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UNITED STATES NUCLEAR REGULATORY COMMISSION

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Workshop on Quality Assurance in the
Medical Use of Byproduct Material

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Nuclear Regulatory Commission
Nicholson Land Building South
Conference Room 013
5650 Nicholson Lane
Rockville, Maryland

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MONDAY, JULY 23, 1990

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9:47 o'clock a.m.

PARTICIPANTS:

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S. Bahadur, NRC
L. Camper, NRC
J. Piccone, NRC
D. Wiedeman, NRC
E. Kline, NRC
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V. Fedio, ACNP/SNM
S. Surrel, SNM
H. Karagiannis, NRC
K. Morris, ACNP/SNM

PROCEEDINGS

[9:47 a.m.]

MR. TELFORD: Welcome. I'm glad to see all of you here today. We would like to have a roundtable discussion with the representatives from the American College of Nuclear Physicians and the Society of Nuclear Medicine.

We have a proposed agenda that we tried to work out.

Would anybody like to make a modification to the agenda? It could be that we are not successful in completing all of the topics today, and if that's the case we'd be willing to meet again.

Any suggestions for modifying the agenda?

MR. HENKIN: I suggest that we not treat the agenda too rigidly and that we can skip around and do whatever we like within it. Is that okay with you?

MR. TELFORD: Sure.

For the introductions, what I had in mind was for people just to go around the table and [illegible]ive their names and their affiliation more or less for the record and kind of to break the ice and let everybody get to know one another just a little bit.

I suppose I should start. My name is John Telford. I am the Section Chief of the Rulemaking Section in the Regulation Development Branch, Division of Regulatory

Applications.

My job is to sort of be the team leader for the folks who write the final rule and certainly was the leader of the folks that wrote the proposed rule, so if you have any questions about the intentions of what we were trying to accomplish during our discussions of the proposed rule, then please feel free to ask.

Why don't we go clockwise.

MR. CAMPER: I'm Larry Camper. I am the Section Leader of the Medical and Academic Section.

Our group is responsible for policy development, technical guidance and what have you for the medical and academic uses of regulatory materials that NRC regulates.

We are working closely with John's group in developing the QA rule.

MR. WIEDEMAN: I am Darrel Wiedeman. I am the Technical Assistant to the Director for the Division of Radiation Safety and Safeguards in the NRC Region III Office.

I am also part of the QA Site Team that is doing the site evaluations.

MR. BRINER: I am Bill Briner. I am Chairman of the Society of Nuclear Medicine's Committee on Government Relations.

MS. ALAZRAKI: I am Naomi Alazraki. I am

President of the Society of Nuclear Medicine.

MR. HENKIN: Robert Henkin, President of the American College of Nuclear Physicians.

MS. SURREL: Sharon Surrel. I am the Chairman of the Government Relations Committee, a Tech Section of the Society of Nuclear Medicine.

MS. FEDIO: I am Valerie Fedio. I am with the Washington Office of the ACNP/SNM.

MR. KLINE: I am Ed Kline from Atlanta, the NRC Regional Office there and I am one of the members of the pilot team.

MS. PICCONE: My name is Josie Piccone. I am a health physicist at NRC Region I. I am also a member of the QA team.

MR. BRINER: Mr. Telford, maybe we'd like to know who these folks back here are too.

MR. TELFORD: Certainly. Let's let them introduce themselves.

MS. KARAGIANNIS: Harriet Karagiannis, health physicist, AEOD/NRc.

MR. WEBER: Mike Weber, Office of the Chairman.

MR. LESAR: Mike Lesar, Office of Administration.

MR. BAHADUR: Sher Bahadur, Branch Chief for the Regulation Development Branch, the branch that is responsible for developing this issue.

MR. TELFORD: Okay. You mentioned that we'd like to maybe skip around. Would you like to go with the second item next?

MR. HENKIN: I think perhaps maybe we should have some opening statements of what we are doing.

MR. TELFORD: Good idea.

MR. HENKIN: It's your meeting. Why don't you start?

MR. TELFORD: Opening statements -- what would you like me to --

MR. HENKIN: Why we're all here -- why are we all here?

MR. TELFORD: We are all here to have a roundtable discussion about the proposed rule, the reporting requirements and the regulatory guide and to discuss the aspects of the ACNP or SNP or JCAHO programs that you feel are recommendable, that should be in such a proposed rule for quality assurance or maybe in place of, whatever your particular recommendation might be, but in general to have a good understanding of what we are trying to accomplish and how we would go about it and the recommendations that you would make.

I look at this as certainly a two-way discussion that we can understand each other's intentions and modes of operation.

The way we're going about this, I feel it will be educational from both sides or to both sides. I am looking forward to having this discussion.

MR. HENKIN: I guess I will speak for ACNP. I will not endeavor to speak for the Society for Nuclear Medicine.

We are somewhat constrained, if you like, in this discussion by the fact that there is an operative resolution of the American College of Nuclear Physicians which requests the NRC to withdraw this rule. The underlying assumption to that resolution is that there is no need for the rule and that it will in fact not affect the public health and safety to have the rule or not have the rule at all.

In addition, we believe that the rule, proposed rule, represents an intrusion into the practice of medicine against the statements of principle that are formulated by NRC with regard to intrusion into the practice of medicine.

We understand the rule to represent an effort to reduce misadministrations and that to be its primary endeavor. It may have secondary endeavors but that is its primary endeavor.

In regard to that, we have asked before and in a meeting with Chairman Carr were assured that the NRC would in the future account separately for sealed and unsealed source administrations because in fact there are entirely

different groups of people involved in the use of those different materials.

Commissioner Curtis presented to Dr. Holmes, Dr. Marcus and myself several years' worth of data on medical misadministrations and asked for our input. When we reviewed that data which I believe went back as far as 1985, if memory serves me correctly, we discovered that the worst year that we had were about four unsealed source misadministrations and the best year was about two, so if one says that the range is zero to six to be relatively conservative, what we are talking about is a great deal of time, effort and money being spent to produce a rule that may affect at a maximum six patients nationwide per year out of ten million administered doses.

That to us seems illogical.

In addition, in a situation in which funds for medicine are becoming tighter, we have a Federal budget deficit, a great deal of funds on both sides are being expended to promote a rule that seems to have little if any impact.

So, with that in mind, we think the first part of the discussion ought to be whether or not such a rule is necessary before we discuss whether or not what this rule might contain, and we have yet to receive from anybody a justification for this rule based upon a maximum of six

patients per year who would be affected nationwide.

MS. ALAZRAKI: On behalf of the Society of Nuclear Medicine, I would like to say that basically the 12,000 physicians, scientists, technologists whom the Society represents also feel that quality assurance practice and implementation in the practice of nuclear medicine is ongoing, has been ongoing for many years now with guidance from the JCAHO and from organizations which do audits.

For example the American College of Nuclear Physicians, to assure that the quality assurance programs are accomplishing their stated goals, the JCAHO has about a 39-year history in quality assurance. It does nothing else, just quality assurance.

It has developed over the years and evolved a program which today I think most people agree is a fairly good program, extremely comprehensive and for nuclear medicine per se covers anything that NRC might be interested in putting into its rule.

If you review the JCAHO site inspections, in general nuclear medicine departments do quite well in comparison with other medical services in hospitals, so we feel that quality assurance is being very well practiced in nuclear medicine services around the country. We are in agreement with everything that Dr. Henkin just stated, and I don't want to repeat it, about the misadministration

situation.

We also feel that there is no need for duplicative quality assurance impositions on our practices.

What I might say is that it would seem reasonable to us for NRC to be sure that all of its licensees are indeed implementing a quality assurance program in line with JCAHO or ACNP audits.

It might be reasonable for NRC to look into whether there are any licensees who are not for one reason or another operating under JCAHO or ACNP audit guidelines.

That is about the only thing that SNM can see is relevant for NRC to do in the area of quality assurance.

MR. HENKIN: May I just make one addition? The American College of Radiology also runs a practice audit program.

MR. TELFORD: Two points to clarify: I assume that your statements are relevant to nuclear medicine diagnostics and nuclear medicine therapy?

MR. HENKIN: Correct.

MR. TELFORD: Your statements about the nuclear area don't extend to teletherapy or brachytherapy?

MR. HENKIN: I am not qualified to comment on teletherapy or brachytherapy.

MR. TELFORD: One other small point is that the objective of the proposed rulemaking is to prevent

misadministrations, not reduce them. That's the --

MR. HENKIN: I think we ought to discuss that.

MR. TELFORD: Okay.

MR. HENKIN: I think we ought to discuss what it is that one can do to prevent misadministrations and what it is that you're proposing to do and how that will change anything. I would like to hear how it will change what is going on now.

MR. TELFORD: Well, we can pick that up whenever you like. Is there an item on the agenda that that fits with?

MR. HENKIN: I'm trying to understand the thinking that goes into this rule that, first of all, perceives the problem, and second of all, believes that it can be corrected by regulation.

MR. BRINER: Let me speak to that point, too. We have been asking for now for four or five years -- I expect it's a sum total of that -- for some evidence that any kind of rule or regulation that is apt to be promoted by the Nuclear Regulatory Commission or any other regulatory body and that sort of thing, is going to have any impact whatever on quality assurance.

We also are quite cognizant that you're spending money for this in a budget year that is a disaster for the Federal Government. We're having a disastrous year, too, as

far as trying to contain health care costs, rather unsuccessfully thus far. To me, it just doesn't make any sense whatever to cause rather large expenditures of public funds from the NRC standpoint and our own funds, in trying to abide a regulation which is not going to be effective for the purpose for which you state.

MR. TELFORD: I can think of two things that may make it worthwhile to discuss this. We're both talking about quality assurance, but I'm not sure that we're communicating.

MR. BRINER: That's correct. We are not sure you know what quality assurance in medical practice is or health care administration is.

MR. TELFORD: Well, Captain Briner, you may be right.

MR. BRINER: That's one admission I was waiting to hear.

MR. TELFORD: Does everyone have a copy of this? If we coudl turn to page 1449 of the proposed regulation, and the particular section is 3535, the basic quality assurance program. This is really the focus of what we're trying to do. Now, let me tell you a few things that we're trying to accomplish to --

It may be that we are using a term that we are familiar with that brings up all sorts of connotations of

other activities of which we don't really have regulatory force. But in Section 3535, the opening paragraph says that we would like each licensee to have a quality assurance program.

We would like that program to be designed to prevent indirect costs of errors in medical use and that the objective would be to provide high confidence that errors in medical use would be prevented. Now, that may be just a euphemism for misadministrations. I just mention that as --

MR. HENKIN: I don't know what else it could be.

MR. TELFORD: That is the basic gist, but the heart of it is the 8 objectives that follow. What they basically say is that, first of all, we would like a nuclear physician to decide that this patient should get byproduct material.

Second, we should issue a directive as to what the dose --

MR. BRINER: You already have said that and that's a regulation. You say that byproduct material shall be used only under the direction and the order of a licensed physician. Now, why and the world should you establish 3535 all over again to make that point, plus the fact that you are not going to prevent errors.

MR. HENKIN: Let me even amplify on that. If anything ever intrudes into the practice of medicine, 3535

does. Most of the rest of what you've got is relatively benign until you get to 3535 in which you decide that a prescription must be issued in which you decide how review is going to be done for appropriateness.

Let me refer you to the Corpus Juris Secundum which is the contemporary statement of American law as derived from reported cases and legislation, Volume 70, 1987. This is under Physicians and Surgeons. "The practice of medicine as ordinarily or popularly understood has relation to the art of preventing, curing or alleviating disease or pain. It includes the diagnosing, treating, operating or prescribing for any human disease, pain, injury, deformity or physical condition. It also includes the application and use of medicines and drugs for the purpose of curing, mitigating or alleviating bodily diseases, but it does not wholly depend upon the adminstration of drugs.

Therefore, 3535 intrudes directly into the practice of medicine as defined in law at the present time.

MR. TELFORD: You're focusing on the first objective?

MR. HENKIN: I'm focusing on all of them; the whole thing does.

MR. TELFORD: Okay. Should I proceed or are there questions that I should answer?

MS. ALAZRAKI: Just to add to that a little bit, the first one, if you want to focus on that, that's the first thing we do in any quality assurance program under JCAHO. We make sure that the study is appropriate to the patient's condition. I mean, that's exactly, word for word, practically --

MR. TELFORD: I was attempting to paint sort of a neutral image of what we're trying to accomplish here with 3535. Shall I proceed, or are there questions that you want me to answer?

MR. HENKIN: I would like you to explain why 3535 is not an intrusion into the practice of medicine, because if it is, it's directly in contradiction to your statement of principles; that you won't intrude into the practice of medicine.

MR. TELFORD: I think you're alluding to the 1979 Commission Policy Statement. Then it goes far before that. It is not our intention to interfere with the practice of medicine. Our intention is to make sure that whatever is directed by the nuclear physician is administered to the patient. We have that narrow focus.

MR. HENKIN: That is the practice of medicine.

MR. TELFORD: Okay, if that's the practice of medicine, then that's what we're -- that's our focus, is just that. After the authorized user, nuclear physician,

has given a directive as to what is to happen, if that happens, 3535 is happy. If that's an intrusion into medicine, so be it.

MR. HENKIN: 3535 prescribes what is to happen. It says "ensure that", "ensure, ensure, ensure and ensure..." That's a "thou shalt." Okay, that says that I must practice according to 3535. That means that the practice of medicine is not in my control but in your control.

MR. TELFORD: Excuse me, Dr. Henkin. There's a very basic misunderstanding that you have. 3535 is a performance-based quality assurance program. These are 8 objectives -- these are merely 8 good things to do that each licensee would design their program to meet these objectives. You can do that any way you like.

MR. HENKIN: No sir, I don't agree with you, because when you take 3535 and turn it around and you inspect against 3535, these become cite-able things, if you don't do them. If you have not satisfied 3535, you are then open to a citation for not having an adequate quality assurance program.

Therefore, they become a standard of practice.

MR. TELFORD: Not quite. 3535 is a performance based rule. It says, here, 8 good things to do. Each license would then propose their own program for their own

facility unique setting so that they could meet the objectives here in any way that they chose to.

Now, what happens after that? A patient comes in -- you're from an agreement state and so are you Dr. Alazraki and so are you, Captain, Briner --

MR. BRINER: Half of my practice goes on to the VA medical center, so I'm under --

MR. HENKIN: Mine go there, too.

MR. TELFORD: For the VA hospitals, then you know that the licensee sends in an application that says how they are likely to meet such a ruling. The application is finally approved and it's really that document which becomes your license conditions against which you operate.

In that document, you have defined how you will meet the objectives of this rule. It's not --

MR. HENKIN: So what you're actually telling me is that the license becomes the conditions of the practice of medicine, which is exactly what we're saying. The license cannot prescribe the practice of medicine. It can only prescribe the safe handling of regulated materials.

It cannot prescribe the practice of medicine.

MR. BRINER: Can we turn this around a little bit.

MR. TELFORD: Excuse me. Let's -- there's a basic misunderstanding here. You're talking about the practice of medicine. Now, if you disregard the words that are here,

just for a moment, and let's talk about the intentions of what's in 3535.

First of all, it says, let's make sure that the right directive is given. Let's -- ideally, let's write it down. Let's make sure that those that are involved understand what's to be done. Let's make sure that any planing is in accordance with that directive that the nuclear physician has given. Let's make sure that we get the right patient, and then let's finally make sure that the byproduct material administered is what was in the directive.

That's the heart and soul of all of this.

MR. HENKIN: Which does not exit in regulation.

MR. TELFORD: If you want to allude that to being the practice of medicine --

MR. HENKIN: It is.

MR. TELFORD: Okay, but that's what this is about. Now, Dr. Briner?

MR. BRINER: There's somebody who doesn't understand what somebody's saying. I'll turn that right around; you don't understand what we're saying. We're saying that you, NRC, have no business in this quality assurance realm of interference because there are professionals out there doing that very thing and people who know what they're doing and are doing an excellent job with

doing that. Now, why try to duplicate -- rather poorly, I must say -- their efforts? Why should you do it? You've not ever explained to me, why should the NRC be getting into this business?

MR. TELFORD: Well, it is rather basic. We have a regulatory responsibility to ensure adequate safety of the public, and that includes patients.

MR. BRINER: You have known shown that the public has been damaged.

MR. HENKIN: What is the risk, what is the hazard you're protecting against? What is the damage that you're proposing to remedy?

MS. ALAZRAKI: And what are you going to do beyond what's alr dy being done with this? Everything that's here is already being done.

MR. TELFORD: That's an interesting discussion and I would like to get into that at some point on the agenda.

MR. BRINER: Let's see how you answer that question, Mr. Telford. Why is it that the Nuclear Regulatory Commission really wants to get into this, you know, knowing full well that you disagree that the JCAHO is, or is it you're feeling that they're an ineffective organization? Is that what you're saying, they're not doing their job?

MR. TELFORD: In 1979, the Commission felt --

MR. BRINER: Please answer the question. Are you saying, by issuing this that they are not doing their jobs effectively?

MR. TELFORD: That's a tough question.

MR. BRINER: Because you are not saying, then we're always going to --

MR. TELFORD: We are saying that, first of all, the JCAHO is a voluntary organization.

MR. BRINER: We'll get into that.

MR. HENKIN: We will talk about that later. It's like the Army being voluntary.

MR. TELFORD: So, in order to carry out the regulatory responsibilities of the Commission, the Commission needs a regulation that is mandatory for all licensees. Now, what's in that regulation is what we'd all like to discuss.

You're really basically asking a couple of questions. One is that, what's the problem that we're trying to fix, and secondly, why do we think we have the --

MR. BRINER: Can it be fixable by what you're suggesting?

MR. HENKIN: Is it fixable by regulation, is the second part of that question.

MR. TELFORD: We think so.

MR. HENKIN: There's a basic rule that goes, one

cannot legislate against stupidity. Do you have any evidence to indicate that zero to six misadministrations per year result from anything but stupidity?

MS. ALAZRAKI: Accidents.

MR. TELFORD: Before we developed this proposed regulation, we looked at the misadministrations in the therapy range from 1980 through '88, then we developed this proposed regulation. At the time, JCAHO didn't have quite the program they have today, as evidenced by these new manuals that have just come out. At the time, the American College of Radiology was developing their model quality assurance program. There have probably been advances that various societies have made in the last two years.

We're interested in finding out what are those good points, but that's really not the question that you're asking. You're asking -- when we look at the misadministrations, you're asking, what do we see, what are we trying to prevent?

MR. BRINER: That can be got out by this sort of thing. It's a very important second question if you're part of that question.

MR. CAMPER: Let me point out something to you, if I may, before you go into that, John. When you say that these misadministrations occur because of stupidity, we look at the misadministrations that occur and we don't come to

the conclusion that they're being caused by stupidity. In may cases, they're being caused by a lack of procedures or a breakdown in procedures. In many cases, there are procedures in place; they're simply not being followed.

The question that we have is, why one looks at JCAH and various procedures that are out that practicing medicine, we still see misadministrations current. Now your response to that would be, well, misadministrations are insignificant. They're such a small number, the frequency of occurrence is so insignificant, that we shouldn't be bothered about it. Or you might argue that NRC has no business being in this area.

The question I would come back to you with is, if indeed there are procedures out that and if indeed there are still breakdowns, they're not being caused by stupidity. They're being caused by procedural error. What should we do as a regulatory agency that has responsibility in this area, what should we do?

MR. BRINER: Procedural error or stupidity, whatever, the fact remains that you are not going to correct that by these kinds of regulations.

MR. HENKIN: In fact, if the proper procedures already exist and people do not follow them, there is no regulation in the world that is going to cause them to be followed.

When errors occur, they occur for several reasons. One of them is fatigue. One of them is overload. People are overworked. Another series, as your own evidence documents, of patient contributions to the era, where the patient identifies himself as the wrong patient, your regulation is never going to cure that.

If the money spent on developing this regulation and attempting to implement it or spent and directed toward increasing staff available to nuclear medicine, we'd have a greater impact on misadministrations than any regulation ever would because our people are stretched so thin and they're fatigued.

I have people that are working 14 hours a day because I can't have enough staff. Those people are more prone to error. A regulation such as this would not prevent an error of an over-tired person.

MR. WIEDEMAN: In your examples, because of misadministration, where does misunderstanding fall in? Many times, you know, misadministrations --

MR. HENKIN: Miscommunication or misunderstanding?

MR. WIEDEMAN: Both. The ambiguous, sometimes redundant, terminology that's used in nuclear medicine.

MR. HENKIN: The regulation doesn't address that, first of all. What does happen from time to time is a referring physician will misorder an examination. The

referring, requesting physician will order a therapy when, in fact, he doesn't really mean a therapeutic procedure. And that, under JCAHO standards, and under most operating standards, is caught routinely. Nuclear medicine departments catch that everyday around the country in their review of procedures. It is very rare for one of these to slip through the system.

The number of times per day that procedures are questioned in a department such as mine or a department such as Naomi's -- we're on the phone with people all day long saying, what did you mean, what did you want, what did you really order. That goes on as a routine basis because we have to satisfy another standard.

We have to satisfy an appropriateness standard that comes out of JCAHO that we are doing something appropriate to the patient's medical condition and to us, that's a greater concern than satisfying your standard because they're going to come around that and we have to have in place screens, monitors, to show that we are providing appropriate medical service to patients and that we're not doing tests that aren't indicated and we're not doing tests that are inappropriate for the medical condition.

So, as part of that, there exists a system to screen for all of these things already and therapeutic

procedures fall into that system because they are procedure. In fact, the consciousness of nuclear medicine people, of therapeutic procedures is so high that most of us require a direct conversation already with the referring physician. We won't take an intermediary order.

In our lab, for example, the physician ordering the procedure must speak directly to a nuclear medicine physician if it's a therapeutic procedure and discuss with him why he wants it.

MS. ALAZRAKI: I can tell you, in our department, I can give you a monthly accounting of exactly how many inappropriate orders we got and what they were. Its in our minutes for JCAHO purposes. This is one of the things which is basic to the practice of nuclear medicine. It really is practice of medicine, that type of a thing.

MR. TELFORD: So, you're saying the first three objectives were already met by your program.

MS. ALAZRAKI: Yes. And documented. Just to add a duplicative administrative burden to redocument this in terminology and inform that for NRC seems ridiculous.

MR. TELFORD: Let's assume that we could clean up the terminology. I think you're making an assumption that this is duplicative. Because this is a performance-based rule, you could in fact propose as part of your application to do exactly what you just said, that you're already doing

it for JCAHO and meet these three objectives.

MR. BRINER: Could we turn that around that a little bit. In Dr. Alazraki's opening statement she made a remark that surprised even me. She surprises me every day, but I think she said something to the effect that, even if you want to go ahead in your regs and say a quality assurance program is in effect at this licensee, and let it go at that, that's within your purview, but don't prescribe what you do in that quality assurance program.

MS. ALAZRAKI: I think it would be perfectly reasonable for NRC to note what quality assurance plan the licensee is operating under and to not that that's an acceptable plan from NRC's point of view, and to identify those who don't operate under JCAHO or any of the practice audit plans.

MR. BRINER: We're having a rare moment when I would disagree with what she said. Remember when you say that, if you modify that plan after you've made such a statement, you've got to let them know and get an approval from them to do it.

MS. ALAZRAKI: They would have to recognize the authority of JCAHO to regulate that.

MR. HENKIN: That's correct. Essentially, they would have to grant the JCAHO legal status.

MS. ALAZRAKI: Exactly.

MR. TELFORD: Excuse me. Could we go off the record for a minute.

[Discussion off the record.]

MR. TELFORD: Back on the record.

MS. ALAZRAKI: We're on the issue of whether or not NRC can recognize JCAHO or any of the operative verbalizations in terms of if they are quality-assurance activities.

MR. TELFORD: I think there are a couple of alternatives there. I mean assuming that we could have a discussion of exactly what the JCH recommends, kind of like we have started to have, that basically we feel the first three objectives have already been met. We could find out exactly, of the interest that we have, how many of those are already being met by JCH, then assuming something could be worked out, then I can think of a couple of alternatives.

MR. HENKIN: Let's do the following: Let's say that we do not at the moment drop our objections to this rule but are willing to discuss with you what it is JCAHO does outside the view of this rule. Okay?

MR. TELFORD: Sure.

MS. ALAZRAKI: Okay.

MR. TELFORD: I think there is still a question in my mind about what are the problems we see.

MR. HENKIN: Having read the reports from

Commissioner Curtis, I cannot see or imagine how anything in this rule would have changed any of those instances over the past 5 years. Okay? There is just nothing that I see that you've done here that would have made a bit of difference in the documents that Commissioner Curtis gave me. Now, maybe in teletherapy or brachytherapy -- I have no idea -- but not in nuclear medicine. It wouldn't have changed the outcome of one of those procedures.

Where somebody picks up the wrong vial of material, thinking it is the correct vial of material, and mis-administers that material is not going to be changed by your regulation, because he believes he has got the right material and he followed procedures.

MS. SURREL: It's a human error.

MR. TELFORD: I've got some cases of misadministration here that we can discuss. These are teletherapy, brachytherapy, and nuclear medicine.

Let me ask your indulgence, because while you can say we're only interested in nuclear medicine, we cannot do that. We have to say we are trying to put in a place a program.

MR. HENKIN: Well, I think you could do that by spreading them into sealed and unsealed sources.

MR. TELFORD: That's a procedural matter. What I'm talking about is I would like you to understand what we

see from our point of view as regulators trying to assure adequate protection of the public from a national perspective.

MR. CAMPER: Let me add to that, too.

It easier for you to say, as practicing nuclear medicine physicians, let us focus only upon nuclear medicine, and we understand that. But we have a larger area of responsibility.

It's very interesting. As I read through all the documents, over the weekend, that accompanied Dr. Marcus' summary of the comments that were received in the public-comment period, there were a number of reoccurring themes. One of them that I was struck by was that, as one goes and looks at the various institutions of differing size throughout the United States, there are varying degrees and degradation of quality assurance in these institutions, and in places where there is highly-sophisticated medicine being practiced, at t' · Dukes and UCLAs and Loyolas, etcetera, there is a level of quality assurance, but it is not the same level that's occurring in some of the community hospitals.

MR. HENKIN: But this is a misunderstanding on [redacted] part, too, and that is the type of procedure we [redacted] tice in a Duke, Loyola, Emory situation is different than what they practice in a community hospital. The number

of therapeutic iodine procedures in most community hospitals is nil.

MS. ALAZRAKI: Very small.

MR. HENKIN: Okay? Very, very low compared to a major institution, so that you're talking about a level of practice that's entirely different, as well. You're talking about liver scans, bone scans, brain scans, and an occasional, once-a-year therapy patient, perhaps. There are exceptions to that rule, but they are some of the better community hospitals that are, in some respects, comparable to some of the university hospitals, and they have the procedures in place to do that. But when you talk about that, I think you have to realize that the level of quality assurance recognized by JCAHO is appropriate to the institution that it operates in. It's a local environmental question. It does not prescribe, across the board, the same thing for everybody, and in fact, JCAHO has recognized that by even using different inspection teams for academic hospitals and for non-academic hospitals, realizing they hold them to a different standard.

MR. TELFORD: That's why we have a performance-based rule.

MS. ALAZRAKI: Well, it took JCAHO a long time to evolve into --

MR. HENKIN: Twenty years.

MS. ALAZRAKI: Twenty years to come up with these differences and these nuances in quality assurance. They are quality assurance experts; you are not.

MR. TELFORD: Would you look at it for at least approaching it as a performance-based rule, so that each facility can tailor their rule to meet the facility needs?

MR. HENKIN: I don't believe it's truly performance-based because of the way you listed your eight criteria. Performance-based would say you must develop a rule to assure that there's appropriate operations at your institution, but you've laid out eight things they must have in that performance-based rule. The sort of removes it from the category of a performance-based rule. It's a sort of hybrid.

MR. TELFORD: I get half a point?

MR. HENKIN: Half a point.

MR. TELFORD: All right.

MR. HENKIN: No more.

MR. BRINER: Just so the rest of the people know who the most recent arrival is, Kris Morris is Director of the ACNP SNM Washington office.

Kris, glad you made it.

[Slide.]

MR. TELFORD: What I'd like to do refer you to the current requirements that are in 10 CFR, go through some

recent misadministrations, and tell you some of the reasons why we think we have a need for a solution to the problem.

[Slide.]

MR. TELFORD: Can everybody see these?

MR. BRINER: I'll think about them when I go to bed at night.

MR. TELFORD: As of April 1st of this year, the 29 agreement states are now required, as a matter of accountability, to report misadministrations. Prior to that date, they were not required to report these. These are basically, as you know, six mistakes that you can make, and if you make one of these mistakes, you're required to report. That's all we currently have is a reporting requirements.

So, this is one is for any pharmaceutical or irradiation other than the one intended; this is to the wrong patient, number two. Number three is via route of administration other than was intended. Number four is a diagnostic misadministration, where the administered dose differs from what was prescribed by 50 percent. Number five is a therapy by radiopharmaceutical such that the administered dose is different than prescribed by 10 percent. And number six is meant to capture teletherapy as well as brachytherapy, and that's where the administered dose is 10 percent different from what was prescribed.

Any points of clarity?

MR. HENKIN: No, except that we're not really prepared to discuss the last one.

[Slide.]

MR. TELFORD: First of all, I beg your indulgence on several teletherapy and brachytherapy misadministrations. The primary reason, from your point of view, could be Mr. Camper's point that sometimes you see -- it was Mr. Wiedeman's point, as well. Sometimes you see a breakdown in what apparently looks like a breakdown in procedures or a misunderstanding of what was supposed to be done.

This happened in Cumberland, Maryland. The nature of the misadministration was that 33 patients received the wrong dose. The problem was that when they changed the cobalt source, they forgot to tell the computer program of the new source information, and as a consequence, 33 patients got overdosed, and the actions taken to prevent was that the licensee is now in an over-check procedure, as well as there has been a change in the physicist.

MR. HENKIN: May I ask you -- since I don't know anything about this, I can ask a dumb question. Were any of those patients injured? Have any of them reported any injury?

MR. TELFORD: I believe in the details of this report, there was some erythema, but I don't think --

MR. HENKIN: They got sunburned?

MR. TELFORD: These 33 patients were --

MR. HENKIN: My limited understanding of radiotherapy is that most patients, including my father, who underwent radiotherapy at the prescribed dose, gets local erythema. So, what you're telling me is that I can't discuss the merits of the case. All I want to know is was anybody injured?

MR. TELFORD: Well, I apologize. I cannot answer your question, because there were a total of 33 patients involved here, and their amount of overdose was in proportion to the dose they received.

MR. HENKIN: So, we just don't know if anybody was injured.

MR. TELFORD: I don't.

MR. HENKIN: Well, then we, as a group, don't.

[Slide.]

MR. TELFORD: This happened in March of '89, and in May is a teletherapy misadministration. The patient was administered 100 rads to the brain instead of the floor of the mouth. This is the wrong site for the kind of problem. The cause is that the names and appearances and even the planning pictures of the two elderly patients were remarkably similar, and the patient requiring the treatment to the lower palate was administered the brain dose instead.

In this case, the patient got 100 rads to the wrong location that the patient didn't need. The actions take to prevent recurrence was that we now have procedures which would require that each patient's identify be verified by a photograph and oral communication or positive identification by a second person.

Questions?

MR. HENKIN: Again, I'm fascinated. These are absolutely fascinating things to look at the cure. The cure is positive identification by a second person. Who might that be?

MR. TELFORD: Well, as long as their procedure works, it could be a technician.

MR. HENKIN: Well, sure. And that, to me, is as worthless as anything else, because you have a busy hospital setting and you have people coming down from the nursing floors. Presumably, the nurse on the floor knows the patient better than anybody else. Most of the time, nowadays, they don't know the patient very well at all.

So, what you've done is impose -- they have imposed -- to satisfy you, they have created a requirement that has no meaning.

MR. TELFORD: This procedure was their choice.

MR. HENKIN: Oh, I no, because they had to do something to make you happy.

MR. CAMPER: Well, their previous procedure obviously didn't work.

MR. HENKIN: This doesn't guarantee that it won't happen again.

MS. ALAZRAKI: As a matter of fact, even in diagnostic administrations of radiopharmaceuticals, which again is different from what you are presenting here, since we don't deal with the sealed-source administration of radiation, but in administering radiopharmaceuticals, even diagnostic doses, we have that type of a routine of two people checking.

MR. TELFORD: That's good. We will get to some nuclear medicine cases in a minute.

[Slide.]

MR. TELFORD: This happened in March of '89 in Indiana. The patient got 300 rads to 9 sites on the left hip and groin, which should have been to the right hip and groin.

Causes were there was the patient -- and that may not be the correct word -- maybe it was a misunderstanding. But that's what's among the licensees technologies.

Probable cause is you get an extra 2700 rads to the wrong hip and groin. And the action taken was they initiated new procedures to verify treatment cycle.

Questions?

MS. ALAZRAKI: Again this is out of our frame. That type of an accident happens in surgery all the time. Of course, the consequences there are much more grave. But the court system takes care.

MR. HENKIN: I can -- I can site a case of one our surgeons who did the wrong-sided carotid endarterectomy, okay; which I think is probably more serious error than any of the errors you're going to present today; and wound up not getting sued for it because he had good relations with the patient.

MR. TELFORD: Off the record, why did he only do one side -- I had both.

Doctors do recognize that surgery is not our regulatory responsibility.

MS. ALAZRAKI: Wait a minute.

[Laughter.]

MR. HENKIN: We're trying to set -- we're trying to set for you an environment that says, are you trying to correct something -- there are grievous errors that occur from time to time in medicine, because of the people involved in medicine, and that not -- everybody recognizes that those errors are not all preventable, because they're human errors.

And we're trying to set for you a relative scale. You've seemed to have developed the idea that these

therapeutic misadministrations represent a severe public hazard, and that you need to take regulatory action to correct that hazard to the public.

We are trying to put this into the perspective of the practice of medicine and where these fall as a hazard within the practice of medicine, so that you have a frame of reference, as to what it is we're dealing with and how much expenditure of public and institutional funds are appropriate in this setting.

MR. TELFORD: Two comments, if I may?

As far as our regulatory responsibility goes for the problem -- it needs to be a problem or a potential problem, for us to become involved.

If -- I like your idea of setting a perspective and I would point out that the proposed rule says it's -- it's a performance-based rule and it says, "designed to prevent."

Now, if you wanted to propose a certain threshold, like -- like an acceptable rate. Like, for instance, the Commission, in the area of reactor safety has said -- almost how safe the plant should be, with the following -- which includes the following statements, not necessarily limited to, but that the cause of death -- or excuse me, probability of a death, due to this reactor, should be a tenth of a percent of all the other causes of death. And the

probability of getting cancer should be a tenth of a percent of all the sources of cancer -- so it would be --

MR. HENKIN: I find that -- fine, we're below that.

MR. TELFORD: Well, if you wanted to propose that that should be the quantitative design objective, okay, we'll listen. But, please keep in mind, the rule is just designed to prevent. And we have -- have a qualitative criteria.

If you want to say quantitatively, that's okay, we would like to entertain that discussion.

Shall I --- shall I go on?

MR. HENKIN: Yes, please.

MR. TELFORD: Are we missing the point?

MR. HENKIN: No. I'm not sure what you just said, but go on?

MR. BRINER: How did we get into that suggestion? We want it quantitative. No way.

[Laughter.]

MR. HENKIN: That's not what we're saying.

MR. TELFORD: You said you wanted to put it into perspective -- that there's a certain rate of occurrence -- you know, I'm reading between the lines here, that ought to be acceptable.

MR. HENKIN: Okay, fine. If we're going to do

that, we should put it into the perspective of the rate of misadministration of all pharmaceuticals in this country.

That rate is approximately 20 percent for nonradioactive drugs. The rate for radiopharmaceuticals is about .6 percent, if I remember correctly. That is, in fact -- we would be glad to take that as a -- as a relationship that we can't exceed the rate of misadministration for all pharmaceuticals in the country, and use that one as a standard.

MR. TELFORD: Unfortunately, we don't have the responsibility for all pharmaceuticals, we only have radiopharmaceuticals.

MR. HENKIN: You just asked me to put it into something that -- there -- there's a system for which the data exists on the rate of misadministration of all nonradioactive drugs for hospital in-patients. It is about 20 percent misadministration, using the definition that differs only slightly from yours, in that they include time. if you don't administer the drug at the correct time, it is misadministered.

In a hospital in-patient as well, that number is 20 percent -- between five and 20 percent, depending on the various surveys you read and the skill of the hospital populations on those surveys.

In that case, why not say that we should be the

same as all pharmaceutical administers, who are: registered nurses, licensed pharmacists and physicians.

You're holding us to a standard that is not a standard that is part of the practice of medicine.

MR. CAMPER: Well the -- the problem is, of course, we don't regulate those other areas; and for that matter, we don't know whether 20 percent is acceptable or not.

MR. HENKIN: That's a different issue. But, we're talking about what goes on and whether we're being held to a standard that is different from the rest of the practice of medicine.

To hold us to a reactor safety standard makes no sense.

MR. TELFORD: Excuse me, I didn't mean to simply reply that we were going to do any of that, I was merely fishing for suggestions, to see if you wanted to -- if you wanted to put things in perspective and propose a quantitative standard, I'm just merely saying that we're open for discussion.

MR. BRINER: There's one other difference between what you're talking about -- the 20 percent rate too; and that is that in the majority of those cases, there is demonstrable harm to the patient. And his note extend to a majority --

MR. HENKIN: We are talking about drugs that include: chemotherapeutic agents, cardiac agents in that 20 percent which, if misadministered can kill the patient.

We do not have that potential in general and nuclear medicine. There hasn't been a death from an administered pharmaceutical as a misadministration in 25 or 30 years now. So, that -- we've done a damn good job.

[Slide.]

MR. TELFORD: And we agree. We think you're -- we think the whole industry's doing a very good job.

MR. HENKIN: May I go on?

MR. TELFORD: In July of '89 in Massachusetts, a patient was administered a dose to the spine, instead of to the right lung. The cause of misadministration was the technology failed to confirm the patient's identify, even though there was an available.

In addition, the technologist failed to recognize the absence of any treatment positioning tattoos, which would have indicated that that was the wrong site.

The consequence was that the patient received an unattended 250 rads to the spine. The actions taken to prevent recurrence was that the licensees instituted procedures which require that each patient's identity be verified by a photograph. And in questionable cases, the physician will verify the patients prior to treatment.

MR. HENKIN: Does that make any sense to you, John, that they apparently had a -- a procedure in place, with a photograph -- nobody bothered to look at the photograph. Their cure for the problem is to tell people to look at the photograph.

MS. SURREL: So, you've just proven that you have a procedure in place and by human error they did not follow it.

MR. TELFORD: You've just proven that you've got -- that you can the procedure there and if it doesn't work --

MS. SURREL: So how, you know, in dealing with -- with this particular rule -- how can you put another procedure in place and eliminate the mistakes that have been made.

MR. TELFORD: This rule doesn't put any procedures in place. This proposed rule says "each licensee should have a quality assurance program.

The procedure that -- procedures that are put into place are up to the licensee to meet their problems. And this was -- this licensees choice to do this procedure.

MR. HENKIN: But John, listen. The licensee had in place, originally --

MR. TELFORD: But, wait a minute -- you're -- you're asking, let's see. You're changing the subject really, because this is -- this is not under the conditions

of the proposed rule; this is under the current reporting requirements.

So, all the licensee has to do here is report. Now, when the NRC finds out about it, it naturally asks, what are you going to do to prevent recurrence.

So, all I'm showing to you is that we have looked at the recent misadministrations. We're attempting to find the cause here -- what's the problem and what are the set of problems to be solved.

Based on this, I don't think you can draw an inference that these rules would prescribe this same sort of action.

MR. HENKIN: No. I can draw --

MS. SURREL: Then how are these rules going to correct those sorts of problems?

MR. TELFORD: That --

MR. HENKIN: This licensee obviously had something in place, with -- included a photograph. Okay. The person didn't follow procedure.

The quality assurance program they had in place, likely would have satisfied your draft regulation.

What you had is somebody who broke his institutional rules. Okay. Your program won't prevent them from breaking institutional rules.

I have institutional rules. Any time we've had a

diagnostic misadminsistration, it has always come down to the same thing -- somebody broke the rules. Not that they didn't know them. They short circuited the system some how.

MS. ALAZRAKI: The last time that we had a -- a misadministration is a similar situation to this, only in a diagnostic setting.

The technologist had just found out that her father had cancer, and didn't want to go home, wanted to stay at work. And that happened. That's human error.

I mean, people are going to be upset and distraught and, for whatever circumstance, and those things are going to happen. Now, you might want to say, no one who is not mentally fit should be doing this kind of work, but that's --

MR. HENKIN: We would be in big trouble.

MR. TELFORD: The NRC can't dictate who and who should not work.

MS. ALAZRAKI: Those things -- those things happen and nobody may know.

MR. HENKIN: Could please skip some of these teletherapy demonstrations. We really -- I mean, we can sit here and chat about it, but we don't know anything about it.

MS. ALAZRAKI: They're not relevant to us.

MR. TELFORD: I thought you were having a very good time listening to the actions to prevent recurrence.

MR. HENKIN: If you want to do that, we can do that, but it doesn't seem to make much sense to us to do that.

[Slide.]

MR. TELFORD: What I was really endeavoring to do is to show you that -- the kinds of problems we see, the causes we see and -- and the actions that the licensees are suggesting that may be appropriate to fix these problems -- these causes, and that we have tried to learn from these -- misadministrations; and tried to incorporate those into the proposed regulation.

MR. HENKIN: Can I -- can I comment that the more you require people to note things and the more that you require them to initial things -- the end result of all of that is generally noncompliance with you rules; rather than any effective outcome. Okay.

That what you do and what has been asserted may be the outcome of implementing this rule, is to simply create more noncompliance out there in a short-staff situation, or more nonsense, where people go back once a month and initial all of them.

You know, that -- that doesn't -- that isn't going to fix the nonexistent problem.

MR. CAMPER: That was something else that came up. The problem we have is that if licensees choose not to

follow the regulations or choose not to follow license conditions --

MR. HENKIN: Or are unable to.

MR. CAMPER: -- or are unable to, as a regulatory agency that is charged with public health and safety, that almost falls on deaf ears. We can't do anything about the fact that licensees will argue that we can't comply, or we don't comply, or we don't choose to comply. We have an inspection mechanism that deals with that.

MR. HENKIN: Your rulemaking, in effect, has a good deal of the force of law.

Now, there is a principle in law that says that an unenforceable law should not be passed, basically. You should not make an unenforceable law.

If you pass a regulation which the majority of people cannot comply with, then you have passed a regulation that is essentially an unenforceable law. And the wisdom of that regulation must be questioned.

MR. CAMPER: So then you are saying that on the proposed rule, that the majority cannot comply?

MR. HENKIN: I don't know that. I'm saying that there is a strong suspicion on the part of many people that compliance with that regulation may be quite difficult, in may settings.

MR. TELFORD: But you are aware of the fact that

we are conducting a pilot program, with approximately 70 volunteers, and you are aware of the fact that we have had workshops with those volunteers to discuss with them the proposed 35.35 and the objectives there, and that they have each developed or modified their program to meet 35.35, and that they did so for a 60-day period.

And we will also have workshops with those folks to find out their suggestions for how to modify the proposed regulation and to hear about their experiences trying to satisfy this regulation, how much trouble it caused them, how much cost it was, et cetera, et cetera.

MR. BRINER: You just touched a nerve.

MR. TELFORD: Yes. Cost.

MR. BRINER: That's part of the public information, right?

MR. TELFORD: Yes, sir.

MR. BRINER: How much did it cost NRC to do this, and what does it cost the individual people in the pilot study operation? Do you have any idea how much it cost?

MR. HENKIN: Yes, that's a very good question. What has the cost to NRC been to date for this rule, development of this rule, and for the pilot program? Do you have any idea?

MR. TELFORD: I have not calculated that.

MR. BRINER: I would advise you not to, or you

will have a sleepless future.

MR. TELFORD: Thank you.

[Slide.]

MR. TELFORD: There's a case of misadministration in March of 1990 in Michigan. This was 3250 rads to the wrong portion of the spine. Do you think that caused any harm?

MR. HENKIN: Yes. And you have to tell me whether this could have been prevented or not.

MR. TELFORD: The cause here was the technologist didn't consult the treatment chart, didn't consult the directions, and used an anatomical market still present from prior treatments. Therefore, the technologist treated the incorrect site. So now they will have a second technologist verify the treatment prior to administering the radiation.

MR. HENKIN: You have increased the staffing requirements of that institution with this solution.

MR. TELFORD: Excuse me. The licensee --

MR. HENKIN: Remember, licensees gives you back what they think you want, okay, and what they think you will accept.

If the licensee were to give you back, I'm not going to change anything, you wouldn't be very happy with that in general. You want them to do something. They've got to do something. Therefore, what they do is they

propose to you something that they are going to do to satisfy you, and somewhere in their system, the cost gets eaten for this, or the staffing requirements are increased, because you are going to use maybe two-tenths of a person to do this.

So that where they had two technologists, let's say before, they really need 2.2 people now to do the same patient load.

This diminishes the quality of care to patients overall, whether or not you realize that. And that's the implications of some of this stuff.

Especially, and I can't speak to what the shortage of radiotherapy technologists is, I know that I am short 2.2 staff technologists right now, and that it hurts bad, to be short 2.2 people. And I cannot legitimately, as a physician, practicing medicine, justify the use of a staff technologist for medical application that don't affect outcome. That's a medical judgment.

[Slide.]

MR. KLINE: It is subjective, I guess, as to which institutional costs are incurred by having a double verification or a redundancy. And it all varies between institutions.

MR. HENKIN: There is still going to be a cost.

MR. KLINE: There is still an associated cost.

Sure. Could be minimal, could be large.

MR. HENKIN: I'm just saying in that case, that might take .2.

MR. KLINE: The other side of the coin, in the hospital, to have the same mistake occur, if you don't institute some corrective action --

MR. HENKIN: That's a hospital decision, based on its malpractice situation and its environment, that --

MR. KLINE: But that's a regulatory position of the NRC, that we have to ensure the safety of the public.

MR. HENKIN: But you said to the hospital, and I'm saying what you are doing is getting into the hospital's management policy, which is not an appropriate place to be.

MR. KLINE: But they have a license.

MR. CAMPER: We're not getting into the hospital management policy. The hospital will choose a corrective action that it deems appropriate. We are looking, though, from a public health and safety standpoint, for corrective action. You're right. We do expect to see some adjustment in your program to prevent this type of thing from happening again. We expect it to be satisfactory. But how they go about doing it, whether it's 1 FTE, .2 FTE, an administrative clerk doing these kinds of things, is really up to the hospital and the licensee. We don't get into that.

MR. HENKIN: The point I'm trying to make, Larry, and it's a point that doesn't seem to be getting through, is that many of these are once in a lifetime occurrences for a technologist. Having made an error of this type, it is unlikely that person would ever make that error again. They are so mortified professionally, and feel so inadequate, that the likelihood of repeating the error is nil.

So what you do is you introduce a system that says an individual made an error; now we are going to forever modify the system at this particular institution when the likelihood of that individual or another one at that institution making the error is very small.

MR. KLINE: Would your recourse be to ignore it and to say the system didn't work, but, well, that was --

MR. HENKIN: Only if you examine the system and find that in the first place the system was no good.

If there was no system in the first place, that would be a justifiable thing; you say well, you didn't have a system, you should have a system.

If in fact they had a reasonable system of some sort, because under your proposed rule, if this occurs, what are you going to do? You are going to go back and ask them to do the same thing they are doing now; how are you going to change your quality assurance plan to assure this doesn't happen. It's the same thing.

MS. ALAZRAKI: It really depends again upon what the real incidence of these occurrences are. And in nuclear medicine, what we've tried to say is that the incidence is so small, that you're not going to improve upon it with regulations or with procedures. We're already doing the optimum quality assurance, based on JCAHO and other things, that NRC is not going to make any kind of an impact on that in our practices.

Now, you are presenting us with a lot of radiation oncology cases, which we are not involved in.

MR. CAMPER: That's a point well made. And no one would argue that the frequency of occurrences for misadministrations in nuclear medicine is very small. We won't argue that.

Again, as John pointed out earlier, what we are trying to do here, and we ask you to bear with us, is to give you the flavor of the environment that we have to look at.

We can't isolate nuclear medicine.

MS. ALAZRAKI: You certainly can.

MR. HENKIN: You certainly can.

MS. ALAZRAKI: It's an entirely different practice, different departments in the hospital, different positions, different technologists. It's a totally different department. And you certainly can isolate it.

MR. HENKIN: Commissioner Carr agreed to that isolation.

MR. CAMPER: When we look at what is occurring in misadministrations across the board, we're saying, at least thus far, that the status quo is not acceptable.

MR. HENKIN: Let me correct that question. How many therapeutic brachytherapy, teletherapy administration are there per year, nationwide?

MR. TELFORD: 150,000.

MR. HENKIN: Okay. 150,000. there were 14 misadministrations last year, medical misadministrations, if I remember you correctly.

MR. TELFORD: 14 this year. 12 last year.

MR. HENKIN: 12 last year. Okay.

MR. TELFORD: Which includes brachytherapy, teletherapy, and nuclear medicine.

MR. HENKIN: Okay. Subtract out the three from lats year that we knew about. That leaves 11 for radiotherapy out of 150,000. Now, is that 150,000 patients or 150,000 sessions?

MR. TELFORD: Patients.

MR. HENKIN: Patients. So a session is on the average of ten per patient, if I remember my radiotherapy correctly.

So you are talking about 1.5 million sessions and

11 errors.

MR. TELFORD: No, no. You can't multiply all of those numbers. Some of them are brachytherapy, which is a one-time implant.

MR. HENKIN: There are obviousl many more than 150,000 sessions.

MR. TELFORD: Administrations.

MR. HENKIN: Administrations. Okay. There are obviously many more. We can argue about what the number is. But there were 11 out of that large number.

I submit, without knowing a damn thing about teletherapy or brachytherapy, that that is insignificant. It falls into your BRC classification.

MR. TELFORD: Be careful. BRC says 10 millirem per patient.

MR. HENKIN: If you spread it over the public, 150,000 exposed people.

MR. TELFORD: If you are going to market something like glow-in-the-dark golf balls or irradiated gemstones or watches, your product, if it is sold to 100 million people collectively, will be more than the 1,000 rem. But if it is to an individual, like it's a product that is only going to go to a few people, then you look at it on an individual basis, and the increase should not be more than 10 millirem per person to be BRC. I don't think these are BRC.

MR. HENKIN: I have another dumb question. And that is, why don't you let the medical malpractice environment take care of this? Because this is the greatest disincentive to screwing up that there is. You can do nothing to a physician or an institution that compares to what one good malpractice suit can do.

MR. TELFORD: Maybe you're right. We can't sue the physician for $10 million. We can only pull the license.

MR. HENKIN: And you wouldn't do that anyway, because if you did that, you would render the institution without service to the patients as a whole, and you know you have a policy against doing that.

MR. TELFORD: I think we've already done that this year, in fact, a couple of times.

MR. BRINER: Not for misadministrations.

MR. KLINE: We're looking now at whether or not we're trying to prevent or diminish the chances, because what is an acceptable rate of misadministrations therapeutically for --

MR. HENKIN: Well, the malpractice report will tell you it is zero, because anybody who has a therapeutic misadministration can turn around and sue. Therefore, they've already got an effective limit, if you like, and it says, by the way, there are severe penalties associated with

a therapeutic misadministration. Those severe penalties may run into the millions of dollars.

If you want to look at a disincentive to have a therapeutic misadministration, I suggest that is a very strong disincentive.

MR. KLINE: That is a deterrent, but not a preventative mechanism.

What is an acceptable rate? What do you submit is an acceptable rate?

MR. HENKIN: There is no such thing as an acceptable rate.

MR. KLINE: That is basically what you are quantitating here.

MS. ALAZRAKI: You can't talk about an acceptable rate. All you can talk about is exceeding, if you can define it, in other words, if there is something procedural above and beyond human error, which you just can't eliminate, no matter what you do.

MR. BRINER: I would say it is that range at which we now are in nuclear medicine. You will not diminish that any more, no matter what you do.

MS. ALAZRAKI: In fact, we believe seriously that by burdening the nuclear medicine community with further paperwork and regulation, you will endanger the low rate which we have, because of the need to pull personnel off to

do this type of administrative paperwork above and beyond what we are already doing. And that further endangers mistakes or endangers the possibility of mistakes.

MR. KLINE: Assuming that we institute these measures, has anyone sat down and looked at the costs in associated personnel and extra time required for the returns.

MR. HENKIN: We have all sorts of estimates on that which have been provided previously. Your pilot study will indicate some degree of what that is, but even if it costs only 5-10 percent of personnel time, which I think is a conservative number to talk about --

MR. KLINE: That's assuming now. Let's look at maybe one to two percent.

MR. HENKIN: There's no way that it would cost one to two percent.

MR. KLINE: The question is; we don't know, and possibly, part of this pilot study might reveal.

MS. ALAZRAKI: We have to establish that it's going to accomplish anything.

MR. HENKIN: What is one percent of nuclear --

MR. KLINE: We haven't established that it will, but we haven't conversely, either. It's an untested rule, that's true, but the argument goes both ways. You can argue that it's not going to affect medicine, it's not going to

help. How do you know?

MS. ALAZRAKI: Because what we're trying to prevent is already at such a low rate.

MR. HENKIN: I'll tell you how I know. We have an analogous situation in another medical specialty. Blood banking is regulated and the reporting of misadministered red cells is a reportable item.

MS. ALAZRAKI: Only deaths.

MR. HENKIN: Causing deaths is a reportable item. Okay, when you take the number of reported misadministrations of red cells leading to death, factor that into the total number, you come out with an identical rate that we have for radiopharmaceutical misadministration, .6 percent.

Okay, there's a message in here. The message in here is that while you have humans in the system, you are going to have an ongoing rate of errors. There seems to be, at least from two diverse medical specialties, -- the only thing they have in common is a reporting requirement. The same error rate comes out.

Both have stringent procedures in place to assure that misadministrations don't occur. So that what we're saying is that in blood banking there is a real risk of the mis-- obviously, they've only got to report deaths. Yet, they still have misadministrations in blood banking. What

does that tell you?

Does it tell you that with all the effort in the world, you may not be able to -- there's an asyntotic approach to zero. The asyntotic approach to zero says that you can never hit zero. The line effectively levels out and parallels the axis forever. You may have reached that line at .6 percent.

MS. ALAZRAKI: That's basically the most important message that we have; that we feel that the misadministration rate in nuclear medicine is approaching the human error rate and you're not going to improve on that. We have instituted quality assurance techniques to ensure against misadministration which are excellent.

MR. TELFORD: So you're suggesting that .6 percent is the --

MR. HENKIN: As low as reasonably achievable.

MR. TELFORD: That the regulation should be designed to acknowledge that each licensee has a rate that's .6 percent or below --

MR. HENKIN: Mine is much better than .6 percent.

MR. TELFORD: Is that what you're saying?

MS. ALAZRAKI: What we're saying is there is no need for NRC to embark upon any unnecessary duplicative regulations.

MR. TELFORD: We were going through the

misadministrations that we say. Let's see, that's brachytherapy, that's brachytherapy and that's brachytherapy -- that's brachytherapy. Those are nuclear medicine.

The reason I bring this case up is because it's probably one of the oldest cases that I've showed you. It's 1988. The patient was -- the misadministration was that the patient got 30 millicuries instead of 30 microcuries of I-131.

The cause, from our point of view, is that the order from the regular pharmaceutical was verbal and the technologist got confused and order 30 millicuries instead of microcuries and that when the dose arrived, it was not checked in a dose calibrator because this is an agreement state. This agreement state does not require dose calibrators and they used the gamma counter and disregarded the high count rate.

MR. HENKIN: This might fit my definition of stupidity beautifully. I mean, here it was clear cut information presented to the person that they had the wrong material and they ignored it.

MS. SURREL: There was procedure here, okay. The pharmaceutical was ordered verbally. Now, the verbal order may have been correct. You're not stating one way or another whether it was.

The point was that the person was confused. In

fact, there is a procedure and the procedure in Texas is not to have a calibrator, okay? There is procedure there that was somehow violated by a human being.

MR. TELFORD: If the order was firm for 30 millicuries --

MS. SURREL: This could have just as likely have happened if the order was --

MR. BRINER: That may not be the only error there. Who ordered it to begin with?

MR. TELFORD: The technologist ordered it.

MR. BRINER: Okay, where's you physician?

MR. TELFORD: The nuclear physician had ordered the technologist to order 30 microcuries.

MR. HENKIN: You believe that writing this down would have changed it?

MR. TELFORD: I am trying to show you problems.

MS. SURREL: We are telling you that a procedure in place may not have changed this particular error.

MR. HENKIN: There are probably three errors in this situation. There are at least three errors in this situation, okay? Now, one of those errors would not have been corrected by your regulations because a dose calibrator is not required in Texas.

Their quality assurance plan wouldn't necessarily have to include a dose calibrator, because their state

doesn't require that.

MR. TELFORD: I'll correct you on that, but go ahead.

MR. HENKIN: Well, correct me on it now.

MR. TELFORD: This requirement would be compatible for all agreement states.

MR. HENKIN: But your quality assurance plan doesn't have to require a dose calibrator. You could have a quality assurance plan that doesn't require a dose calibrator.

MR. TELFORD: In the Regulatory Guide which accompanies this, it talks about checking the dose in the dose calibrator.

MR. HENKIN: What you're doing is that you're assuming the authority in the agreement states as well, that if the agreement states don't believe that this is appropriate, they've still got to do it.

MR. TELFORD: That's an interesting statement, but we've met with folks from the agreement states, and some agreement states would go further than this proposed regulation.

MR. HENKIN: And they certainly can. They have the freedom to do that.

MR. TELFORD: That's exactly right, but what this would envision is that all agreement states would come up to

a certain level.

MR. HENKIN: Are you implying that the agreement states are not doing an adequate job right now?

MR. TELFORD: No, I think you are.

MR. HENKIN: Well, I'm trying to figure out what you're saying.

MR. CAMPER: This rule for be an area for compatibility for agreement states.

MR. TELFORD: It will be.

MS. ALAZRAKI: In the long term.

MR. TELFORD: It will be a matter of compatibility.

MR. CAMPER: In the area of medicine, much of what we do in part 3535 does not require compatibility for the agreement states. There are only a couple of misadministrations. This rule would be an area of required compatibility for all the agreement states.

MS. ALAZRAKI: You have the capability of doing that right now without any kind of quality assurance program; don't you?

MR. TELFORD: We can --

MS. ALAZRAKI: No, in terms of how the institution documents a dose. You don't have that capability?

MR. TELFORD: Well, the answer is the regulation.

MR. HENKIN: No, the answer to most things is not

a regulation.

MR. TELFORD: A mechanism for agreement states is a regulation.

MR. CAMPER: If I understand your question, would we give a great deal of leeway to the agreement states in regulating the use of medicine? There are very few things that we require strict compatibility for at this point in time.

MS. ALAZRAKI: Misadministration is one. What else?

MR. TELFORD: All they have to do is report the misadministration. What I was trying to do was to show you some causes and what the licensee has decided to do so that we can understand the cause and whether or not you think the actions taken to prevent reoccurrence are even interesting.

MR. BRINER: Who ordered this to begin with?

MR. TELFORD: Who ordered what?

MR. BRINER: This thing that precipitated the misadministration?

MR. HENKIN: This wasn't the therapy dose initially started out. It was the non-therapy does, therefore, the ordering by the nuclear physician wouldn't prevent this error again.

MR. BRINER: That's exactly right.

MR. TELFORD: That's what the state of Texas

decided to do.

MR. HENKIN: I'm just pointing out to you it's an illogical solution.

MR. TELFORD: I agree with you, and that's why in the proposed regulation, it says that if you're going to order any I-131 procedures, 30 microcuries is the --

MR. HENKIN: What am I going to do with renograms that are 300 microcuries each, using I-131? Am I going to have to go through this song and dance before I can do those?

MR. TELFORD: The song and dance that you allude to is for a therapy procedure, just a written directive. You do not issue a written directive for your procedures?

MR. HENKIN: A written directive meaning what?

MR. TELFORD: Something that you sign and directs the technologist to do something?

MR. HENKIN: Not for an individual patient and not necessarily. There's a standard dose in the procedure manual. The Joint Commission requires that the physician review the procedure manual and initial the procedure manual to indicate his approval of that procedure manual.

MR. TELFORD: Good, that's exactly what we have.

MR. HENKIN: Then we don't need it.

MR. TELFORD: Do you issued a verbal directive?

MR. HENKIN: It depends. It may not be anything.

It may be just okay, that's a renogram, fine. Everybody knows what we do with a renogram; it's in the procedure manual.

MS. ALAZRAKI: The physician checks that the study is appropriate for the patient. That's medical practice. That the study is appropriate for the patient.

MR. TELFORD: How do you do that?

MS. ALAZRAKI: Based on the history.

MR. TELFORD: Do you initial something?

MR. HENKIN: No, not necessarily.

MR. TELFORD: All right.

MR. HENKIN: It varies institution to institution, widely. In our case, we go through the requisitions and we pull out those that we have question about; the rest are handed to the technical staff.

MS. ALAZRAKI: What is recorded is any inappropriate order.

MR. HENKIN: Right.

[Slide.]

MR. TELFORD: The nuclear end procedures we are well aware of because of the pilot program we're doing. And I think that they are going to offer us a very good solution here.

MR. HENKIN: The solution is they may all disappear, because there is a new pharmaceutical approved

that will probably replace it.

MR. TELFORD: This has happened in March of 1989 in Boston, Massachusetts. The patient received the wrong radiopharmaceutical. The patient was to receive I-123; instead the patient received five millicuries of I-131. The technologist misunderstood the wording in the notes made by the referring physician in the patient's chart. This is the referring physician and not the nuclear physician. And the patient got 500 rads to the thyroid, approximately. And this licensee proposed a new procedure to verify what is to be done in each diagnostic step.

So this is just a simple overcheck that they proposed to do.

MR. HENKIN: We don't know exactly what they proposed to do. But that's okay.

[Slide.]

MR. TELFORD: This is May of 1989 in Minnesota. This patient received 30 millicuries instead of 300 microcuries. The technologist misunderstood the referring physician's request, what it was, what the pharmaceutical was to be, and the patient got 3000 rads to the thyroid, approximately. And the licensee decided that a new procedure would be used. He said that a patient is not to be administered without prior approval by the nuclear physician. The nuclear physician was not in the loop here,

prior to this.

MR. HENKIN: Let me make a point about this. And that is that this hospital's quality assurance probably acted on this as well. Since it is a 1989 case, they had to have a quality assurance by 1989. And more than likely, the recommendations of the internal quality assurance group are what you got here.

So that somebody, formally, within the hospital, would have reviewed this without a misadministration report to NRC. And what you got back were the -- just guessing -- the recommendations of the quality assurance group in the hospital as to what should be done, so that, looking at a 1989 date, and that that would function whether or not they had to report it and whether or not you had a plan in place, because they have to deal with those kinds of things. That's their job.

We have a whole group that does nothing but hospital quality assurance, and that we are constantly prodded to do quality assurance studies within the department that look at two different things. We have two levels of quality assurance studies. One are administrative issues, such as this. This is an administrative issue.

Another one, which you can concern yourself with, and is really important, is outcome.

MR. BRINER: That's right.

[Slide.]

MR. TELFORD: This is a case in October, 1989, Minnesota.

The patient ten times the prescribed dose. The cause was that the referring physician here checked the wrong box on the form. This institution at least had a form for ordering doses in diagnostic case, but somebody checked the wrong box and the patient got 100 rems to the thyroid.

I realize this reporting requirement was triggered here, because it was ten times the dose, and in the diagnostic case, 50 percent larger. This hospital decided to revise its procedures to require the nuclear medicine and not the referring physician here to review and approve the request, and to write the dosage on the referral form, to get the nuclear physician into the loop.

MR. HENKIN: This is a very interesting hospital. It's a very interesting hospital, because I inspected this hospital as part of a practice inspection program recently. And they have just been pressured by Joint Commission, they had no in-house quality assurance program. They didn't have one, despite the size of the institution.

Joint Commission turned around on them and said we will not accredit you again until you have a quality assurance program in place.

So that this is a demonstration, if you like, of

the power of Joint Commission to make this particular hospital, in-nominate at the moment, but well-known, and to say that Joint Commission can turn the screws on that hospital to force them to put a quality assurance program in place.

MS. ALAZRAKI: It is also a good example of why NRC perhaps should check that all their licensees do have a quality assurance program.

MR. TELFORD: I can't believe you said that.

MS. ALAZRAKI: A quality assurance program such as JCAHO, I mean, every licensee should have some quality assurance program, and you should recognize that JCAHO's quality assurance program is a better one that you are probably going to be able to devise, and already in place, and if not in place with any licensee, they should get it in place.

MR. TELFORD: Gee, I think we all agree with that.

MS. ALAZRAKI: Not an NRC program, but the JCAHO program.

MR. TELFORD: Well, we haven't gotten to discussing form yet.

MS. ALAZRAKI: We've been discussing that. That's what we're doing.

[Slide.]

MR. TELFORD: This is the case in Arizona in

November of 1989 that everybody is probably familiar with where the patient got 100 millicuries instead of 100 microcuries. There were several causes.

The order for the radiopharmaceutical was verbal. In fact, I think it was changed once, also verbally. The dose was not measured in the dose calibrator, even though Arizona, as an agreement state requires that. There was miscommunication between to technologists.

One technologist says the dose has arrived, just give it to the patient; the other technologist assumed that everything else had been done, without checking the packing slips and checking the dose calibrator, et cetera.

The horrible consequence, no doubt, was that the patient's thyroid was destroyed. The state here suspended the use of I-131 until the licensee could show how these types of misadministrations could be prevented. On a subsequent day they allowed them to use up to 100 microcuries without state approval.

MR. HENKIN: Let me make some comments on it.

Number one, classic stupidity. I mean, just classical stupidity. They violated the state's regulations. They violated good practice regulations.

How come nobody noticed that this container weighed a ton when they went to lift it up? I mean, you know, you get 100 microcuries of iodine, the shielding is

considerably different than 100 millicuries of iodine.

It never triggered in anybody's brain that this thing that weighed a ton might not be the right thing.

So what you got is a lot of folks who were real stupid. And again, I submit, you cannot legislate against stupidity.

MS. SURREL: And again, I submit to you there is procedure there. Procedure was just not followed.

[Slide.]

MR. TELFORD: Okay. Well, unfortunately, you know, we have this regulatory responsibility to ensure adequate safety of the public. And when we see cases like this, and they go on and on, we don't have the option to say, well the agreement state or the licensee has a procedure in place, therefore everything is all right. These cases keep recurring.

MR. HENKIN: And they are going to, forever and ever and ever.

MR. CAMPER: That can be the case. And we here this again and again and again. But let me just emphasize that, at least at this point in time, the frequency of occurrence of the major misadministrations is not acceptable to the Commission.

MR. HENKIN: Three per year?

MS. ALAZRAKI: Out of 10 million administrations?

Come on.

MR. CAMPER: The point is, we would not be here going through this drill and having this discussing if it was acceptable to the Commission.

MS. ALAZRAKI: That is totally unrealistic. That's unacceptable and unrealistic.

MR. HENKIN: That exceeds the standard of practice for every area of medicine, for most industrial applications of anything.

MR. CAMPER: That could certainly be the case, and your argument has merit. But I'm just simply saying, to look at where we are now, the frequency of occurrence is --

MR. HENKIN: Are you telling us we need to go back and meet with the Commissioners about this again?

MR. TELFORD: All we're saying, you're saying to us, the rate is low.

MR. BRINER: We are saying to you the rate is as low as it can be.

MS. ALAZRAKI: As low as reasonably achievable.

MR. TELFORD: I appreciate your opinion. I won't say this is established fact, because the data is somewhat a little soft, both on exactly how many administrations were given or exactly how many misadministrations really occurred. I mean, today is a little soft.

But let's take it as an assumption that the rate

is very low. Okay? And we could argue, I mean we could debate that the rate of misadministrations are apparently low. But what we're seeing is that there's a problem out there. Something is broken.

MR. HENKIN: How is it broken?

MR. TELFORD: Well, here is a case of it being broken. November, 1989, Kuakini Medical Center, Honolulu, the wrong patient received a therapeutic dose of 9 millicuries of I-131. Now, I'm sorry guys, but we've got the responsibility of assuring adequate safety for these patients.

Do you want me not to try?

MR. HENKIN: You've tried.

MS. ALAZRAKI: You've tried.

MR. TELFORD: No, we haven't. No, we haven't. We have not tried at all.

MS. ALAZRAKI: How are you going to improve upon the current JCAHO quality assurance program?

MR. TELFORD: I didn't say we were. We haven't gotten to that point yet.

As a matter of fact, I have a very interesting example of a JCH program that you sent in. And with your permission, I would like to hand it out and I would like to talk about this JCH program, because that is on the agenda. And I would like to share with you, or we would like to

share with you what we see of that program that is on paper.

Now, it could be that you are doing much more in your actual practice than what is on paper.

MS. ALAZRAKI: Let me say that what JCAHO wants on paper at the time that that was written was one indicator in the professional, and we do many more than just one indicator. If you had the year's minutes from our meetings, which JCAHO inspects when they come, you would see that there are many more indicators than one. And one indicator on appropriateness.

MR. TELFORD: But, see, I would like to understand exactly in detail, as a one to one comparison of what the objectives that we have are, what of those are already being met by what JCAHO requires today?

See, it could be that that is a great boon for us, because we have a couple of alternative ways to incorporate their requirements, or indeed we may be, just in theory we could say, if you are JCAHO certified, it could be that you are exempt from the requirements as stated in our rule for nuclear medicine diagnostics.

MR. BRINER: Let's get the terminology there; it's accredited, not certified.

MR. TELFORD: I stand corrected, Captain Briner.

MR. BRINER: All right. If you're in the quality assurance business, you ought to know what the terms are

that we go by.

MR. TELFORD: You are correct.

MR. BRINER: All right.

MR. TELFORD: In this case, the cause was the technologist called the patient. Patient B responded and received the I-131 dose, instead of Patient A.

Did I get that right?

MR. HENKIN: Well, it doesn't matter. We got the message.

MR. TELFORD: Okay. The wrong patient responded. The patient was to receive 20 millicuries of technetium for a bone scan, but because it got the wrong patient, then the patient got the 9,000 rads to the thyroid.

This licensee proposed that they would have a single technologist who has the responsibility for recognizing patients -- to do so prior to therapy; and to handle all aspects of Iodine-131.

Also they'll have the patient and the physician and the technologist sign the therapy worksheet, prior to treatment.

This is what they proposed. And I've shown you a variety of these; and they're all -- they're all kind of different.

MR. HENKIN: Can I comment on this one too?

MR. TELFORD: Sure.

MR. HENKIN: Because this one's fascinating. Because we almost had a diagnostic misadministration recently that paralleled this; and it was caught only by accident, because somebody was very alert.

MR. TELFORD: Okay.

MR. HENKIN: We had a patient coming in for a bone scan. We had another patient coming in for a hepatobiliary study. Okay.

The lady for the hepatobiliary study was delayed. Her -- the machine to do her on was not available and she had to wait in the waiting room for a while. She saw a number of people going ahead of her for studies. So, the next name that was called out, she responded to.

Okay, she responded to that name because she felt she was losing her place in line, okay. And she got all the way back to the hot lab, when the technologist picked up the requisition, he realized that this patient was probably not 69 years old, the way it's stated on the requisition -- she looked more of about 35 years old. And he started to question what was going on.

But, in fact, if he hadn't looked at the age -- this lady kept swearing she was the other person, because she was losing her place in line and all these other people were going ahead of her.

So the causes are not always within the nuclear

medicine staff for these errors.

[Slide.]

MR. TELFORD: Well, that was a very good action that the technologist took.

MR. HENKIN: But, no quality assurance program in the world would mandate that. That's a smart person, that's all. You just got a smart person in there, who had the time to look at the requisition that day.

If I have to devote people to administrative actions, I may not have the time to be reading the fine print on every requisition.

MR. WIEDERMAN: If I remember, at Loyola issues a little plastic card to all out-patients, and I assume.

MR. HENKIN: They do not necessarily have that card on the first visit -- that's -- most of our people -- many of our people are single visit for diagnosis only. They are not in the Loyola system. That card is not always issued on the first visit. It sometimes comes in the mail, subsequently.

But that -- you know, this is this question that's been raised -- should we check driver's licenses. Well, if you believe driver's licenses -- that -- we have a lot of 17 year-old kids with forged driver's licenses that say they're 21, okay, for obvious reasons -- that any of this documentation is, first of all, a tremendous burden, and

second of all, the only time you really get concerned is when the patient cannot identify himself -- he's comatose, okay, or you have a question as to the patient's mental ability, and he's not banded.

A hospital -- all hospital in-patients are supposed to be banded. From time to time there's one who isn't banded. Our standing rule is that if they patient isn't banded and cannot identify himself, someone from the nursing service must come and identify that patient and band him on the spot.

But, I describe to you situations in which misadministrations occur, that are not the fault of nuclear medicine's staff and would not be preventable. We almost had a diagnostic misadministration because this lady wasn't going to lose her place in line.

MR. WIEDERMAN: Now, in your institution, doctor, I assume you examine each one of your -- your therapy patients?

MR. HENKIN: One of us -- one of us would speak to and meet with each one of the therapy patients, that's correct.

MR. WIEDERMAN: And then a dose is given that day?

MR. HENKIN: It's given -- well, it doesn't matter, there's always a physician present when the dose is given. It may not be given that day, but whenever the dose

is given, there would be a physician present.

MR. WIEDERMAN: So, you have sort of a -- a redundant system in place already?

MR. HENKIN: Yes, and I don't think we differ --

MR. WIEDERMAN: Since you not only have your technologist --

MR. WIEDERMAN: -- that much from most institutions in how it's done. You know, that I think that most of the time, somebody meets with the patient and discusses the therapy with the patient. Because that's the way you don't get sued, is to discuss the therapy.

MR. WIEDERMAN: I totally agree 100 percent; but what we're finding is a lot of institutions out there -- the physician doesn't even see -- the nuclear physician doesn't even see the patient.

MR. HENKIN: That needs to be addressed by somebody other than NRC, however, because that's an issue of quality of practice -- quality of medical care. That's not necessarily an NRC issue, that's an issue that deals with quality of medical care as such.

MR. KLINE: But, if the wrong patient is given the wrong --

MR. HENKIN: The physician could still give it to the wrong patient.

I will point out to you, at the hospital that we

talked about a few minutes ago, whose name we wouldn't cite -- a physician misadministered a dose to a patient.

MR. BRINER: That's one of the rounds that can go wrong. But still -- there's still a number of different mechanisms that could be prevented by simple checks.

I think, that the point is here is that a lot of facilities are doing it -- like yourself. I believe you probably had a very good quality assurance program; but can you speak for the moral majority, or are there others out there that are as good as your quality assurance program at detecting these errors as they come through the front door?

MR. HENKIN: The quality assurance program is related to the type of practice the institution has. That's really what Joint Commission does -- it relates it.

And when it comes through nuclear medicine, one of the question they ask you is about therapeutic procedures. They always ask about therapeutic procedures.

And they actually ask questions far more extensive than NRC asks. They want to know how you go about evaluating patients for therapy. They want to know how you follow up your therapy patients to see that the doses you're using are, in fact, the appropriate doses that you may be prescribing them.

You're only saying we have to prescribe them. Joint Commission wants to know we're prescribing the right

does, and that we some how are following up our therapy patients to see that we're having an appropriate effect on those patience.

MR. KLINE: Okay. So, you're looking at longevity -- and you're looking at recurrence --

MR. HENKIN: We -- we have our people come back for a year, if they will. But you can't force them to come back.

MR. KLINE: But see, now we're getting into something different. We don't look at that end, because we're not into clinical medical sense.

MR. HENKIN: But, they are far more extensive in what they ask for.

MR. KLINE: Yes. I realize what you're saying. Yes, they do go further.

But, we're just simply looking at the preventative measures. And, believe it or not, there are, I would speculate, just as you might speculate the opposite, a lot of hospitals that don't have these sort of checks in place.

Now, how do you assume that they have them in place, and how do you assume that they do have a good quality assurance program?

MR. WIEDERMAN: That's the Joint Commission's function. That's what they're out there for. What about the outpatient, private practice patients?

MR. HENKIN: I think we have to discuss that as a separate topic. Because they don't have to compose anything, except their licensees.

MS. ALAZRAKI: Accept if they're licensees of yours, you can ask them to comply with JCAHO, as a quality assurance --

MR. HENKIN: There is an increase.

MR. WIEDERMAN: You're saying, we should ask the private practice but we shouldn't ask the hospitals?

MS. ALAZRAKI: No. You can require it of all your licensees, as long as we're hooked up with a quality assurance, or appropriate --

MR. HENKIN: Or hove them present other acceptable evidence that is discussable as to other acceptable evidence; but there's nothing that stops Joint Commission from inspecting out-patient facilities, okay. And, in fact, if the reimbursement trends continue the way they are --

MS. ALAZRAKI: They will.

MR. HENKIN: -- it's probably going to be required any way, so that down the road, it's Medicare who's probably going to require that at some point. They require it now for in-patient facility.

[Slide.]

MR. TELFORD: We looked at misadministrations from 1980 to date. We see a lot of mistakes being made.

MR. HENKIN: You see some mistakes.

MR. TELFORD: Our reaction is, we'd like to try to prevent these misadministrations. In fact, the exact reaction that Dr. Alazraki had, was that everybody should have a quality assurance program, everybody should be trying to prevent.

MR. HENKIN: No, we don't argue with that.

MR. TELFORD: That -- that's our basic intent, we'd like to prevent.

Now, if you want to discuss how to do that, let's do that. But, basically, we'd like to prevent --

MR. HENKIN: The question is --

MR. TELFORD: -- the errors in medical use.

MR. HENKIN: -- whose job is it to prevent? That's what the bottom line is.

MR. TELFORD: Whose job?

MR. HENKIN: We believe that is a function of the practice of medicine -- to prevent medical errors. No other Federal regulatory agency is involved in the prevention of medical practice errors.

MR. TELFORD: This is a technology statement.

MR. HENKIN: It's a medical -- I read you -- do you want to hear the definition of a medical practice?

MR. TELFORD: Okay. It's a medical error.

MR. HENKIN: It's a medical practice error.

MR. TELFORD: It's a medical practice error.

MR. HENKIN: Again, I will take the analogy I took with you in a private discussion. If I'm an internist and I run a private office and I do no nuclear medicine, I'm not licensed by the NRC --

MR. TELFORD: Okay.

MR. HENKIN: -- however, I have a nurse working for me in that office and she give B-12 injections to patients, common thing that happens in a private office setting for an internist.

If she misadministers B-12, or gives something other than B-12 in the injection; what Federal agency is interested or responsible for that?

MS. ALAZRAKI: None.

MR. HENKIN: None.

Whose head is it on? Mine. It's my medical practice. Everybody in that practice I am responsible for. I will be sued if any of them do anything stupid, criminal or anything else. So that is no difference in a nuclear medicine practice.

The people who work in that practice, in the hospital I am responsible for legally. It is my practice, as if it were an internist private office practice. And we do not believe there is anything in Federal law that entitles you to get into a medical practice. And that is

what you're doing.

We come back to the very beginning. The internist who misadministers a drug in his office, no matter what it is, the FDA has no right to go in there and do anything with it. Neither do you have any right to involve yourself in a -- the practice of medicine.

And that's what we're talking about. No matter what the merits may be, we can argue over the merits.

MR. TELFORD: Let's say that -- it's not you, because you have a --

MR. HENKIN: No, no. Let's say it is me.

MR. TELFORD: Let's say -- let's say -- while you say it's -- where's the nearest you know what? I need to take a pit stop here.

MR. HENKIN: We'll go off the record a minute.

[Brief recess.]

MS. ALAZRAKI: Except their licensees.

MR. TELFORD: Back on the record.

Let's continue. I'd like to finish with this line because I'm going to respond to your question of need. Then we can break for lunch and come back and perhaps fruitfully get into a discussion of what the JCAHO requires.

The first point here was that we see these misadministrations and we have the reaction that Dr. Alazraki had, that we think everybody should have a quality

assurance program and should try to prevent and not only that, it's our regulatory responsibility to make sure that adequate safety is provided for members of the public including patients.

Now what we see is that we're -- the total collective "we" here including the NRC and the agreement states which comprises something like 2,000 facilities for NRc and 4000 facilities for agreement states is that we seem to be going around one at a time and we see one problem like a teletherapy problem at hospital number one, a brachytherapy problem at hospital number two, and then we see a nuclear medicine therapy problem at hospital number three, then we see a patient identity problem in hospital number four, so we can iterate through our 6,000 facilities, one's for teletherapy, one's for brachytherapy, one's for nuclear medicine, one's for patient identity, we could go around that loop 24,000 times, which seems to be an inefficient way to proceed.

Rather, we would like to have a generic solution, to have a performance based set of requirements that in part could be driven by JCAHO, indeed maybe should incorporate everything there that is worthwhile but we favor a generic solution. That is another need for rulemaking.

Thirdly, we would like to bring all the licensees up to the same minimum sufficient level of standards. It

could be that because 79 percent of hospitals belong to JCAH that they are already up to a certain level of standard and it could be that it turns out that the final rule could be nothing of an impact to those folks to speak of because they already have JCAH requirements in place, but there are those out there that don't have those same minimum sufficient levels, so that is the third need for the rule.

I am sure you have some comments to make.

MS. ALAZRAKI: When you say a generic solution, do you mean sealed sources, unsealed sources? Do you mean -- what are you talking about?

MR. TELFORD: Generic solution means one solution -- the form is for everyone, like --

MR. HENKIN: One size fits all.

MR. TELFORD: One size fits all. It's in this case a regulation that's --

MS. ALAZRAKI: And "one size fits all" could be JCAHO type of quality assurance compliance would be acceptable.

MR. TELFORD: The JCAHO type requirements could be included in that generic solution as being applicable to nuclear medicine diagnostics.

MS. ALAZRAKI: As opposed to radiation therapy or --

MR. TELFORD: As opposed to what we have invented

so far.

MS. ALAZRAKI: Okay.

MR. HENKIN: I don't think I am prepared to comment on that as a solution at the moment. It is certainly one of the viable solutions is to say that compliance with JCAHO will satisfy NRC. That is certainly a potentially viable solution, okay.

Whether it is the best solution is another question.

We have yet to deal with the issue that is at the heart of this and that is whether or not you have gone beyond the limits of the Atomic Energy Commission Act and whether you have gone beyond the statements of consideration in terms of involvement in the practice of medicine and that I think is an issue that is key to all of this, whether or not it is JCAHO or anything else.

MR. CAMPER: Let me make a comment about that and certainly we're not prepared at this moment in time to answer that question. That is a question that would have to involve the Office of General Counsel obviously and things like that.

What I would rather do though is try to focus upon where I think we are now and that is, as you and I discussed, Dr. Henkin, after the meeting that this rulemaking has a history. There have been some steps that

have been taken along the way including the fact that the medical community asked the Commission to pursue a performance-based rulemaking, which it is doing, that asked the Commission to conduct a pilot program, which it is doing.

I think to try to be as constructive as possible for today's meeting we should focus upon or draw attention as to whether or not the JCAHO criteria will address our needs.

We also should focus upon whether or not the idea and the possibility of categorizing nuclear medicine and brachytherapy and teletherapy in some separate fashion is the best way to go.

We start getting into the argument of whether or not the rule is necessary. Are we invading the practice of medicine and so forth and so on.

You are entering into a different area, a different arena than I think we are capable of dealing with here today. Our primary focus, and John can correct me if I'm wrong, is to try to take a look at given where it is today in the history of the rulemaking process thus far, to what extent, in what fashion can we take a look at existing programs out there and see if they will work.

As John pointed out earlier, we would like to go through one of these JCAHO programs and try to compare and

contrast how it relates to what we are specifically asking for.

Another thing I think is very important is to try to get back to the point -- your earlier comments about 35.35 and the eight objectives and the language in those eight objectives and in trying to draw some clarification as to what we can do if anything to wordsmith, if you will, those objectives so that they address your concerns about invading the practice of medicine while at the same time trying to address our concerns about a performance-based quality assurance program.

I think that would be more constructive.

I am not sure we are really in a position to answer the question --

MR. TELFORD: Well, we could discuss these. Dr. Henkin is alluding to the 1979 Commission policy statement.

MR. HENKIN: We can further than that.

MR. TELFORD: We can discuss those. I mean that's really the basis for --

MR. HENKIN: Well, if you're telling me that you need a ruling from the Office of General Counsel on whether or not you're within your bounds in terms of the statements of consideration, I think that's reasonable, okay?

I think by the same token we would have to obtain a legal opinion in that situation as well because that

becomes a legal proceeding then and I think that is a very, very key thing to decide because in a way you are setting precedent for Federal regulatory agencies and this is what worries us -- so that you need to understand why we are so concerned about this topic as to whether or not you are within the bounds of your regulatory authority to do so.

MR. CAMPER: Let's go off the record for a minute.

[Discussion off the record.]

MR. TELFORD: Let's go back on the record. Let me see if I understand your question correctly, Dr. Henkin.

I think you are alluding to the 1979 Commission policy statement, in fact Item 3, which says "The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part and a practice of medicine."

This statement says that the NRC will minimize intrusion.

MR. HENKIN: That's correct.

MR. TELFORD: But the first one says that the NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public, so it says it will continue to regulate all medical uses and the second statement is that the NRC will regulate the radiation safety of patients where justified by the risk to the patient and where voluntary

standards or compliance with these standards are inadequate.

MR. HENKIN: There is also a statement that you have made any number of times as an agency on the record which basically says that you are interested only in the safe handling of materials, okay, the storage and handling of active materials safely.

This again goes well beyond that and it goes to the point of prescribing things that are already prescribed by medical -- by parts of the medical practice, that there are at least three groups that are involved in quality assurance in nuclear medicine at the present time. Therefore, okay, this is already part of the practice of medicine because the medical groups themselves are involved in it.

It brings it in as part of the practice of medicine. It's a standard of practice.

If you look at ACNP's manuals, those things are labelled standards, okay, therefore my argument rests on the fact that you are in fact extending your intrusion into the practice of medicine where such organizations already exist and I think you can make a very interesting case for whether or not you ought to be there and I would hate to see it come to that but the feelings of the professional societies and the professions are very, very strong in this area because it sets a precedent for Federal regulatory agencies to

regulate the actions of individual physicians. That is not an acceptable precedent.

MR. TELFORD: I think your point is in part on number two, where it says voluntary standards would be used unless they are found to be inadequate.

MR. HENKIN: Now we have some question as to who can judge adequacy of medical standards. You have no physicians, no nurses in your employ. How can you judge medical standards?

MR. TELFORD: This doesn't necessarily say we are going to judge medical standards.

I think the key phrase in number one, one of the key phrases, is medical use. Medical use is a term defined in 10 CFR 35.2, which says roughly that it is the administration of byproduct material or the radiation therefrom to patients in the practice of medicine, so that when the Commission's policy statement says that it will continue to regulate the medical uses of radioisotopes, that is very specific.

MR. HENKIN: This is not a medical use that you're regulating. These are areas outside the direct use, okay?

You are not regulating -- I mean if you want to talk about regulating the use that's one thing. This is not regulating the use. This is administrative procedures not directly related but indirectly related to use.

MR. KLINE: But if it's a use of materials to be regulated, a function of misadministrations --

MR. HENKIN: We're back to misadministrations again. That is a place we don't want to be. We want to talk about this is the abstract.

If we talk about misadministrations you get into a whole other numbers game that I think is very difficult for you to justify.

MR. KLINE: But your statement that we regulate only the safe handling of material, this seems somewhat contradictory with current regulations that we have.

MR. HENKIN: I think you guys have never decided what it is --

MR. KLINE: Okay, so now we're going back to rules that are already in effect, you are saying --

MR. TELFORD: Well, we have decided and it is medical use, as defined in 35.2.

MR. HENKIN: I submit that we need to sit down with the Commissioners and we need to discuss with the Commissioners exactly what their direction is for this because obviously there is conflicting direction for what is to be done.

MR. TELFORD: Not on our part.

MR. HENKIN: We view that -- okay, at one point they are telling you to stay as much as possible out of the

practice of medicine but you're interpreting another part to say that you need to be involved here, in this which is a medical practice area.

MR. TELFORD: It says minimize intrusion into medical judgments.

MR. HENKIN: This is judgment. It is all judgment. Quality assurance is completely judgment. There is no right and no wrong in quality assurance. It is all a call.

It is a baseball umpire.

MR. TELFORD: It seems to us that if you're talking about medical use and the nuclear physician decides that a patient should get 30 millicuries of I-131, that's exactly what should happen. That patient should receive that dose, that isotope.

MR. HENKIN: And it's his responsibility to see that occurs and nobody else's.

MR. TELFORD: If that happens, then the safety of that patient has been adequately assured. So we're really after the same goal.

MR. HENKIN: Let me give you the other part of the coin. In my practice, I use a drug called Adenosine to enhance the quality of myocardial profusion studies. It's a dangerous drug; it can cause complete heart block. I prescribe it at the dose of 140 micrograms per kilogram per

minute for 6 minutes. What paid federal agency is responsible for seeing that drug is given at that rate in my practice? There is none. There need be none. It is my responsibility to see that that occurs.

My medical license in the state of Illinois, has described again in here as to what a licensed physician is and what the responsibilities of a licensed physician are, and I use that drug in conjunction with a radioactive drug. I can do far more damage with that drug -- I can kill somebody with that drug. I can't kill him with the concomitant radioactive drug.

MR. KLINE: But that decision on the quantity to use --

MR. HENKIN: Is mine.

MR. KLINE: That's correct.

MR. HENKIN: And I have to see that it's executed properly.

MR. KLINE: Are there not a lot of variables that you have to consider before you would determine the quantity of that drug to use?

MR. HENKIN: No. As a matter of fact, I give the same dose to everybody.

[Laughter.]

MR. KLINE: You give the same dose to everybody. Okay.

MS. ALAZRAKI: That would be under his purview.

MR. HENKIN: But I could change it on any patient I want to change it on. It's a prescription I've written, a standing order, if you like, in the department that says --

MR. TELFORD: How about the by-product material?

MR. HENKIN: A by-product material is often changed. It's more often changed than --

MR. TELFORD: Not a by-product material.

MR. HENKIN: We're not using a by-product material for this, but we could very shortly. If the FDA gets its act together and approves Cardiolite, it could be used in conjunction with Cardiolite.

MR. BRINER: You ought to tell them also the halftime of that non-radioactive drug you're talking about.

MR. HENKIN: It's ten seconds, eight seconds, something like that.

MS. ALAZRAKI: Very short.

MR. BRINER: You're not going to catch him in an error very quickly, very often.

MR. HENKIN: You see, the parallel I'm trying to draw, that I'm using at the same time a radioactive drug and a non-radioactive drug, both of which I am responsible for. The drug that is potentially lethal, I need deal with no federal agency on. I could kill somebody with that drug and it's not the responsibility of a federal agency to stop me.

And it is part of the practice of medicine, as I am licensed by the state of Illinois to practice medicine.

MS. ALAZRAKI: However, if you did kill someone or hurt someone with the non-radioactive drug, it would come under the quality assurance program in review, and that is the control.

MR. HENKIN: Even if I didn't -- as a matter of fact, the Pharmacy and Therapeutics Committee of the hospital approves my use of that drug in that application in that does.

MS. ALAZRAKI: Well, the hospital altogether --

MR. TELFORD: Well, I'm sorry, Dr. Henkin, but I think we're involved. I mean, the guidance that --

MR. HENKIN: Well, then we have a basic disagreement and I'm not sure there's much more to talk about because to talk further would be deemed an endorsement of what you're doing and we don't endorse it.

MR. TELFORD: You made the suggestion earlier that -- which I agree with, that we could just assume that, you know, we set those objections or concerns aside for a moment.

MR. HENKIN: But they keep coming back. They keep resurfacing.

MR. TELFORD: Not to bury them, but just to set them aside so that we can discuss in detail what JCAH would

require.

MR. HENKIN: We can discuss what JCAHO does and what its requirements are, but I don't see this as applicable to the rest of this discussion simply because you are starting from a place that we cannot accept.

MR. CAMPER: Let me address that. Let me, if I can, so we can come to some conclusion on this point at this moment in time, try to characterize what I think I hear you saying. It goes something like this.

On April 7, 1988, members of the medical community, including several members of the ACNUI, briefed the Commission on their concerns regarding the 1987 proposed rule. They stated that a performance-based rule should be promulgated rather than a prescriptive rule. They also suggested a pilot program would be useful for determining whether the proposed QA steps would interfere with clinical practice.

MR. HENKIN: I think that's a mischaracterization of what happened. What happened was there was total objection to any rule of any sort, and very much, as at this meeting, that's why we refuse to make the same mistake again, because it was taken out of context as to what the medical community said.

The medical community said there's no need for any rule. And NRC said there's going to be a rule. Well, we

said if there's going to be a rule it should be performance-based. But that has been taken out of context. It is not a correct interpretation, and I think Bill was involved.

MR. BRINER: That's right.

MR. CAMPER: So then, at this point you're saying that the medical community still questions the need for a performance-based rule.

MR. HENKIN: We don't question it. We know there's no need for a --

MR. TELFORD: You mean, the nuclear medicine community.

MR. HENKIN: ANCP and SNM. If you know of others, that's fine.

MR. TELFORD: Well, for instance, the American College of Radiology and others.

MR. HENKIN: Have they endorsed this rule?

MR. TELFORD: I don't want to put words in their mouth. We have met with them. We do not hear similar statements from --

MR. HENKIN: The American College of Radiology doesn't really represent nuclear medicine.

MR. TELFORD: I didn't say that.

MR. CAMPER: That's a result of my statement, the medical community. It looks like we're drawing a clarification as to what we're calling the medical

community. That's a very good point.

MS. ALAZRAKI: When you talk about the American College of Radiology, that concerns both the sealed source and unsealed source administrations.

MR. CAMPER: Despite this position at this point in time, despite the fact that you believe that this Federal Register notice does not adequately characterize the proceedings of 1988, can we, would it be worthwhile to set that aside for the time being and look at what to what extent the JCAH criteria would address our concern.

MR. HENKIN: I think we can talk about that. I just don't want it in any way taken out of context the way that was to say that we recommended the use of JCAHO criteria. That is not at all what we're recommending.

MR. TELFORD: If we characterize it as offering you the opportunity to educate us as to what a program would look like if it were following JCAH so that we could then compare it to the objectives that we're trying to achieve, we could either understand how to do that better or how to change ours so that we could be more in alignment.

MR. HENKIN: We could discuss what it is that JCAHO does and how it does it. Yes, I think that is a fair discussion to occur so you understand what it is Joint Commission does.

MR. BRINER: Beyond that, with the exception of

you referencing JCAHO as an appropriate way to effect a quality assurance program, I don't want you to infer from our discussion the fact that you should present a mirror image of JCAHO. That's not what we're saying. We're simply saying you don't belong in this quality assurance business, period.

MR. CAMPER: As we look at JCAHO, I think two things would be useful. One would be, we try to, as John alluded to earlier, take a program and the specific line items and compare how they do relate to our eight major objectives, also with come consideration in that regard for the accreditation manual.

Then, the other thing that I have some concerns about is enforceability.

MR. HENXIN: Can we discuss that first? That's the easiest one to address.

MR. TELFORD: Do we want to break for lunch at some point?

MS. ALAZRAKI: Yes, at some point.

MR. TELFORD: Would anybody object to breaking for lunch. It's about 12:20.

MR. BRINER: Let me ask you this, how much longer do you think this is going to take?

MR. TELFORD: Until about 5:00.

MR. BRINER: I don't think it's going to take that

long.

MR. TELFORD: Or as long as you're willing to stay and discuss with us.

MR. HENKIN: Well, we will stay as long as there's a productive discussion going on.

MR. TELFORD: I would really like to get through most of these items on the agenda. I think there's a lot of fruitful areas there to discuss and I think you all could give us a really good insight into what you think should happen or how to change these things or how to improve them from your point of view, and by golly, we all came a long way to come here today. We have people from Chicago, a person from Atlanta and a person from the Philadelphia area.

We all came here in earnest to engage in a good roundtable discussion, and we truthfully want to learn from you.

MR. HENKIN: We're very willing to discuss with you how these other things work and what they do. I don't think that -- we have no problem with discussing these other programs that exist and how they operate, what they're designed to do. I think that's fine.

MR. TELFORD: Does that mean you don't want to discuss the other items on the agenda?

MR. HENKIN: I'm not sure. I don't know what I want to say about insight from comments. I mean, you've got

comments --

MR. TELFORD: That was your idea.

MR. HENKIN: Well, you've got the comments on the comments now from Dr. Marcus. I'm not sure you we can do much more than the comments on the comments.

MR. TELFORD: How about Item 4?

MR. HENKIN: I think we've been discussing 35.35 extensively.

MR. TELFORD: We haven't discussed it in detail. Maybe after we've discussed this, maybe after we've discussed where the JCAH facility operation might look like, then we could compare it to the 35.35 objectives.

MR. CAMPER: I think that's extremely important, just to try to get a comparison that's close to be a line item-by-line item as possible. We have a great deal of interest in your comments at the ASMUI meeting as to whether or not JCAHO would address the nuclear medicine component. I think we all recognize the brachytherapy and teletherapy pose certain problems.

MR. TELFORD: Great. It's about 12:25. Should we break for lunch and come back in an hour? Is that acceptable to everybody? Let's take a break and go off the record.

[Whereupon, at 12:25 o'clock p.m. the meeting was recessed for lunch, to reconvene at 1:25 p.m.]

AFTERNOON SESSION

[2:13 p.m.]

MR. TELFORD: Shall we resume. This afternoon, first thing, let me propose that we take an example program that supposedly meets JCAHO requirements, use this as a discussion vehicle to do a couple things.

One would be so that we could learn what would be required of any licensee if they were following JCAHO to the extent of our interest of making sure the patient gets the dose as directed.

And secondly, to compare it to the objectives that we have -- this would be on page 1449 of this handout. Now, does everybody have one of these? Captain, Briner, do you have one of these?

MR. BRINER: Yes.

MR. TELFORD: We would like to understand what procedures would come into play if a licensee were following the JCAHO quality assurance program. How would you like to proceed? Would you like to discuss the plan or would you like us to discuss the plan?

MS. ALAZRAKI: Let me just point out, since I know this plan, that the JCAHO quality assurance programs involve mandatory monthly meetings at which time each indicator or point of any incident which has happened over the past month is reviewed in some detail so that the minutes of the

monthly meeting are a part of the program.

The indicators change from time to time so that this is a bunch of indicators that you have here for a specific time period and you may find different indicators several months later in the plan.

It's a dynamic program, in other words. It doesn't remain static, so that while what you have here is some indicators from one point in time, you cannot really -- you don't have everything to evaluate the total scope of the program, which would include the procedure manuals, the appropriateness journals which we keep, the minutes, and probably even more documentation than is included in all of those items.

MR. TELFORD: Okay. Could we go through these? I'll take the first one -- to offer diagnostic and therapeutic procedures, which are both useful to the referring clinician and regarded as appropriate by the medical community.

The indicator that you spoke of is really some action step that needs to be taken, and this one is to monitor requisitions in order to judge the appropriateness of requested procedures.

And then criteria stated in this book, in the "data and reviews" column, says the resident is to review every requisition and resolve any questions regarding

possible inappropriateness prior to commencing procedure.

So we would look at this and say that the intentions here seem to be to have a procedure which ensures that the correct procedures is about to happen and you have a physician under the supervision of a nuclear facility, an authorized user, to review the referral prior to administration.

I think that's one of the ones that we would be in agreement with as something very similar to an objective that we would have.

MR. WIEDEMAN: In my review of this it appears that this first one would satisfy the objective no. 1 of 35.35.

MS. ALAZRAKI: Well that would satisfy that objective. This is a practice of medicine indicator.

MR. WIEDEMAN: Well the indicator being monitored to requisitions in order to --

MS. ALAZRAKI: Appropriateness.

MR. WIEDEMAN: Appropriateness, yes.

MR. TELFORD: And, Darrell, would it also perhaps satisfy the one where depending upon if they have the resident somehow initial or somehow indicate that the review happened, wouldn't that be the same as having the authorized user direct this --

MR. WIEDEMAN: As they're working under the

supervision of the authorized user?

MR. TELFORD: Yes, directed this -- well, is it a diagnostic or therapeutic? This one step may cover more than one.

MS. PICCONE: Does JCAHO require that all requisitions be reviewed, or is that the way you have interpreted it?

MS. ALAZRAKI: Well, what they require is that we ensure appropriateness.

MR. HENKIN: Well, there are two JCAHO documents, and I think you can't confuse them. One is their quality assurance manual, one is their accreditation manual. The accreditation manual can be viewed to similar Part 35 in terms of its effect, and it's a "thou shalts" and you've got to do all those "thou shalts" to get accredited so that you can't divorce these two, because whether or not you have a quality assurance program in place, you still would have to comply with everything in this nuclear medicine section in the accreditation manual.

MR. TELFORD: Does the accreditation manual require that all requisitions or referrals be reviewed?

MR. HENKIN: Well, hold on a second and I'll give that to you.

MS. ALAZRAKI: I'm not sure that they actually say that. They do want you to show them how you ensure

appropriateness of the studies. I'm not sure that they spell that out.

MR. HENKIN: There is something in here that deals with it. I didn't underline it so I need to go through it for a second.

MR. WIEDEMAN: It is right before standard.

MR. HENKIN: A planned and systematic process for monitoring and evaluating the quality and appropriateness of nuclear medicine services.

MS. ALAZRAKI: Yes, so this is the process that we use. And that's a medical question.

MR. HENKIN: That's required characteristics under the first section. Now you see you have to grade yourself and then the inspector has to grade you as well as to whether you've done that.

MR. BRINER: Why don't you explain about the accreditation manual has standards, and that happens to be under standard no. 1, NM.1, and the required characteristics under that standard listed, and this happens to be 1.3.9, and all of these things have to be there in order to satisfy that standard.

MR. TELFORD: Well let's look at the second function -- to offer procedures and render diagnostic interpretations in a timely manner so as to assist the medical treatment of the patient. And the indicator is

monitor the interval between the completion of procedures and the distribution of the final reports.

The review is, timeliness data will be gathered from a random sample of not less than 10 percent of all diagnostic procedures performed in each month. The average monthly value will be reported and compared to the threshold value.

So the intent here is to make sure that the reports are delivered in a timely manner. Is that true?

MS. ALAZRAKI: Yes.

MR. TELFORD: Okay, this is an area that we will not delve into.

MS. ALAZRAKI: Right.

MR. TELFORD: So while this may be something of interest to JCAHO, we would not delve into this.

MS. ALAZRAKI: And then again, this is just one indicator which comes under this function at one point in time, but actually over the course of two years we may have four different indicators that would come under this function at different times.

MR. TELFORD: The other indicator under that same function is to monitor the scheduling delay for routine outpatient bone scans.

MS. ALAZRAKI: As an example.

MR. TELFORD: As an example?

MS. ALAZRAKI: Because it's a procedure that we do a lot of.

MR. TELFORD: Okay.

MS. ALAZRAKI: So there's a good indicator of what the scheduling delays are.

MR. TELFORD: All right, so we found --

MR. HENKIN: I would also refer you to the ACNP inspector's manual, the 1988 edition, page 15, in which we have principals -- we don't call them standards, but they have the same effect in terms of practice accreditation -- and in 1-10 it says, "The nuclear medicine physician shall be responsible for the quality and safety of all procedures performed at his direction. This responsibility includes assuring that the staff, under his direction, are properly trained and competent to perform each procedure in which they are directed to participate. Only the responsible nuclear medicine physician shall delegate responsibility to other persons to perform patient care tasks."

MR. TELFORD: Does JCAHO have a similar requirement?

MR. HENKIN: They make safety the responsibility of the physician as well.

MR. TELFORD: How about FERT? This basically says that the people under your direction have to understand what they're about to do before they do it, and it's the

responsibility of the nuclear physician to ensure that.

MR. HENKIN: Okay, well here, NM.1.13 out of JCAHO, where "Responsibilities of the director of the diagnostic and/or therapeutic nuclear medicine department/service which may be appropriately delegated include, but need not be limited to, the following," and they go through half a page.

MR. TELFORD: All right.

MR. HENKIN: "Approaching the process or processes for determining the qualifications and competence of department/service personnel who are not independent practitioners and who provide patient care services." That's NM 1.3.3. So, I think that that does cover that question.

MR. TELFORD: Where's the one about making sure that people understand?

MR. HENKIN: Qualifications and competence.

MR. TELFORD: Okay. I am not sure that -- what do you want beyond qualifications and competence?

MR. HENKIN: Oh. Well, it's the language in 1-10 under ACNP.

MR. TELFORD: ACNP is considerably wordier [illegible] JCAHO.

[Laughter.]

MR. HENKIN: That's okay.

MR. TELFORD: Once again, 1-10, in my interpretation, would meet the objective of 35.35 number 4, objective number four, "Assured current medical use -- no, no. I'm sorry. Not that one. It would be five.

MR. HENKIN: Well, four is pretty close.

MR. BRINER: Now, you've got 1.3.7, too, which says "Developing comprehensive safety rules in cooperation with the hospital's safety committee and the hospital's radiation safety committee if one exists."

MR. WIEDEMAN: It's the end of number four. ". . . is understood by the responsible individuals." Of course, that's how the institution would implement that particular objective. Training, qualifications.

MR. BRINER: Now, if you want to go back to NM.4 under Standards, how do you know that something is being looked at after the fact? In that standard, it says, "As part of the hospital's quality assurance program . . . " the hospital's quality assurance program, I'll emphasize, ". . . the validity and appropriateness of diagnostic and/or therapeutic nuclear medicine services are monitored and evaluated in accordance with certain standards under the QA manual that can be picked up that way." That's Standard No. NM 24, saying that the hospital itself is looking at --

MR. TELFORD: Where in this program does it address things like the training?

MS. ALAZRAKI: Okay. That comes under the hospital's QA program, which we are part of, but it's not in here.

MR. TELFORD: Okay.

MS. ALAZRAKI: But the hospital credentials and authorizes every physician.

MR. TELFORD: Let me ask -- does it say that the technologists have to be trained and understand the clinical procedures manual and trained in the procedures they're about to do. So, that's covered elsewhere.

MS. ALAZRAKI: Right.

MR. TELFORD: Okay.

MR. HENKIN: Basically, it requires that a job description exists for everybody, okay, that's out there, and that the job description be appropriate to the tasks undertaken.

MS. ALAZRAKI: And that the credentials of the individual be appropriate for the job.

MR. TELFORD: Shall we go to page two?

MR. HENKIN: I guess I had one more I wanted to read you out of here. We lost it for a second. NM 3.1 on page 123, "Requests/referrals for diagnostic and/or monitoring and/or radionuclide therapy procedures include the study or studies requested and appropriate data to aid in the performance of the procedure requested."

MR. TELFORD: Which one is that?

MR. HENKIN: NM 3.1 in the JCAHO.

MR. TELFORD: Thanks. What effect does that have in the department? What does that bring about?

MR. HENKIN: That's addressing your issue of making sure there's appropriate therapy and appropriate supervision of therapy, okay, and that the studies be reviewed. That's a good deal of what you've been talking about.

MR. BRINER: And it goes back to the standard on the previous page, NM.3, where, "Reports of consultations, interpretations of diagnostic studies and radionuclide therapy procedures are included in a patient's medical records."

MR. TELFORD: Okay.

MR. HENKIN: Now, again, I think one of the things you have to realize is that JCAHO requires the hospital to identify the privileges that every physician has.

MS. ALAZRAKI: Exactly.

MR. HENKIN: For example, I'm credentialed by the hospital to perform diagnostic and therapeutic nuclear medicine procedures. I am not credentialed to perform radiotherapy with sealed sources, for example, even if I might so qualify, or diagnostic radiology. The hospital does not accredit me to do that.

When you look here, it's discussing the fact that only individuals with delineated clinical privileges to perform and/or interpret diagnostic and/or monitoring procedures and supervise radionuclide nuclide therapy procedures authenticate reports. That refers back to the first page, describing what JCAHO thinks a nuclear medicine physician should be who is supervising the department, which are considerably more stringent standards than NRC has, as it turns out.

MS. ALAZRAKI: That's right. They require Board certification for the director of a nuclear medicine department, either ABNM or ABR Nuclear Radiology Special Competence.

MR. HENKIN: And in 1.2.1.

MR. TELFORD: Could we go to page two of this plan? The first item is -- the function is "To perform each procedure in such a way as to optimize the quality of the diagnostic information available. The indicator is to monitor the accurate preparation and administration of all radiopharmaceuticals." The review says to be reviewed and summarized monthly. So, I take that to mean that there's a report that's issued monthly as to what was administered?

MS. ALAZRAKI: Exactly. Right.

MR. TELFORD: Okay. Tnat the correct isotope, chemical form, dose, etcetera --

MS. ALAZRAKI: Well, what's reported is any deviation from the correct isotope.

MR. TELFORD: Okay. So, you identify any deviations --

MS. ALAZRAKI: Although, in our records, you could go through and find every radiopharmaceutical that you want which has been administered during the month.

MR. TELFORD: So, your records would indicate --

MS. ALAZRAKI: But the minutes will reflect --

MR. TELFORD: -- what was directed.

MS. ALAZRAKI: Exactly.

MR. TELFORD: What was supposed to have been given in terms of dose, chemical form, physical form, isotope, etcetera.

MS. ALAZRAKI: No. The minutes won't --

MR. TELFORD: No, the directives.

MS. ALAZRAKI: Right.

MR. TELFORD: Your records.

MS. ALAZRAKI: Right.

MR. TELFORD: But the minutes talk about identifying any deviations --

MS. ALAZRAKI: Any deviations, because otherwise, our minutes would be 70 pages long.

MR. TELFORD: -- that were not according to the directives which were in the record.

MS. ALAZRAKI: Right.

MR. TELFORD: Okay. Well, that's exactly what we've got in Number 7. "Ensure that any unintended deviations from a prescription or a diagnostic referral to the clinical procedures manual is identified and evaluated." But you issue a report monthly. Who signs the report?

MS. ALAZRAKI: We issue the minutes monthly, and I sign the minutes.

MR. TELFORD: Okay. Authorized user, nuclear physician signs minutes. Okay.

This other indicator here of "Monitor the performance of all imaging and CAT instrumentation through routine quality control testing," and then the review is daily or weekly or monthly. You want to be within five percent of a mean for uniformity. This is really equipment quality.

MS. ALAZRAKI: This is quality control.

MR. TELFORD: Of equipment, right?

MS. ALAZRAKI: It's quality control.

MR. TELFORD: Make sure that the camera is flooded, and all that?

MS. ALAZRAKI: Right.

MR. TELFORD: Okay. Well, the first item on this page, the reporting of what was actually administered, that certainly is in accord or in concert with one of the

objections, whereas the second one of equipment quality, we haven't gotten into that. With any luck, we won't.

MS. ALAZRAKI: Right.

MR. KLINE: Let me comment also on the second page of the annual quality assurance plan. Your data and review mentions to be reviewed and summarized monthly. You're somewhat indicating that this one criteria is audited monthly. So, you're falling into part of Item 8, though this is focused only in this one area.

MS. ALAZRAKI: What -- item 8?

MR. KLINE: Item 8 of 35.35, where they talk about a comprehensive audit, though this is not comprehensive, but this is one aspect of an audit. So, you're starting to address that issue, also, when you specify a time interval, which is satisfying that 35.35 (8)(b)(1). Do you see that, where they call out a procedure for conducting an audit at intervals no greater than twelve months to verify compliance of all aspects of the quality assurance program.

This is part of what you're doing here, though it's not maybe a comprehensive audit. I think the latitude is that if you have other examples in here -- no doubt, you do, where you talk about quarterly and some other things -- these also can fall into that, and it does become comprehensive in that sense, again addressing these elements -- the intent is to address each of the one through seven

elements in this comprehensive review, assuming that the seven elements are met in the existing JCAHO guideline in this example that you brought forth.

MR. TELFORD: What Ed is saying that the proposed 35.35 envisions an annual audit to allow the licensee to review their program to see if it's still adequate.

MR. BRINER: No, no. It's up to you. You can do as many as you want, but once every twelve months.

MS. ALAZRAKI: Well, the way the quality assurance program works, at least in our institution, I mean in addition to the one-month minutes, there is a quarterly review which is done by the hospital QA committee.

MR. CAMPER: When we look at nuclear medicine services and we see the various standards, this is all encompassing in that it would address brachytherapy --

MS. ALAZRAKI: We have nothing to do with brachytherapy and nothing to do with teletherapy. Unsealed sources. Unsealed sources.

MR. CAMPER: Is there a section similar --

MR. HENKIN: Yes. I have never looked at it but I know it exists. It exists for every hospital service department.

MR. CAMPER: I have the same problem. I've not seen one on brachytherapy.

MS. ALAZRAKI: I have never seen one either,

frankly.

MR. KLINE: The Quarterly Review by the Quality Assurance Committee usually involves that, so you have somewhat --

MR. HENKIN: That is a hospital-wide effort.

MR. KLINE: -- somewhat of an audit function in that sense --

MR. HENKIN: Each department's quality assurance report is brought before the hospital-wide quality assurance committee usually at a quarterly meeting. If you have got three reports they may lump them together as one but they will present each department's quality assurance efforts.

MR. CAMPER: Does the JCAH have a requirement as relates to time interval for a comprehensive audit?

MR. HENKIN: It's an ongoing process in the JCHO's view. It is not one that is done once a year. It's a continuing process.

MR. TELFORD: Monthly and quarterly.

MS. ALAZRAKI: Monthly and quarterly, right.

MR. HENKIN: They want to see that you are consistently reviewing quality assurance, not that you do it once a year or just before their inspection. They don't buy that.

MR. TELFORD: Okay, could we go to page 3?

The function is to report the findings of each

procedure in an accurate and consistent manner. The indicator is to monitor the interobserver variability for three phase bone studies and SPECT Thallium studies.

The review is these results will be summarized quarterly. Any individual whose interpretations exhibit a pattern of both consistence and significant nonagreement will undergo structured re-education.

This is to make sure that the people that are reading the films are doing so correctly. This is an area that we would not get into because this truly is medical judgment.

MS. ALAZRAKI: Right.

MR. HENKIN: It is an area that the joint commission may be backing out of too. They've got a lot of trouble with this.

MR. TELFORD: The next function is to provide a safe environment for patients and staff.

The indicator is monitor staff compliance with Universal Precautions Policy and Infectious Control procedures.

The review is supervisors will report all deviations from this policy.

The results will be summarized on a monthly basis. Corrective actions will be undertaken for each deviation.

MS. ALAZRAKI: So you have to look at the minutes

to see whether there have been any deviations. Basically the Infection Control procedures are well documented in the hospital quality assurance plan and the university precautions policy is also well documented, so the details of that are in other documents

MR. TELFORD: Your first indicator is infectious diseases --

MS. ALAZRAKI: Infection control.

MR. TELFORD: Infection control, excuse me. The second indicator is monitor staff radiation exposure and the review is whole body exposures will be measured by film badge not to exceed 160 millirems per month and exposures measured by TLD not to exceed 5.5 rems per month. Data to be summarized monthly.

This is an area that of course the Commission is involved, interested in, but it is from Part 20, not from Part 35.

Your third indicator under that same function would be monitor the laboratory and patient areas to determine the presence of radioactive contamination.

The review is any readings which exceed either three times background level or twice the previous reading will require the initiation of immediate corrective action.

Again that is a Part 20 requirement and not a Part 35 requirement.

Okay, page 4. Page 4 doesn't have any functions. Are these continuations --

MS. ALAZRAKI: Continuations, right.

MR. TELFORD: We are continuing the function to provide a safe environment for patients and staff.

Okay, the first indicator is monitor staff compliance with EUH requirements for an annual BCLS CPR recertification, so that's outside of Part 35 interests.

The second one on this page is monitor the readiness of the emergency resuscitation equipment. Again, that is outside of Part 35 considerations.

The third indicator is monitor staff radiation exposure and thyroid radiation burden due to participation in the therapeutic administration of Iodine-31 for treatment of Graves Disease or Thyroid Cancer.

The review there is corrective action will be initiated whenever a bioassay measurement exceeds 24 microcuries. Results will be summarized monthly.

So this is for safety of workers and it's really not a Part 35.

It is a Part 35?

MR. WIEDEMAN: Yes. Whenever they do CA therapy ey have to do a bioassay.

MS. ALAZRAKI: Right, right.

MR. TELFORD: It's part of 35 but not 35.35.

MR. WIEDEMAN: Right, that's correct.

MR. TELFORD: Okay, thank you, Darrell. Keep me honest.

There is one more page, which is the addendum.

The function is for implementation during March.

The indicator is monitor the time interval for the completion of all diagnostic reports in order to identify any outliers which require more than seven days for completion and distribution.

The review is all outliers identified by this monitor will be reviewed for patterns of similarity with regard to report generation and verification process.

This is --

MR. BRINER: They will be involved at six o'clock in the morning every morning until they are not outliers anymore.

MR. TELFORD: This is to ensure timely reports, timely diagnostic reports.

MS. ALAZRAKI: Yes.

MR. TELFORD: So this would be outside 35.35 so after we review this plan then we find two sets of function indicator review that apply to --

MS. ALAZRAKI: Well, probably most of the others would fall under these functions, except you didn't specifically identify them.

MR. HENKIN: Some of the others are required by the accreditation manual anyway.

MS. ALAZRAKI: Right.

MR. HENKIN: So they don't fall into the plan. If you look at --

MR. TELFORD: Let's go to the eight objectives of 35.35.

Let me tell you which ones we have already picked up so far.

MR. HENKIN: You're here to tell us the ones we have to worry about.

MR. TELFORD: Maybe you have done that well.

That would be good.

Number one is ensure that any medical uses indicated for the patient's medical condition. You have taken care of that one in this plan.

Two, ensure priority in medical use, that a prescription is made for any therapy procedure, any diagnostic or any pharmaceutical procedure involving more than 30 microcuries of IO-125 or IO-131.

Let's go off the record a minute.

[Discussion off the record.]

MR. TELFORD: Number two then is probably covered.

MR. HENKIN: One and two are both covered.

MS. PICCONE: I don't understand how that's

covered.

MR. TELFORD: Okay.

MS. PICCONE: This is one institution's quality assurance plan.

MS. ALAZRAKI: Correct.

MS. PICCONE: This is their response to JCAHO and their response to their function is to review every requisition. The hospital down the street can review ten --

MR. BRINER: This is what we are talking about right now, this one program. That's all we're asked to evaluate.

MR. HENKIN: All he's doing is he's just doing that one.

MS. PICCONE: Not JCAHO in general.

MR. TELFORD: No, we're taking this program as an example of what a program would look like if it were following JCAHO. Given that there is some variability among programs that would follow JCAHO --

MS. PICCONE: That's just my point. To follow JCAHO, you don't need to do this. Is that correct?

MS. ALAZRAKI: Well, you need to satisfy all of this.

MS. PICCONE: But you can satisfy it by --

MS. ALAZRAKI: -- by some other approach.

MS. PICCONE: By looking at ten requisitions a

month?

MR. HENKIN: I think the point of the JCAHO plan is that institutions identify those areas that represent potential problems for them and that is what they are supposed to monitor.

In other words, if you don't have a problem in a given area, JCAHO isn't asking you to monitor that. They are asking you to identify the areas of particular problem that you think you have got at your institution and monitor those areas.

For example, many institutions have problems distributing radiology and nuclear medicine reports -- just the physical distribution, so there is an area that they included in their quality assurance plan because they know they have got a potential problem with that and they are monitoring it.

If they have never had a therapeutic misadministration, would it be appropriate for them to be monitoring therapeutic misadministrations?

MR. TELFORD: Let me ask the question like this. This plan says that this is for both diagnostic and therapeutic procedures.

It has the same review function, that is to have a resident review every requisition.

Do you in fact do something different for therapy

procedures that is a little bit over and above what you would do for diagnostic procedures?

MS. ALAZRAKI: Well, the appropriateness is the same thing, whether it is therapy or diagnosis. You establish the appropriateness and the attending physician is more involved in every therapeutic administration than in the diagnostic administrations.

MR. HENKIN: The answer to that is it depends on the hospital, that in a teaching hospital considerably more time goes into a therapeutic procedure because you are trying to teach the resident how you evaluate the dose, how you evaluate the patient, et cetera, et cetera, and the opportunity for teaching that is considerably less than on the diagnostic procedures.

If you look at the data that just was received last week from the Tsaio Report, the RBRVS Time Effort Report, he concludes about four hours of physician time go into a therapeutic nuclear medicine procedure by survey. That is data he collected by survey. I think I am quoting that right. It's about four hours that -- across the board.

Now there is no way four hours goes into most diagnostic procedures so the answer is there is an order of magnitude difference in the therapeutic procedure according to Tsaio's measurement. The average physician time, if I remember correctly -- I'm sorry this is in the record -- but

somewhere between 20 and 40 minutes for a diagnostic procedures depending on some of the procedures but it is about four hours for a therapeutic procedures.

MR. TELFORD: So what you're really saying is --

MR. WIEDEMAN: What you got away with. You at least have to call the drugstore, don't you, to tell the pharmacist you're going to send Joe Blow down to --

MR. HENKIN: Sure. But in essence I've called the drugstore by prescribing for a bone scan that you are to use 20 millicuries of 99 MDP, unless it was a child. In the case of a child, use the following computation method to compute the dose. That's my prescription.

MR. TELFORD: Okay, and that's in the manual?

MR. HENKIN: That's in the manual, yes.

MR. TELFORD: Can you believe it, we're agreeing? Objective 3 is merely, first of all, recognizing the way business is done and incorporating those procedures --

MR. HENKIN: Can you read objective 3 again?

MR. TELFORD: And it's even in accordance with JCAHO. 35.35, this is for diagnostics that prior to medical use you have a referral, oral prescription if you like, and it's made for any diagnostic procedure. Now, the reason that I know that the vast majority of hospitals operate on oral directives and referrals is that our proposed regulations envision a written referral.

Now, when I conducted five workshops with 70 licensees, let me tell you how many times I heard, we don't do business that way. Our folks were referred by the phone. Only military hospitals.

MR. HENKIN: Well I agree with you, I think that's a correct statement. It happens not to be the way we work, but it happens to be a correct statement, that most outpatient referrals are by telephone, that is correct.

MR. TELFORD: Yes.

MR. BRINER: But somewhere in the record of that patient at that institution there better damn well be an order signed by a physician.

MS. ALAZRAKI: Oh, yes, there's an order on a chart somewhere.

MR. BRINER: On a chart.

MR. TELFORD: When is it signed?

MR. HENKIN: It may actually be in our case, for example, if you come from outside our system, if you're not part of the Loyola system as a patient, you come with a prescription blank from your doctor for the test, okay, which gets stapled in as part of your medical record.

In the internal system, there's an order sheet in the patient's chart on which the physician order the test. And then there's another sheet he has to sign his name on that's transmitted to nuclear medicine and made part of the

permanent record. So that most of your scheduling is done orally. At some point there's usually a piece of paper that shows up.

MR. TELFORD: After the fact.

MR. HENKIN: After the fact.

MR. TELFORD: Okay. In this plan we have a resident reviewing every requisition, whether it's diagnostic or therapeutic. We're paying a little more attention to therapy, quite a bit more to therapy, in our objectives here, objective 2, to endeavor to get the authorized user in the loop.

In 3, it's clear that sometimes the authorized user is not in the loop. But in this plan, how do we distinguish between what happens for diagnostics and what happens for therapy, because clearly we're looking for a little bit more.

MS. ALAZRAKI: Well, in fact, no therapy is ever done without the certified physician being involved. That just doesn't happen.

MR. TELFORD: Okay.

MS. ALAZRAKI: A resident physician would never institute a therapy in nuclear medicine without having discussed it or consulted or involved the nuclear physician.

MR. TELFORD: Is that an unwritten requirement?

MR. HENKIN: That's what called "stupid" again,

because any attending physician that permits resident physicians to initiate therapy procedures on his own is crazy and self-destructive.

MS. ALAZRAKI: Well that's practice of medicine.

MR. TELFORD: Therefore, there is a practice that you do, but it's not here, so am I to correctly conclude that it's not required by JCAHO?

MR. HENKIN: Yes, JCAHO permits us to delegate within the department certain things. And if you look, you can delegate certain things. I could delegate to a resident the therapeutic procedure if I so desired.

MR. TELFORD: Or does 2.2.3 cover it?

MR. HENKIN: Yes, that simply requires my supervision, it doesn't require me to be personally, physically involved -- rather, it requires me to be personally involved but not physically involved. And very commonly, that's the way the case is, that the resident sits down with the attending physician, they talk about the patient, look at the lab tests, decide what they're going to do with it, and the resident goes off and does it.

MR. TELFORD: Part 35 would allow the same thing, because it says the authorized user or any physician under the supervision of an authorized user.

MR. HENKIN: What you're proving to me is we don't need Part 35 because it's all here in JCAHO already.

MR. TELFORD: So you either have the first three or something very close.

MR. HENKIN: Okay.

MR. TELFORD: And I'm giving credit for some procedures which are not in the plan.

MR. HENKIN: Okay.

MR. TELFORD: Item 4 in the objectives -- ensure prior to medical use that either you have a diagnostic referral and a clinical procedures manual or the prescription, as understood by responsible individual. Of course you have the diagnostic referral for the diagnostic case, you have the prescription for the therapy case.

So in no. 4 we have seen a lot of cases and misadministrations where there was miscommunication or people just didn't understand, sort of a lack of supervision or a lack of something.

MS. ALAZRAKI: I don't know whether it was a lack of supervision. What we said was in those misadministrations was it was human error.

MR. HENKIN: That they didn't understand what was said to them.

MR. WIEDEMAN: Or they couldn't read the doctor's handwriting.

MR. HENKIN: Or they couldn't read or they didn't know. I think we agree that there is miscommunication at

times among all medical personnel and among all people. We're having some of it today. And that people say one thing and another person hears something else. The game that gets played is called telephone, and we whisper in somebody's ear and it goes around the table and you see what comes out at the other end of the table, if it's anything like what went in the first ear.

But that is a well-known phenomenon and that is like talking to your children. How many times do you say the same thing to your children before they finally get what you're saying?

MS. ALAZRAKI: But that is not a usual event. That is a rare deviation.

MR. HENKIN: That's right.

MR. TELFORD: Well, I didn't want to put words in your mouth. What I was really trying to say was, when we looked at the misadministrations we saw examples of miscommunication and lack of understanding, et cetera. Therefore, our intention was to have an objective that ought to be part of a performance-based program that that issue or those concerns be addressed. I didn't say that I see it in this example program.

MR. BRINER: That comes under NM.2 for the standard. The standard says there are policies and procedures to assure effective management, safety, proper

performance, equipment, effective communication, and quality control in increments as far as service.

MR. TELFORD: Effective communication, which one is that?

MR. HENKIN: NM.2 as a standard.

MR. TELFORD: Oh, NM.2 standard.

MR. BRINER: And you look under that and --

MR. TELFORD: How about 2.2.4?

MR. BRINER: That's it. There are policies and procedures for the preparation of patients for diagnostic or therapeutic procedures.

MR. HENKIN: I think even .7 would fit in there, the preparation, administration of diagnostic agents.

MR. TELFORD: How does that fit?

MR. HENKIN: Well, that's the really the key to some of your misadministration questions. How do you prepare and administer the stuff you give? It says you've got to have written procedures for that, they're requiring a written procedure for that.

MR. TELFORD: The other clinical procedures manual?

MR. HENKIN: Yes, it's part of the clinical procedures manual.

MS. ALAZRAKI: Right, procedures manual.

MR. HENKIN: How you reconstitute a kit, how you

identify a patient.

MR. TELFORD: So you would be instructing the technologists in making sure that they understand all those procedures and can carry them out appropriately?

MR. HENKIN: That's right.

MR. TELFORD: So if you took all of those, NM.2, 2.2.4, 2.2.7, then you would get --

MR. BRINER: The sum total of that you'd have the --

MR. TELFORD: Objective no. 4?

MR. BRINER: That's right.

MR. TELFORD: Okay.

MR. HENKIN: I think 5 is covered by the same thing, it's the same group, I think, covers 5.

MR. TELFORD: To make sure that the medical use in accordance with either the referral or the prescription. I should say the referral and the manual because they work together. Well now this doesn't speak to communication as much as it speaks to what's actually done. For therapy, then, maybe 2.2.3 speaks to --

MR. BRINER: Okay, NM.2.2, 10.1.3.

MR. TELFORD: 10.1.3, okay.

MR. BRINER: Identity of recipient, identity of radionuclide activity of radionuclide administered and date.

MR. TELFORD: Okay, who does that?

MR. HENKIN: Maintenance of records, that it allows me to decide who's going to maintain those records and how the records are going to kept.

MR. TELFORD: I don't mean to quibble, but objective 5 says "prior to medical use." No, I'm sorry, I'm wrong, it just says make sure that the medical use in accordance with. So, it's not prior to. I stand corrected.

MR. HENKIN: Let me point out that --

MR. TELFORD: So you would say the record --

MR. HENKIN: You don't do these records retrospectively, because you can't. I don't know of any physicians who will administer a dose that hasn't been calibrated, and that to calibrate the dose, the dose slip has the patient's identity on it, it has the date, it has the nuclide and it has the amount, in a minimum, some of them have more than that. But that's the minimum that we'd find on a dose sheet in any nuclear laboratory, and like I said, they may have more, they may have much more than that depending on how they're organized, but that's certainly the minimum.

MR. TELFORD: Does it have the chemical form here?

MR. HENKIN: Does it have the chemical form? The dose sheet normally would have the chemical form.

MS. ALAZRAKI: Yes, it would.

MR. TELFORD: This says --

MR. HENKIN: Identity of recipient right on the form.

MR. TELFORD: What?

MR. HENKIN: It says identity of recipient, identify of radionuclide, activity of radionuclide. Identity to me is chemical form. I mean it's not I-131, but sodium iodide.

MS. ALAZRAKI: I think that's fairly standard on those records.

MR. HENKIN: That would be pretty standard in most places.

MR. TELFORD: All right, so you would say that because JCAHO requires the records of what was administered, then you have objective 5.

MR. HENKIN: Now that's a contemporary record, that's made at the time you're doing it because there's no way to do it after the time you do it.

MR. CAMPER: Allow me to pick up what I think I hear, I think, going on and the point you're trying to making. Is it fair to say that the JCAH program is a performance-based program?

MR. HENKIN: Absolutely.

MR. CAMPER: Then to look at a particular example of any given institution it's going to show you how that institution has approached a standard.

MR. HENKIN: Correct.

MR. CAMPER: Okay. It seems then that the thing that would be very useful to the Commission would be an analysis where each of the eight objectives were looked at separately and the standard and the required characteristic were identified and linked to each objective.

MR. HENKIN: That's what we're doing here.

MR. CAMPER: What we're doing is we're stepping through one example.

MR. HENKIN: I'd like to do that --

MR. CAMPER: What I'm suggesting is, as we proceed from this point forward, if the ACNP and the SNM are willing to do it, if someone could go through and take each of the objectives --

MS. ALAZRAKI: We could do it right now.

MR. CAMPER: But I mean in something that we could use, in written form.

MR. TELFORD: If we could do that, it will be on the record.

MR. CAMPER: Are we really going to now go through every one of these and take every standard and identify it in a fashion that we'll have something to work with in the future?

MR. TELFORD: That is a good question. I mean, let's give it a go here and then resolve the completeness

theorem when we get done.

MR. BRINER: I think it might be more beneficial to us for you to tell us what is not met by that standard, what's missing, that we've been going over this thing 40 ways from Sunday here today.

MR. TELFORD: Let's do it this way. I can tell you what we're trying to do here --

MR. BRINER: Look at JCAHO, and you tell us what is missing and, I don't think you can do it --

MR. HENKIN: Dr. Alazraki's plan conforms to JCAHO. How many items in your group of eight did it miss on? And, are those covered in other parts of the JCAHO requirements?

MS. ALAZRAKI: Yes, because it's over a period of several years we will cover everything ultimately.

MR. TELFORD: Okay. Let's step through them.

MR. WIEDFMAN: The plan we're talking about is just this plan, and not that.

MS. ALAZRAKI: That's what it's based on.

MR. HENKIN: What I'm saying is they be viewed together --

MR. TELFORD: Okay. So that we are talking about both of these.

MR. HENKIN: -- because no matter what's in your quality assurance plan, you have to conform with everything

in the accreditation plan.

MS. ALAZRAKI: Right.

MR. HENKIN: And we're going to use the ACNP.

MR. TELFORD: Well, ACNP is much more extensive than JCAHO.

MR. WIEDEMAN: The point I'm trying to get across is what has been -- you know, unofficially, what are we considering as being submitted to the NRC for evaluation? Is it this plan? Is it a combination of both of these?

MR. HENKIN: The plan was a sample.

MS. ALAZRAKI: Also, you have to understand that what you have here is not the whole plan. The hospital has a whole QA plan which impacts nuclear medicine as well. It's just that on a monthly basis, we don't review the credentials of every physician; we don't review job descriptions for every --

MR. WIEDEMAN: Sure.

MS. ALAZRAKI: And there are a host of other things that you would find if you went through the whole hospital manual.

MR. BRINER: If you want a document that is functionality at the majority of hospitals, we'll say, in this country, JCAHO is it. ACNP is not, because how many hospitals --

MR. HENKIN: I can't even tell you off the top of

my head.

MR. BRINER: But JCAHO is widely used throughout the hospital industry.

MS. ALAZRAKI: The other thing is that JCAHO over a period of many years has evolved in understanding of and now is getting to the point of being able to deal with the tremendous variation in hospital nuclear medicine structures. In other words, there are teaching hospitals, there are community hospitals, there are military hospitals, VA hospitals. They all have different routines, different missions in a sense, other than the core of patient care, and that all impacts on what is reasonable to do in a quality assurance program.

MR. TELFORD: What drives the hospital to have its quality assurance program?

MS. ALAZRAKI: JCAHO.

MR. TELFORD: Okay. We're doing Item 1 under the objective, Objective No. 1. It looks like you're doing it.

Item 2 really says that you should have a prescription for --

MR. BRINER: Okay. Let's stop right there. How do you define a prescription, because there's a very precise definition under the law.

MR. TELFORD: Well, we defined it in the proposed rule as being a written directive.

MR. HENKIN: That's not the way the law defines it.

MR. BRINER: That's not the way the law defines it.

MR. HENKIN: The law defines a prescription as the direction of a remedy or remedies for disease.

MR. TELFORD: I'm guilty. I'm guilty. Hang me.

MR. BRINER: That is not meant to be facetious. It's typical of someone writing regulations in an area where they really aren't well informed about --

MS. ALAZRAKI: On a day-to-day practice.

MR. TELFORD: For the purposes of discussion, could we think of this as a written directive?

MR. BRINER: No.

MR. HENKIN: No, because it isn't always a written directive, and it need not be a written directive.

MR. TELFORD: Okay. How can we describe this?

MR. HENKIN: I think the way the law describes it is quite nice.

MR. TELFORD: Okay.

MR. HENKIN: A prescription is a direction of a remedy or remedies for disease. It's a physician direction to somebody to do something. Prescriptions can be for procedures, they can be for pharmaceuticals, they can be for any one of a number of things.

MR. TELFORD: Okay. We are talking about a therapy case here, so the physician in the case you've quoted analogously would be an authorized user, a nuclear physician?

MR. HENKIN: I presume so.

MR. TELFORD: Can we use that as our working discussion level definition?

MR. HENKIN: Okay. You've got an authorized user who wants to decide how to treat somebody.

MR. TELFORD: Okay. So, he or she either writes it down or verbally directs it.

MR. HENKIN: Okay.

MR. TELFORD: Is that acceptable?

MR. HENKIN: That's fine.

MR. BRINER: That's fine.

MR. TELFORD: Okay. Objective No. 2 would like the authorized user to direct that the therapy be performed or brachytherapy procedure -- excuse me -- teletherapy, brachytherapy or nuclear medicine therapy if it involves more than 30 microcuries.

MR. HENKIN: I think that JCAHO NM 3.2 deals with that.

MR. TELFORD: NM 3.2. I was going to point out what our Objective 2 tries to do, and then Objective 3, and then look at how the example plan that we have does anything

different, okay? So, Objective 2, then, gets the authorized user into being the director, into being the issuer of the prescription as you've defined it. Objective 3 deals with diagnostic referrals. So, it envisions that a referral comes in, the referral agrees with the clinical procedures manual, and the referral could be from a non-nuclear physician, and that happens before a diagnostic procedure is done or a prescription is issued.

MR. HENKIN: Okay. A clinical procedures manual will not normally contain the indications for a procedure; it will contain the procedure to be followed to carry out the procedure because the decision on whether or not a physician is appropriate is a physician decision that is not prescribed in a procedure manual. A procedure manual is what it says it is -- it's a how-to. It's a cook book.

MR. TELFORD: Yes, but didn't we do that back in Objective 1?

MR. HENKIN: Not in the procedure manual, though.

MR. TELFORD: I didn't mean to imply that. The referral comes in, and it says "bone scan."

MR. HENKIN: Fine. Somebody decides that's appropriate.

MR. TELFORD: And this referral is from a GP, a non-nuclear physician.

MS. ALAZRAKI: Correct.

MR. TELFORD: It comes to your department. Your technologist then, using Objective No. 3, would say, "Bone scan. It's in the clinical procedures manual. The patient is here; it's the correct patient." The technologist will handle the patient and do whatever the clinical procedures manual says, which, incidently, was approved by the authorized user, which is what you said, and then carry out the study based on their training and the procedure described in the manual. So, that's what's really envisioned by 2 and 3.

In Objective 2, we have envisioned that the authorized user, the nuclear physician, would be directly involved to issue the prescription as you've defined it; whereas in 3, it more or less recognizes the way that diagnostic procedures are practiced in a majority of the hospitals, with the nuclear physician not being directly involved to issue a prescription or give any directions for the diagnostic case; whereas in your plan --

MR. HENKIN: I'd like to see the evidence documenting that nuclear physicians are not involved in the therapy patients. I want to see somebody show me numbers and data that says that's the case, because, for one thing, they're in violation of JCAHO, and they're in violation of good medical practice.

That may happen from time to time. I'm not saying

it doesn't happen. I want to see that it happens in overwhelming numbers, justifiable to being fixed.

MR. TELFORD: Your first point that it's in violation of JCAHO?

MR. HENKIN: Yes. It says here in NM 2.2.3 --

MR. TELFORD: Wait a minute. Let me find it. Two-point-two-point-three.

MR. HENKIN: Page 121. The prescribing of nuclear medicine, radionuclide therapy, and the supervision of the cost of therapy by a qualified physician, and that's the written policy and --

MS. ALAZRAKI: That's therapy.

MR. TELFORD: That's therapy. We're talking diagnostics.

MR. HENKIN: I thought we were talking diagnostics.

MR. TELFORD: No, sir.

MS. ALAZRAKI: There was a mix-up there.

MR. TELFORD: In Objective 3, it's just for diagnostics.

MR. HENKIN: Okay. Try 2.2.4.

MR. TELFORD: Okay.

[Laughter.]

MR. TELFORD: Do you want to read it for me?

MR. HENKIN: The scheduling of and instruction and

procedures for the preparation of patients for diagnostic or therapeutic procedures.

MR. TELFORD: What does it mean? What does it say?

MR. HENKIN: It means that we are supposed to provide instruction to our people how to prepare patients and how to do diagnostic and therapeutic procedures.

MR. TELFORD: Okay. You could do that via a clinical procedures manual, couldn't you.

MR. HENKIN: You could that in any number of ways. This gives you the freedom to do it; it's just telling you you've got to do it.

MR. TELFORD: Okay. That's directly in accord with what I described.

MR. HENKIN: Right.

MR. TELFORD: The patient arrives from the GP to your department to have a bone scan. You've complied with 2.2.4 of scheduling and instructing the technologist via the clinical procedures manual. The nuclear physician does not necessarily have to be directly in the loop to issue a prescription using your definition in order for the diagnostic procedure to be carried out by the technologist. That's all we're saying, is that that's the practice -- excuse me -- the business is done --

MR. HENKIN: And that is the practice of medicine.

MR. TELFORD: Fine. No disagreement.

MR. HENKIN: That if a physician -- I mean, if I call Walgren's and order tetracycline for a patient and never give -- I'm not required to give Walgren's a written prescription. Except for a narcotic, Walgren's need not have a written prescription. They'll just take my verbal order, and when the patient comes in, they'll hand him his bottle of pills, and I don't have to follow it up with a written prescription.

You have to do it right when the patient is standing there.

MR. TELFORD: Then you would say likewise that objective No. 6, to make sure you have got the right patient is --

MR. HENKIN: It's also in there.

MR. TELFORD: -- 2.2.10.1.3.

MR. HENKIN: Yes.

MR. TELFORD: Is that correct?

MR. HENKIN: Sounds good.

MR. TELFORD: Okay, we're up to objective No. 7 then, ensure that any unintended deviation from either referral in the manual or the prescription is identified and evaluated. We saw that in the example program.

MR. HENKIN: That's NM.4 actually in the JCAHO. It says as part of the hospital's quality assurance program

the quality and appropriateness of diagnostic and/or therapeutic nuclear are monitored and evaluated in accordance with a whole bunch of other standards that they got in other places but basically that says that you have to identify things that go wrong in your system.

MR. TELFORD: Okay, and that's why this plan has that particular objective covered on page 2 of the monthly reports, as stated in the meeting minutes, to report any deviations and report those monthly and that's signed by the nuclear physician.

MR. HENKIN: Most hospitals have at the present time as part of their quality assurance program an incident reporting system for all misadministrations that occur in the hospital, diagnostic or standard therapeutic drugs, and those are all reviewed by the quality assurance group looking for systematic errors.

MR. BRINER: When the patient slips in the hospital.

MS. ALAZRAKI: Right, that's an incident.

MR. HENKIN: That gets reviewed to see whether the hospital is salting its front steps correctly in the winter and things of that sort. That all is part of the same system.

And No. 8 thank god we don't have to deal with, right?

MR. TELFORD: No. 8 applies to teletherapy and brachytherapy and is not your concern.

MR. HENKIN: That's right. When were these issued?

MR. BRINER: These are issued yearly. This is the 1990 version.

MR. TELFORD: How much of a change from '89?

MR. HENKIN: Not much.

MR. BRINER: Not a great deal.

MR. HENKIN: Not very much change from '89. The last big change was mid-'80s, okay, but their words changes a little bit from year to year but the basic outline stays pretty much the same.

They haven't changed much actually since '86, '85, something like that.

There was a big change around '85 and then trickled changes after that.

MR. TELFORD: You said that ACNP -- did you say something like more rigorous --

MR. HENKIN: I said wordier is what I said.

MR. TELFORD: Wordier?

MR. HENKIN: Yes. We take 15 or 20 pages to say what they say in a smaller number of pages but we are directing, first of all, we are directing it specifically at a number of patient-related issues in nuclear medicine as

well that are of interest to you and I think you should look at that to see what it says.

Anybody who goes through a JCAHO order would more than satisfy anything you -- I mean an ACNP order would more than satisfy anything in your draft because we are far more extensive than even JCAHO is, but we are a purely voluntary system.

I think this question of JCAHO being voluntary is a little bit confusing. You must volunteer for a JCAHO inspection if you want to be reimbursed for your hospital's bills. If you do not have JCAHO accreditation, no third party insurance company will pay you, so in that regard it's a voluntary system. However you volunteer to go out of business if you don't volunteer for the system, so that while technically it's voluntary, in fact it is anything but voluntary.

MR. WIEDEMAN: How about VA hospitals?

MR. HENKIN: They are now under JCAHO.

MS. ALAZRAKI: VA has multiple -- I mean more so, more than JCAHO. They have their own internal audit programs which touch -- which do quality assurance too. VA also is on JCAHO.

MR. TELFORD: We have been through this example program. We have touched on some of these requirements as they were applicable to our objectives.

It turns out that this program embellished by some of the hospitals' QA programs and embellished by the requirements of JCAHO, although not written here, have to be complied with because they are enforced by JCAHO.

Taking all of that, the eight objectives are met so the question is what would you change?

MR. HENKIN: I would leave it alone. JCAHO is doing a wonderful job. Why change anything?

MR. TELFORD: JCAHO is doing a good job. Let's take that as a given but if we were going to evaluate these objectives and say would we modify any of these, would we delete any of these, would we retain any of these?

MR. BRINER: Why? I keep going back to why would you want to do that?

MR. TELFORD: Let me see if I understand this correctly, Captain Briner.

You would say merely somehow endorse JCAH program. Let everybody comply with that.

MS. ALAZRAKI: That is what we would recommend.

MR. TELFORD: Why pick out only eight of the ones that you are already complying with? Let people be accredited by JCAH and grant them an exemption in nuclear medicine for any regulations we might have.

MR. HENKIN: I still have a problem with that. You are granting them an exemption for something you

shouldn't be regulating in the first place.

I think you should feel comfortable that you don't have a problem because the joint commission is already doing all of this and as a matter of fact takes a little more every year that it's doing.

Every year it adds another layer to their system, partly as the demands of the general public to assure that there is quality health care overall and that as a result of that there is already an accrediting body in place that is doing the job.

Therefore, there isn't a need for anybody to even lay down a regulation that says you have to conform with joint commission because you have conform with joint commission anyway.

Now if you want to discuss anything, and I am not sure I am competent to discuss it, you may want to discuss whether or not you have a role in free-standing operations that are not joint commission accredited.

MS. ALAZRAKI: Or licensees that are not joint commission accredited.

MR. CAMPER: And/or hospitals that are not JC accredited.

MR. HENKIN: I think you will not find any with nuclear medicine departments who are not JCAHO accredited.

Those that are not JCAHO accredited tend to be

long-term psychiatric facilities --

MS. ALAZRAKI: That's right.

MR. HENKIN: -- things of that type that don't provide these services on site.

I would be very surprised to see any NRC licensees in that group of 21 percent or so that don't comply to JCAHO.

They are usually a very special type of hospital, drug rehabilitation or alcoholism, something like that that fall outside the standard acute care hospital setting.

I strongly recommend that you not stir up this hornet's nest because what we are trying to do is reassure you that in fact everything you want to have done is already being done and at times a good deal more than what you want to have done is being done.

MR. BRINER: People don't understand how to approach this problem.

MR. TELFORD: I understand, so that if the Commission needs an enforceable regulation in this area that it's highly relying on what the JCAH program. Okay.

MR. CAMPER: Do you have any thoughts on the enforceability of JCAHO as it relates to NRC's enf cement?

MR. HENKIN: It's enforced differently, okay, than you would enforce. They do use a citation system, but their penalty system is different than yours.

The ultimate JCAHO penalty --

MR. BRINER: I think he means how can they enforce it --

MR. CAMPER: Let us operate under the assumption for a moment that we go through with the rule and that rule contains language similar to what you're saying but some clause that would say that this criteria can be met by a hospital demonstrating that it has a JCAHO approved quality assurance program, okay?

MR. HENKIN: Well, JCAHO accredited.

MR. CAMPER: Fine, accredited program. How do we, how does the NRC then enforce?

MR. HENKIN: Well I would do it if I were you, I'd do it by license condition.

MR. TELFORD: That's how you license, how you set them up to give them the business license to operate, but how do we --

MR. HENKIN: You've got to mail in a copy of your JCAHO letter. That is easy enough to do.

MR. TELFORD: Okay, so you would let JCAH inspect the hospital --

MR. HENKIN: Sure, of course. They're doing it anyway.

MR. TELFORD: You'd put a copy of the JCAHO inspection report.

MR. HENKIN: Well, they send a letter of accreditation to the hospital. That is what you've got to, if you want to do anything with it, which I still don't think you ought to do, but if you want to do anything with it, at the time you renew your license please enclose a copy of your most recent JCAHO accreditation certificate.

It's actually a thing you put on a wall and it tells you for how long this hospital is accredited, from what date to what date.

MR. TELFORD: Okay.

MR. HENKIN: And they don't accredit now for longer than three years.

MS. ALAZRAKI: Three years.

MR. HENKIN: Three years maximum accreditation, I think, before they come back, which is about the maximum inspection interval that you guys can run, if I remember correctly, right?

MR. TELFORD: So if the hospital had some mistake they made that we felt shouldn't have been made, then we might could cite them for that against the JCAHO --

MR. HENKIN: You can always cite them for doing something evil. I mean there is nothing that stops you.

If they have broken your regulations anyplace, you can go ahead and cite them. That doesn't prevent you from citing them.

MR. TELFORD: But we have to have a regulation that we can cite them against.

MR. HENKIN: You have got loads of them right You cite people for therapeutic misadministrations, right?

Haven't people been fined for therapeutic misadministrations?

MR. WIEDEMAN: No, just for not reporting the misadministration.

MR. HENKIN: I think that's reasonable but I don't think you need to fine them for that or cite them for that because they are going to be cited for that by JCAHO, which must make its reports public, by the way.

MR. TELFORD: Okay. This leads us to the diagnostic reporting requirements which is a backhanded way of defining misadministration.

I mean look at how in 10 CFR 35.2 currently it says if you make one of these six mistakes you have a misadministration. If your diagnostic administration were 50 percent different from what was directed, you have a misadministration.

Remember?

MR. HENKIN: I vaguely remember.

MR. TELFORD: So that is a way of defining what a misadministration is, is by the finding of what should be reported.

That is the way it's done.

MR. HENKIN: You have got that in the regs now, right?

MR. TELFORD: Okay, would you like to look at the proposed reporting requirements --

MR. HENKIN: Sure. Why not?

MR. TELFORD: -- for diagnostics because some changes have been proposed.

That is in this handout, here, page 1442. Everybody have this one?

MR. HENKIN: 35.33.

MR. TELFORD: 35.33. These are for what's here called diagnostic events or misadministrations -- oh, I'm sorry. I gave you the wrong page.

Let's go to 1447. That's the preamble that I referred you to previously.

The section is marked 35.33.

Revised to read as follows: Under the paragraph (a) these are events.

(1) is any diagnostic medical use not authorized in the license. That's just something you shouldn't be doing. Maybe you don't have the license to handle that kind of material or something -- it's really outside your license.

(2) would be any diagnostic medical use without a

prescription or referral.

Does that ever occur?

MR. HENKIN: I would hope not.

MS. ALAZRAKI: Not prescriptions as we've defined it here.

MR. TELFORD: This is really a diagnostic case so the diagnostic referral is probably the most operative.

MR. HENKIN: I can't conceive of a situation except, well -- it would still be referrals.

MR. WIEDEMAN: I can envision a referring physician would call you and say, Dr. Henkin, I have got a possible pulmonary embolism, I'm sending her down right away.

MR. HENKIN: I don't think that's covered in this.

MR. BRINER: Here again, your terminology is confusing -- diagnostic misadministration and somewhere I see creeping into it the wrong treatment is given.

MR. TELFORD: We are on (a)(2).

MR. HENKIN: A diagnostic medical use without a prescription or a diagnostic referral. Again, you are treading into the practice of medicine because diagnostic referral encompasses what? What is a diagnostic referral?

MS. ALAZRAKI: Let me give you an example where it is really the practice of medicine but it might not fit in what you have said here. That is, say we do -- let's see,

a good one -- let's say we do a MIBG scan and we find an abnormality which might be associated with a particular kind of tumor and it is very hard to localize that abnormality without injecting a renal agent to see where the kidneys are and if this is really in the adrenals or where it is, so we would go ahead as part of the examination. All we have been asked to do is an MIBG scan to identify a tumor. We would go ahead and inject the renal agent to localize. We do that all the time.

We consider it part, a legitimate part of the MIBG exam but we don't do it in every patient. We only do it when we feel it is indicated but it would not be a separate so-called referral or prescription for that renal injection.

MR. TELFORD: It's directly from the authorized user.

MS. ALAZRAKI: That's correct. It's all medical judgment.

MR. HENKIN: Why is it -- I don't know what this issue of a diagnostic referral means in here.

MR. TELFORD: that is the patient that comes from the outpatient.

MR. WIEDEMAN: I know of a case where they were cited for this particular part -- any diagnostic medical use without a prescription or a diagnostic referral.

This was a VA hospital. A technologist's sister's

been diagnosed with some kind of a bone disease and so she had her sister come in in the middle of the night and the technologist injected her sister and did the bone scan and then she left the scans on the doctor's desk and normally in a VA hospital you don't see too many female patients -- at least this one -- and that was when the doctor said now wait a minute, who is this woman. She said, well, that was my sister. He says, well, who ordered this scan and found out a physician did not order that particular scan.

MR. HENKIN: And why is NRC concerned about that?

MR. WIEDEMAN: Because it was a use --

MR. HENKIN: Why is NRC concerned about that clinical scenario?

MR. WIEDEMAN: Because it met the definition of a misadministration.

MR. HENKIN: Okay, should you be concerned about that clinical scenario? Was the patient exposed to an amount of radiation that was judged to be harmful?

MR. CAMPER: No, but by definition it was a misadministration therefore we are concerned under the current --

MR. HENKIN: We could open up this issue of diagnostic misadministrations, which I don't think we want to do. I think the wording here is very confusing.

MR. BRINER: Let's go down to (b).

MR. TELFORD: We will get to it. Let me alleviate the confusion, Dr. Henkin. The prescription is what comes from the authorized user.

MR. HENKIN: If you just ended it at prescription, what would the problem be?

MR. TELFORD: The referral comes from the non-nuclear --

MR. HENKIN: That is part of the practice of medicine that you are not in. Let me say that if in fact his situation would be covered because there was no prescription -- if you ended it right here after the word "prescription" what's the difference, because it's that diagnostic referral that muddies this sentence up considerably.

MS. ALAZRAKI: That's true.

MR. BRINER: I don't want to discuss this any further.

MR. TELFORD: I don't quite understand how it muddies it up.

MR. BRINER: Diagnostic misadministration was not something we really wanted to discuss today.

MR. HENKIN: I think I agree with Bill and by the way I would point out that your definitions of terms of diagnostic referral means a written request dated and signed by a physician before a diagnostic medical use.

You just told us that's not what it means at all in the other section. You just said oral, verbal, everything was fine.

Here you defined it differently.

MS. SURREL: The definition says a written request.

MR. TELFORD: I just told you that. I told you that ten minutes ago, that the referral was a written directive signed by a non-nuclear physician. Prescription is --

MR. HENKIN: That's what your people have told you too, that that is all oral.

MR. TELFORD: Wait, wait, wait. We are operating under the guise that your definition of prescription was okay for the purpose of discussion, that we would recognize your definition of prescription, that it's a written or oral directive given by a nuclear physician. That's the applicable case.

I told you that the reason that I knew about all of the diagnostic patients being handled under oral referrals was all of the folks in the pilot program, so we are quite aware that even though we stated what we thought was the ideal case is to have written directives, be it for diagnostic cases or therapy cases, that is not the real world.

That is not the way things are so I said granted that we'll look at this example program --

MR. HENKIN: I am more confused now than when we started.

MR. BRINER: While we're on this thing I wanted to bring to your attention where you again make a terrible mistake in your use of terminology.

We're talking about diagnostic medical uses, right, under (b)(1). Any diagnostic medical use other than the one stated in the prescription or the diagnostic referral in the clinical procedures manual, incorrect medical use would include treatment.

MR. TELFORD: Okay.

MR. BRINER: And I use the term "treatment" with disdain because there again you imply there is a bad effect that will occur to this patient if something like this happens and nothing could be further from the truth.

That's not treatment.

MR. TELFORD: What is it?

MR. BRINER: Treatment infers a therapeutic procedure of some sort.

MR. TELFORD: The sentence says incorrect medical use. Now "medical use" --

MR. HENKIN: That is malpractice by definition. You are not capable of judging malpractice. That is the

definition of malpractice.

MS. ALAZRAKI: Incorrect medical use.

MR. CAMPER: Were these points the trouble that you're expressing with the definition addressed in your comments?

MR. BRINER: I can't even remember. I don't even remember anymore.

MR. HENKIN: We certainly did address the issues of written prescriptions and written diagnostic referrals but these things are 'way out of line in terms of how they fit in the practice of medicine.

MR. TELFORD: Would you believe this is currently covered under 35.2?

MR. HENKIN: These definitions are in 35.2?

MR. TELFORD: Well, the same things, diagnostic misadministration is in 35.2.

MR. HENKIN: But we aren't real happy with some of the -- we've never been happy with the diagnostic misadministration. We've never been able to get anywhere with it, that's all. We were not happy with that from Day 1.

MR. BRINER: That's right.

MR. TELFORD: Would you bear with me here just for a minute on this sentence.

MR. BRINER: What sentence?

MR. TELFORD: Your sentence, incorrect medical use. Medical use is a defined term.

MR. BRINER: Okay.

MR. TELFORD: So that means the administration of byproduct material or the radiation therefrom, so we have incorrect, some sort of incorrect medical use.

MR. BRINER: But in a sentence where in exceptions you are dealing with diagnostic misadministrations, treatment should not ever appear. Bottom line. Period. End of comment.

MR. TELFORD: Okay, let's take out the word "treatment" then for our discussion.

MR. BRINER: Why not take out diagnostic misadministrations? That's what we advised you to do years ago.

MR. HENKIN: That solves the problem

MR. TELFORD: Could we address these one at a time? I am perfectly willing to entertain that.

We'll go back to the sentence: Incorrect medical use.

MR. BRINER: We are not getting anywhere. We've reached an impasse.

MR. TELFORD: Hang for on a minute. Hang on for a minute.

I don't know, if the sentence said incorrect

medical use would include -- skip treatment --

MR. BRINER: No. I am not buying off on any part of this section.

MR. TELFORD: I didn't ask you to buy off on it, sir. I just asked you to consider the sentence in some way to repair it.

You bought up an objection to the sentence. I was trying to look for a solution.

MR. HENKIN: We don't want to repair it. We want it all to go away because it is inappropriate.

It's an inappropriate -- I mean we have agreed to play along on this therapeutic misadministration question and to discuss this issue, all these issues revolving around therapeutic misadministrations. Diagnostic misadministrations are of no consequence to anyone, therefore it isn't worth the time to discuss them.

MR. TELFORD: Okay. Let me rephrase -- let me put the other question in.

How would you declare a threshold or structure a reporting requirement for either a diagnostic case or an I-131 case --

MR. HENKIN: Why don't you talk to the state of Illinois. They have some very interesting draft regulations for what it is that diagnostically would have to be reported and I can't remember all of them offhand, but I think one of

them is that in a diagnostic situation you'd have to be in error by 500 percent before you had to report anything to anybody.

MR. TELFORD: This is a diagnostic case?

MR. HENKIN: Yes.

MR. TELFORD: Typically like technetium.

MR. HENKIN: Typically like anything -- they regulate accelerator products as well, so you have to remember that that includes their accelerator products as well.

I don't remember the details of all of that but I am sure you can get it from Kathy Allen at IDNS, a copy of what IDNS has talked about.

MR. TELFORD: Okay.

MR. HENKIN: It is something the medical community in Illinois has not found terribly objectionable but apparently the agreement states folks have had a little problem with -- but it is a much more reasonable situation that says you have to make a flagrant error before you have to report it to anybody.

MR. TELFORD: So something like the --

MS. ALAZRAKI: Something like a death from a transfusion.

MR. TELFORD: -- the medical use as administered is 500 percent different from --

MR. HENKIN: I don't remember all the details and I don't really want to quote those details because I don't remember them but I'm sure you can get it from the Illinois Department of Nuclear Safety, a copy of what they have been kicking around as a draft document.

MR. TELFORD: Do you feel there should be some threshold in terms of a dose to the patient like X rem effective dose equivalent, in addition to the 500 percent or is that sufficient?

MS. ALAZRAKI: I know that the percent is --

MR. BRINER: 500 percent of what?

MS. ALAZRAKI: -- of the prescribed dose, the indicated dose.

MR. HENKIN: I mean all they are trying to get at, and I think the thing we would not object to, is the report of a flagrant error. The stuff we have got now is nonsense and has no meaning, okay, to anybody.

MR. TELFORD: Currently in 35.2 it says 50 percent different for diagnostics and if you get the wrong patient, et cetera.

MR. HENKIN: I don't want to discuss how to rewrite the regulation.

MR. TELFORD: Could you define "flagrant" for me?

MR. HENKIN: I can define flagrant as a gross error. That's all I'll say.

MR. BRINER: I would have great difficulty in providing you any advice on diagnostic misadministration.

MR. TELFORD: Okay, let's go to therapy then.

MR. BRINER: We have just been talking about therapy all day long.

MR. TELFORD: How about I-131? Would you like to see criteria there for if the dose, the whole body dose or thyroid dose exceeds certain specifications then it should be reported?

MR. HENKIN: I think you guys are in the wrong business, collecting this material, because first of all it leads you to do inappropriate things like this quality assurance rule, the draft quality assurance rule, because you draw incorrect conclusions from the data you have collected because you don't know how to analyze that data.

That is problem one.

Problem two is that I don't, I believe that these are issues that are addressed within the medical community and belong to the medical community to address.

They are our responsibility to address, not to defend, to address the issue of how we train our people appropriately and I mean the specialty boards and the nuclear medicine technology certifying board certify people to practice nuclear medicine in the various levels they practice at.

It is the responsibility of those folks to see that people are appropriately trained. It is the responsibility of physicians to see that their practices are run properly, okay, and I come back to the same set of issues again.

I don't know why NRC thinks it has a role that no other Federal agency has in the practice of medicine -- because FDA regulates pharmaceuticals does not give it a role of the right to get into physician offices.

MR. TELFORD: If we would accept the JCAHO accreditation, then that would be all right?

MR. HENKIN: No! I don't say for a minute that's all right. You said that!

I think you have no business in this at all!

Your question to us earlier this afternoon is can we discuss the JCAHO program and what it does.

The answer to that is yes. However, the stipulation we placed on that is that was outside the discussion of a quality assurance rule.

MR. CAMPER: So that translates into, you are saying that requiring JCAHO certification -- accreditation, excuse me -- accreditation would not be sufficient to address our concern, would not be a satisfactory means to address our concern --

MR. HENKIN: It is an inappropriate thing for you

to be involved in this at all. Therefore we certainly can't endorse JCAHO or anything else as a standard for something that is inappropriate in the first place.

MR. TELFORD: We were talking about reporting requirements. Now what you are saying is don't do anything.

If we do nothing, then the current requirements remain, that are currently in 35.2, which is a diagnostic administration and it's 50 percent different from what's prescribed and in radiopharmaceutical therapy a 10 percent different.

MR. HENKIN: What you have got written out there makes no sense right now. If you are going to use those definitions to define a misadministration reporting system, they are no good. They have got to be reworked.

They don't make any sense in terms of the practice of medicine.

MS. ALAZRAKI: Our basic premise is that what we started with earlier this morning is that your reason for wanting to get into this is the misadministration problem.

We say the misadministration problem is really not a non-problem because the occurrence of those misadministrations as you have defined them approaches what we consider human error, that no additional procedural modification is going to be able to impact that, that also in addition to the fact that it is not of any impact to try

to do anything about misadministration because it's a non-problem that you are getting involved in practice of medicine, which of course we are not prepared to accept as a regulatory agency.

So we are stymied here I think.

MR. TELFORD: So is Dr. Henkin's point is that we don't have the legal authority to do this and Dr. Alazraki's point is that we shouldn't be trying to reduce or prevent misadministrations beyond the current --

MS. ALAZRAKI: Diagnostic, right.

MR. BRINER: I think we're at the point where nothing can be done to further reduce it. That is the problem.

MR. CAMPER: Let me ask you this. Given that there is currently a misadministration defined in Part 35, and drawing your attention back to the April the 7th, 1988 meeting, at which it was expressed that the definition of the term misadministration is unclear and the related reporting requirements are confusing, is there anything that we can do at this point in time constructively as we look at and talk about the definitions that are now set fortn in the proposed rule?

We seem to have come to an impasse as it relates to any additional constructive dialogue about those definitions as now defined.

MR. BRINER: We have about diagnostic misadministration. We're at a point where --

MR. HENKIN: I indicated to Mr. Telford on the telephone when we talked about this meeting that we were not prepared to discuss the issue of diagnostic misadministration because there is just in our minds no justification for any of it and -- do what you want with it sort of situation that we are going to oppose it.

We are going to continue to oppose it. We believe it is unjustified. We believe it has resulted in no benefit to anyone.

MR. TELFORD: Larry's question is can we have a constructive dialogue about that? If we do nothing than -- currently, 10 CFR has 50-percent difference.

MR. HENKIN: The only constructive dialogue --

MR. TELFORD: Should it be left there?

MR. HENKIN: -- is to consider removing the reporting requirements completely. If that's what you want to talk about, we'll be glad to talk about it. Revising diagnostic misadministration reporting in any other way is not something we're going to talk about.

MR. TELFORD: Okay. What would be my basis for removing the reporting requirement?

MR. HENKIN: That you have demonstrated they're not a danger in the public health and safety. Your own data

has demonstrated that. You've got the data that shows that the diagnostic misadministrations in this country do not represent a danger to public health and safety.

MR. TELFORD: Oh, okay. Just the diagnostic ones, not the ones that result in the therapy range, like the I-131 misadministrations.

MR. HENKIN: I could --

MR. TELFORD: Like the Arizona case, for instance. The lady lost her thyroid.

MR. HENKIN: Are we talking about diagnostics or therapeutics? We keep getting mixed up.

MR. BRINER: Undoubtedly, here on Rockville Pike today, someone nearly got killed by an automobile. Has that been sufficient reason for Montgomery County to ban or to indicate that only so many cars per unit of time can go by here on Rockville Pike? How far do you think they'd get with that? About as far as you're going to get with a diagnostic misadministration conversation today.

MR. TELFORD: How about therapy misadministrations then, not diagnostic?

MR. BRINER: What are we talking about? We've been talking about therapy most of the day. What are we rehashing it for?

MR. CAMPER: We're talking strictly about therapy here.

MR. HENKIN: I thought that's where we were, Iodine-131 misadministrations.

MR. CAMPER: We're talking about diagnostic nuclear medicine and segregating that into brachytherapy and teletherapy.

MR. BRINER: Yes. But most of the discussion today centered around the therapeutic use of radionuclides in other sealed sources.

It's getting close to the time where it's going to take us 2 hours to get back into town, and I'm not about to have that happen.

MR. TELFORD: Is there a time that you would like to --

MR. BRINER: Half an hour.

MR. TELFORD: -- adjourn the meeting?

MR. BRINER: Yes. A half an hour is okay.

MR. HENKIN: I don't think we're getting anywhere on this topic.

MR. BRINER: Absolutely not.

MR. HENKIN: The only statement we can make on diagnostic misadministrations is that they won't present more hazard to the public health and safety. Since that is the case, there should be no reporting requirement for them. Anything other than that doesn't fit reality.

MR. BRINER: That is something we've said

repetitively for years. So, it's not coming as any surprise.

MR. CAMPER: Okay. Can I make one different point, then?

We've spent a fair amount of time talking about the utilization of JCAHO accreditation as an alternative to our proposed QA Rule 35.35 for diagnostic nuclear medicine.

MR. HENKIN: Well, I don't think that's exactly what we discussed. What we discussed is whether JCAHO accreditation accomplishes the same goals that your proposed rule would accomplish.

MR. CAMPER: Let me phrase it differently.

If we were to consider using JCH accreditation standards to satisfy the concerns that we have expressed in the eight objectives in 35.35, as proposed, would it be -- would ACNP or SNM consider preparing an analysis or a brief description categorizing each of these eight objectives and then identifying the standard and the part of the accreditation manual that applies?

MR. HENKIN: Want my gut reaction?

My gut reaction is no, because we're opposed to the entire thing in concept. That's my gut reaction. Okay? And that is that we've spent the entire afternoon demonstrating that JCAHO does what you wanted done. Therefore, there is no need for you to do anything more.

But to consider going ahead now means that you're going to put into place something that's already there, and it makes no sense at all. And I, for one, am not adverse to going back to the Commissioners and asking them why we're going to do this.

Why is this going to happen? Because we had a very productive discussion, Dr. Holmes, Dr. Marcus, and I, in February, with the Commissioners. I think we got the furthest along with them we've ever gotten. They were receptive. They were willing to discuss. And I think they understood the issues better than I ever hoped for them to understand the issues. But now I think it may be appropriate to go back and say, in place of that, maybe it hasn't trickled down from their level, that they understood that -- where we were and the allocation of resources and things of that sort.

I don't see that that's occurring here, that you're talking about another system layered on top of something else, even if you refer to JCAHO, and all of your goals are currently being met.

MR. TELFORD: Well, we're looking for an enforceable regulation, and we need to --

MR. HENKIN: Do you want to fine somebody?

MR. TELFORD: Pardon me?

MR. HENKIN: Do you want to fine somebody? Is

that the goal of this?

MR. TELFORD: Well, it may be true that the JCAHO requirements apply to the vast majority of hospitals and facilities, but a few kind of slip through.

MR. HENKIN: Could you prepare an analysis on how many NRC licensees are not JCAHO accredited?

MS. ALAZRAKI: That would be worthwhile. Fine out how many there are, and then we could respond to that.

MR. HENKIN: How many NRC licensees, as institutions, are not JCAHO accredited?

MR. TELFORD: Well, we could consider doing that. There would be a few that would not be JCAHO accredited, and we would need some sort of enforceable regulation to bring those folks up to the minimum -- some minimum sufficient standards.

MR. BRINER: Well, let's see who they are and what you're talking about.

MR. TELFORD: And then we would have to achieve some sort of equality between those folks and the ones that are JCAHO accredited. But to date -- the ACNP and SNM sent in a petition, or a resolution -- excuse me -- to have -- to propose that the quality assurance rulemaking be withdrawn.

MR. HENKIN: Correct.

MR. BRINER: It still stands.

MR. TELFORD: The response you received in a memo

dated, I think, February of '89, which said that that resolution would be considered among all the other public comments during the period in which the other public comments or all the public comments would be evaluated.

The Commission has given us no change in direction.

MR. HENKIN: Then I think we should go back to the Commission.

MR. TELFORD: The staff is operating under what's called a staff requirements memorandum, dated December 21st of '89, in which we are to conduct -- have the public-comment period, conduct a pilot program, and prepare a final rule to be delivered to the Commission in March of '91. So, that's the directive that we're under.

MR. HENKIN: You understand that we are operating under directives, as well, and our directives are to see that this program is withdrawn, no matter what it takes.

MR. TELFORD: You're entitled to that opinion.

MR. HENKIN: It is not an opinion. We are responsible to our organizations. We have been given a directive, a direct directive to see that this program is withdrawn, not to see that it's modified, not to see anything else, to see that it is withdrawn.

MR. TELFORD: In spite of all that, I think the discussion today has been helpful to me and certainly

educational about the JCAH requirements and the example program and how these meet or, at least, almost meet or, in fact, meet the end objectives that we have in the proposed regulation. I thought today's discussion was very helpful.

We seem to have come to an impasse over reporting requirements. You have given us the suggestion that we talk to the State of Illinois; we will do that. We know Kathy, and she was at the workshop that we had. We will make that inquiry to find out what they are proposing for diagnostic reporting requirements. We would like to seek your advice and advice of others as to how those ought to be changed, because if we do nothing, then the current requirements stand.

MR. BRINER: For the moment.

MR. TELFORD: The medical community made the suggestion at the Commission meeting in '88 to change the definition of "misadministration." So, we're trying.

MR. HENKIN: If I remember, they also made the suggestion that the whole thing be dropped, too.

MR. TELFORD: Well, the directive that we got was to look into rewriting the definition of "misadministration."

MS. ALAZRAKI: You can rewrite it to exclude diagnostic.

MR. TELFORD: That would make you happy. Right?

Okay.

MS. ALAZRAKI: That would make sense.

The other which perhaps we have discussed that seems reasonable to me is for NRC to look into how many and if there are licensees who are not under some QA program, nothing to do with NRC.

MR. TELFORD: Licensees not covered under JCAH?

MS. ALAZRAKI: If there are any.

MR. HENKIN: Or other practice audit programs. There are two other practice audit programs out there.

MR. TELFORD: Which are?

MR. HENKIN: ACNP and American College of Radiology.

MR. TELFORD: Okay.

MS. ALAZRAKI: Consider redefining "misadministration" to be just therapeutic; eliminate diagnostic.

MR. TELFORD: Okay.

Would anybody like to have any closing remarks?

MR. HENKIN: I think we've made them all day long.

MS. ALAZRAKI: We've made closing remarks.

MR. TELFORD: Does anybody here want to make any closing remarks?

[No response.]

MR. TELFORD: Okay.

Well, thank you all for coming. I truly found it helpful.

Let the meeting stand adjourned.

[Whereupon, at 3:57 p.m., the meeting was concluded.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

in the matter of:

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were held as herein appears, and that this is the original transcript thereof for the file of the United States Nuclear Regulatory Commission taken by me and thereafter reduced to typewriting by me or under the direction of the court reporting company, and that the transcript is a true and accurate record of the foregoing proceedings.

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