-ESTABLISHED DIAGNOSTIC AND THERAPEUTIC PROCEDURES
   - LIMITED STAFF, FACILITIES AND EQUIPMENT

PRINCIPAL CONCERNS:

- PHYSICIANS' QUALIFICATIONS
- RADIATION SAFETY PROCEDURES

FROM PROPOSED FORM NRC-313MH, PART III, No. 23.: AUTHORIZED USERS

1. NAME _____ _____ ☐ MD ☐ DO

2. USE GROUP(S) ☐ GEN/I ☐ II/III ☐ IV/V ☐ VI ☐ VII ☐ VIII ☐ SR-90

3. MEETS TRAINING AND EXPERIENCE REQUIREMENTS BY:

☐ APPROPRIATE BOARD CERTIFICATION ☐ ABNM ☐ ABR ☐ AOBR ☐ OTHER(SPECIFY)

☐ REQUEST FOR EXEMPTION FROM 10 CFR TRAINING AND EXPERIENCE REQUIREMENTS

(DOCUMENTATION ATTACHED)

☐ TRAINING AND EXPERIENCE AS SPECIFIED IN 10 CFR SUBSECTION J

(SIGNATURE OF AUTHORIZED USER): _____ (DATE) _____

RADIATION SAFETY PROCEDURES

CURRENTLY APPLICANTS SUBMIT:

- COPIES OF PROCEDURES THAT THEY OR THEIR CONSULTANTS DEVELOP
- COMMITMENTS TO FOLLOW PROCEDURES IN SPECIFIED APPENDICES TO REGULATORY GUIDE 10.8 (E.G., APPENDIX __ OF REGULATORY GUIDE 10.8)
- SOME COMBINATION OF THE ABOVE

SOME OPTIONS REGARDING RADIATION SAFETY PROCEDURES

- CONTINUE CURRENT PRACTICE OF REVIEWING RADIATION SAFETY PROCEDURES
- INCORPORATE INTO 10 CFR PART 35 THE PROCEDURES IN THE APPENDICES IN REGULATORY GUIDE 10.8
- REVISE 10 CFR PART 35 TO SPECIFY CERTAIN MINIMUM FEATURES THAT EACH TYPE OF PROCEDURE MUST INCLUDE
- AT TIME OF APPLICATION, OBTAIN COMMITMENT FROM APPLICANT THAT HE HAS PROCEDURES FOR SPECIFIC RADIATION SAFETY ACTIVITIES AND, AS A MINIMUM, HIS PROCEDURES INCLUDE X, Y, AND Z (WHERE X, Y, AND Z ARE KEY FEATURES IDENTIFIED BY NRC)

COMMENTS OF

WILLIAM H. SPELL

REPRESENTING THE
ASSOCIATION OF AGREEMENT STATES
AND THE
CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

BEFORE THE

U. S. NUCLEAR REGULATORY COMMISSION

IN THE MATTER OF

REVISIONS TO 10 CFR, PART 35

WASHINGTON, D. C.

APRIL 19, 1983

COMMENTS OF WILLIAM H. SPELL
REPRESENTING THE
ASSOCIATION OF AGREEMENT STATES
AND THE
CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.
BEFORE THE
U. S. NUCLEAR REGULATORY COMMISSION

IN THE MATTER OF REVISIONS TO PART 35 OF TITLE 10 OF THE CODE OF FEDERAL REGULATIONS:

CHAIRMAN PALLADINO AND COMMISSIONERS, MY NAME IS WILLIAM H. SPELL. I AM ADMINISTRATOR OF THE NUCLEAR ENERGY DIVISON, OFFICE OF ENVIRONMENTAL AFFAIRS, LOUISIANA DEPARTMENT OF NATURAL RESOURCES. I PRESENTLY SERVE AS CHAIRMAN OF THE GROUP OF 26 AGREEMENT STATES WHICH HAVE ENTERED INTO AN AGREEMENT WITH THE NRC, PURSUANT TO SECTION 274.B OF THE ATOMIC ENERGY ACT OF 1954, FOR THE PURPOSE OF REGULATING, TOGETHER WITH THE NRC, BY-PRODUCT, SOURCE AND SPECIAL NUCLEAR MATERIAL IN THE STATES. I HAVE ALSO BEEN DESIGNATED BY THE EXECUTIVE COMMITTEE TO ACT ON BEHALF OF THE CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC. MY OWN INVOLVEMENT WITH THE USE AND CONTROL OF RADIATION HAS BEEN IN HIGHER EDUCATION OR IN LOUISIANA'S REGULATORY PROGRAM FOR THE PAST 20 YEARS.

WITH ME TODAY IS MR. KIRK WHATLEY, CHIEF OF RADIOACTIVE MATERIAL LICENSING, DIVISION OF RADIOLOGICAL HEALTH OF THE ALABAMA STATE DEPARTMENT OF PUBLIC HEALTH. MR. WHATLEY HAS SERVED ON AN AD HOC COMMITTEE APPOINTED BY THE CONFERENCE TO REVIEW NRC PROPOSALS RELATIVE TO 10 CFR 35. AS A MEMBER OF THIS COMMITTEE, HE HAS BEEN INTIMATELY INVOLVED WITH PREVIOUS PROPOSED CHANGES TO 10 CFR 35 AND IS QUITE FAMILIAR WITH THE MEDICAL LICENSING PROCESS, PARTICULARLY IN THE STATE OF ALABAMA. I AM INDEBTED TO MR. WHATLEY AND OTHERS IN VARIOUS STATES FOR PROVIDING INSIGHT IN THE PREPARATION OF THESE COMMENTS.

To clarify the interest and involvement of the Conference in these proceedings, there are several States which are in various stages of negotiation with the NRC to become "Agreement States." There are also those States which license naturally-occurring and accelerator-produced radionuclides, some of which are used in medical diagnosis and therapy, and these are designated as "Licensing States." Each of these groups has a vested interest in the outcome of any revision to 10 CFR, Part 35. The Conference also has a task force which is charged with the responsibility of maintaining a section of the "Suggested State Regulations for the Control of Radiation" which deals with licensing the use of radionuclides in medicine and which serves as a model for States to adopt if they so desire. Most States do so with minor modifications to fit their own particular needs.

At the annual NRC-Agreement States meeting in Gaithersburg, MD, this past October, there was enough concern voiced regarding proposed revisions to 10 CFR 35 to prompt the following resolution:

> "The Agreement States request that a representative of their group be afforded the opportunity to testify before the Commissioners prior to the proposed rule making on 10 CFR 35."

We do express our appreciation now for this opportunity to provide comments. I shall attempt to be brief and to address the major issues, leaving the details for later. These comments are an effort to coalesce the views of a number of State program personnel who were kind enough to respond to my call for assistance.

THE STATES COMMEND THE COMMISSION STAFF FOR ITS EFFORTS TO DEVELOP A REVISION WHICH INCORPORATES FORMER REQUIREMENTS OF LICENSE CONDITIONS AND THE OFTEN STRONG SUGGESTIONS OF REGULATORY GUIDES DIRECTLY INTO THE REGULATIONS. THIS PROCEDURE STRENGTHENS THE ENFORCEMENT ASPECT OF THE NRC'S REGULATORY PROGRAM, AND I HAVE RECEIVED NO SIGNIFICANT CRITICISM OF THIS ASPECT OF THE REVISION.

THE ISSUES WHICH HAVE BEEN RAISED CENTER MOSTLY ON THE METHOD OF IMPLEMENTING PROPOSED CHANGES AND ON PROTECTING THE PUBLIC HEALTH AND SAFETY. IT IS IMPORTANT TO NOTE THAT THE BULK OF MY PRESENTATION FROM THIS POINT SHOULD BE CONSIDERED AS OPINIONS OF SEVERAL AND NOT NECESSARILY SHARED BY ALL WHO WORK IN THIS AREA.

OF PARAMOUNT IMPORTANCE, I THINK, IS THE QUESTION, "WHY IS IT NECESSARY TO CHANGE THE METHOD OF IMPLEMENTING 10 CFR 35?" IS IT BECAUSE OF THE COMMISSION'S COMMITMENT TO "DECENTRALIZATION?" IS IT BECAUSE OF THE COMMISSION'S LONG TURN-AROUND TIME TO ISSUE A LICENSE? IS IT BECAUSE THERE HAS BEEN LITTLE EVIDENCE OF INJURY TO THE POPULATION FROM MEDICAL USES OF RADIONUCLIDES; ERGO, WE SHOULD LIGHTEN THE REQUIREMENTS? IS IT BECAUSE THE COMMISSION CANNOT CHARGE ENOUGH IN FEES ON A COST-RECOVERY BASIS TO CONTINUE THE PRESENT PRE-LICENSING REVIEW PROCESS WITHOUT CAUSING A FUROR IN THE MEDICAL COMMUNITY?

I DO NOT CLAIM TO HAVE ANSWERS TO THESE QUESTIONS, BUT I SHALL ATTEMPT TO ADDRESS SOME OF THEM FROM THE STATES' POINT OF VIEW. CERTAIN ASPECTS OF DECENTRALIZATION APPEAL TO THE STATES, BUT IT IS TOO EARLY FOR THE STATES TO RENDER A COLLECTIVE OPINION; WE RESERVE THE RIGHT TO COMMENT ON THIS LATER. HOWEVER, IT WOULD SEEM THAT BY TRANSFERRING THE LICENSING PROCESS TO REGIONAL OFFICES, SOME OF THE PREVIOUS UNIFORMITY IN THE PROCESS IS LIKELY TO BE LOST. ON THE OTHER HAND, IF IT TAKES TOO LONG TO ISSUE A LICENSE OR AN AMENDMENT, IS IT LIKELY TO TAKE LESS TIME WITH THE SAME NUMBER OF PEOPLE DIVIDED AMONG THE REGIONS? I THINK NOT.

I AM TOLD THAT IT TAKES TWO REVIEWERS AND ONE ADMINISTRATOR TO OVERSEE APPROXIMATELY 900 MEDICAL LICENSES IN THE STATE OF TEXAS, AND THEY HAVE A TWO-WEEK TURNAROUND TIME FOR LICENSES AND AMENDMENTS. FOR ABOUT 300 LICENSES, IT TAKES ABOUT 2½ PERSON-YEARS OF EFFORT FOR BOTH LICENSE REVIEWS AND INSPECTIONS IN MY OWN STATE OF LOUISIANA. CURRENT PROJECTIONS OF TURNAROUND TIME FOR NRC LICENSEES SUGGEST THAT SOME CONSIDERATION OF WAYS TO IMPROVE EFFICIENCY MAY BE IN ORDER. A BACKLOG OF LICENSE APPLICATIONS AND REQUESTS FOR AMENDMENTS OR RENEWAL SHOULD NOT BE THE SOLE REASON FOR CHANGING A REGULATION OR A METHOD OF DOING BUSINESS. ON THE OTHER HAND, IMPROVEMENTS IN HEALTH AND SAFETY GIVE SUFFICIENT REASON FOR SUCH CHANGES AND ARE TO BE COMMENDED WHENEVER IMPLEMENTED.

PROBABLY, THE GREATEST CONCERN OF THE STATES TO THE ENTIRE PROPOSAL IS THE LACK OF A PRE-LICENSING REVIEW OF RADIATION SAFETY PROCEDURES AND PHYSICIAN QUALIFICATIONS. VARIOUS ESTIMATES HAVE PLACED THE NUMBER OF DEFICIENT NEW APPLICATIONS PRESENTLY BEING RECEIVED AT ABOUT 40% AND THE NUMBER OF PHYSICIANS WHO THOUGHT THEY WERE QUALIFIED, BUT WHO WERE NOT, AT 15%. IT IS NOT AT ALL CLEAR HOW THE PROPOSED CHANGES WILL REDUCE THE PERCENTAGE. UNDER THE PROPOSED CHANGES, DEFICIENCIES COULD BE IMPLEMENTED BY THE LICENSEE OR AN UNQUALIFIED PHYSICIAN COULD PRACTICE NUCLEAR MEDICINE OR THERAPY, AND NONE WOULD BE DETECTED UNTIL AN INSPECTION IS CONDUCTED, IF THEN. TO DELAY THE DETECTION OF DEFICIENCIES IN A SUBSTANTIAL NUMBER OF PROGRAMS MAY RESULT IN UNNECESSARY RADIATION EXPOSURES WHICH COULD HAVE BEEN PREVENTED. THIS SIMPLY IS NOT GOOD HEALTH PHYSICS PRACTICE.

ANOTHER ASPECT WORTHY OF CONSIDERATION IS THAT OF "COMPATIBILITY." WHILE IT HAS BEEN STATED THAT THIS WILL NOT BE A MATTER OF COMPATABILITY FOR AGREEMENT STATES, IT IS GENERALLY AGREED THAT THERE NEEDS TO BE A DEGREE OF UNIFORMITY AMONG THE STATES AND THE NRC. IF THE NRC'S FINAL REVISION IS PERCEIVED AS BEING LESS

RESTRICTIVE ON THE MEDICAL COMMUNITY, THERE WILL BE CONSIDERABLE PRESSURE ON THE STATES TO ADOPT SIMILAR, IF NOT IDENTICAL, REGULATIONS. FURTHERMORE, SUCH REGULATIONS COULD HAVE AN ADVERSE IMPACT ON COMMERCIAL SUPPLIERS OF RADIOACTIVE DRUGS. WE PROBABLY HAVE ALREADY GIVEN THIS GROUP OF LICENSEES ENOUGH HEADACHES WITHOUT COMPOUNDING THE PROBLEM.

PHILOSOPHICALLY, PERHAPS WE SHOULD CONSIDER WHETHER OR NOT ABANDONING REVIEWS OF PROCEDURES FOR MEDICAL APPLICATIONS SETS A PRECEDENT TO DO THE SAME IN ALL OTHER AREAS WE REGULATE. I CAN ASSURE YOU THE STATES ARE NOT READY TO DO THIS, PARTICULARLY IN CERTAIN INDUSTRIAL AND RESEARCH SETTINGS. IT DOES APPEAR THAT THE PROPOSED APPROACH PLACES A GREATER BURDEN ON INSPECTORS TO UNCOVER PROBLEMS, AND THIS IS IN AN AREA WHERE THE NRC HAS SHOWN A LOW FREQUENCY OF INSPECTIONS IN THE PAST. FOR EXAMPLE, FOR THE PERIOD 1/1/82 THROUGH 6/30/82, THE LAST PERIOD FOR WHICH STATISTICS ARE AVAILABLE, THE NRC ADMINISTERED 2622 MEDICAL BY-PRODUCT MATERIAL LICENSES WHILE THE STATES COLLECTIVELY ADMINISTERED 4691 MEDICAL LICENSES OF ALL DESCRIPTION. FOR THE SAME PERIOD, THE NRC PERFORMED 51 BROAD LICENSE AND 314 OTHER MEDICAL LICENSE INSPECTIONS, WHILE THE AGREEMENT STATES PERFORMED 54 BROAD LICENSE AND 1001 OTHER MEDICAL LICENSE INSPECTIONS. IN BOTH CASES, SOME OF THE BROAD LICENSES WERE MEDICAL LICENSES. IN ALL FAIRNESS, THE SAME PRIORITY SYSTEM FOR INSPECTIONS IS NOT IN UNIFORM USE THROUGHOUT.

THE STATES SUPPORT THE CONCEPT THAT A GOOD REVIEW OF AN APPLICATION FOR A MEDICAL LICENSE CAN PREVENT A COMPLETE MISUNDERSTANDING LATER ON, ONE IN WHICH THE LICENSING AGENCY MAY BE PERCEIVED TO BE GUILTY OF CONTRIBUTORY NEGLIGENCE. THIS CONCERNS THE STATES, BECAUSE THE STATES DO NOT POSSESS THE LEGAL STAFF TO COPE WITH THIS TYPE OF PROBLEM VERY OFTEN.

In order for implementation of the NRC's proposed changes to 10 CFR 35 to work, it appears that there must be an exceptional commitment on the part of the NRC to do more at the regional level, both in reviews of applications for new licenses, renewals and amendments, and in the inspection effort. In most medical institutions, an inspector is someone who is marginally welcome, if at all. It is difficult for me to envision how the inspector can perform a post-licensing review of those things that in the past have been considered necessary prior to the issuance of a license. Physicians will likely not have time to discuss items in detail without interruption and patient needs will always come first. Assuming the lag between licensing and inspection to be short, there may be large inefficiencies not here-to-fore addressed that are built-in with this kind of system. If it takes an experienced license writer ten (10) hours to review an application in his office, how much longer would it take the inspector in the field? In fact, I have seen no indication that the Commission's Value/Impact Statement addresses the added cost to the Office of Inspection & Enforcement due to added duties involving the reviews of procedures for adequacy and reviews of physician qualifications.

It appears that the version of 10 CFR 35 which is being offered today is not the one which all States have had an opportunity to review. Furthermore, to state that the Agreement States totally support the present version is without basis, since only a very few have seen it, much less commented on it. We are not even sure whether or not previous comments of a number of the States have been given serious consideration. It is this kind of regulation development which prompted an earlier resolution at the aforementioned meeting of the NRC-Agreement States, to wit:

"THE AGREEMENT STATES ENCOURAGE NRC TO DEVELOP CRITERIA FOR REVISING OR DEVELOPING REGULATIONS BASED ON HEALTH AND SAFETY AND TO SOLICIT CONCURRENCE FROM STATES ON THESE PROPOSED RULES PRIOR TO PUBLISHING IN THE FEDERAL REGISTER (E.G., URANIUM MILLS REGULATIONS)."

TO SOME EXTENT, THIS HAS BEEN DONE. BUT WHEN A STATE ENTERS INTO AN AGREEMENT WITH THE NRC, THE RESULT IS A PLEDGE, EACH TO THE OTHER, TO EXERCISE THEIR BEST EFFORTS IN PROTECTING THE PUBLIC HEALTH AND SAFETY. WE BELIEVE THAT IT IS TIME TO CONSUMMATE THE PARTNERSHIP BY ALLOWING THE STATES TO PARTICIPATE MORE FULLY IN THE DEVELOPMENTAL STAGES OF REGULATIONS WHICH IMPACT THE STATES, EVEN IF THE REGULATIONS ARE NOT TO BE MADE A MATTER OF COMPATABILITY. JUST AS THE NRC AND OTHER FEDERAL AGENCIES ASSIST THE STATES IN DEVELOPING REGULATIONS, WE OFFER THE FULL COOPERATION AND ASSISTANCE OF ALL THE STATES WITHIN THE LIMIT OF OUR RESPECTIVE RESOURCES AND TRUST THAT OUR COLLECTIVE EFFORTS WILL RESULT IN A MARKED IMPROVEMENT IN PROTECTION OF THE PUBLIC HEALTH AND SAFETY, AS WELL AS THE ENVIRONMENT.

MR. CHAIRMAN, THANK YOU AGAIN FOR ALLOWING THIS OPPORTUNITY TO PROVIDE COMMENTS ON SUCH AN IMPORTANT ISSUE. MR. WHATLEY AND I SHALL BE PLEASED TO TRY TO ANSWER ANY QUESTIONS YOU MAY CARE TO ASK.

COMMENTS FOR

THE NUCLEAR REGULATORY COMMISSION

regarding proposed Part 35

from

THE AMERICAN COLLEGE OF RADIOLOGY

Otha W. Linton

Director, Governmental Relations

19 April 1983

My name is Otha W. Linton. I am director of government relations for the American College of Radiology, a national professional society of 16,000 physicians and radiation scientists. Radiologists specialize in the uses of x-rays and radioactive substances to diagnose and treat disease. Many members of the College hold various types of licensure from the Nuclear Regulatory Commission and the agreement states.

My comments regarding the draft Part 35 represent the opinions of the College Commissions on Nuclear Medicine and Radiation Therapy. They have considered the concept in the draft and some members have reviewed parts of the proposed text.

We think that the proposed Part 35 should be completed, submitted for public review and adopted by the commission. As nearly as a document can be judged in advance, it should meet most of the goals it sets for itself in clarity, consistency, economy and efficiency for all concerned. We found it easy to read and follow. Applicants for licensure should find their tasks made substantially simpler.

In previous testimony, the College has suggested that the paternalistic anachronism of federal control of medical uses of byproduct material has largely been succeeded by the medical mechanisms of specialty training and credentialing boards. We have noted, as well, the creation of radiation control programs in the states, resulting from the 1959 amendments to the Atomic Energy Act. Yet, in 1979, the Commission concluded that it has a continuing role in this area. Thus, our present comments relate to our mutual objective of making your regulations as practical and reasonable as possible.

To an encouraging extent, the draft regulations recognize the existence of professional credentials as meeting the federal standards for proficiency and competence. This is more explicit than in earlier versions, and commendably so.

We also find commendable the concept of bringing into one relatively readable and consistent part the commission's requirements for medical users of byproducts. We think that the commission's responsibilities can be met by emphasis upon the demonstrated competence of licensees to use isotopes safely and effectively, rather than in duplicating the criteria for medical competence found in professional credentials.

A recent study by the Hospital Association of New York State suggested that 25 percent of hospital dollars were spent in complying with regulatory requirements of federal, state and local agencies. Any reduction in such requirements and the costs of responding to them can only be applauded in these days of soaring health costs and dramatic efforts to reduce them.

Within the current draft of Part 35, several points warrant brief mention for your consideration.

1. Our committees suggest amplification of Part 35.75 relating to the institutional stay of patients containing radioactive materials. Patients receiving doses of 150 to 200 millicuries should be hospitalized and the discharge criterion is a valid one. It is objective, cost effective and reasonably safe for the technical personnel making the determinative measurements.

In our opinion, a distinction should be made regarding patients who receive therapeutic doses of less than 30 millicuries. Unless there is other cause for hospitalization, it is our opinion that patients receiving doses of 30 millicuries or less need no hospital commitment and need no measurement of external dose to assure the safety of others. We urge application of a "deminimus" concept to avoid complicating this circumstance.

One complication, if you have noted, is that all of us in health care are being pressed currently by other agencies of the federal government to reduce costs by every available means. Adding or re-emphasizing a requirement which would require hospitalization for technical reasons would be a problem for all of us. We don't wish to place money over safety. But we do need a supportable balance.

2. In Part 35.920, our committees feel that the total amount of training specified as an alternative to recognized board certification is appropriate. However, as written, the allocation between work experience (500 hours) and clinical experience (500 hours) is unduly rigid. We would welcome an opportunity for more detailed discussion of this in the public comment period.

3. Part 35.37 should be dropped. As we understand it, this will require an action by the commission to reverse its recent vote. The ACR and other concerned organizations anticipate submitting a formal petition for such action, if necessary to gain reconsideration.

The reports to NRC since the "misadministration rule" was adopted indicate clearly that a violation rate of less than .01 percent makes the result not worth the effort, either for the commission or for others concerned.

We will not argue the details of the ruling here, since the comment notes the intent to furnish another forum for that. However, we note with dismay that when the ACR and others requested under the Freedom of Information Act SECY 82-388, it was refused by staff. In the absence of national security issues, we strongly urge the commission's reconsideration of this refusal. If the commissioners had good cause to retain the requirement, public disclosure might help us to understand those reasons. If not, then we have all the more reason for insisting upon reconsideration.

With those suggestions for change and on behalf of the American College of Radiology, I urge your favorable action on proposed Part 35 toward its submission for public comment and subsequent adoption.

I would be pleased to respond to questions.

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American College of Nuclear Physicians

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202-857-1100

SNM
The Society of Nuclear Medicine

STATEMENT BY

THE AMERICAN COLLEGE OF NUCLEAR PHYSICIANS

AND

THE SOCIETY OF NUCLEAR MEDICINE

BEFORE THE

NUCLEAR REGULATORY COMMISSION

April 19, 1983

ACNP
American College of Nuclear Physicians

1101 Connecticut Avenue, N.W., • Suite 700 • Washington, D.C. 20036
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SNM
The Society of Nuclear Medicine

Chairman Palladino, Members of the Commission; I am Ralph G. Robinson, Head of the Division of Nuclear Medicine at Kansas University Medical Center and President of the American College of Nuclear Physicians which is an organization of approximately 1,200 physicians actively engaged in the practice of Nuclear Medicine.

These comments are presented on behalf of the College and also represent the views of the Society of Nuclear Medicine, a professional organization of over 10,000 scientists, physicists, pharmacists, physicians, technologists and other professionals involved in Nuclear Medicine. The combined membership of these organizations represent the Nuclear Medicine community in the United States.

The College and the Society are grateful for this opportunity to appear before you and present our views on the proposed revision of the Nuclear Regulatory Commission's regulations for Human Use of Byproduct Materials (10 CFR 35). We urge the Commission to act favorably and move the proposal forward for publication in the Federal Register.

No set of regulations affects the day-to-day practice of Nuclear Medicine more directly than 10 CFR Part 35. The licenses issued by NRC under these regulations define the parameters under which the use of byproduct radioactive materials for diagnostic and therapeutic medical purposes occurs. Therefore, the proposed revisions under consideration today are of the utmost importance to the membership of the College and the Society.

Mr. Chairman and Members of the Commission we would like to compliment you and your staff for their initiative to consolidate and streamline the requirements of 10 CFR 35. For a number of years the Nuclear Medicine community has operated under requirements scattered among several documents, including Inspection and Enforcement orders, regulatory guides, technical reports and various conditions attached to individual licenses. This has often resulted in confusion and unnecessary and/or duplicative paper work. It is undoubtably to the advantage of all affected parties including NRC, the Nuclear physician and most importantly the patient that regulatory requirements be developed as succinctly and clearly as possible. The proposed revision of 10 CFR 35 will accomplish much of that objective and we strongly urge you to support this effort.

Existing licensing review procedures relating to the Human Use of Byproduct Materials are cumbersome and unnecessarily lengthy. In our view, the informational requirements currently

required complicate the licensing process by forcing applicants to include detailed copies of procedures to be used in complying with the regulatory requirements in addition to the necessary information relating to radiation safety. The volume of information currently required often results in the need for more information from the reviewer's perspective. Frequently this need for additional information does not concern matters of radiation safety, which are of primary concern to the College, the Society and the Commission, but rather involve minor procedural issues. This often results in "Deficiency Letters" which greatly increase the time required to complete a license review and creates a prolonged paper shuffling excercise.

The modifications proposed in this draft will help eliminate some of the unnecessary paper requirements, produce more timely decisions and better reflect the sophistication of today's Nuclear Medicine practice, there-by enabling the medical community and NRC to more appropriately focus their resources.

We understand that information relating to procedures and other requirements must still be developed and maintained by the licensee. Thus, the substantive details needed by NRC for judging the adequacy of a licensee will be maintained and readily available for inspection.

We also concur with the recommendations contained in the draft to eliminate the general license. In view of the advances in the practice of Nuclear Medicine, the general license approach in effect creates a dual licensing system. The use of specific licenses and specific licenses of broad scope obviates the need for a general license catagory.

Mr. Chairman and Members of the Commission, while we are in general agreement with and strongly support the thrust of the proposed revisions, there are some specific requirements in the current draft that we feel should be modified. However, it is our intent to address these issues through official comments from our respective organizations once the proposed revisions appear in the Federal Register. We will provide a detailed analysis, once the full text of the proposed revision is published.

In summary, let me reiterate our general support for the proposed revisions, and assure the members of the Commission that the Nuclear Medicine community shares your committment to provide for the safe and effective delivery of Nuclear Medicine patient care, ranging from mobile service to the most sophisticated hospital setting. The College and the Society have had a long-standing and continuing interest in maintaining quality health care and probably have more

quality assurance efforts underway than any other medical specialty. We believe that the proposed revisions will serve to enhance the objectives of the Commission and of the Nuclear Medicine practitioner.

Thank you again for this opportunity to appear before you and I will be happy to answer any questions.

12/82

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Meeting Title: Briefing on Secy-83-62 Proposed Rev to 10 Cfr Pt 35 "Human Use of Byproduct Material"

Meeting Date: 4/19/83 Open X Closed ____

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2. Secy-83-62	2	*	___	1	___
3. Comments of W H Spell dated 4/19/83	1	*	1	___	___
4. Comments of Otha W. Linton dated 4/19/83	1	*	1	___	___
(5.) Statement by The American Coll of Nucl Physicians + Soc of Nuc Medicine dtd 4/19/83	1	*	1		

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