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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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MEETING WITH

JOINT COMMISSION ON ACCREDITATION

OF HEALTHCARE ORGANIZATIONS

ON THE

PROPOSED QA RULE AND REPORTING REQUIREMENTS

Nuclear Regulatory Commission

Oakbrook Terrace, Illinois

Monday, December 17, 1990

The above-entitled proceedings commenced at 9:10 o'clock a.m., pursuant to notice. John Telford, Discussion Chairman, presiding.

PARTICIPANTS:

John L. Telford,	Chief, NRC
Jean Carroll, Ph.D.	Director, Standards Development, JCAHO
Robert H. Wagner, M.D.	
Jeff Green	A.H.A. News
William F. Jessee, M.D.	JCAHO
Carol Jewett	JCAHO
Pam Schumacher	JCAHO
Anthony Tse	NRC
Larry Camper	NRC
Ed Kline	NRC
Robert Henkin, M.D.	American College of Nuclear Physicians / Society of Nuclear Medicine
James E. McManus, M.D.	JCAHO
John E. Milton	JCAHO
P. Van Schoonhoven, M.D.	JCAHO
Ode Keil	JCAHO
Darrell Wiedeman	NRC - Region 3

PROCEEDINGS

[9:10 a.m.]

DR. JESSEE: I would like to welcome you all. You will have an opportunity over the course of the day to compare notes and see how what you're doing and what we're doing can fit together, and try to maximize the opportunity for constructive interaction.

Let me just introduce the folks around the table.

MR. TELFORD: May I suggest that we let everyone introduce themselves, and say what their names are and what their positions are.

DR. JESSEE: That would be fine.

MR. TELFORD: Or, if they represent from a hospital or anything like that, if they have that capacity

DR. JESSEE: Right. Let's -- I'll start with myself and then we'll work around table.

INTRODUCTION OF PANEL

DR. JESSEE: I'm Bill Jesse. I'm a physician and Vice President for Accreditation Surveys at the Joint Commission.

MR. van SCHOONHOVEN: I'm Peter Van Schoonhoven, a physician, and Associate Director with the Department of Standards.

MS. CARROLL: I'm Jean Carroll, Director of Standards Development, currently one of the Acting Directors

with the Department of Standards.

My field, actually, is organization theory.

MR. MILTON: I'm John Milton, Senior Associate Director in the Hospital Accreditation Services here.

DR. McMANUS: I'm Jim McManus, a physician, and Associate Director of Hospital Accreditation Services.

MR. KLINE: My name is Ed Kline. I'm with the Office of Nuclear Regulatory Research in Washington.

MR. CAMPER: I'm Larry Camper. I'm a Section Leader for the Medical and Academic Section, NRC Headquarters.

MR. TELFORD: My name is John Telford. I'm the Section Chief in charge of this rule-making effort.

MR. TSE: My name is Anthony Tse. I'm from Research, Washington NRC. I am the Project Manager of this project.

MS. JEWETT: I'm Carol Jewett, Associate Director of Government Relations.

DR. WAGNER: I'm Robert Wagner. I'm a nuclear physician at Loyola University.

DR. HENKIN: I'm Robert Henkin. I'm a physician. I'm representing the American College of Nuclear Physicians and the Society of Nuclear Medicine.

MR. GREEN: I'm Jeff Green. I'm a staff writer with American Hospital Association's newspaper.

MS. SCHUMACHER: I'm Pam Schumacher. I'm Associate Director with the Department of Public Relations

DR. JESSEE: Just in time, Ode.

MR. TELFORD: Your name, please.

DR. JESSEE: Your name, rank and serial number.

MR. KEIL: I'm Ode Keil. I'm Director of Plant and Technology Manager.

DR. JESSEE: Also with the Joint Commission.

MR. KEIL: Right.

DR. JESSEE: We thought we'd go ahead and let you folks kind of work through the agenda. I'm only going to be able to stay until about 11 o'clock. But the rest of the staff will be able and ready to work with you, and try to work on through the issues that you've got on your draft chere.

MR. TELFORD: I'd like to suggest that we have a look at the agenda that we proposed and see if all the items are there that you would like to see there. We can add or subtract if you like.

Basically, I thought the purpose of the meeting would be to discuss what we're trying to do.

We can discuss the applicable and comparable standards so that we can come to understand both organizations and both purposes, and both modes of operation. Sort of as a preliminary.

Then we could get down to the details of our proposed rule versus your standards, and kind of have a comparison. And then wind up with sort of a feasibility and kind of analysis or examination of the two functions.

Is the agenda acceptable to everyone.

DR. JESSEE: The agenda seems fine. We may want to collapse down some of the front end.

MR. TELFORD: Okay.

DR. JESSEE: It may not take quite as long to go through some of the background. But otherwise, it looks good.

MR. TELFORD: All right. Okay, the 9:15 item, we wanted to give you a quick overview of the NRC. Some of you may have had experience with the NRC as the licensee. Some not, especially if you've been working in the agreement state.

So, Mr. Camper is going to give you a quick overview so that he can tell you sort of a thumb nail sketch of the Agency. In particular, it covers some differences that we think exist between the way we do business and the way other folks do business.

MR. CAMPER: Hopefully, it will be a collapsed overview.

The Nuclear Regulatory Commission exists primarily at this point in time to protect public health and safety.

We find ourselves involved in the medical community as a result of the Atomic Energy Act of 1954, as amended, and as a result of certain memoranda of understanding between NRC and FDA, particularly as it relates to the regulation and use of radiopharmaceuticals.

To carry out our mission, we do this through an operation process which includes Federal Regulations and the issuing of licenses.

The Regulations are primarily identified in 10 CFR. The one that's most apropos to medicine, of course, is 10 CFR part 35, and 10 CFR part 20, which deals with radiation protection standards.

In the process of issuing licenses we will review medical programs to determine if their radiation safety program meets our minimum standard to protect public health and safety.

In this process we specifically look at their licenses and then issue licenses which will contain conditions that include commitments with the licensee as made to the Agency, as well as so-called tie down condition which reminds and ties the licensees to the requirements of Part 20, Part 19 and Part 35 in particular.

To implement our regulatory process, we then go about conducting inspections. These inspections are both routine unannounced and routine announced inspections. We

also will respond to various allegations, incidents or emergencies which take place by send inspectors on site and addressing these issues.

Licensees are made aware of inspection results, whether they are positive or negative. In many cases there are no violations of a Regulation. In some cases there are notices of violations.

In addition to inspecting and making the licensees aware of the findings, we also have an enforcement policy that we deal with. These can be dealt with through confirmations of actions that the licensees have identified to us they will take as a result of our inspections, so-called confirmatory action letters.

Sometimes there is a need to modify the license. Sometimes there is a need to impose orders to modify the license. Occasionally -- fortunately not too often -- in the medical community there is the imposition of civil penalties or the suspension of the license.

We spend a great deal of time trying to monitor problem licensees if there are any through increased inspection frequencies and through licensees submitting to the Agency status reports of improvements in their program and what have you.

With regards to the quality assurance rule in particular, which we are here to discuss today, this is a

joint effort that is taking place between my department which is responsible for regulatory policy and technical guidance for the medical, biomedical and academic uses of radioactive materials that NRC regulates, and the Office Inspection which is the group within the Agency that's primarily responsible for writing and developing rules, regulations if you will.

And the QA rule is something that's been going on now in various stages for about four years, and it primarily was designed to ensure that radioactive drugs, radiopharmaceuticals, are administered as prescribed by the requesting physician, or the authorized user, to prevent misadministration of those radioactive drugs, and to detect and correct causes of mistakes that might lead to misadministration.

In developing this rule, we have taken considerable steps beyond the normal rule-making process which I will let Mr. Telford explain to you in more detail.

Any questions at all, basically about the Agency's role?

There are approximately -- I didn't mention -- there are approximately six thousand licensees, medical licensees. About two thousand of those are NRC. Four thousand of those are in agreement status.

DR. JESSEE: Of those six thousand -- that was one

of my questions. What's the distribution? How many of those are hospitals and how many of them are not hospitals? That includes --

MR. CAMPER: Well, of the six thousand, I don't have a percentage at the tip of my tongue. But my guess would be that, of the total six thousand medical licensees, 75 or 80 percent are hospitals.

DR. JESSEE: And the balance?

MR. CAMPER: The remainder are private practice scenarios. Imaging -- private practice imaging centers and what have you.

MR. KEIL: How often do you inspect them?

MR. CAMPER: Three years, generally speaking. Every three years.

MR. TELFORD: For the small hospitals. The larger hospitals, what we call the broad scope licensees, are approximately once a year.

MR. CAMPER: Right. That frequency, by the way, has been becoming more narrow.

MR. KEIL: Who does that inspection for you? Do you do that with contracts with State agencies or do you have a staff of the NRC that does those inspections?

MR. CAMPER: The NRC has five regional offices. All licensing and inspection programs run out of those regional offices. In each of those regional offices there

is an area or department, or section if you will, that has responsibility for the inspection process.

The inspectors are full time NRC employees who have various backgrounds in science and technology, who have gone through training programs put on by the Agency, who have worked with other NRC inspectors, and what have you.

MR. KEIL: How do you determine which of the license holders get a -- well, an unannounced survey, and those who get an announced survey?

MR. KLINE: The majority of these inspections are unannounced. The reasoning behind that is to get a picture of what activities are normally proceeding in that licensee's daily curriculum.

The announced inspections usually are incurred due to logistics with meeting with individuals, locations that are quite remote where we have the inspectors who have to fly out and geographically speaking are difficult to get to. And sometimes an announced inspection is the only method by which these individuals can set an appointment time.

Announced inspections also can follow some of the other subsets of problem areas where we have maybe an allegation that an employee might call in, or an incident or an emergency, that sort of criteria.

But again, the majority are unannounced.

MR. KEIL: But for an metropolitan area like

Chicago, then, you or somebody from the staff that does that on a regular basis would show up, show their badge and say I'm from the NRC and I'm here to help you?

MR. KLINE: Well, selected -- oh.

MR. TELFORD: Well, let's note that NRC is an agreement state, so we wouldn't inspect in Illinois.

MR. KEIL: A for instance, is that basically the method that you use? Do you actually show up at the door on the day of the survey and identify yourself and go to work?

MR. KLINE: That's basically correct.

MR. KEIL: Do they have the right to turn you down?

MR. KLINE: Yes, they do.

MR. KEIL: So, it's similar to the OSHA unannounced inspections, where they can -- unless you're carrying paper that says we have cause to believe that you're in violation of your licensing agreement, and you have a court order or something.

So, it is, in a sense, a voluntary participation?

MR. KLINE: Well, it's not voluntary. It's required via the license application process and Federal Regulations that an inspector be allowed within reasonable time to inspect a facility.

Part of the Federal Regulations in Part, I believe, 19, discuss how workers or licensees can have

representatives, how certain representatives can be interviewed. The protection of workers from the management of the facility during the inspection process.

We don't want to have people that are volunteering safety significant information regarding alleged problem areas that can be hampered during the inspection process because their management is present and will not allow them to speak candidly.

MR. KEIL: So they don't get intimidation at work?

MR. KLINE: We have documents which we post, by law, in the departments that address if you are a licensee and you're a worker, who to contact if you have a problem.

We can guarantee that there will be in anonymous nature pursuant to the notification, so that there will be no repercussions taken against that individual.

Also, we have the Department of Labor laws that we can refer problem areas where we think that's happened.

MR. TELFORD: But isn't -- I think it's possible that, if we show up for an unannounced inspection and everybody in one department is off on vacation, it's an alternative that we could inspect part of the program, come back later for the part that's missing, if you will.

MR. CAMPER: I deferred that question to Mr. Kline. He just finished about three years or so --

MR. KLINE: It was four.

MR. CAMPER: Four years as an inspector in Region 2. And he has also been a member of the quality assurance team that's been evaluating and inspecting, if you will, the facilities that participate in our pilot program to evaluate the impact of the Quality Assurance Rule. So I felt he was the best person to answer those particular questions.

Yes, sir?

MR. van SCHOONHOVEN: The Joint Commission on Credits organizations, you license if I'm correct?

MR. CAMPER: That's correct.

MR. van SCHOONHOVEN: So that's the commonality, not individuals but organizations?

MR. CAMPER: We license institutions, which are hospitals. We also license individual physicians in the private practice scenario that want to possess and use radioactive materials that our Agency is responsible for regulating.

MR. van SCHOONHOVEN: So it's both?

MR. CAMPER: It's both, yes.

MR. TELFORD: You could think of it as a legal entity that it's either a hospital that is a licensee or, in the case that Mr. Camper mentioned, it could be a private practice physician who could be in business by himself, and we would license that individual as the licensee.

MR. van SCHOONHOVEN: Do you require a so-called

response from the head of the institution?

MR. CAMPER: Part of the licensing process is to have the application signed by a management representative of the institution that the license is going to be issued to.

In the case of hospitals the license is issued to the hospital. There are authorized physician users designated on the license, except in the case of broad licensees. In those cases, the Radiation Safety Committee of the institution has the authority inherent in that particular type of license to authorize physician users, provided they meet certain minimum training and experience criteria that the Agency has to use radioactive materials.

But the management involvement and the management commitment in the licensing process is a crucial part of the process. And it is the institution that the NRC will take issue with if there are violations or problems with the license.

MR. KEIL: Do you issue separate licenses for things like radiotherapy with cobalt and nuclear medicine, and RIA for laboratories?

MR. CAMPER: That's correct, we do.

MR. KEIL: So if somebody wanted a license in each of those areas, they would have to go through three application processes?

MR. CAMPER: There are different types of licenses issued for the teletherapy scenario and for nuclear medicine.

Typically, in nuclear medicine, particularly in the larger institutions, it will include both diagnostic and therapeutic uses of nuclear medicine materials.

MR. KEIL: Okay.

DR. JESSEE: Do you have any instances where the licensee in an institution is an individual, where the institution has elected to have it organized around a private practice physician who may provide the service within that hospital?

MR. KLINE: If I understand your question properly, do we issue a license to one individual in a facility that supervises other facilities? Or --

DR. JESSEE: Well, I was thinking of the situation where a hospital may elect not to be the licensee, but simply rents space to a physician who practices within the institution?

MR. CAMPER: Yes, I understand your question now. That has happened. It is rare. The guideline, though, is that the institution, the hospital, has a license. The Agency will not issue a license to a private practice physician in that institution.

DR. JESSEE: In that -- in the physical premises?

MR. CAMPER: That's right, in that institution. But there are rare instances where hospitals will defer and allow a physician to be the primary player, if you will, in the license. That is unusual, though.

MR. KEIL: If you grant a license to a physician who doesn't rent space in a building, is it specific to his own facilities to license? Or could he carry the license from place to place?

MR. CAMPER: No. If you issue a license -- let's take the case of a nuclear medicine physician who has a private practice situation, and [illegible] that private practice location he chooses to do a broad spectrum of nuclear medicine imaging.

Part of the process that we look at in the application is to look at the radiation safety program that's going to be in place in that facility. This includes a diagram with a layout of the facility, where the lead shielding is going to be, L-block shields and things like that. Where the radioactive materials are going to be stored, and what have you.

The license is issued to that physician for that location. He may not then take that license and go to a hospital, if you will.

MR. KEIL: And market himself as a licensed physician?

MR. CAMPER: Well, he can go to them and say I have a license to use radioactive materials, but his specific license is for that location.

Now, what happens in many cases is that a physician will be a member of a nuclear medicine department on the staff of a hospital. He will be listed as an authorized user on the hospital's license and also have a private practice license issued to himself for a given location. But they are separate and distinct.

MR. TELFORD: We do have a few licensees that provide a mobile service for diagnostic tests.

MR. KLINE: We also do allow on licenses the availability of a physician to practice on a visiting sort of concept at another institution, though he does not possess a license at that institution.

But there are certain criteria and limits as to the time he's allowed and what disciplines he is qualified to do at that institution that he would be visiting. Because we do realize that people have to take vacations. You have individuals who might come in during periods of time when other individuals are not available. And that's, I believe, the reasoning behind institutions which are remote, in rural areas, so that they can have the option to have patient care administered by a physician which might be at one location, but allowed to go to another location.

MR. KEIL: Would the institution, under those circumstances, have to have its own license?

MR. KLINE: Yes. That's correct. The institution at which the visiting physician is practicing would have to have their own license.

And those procedures which he would be conducting have to be allowed under that current license, via I guess the review process of the management of that hospital to ensure that both capabilities and facilities match.

MR. MILTON: Is there a charge to the organization for the services you are providing?

MR. KLINE: There is a -- there are a number of charges that are implemented. There is a licensing charge, or a licensing fee, in order that institutions apply and receive an NRC license. There is also an inspection fee by which the institution, upon inspection, will receive a cost or a billing for that particular inspection.

MR. MILTON: Is it a token kind of thing, or is that something that's intended to cover your costs for doing what you're doing?

MR. KLINE: The Agency is somewhat self sufficient to a certain percent on that cost. We're just reimbursed through the inspection and licensing process.

DR. JESSEE: What's the initial license fee?

MR. KLINE: It varies. We have a number of

licenses, and we have a number of inspection fees. We rate the fees based on the category, the size of the facility which sometimes dictates the category into which the facility falls. The type of material, and conversely the inspection process, the type inspection.

MR. MILTON: What's a ballpark figure for what it might cost to do what you do for a given organization, typical hospital? What's a ballpark figure?

MR. CAMPER: Well, addressing the licensing component of the process, typically I would say that the fees associated with average sized hospitals is on the order of $300.00 to $800.00, in that range.

Amendments are in the order of $150.00 to $300.00, roughly in that range.

DR. JESSEE: And the inspection fees?

MR. CAMPER: I'm not certain on the inspection fees. I don't know. Ed, can you shed any light on that?

MR. KLINE: They recently have been increased in the neighborhood -- I'm speculating again -- in the neighborhood of $300.00 to $500.00.

DR. JESSEE: Okay. Quite modest.

MR. MILTON: Token fees.

MR. KLINE: Now, if a facility has a number of licenses, say if you have what we call a broad scope license which is usually issued to a university or a university

which has sublicenses under it, where they might different modalities of treatment, and each license is inspected separately. Then associated inspection fees apply towards that license.

MR. CAMPER: Now, you can imagine if there were some fees associated with say the nuclear power industry are quite different. They are quite different. I mean the numbers are profoundly different.

MR. KEIL: How long does a typical inspection take? Do you spend a whole day up there, or a few hours?

MR. KLINE: It can -- it's a function of the size, the magnitude of the facility, the logistics and the location. If there are satellite facilities, if there are separate buildings or laboratories.

Since we extended the byproduct of end use, it can be research facilities, also, besides medical, industrial applications.

So, in the medical end, though, it typically let's say maybe a 300 to 500 bed hospital that is doing routine nuclear medicine procedures which might include therapeutic and diagnostic, it would take approximately three quarters of a day.

And a teletherapy, therapeutic cobalt-60 type facility, your seizing 137 facility, though there's not much use of that anymore. It would entail about three quarters

of the day also, depending on the size, the number of machines, that sort of thing.

MR. KEIL: Do you look at the physical facility and records, and interview people during that time?

MR. KLINE: The inspectors, in order to prepare for the inspection, they review the facility's license and associated license application which is incorporated by reference into that license. And the application comes via the licensing process.

The inspector will review the conditions of the license and the applicable requirements for the standards by which the facility has addressed the program areas that we request we request that they respond to in the application process.

Also, the inspector should be familiar with the Federal Regulations, which is more of a skeletal format, that are the minimum requirements that the licensee follows during the application process.

They will go back and look at prior inspection performance. We keep data on the number of inspections, the number of violations, the types of violations. He should review any prior problem areas and verify that there have been corrective actions taken, and that they are effective.

He will look at all these elements and then assess whether or not the facility is still in compliance and has

no major, nor even minor, areas. Then, at that point, an exit is given to the management -- I guess that would be the hospital administrator -- and the authorized user to let them know what the problem areas appear to be. And if there's any contesting or explanation that's not clear, the resolution period occurs at that point.

At a subsequent date, if there are problem areas and a letter comes out from our Agency addressing each of the alleged violations. Then a sequence of events ensues regarding responding to the violations and how they will fix them and prevent them from recurring.

DR. JESSEE: What proportion of your inspection would you estimate requires some kind of follow-up in terms of plan of correction?

MR. KLINE: It's very difficult to say.

It's difficult in the sense that certain facilities develop patterns where they may have a number of problems over the years. In order to address those problem facilities, increase the inspection frequency and try to monitor them more closely.

Certain other facilities may have an excellent program and keep at a relatively normal frequency of inspection, and it's difficult to separate out how many facilities -- we can tell you which facility is doing what and what the problem areas are, but to separate out and

group and average them by violations per facility and average response time per facility, I don't know if we'd do that justice, and the data would not be correct if I said we had an average of so many violations per facility.

MR. KEIL: Do you deal with most of the violations and the followup through reports, or do you go back and do a lot of second visits to check on changes in conditions?

MR. CAMPER: It's a mixture.

I would say, generally speaking, medical licensees' inspections tend to go favorably, generally speaking. There are a number of instances, though, where significant breakdown in management control of the radiation safety program is demonstrated.

In those cases, the licensee -- normally, what happens is a licensee will file a response to a notice of violation, and it will say either we deny the violation or we acknowledge the violation and we intend to take certain corrective action. Typically, that will suffice.

It may require some additional follow-up communication from the agency to the licensee saying, well, we want you to fine-tune this, we want this particular commitment or that particular committment, what have you, and generally, that will work.

However, in those cases where there is a significant management breakdown and it's clear that

management, through its radiation safety officer, its radiation safety committee, has lost control of the program, this is usually demonstrated either by multiple violations -- 15, 20 violations, on that order -- or a particular mishap, like a significant contamination spill type of thing, for example, or workers being overexposed or things of that nature, and in those cases, we're going to follow up closely with unannounced inspections and continuing interactions, both written and verbal, with the licensee, enforcement conferences and those types of things.

But generally speaking, the medical licensees tend to do well, and in those cases where significant problems are identified, they're easily recognized as being significant problems.

Dr. Henkin?

DR. HENKIN: Could you give everybody an idea of the frequency of the significant violations; how frequent, in your 2,000 or so licensees that you inspect medically, you encounter significant violations that require that type of action?

MR. TELFORD: I think we need to make a point of order.

There is a place on the agenda, at the end of the day -- it's a 4:30 item here -- we'll take questions and comments from members of the public. I hate to say this,

but we're here to talk to the representatives of the JCAHO, so that we can conduct this comparison and conduct business in that way.

I would like to postpone an answer to that question until that time on the agenda, unless there are any objections.

MR. CAMPER: But we will come back to your question.

DR. JESSEE: In addition to the 2,000 that you are responsible for directly, there are about 4,000 licensees that are handled under arrangements with the states. Is that correct?

MR. TELFORD: Yes. There are 29 agreement states, Illinois being one.

DR. JESSEE: Under those agreements, a responsible state agency has direct supervisory responsibility. Then there's some reporting to the NRC?

MR. TELFORD: Essentially, the state is -- through an agreement, a formal contract, is extended the authority of the NRC, and they are responsible for licensing and inspection. In this area, in Part 35, for instance, with misadministrations, as of April 1st of this year, the agreement states now have to report those to the NRC. Prior to that, they did not have to report to the NRC.

This rulemaking that we're working on, if it

becomes a final rule, then the agreement states would be subject to -- the agreement state licensees would be subject to this rulemaking as a matter of compatibility, so all their recordkeeping and reporting requirements.

DR. JESSEE: I presume that would be handled much as the Health Care Financing Administration to handle its agreements for the administration of Medicaid, that the states would have to make amendments to their plan that would incorporate these new regulatory requirements and that that amendment to their plan will be subject to NRC approval and then it would be implemented?

MR. TELFORD: The thing that would be subject to NRC approval would be that, if this rule becomes a final rule, the agreement states would have to implement -- have the licensees implement programs which are at least as stringent as this program. They are completely free to go over this in areas that they -- often, they are the department of health and they license the physicians.

So, if they wanted to say, for instance, that only authorized users can sign a prescription, what we call a written directive, they are free to do so; whereas, our licensees have another alternative. The physicians under the supervision of an authorized user could sign a prescription under our regulations.

MS. CARROLL: Such as a resident.

MR. TELFORD: Yes.

So, it's almost as you described.

MR. CAMPER: Let me add two points, though, just to help further clarify.

One is that the agreement states deal with our regulation by levels of compatibility, so-called divisions of compatibility. There's something, for example, as Division 1 compatibility, and their regulatory requirement would essentially be identical to ours. The regulation must be verbatim. Division 2 compatibility is more along the lines of what John was just suggesting, and that is that they have to be at least as stringent as ours; they may choose to be more so.

The other point is that, in the medical area, again I would emphasize, as he pointed out, that the area of medical regulation is not an area of Division 1 compatibility for the agreements, and their requirements are very similar to ours. In some cases, they're quite different.

The classic example that sometimes will show the striking difference is, in the practice of nuclear medicine, we require the use of a dose calibrator to assay patient doses prior to administrative to the patient to ensure that it's within plus or minus 10 percent of the required dose. The State of Texas does not have the requirement to use dose

calibrator, as an example.

So, I show you that example to point out that the regulation of medicine amongst the agreement states, given that it's not a Division 1 compatibility requirement, is variable, and in -- and this rule, if it would become a rule, would be an issue of compatibility, although most probably not at Division 1; most probably at Division 2, we surmise, at this point, but that's not certain yet.

DR. JESSEE: At risk of jumping ahead on the agenda, let me ask a question then.

In the event that, after this discussion, you determine that there is sufficient equivalency between our standards and your proposed rules or that there could be sufficient equivalency established with some modifications, to go ahead and rely upon Joint Commission Accreditation as an alternative for NRC licensees, that, then, would only apply in those states that did not have a contractual relationship, or could it be included in the rule, so that it would also apply in the other 29 states?

MR. TELFORD: I think, in theory, it would apply to all states.

DR. JESSEE: Okay.

MR. CAMPER: This is going to be an issue of computability for the agreement states, if this rule becomes a rule. Whatever it ends up being would be an issue of

compatibility, the only question being at what level, what division of compatibility would it be? But yes, in theory, if that were to happen, it would apply to all states.

DR. JESSEE: Okay. That makes life easier.

MR. CAMPER: Any other questions about how we go about doing our --

DR. JESSEE: Let me ask one other question.

Many of our questions have been related to organizational issues, and we're finding that's one of our biggest nightmares, is trying to decide what is it that we're surveying and accrediting, as health-care institutions become more complex, and they have created all sorts of subsidiaries and contractual arrangements with other providers, often for purposes that have nothing to do with accreditation or, in your case, with regulation, but nonetheless, it makes it very complex to try to sort out the pieces.

What do you do if you've got a large organization that may have the provision of nuclear medicine services in multiple sites? Does each site have a separate license, or is there a single license for the organization but covering multiple sites?

MR. TELFORD: I think the answer is yes. I'll talk while Mr. Kline thinks.

I think, in my experience, it's a broad-scope

licensee, and you may have a campus in one part of the state and another campus in another part of the state. I think the answer is yes, each site would have its own license, and you probably would have different authorized users listed on each license.

MS. CARROLL: The same would apply, would it, let's say, to a hospital that had branches around the county? I'm not talking about the distance involved with the University of California, with all its branches. But suppose we were talking about a medical center.

DR. JESSEE: The Greenville Hospital System.

MS. CARROLL: Right. Yes.

MR. CAMPER: Well, generally, if you're talking different geographical locations, more times than not there would be a license for each location. If you're talking about a broad medical licensee, a university medical setting, for example, where you have multiple research laboratories on campus, there will be one broad license with multiple uses throughout the campus. When you start getting into different geographical locations, there are typically multiple licenses issued.

MR. TELFORD: Yes. One campus spread out over 10 square miles, huge campus, that's one license. Well, you could have three licenses there. You could have teletherapy, brachytherapy, and diagnostics.

MR. CAMPER: Research, as well.

MR. TELFORD: Research, as well.

But if you have 50 miles between two cities, it may be the same state organization, the same state campus, but we would have different licensees.

MS. CARROLL: Treat them separately.

MR. TELFORD: Yes.

MR. KLINE: That's a good question, because there are situations where facilities, hospital-based corporations, are expanding and building hospitals under one management, under one health-care company, and then you get into the logistics of, well, since you have one management, how do they oversee all these operations? Who is responsible if the billing comes into one company, so to speak, and the profits come in from the satellites?

In the past, I think the NRC had originally leaned, in these sort of areas, towards one license and found, over the years, that it wasn't feasible, that we were having problems, but I guess too much deregulation in the hospital of responsibility, satellites became too autonomous, and there were problems that were developing because people were not available to address these sort of requirements that we look at and we inspect at each facility.

So, I think the pattern has shifted towards the

licensing of the facilities as a separate identity, though the company is -- the facility is owned by one company and one hospital.

MS. CARROLL: We often run into that issue. It requires determination and, for example, definition of who is the governing body.

MR. KLINE: Yes. We get that same problem.

MS. CARROLL: It can be very difficult.

DR. JESSEE: Any other questions?

[No response.]

DR. JESSEE: Hearing none, let's do a quick overview of the Joint Commission and focus a bit more specifically on how we survey nuclear medicine services in the organizations that we accredit.

The Joint Commission is a private, not-for-profit 501C3 that was originally organized in 1951 as the Joint Commission on Accreditation of Hospitals. We changed our name in 1987 to reflect the fact that, over the course of the years, the scope of our accreditation activities had expanded beyond hospitals, and currently, we accredit about 5,200 general hospitals, and psychiatric hospitals are included in that group.

In addition, we accredit something in excess of 3,000 other types of health-care organizations, which include non-hospital mental health facilities, long-term

care facilities, nursing homes, home care agencies providing home care services, and a variety of ambulatory care organizations, which I would have to say is a real potpourri, everything from the ambulatory surgical clinics to college health services to occupational medicine programs for some large employers, all of which have absolutely no common thread, other than the fact that they have elected to comply with our standards.

The organization, historically, has been viewed as a purely voluntary process. The standard-setting process is not a public one in the classic sense of that word, but it is certainly one that seeks broad input from all affected parties.

Generally, our standards-development activity is done over a period of one and a half to two years, during which we publish statements of purpose, and we publish them in professional literature, in our own official newsletter, widely covered throughout the industry in the trade press; then draft proposed standards, and ultimately, the intent is to arrive at standards that represent consensus of the health care industry as to statements of good practice, if you will, in the management of a health-care organization.

Philosophically, since the mid-'60s, our standards have represented optimal standards, rather than minimums standards. That's been the official philosophy, and the

rationale behind that was that, in 1965, when the medical program began, the then-current accreditation manual was plagiarized by the Department of the Health, Education, and Welfare and published in the Federal Register as the original set of Medicare conditions of participation, more or less; a few word changes here and there, but if you did a side-by-side comparison of the 1965 joint accreditation standards and the first conditions of participation, they are virtually identical.

That led the Commission, in '65, to make a decision that they would rewrite the standards manual to crank things up a notch. If those standards, which had been viewed as minimum standards, were then put in place for any hospital that wished to receive Medicare and Medicaid funds, it seems only logical to change the role of the private sector organization to one that would set some standards that were aiming to move the level of performance higher.

As a consequence of that, most of the organizations that we survey -- in fact, in the hospital field, about 97 percent of those organizations have one or more -- what we refer to as Type 1 recommendations, areas in which they are not in significant or substantial compliance with the standards and for which we engage in some followup, either through a written report or, in some cases, a revisit, depending upon the nature of the problem.

We survey all of our organizations that participate in the accreditation process on a triennial basis. However, we also conduct unscheduled or unannounced surveys in any accredited organization. They agree at the time they apply for accreditation that they will operate their organization in compliance with the standards on an ongoing basis and grant us the right to visit them on an unscheduled or unannounced basis, and we generally do so in response to either complaints or media coverage that alleges a problem that might be relevant to standards compliance.

We also, as you might expect, receive a lot of complaints that aren't relevant to standards compliance, such as "My bill was outrageous." Since we don't have a standard for that, we generally don't follow up on those.

In addition to the regular triennial surveys or unscheduled or unannounced surveys, we also do what we call focused visits, which are the followup on problems that have been identified through the regular survey. The last time we looked, I think the average in the hospital field was about 2.4 follow-up activities per triennial survey.

So, there are about 2.4 either written reports or follow-up focused visits that come out of each triennial survey, on an average. Some few institutions that do extremely well have no followup, and therefore, some that don't do well have considerably more than 2.4, to come out

at an average of 2.4 nationally.

We try to grade the overall performance and, as of January 1st, we will have four categories of decision that can come out of our survey process.

For the institutions that do extremely well, starting next year, we will award accreditation with commendation. It's a way of recognizing better-than-expected performance. And we're estimating that it will probably be the upper 10 or 15 percent of the organizations that we survey.

Most organizations will be accredited. Those that have significant numbers of standards-compliance problems but which, in our judgement, can remedy those standards-compliance problems within six months, will fall into what we call conditional accreditation.

In essence, they are informed that they are in serious jeopardy, that unless they make significant progress towards improving their level of standards compliance, which is then assessed through a follow-up survey in six months after the decision, then they can lose their accreditation if they have not made sufficient progress at that point. That is currently running about 5 to 8 percent of the total number of organizations surveyed annually.

Finally, the fourth decision that can result is a denial of accreditation, and that usually is two different

categories. One is organizations which have so many standards-compliance problems that we do not believe that they can reasonably be expected to move up to a level that would allow them to continue their accreditation within six months. That's just a sheer volume of problems that they can't adjust in that timeframe. Or an organization which has one or more conditions which pose an immediate threat to patient health and safety, and you can be doing great except for that one thing, and that can be sufficient to generate a recommendation for immediate non-accreditation.

Annually, we are now running about 1 to 1 1/2, sometimes 2 percent of accreditation surveys that we conduct result in a non-accreditation decision. Interestingly, we find that many of the organizations that lose their accreditation reapply. They make efforts to resolve the issue and the reapply and are re-surveyed and regain their accreditation at some point in the future.

In terms of mission, our mission is to improve the quality of health care provided to the American public, and that results in, if you will, what I refer to as a schizophrenic balance between a public-sector purpose and recognition that this is a private-sector organization that comes primarily from support from the industry, from physicians, from hospitals, and from other health-care organizations.

So, on the one hand, we try to balance the importance of achieving consensus amongst the members of that industry as to how quality can be furthered but, at the same time, recognize that our true constituency is the public whom those organizations serve and that if there is a conflict between the interest of the institution or the profession and the public that we resolve it in favor of the public.

Generally, we take the perspective, though, that the interest of health-care organizations and health professionals and the interest of the Joint Commission are concordant and that both are there to serve the public interest. But when we get down to an individual case, from time to time, those things may bump into one another.

MR. CAMPER: I have a question for you.

DR. JESSEE: Yes, please.

MR. CAMPER: The accreditation process itself, though, is voluntary?

DR. JESSEE: It is voluntary. Let me hang a "however" on that.

However, since 1965, it has become increasingly intertwined with a variety of public processes. Part of the reason why it is -- why accreditation is so dominant in this country, unlike most of the other countries in the world, is because it had roots in the hospital industry that went back

to 1917.

The American College of Surgeons started what they called the Hospital Standardization Program in 1917. The Joint Commission, when it was formed in '51, was a successor to that original program, and it really came about simply because, after the Hill-Burton Act and all the post-war hospital construction, the College of Surgeons found they could no longer manage the program, because the numbers of hospitals had expanded so substantially. So, they looked for some partners and brought in the College of Physicians, the AMA, the American Hospital Association to form the Joint Commission in '51.

When the Medicare law was enacted, that was so firmly established in the hospital industry that the original Title 18 of the Social Security Act provided that hospitals that were accredited by the Joint Commission would be deemed to meet the conditions of participation that we established by regulation, by the Secretary of then-Health, Education, and Welfare. And that was the first public-private relationship, so that if you're an accredited hospital, you do not have to have a separate survey for purposes of Medicare participation.

There are about, last I looked, about 6,300 Medicare-certified hospitals and about 5,200 are certified by virtue of their accreditation. The remainder are

certified by virtue of a survey conducted by one of the state health departments, under contract with the Health Care Financing Administration.

In addition, as the Medicare law has been amended over the years, the Health Care Financing Administration conducts validation surveys on a sample of Joint Commission-accredited organizations, and this year, I think it's running about 250 -- they draw a sample of 250 hospitals and do look-behinds, in essence. After we have surveyed, they send them to state agencies to do a look-behind survey.

MR. MILTON: Bill, you may want to add the state licensure, too.

DR. JESSEE: In something like 41 states, state government relies upon accreditation, in whole or in part, for purposes of hospital licensure, and that's a real patchwork quilt. Some states simply do not do licensure inspections in accredited organizations. Others do licensure inspections on licensure requirements that may be different from those that are contained in the accreditation standards.

MR. CAMPER: The "O" in your name, "Organizations," consists of what? What are these organizations that you're looking at and accrediting?

DR. JESSEE: They are hospitals and other health-care organizations, such as long-term-care facilities,

mental-health organizations, ambulatory-care facilities of various types, and home-care agencies.

MR. CAMPER: But no private-practice physician office scenarios?

DR. JESSEE: Well, conceivably. In our eligibility criteria, we have not come up with an accreditation program that will cover the solo practitioner. But the ambulatory-care program is structured such that a fair number of small physician group practices, usually specialized in a single specialty area, have sought accreditation.

In the mental health area, we also have some groups of psychiatrists and psychologists that provide mental-health services on an outpatient basis that have decided to seek accreditation. That often is tied to relationships with other entities, like payers.

In some states, Blue Cross, for example, will not make payment in a non-accredited facility. It's more prevalent in the mental health field than in some of the other fields, but often the insurers will requires accreditation as a precondition for payment.

So, I say it's voluntary, but over the years, a lot of other forces have hung their hat onto the accreditation process, and therefore, for many types of organizations, it's become a necessity, rather than a purely

voluntary activity.

MR. TELFORD: My impression is that there is approximately 6,000 hospitals in the U.S. The numbers you're mentioning -- I'm curious about what's the total of what's the percent of participation?

DR. JESSEE: It's a little higher than that, the last I heard. Medicare was 6,300.

MR. MILTON: Well, the AHA, American Hospital Association Guide issue, which is published every year, lists obviously, all of its members. There are typically 7,000 to 7,200 organizations listed there and, as Bill said, we have 5,200 organizations accredited. The difference includes a large number of organizations that don't meet the eligibility criteria. So, but you can't count them as even potential accredited organizations. The others in there that would be eligible have chosen, for whatever reason, usually their very small, not to be accredited.

But, like you said, we have some university health-type, you know, dispensaries and so forth, that are members of the AHA but they're not -- they don't come close to being eligible for a survey.

DR. JESSEE: The numbers depend entirely on what you define to the hospital. Some organizations call themselves a hospital; but if they have an average length of stay greater than 30 days, we don't consider them a

hospital, we consider them a long-term care facility.

MR. CAMPER: In those institutions, hospitals shall we say, that either fail your accreditation process or choose to withdraw, are they then penalized with regards to reimbursement for Medicare and Medicaid? Can they still obtain funding, if they're not accredited?

DR. JESSEE: Yes. And many do. If they lose their accreditation or withdraw from accreditation -- take a typical hospital, they will then call the State Health Department and ask to be surveyed for Medicare participation purposes as soon as possible, in order to maintain their flow of Medicare funds.

MR. CAMPER: Are the Medicare/Medicaid standards, in that case, the same as yours, stronger than --

DR. JESSEE: They were in 1965. But, as you know, the Federal rulemaking process is complex and time consuming and there really has been one major rewrite of the Medicare condition to participation for hospitals since 1965 and that was done in the late '70s.

As our manuals are revised annually, obviously not completely rewritten, but we, each year, publish a new manual which contains changes from the prior years. So our standards have evolved on an annual basis, whereas, Medicare conditions have remained relatively static.

Medicare has managed to keep their survey process

a bit more current by relying upon administrative instructions through what they call a State Operations Manual, which is their instructions to the state agency. But their -- their constrained by what is in the regulations. Obviously, they can't do something that's not in the regulations; but there's a fair amount of latitude in the interpretation that's put on most regulations.

MR. CAMPER: Does the Medicare/Medicaid evaluation, is it conducted in a fashion similar to yours, in that there's on-site inspections --

DR. JESSEE: Yes.

MR. CAMPER: -- and an in-depth review of the process?

DR. JESSEE: Yes, but the processes are similar and yet different. Medicare -- the total number of people involved in the survey and certification process -- the Health Care Financing Administration in Baltimore is five. So it's a small program, centrally. In fact, I don't think they have any people designated in the regional offices that is responsible for survey and certification.

But they do rely upon the states. They contract, and that's in accordance with the statute. They contract with the states, with the State Health Department, to conduct certification surveys for them. In fact, those are federally reimbursed to the states for conducting that

activity.

But if you're a smart state, also piggy-backs some licensing requirements onto that so that they -- they're not really paying anything for the state licensing function; they're getting it almost entirely reimbursed by Federal funds for performing the Medicare certification surveys.

Each of the 50 states is responsible for their own survey and training and for their selection of surveys. There is a fair amount of variability from state to state, in the types of professional backgrounds that surveyors have to conduct the Medicare certification surveys.

They are conducted annually, as opposed to tri-annually. They are, I believe, all unannounced. Is that --

MS. CARROLL: No. I've run into places where they said they were about to handle it, so there must be some.

DR. JESSEE: So they're a combination then.

MR. TELFORD: For the organizations that fail your accreditation survey, what does HCFA do? Do they ensure that some other organization comes out to do a survey, other than the state?

DR. JESSEE: For the organizations that are accredited?

MR. TELFORD: No, that fail.

DR. JESSEE: That fail.

MR. TELFORD: Either fail your accreditation or a

second category that never applied?

DR. JESSEE: Well, when we either -- you're getting into an area that I think is pretty important, and that is, if you look upon our relationship with HCFA as, in essence, a public/private partnership, where we're both trying to accomplish the same ends and trying to do it in the most efficient and least duplicative manner possible, it requires good sharing of information.

Historically, that has not been the case. In the last 2 to 3 years that has improved markedly, both by virtue of changes in the statutes and by us and HCFA recognizing that is was in everyone's best interest to do that.

Currently, we notify HCFA, not only of organizations to which we deny accreditation, but we also notify them whom we conditionally accredited for an organization, so that they're aware of an organization which we consider to be on the watch list, if you will.

Their posture, so far, has been not to do anything with those on the watch list, the conditional group, but at least they have the information in the event that something else should come to their attention that would indicate that maybe they need to -- to go in and do an -- an unannounced survey on one of these. They retain the right to do unannounced surveys, even in accredited organizations, in response to -- to an allegation or complaints investigation.

In the non-accredited group, then my assumption is that they will, as soon as they receive a notification of non-accreditation, they would routinely notify the facility of their intent to terminate that facility from participation in the Medicare program, to which the facility would then respond by requesting the state certification survey and, if they were successful in passing the state certification survey, then their participation would continue.

MR. TELFORD: Does HCFA, in those cases, sometimes either take on the responsibility to inspect those facilities or employ a contractor to do that?

DR. JESSEE: They do a hundred percent through the states.

MR. TELFORD: Through the states, okay.

DR. JESSEE: Yes. All -- all the states function as contractors to HCFA.

MR. TELFORD: Okay.

DR. JESSEE: And the district.

MR. CAMPER: I want to make sure I have an understanding of the numbers here. We have said that there are approximately 73-7,400 hospitals listed in the most recent AHA publications; is that essentially correct?

MR. MILTON: My recollection was about 7,200; but that probably fluctuates from time to time.

DR. JESSEE: My recollection is about 6,300 Medicare-certified hospitals, Medicare participating hospitals.

MR. CAMPER: And there are approximately 5,200 of those that are certified by AHA?

DR. JESSEE: That we accredit.

MR. MILTON: Accredit.

DR. JESSEE: Accredited, right.

MR. CAMPER: So that the other 2,000 or so are covered by the Medicare/Medicaid process that you have described?

DR. JESSEE: Well there's only about 1,000. The discrepancy between the number we accredited and the number that are Medicare-surveyed is only a little bit over a thousand. There may be some other organizations which call themselves hospitals that are not certified as a hospital for -- by Medicare and therefore not eligible for Medicare Part A reimbursement.

MS. CARROLL: There are facilities in certain states that will define themselves as hospitals, for licensing reimbursement purposes; but they actually do not meet our conditions of eligibility in terms of functions.

DR. JESSEE: Amongst the Medicare-certified hospitals, we accredit about 83 percent, but we cover about 97 percent of the beds. So, the number -- the organizations

that are not accredited that do participate in Medicare are predominantly small and my guess is they would be amongst the least likely group to hold a license from NRC.

MR. TELFORD: We have a fair number of licensees that are private clinics that do both diagnostic and therapy procedures, that would probably would not be a hospital in your eyes.

DR. JESSEE: Well, there could be some of those that we would accredited under the ambulatory care standards. But I have no way of -- the only way we could possibly determine how many they might be is simply to do a cross-check with the listings.

We do publish a -- a directory of accredited facilities. If someone has a long weekend and nothing to do, they can go through manually and look at that whole list and see how it conforms to your list of licensees. A GS3 could do that.

Let me briefly describe our survey process. Tri-annually, we visit each institution. I'm going to focus primarily on hospitals now; that's -- that's the lion share of what we're talking about. Tri-annual survey is done on an announced basis. The facility gets 4 to 6 weeks of notice regarding the exact dates.

The reason for that is very practical. We're surveying the entire inscitution and it is going to be a

much more productive process if all the relevant people are there when we arrive. As you -- anything as large and complex as the hospital, if we -- if we did unannounced surveys, we would find a lot of key people simply not there on that day.

In particular, a lot of what we look at involves medical staff, and for the dominant model of hospital in this country, that's a voluntary medical staff -- rather than an employed medical staff. If we turned up on the doorstep at 1:00 to the chief of staff, the chances of that person being available are somewhere between slim and none. So we have relied on scheduled surveys and then used the unannounced surveys as a way of dealing with the potential problem; still reserving that right. But in a regular survey it is announced.

The minimum duration of a hospital survey is 2 days and it is longer depending upon the size and the complexity of the facility. I think the longest survey we're doing of hospitals now is about 5 days. That would be a large university medical center with multiple services.

Core team consists of a physician, a nurse, a hospital administrator, and in slightly more than half of the hospitals we surveyed, laboratory technologists.

If the hospital has a laboratory that is accredited with the College of American Pathologists, we

omit our medical technologist for the team -- from the team and review the CAP information against our standards and pull that in, in essence, relying upon the CAP surveyors for findings.

In many areas, our physician surveyor, even in those circumstances, does review some of the laboratory functions so that we do have some review of the laboratory, even when we're using the CAP information.

We'll add other surveyors to the team, depending upon the types of services the organization provides. Rehab hospitals could say podiatrist; at a hospital that has an alcohol or drug abuse program will often get an alcohol specialist added to the team. So it depends upon the team composition, depends upon the nature of the services offered.

MR. CAMPER: Can I interject a question there?

DR. JESSEE: Yes.

MR. CAMPER: How do you determine, in preparing to inspect or get into the hospital facility, how do you determine the degree of attention that would be devoted to the nuclear medicine department or the teletherapy practice? How do you arrive at that?

DR. JESSEE: Let me ask Jim McMannis to talk about that because those areas are covered by the physician surveyors. Actually, what I'd like to do is ask Jim to talk

about the physician surveyors part of the survey, with particular emphasis on nuclear medicine and related services, then devote a few -- talk a little bit about what we do in terms of looking at the physical premises and the safety management program, because those also relate back to that area too.

DR. McMANUS: Are you familiar with this manual?

MR. CAMPER: Yes.

DR. McMANUS: Okay. The manual describes the eligibility criteria that Dr. Jessee mentioned on roman numeral 19 and 20 and lists those services that need to be present before the hospital is eligible for a survey.

If you look at those eligibility criteria, you'll see that diagnostic radiology services must be provided for; nuclear medicine services must be provided for, except in psychiatric and substance abuse hospitals; and radiation oncology services are not necessarily to be provided for in all hospitals that are surveyed. So, we have differences between the 3.

Then, if you look through the standards, you'll see that the survey of those 3 services are in separate chapters, instead of 1 chapter, we have a diagnostic radiology nuclear medicine and radiation oncology chapters.

Specifically, the physician in a 2-day survey, will spend approximately 1 hour surveying diagnostic

radiology, 1 hour in nuclear medicine and, if there's a radiation oncology, about 1 hour; so about, in the average 2-day survey, I would say about 3 hours are devoted to those 3 chapters.

In the longer surveys, 3 days, 4 days and 5 days, they're increased by the number of days in the survey. So, you might spend a couple of hours surveying each of those 3 services in a 3-day, 4-day, 5-day service.

In the physician's schedule, he actually goes to the diagnostic radiology department, nuclear medicine department and radiation oncology department, it's not a sitting in the CEO's office and surveying it. It's an on-site survey, going through compliance with the standards as they are.

We have scoring guidelines that help the surveyor and the organization comply with these standards. I don't know whether you have a copy of the scoring guidelines?

MR. CAMPER: Yes, we do.

DR. McMANUS: Okay.

MR. TELFORD: May I interject a question?

DR. McMANUS: Sure.

MR. TELFORD: Is this the -- the person that's going to go survey in the nuclear medicine diagnostic department, or in the therapy department? I understand that you have standards and the hospital has developed a program

to meet those standards. Upon arrival, is that the first contact that the surveyor has with the hospital's program?

DR. McMANUS: No, there's an application --

MR. TELFORD: Okay.

DR. McMANUS: -- which the hospital submits several months before the survey on that application that he encounters, relative to the number of x-rays, etcetera, number of departments, whether they're separate departments, or whether they're merged. Maybe there will be a list also of who the directors are, in terms of -- so there is a certain amount of data that the physician is aware of. He also gets a copy of the medical staff bylaws. The administrator gives the governing body bylaws, etcetera, and there's some statement of construction and various other material that's sent in before the survey.

MR. TELFORD: In terms of things like indicators that the hospital has chosen for -- or that department has chosen, is the surveyor aware of those things before he arrives, or he/she arrives?

DR. McMANUS: No, ordinarily not. Ordinarily that's determined at the time of the survey and reviewing the monitoring and evaluation process. One of the first questions would be, what indicators are you using to assess your quality of care that you provide.

MR. TELFORD: Okay.

DR. JESSEE: I should mention that 1 project that we have underway now is looking at revising our survey process to try to make better use out of our on-site time. One of the proposals that's been discussed is to increase the amount of material.

Right now we do spend a lot of time on-site reviewing documents. If you consider the efficiency of the process, that's not making a maximum use of the opportunity to sit down and talk with people and find out what goes on. So, 1 of the things that we're looking at now, is how we might do more of the documentary review in Chicago, on a centralized basis, prior to the on-site survey.

One of the difficulties we're trying to figure out is exactly how you then do that document review centrally and communicate what you found to the guy who's actually waiting to come out and do the survey. It may well turn out that we'll have to work out some kind of an arrangement where people who are doing the document review here might then go out and participate in the survey process.

MR. KLINE: During your review of the information that is -- well, I guess, let me re-word that. In preparation for your inspection of a facility, do you request that the facility, and let's say you're looking at nuclear medicine, do you request that the facility have a representation patient, clinical studies, or do you request

that certain documents be available so that there is a schedule during that 1 hour that you can look at certain aspects of that program?

DR. McMANUS: Yes, if you look at the standards, the standards do ask for evidence of policies and procedures, etcetera, etcetera.

MS. CARROLL: They have, in their handouts, the current chapter. Also the proposal.

DR. McMANUS: Okay. If you want, just take the nuclear medicine chapter.

DR. JESSEE: This [illegible] nuclear medicine standards.

DR. McMANUS: And look at NM2. It says "there are policies and procedures in place." Now, we would -- having had surveys in the past, both hospitals will know that we'll go down there, we're going to look at their policies and procedures. These are updated, they're supposed to be current, they're supposed to be approved and they're supposed to cover the areas that are listed in that chapter.

Then if you look at some of the other areas in nuclear medicine too, you'll see that there are reports that have to be generated that look at performance valuations, dose monitoring, monitoring for -- for the procedures, themselves, and monitoring the absorbed doses. How do you

-- how do you do that? Then they would bring out and have in hand reports to that effect.

There would be a notice of receipt, storage, preparation and use areas for radionuclide. Can I see that? And you would look to see back, again, on 22101 on page 121, you would look to see information in records that includes at least those items that are listed there: the date, the method of receipt, the supplier, the lot number.

You'd look to see the safety policies and you would ask, do you have a quality control program, 228, I'm going backwards, designed to minimize patient, personnel and public risk and maximize? You'd look to see a written quality control program that addresses those areas.

In the standard experience --

MR. TSE: Again, in the standard experience, when you look to see if they have those procedures, but you probably don't have time to look into the details. The procedures need certain.

DR. McMANUS: No, you don't look to see if they've applied to those procedures; you're right, although you will ask in your quality control program, have there been any problems related to that quality control program. If there's been a misadministration, for instance, when was the last misadministration that you had? How did you deal with it? Did you change your policies and procedures related to

it?

So, you'd follow up on any problems that they've recognized. Also, as you survey, you get to see, onsite, how well it's run, even though you're only there for that one short spot in time. You get an idea of how well it's run, so it's kind of an overall assessment.

MR. KLINE: If you had a checklist format like this with respect to process, and during that one hour in nuclear medicine, you had to go through that checklist, do you have a feel for -- I know certain areas overlap from one characteristic to another, but do you have a feel for the total number of these characteristics you'd be able to cover in a typical, average hospital?

DR. McMANUS: I didn't bring the survey report form with me, but not all of these required characteristics are surveyed. If you look at the standards, you'll see that some are asterisked and those are the key items. The surveyor will pay attention to those key items. Those are the ones that have the most impact on the survey result.

DR. JESSEE: That are routinely scored.

DR. McMANUS: Those are the ones we routinely scored and scaled on the survey report form which resembles this.

DR. CARROLL: You can see an example of it. The report form follows this format.

DR. McMANUS: There is a scale next to that.

DR. CARROLL: The surveyor report form follows that.

DR. McMANUS: The surveyor report form will have a scale where the asterisks are.

MR. KLINE: Do you use any sort of weighting process where certain standards are more significant than others?

DR. McMANUS: Yes.

MR. KLINE: Thereby, one standard versus three standards that are not as significant would be more significant?

DR. McMANUS: Right. There is an aggregation of the various scored items in the SRF so that the organization gets back a single grid score. All those scores are compressed into a single grid score.

Now, you haven't seen the grid yet and I don't want to get into that, but each one of these -- the organization gets a single score for nuclear medicine services, so each one of these scaled items contributes to that single score. The way it's done is a complicated algorithm of compression of the various scores into a single score.

DR. JESSEE: But it's a weighting process with weights?

DR. McMANUS: Yes.

DR. JESSEE: It basically says that three of these has about the same weight as one of these and the more important items can go directly through to your grid square on that element. Less important items, you have to be deficient in several areas before that will go through.

MR. KLINE: During your inspection process, do you ever request to see an NRC inspection report?

DR. McMANUS: Yes.

MR. KLINE: Is that part of your grid?

DR. McMANUS: No, it isn't. It's part of the scoring of reports. When was the last one that you had? Can I see a license, evidence of license? Can I see the last medical radiation physicist's report? That's another one we would ask for.

In nuclear medicine, this would be part of it.

Are there any other areas?

MR. TELFORD: You mentioned that sometimes in the survey that it might last 3 days or 5 days.

DR. McMANUS: The survey might last 3 days to 5 days. Incrementally, your survey of nuclear medicine and diagnostic radiology and radiation oncology would be increased more than the hour that you've spent. It would be perhaps a separate department, not only a separate department but it would cover other areas than the hospital

itself.

There may be a radiation oncology center. There may be an MRI. There may be other areas that the surveyor would survey in those large organizations.

MR. TELFORD: In the maximum case, 5 days, what would be the maximum time that a surveyor might spend in the nuclear medicine department?

DR. McMANUS: Two hours, I would think.

MR. TSE: In the core members of your team, you mentioned MD.

DR. McMANUS: Right.

MR. TSE: That's for the entire survey fo the entire hospital. Is this anything specific like a nuclear medicine physician or oncologist when you survey the nuclear medicine or oncology department?

DR. McMANUS: A member of the Joint Commission surveyor?

MR. TSE: That's right.

DR. McMANUS: No, they are not arranged by specialty.

MR. TSE: Only in special cases. You mentioned --

DR. McMANUS: Oh, in rehab. Yes, pysiatrists will go to a comprehensive rehab department attached to an organization or a free-standing rehab hospital. Then we have psychiatrists -- are there eligibility criteria for

when a psychiatrist consultant will be assigned, but that's as far as it goes.

DR. JESSEE: There really have been no instances in which we've tried to add someone who is trained as a nuclear medicine specialist to survey the nuclear medicine department. It is simply not that large a department in the vast majority of organizations that we survey. There are not enough of them around to survey all of these places.

Keep in mind that while the physician has primary responsibility to review those standards, there are a variety of other standards that cut across and cover aspects of the operation of the department, such as safety management, equipment management.

They will be -- aspects of the nuclear medicine service will be covered in standards other than the nuclear medicine chapter, per se.

MR. KEIL: They're looked at as an integrated piece of an organization-wide program. They're not looked as an excised organizational component or box in the organizational chart. In safety management, it's a step-down process that starts with the worker's right not to be injured, as well as visitors and patients.

That's explained in general terms by the organization and then it's cut into specific needs by departments so nuclear medicine hazards that exist there

would be dealt with specifically for the employees and others who might be exposed through trash pickup or other housekeeping processes or whatever it happens to be.

We look at that through a hazards surveillance program which is probably a bad word. It's more or less environmental monitoring to see that the management process of safety goes on in accordance with the established rules and procedures, incident report evaluation, interaction among fo[illegible] like the safety committee, radiation safety committe[illegible] inspection control, QA and risk management so that there's a tying together of all the sources.

That way, you don't get stuff lost in the wastebasket or the file cabinet out of fear of litigation or whatever it happens to be. The other part of that we look at is dealing with hazardous materials and waste, radioactive is part of that. It's one of the areas we always ask questions about in terms of storage and handling and disposal and licensing and permits and tracking and all those kinds of things.

Under equipment management, we deal with it from two perspectives: One is; do you take care of the machine aspects of whatever your toys are, so that it's receiving proper maintenance calibration and those kinds of repairs. The other is the human interaction with the machinery where about 80 percent of your incidents are going to come from.

We look at orientation, continuing education and evaluation of competence which is working its way into a lot of our standards as we move down the road towards quality improvements. You begin to look at systems instead of handling things as a box of this and a box of that.

You start putting together technology defined as the people and the equipment instead of picking on one with the other. Typically, we've left the people alone to a great extent and we've locked at the pretty straightforward process of testing, maintaining, inspecting and repairing equipment which is really sort of a no-brainer if you have halfway qualified technicians. The hard part is keeping the people up to speed.

MR. KLINE: Since your organization is based on voluntary participation by the host facility and, I guess, the inspection process would subsequently be a voluntary process to allow you on the premises for the evaluation; if you were to discover during the inspection process, an area which appeared to be relatively significant, whether it be something to do with an electrical hazard, let's say an OSHA area of concern, EPA area of concern or an NRC area of concern, do you have the latitude or would you exercise the latitude to notify that associated organization of that problem area for possible review by that organization?

MR. KEIL: That's a real rare case. We don't see

too many too-horrible-to-mention situations out there. Most of the time, when it's discovered by a surveyor and they bring it to the organization's attention, there's immediate remediation.

For those rare cases where there is an immediate threat to life, where there are identifiable violations, clearly identifiable violations of other agencies' standards, we have let them know that there were problems that should be addressed.

DR. JESSEE: There's a provision in the general administrative policies and procedures that states that when a survey identifies any condition that poses a threat to patient or public safety, he promptly notifies the president of the Joint Commission and the president or his designee promptly recommends to the Accreditation Committee, that the hospital be denied accreditation. This action by the president is reported by telephone and in writing to the hospital's chief executive officer and in writing to the authorities having jurisdiction.

I would not, however, guess that we have been exhaustive in trying to cover the authorities that might have jurisdiction. What we generally think of when we do that is the state licensing agency and the Healthcare Financing Administration.

I'm not sure how good we are about trying to hit

some of the other regulatory agencies that might have that jurisdiction in that particular case.

MR. TELFORD: On the topic of patient safety, I understand you look at an indicator like retakes. When you're looking at nuclear medicine diagnostic tests, do you look at any other indicators that your surveyor is going to be looking for that's not been nominated as an indicator by the hospital itself?

DR. McMANUS: The quality control --

MR. TELFORD: Well, we have a very narrow focus. You have the overall umbrella of quality of care. I don't know what the key phrase is to appropriately characterize what you're really looking for, but you're more or less looking for the fact that the patient got treated appropriately? Is the hospital running a good quality program?

Whereas, we're looking very narrowly at; was the patient administered the byproduct material that was prescribed and directed. Where our two spheres intersect, one area is retakes which you're probably more concerned with than we are. In terms of what we would think of as a misadministration; somebody got an overdose of material or not quite the proper dose, the wrong radiopharmaceutical, wrong patient --

DR. McMANUS: Let me try to respond to that. The

indicators that we look at are identified by the hospital, number one, as being the ones that they feel that they should look at to look at the care they are giving. These are usually sentinel events.

We base our review on the number of sentinel events that they've identified during a given period of time, usually 12 months before the survey date, and rate-based indicators which are, what's your percentage of retakes -- you mentioned one.

The sentinel event would naturally include anything as reportable to the NRC and it would be misadministrations or any accident that occurred -- wrong patient, wrong dose -- and in most hospitals, it's mandated that we look at these. You don't even have to ask them about that indicator.

The indicator is, did anything happen to any patient in nuclear medicine in the past year? We have to do that because we're required to do that; is what the response is by the hospital staff in nuclear medicine. It's the same way with radiation oncology.

We will say, now, you haven't had any sentinel events in the past year. Are you looking at anything else? We try to encourage them to develop rate-based indicators so that they can improve over a little bit from the previous year's rate.

MR. TELFORD: Okay, but the indicators, if I understand this correctly, are optional or are developed by the hospital.

DR. McMANUS: Right.

MR. TELFORD: They're not a list that the surveyor has in mind to look for.

DR. McMANUS. That's right.

MR. TELFORD: Rather, you're following the hospital's lead as to; these are the indicators. except for the ones like misadministrations.

DR. McMANUS: Right.

DR. JESSEE: The guidelines that we look for are; has the hospital developed indicators to encompass high volume, high risk, problem-prone aspects of the service that it provides? There is an assessment of the adequacy of the indicators that they've developed.

There's also -- in the medical staff chapter, there's a standard on risk management activities that requires the medical staff to participate in identifying areas of potential risk and the clinical aspects of patient care and safety, developing criteria for identifying specific cases with potential risk in clinical aspects of patient care and safety and in evaluation of those cases.

Correction of problems in risk and the design of programs to reduce risk, in that area, too, we will look at

which kinds of incident reporting systems do you have and how that information is being used by the medical staff to try to make revisions in policies and procedures to reduce the likelihood of having the same event recur.

MR. TELFORD: Since you're there looking at the whole hospital, do you always go to the nuclear medicine departments?

DR. McMANUS: Yes, we're required.

MR. TELFORD: Each survey team always goes?

DR. McMANUS: Always.

DR. JESSEE: Anything for which we have standards and for which the organization provides services, must be surveyed. That's where we get into some differences of opinion from time to time.

A large hospital in a southwestern state, which will remain nameless, has a diagnostic radiology department which they contend is not a hospital service; it is operated by a clinic which is in association with the hospital and physically in an attached building. But the diagnostic radiology department, all the employees are employees of the clinic and not the hospital. All the equipment is owned by the clinic and not by the hospital.

The hospital merely leases to the clinic, the physical premises in which the diagnostic radiology department conducts its activities. They recently took the

position with us that we shouldn't survey the diagnostic radiology department because it wasn't part of the hospital.

As you might expect, we got our lawyer and they got their lawyer and we had a long discussion about what is a hospital and what are the services? But that's the kind of issue that we're starting to see come up more often as organizations, for lots of reasons, try to separate out their pieces.

We've taken the position that there are certain core services that are integral to the operation of the hospital and that regardless of the contractual or organizational arrangements, that we will survey those services when they are located on the premises.

That's a tough area for us.

MR. TSE: You said that you looked at the misadministration in the nuclear medicine department. That's because the department must keep a record of misadministrations --

DR. McMANUS: Right.

MR. TSE: How about one patient in other department; do you look at one patient in the other area other than nuclear medicine?

DR. McMANUS: Do you mean in the operating room and the wrong kidney?

MR. TSE: Maybe somebody got wrong pharmaceutical.

DR. McMANUS: Sentinel events, errors in medication, always are parts of the survey. The nurse surveyor would be looking at medication errors related to the nursing part of the survey and we would be looking at the operating room sentinel events, anesthesia sentinel events, et cetera.

MR. TSE: So there are some standards or some -- I do not want to say requirements -- or consensus or something -- the hospital is keeping record of those?

DR. McMANUS: Yes. They are either state mandated or Medicare mandated or there is some mandate relative to the events, yes, sir.

MR. TSE: Thank you.

DR. JESSEE: Keep in mind that our principal focus is looking to see what was the institutional response to the event. Did they take steps to assure that this -- to evaluate why this event occurred to reduce the likelihood of the same event recur in the future? I mean, we take the perspective that you're never going to have in a human system, zero defects, but that the characteristic you're looking for is the reduction of systematic error and the analysis of defects when they occur to try to reduce the likelihood of having the same defect occur in the future.

MR. TELFORD: In other words, you don't really have a standard that you compare a frequency of occurrence

to, of a particular type of mistake; rather, you're looking for a way to fix that? You're looking for a cause and a program or procedures to fix that type of mistake.

In nuclear medicine diagnostic misadministrations, about 60 percent of those are -- we see -- are the wrong radiopharmaceutical.

DR. JESSEE: Wrong in terms of different than the pharmaceutical that was ordered?

MR. TELFORD: Yes.

DR. McMANUS: We have that in blood transfusions also that certainly is reportable and certainly reviewed during the survey, so those kinds of things are part of the survey.

MR. TELFORD: Another thing we see a lot of is the wrong patient.

MR. KEIL: What do you mean about a lot of?

MR. TELFORD: As a per cent of, of what we have reported for instance in diagnostics, it's approximately, if I recall the figures correctly, it's approximately 60 percent of the ones reported are wrongly pharmaceutical. I believe around 12 percent are the wrong patient but that's not our real interest.

MR. KEIL: What kind of absolute numbers are you talking about?

MR. TELFORD: 400 in nuclear medicine diagnostic

misadministrations per year.

DR. JESSEE: Do you have any idea what the denominator is, how many administrations of nuclear medicine diagnostics take place annually?

MS. CARROLL: 7 million, you stated here, an estimated 7 million diagnostic procedures performed annually.

MR. TELFORD: But that is not really -- the rate is not really our concern. I think Dr. Tse brought up the term "standard" to find out if you utilize any absolute standards that you may be perhaps willing to say that amount is low enough. You see, the NRC has applied what is called safety goals in the area of reactors.

For instance, if given Reactor A, that reactor must be safe enough such that probability of a person living in the immediate neighborhood of getting cancer from that reactor is a tenth of a percent of all other sources; similarly for death, a tenth of a percent.

In other areas the Commission has adopted a safety goal. Now it gets very complex as to how that is applied but that's not really our concern.

Our concern is -- you know, that was a question that we wanted to find out because we'd been asked -- are we really talking about prevention or are we talking about minimization?

We are talking about prevention.

Now it's prevention with a program that is there to prevent. We realize that zero is not attainable but zero is the goal.

So it would be first of all interesting if you have a standard that you use but secondly the rate is not the driver, not the major motivator.

Our issue is protection, adequate protection of the public and currently we're saying to all licensees you have to report these misadministrations.

It's sort of a tenuous argument that you could say we're currently doing our job, which is protection of the public. What we see is there's a need for something more than just reporting, especially if you look at the types of events or whatever you want to call them that occur.

I mean a thing like the wrong pharmaceutical, the wrong patient for gosh sake -- it seems like somebody should say, gee, don't you think you ought to try not to do that?

DR. JESSEE: Yet whether it's the surgery that's performed to the wrong patient or radionuclides that's administered to the wrong patient, I would venture that for every one of those incidents the cause is different in each institution, that there has been some other -- and if you did a fish-bone diagram and tried to back up the what with what were the processes that led to that misadministration

you are probably going to find different problem sets.

The focus of what we are doing is trying to look at what is the institutional response? Did they take this event and use it as a kick-off to try to analyze how their policies and procedures might be revised to minimize the likelihood of having the same error recur.

It's taking the perspective that the science right now is inadequate to allow one to set a standard for what an acceptable rate of misadventures is, but even what little information there is about the normative rates would indicate that the frequency of these events is so rare that on an institution-specific basis, you just have to observe them for a period of many, many years before you had enough events to tell you that there was any statistical significance to the frequency in that institution.

Therefore we have taken the perspective of looking at each one of those events as a simple event and trying to, taking the perspective that our interest is in what the institution does to prevent some of our recurrences.

MR. TELFORD: We agree. I mean that's sort of our thrust too, is to say what is the procedure that you could put in place to prevent reoccurrence?

When we look at the -- for the Federal Register notice we did an analysis of the events that happened from '80 to '88 and since then we have looked at the '89 and the

'90, 1990, misadministrations.

There is a theme that keeps recurring, though, and three things come to mind. One is the person just was not paying attention to detail or not paying attention at all.

For instance, you might have a patient that is supposed to get a therapy dose to the lung with an external beam. Technician just assumes, oh, I'm going to give it to the patient's brain today. They don't look at the treatment chart. It's just fairly gross, you know, gross inattention to detail.

Or worse yet, you find there are no procedures for quality steps at this institution. They either are totally inadequate or just don't exist.

Thirdly, supervision -- just really inadequate supervision or not at all. I mean we had cases of an x-ray tech that's on weekend call. The supervisor is at home. The tech calls and says, look, I've got this patient to do this, what do I do? They get some coaching over the phone. You know, in preparing the kit and using the generator it's all messed up.

You don't have to have very much science to do an analysis of the things that have occurred and come away with those three very, very clear trends that are there.

We are trying to concentrate on those things in this rule-making that are the large drivers of the kinds of

mistakes we see so that we want to be able to go back to our commission and say, okay, we do have procedures to address these sort-of clearly known causes.

The question about the absolute standard is an interesting question.

Perhaps one day we will all arrive at something.

DR. JESSEE: One thing that we are doing is, and this is a mid-'90's objective, is trying to begin to take certain indicators and use them in all hospitals and ask them to submit data to us on the frequency of those events so that we can at least tell what is the distribution, what is the normative behavior, how wide is the distribution on this event and feed that information back.

Our expectation is if a hospital finds itself at the 90th percentile on the distributions of an important event that they will want to do an analysis of why there's such an outlier even though that particular performance may be solely related to random variation in that reporting cycle. Nonetheless, if you are that far out on the distribution it's worth analyzing.

The problem we have run into is that many of the events that you would really like to be able to profile occur so rarely as to make it not statistically meaningful to profile it so we're treating those as simple events.

MS. CARROLL: This is addressed in the quality

assessment improvement standards, of which you have a copy, the proposed standards for 1992 but it is also addressed in slightly different terms in the present quality assurance standards in the manual with reference to the need for monitoring in the evaluation.

DR. JESSEE: I have to excuse myself --

MR. TELFORD: There is an interesting analog that was brought up in a public comment letter, that being the patterns of care study.

The writer was I think trying to say that if you look at the institutions that are I won't say appropriately but -rib well staffed and terribly well equipped that are better equipped and better staffed, if you look at their cure rates, it's a lot higher than those that are not.

The writer went on to say that look at the institutions that are reporting things like misadministrations. It's the same institutions. It's not the fact that they have got a bad program but in fact, one wonders --

DR. JESSEE: They have enough staff and enough good programs to detect these problems as they occur so what therefore of the institutions that are located in the outback of Michigan or some other small state -- I mean, you know, less densely populated state, and fairly understaffed or underequipped department, are they reporting?

The false negatives are of much greater concern. They are probably not even aware of the event. That's the one you really worry about.

MR. TELFORD: Yes, sir.

DR. JESSEE: In our efforts to try to develop some indicators that we can compare nationally, one of the key problems we've run into is trying to develop reliable data.

We have thrown out a number of indicators that we thought were quite important simply on the grounds that we decided we simply could not collect reliable information, that it was too subject to recognition and reporting in the medical record and if it wasn't recognized and reported then there was no way in the world you were ever going to be able to collect information.

Adverse drug reactions is a classic. There are probably many more adverse drug reactions that are never reported simply because those are not recognized as an adverse drug reaction.

I am much more worried about the place where it isn't recognized than I am about the place where it is recognized and dealt with.

MR. CAMPER: Just a quick question for you before you go, Dr. Jessee.

It's been mentioned that if your inspectors identify problems that cut across federal regulatory agency

concerns like OSHA for example, you notify those agencies.

Do you in fact currently carry out any inspection process for federal or state agencies at this time?

DR. JESSEE: Not for -- no.

MR. TELFORD: Sir, in concert with HCFA which is HHS but not really for, you're saying?

DR. JESSEE: Right. I mean there's no contractual relationship even with HCFA. There is a statutory requirement on HCFA to rely upon our findings and in carrying that out we worked out an information sharing arrangement but there are no other agencies with which we have a similar kind of relationship -- unless you want to count the Department of Veterans Affairs and the Defense Department.

We tell them everything we find in all our hospitals.

MR. TELFORD: For the VA hospitals.

DR. JESSEE: Yes, and the Defense Department. We have 160 - 168 DOD facilities and about 145 VA hospitals.

MR. TELFORD: And those are licensees too.

DR. JESSEE: You mean VA wasn't exempted?

MR. TELFORD: No. They have every piece of legislation we see --

MR. KLINE: As far as medical, nuclear medicine license or NRC license, yes. The VA is exempt from the

fees.

DR. McMANUS: How about abroad? Do you have federal hospitals abroad?

MR. KLINE: They are not included in your statement, abroad, unless it is a U.S. territory. Military bases.

DR. McMANUS: Do we survey those?

MR. KLINE: Yes and no. It gets more complex over time as for example the Air Force, the Navy, the Army.

The Air Force has and the Navy currently just started what they call a broad scope program of their own which over the years we have I guess had a dialogue ongoing with let's say the Department of the Navy which was focusing on their ability to conduct their own activities, to do their own inspections, and follow NRC requirements in their own statute.

Finally the Navy proposed a program by which they issued permits which are very similar to our licenses and they started their own program, which minimally met our standards but often would exceed them.

The Air Force also does this. The Army does this.

The NRC does do inspections at these programs but we rely as the NRC would with an Agreement state, which we also have inspections in Agreement state programs that that data they feed us as it would be indicated from a hospital

is correct and we do periodic inspections for team, group inspections to verify that the information that they are collecting and the way that they are following our minimal guidelines is appropriate.

We do still as with the Agreement states have jurisdiction in those areas though we exercise the vested authority and allow them to run their program as they see fit -- if that makes sense.

MR. TELFORD: One final question, Dr. Jessee. In theory, you say you have worked out information sharing with HCFA and the Department of Defense and the VA.

Is information sharing like inspection reports? Is that in theory possible, say, with the NRC?

DR. JESSEE: It is in theory possible, yes.

MR. TELFORD: Okay.

DR. JESSEE: Again, it's -- with HCFA it's been made easier by virtue of the fact that the Social Security Act was amended in '88 -- right?

MS. SCHUMACHER: For '89.

DR. JESSEE: Oh, for '89, to permit HCFA to have access to any information we have about an accredited facility which relied upon its accreditation for deemed status. That made it very easy.

That way we can say to our customers, if you will, the hospitals -- that anything that HCFA asks for we have to

give.

On the other side of the coin, HCFA does not want everything we have because if they had everything they would have to buy a new place to keep it and secondly, they would be in the uncomfortable position of having to theoretically follow up on every problem we found.

They would just as soon not be in that box so it's been a fairly symbiotic relationship. We worked out an arrangement where they are comfortable that we are alerting them to high risk situations.

That permits them to carry out their public responsibility and at the same time enables us to maintain a good working relationship with the organizations that have agreed to seek voluntary accreditation.

MR. TELFORD: Okay.

DR. JESSEE: I am going to try to return this afternoon, but you all can continue.

MS. CARROLL: Yes, I am looking forward to the -- well, it's really the item that you have listed for 10:30 after the break, discussion of elements common, a sort of cross-walk.

I would like to do that.

You have in your handouts a copy of the next proposed version of the quality assurance standards not yet in effect. It is out for field review but I thought we

might look at that as part of the model and then your material, which I found very interesting.

MR. TELFORD: Okay. Would you like to take a break?

MS. CARROLL: Yes, I think it's a good idea.

MR. TELFORD: Let's take a five minute break.

[Recess.]

MR. TELFORD: Let's go back on the record.

MR. KEIL: Using your numbers, you've got an error rate of about 57 in a million?

MR. TELFORD: Well, you can estimate the error rate. We've, you know, various things like in diagnostics or in therapy, we tried to objectively say in the Federal Register Notice back in January that these are the estimates. One could be suspicious about the numerator or the denominator and recognize that it's kind of fuzzy data, but pick a number, I mean, one in 10,000; one in 100,000, whatever you like.

MR. KEIL: I'm not going to argue about the absolute numbers. But the relative order of magnitude of error is small.

MR. TELFORD: Okay.

MR. KEIL: Okay. That's a fair statement.

MR. TELFORD: Okay.

MR. KEIL: And in some of the stuff that you've

got here, you have said that you think a QA program is the best way to remedy that.

Why do you believe that?

MR. TELFORD: Oh, because the errors, you can collect into three categories for almost all of them that you see, either inadequate or no supervision, inadequate or no procedures, or simple inattention to detail. The technologist made an assumption that could have been easily refuted had they even looked at the chart at all. So that the mistakes that are made are simple, I mean they're gross, they're super-obvious, so that those kinds of mistakes lend themselves to a quality assurance or quality management kind of solution. You just look at those and it jumps right out at you.

The other thing is, you look at what's currently happening around the 6,000 facilities across the country. Whenever these misadministrations are reported, the inspector shows up and says, we got your report, we understand you had this event, what actions are you going to take to prevent recurrence? And you can look at the actions proposed by the licensees themselves for events that happened in teletherapy, brachytherapy, and nuclear medicine therapy and nuclear medicine diagnostics. And it comes down to those same three things. More training for the folks, sitting them down and counseling them and telling them,

okay, here's the procedure, you will follow it; or, if it was an inventive kind of mistake, such that it escaped the procedures, it wasn't being addressed by the procedures, they fix the procedure, they modify the procedures; or, if it's a supervision problem, then they just fix that.

So you can pick up the solutions that have been proposed by the various licensees, and it's the same, same trends, same solutions. It's, I would say, really very obvious.

The only other thing is that see, our role is pretty simple. If the byproduct material is administered as prescribed or as directed, then we're happy. That's really the purpose of our program.

MR. Van SCHOONHOVEN: Whether it's indicated or not?

MR. TELFORD: See, the indication is up to the physician. If the authorized user decides to give 10 microcuries of I-131 to a patient, if 10 microcuries are administered, we're happy, regardless of whether 10 microcuries are what should be administered. That's the physician decision. We want to stay out of the thought-making process, the thought processes of the physician. They get to decide what to do. That's what they're license do to.

MR. KEIL: So you're looking at the mechanical

aspects of it, in the sense that --

MR. TELFORD: Yes. If 20 millicuries are administered to this patient, yes, we think that's not so good. We think that that's something that should not happen. So we say we'd like each institution to have a procedure to prevent that, to make sure the byproduct material gets administered as prescribed.

MR. Van SCHOONHOVEN: Do you have a profile at all on places where you see this type of misadministration?

MR. TELFORD: By profile, do you mean a description of the --

MR. Van SCHOONHOVEN: Big place, medium, small, rural, urban, parts of the country, doctors offices?

MR. TELFORD: Actually, I could review for you the cases that we have seen, most of them in '89 and '90. And they're not the small, out of the way places; they are the hospitals --

MR. Van SCHOONHOVEN: So there is no set pattern at this point in time?

MR. TELFORD: I don't see any set pattern. I don't think we can say that it's --

MR. Van SCHOONHOVEN: A busy, big place.

MR. TELFORD: Busy, big places, that's a good suspect. It depends on the place, of course, and how hard they're trying already. But it's not a case of saying oh,

the rural community hospital, that's the real problem. I don't see that.

I mean, as a matter of fact, you could be very suspicious about those programs that aren't well-staffed and well-equipped with a lot of procedures to make sure that material is administered as prescribed. You're suspicious of if they detect these mistakes are not.

MR. KEIL: Why do you believe that that number, whatever it is, that small number, represents something greater than background noise?

MR. TELFORD: Oh. I don't even ask any questions about that rate. The rate is not the driver. It's not an issue. I mean, the Commission publicly has acknowledged that, in general, most hospitals are doing a great job. That's not the issue.

The issue is, if you look at what's happened, and you say, if I ask myself the question, am I doing my job; and what am I doing? I'm saying okay, if you make a mistake, you have to report it. Is that protection of the public? No. I'm coming around, after the horse has jumped out of the stall, and I'm closing the door. You know, I'm coming around after the fact and saying oh, you had a mistake; what are you going to do to fix it?

And if you iterate through the 6,000 facilities, on teletherapy; iterate again on brachytherapy; iterate

again on nuclear medicine therapy; iterate again on diagnostics, you could be there a long time. I don't think that's anywhere near effective, anyway near the way you ought to approach a problem.

You ought to just say, look, it's clear that some hospitals have QA programs, and they're pretty good, you know, very good. Others, it's clear, they don't have programs at all.

So the second thing you should say --

MR. KEIL: But are their outcomes any worse?

MR. TELFORD: It's the false positives I'm worried about. I mean, if, in a well-equipped, well-staffed department, these mistakes still occur, what's happening at the ones that are less so?

MS. CARROLL: False negatives.

MR. TELFORD: Well, the nonreporting of misadministrations. I mean, a positive being a positive indication they had a misadministration. I don't have any feel for --

MR. KEIL: Let me -- I'll tell you what the general concern is. You're working with such small numbers that, at best, if you have an occurrence, and they report it, and you come back, and you say look, you have to change this because you didn't have a policy that looked at that. Let's say it's a medium sort of average, whatever that is,

type of place, where they do X number of thousand average profile administrations in a year, and they never had one of these before. All you're doing is making a scientific wild-ass guess that it might prevail in the future. And there's a lot of work --

MR. TELFORD: Oh.

MR. KEIL: -- in the department. Because let's say they've been doing this since 1960, and they never had one like that before, now they've got a misadministration. Now, we're going to add a new step, we're going to add a new procedure, we're gong to add a nw monitor. But that monitor's value is that it indicates something once in 30 years.

MR. TELFORD: No, that's a misconception. You see, all we're saying is, that licensee has been doing this procedure since 1960, for 30 years now. As far as they're concerned, they've never had a problem. What we're saying to them is okay, you tell us what you're QA program is, to prevent misadministrations. They may already have one. Whatever they have, it seems to be working. They submit their QA program, they get licensed, they go on with business.

We didn't add any monitors. See, this is a performance-based rule. We're only saying to each licensee, you shall have a quality assurance program, or whatever we

call it. In the rule, we list eight good things to do. But each licensee says, here's how I'm going to address each of those.

So, they get to define the program. It's not like we're telling them to do these 12 things or eight things, whatever the case may be. We're just saying, you need a program; everybody needs a program; everybody needs to come up to these minimum sufficient standards.

So as far as that particular licensee is concerned, the QA rule, you know, this licensee could be completely transparent to this QA rule; it could have no effect at all.

MR. KLINE: One other point we might want to talk about, currently we realize that the total number of diagnostic and therapeutic misadministrations per year reported is relatively small.

MR. KEIL: What do you project the underreporting rate is?

MR. KLINE: Well, I won't address that. But we look at trends, we look at this past year, twice the number of therapeutic misadministrations to date than we had last year, therapeutic. But we also look at the tremendous resources the NRC spends in fixing, reviewing, documenting, remedial action sorts of things that are ensuing, pursuant upon the receipt of a misadministration report, and

particularly therapeutic. It also could apply to multiple diagnostic misadministration that provide more of an acute problem with licensees.

But the various regions do devote a lot of time and money reviewing each case and fixing, hopefully preventing that problem from recurring, by requesting that the facility institute some sort of mechanism by which this particular misadministration could be prevented in the future.

So with this ongoing large number of people at each region that are inspectors and license review people, that are fixing these problems, we've come to categorize these problems over time through our database and found that there were three or four major reasons for these problems.

And we feel that if there could be an element that addressed each of these items, though nonprescriptive, based on how the facility would like to address this broad topical area, not point on point, but broad, then that could save the agency and the licensee a lot of money, time, and effort, to allow them to maybe prevent these before they recur, because then they would have a program in place; not step backwards and have to fix things here, fix things there at Hospital B, fix things here at Hospital C, that are the same problems, in essence.

MR. KEIL: Well, just a philosophical point of

view. I think you're trying to regulate against stupidity. And everybody's got a God-given right. And although those events will fit into a broad category of misadministration, policy or procedure, the individual bits and pieces of that conclusion probably aren't too repeatable from place to place. And I don't think you'll see much of a decrease in the rates, because you have an increase in QA programs.

I still think these are random; my personal opinion, at this level is, you're dealing with random error, and it could come as a result of a new hire; it could come as a result of we got 50 people lined up in the hallway and I got eight doctors screaming at me, so hurry up and do all of these people right now. It's those kinds of pressures that defeat most QA programs.

MR. CAMPER: Well, the problem we have, though -- you're correct that it may be random error -- but the problem is, when you're an agency and you're charged with protecting public health and safety, and you read some of these incidents and some of the grave consequences that go with some of these incidents, the question we have to ask ourselves is which one of these random errors is acceptable, which one would you want to be? And our concern is that we take steps to protect public health and safety.

And at this point in time at least, the Commission has looked at this problem and said, we feel that there's a

need to pursue a rulemaking that would develop quality assurance programs and hope to prevent these things from occurring. Because in some cases, particularly with the therapeutic ones, of course, the consequences are significant. And while it may be random, it is no less significant.

And, as Mr. Kline pointed out, the idea to try to do something where you approach the problem across the board, not always reacting to individual situations, we don't know yet, obviously, if the quality assurance rule, if it comes to be, will reduce the number of misadministrations. We would hope so. But you're right, we don't know that for certain.

But on the other hand, the Commission looks at its responsibility and looks at these event that are occurring, and it says we feel there's a need to do something.

MR. TELFORD: May I add a comment here?

In part, you may be right, in that some of these are due to stupidity. But if you just read all of the misadministration reports for '89 and '90, just the most recent ones, you can't possibly come away with that conclusion.

Here we have many examples of just no supervision, at all. And that's not stupidity. That's a management breakdown. Those people just aren't running that department

very well.

And secondly, you see, no procedures at all for doing this. I mean, for things like when you stop a teletherapy treatment, somebody writes a note in the chart, you know. There are no procedures for telling the technologist to always look at the chart, at this point or that point. There are no procedures. That's not stupidity. That's not a simple, stupid mistake. That's just completely inadequate procedure on the part of the licensee. They're simply not trying to prevent that mistake. They're trying to do their job as rapidly as they can.

So, only in part do I agree with you. But in large measure, if you look at these, you just can't possibly come away with that conclusion.

And you see things like, you're supposed to get 100 or so of 123 and you get a large dose of I-131.

MR. CAMPER: So the question that's asked there is, when you go from 100 microcuries of I-123 as prescribed and a technologist orders 100 millicuries of I-131, the question there is, to what extent has the institution in question thoroughly acquainted that technologist with the difference between millicurie and microcurie quantities of I-123 or I-131. It's not only stupidity; it's a question of adequacy of provision.

MR. KEIL: It becomes an issue of education.

MS. CARROLL: Yes, but we're talking here basically about application of the principles of CQA, if anything.

MR. TELFORD: We also did a retrospective analysis of the cases from '80 to '88, with an old version of the rule. And in our estimation, 80 percent of those would have been prevented if these procedures were followed.

So, if I weren't certain that events like, this would be prevented in the future, I wouldn't have near the enthusiasm I have for wanting to do something like this.

MS. CARROLL: I have a very primitive and simple kind of concern about all this, too, having dealt with a lot of these issues of writing policies and procedures, on how can you ensure that personnel are going to follow them.

I mean, it's more than just having a procedure.

MR. KEIL: What I was kind of leading this all around to i a bigger question: did you consider some alternatives, say for instance, requiring a couple of hours of annual continuing education for all the people that work in the department?

MR. TELFORD: That's a related issue of training, qualifications, that we're pursuing separately at this time.

We have an advisory committee, the Advisory Committee for the Medical Uses of Isotopes, and we had a meeting with them last Summer. And we asked their advice on

the need for any training and minimum qualification requirements. And they were not convinced that they were necessary. So they asked for us to bring some information, some data that shows the magnitude of the problem.

So we're collecting that. But you share the same kind of, I don't know, gut feel, or interest that many other do that we've talked to, throughout this rulemaking. And many, many people have told us, look, if you want to have a big impact here, you really want to make an improvement, make sure you got qualified people.

MR. KEIL: At least trained.

MR. TELFORD: At least trained, yes.

MR. KEIL: Policies and procedures and systems of administering things, in and of itself, have very little to do with outcome. It's whether or not people know and use them.

MR. TELFORD: That's essential.

MR. CAMPER: The trained personnel question, in nuclear medicine, in particular, poses a concern that I have and some others have in the agency. And that is, we are continuously hearing that there is a reduction in the number of certified individuals that are out there. And we understand that. But we don't see a related reduction in the number of procedures being performed. The question that goes begging then is, who is handling the radioactive

material? What is the training and experience of those individuals? And what bearing does that have on the number of misadministrations that occur or the number of violations that occur?

At this point in time, we don't know the answer to that. But we are going to do what the advisory committee has asked us to do, and that is, over the next couple of years, continue to gather information, not only as it relates to misadministration, but also to violations, and see if there is some relationship in that regard. There could well be. It could be that training and experience is a significant factor. But it is certainly a very interesting question if you stop to think about it.

MS. CARROLL: Are we ready to move on to the crosswalk, or do you want to break and have lunch and then do that?

MR. KEIL: It's 12:00 O'clock.

MS. JEWETT: Can we talk about the schedule a minute, how we're going to catch up? Some of us were questioning the 5:00 O'clock --

MR. TELFORD: 5:00 O'clock; we're here until you want to stop talking.

MS. CARROLL: Well, I realize you have other commitments. And the crosswalk, I'll be glad to give you my summary of it.

MS. JEWETT: That's fine. No, I just wanted to know if we should talk about if there's going to be any adjustment. I would like to know now if we are going to adjust it, just so I understand.

MR. TELFORD: Is it safe to say that we would proceed through the agenda?

MS. CARROLL: I'm playing this by ear. You know, as I told you on the phone, I don't know how long. But we're available.

MR. CAMPER: I would suspect that we'll be able to adjourn at 5:00, as per the schedule.

MS. JEWETT: Okay.

MR. CAMPER: I would suggest that we go for half an hour to 12:30 or so, and then break for lunch.

MS. CARROLL: But lunch is being served, even as we speak, in another room.

MR. CAMPER: I see. Yes, we're flexible.

MR. TELFORD: You're saying it's highly advisable to break for lunch now?

MS. CARROLL: It sure is.

MR. TELFORD: Well, let's do so, then.

MS. JEWETT: Can we work through lunch?

MS. CARROLL: Yes.

MR. KEIL: We're used to talking with our mouths full.

MR. TELFORD: We do have a recording problem, though.

MS. CARROLL: Yes. The transcriptionist would have to set up.

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

[Discussion off the record.]

[Whereupon, at 11:55 a.m., the meeting was recessed for lunch, to reconvene the same day, Monday, December 17, 1990, at 12:57 p.m.]

A F T E R N O O N S E S S I O N

[12:57 p.m.]

MR. TELFORD: Let's go back over the record. Let's pick up with the item of discussion of elements common to the -- the post QA rule and the JCHO requirements.

MS. CARROLL: Right.

MR. TELFORD: You've referred to that as the crosswalk?

MS. CARROLL: Yes, a sort of crosswalk.

MR. TELFORD: We have a --

MS. CARROLL: You have a document.

MR. TELFORD: We have an outline of that crosswalk that we handed out to everybody, where we have, on the left --

MS. CARROLL: I'd like to point out though, too, that it's a partial crosswalk because you didn't include our quality assurance or quality assessment and improvement check.

MR. TELFORD: Yes, we meant this to be a beginning of the point of discussion where --

MS. CARROLL: Okay.

MR. TELFORD: -- on the left we have the section 35.35 objective, and in the right column we have the -- the JCHO standards. So, we suggest these as places to start. That way we can look at what the objective says and you can

tell us -- you can discuss with us what these standards, what they say and what they mean and then add others that would be applicable to this objective. We mean this as a start of further discussion.

In the proposed 35.35 we had 8 objectives as the 8 good things to do. You'll notice here that we have 7 listed on this page. Now, the eighth one applies to the therapy, the planning of brachytherapy and teletherapy. So, we've restricted this outline to -- to diagnostics.

So, let me suggest that we just go one at a time and I can tell you what we meant by the objective and then you can, if you would, review these standards with us, what they -- what they really intend, and others as you think they are applicable.

MS. CARROLL: Would you like me to introduce this gentleman?

MR. TELFORD: The gentleman who has joined us, I would like for him to introduce himself.

MR. WIEDEMAN: My name is Darrel Wiedeman, I'm with the NRC Region 3 office, here in Glen Ellen, Illinois. I'm the Technical Assistant to the Director for Radiation Safety and Safeguards.

MS. CARROLL: How do you do. I'm Jean Carroll, Director of Standards Development for the Joint Commiss on.

MR. KEIL: I'm Ode Keil, I'm Director of Plant

Technology Management, to show you how well you play with your toys.

MR. WIEDEMAN: Glad to meet you.

MS. CARROLL: Dr. James McMannis.

DR. McMANUS: Jim McMannis.

MR. WIEDEMAN: Glad to meet you.

MR. TELFORD: Welcome.

MR. WIEDEMAN: Thank you.

MR. TELFORD: Okay. The first objective we thought of as a necessary first step, someone needs to make sure that the by-product material, if it's going to be administered to this patient, is really necessary. Typically, this is the step that the physician takes, the authorized user, to decide that this patient should get by-product material.

DR. McMANUS: Did you all do the -- the crosswalk?

MR. TELFORD: The listing of standards?

DR. McMANUS: Yes?

MR. TELFORD: We had help.

DR. McMANUS: Oh, because -- let me -- let me just say that NM4 addresses the number 1 better than any of the others; and that is that the appropriateness of the use of the medication is evaluated.

MR. TELFORD: Okay, now, you said appropriateness?

DR. McMANUS: Right. That's --

MR. TELFORD: This objective just speaks to -- to whether it's -- it's necessary.

DR. McMANUS: Yes, that's what we say, for appropriateness. The appropriate use is over-utilization or under-utilization or just right on the money. Therefore, if a department is looking at its indications for the use of various things, we would score under NM4. That would be that -- as part of the hospital's quality assurance program -- the quality and appropriateness, so that would be underlined there.

MR. TELFORD: Have you changed the statement of NM4?

DR. McMANUS: In '91?

MR. TELFORD: What I have is -- as part of the hospital's quality assurance program?

DR. McMANUS: Right.

MR. TELFORD: The quality an appropriateness --

DR. McMANUS: Right.

MR. TELFORD: -- of diagnostic or therapeutic nuclear medicine services are monitored and evaluated --

DR. McMANUS: Exactly.

MR. TELFORD: -- in accordance with standard QA3 -- -

DR. McMANUS: Right.

MR. TELFORD: -- etcetera?

DR. McMANUS: Right. It refers you to a process as -- as the process begins, with assigning responsibility and identifying important aspects of care or services.

MS. CARROLL: You'll find that on -- in the quality assurance, quality assessment chapter, beginning on page 6, the monitoring and evaluation.

DR. McMANUS: That's a gereric list of things to do for all departments and services. Some surveyors survey this standard first then go in and say, show me how you're reviewing the quality and appropriateness of nuclear medicine services. What are you looking at and how are you assessing it?

So, indications for the use of the nuclear medicine would be graded 50 percent of that score; the other would be on how well is it done in terms of show me ways in which you've improved or ways in which you've assessed the quality of the services that you've provided. That mostly has to do with the interpretation of imaging rather than -- and correlation with other things going on in the hospital rather than set events; but a lot of them are looking at some the events, as I said.

MR. TELFORD: Do you use anything like an examination of the patient or the patient's medical history as an indicator for any of these?

DR. McMANUS: If the hospital uses the patient or

the clinical history, we would take a look at that, yes.

You mean the weight of the patient, the size of the patient?

MR. TELFORD: No, I mean, as an indicator -- as an indicator that something like this -- this necessary step is happening?

MS. CARROLL: Look at the diagnosis, you mean?

DR. McMANUS: Why do you say look at the patient? Isn't that the -- the list of indications would be that the patient has to have these indications before you would --

MR. TELFORD: As indicators, that you might survey?

DR. McMANUS: What would be the indicator in that? That all patients -- let's see, that all patients who are receiving this therapy meet these criteria.

MR. TELFORD: That all patients, either you look at their chart, their clinical history or you examine the patient. That might be the indicator.

DR. McMANUS: The indicator would be that no patient receiving this therapy doesn't have some physical evaluation and review of the history.

MR. TELFORD: Or review of the history, yes.

MS. CARROLL: Oh. I didn't understand that that was what you meant when you used the word "indicator." I thought you were talking about our type of indicator, you

know, the -- the percentage of occurrence of a given, let's say --

DR. McMANUS: This could be an indicator. If you said that 100 percent of patients would have to have their history and physical examination reviewed and documented.

MR. TELFORD: That's what we mean --

MS. CARROLL: Okay.

MR. TELFORD: -- that the use of the by-product material was necessary for this patient.

DR. McMANUS: You see, the indicator requires some quantification.

MR. TELFORD: Yes.

DR. McMANUS: So, you would have to add something to that history and that physical, when you say look at the patient. Because looking at the patient is part of the, you know, as part of the things that you do everyday. But you want to -- what you want to link is what, in that patient, do you want to see documented before the therapy is given.

MR. TELFORD: The key question we're asking here is when we wrote this proposed rule, we thought it was a good idea to ask has someone decided that this product, that this patient should get by-product material. So, our question to you is do you agree? Secondly, what standards do you have which addresses the same issue? So, now do you still say it's 4?

DR. McMANUS: Yes.

MS. CARROLL: Yes.

MR. TELFORD: Okay, it's still 4?

MS. CARROLL: And also QA3 and 3.1, which address the same issue.

MR. TSE: Your 4 is the evaluation after the fact -- after, meaning after the treatment or diagnosis is completed, or it's before?

DR. McMANUS: All right. Let me address it. Suppose the indicator indicates to the hospital that there's something wrong, okay, with this evaluation that they're doing, then the policy or procedure would be adjusted and changed so it would work proactively for the future. But until you do the study, until you do the ongoing review, the results cannot be used to change policy and procedures.

I mentioned, at a misadministration, having 1 person give a dose to the wrong patient, why not have a second person say, oh no, that's not the right patient. In other words, we've changed our policies and procedures, because now we want to double check it triple check it before we give it to the patient.

So if we found that, in studying these misadministrations, that only 1 person was making the determination as to who the patient was, we'll change our policies and procedures for the future. That's what you

want to put into effect. You want an outcome to influence -- influence process. The process would be changed to prevent that sentinel event from happening again.

The whole purpose here is to try to get the hospitals to evaluate this in terms of changing their process.

MR. TSE: But the evaluation -- still, the evaluation of the process you have done previously?

DR. McMANUS: The evaluation of the process is ongoing, for a year, let's say, after which we make a determination or, if it's a misadministration, you wouldn't need a year, you'd do it right away. Then you'd change your process. Isn't that what you're after?

MR. TELFORD: Yes, we agree with your -- you saw the statement of strategy?

DR. McMANUS: Right.

MR. TELFORD: That's what you're saying?

DR. McMANUS: Right.

MR. TELFORD: I believe we agree with that.

DR. McMANUS: Okay.

MR. TELFORD: But, see we looked at 2 -- 2.2.2.

DR. McMANUS: What about 3 and 3.1?

MR. TELFORD: Well, I guess what I'm attempting to do now is to give you some feedback as to how we are focusing on selected key words. 2.2.2, the access to and

availability of consultative, diagnostic and therapeutic nuclear medicine services regarding appropriateness and sequencing of diagnostic and therapeutic procedures.

Appropriateness of -- someone is deciding here that, based on information available, this is appropriate.

MS. CARROLL: The medical conclusion warrants this use.

MR. TELFORD: Yes. So that -- we're trying to say, okay, there's an element, excuse me, there's a standard that you have that's common to what we're addressing in this objective.

DR. McMANUS: All right. Now, we're going to have to asterisk it. In other words, we're going to have to increase its weight.

MS. CARROLL: Incidentally --

MR. TELFORD: Well, let's not reach that conclusion yet because, for this first crosswalk, let's -- let me suggest --

DR. McMANUS: Let's just look and see what we have.

MR. TELFORD: Let's look and see what we have. We don't want to imply to you that --

DR. McMANUS: I was just saying, that if we're going to say that the surveyor is going to look at this, we're going to have to then emphasize it.

MR. TELFORD: Yes, if -- if this one says in -- if objective 1 stays in --

DR. McMANUS: All right.

MR. TELFORD: -- then we would need to.

DR. McMANUS: All right.

MR. TELFORD: Let's come back to that because, as Mr. Camper alluded to this morning, I could describe for you the normal rule-making process, following administrative procedures act and then I can describe for you the process that we've been following for this rulemaking. To make a very long story short, you would see that we're going to 10 times as much effort, at least 10 times as much effort as we normally do. Perhaps double or triple that. I mean, it is an unbelievable amount of work that we're going through.

So, this particular one, or any particular one, we're already working on what the draft final rule shall look like, and so, let's don't say that this one will stay or go yet. Let's just see what we've got and see how we can relate the 2 sets of standards.

MS. CARROLL: Oh, I agree.

MR. TELFORD: Okay, so you've said to add 3 -- 3.1 and 4.0 as being applicable to objective 1?

MS. CARROLL: Yes.

MR. TELFORD: Pardon me?

MS. SCHUMACHER: Which ones, Jean, are we adding?

MS. CARROLL: NM3 and you now, the others that we sub-10 and under it, and NM4; isn't that right, Jim?

DR. McMANUS: Yes.

MS. SCHUMACHER: All under number 1?

DR. McMANUS: Yes.

MS. CARROLL: Yes. Under insuring the appropriateness of medical use.

MR. KLINE: Did you say also NM3.1 or just 3.

DR. McMANUS: 3.1 through 3.3.

MR. KLINE: Okay.

MR. CAMPER: The term "medical use." If we replaced that term with the words "administration of by-product material," rather than using the term, "medical use," would that have any impact on the comparability of our requirement or that objective with your standards? In the sense that, using the term "administration of by-product material," as compared to medical use, makes it far more specific. Do you see that as posing a problem?

MR. TELFORD: Maybe the other way to ask the question is, would it help your understanding of what we're trying to do if we ask you to make a translation there, when you see the phrase medical use, if you can interpret that as "administration of by-product material or radiation from the by-product material. That's what we're really after.

Okay, shall we move to --

DR. McMANUS: I guess I have a little problem with the -- with the by-product material. The definition of by-product material is always going to be constant?

MR. CAMPER: Yes.

DR. McMANUS: Okay. It's not going to vary?

MR. CAMPER: No.

DR. McMANUS: All right. Then I would agree.

MR. TELFORD: Are we ready to move to Objective Number 2?

Now, what we're trying to say in Objective Number 2, is that we have what commonly is referred to as the prescription for either teletherapy or brachytherapy or nuclear medicine, radiopharmaceutical therapy, let me say, or the use of greater than 30 microcuries of I-131 or I-125.

MS. CARROLL: Excuse me, but isn't a prescription always written for any of these administrations, regardless of the number of -- you know, the size of the strength of the dose?

MR. TELFORD: Not necessarily for smaller amounts of -- relatively small amounts of I-131 or I-125.

MS. CARROLL: Okay, you're differentiating between an order and a prescription, right?

MR. TELFORD: Yes.

MS. CARROLL: It would have to be ordered. It

sure would in any hospital.

DR. McMANUS: You could have a telephone order.

MR. TELFORD: Let me --

MS. CARROLL: But -- from a physician?

DR. McMANUS: Well, now, what they want is a written document that before any administration.

MR. TELFORD: Let me translate one more time, or maybe Mr. Camper wants to translate one more time for prescriptions.

MR. CAMPER: Substitute, if you would, the term written directive for prescription. The point then being that for 30 microcuries and greater of I-125 or I-131 would be looking for a written directive --

DR. McMANUS: Right.

MR. CAMPER: -- as compared, if you will, to say a diagnostic referral, which can, in fact, be a telephone request.

DR. McMANUS: Right.

MS. CARROLL: Eventually, wouldn't the telephone request have to appear in written form in the record?

DR. McMANUS: Well, what they're trying to do is make it more stringent, Jean. They say that the chances of it being misconstrued is greater over the telephone than it is when it's written.

MS. CARROLL: Fine.

MR. CAMPER: Dr. Carroll, you do raise a good point, in that I can tell you that even under the concept of a diagnostic referral, we have some interest in seeing that diagnostic referral documented, on the receiving end, by the institution that would be asked to perform the study.

MS. CARROLL: I'm looking at it from the standpoint of the consumer, you know, the patient, to whom all this stuff is going to --

MR. CAMPER: And, to some degree, so are we.

MR. van SCHOONHOVEN: The doctor -- the doctor, most of the time, doesn't know anything to order except a thyroid uptake.

MR. KLINE: You mean the referring physician?

MR. van SCHOONHOVEN: The physician.

MR. TELFORD: The referring --

MR. van SCHOONHOVEN: The practicing physician. He doesn't know how much iodine 131 is involved or anything else.

MS. CARROLL: Who decides then?

MR. van SCHOONHOVEN: That is the director's responsibility and it may be based on a bunch of parameters, such as the patient's weight, size, age, all kinds of things. So, to try to say that you have to have a prescription for each administration is wrong. It's prescribed the same as blood, it requires a physician's

prescription, but he writes the order on the chart.

DR. McMANUS: So, let me see if I've gotten it straight, Peter. What you're saying is that the prescription need not include the dose?

MR. van SCHOONHOVEN: That the average physician today is requesting for an imaging study of an organ, such as your liver, he does not prescribe the dose.

DR. McMANUS: He doesn't prescribe the dose.

MR. van SCHOONHOVEN: He doesn't know it.

DR. McMANUS: But it still · · it still represents a written directive?

MR. van SCHOONHOVEN: To me, it's a directive.

DR. McMANUS: Okay.

MR. van SCHOONHOVEN: That covers it.

DR. McMANUS: Okay, I'm satisfied too. The thing is, this is more stringent than our standards.

MR. van SCHOONHOVEN: Yes. If they want to put a blocker in or a benchmark, as I call it, that's perfectly all right, because they've got enough evidence to realize that when you hit 30 or more millicuries, they better know what the heck they're doing. So, they definitely want, instead of a protocol that the medical staff have agreed upon for so many microcuries of iodine for a thyroid update, they're going to start using this kind of dosage, then there has to be a physician's --

DR. McMANUS: So they're differentiating between less than 30 and more than 30?

MR. TELFORD: Let me explain 2 and 3. Because objective 2, we're after therapy, and 3, we're after the diagnostic procedures. That's what we're addressing. In 2, we're saying all of teletherapy, all of brachytherapy, all of radiopharmaceutical therapy and anything -- any procedure involving greater than 30 microcuries of I-131 and I-125.

Now, what you folks have been discussing here, Peter, is that they're diagnostic procedures. Now, that's objective 3. We call that a referral. The -- if you would, replace the word "prescription," with "written directive, signed by an authorized user physician for therapy."

In 3, it's a referral. In our proposed rule, we talked about a written referral, which not many people liked. So, what we're not thinking about is something that would be a telephone referral, where certain information is documented on the receiving end. As Peter said, the primary care physician may call the department, the nuclear medicine department and say, my patient should get a liver scan, gall bladder scan, thyroid scan.

Where we've seen difficulties arise, is somebody gets carried away or misspeaks and says, oh, I want an I-131 scan with caps. So, they'll think, caps, oh, I get those in a certain -- certain level of activity, so, oh, they must

mean, whole body scan, so they right that in there, you know, and that's what happens to patients, but that's not what they should have gotten at all. They should have been given maybe 100 microcuries of I-123, but instead they got 5 millicuries of I-131, or 1 millicurie of I-131, something quite different.

So, for referrals, think of objective 3 as addressing all the diagnostic studies, the requests for all the diagnostic studies.

MR. van SCHOONHOVEN: Make that very clear then that too, is therapeutic on not diagnostic because you're covering it then on the 3 -- diagnosis.

MS. CARROLL: It says, "for any therapy procedures."

MR. TELFORD: Yes, we'll fix the words. We agree with you.

MR. van SCHOONHOVEN: It's 2, therapy and 3 diagnostic.

DR. McMANUS: But you're not differentiating here between written and unwritten, either in 2 or 3.

MR. TELFORD: Are you going to give a written direction as being required which will have to be signed by --

DR. McMANUS: But are you going to specify it, because prescription is the same in 2 and 3.

MR. TELFORD: We're going to take prescription out of No. 3. We're going to talk about a written directive which is a written order signed by an authorized user as being required for No. 2.

DR. McMANUS: Okay. Then a referral for -- it would be for a diagnostic?

MR. CAMPER: A diagnostic referral; that's correct.

DR. McMANUS: You would take prescription out?

MR. CAMPER: Yes, that's correct.

DR. McMANUS: So, in short, prior to any medical use, that a diagnostic referral is made?

MR. CAMPER: Yes.

DR. McMANUS: Now, how would that be evidenced?

MR. CAMPER: There are primarily three ways that emerge: telephone, a written request or and electronic transmission.

MR. TELFORD: So certain information would be documented on the receiving end like the physician's name, the patient's name, some other means of identifying the patient, like date of birth, social security number, so that the patient can be redundantly identified, the clinical history, the requested study -- those are the minimum things that you would need.

MR. van SCHOONHOVEN: This is invariably done in a

hospital.

MS. CARROLL: It's covered in the medical records chapter.

MR. van SCHOONHOVEN: It's done with a piece of paper or a form that goes to nuclear medicine with what they want done.

MR. TELFORD: What about outpatients?

MR. van SCHOONHOVEN: It's the same way with outpatients, with a prescription blank. Usually they provide them with the forms or he uses a prescription blank on a policy that they've decided. In other words, you see, I want to see us say in there that there's written -- get off this phone stuff -- that there's something written on the service requested.

MR. CAMPER: Even for diagnostic procedures?

MR. van SCHOONHOVEN: Even for diagnostic. There's more goof-ups that occur because of misunderstanding of telephone calls, wrong patient and everything else. I always tell the hospitals, get some kind of a system. Either you provide them with the forms that you use in the hospital on hospitalized patients --

DR. McMANUS: But that's not what your standards say.

MR. van SCHOONHOVEN: I know they do, but you've got to get the intent. You don't necessarily have to have

the words, you work on the intent.

MR. TELFORD: Where would that come from? The authorized user at the hospital or from the referring physician.

MR. van SCHOONHOVEN: Referring physician.

MR. TELFORD: He would fill it out, but he's saying the authorized user could generate forms and give it out to the referring physicians and say, please use this.

MR. van SCHOONHOVEN: On non-hospitalized patients or even on clinic patients. Let me just check one thing with you fellows.

Is it a federal rule that only radionuclides, diagnostic therapeutics may be administered only with a physician's prescription? The FDA Bureau of Biologics has this for blood.

MR. CAMPER: The procedures must be requested by a physician.

MR. van SCHOONHOVEN: Okay.

MR. CAMPER: Now, the use of the term, "prescription" gets into the area of some confusion. Allow me, if I may, to make a point about the diagnostic referral versus the written prescription for diagnostic procedures. We have been told on a number of occasions that to require a written directive for a department of nuclear medicine to perform a diagnostic procedure, particularly on outpatients,

would impose a significant hardship on the normal operations and the conduct of the nuclear medicine imagining procedures.

They have told us repeatedly that many of their studies are ordered by telephone requests and that if we required a written directive, it would have a significant financial impact and the referring physicians would have a tendency to go to other departments of nuclear medicine.

MR. van SCHOONHOVEN: They can use a fax machine. They're starting to practice medicine over the telephone line too much. I'm on a soapbox on this now. It's a rare physician that doesn't have a prescription blank of his own or something available that he can fill out and hand to the patient.

DR. McMANUS: Are you recommending a written directive for both 2 and 3?

MR. van SCHOONHOVEN: Well, this is one way to get it covered that it must be documented, the request.

MR. TELFORD: Are you saying, in 3, use a written referral? What if the telephone was used for the referral, but you have a form that the person receiving the request has to fill in all of the blanks and check all of the boxes to get the minimum sufficient information on this end?

MR. van SCHOONHOVEN: I don't care; that's all right.

DR. McMANUS: That bothers me a little bit because the physician on the receiving end, the director, always has the choice of whether or not to do anything on any patient. You might say, I want this patient to get radioactive iodine for therapy.

The physician on the receiving end can turn that down, based on what he finds. I don't think that the physician -- I think the physician on the donor side should fill out certain specs also before sending the patient.

MR. van SCHOONHOVEN: That goes with giving the information.

DR. McMANUS: Absolutely. I think that that kind of form, more and more hospitals are requiring that kind of information to go down to radiology, nuclear medicine radiation before any tests are done.

MR. TELFORD: What we found is that a lot of people have told us that a physician is not on the receiving end; you have a technologist on the receiving end. Many nuclear medicine departments are operating under what we would call a standing order.

DR. McMANUS: For therapy?

MR. TELFORD: No, diagnostic studies, just diagnostics.

DR. McMANUS: All right, let's talk about therapy.

MR. TELFORD: Each department has a clinical procedure manual. So, for things like liver scans, thyroid scans, et cetera, the procedure is described there as to what procedure the technologist will follow to perform those diagnostic studies.

The technologist receives -- the receptionist or secretary schedules the patient. The patient arrives. As long as you get the right patient associated with the right requested study and the study makes sense and it's supported by the clinical history or the diagnosis or something and it matches something in the clinical procedures manuals so the technologist knows what to do and therefore is operating under the directive of the authorized user, then that's the way that we're trying to structure this so that we're allowing people to do business about they way they do it now, but put some hard facts down so that they know exactly what to do to document it on the receiving end.

Is that anywhere near sufficient?

MR. van SCHOONHOVEN: It's all in the mind of the beholder out there now. It's just like, I can talk personally and I can talk indirectly about family members and such. It never went on in some of the ways it's going on today in the past.

DR. McMANUS: Let's require that a written referral order is made, number one, on the donor side, and

not a telephone call and see what happens.

MR. TELFORD: We did that in the proposed rule. We got a lot of heat over that. Some people -- in our pilot program, we heard from our volunteers and some of them objected to that strenuously. Other said they went back home and during the 60 day period in which we asked them to try out the rule, they said, gee, we tried that written referral and it took me 30 days to ge it in place and it's working very well and I'm going to keep it. Now I know exactly what to do and that minimizes my mistakes. It's not universally accepted.

MS. CARROLL: One would think the hospital's counsel would recommend it.

MR. TELFORD: Maybe.

MR. WIEDEMON: A lot of the small cardiology clinics that many times 75 percent of their patient load comes from telephone referrals. That's the group that adamantly complained about the proposed rule and having something written before the patient walks in the door because they said that the patient will go see the cardiologist, the cardiologist decides, I'm going to send them over and have a MUGGA or a thallium study.

They show up at the front door without any papers. The physician calls and talks to the authorized user and that's when they determine what study they're going to do on

the patient.

MR. van SCHOONHOVEN: Then one of them at the location has signed something to go ahead with the study.

MR. WIEDEMON: Not always. Many times, the technologist takes the order. If the referring physician is very specific on what he wants -- it's so routine for the cardiology type scanning that, you know, if they order a MUGGA or a thallium stress test, they know exactly what to do and what dose to give. Many times, when it comes to cardiac problems, the authorized user, who is also a cardiologist in many cases, will make the ultimate decision on what type of study and how it will be performed, then it's documented.

MR. WIEDEMON: Or there will be a clinical procedures manual in the department by which the appropriate dose range and the clinical indications will be referenced by which the technologist --

MR. van SCHOONHOVEN: But there's a break in this link somewhere. You still can't give blood to anybody without a physician's request or a prescription for it.

MR. WIEDEMON: We've had some hospitals infer that if they were to incorporate a mechanism by which the referring physician issued a written directive and gives it to the patient and the patient has to bring it to the hospital, that that hospital would start to lose business

because the referring physician would not render services or refer this patient over to that hospital.

Therefore, in order to be competitive, they want it to stay with a system which was less incumbent upon the referring physician, less problems in writing this written directive.

DR. McMANUS: In your studies, how many of these problems related to the telephone order? The great majority?

MR. WIEDEMON: A great majority of the ones reported, yes. I mean, you get a lot of wrong radiopharmaceutical/wrong patient.

MR. TELFORD: Well, why don't we -- so what we're looking for is the documentation which says, this is the patient and here is redundant information on how to identify the patient.

DR. McMANUS: There's 2.2.1 here. Diagnostic and therapeutic nuclear medicine services performed at the request of individuals licensed to practice independently, authorized by the hospital to make such requests. We coudl use the scoring guideline and we wouldn't have to change the standard; that the request would be in the form of a written document.

MR. van SCHOONHOVEN: You see, this was put in here in all three standards we've been talking about, to

allow a hospital to provide this service for non-hospitalized patients of physicians who weren't even on their medical staff, if they wanted to.

It was put in to clarify that to avoid nurses making the request, lay people being able to make the requests and that type of thing. That's why the individual is licensed to practice independently.

MR. KLINE: You don't mind if we go farther than you?

MR. van SCHOONHOVEN: No.

MR. TELFORD: We sort of have a choice now. We can either recommend that the final rules say all referrals will be written, in which case the -- nobody will be able to say that they'll go to another hospital because every hospital will be subject to the same requirements, or we can, as we've been trying to do, develop something that we hope will be and believe to be sufficient, but somewhat less burdensome.

DR. McMANUS: All right, the score of 3 here; there's evidence of two or more incidents in which nuclear medicine services were performed without verbal or written requests of an individual licensed to practice independently. That could be changed very easily.

MR. van SCHOONHOVEN: While I think of it, look at NM 2.2.3. Now, this was put in to make sure that any

therapy was only performed by qualified physicians. If this turns out to be only the director of a given nuclear medicine services, then this is hitting right at him and he's the one that's accountable.

MR. TELFORD: What do you mean here by "qualified physician?"

MR. van SCHOONHOVEN: Qualified -- we talk of a qualified physician, in the glossary, as a --

DR. McMANUS: He's a doctor of medicine or osteopathy who, by virtue of clinical privileges granted by the hospital is permitted to perform a special, specific diagnostic or therapeutic procedure. He would have to be privileged to do this.

MR. van SCHOONHOVEN: That is a qualifier, because everybody isn't privileged to do the same things. He's qualified for these particular --

MR. TELFORD: This would be a radiation oncologist that's done teletherapy or brachytherapy.

MR. van SCHOONHOVEN: Right. The same wording is there for the radiation oncology.

MR. WIEDEMON: If a physician were named on an NRC license, would that be considered -- just that alone -- as being a qualified physician?

MR. van SCHOONHOVEN: Well, that's towards being a qualified physician. Again, are there any limitations or

what is it for? That's what it basically comes down to.

MS. CARROLL: Which one are you talking about here?

DR. McMANUS: 2.2.1.

MR. TELFORD: If I could recap on No. 3, what you've given us is a suggestion here that these, first of all, ought to be written referrals and, second, if they're not written, they ought to be standardized to a form and those forms ought to go out from the hospitals to the referring physicians such that the message is clear.

DR. McMANUS: If the information that is required to be filled out at the hospital is what's wanted, then I would think the same information should be forthcoming from the offices and outpatients as well.

MR. TELFORD: In other words, if both ends of the telephone conversation are looking at the same form; this is the information we want; do you think that information could be passed over the telephone?

MR. van SCHOONHOVEN: You open yourself up to possible violation in states there. It's that old story of; line 20 people up and start the wording at one end and what do you get out at the other end.

DR. McMANUS: It's always less likely if it's written than if it's on a telephone order -- something could happen like bone scan instead of a thyroid scan and if you

write a bone scan, you make that -- certainly, in a patient, if you want a thyroid scan -- but I think it's less likely to happen because there are two areas.

There is the person giving and the person receiving, so it's twice the risk.

MR. CAMPER: May I ask for clarification? This 30 microcuries, I take it, is a benchmark that you fellows have decided is an important benchmark?

MR. TELFORD: Yes.

MR. van SCHOONHOVEN: So you want to qualify these that you're specifically talking about anything in excess of.

MR. TELFORD: Yes.

MR. van SCHOONHOVEN: That's the key.

DR. McMANUS: But not 3.

MR. van SCHOONHOVEN: You're not going to get excited about 3.

DR. McMANUS: Yes, that's what we're getting excited about right now.

MR. van SCHOONHOVEN: It's more than 309 microcuries.

DR. McMANUS: that one, we've already asked for written. Now, we're talking about the one for diagnoses under 30.

MR. van SCHOONHOVEN: Not involving more than 30.

MR. TELFORD: Objective No. 3.

MR. van SCHOONHOVEN: Could you change that number? No, that wouldn't work.

DR. McMANUS: If we make a written prescription for both.

MR. van SCHOONHOVEN: Suppose you take that 30 out.

MR. TELFORD: And just say all I-131 and I-125?

MR. van SCHOONHOVEN: You wouldn't need it if we were going to have written for both.

MR. TELFORD: We're especially worried about I-131 and I-125 doses in the therapy range.

MR. van SCHOONHOVEN: Okay, therapy is the key. We're going to have that 30 cut on the therapy.

MR. TELFORD: Yes.

MR. van SCHOONHOVEN: Do we need even to mention it on the diagnostic?

MR. TELFORD: No.

MR. van SCHOONHOVEN: Well, then, let's take it out.

DR. McMANUS: Right.

MR. TELFORD: We agree. We'll just talk about diagnostic procedures and take out the --

MR. van SCHOONHOVEN: Thirty or more is the break point.

DR. McMANUS: I don't understand. Twenty-nine microcuries with a verbal order is not a good idea either.

MR. van SCHOONHOVEN: The guy doing it, he isn't going to be prescribing it, the average practitioner.

DR. McMANUS: But it might be the wrong patient.

MR. van SCHOONHOVEN: Okay.

DR. McMANUS: I don't think 30 is important. I think that the test is important. If it's injecting a radioactive material, a radiopharmaceutical material into a patient, why do we need to differentiate between diagnosis and therapy?

MR. TELFORD: The way that we would word No. 2 --

MR. van SCHOONHOVEN: I see your point.

MR. TELFORD: Maybe I missed it. Try it again.

DR. McMANUS: I don't think there's any difference.

MR. van SCHOONHOVEN: If 30 is the cut point, why worry about the difference between diagnostic or therapeutic and just say 30, whether diagnostic or therapeutic.

DR. McMANUS: You wouldn't use more than 29 for a diagnostic procedure?

MR. TELFORD: The way that we would word Objective No. 2 is to say that a written directive is made for A, Teletherapy, B, Brachytherapy, C, Radiopharmaceutical Therapy, D, any procedure involving greater than 30 --

MR. van SCHOONHOVEN: I see, diagnostic or therapeutic.

MR. TELFORD: Any procedure involving greater than --

MR. van SCHOONHOVEN: That's better.

MR. TELFORD: In No. 3, we would just say --

MS. CARROLL: Why not delete No. 3?

MR. TELFORD: -- that a referral is made for any diagnostic procedure.

MR. CAMPER: That gets you back to the point that Dr. McMannis was making a moment ago about having a written directive versus only a diagnostic referral for even a diagnostic procedure.

MR. TELFORD: Now if you wanted to say that you wanted a written referral, we could say that in No. 3. I think that's what you're really telling us.

DR. McMANUS: That's what we have to mull over.

MR. TELFORD: But we can fix the words, if you just settle on the idea.

DR. McMANUS: Well, we won't be able to settle it. We'll have to bash it around a little.

MR. van SCHOONHOVEN: We can go with what you came up with; it's good.

MR. TELFORD: All right.

MR. TSE: There's a question raised in some of our

meetings. How come a physician can call up a pharmacist and use telephone order to order a pharmaceutical for a patient; how come they cannot do it with radiopharmaceuticals?

MR. van SCHOONHOVEN: He still has to get a prescription blank.

MR. TSE: Right, but later, not at the time when they --

DR. McMANUS: I don't think they ever have to send in a prescription for a diagnostic scan, later. They can do it by telephone and that's it.

MR. TELFORD: Currently.

DR. McMANUS: Whereas a prescription, you need to follow up, or you're supposed to, by law, follow with a written prescription.

MR. van SCHOONHOVEN: The patient apparently goes in with the prescription to pick up what has been already ordered.

DR. McMANUS: Or the pharmacist will call you up and say, I haven't gotten the prescription yet on that patient.

MR. TELFORD: Can't a physician call? Can't a licensed physician call a registered pharmacist and say, I'm going to send Mr. Jones over and he needs this pharmaceutical. Not a regular pharmaceutical, but this pharmaceutical. He's coming from his house, you know. I

haven't seen him, but I've seen this patient before. Please give this patient that pharmaceutical.

DR. MCMANUS: Right.

MS. CARROLL: Then he also says to --

DR. HENKIN: Then he has to follow it up with a prescription.

MS. CARROLL: He always says I'll get the prescription in the mail tomorrow morning at the office.

DR. HENKIN: That can change. It's not required.

MS. CARROLL: Well, it may not be required, but all the doctors I know do it.

MR. TELFORD: It's probably true for a lot of states, but --

DR. HENKIN: Well, all right. I'm sorry.

MR. TELFORD: But it may not be true in all states.

DR. HENKIN: Okay.

MR. TELFORD: But what you're really saying is your understanding of an exceptional procedure for that would be that the patient be given the pharmaceutical, but that the prescription arrive in tomorrow's mail?

MR. van SCHOONHOVEN: The prescription is, yeah, as I'm dictating this over the telephone, I'm writing out a prescription that I'll put in the mail or I'll give to you tomorrow when I see you, or something to that effect. Or

I'll bring to the hospital.

That's the only way you could do it in a certain state that I know.

MR. TELFORD: And as a comparison to the use of the regular pharmaceutical in a diagnostic study --

DR. MCMANUS: You would never have to do that. You could order it by telephone. You could order a bone scan and you would never have to write anything down.

MR. van SCHOONHOVEN: Yeah.

MR. TELFORD: But you're saying the preferred way, certainly, in your view is to have a written referral going in.

DR. MCMANUS: Right. The way you explain it is that a physician may never know about that referral. The test would be done, the images would be read, and it was presumed that this was the right procedure and the right patient. There was no checking.

The only way I would say that it should start with would be a written referral. It doesn't have to be very complicated.

MR. van SCHOONHOVEN: No.

DR. MCMANUS: But it should be similar to what's filled out at the hospital.

MR. KLINE: Could that written referral be written by a designee of the referring physician?

MR. van SCHOONHOVEN: When you start that you get down to --

MR. KLINE: Such as a physician's assistant?

MR. van SCHOONHOVEN: The next thing you know you're going to have the receptionist doing it and if she makes it out wrong, or if she makes that phone call over there which is --

MR. KLINE: The physician's assistant?

MR. van SCHOONHOVEN: There is real case or good cases where guys have gotten into a lot of trouble with their receptionist making the phone call and getting the decimal points wrong.

In fact, I saw a guy go into acute renal failure over sulfur diazide. When he was to get 5 grams he got 50 grams, because of the wrong number.

MR. TSE: In our idea of this diagnostic referral, the numbers are not there.

MR. van SCHOONHOVEN: Right.

MR. TSE: No, but --

MR. van SCHOONHOVEN: On the diagnostic order. Right, there's nothing there, even probably on the therapeutics most of the time there isn't.

MR. TSE: No, but therapeutic, the way we envision here is that you have to have the prescription from the nuclear physician.

MR. van SCHOONHOVEN: That qualified physician, he's seen the patient, now he decides and he writes.

DR. MCMANUS: The written -- there's a written request. Is there not a written request from the referring physician, followed by a written prescription by the --

MR. TELFORD: Well, the therapy -- the authorized user physician, in our language, gets involved. They examine the patient. I mean, they're --

DR. MCMANUS: That's relative first from the diagnostic.

MR. TELFORD: Yes.

MR. van SCHOONHOVEN: They've got to get involved.

MR. TELFORD: Yes. In the strict sense of the word. Then, the authorized user physician prescribes the therapy. And probably has help from dosimetrists and physicists --

MR. WIEDEMAN: Medical physicists

MR. TELFORD: -- And to find the treatment plan and to carry it out.

MR. TSE: But John, even in diagnostics, the way we envision, the qualified physician still controls through the use --

MR. TELFORD: Policies.

MR. TSE: In terms of the use of a clinical procedure.

MR. TELFORD: Yes. Well, I think what they're telling us is that, for things like gallbladder scan or thyroid scan, or liver scan, we're better off if we start with a written referral that says one of those. And with the other pertinent information.

I think they're really telling us that it's riskier if we design a system that takes all of that over the phone. So, I mean, that's their opinion. It's more risky. I understand that.

DR. MCMANUS: If you're reducing risk -- let's assume --

MR. van SCHOONHOVEN: I can't call a bank and tell them, hey, you're coming over and give him $50.00 and order on my account.

DR. MCMANUS: Listen, Peter, let's say that you ask the hospital how do you get your orders for diagnostic nuclear medicine procedures? They say we take them over the telephone, we'll take them any way, from a computer print out and we'll take them by written referral.

Have you had any problems? Yes, we've had some problems related to that, and we've gone now to 100 percent written order.

In other words, should that be the result of problems rather than a Joint Commission saying that this should be a written order in every single case? I guess

that's what we're trying to figure out.

MR. TELFORD: Yes. If I'm hearing what you're saying correctly, you're saying, well, we could start out saying, all right, for diagnostic referrals we could give you three choices. We could give you written referrals, we could give you electronically transmitted referrals from computer printouts, we could say telephone referrals provided you use a form and you contain certain information and you check it from both ends.

Then let them try it and then let them analyze how they're doing each year. Then if it is a problem for that hospital, then okay, restrict them or have them beef up their procedures. If not, then let them go.

That's an idea.

MR. van SCHOONHOVEN: What, Joan? Any reaction to that?

MS. CARROLL: No.

DR. MCMANUS: All right. The consumer speaks.

MS. CARROLL: Yes. The consumer.

MR. TELFORD: How does the consumer look at that?

MS. CARROLL: Probably okay.

MR. TELFORD: Probably okay? Okay.

MS. CARROLL: I just want to be protected.

MR. TELFORD: There ought to be some procedures in place that --

MS. CARROLL: I want my doctor to know what he ordered, and the doctor who gets the order to know what was ordered.

MR. TELFORD: Okay.

MS. CARROLL: And my lawyer to be able to find it on the chart.

[Laughter.]

MR. TELFORD: Are we ready to move to Objective number 4, under 35.35?

DR. MCMANUS: Yes.

MR. TELFORD: In number 4 we were after some sort of mechanism to get some assurance that the hospital had procedures in place where they had training, or they had testing, or they had some sort of supervision and counselling system where they knew that.

For instance, in the case of these diagnostic procedures, that technologists understood what the procedure was that was described in the clinical procedures manual, they thoroughly understood what to do, and there were no questions, and they could efficiently and effectively do those, carry out those procedures.

We left it completely open as to how they would do that. I mean, they could hire certified folks, they could have training. Any way they wanted to do it. We were just after a very simple idea of let's make sure that these folks

indeed know what they're doing before they go after them.

We've seen cases of where there were X-ray techs that were there on the weekend and had very little training and very little experience and, gee whiz, isn't it strange that they goofed up.

MS. CARROLL: I sympathize completely. You know. I can read what you've written here. But I, too, have been confronted with the idea of how to ensure. I don't know. It's very praise-worthy.

MR. TELFORD: Well, one way to think about this is take out the word ensure, and just say that -- think of it as your program will contain procedures that address.

DR. MCMANUS: That's how we would write it.

MS. CARROLL: Yeah.

MR. TELFORD: All right. Did we get -- let's look at some of your standards to see --

DR. MCMANUS: All right. It would say prior to any medical use, the prescription or the diagnostic referral is understood by responsible individuals.

MR. van SCHOONHOVEN: Show me how you address that? How do we know that responsible individuals understand the prescription or the diagnostic referrals?

DR. MCMANUS: It would bring out some kind of educational reports. Perhaps in-services, perhaps evidences that five of the technologists looked at one prescription

and clearly explained it to their chiefs, or something like that.

MR. TELFORD: In 1.3.1, it speaks of the working relationship. Does that idea contain anything to do with understanding your job and how to do it?

MR. van SCHOONHOVEN: No.

MR. TELFORD: Okay.

MR. van SCHOONHOVEN: That wasn't the intent of it. The intent of it was to create a working relationship and communications, and understanding, and primarily related to management issues.

MS. CARROLL: And utilization of the services?

MR. van SCHOONHOVEN: Yes.

MR. TELFORD: So, that one is not too appropriate?

MR. van SCHOONHOVEN: No.

MR. TELFORD: How about 1.3.3, where it talks about determining the qualifications and competence of the department of personnel.

DR. MCMANUS: Yes. That's good.

MR. van SCHOONHOVEN: That is -- because that is related to what services they're going to provide. Now, for instance -- I don't know. Jim, tell me if you did it this way.

I used to go in and say, okay, start me off right at your front desk here, or reception area, where they

request for services. Now, carry me through right until the patient leaves.

MR. TELFORD: Yes.

MR. van SCHOONHOVEN: It doesn't take long to do it if they know what they're doing. But it takes you through the facility and you get a tour of it at the same time.

MR. TELFORD: So, if that were a nuclear medicine diagnostic department, then you would get an idea of whether or not the people understood their jobs, how to do them?

MR. van SCHOONHOVEN: What they were doing, right. It doesn't take a lot of brains out there, either.

DR. MCMANUS: I think it's also addressed generiсly under management at --

MS. CARROLL: It is in management and also

DR. MCMANUS: And performance evaluations.

MS. CARROLL: Right.

DR. MCMANUS: The QA chapter.

MS. CARROLL: Yes. It's in the standard for QA.

MR. TELFORD: So, we pretty much have it covered with 1.3.3?

MR. van SCHOONHOVEN: Yes. I think that's the key one.

MR. TELFORD: All right. Well, are we ready to move to Objective number 5, or 35.35?

In this one, what we're saying is that, have procedures -- QA 2.53, the mechanisms review. Develop end findings from the quality assurance. The mechanisms used to appraise the competence of all those individuals not permitted by the hospital practice independently, is an ongoing evaluation that's reported to the Government by QA 2.53.

What mechanism is used to appraise the competence of the nuclear medicine technologist?

DR. MCMANUS: Where does that come from?

MR. TELFORD: That's the QA chapter --

DR. MCMANUS: The scoring?

MR. TELFORD: Chapter 2.53 in the standard.

DR. MCMANUS: Is it a scoring?

MR. TELFORD: No, standard.

DR. MCMANUS: A standard?

MR. TELFORD: Yep.

DR. MCMANUS: Okay.

MR. TELFORD: So, you would add it to your --

MR. van SCHOONHOVEN: I think we've got that tied in with --

MR. TELFORD: In 1.3.3. Yes.

MR. van SCHOONHOVEN: It should be 115.

MR. TELFORD: Yes, 2.53. And that's related to Objective number 4.

DR. MCMANUS: That's related to Objective number 4, yes sir.

MR. TELFORD: Okay. Any others on that one?

[No response.]

MR. TELFORD: Are we ready to move to Objective number 5?

DR. MCMANUS: Well, you're going to leave the others that you've got there, aren't you?

MS. CARROLL: Yes.

[Pause.]

MR. TELFORD: We're just trying to determine if, once you understand what we're after in the Objective, if you share that same sentiment and you've covered it someplace, and you explain to us where you've covered it so that we're interpreting your standards correctly, is all.

Okay, Objective number 5, are you ready for that one?

DR. MCMANUS: Yes.

MR. TELFORD: Yes?

MS. CARROLL: Would you please explain the difference between numbers 2 and 3?

MR. TELFORD: Two and three?

MS. CARROLL: And five.

MR. TELFORD: Okay. Two says you should have a written directive. Three says you should have a referral.

Five says that the dose or the byproduct material administered should be what was prescribed.

MS. CARROLL: Well, how about changing medical use then to administration?

MR. TELFORD: Yeah, that's what we are doing.

MR. CAMPER: Change medical use everywhere to administration of byproduct material. Take out that phrase entirely.

And similarly again, remember that prescription is always replaced with a written directive.

MS. CARROLL: All right. I didn't realize we were changing medical use.

MR. TELFORD: Okay.

MR. CAMPER: Is there a general reaction on either one through five, or for that matter, one through seven, regarding deleting the term insure at the beginning of each objective, and replacing it with --

MR. van SCHOONHOVEN: Yeah, I would.

MS. CARROLL: Let's get them out of there.

DR. MCMANUS: I would take them out.

MR. van SCHOONHOVEN: Provide for?

MR. CAMPER: Yes. Just prior to --

MR. van SCHOONHOVEN: The attorneys will jump all over this --

DR. MCMANUS: I would just start out number 5 with

the administration of byproduct material.

MR. TELFORD: We're trying to --

DR. MCMANUS: Then, just state how do you insure that. Let the surveyor ask that.

MR. TELFORD: We're trying to list the objectives, the good things to do. So the objective is that, byproduct material is administered as prescribed.

DR. MCMANUS: Right.

MR. TELFORD: Or as directed.

DR. MCMANUS: Right.

[Pause.]

MR. TELFORD: Is your NM.2, is that too broad to capture this same thought? Maybe it's 2.2.10?

MR. van SCHOONHOVEN: Right. Okay.

DR. MCMANUS: Yes. That's the overall lot that comes into the hospital. But some of them come in with a dose related.

MR. van SCHOONHOVEN: You're right.

DR. MCMANUS: I don't think they come in with the exact dose fixed.

MR. van SCHOONHOVEN: Radiopharmaceuticals.

DR. MCMANUS: Right.

MR. TELFORD: If you have an inpatient for therapy.

DR. MCMANUS: Right. The exact dose may be

delivered to tne hospital.

MR. TELFORD: Radiopharmaceutical therapy?

DR. MCMANUS: The -- well, therapy is a little different.

MR. TELFORD: More or less. I mean, you would order a certain activity and you'll get close to that from the regular pharmacist.

DR. MCMANUS: From the source.

MR. TELFORD: Yeah.

DR. MCMANUS: And then it's allowed to decay until point which --

MR. TELFORD: Well, there's a window that you can be within and still deliver that.

DR. MCMANUS: Right.

MR. TELFORD: Or, if it's markedly different, then the authorized user says yeah that's what I want and signs off on it, and it's delivered.

DR. MCMANUS: That would be part of it, certainly, 2.2.10.

MR. TELFORD: But we also envision the use of dose calibrators so that you would know, the technologist would know what dose they have in hand before they administer. So, that's how you would know.

MR. van SCHOONHOVEN: Do you require that on organization -- material you get from organizations

providing the radiopharmaceutical, or is it only if you're generating it, that dose calibrating?

MR. TELFORD: Both.

DR. MCMANUS: More so with the outside source.

MR. WIEDEMAN: If you order a radiopharmaceutical from, say, a local nuclear pharmacy, you're still required to re-check it in the dose calibrator.

MR. van SCHOONHOVEN: Because I've seen where that's been a lot of wasted time by some places.

MR. KLINE: Well, one of the problems that results is that a pharmacy sometimes are at great distances, or --

MR. van SCHOONHOVEN: In that case you give them a big take, or a kind of insert with it.

MR. KLINE: Well, we feel that's true. You can. But all people make mistakes on reading graphics, on decay tables.

DR. MCMANUS: Gee, I wouldn't want to calibrate it at the hospital.

MR. van SCHOONHOVEN: If I was in some hospitals, I would want to calibrate than the pharmacy.

MR. TELFORD: The famous case in Arizona, they ordered 100 microcuries of I-123 over the phone, and 100 millicuries of I-131 was delivered and given to the patient without going through a dosimeter.

MR. van SCHOONHOVEN: Well, there's a certain

thread point. If I was the director, too, I'd want to check on a dose calibrator. But on some of these diagnostic studies I don't know whether we're spinning wheels on reputable organizations under your control who are providing these radiopharmaceuticals. And not do just occasional spot checks, maybe. But not every one.

But, you say every one has to go through this?

MR. KLINE: Some of these reputable radiopharmacies have had problems with the proper radiopharmaceutical also at the proper dosage. So, they have been in violation of NRC requirements in these areas.

So we feel that you can complicate by assuming that they're correct, one error, into a number of errors. Unless there is a mechanism to catch that error. That would be the dose calibrator, your double check.

MR. WIEDEMAN: We also had a case in Wisconsin a couple years back where the physician ordered a thyroid uptake, a very simple diagnostic study. And normally you'd only use around 10 microcuries of Iodine 131.

And the nuclear pharmacy claimed they ordered the 10 microcuries. Oh, I'm sorry, they ordered 10 millicuries. The technologist said I ordered 10 microcuries. The pharmacist filled 10 millicuries. It was sent back. It was not checked in the dose calibrator. The technologist administered the dose, and I think they had the patient come

back for like a 6-hour or a 12-hour --

MR. van SCHOONHOVEN: No label on it?

MR. WIEDEMAN: There was a label on it. She didn't realize the difference between microcuries versus millicuries.

And in doing so, administered the dose, checked the patient six hours later. The machine went crazy because it just overloaded the machine.

She thought there was an error in the setup of the machine, so she sent the patient home. It wasn't until late in the afternoon the following day that she told the authorized user that she had made an error in the dose administration. By then it was too late.

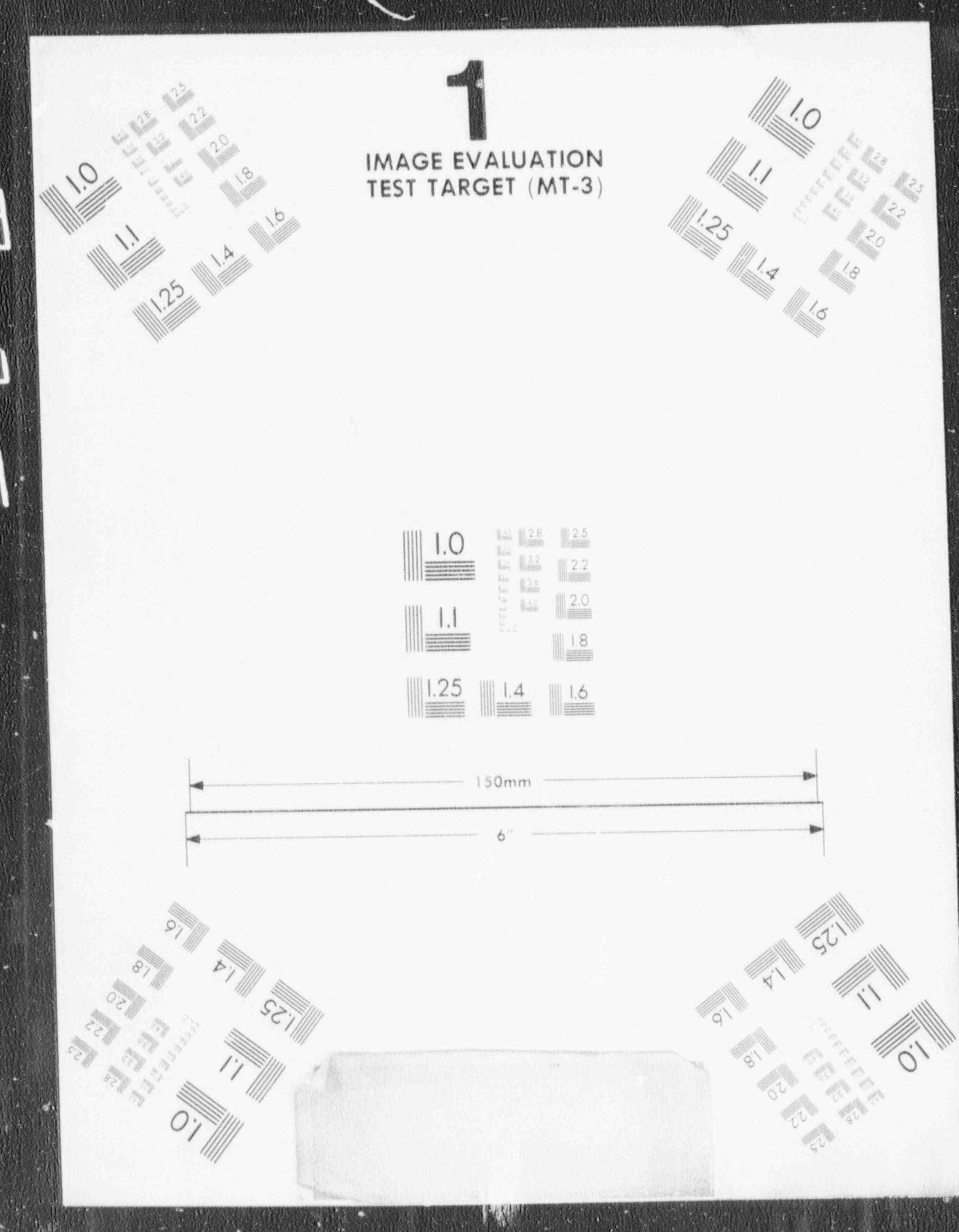
MR. TELFORD: Let me ask you about two of your standards. It would appear that you capture this same thought in two of your standards, NM.2.2.10.1.3 where it says identify the recipient of the radionuclide and the activity administered and the date.

And then, in 2.2.14.2, it says monitor doses administered. I'm looking for a connection between what was supposed to have been administered and what was administered.

In 14.2 we get what was administered.

DR. MCMANUS: Yep.

MR. TELFORD: Do you connect the two somewhere?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DR. MCMANUS: Yes. You connect the two right there. At 2.2.14.2. What they got was what was prescribed.

MR. TELFORD: So that monitoring, in 2.2.14.2

DR. MCMANUS: Right.

MR. TELFORD: It says, monitor dosage administered to patients for acceptable agreement with prescribed doses.

DR. MCMANUS: Right.

MR. TELFORD: That's where you get the check?

DR. MCMANUS: Right. Now, that's not every patient.

MR. van SCHOONHOVEN: That's the point I want to make.

MR. TELFORD: It's not every patient?

DR. MCMANUS: No.

MR. van SCHOONHOVEN: No. It wasn't meant to be every single patient.

MR. TELFORD: Okay.

DR. MCMANUS: But it doesn't mean that you don't calibrate the dose of radionuclide before you give the patient the prescribed dose, though. That you do.

But this is the dose administered to patients for acceptable agreement with prescribed doses are reviews, periodic reviews, carried out by an outsider.

MR. KLINE: Is that for the clinical prognosis, appropriate doses agreement?

DR. MCMANUS: The outsider, qualified physician, qualified medical radiation physicist, or other qualified physician, individual comes in and does reviews.

MR. KLINE: Okay. So, the appropriateness of the study and the appropriate dose to be administered for --

DR. MCMANUS: And, does the dose match the prescribed dose. But in a day by day, patient by patient, you are calibrating the dose that you're giving.

MR. TELFORD: In a dose calibrator?

DR. MCMANUS: In a dose calibrator.

MR. TELFORD: How many patients do you look for this agreement on? You said it wasn't every patient?

DR. McMANUS: No, it's reviewed and it says --

MR. Van SCHOONHOVEN: This is sort of like having a column, if you can picture it. Maybe it's a raft of requests with all the data on it; maybe it's a logbook they have, or something like that. But coming down and seeing that what was transcribed there to the record of what was to be administered was administered. And that's why I asked about that girl, because why wasn't she writing it down and realizing it was two different things, in Wisconsin? A lot of them do it right on the forms. And of course, the nuclear medicine fellow will often incorporate the dosage given into his report.

DR. McMANUS: The reports that the surveyor looks

at are quarterly reports of the radiation physicists relative to these required characteristics, that the patient-by-patient review is done right there.

MR. TELFORD: So what you're saying is, when you go out and survey this department, you're looking at a logbook of administered oral doses versus --

MR. Van SCHOONHOVEN: A bunch of file copies of, it's got all the data on it.

MR. TELFORD: So then you sort of on the spot decide what's a representative sample to look at, look at the sample and --

MR. Van SCHOONHOVEN: Look at everything.

MR. TELFORD: -- and decide in your own mind --

DR. McMANUS: That's how we do, but we would also look for the radiation physicist's report.

MR. TELFORD: But does the radiation physicist look at every patient?

DR. McMANUS: No. Quarterly.

MR. TELFORD: Quarterly.

DR. McMANUS: A quarterly visit, quarterly evaluation of these required characteristics. So we would have that in hand, plus the daily log.

MR. TELFORD: So the radiation physicist quarterly takes a representative sample.

DR. McMANUS: Right.

MR. TELFORD: And makes a determination of whether there's acceptable agreement or not.

DR. McMANUS: Right.

MR. KLINE: Now, is this radiation physicist, is this the in-house physicist or is this a --

DR. McMANUS: Could be.

MR. KLINE: Is it all hospitals quarterly that are reviewed by nuclear medicine --

DR. McMANUS: Or qualified individual.

MR. KLINE: -- annually for radiology, monthly for radiation oncology. So four times a year then we will want to see physicist's reports. Most of them have a physicist.

MR. Van SCHOONHOVEN: We want to see these functions carried out, as Jim is saying. But we don't give them the criteria as to who is qualified. This we leave to the organization.

DR. McMANUS: We have a definition of a qualified individual.

MR. KLINE: Okay. So in other words, the hospital has to provide to you information that shows that if you don't have a physicist on-site, if you have contracted, one came, you review your radiation program, nuclear medicine program, and looked at a number of things, which included --

DR. McMANUS: Which are listed here.

MR. Van SCHOONHOVEN: Comparison of what was

ordered and --

DR. McMANUS: And of course, physicians who are not nuclear medicine physicians, or radiologists, depend a lot on the physicist's report.

MR. KLINE: Do the reports verbatim call out that they compare these variables?

DR. McMANUS: You probably could tell us better. The radiation physicist's report perhaps is three or four pages in length, and there's a paragraph devoted to the dose actually received versus the dose prescribed.

MR. TELFORD: Where is this procedure that this physicist goes through, where is that described, to do this quarterly?

MR. Van SCHOONHOVEN: Right here on 2.2.14.

DR. McMANUS: 2.2.14.

MR. TELFORD: Monitors performance --

MR. Van SCHOONHOVEN: They don't tell them how to do it.

MR. TELFORD: You're explaining to me what they really do, but the words here in 2.2.14.2 don't really tell me that.

DR. McMANUS: Well, that's how we interpret it.

MR. TELFORD: Okay.

MR. Van SCHOONHOVEN: In other words, we're not going to tell them, because this is going to be depending

upon equipment, depending upon what they're doing. All kinds of things. And we can't get any more specific.

MR. TELFORD: Does this physicist get some guidance someplace else?

MR. Van SCHOONHOVEN: You know, it was the physicists on this committee that put 2.2.14.1, with the frequency of jacking it up like they did, and then two, three, and four.

MR. KLINE: Two, three, and four are quarterly, also? Is that the revised?

MR. Van SCHOONHOVEN: Well, I'm talking 2.2.14.2, 2.2.14.3, 2.2.14.4.

DR. McMANUS: The score of one for that 2.2.14 says that reports clearly show that a qualified individual performs quarterly evaluations and that identified problems are promptly addressed and resolved.

DR. HENKIN: Can I make an editorial comment just to reduce some of the confusion?

As currently employed, many nuclear medicine departments are using computers to monitor dose delivery. Those computers no longer permit you to dispense a dose outside set limits within the computer.

MR. Van SCHOONHOVEN: You have to put the tube under the --

DR. HENKIN: You've got to put in what the dose

calibrator says into the computer. The computer will not issue a label for dispensing if it doesn't fall within certain guidelines. So that a quarterly reporting system may or may not work because it's done on every dose now by the computer.

MR. TELFORD: Okay. So what I'm hearing on number 5 is that you've got it covered, by combining a couple of your standards, and you even have it determined by an outside individual on a quarterly basis.

DR. McMANUS: Right.

MR. TELFORD: A sampling basis. But it's not determined for every dose, necessarily. Your standards don't require it to be determined for every dose. We have the same idea in mind. But you pursue it in a different fashion. You pursue it quarterly; we would pursue it on an every-dose basis, if I'm understanding this correctly.

DR. McMANUS: Well, 2.2.10.1.3, the identity of the recipient, the identity of the radiopharmaceutical, the activity of the radionuclide administered. Doesn't that say that you're getting the dose that we prescribed?

MR. TELFORD: It doesn't tie it to what was prescribed.

DR. McMANUS: It doesn't?

MR. TELFORD: No.

DR. McMANUS: It just says how much they got.

MR. TELFORD: Just, 14, 2.2.14.2 ties it to, looks for acceptable agreement --

DR. McMANUS: Okay.

MR. TELFORD: -- prescribed doses.

DR. McMANUS: All right.

MR. Van SCHOONHOVEN: Just think of that more as a snapshot-type of thing that's going on.

MR. CAMPER: Well, I think that's the essence of what I was concerned about. The standards you're referring to, though, are designed to be a random process. It is a snapshot. It's not designed to ensure that for every patient administration.

MR. CAMPER: No, it's not.

MR. TSE: Is the word monitor means --

MR. Van SCHOONHOVEN: To look at.

MR. TSE: -- to check the paper trail, instead of actually physically --

DR. McMANUS: Not necessarily paper. A qualified individual may actually monitor.

MR. TSE: Agree. Agree. But if the qualified individual says I checked with the label come in, and the prescription, I did my monitor; is that true?

MS. CARROLL: I don't know. You'll have to ask the qualified individual how it does that. But --

MR. TSE: Well, if a qualified individual say that

to you.

DR. McMANUS: Suppose that person is there when I survey the hospital?

MR. TSE: Right. And says, you ask me how do I monitor, I said I check the incoming label, I check with physician prescription, it matches, therefore I did the monitor.

MR. TELFORD: Well, I think in 2.2.10.1.3, here they are writing down the identify of the recipient, the radionuclide and the activity. If that also recorded the prescribed dose, then we would have it. But you don't do that on an every-dose basis. You come back later and --

MR. Van SCHOONHOVEN: Now, wait a minute. 2.2.10 -- is done on an every-dose basis.

DR. McMANUS: You don't have the prescription there.

MR. Van SCHOONHOVEN: The prescription is another issue.

DR. McMANUS: Well, it says identify, you identify it, and then you tell how much you administered, but you don't tell how much was ordered.

MR. Van SCHOONHOVEN: No, that's true; not on this one here.

DR. McMANUS: And what we would have to add then for every patient --

MR. Van SCHOONHOVEN: What we were relying upon, though, Jim, was the 2.2.14.

DR. McMANUS: That is done randomly.

MR. Van SCHOONHOVEN: Yes.

MS. CARROLL: Do you want to add that to the standard?

DR. McMANUS: Yes.

MS. CARROLL: Okay.

DR. McMANUS: For every patient, the identify of the recipient, the identity of the drug, the amount prescribed, and the amount administered.

I think that would probably cover that area. And then we would have it reinforced by 2.2.14.2.

MR. TELFORD: Okay. Are you ready for Objective Number 6, under 35.35?

MR. Van SCHOONHOVEN: That's 2.2.10.1.3 again.

MR. TELFORD: This is patient identity. I think you're right. Identity of recipient.

Now, when we rewrite Objective Number 6, we will say that the patient's identity is redundantly verified.

DR. McMANUS: What is verification?

MR. TELFORD: You check it.

DR. McMANUS: Confirmed.

MR. TELFORD: Okay. Confirmed, verified, whatever word you want.

DR. McMANUS: Wrist bracelet?

MR. TELFORD: Wrist bracelet, signature. You ask the person their name, you ask the person their date of birth, their Social Security Number.

DR. McMANUS: Okay.

MR. TELFORD: Their address. We'll have a long list of six or seven things, and we'll say please use any two of the following.

DR. McMANUS: Okay.

MR. TELFORD: Yes, sir. Fingerprint. Photograph. Take a photograph.

MR. Van SCHOONHOVEN: Okay.

MR. TELFORD: That's one. So in 2.2.10.1.3, you just say identified, you don't say redundantly identified. Do you really mean that? Or do you rely on just one method?

DR. McMANUS: We didn't say verified identity. We just say identity. You're right.

MR. Van SCHOONHOVEN: We could have just said recipient.

DR. McMANUS: The identity of the recipient.

MR. TELFORD: Okay. So that's the only difference.

DR. McMANUS: Yes, you're asking for verification of the identity.

MR. Van SCHOONHOVEN: Confirmation.

MR. TELFORD: Yes. Just sort of first identify, then confirm by other, by another piece of information.

Are you ready to move to Number 7?

DR. McMANUS: Now, ensure that any unintended, and unintended is intended there, right?

MR. TELFORD: Unintended meaning it was not intended. If you intended to give something different, then the authorized user just signed off on it and said okay, I know the dose is different, but give it; it's okay. That's an intended deviation. This is an unintended deviation where you intended to give two millicuries, but you gave three, or two and a half, or six.

DR. McMANUS: So that any unintended deviation from the prescription or diagnostic referral and clinical procedures manual is identified and evaluated.

MR. Van SCHOONHOVEN: The closest thing we've got to it is 2.2.18, in the event of radionuclide contamination of the environment, patients, personnel or equipment. And you could say that that includes misadministration, misadministrated dose, or something like that. It's implied. It's not specific.

MR. TELFORD: Seeing Number 7, do you have the approach of looking at various indicators? You're monitoring these indicators. So this could be an indicator. A set of indicators for this is differences in doses or

dosages that were administered versus what's prescribed.

MR. Van SCHOONHOVEN: Well, again, 1.3.6, maintain the quality control program, you know, can be built-in on this one.

MR. TELFORD: How about 1.3.9?

MR. Van SCHOONHOVEN: That's a responsibility to lead to quality improvement.

DR. McMANUS: The director's responsibility. But it goes to 4. You're right. Unintended deviation from a prescription.

MR. Van SCHOONHOVEN: The only other thing you can climb into with ours on this issue is when we get to 2.2.15 or 2.2. -- well, it's 2.2.18. Because it's all through implied on misadministrations, that they'll look into this.

MR. TELFORD: So you think it's NM-4, that captures this idea?

MR. Van SCHOONHOVEN: No.

DR. McMANUS: Well, it is. It's monitoring, evaluation of the dose prescribed.

MR. Van SCHOONHOVEN: You can build it into that one.

MS. CARROLL: This is specified.

DR. McMANUS: No, but it could be.

MS. CARROLL: It should be, yes. It could become an indicator.

DR. McMANUS: Right.

MS. CARROLL: It probably will be.

MR. TELFORD: Remember the one we were discussing a while ago, that was 2.2.14.2, monitoring doses for acceptable agreement? That's identifying unintended deviations.

MS. CARROLL: Yes.

MR. TELFORD: What do you think of that?

MR. Van SCHOONHOVEN: Well, again, it isn't specific in the sense of maybe what you're looking for, but it's implied, again.

MR. TELFORD: All right.

DR. McMANUS: This is monitoring doses administered to patients that are different from the prescribed doses, without reason.

MR. TELFORD: It's monitoring the doses that are administered, and identifying those cases that are different.

DR. McMANUS: Right. And then we have two groups, intended and unintended.

MR. TELFORD: Yes.

DR. McMANUS: And of the unintended, we want discussion, evaluation, and conclusions, recommendations and actions. And so it's an indicator.

MR. TELFORD: I think so.

MR. Van SCHOONHOVEN: 2.2.14.2 --

DR. McMANUS: And play with it.

MR. Van SCHOONHOVEN: See, I'd like to keep it out of that quality improvement, as we talk of it, and assure it stays in the quality control mode.

MR. TELFORD: Objective 7?

MR. Van SCHOONHOVEN: Stays in the true quality control mode.

MR. TELFORD: That seems like --

MR. Van SCHOONHOVEN: I'm subject to change, if you guys want to. But I just think we're better off if we can do it that way, looking at the overall picture of quality improvement, because that's just one facet. There may be others that they ought to deal with.

DR. McMANUS: Can I go back to Number 4? You had 2.2.20. That's the education piece there. You're going to keep that, right?

MR. TELFORD: Yes.

DR. McMANUS: Good.

MR. TELFORD: On Number 4, we focused on 1.3.3.

DR. McMANUS: 3.3, QA 2.5.3, and then the education.

MR. TELFORD: Which is 2.2.20.

DR. McMANUS: Right.

MR. TELFORD: So if I could summarize here on

these seven objectives that are applicable to nuclear medicine diagnostics, we have something close to equivalence, or it would be fairly easy to achieve equivalence on one level, which I would describe as the regulation level.

Does everybody fairly well agree with that statement?

DR. McMANUS: Right.

MR. Van SCHOONHOVEN: It's a fair statement.

MR. TELFORD: Okay.

MS. CARROLL: We have sodas and pop outside, if anybody wants it.

MR. TELFORD: Let's continue on for a little bit.

The next item on the agenda is what we're calling a discussion of practical comparison of the regulations with the JCHO standards.

What we have in mind here is that we're looking for a comparison on three levels. We've just gone through a comparison at what I would call the regulation level of 10 CFR requirements versus Joint Commission standards.

There are two other levels of interest to us. And the second level down from that is what we call licensing. It's where we go through an application program review and acceptance or modification and acceptance of the licensee's program.

Maybe we should discuss that. And there's a third level, that's inspection, that it's fairly obvious that we use unannounced and announced inspections as we described this morning.

So I would like to suggest that the next item that we discuss is sort of a comparison of our licensing versus maybe what you call accreditation.

MR. Van SCHOONHOVEN: Has to be.

MR. TELFORD: Has to be?

MR. Van SCHOONHOVEN: We don't license.

MR. TELFORD: Okay. Do you proceed in a way that's similar to ours where you get everybody's program, each hospital sends in an application, says here's my program, it meets your standards, examine my program; and then you say all right, if you'll change this and this and this, and on these three areas, approve it and sign off on it and say all right, if you follow this, then you'll maintain your accreditation?

MR. Van SCHOONHOVEN: We're surveying to see whether an organization is in substantial compliance with the intent of the standards.

MR. TELFORD: Okay.

MR. Van SCHOONHOVEN: Nobody can write perfect standards. These are contemporary, hopefully. So that all aren't going to always have a minimum to meet in the way of

a number or something like that, because they can be in not too good shape in some areas, but they're excellent in 90 percent of the other. And they'll probably get accreditation without any problem.

So don't look at it that we're going in and telling them how they have to do it to be in compliance with or in substantial compliance with the intent. There could be other alternatives. And that's a flexibility we want to maintain for our own credibility.

MR. TELFORD: That's not quite what I was after.

MS. CARROLL: I think you're asking, do we prescribe the details of the plan.

MR. TELFORD: No, no. That's not it either. We're not prescribing the details of their plan. It's just that okay, here's the regulation, here are the things to address.

The licensee sends in an application, and our license reviewer sits down and says okay, what do they have to address objective one; is it sufficient? Okay. It's all right. How about objective two? Well, I'm not too happy with what they're proposing here. If they'll just beef it up a little bit here, I'll take it. How about objective three? Well, okay, it's all right. And continue all through the regulation. So it's a comparison for acceptance, but it's on paper and it's before any inspection

is done. It's really in theory before they do business in this area. So it's what we call licensing. And we're not telling them how to do it. We're merely accepting their plan, their application for how to do it.

Now, they have to measure up to certain minimum standards. But see, Peter, we don't know if they're going to meet these things or not yet.

MR. Van SCHOONHOVEN: It's our eligibility criteria that we use.

MR. TELFORD: Okay.

MR. Van SCHOONHOVEN: And we don't go into anywhere near that depth of reviewing. When you consider the total documentation and organization we have, or policies and procedures, we cannot handle that stuff in the central office on every issue. I mean, there's just key things like maybe to expedite things, copy their bylaws, some demographic information on them, data that helps them getting some idea of what types of services they provide, and that type of thing.

But no, we don't, in the central office we don't go anywhere near what you're talking about. We rely upon the surveyors at the site, or the organization.

DR. McMANUS: We know in advance, pretty much in advance, that if a 35-bed hospital has any nuclear medicine at all, it's going to be very rudimentary. We know in

advance that an 800-bed hospital that's an academic medical center is going to have a very complex nuclear medicine setup. That's about all.

MR. TELFORD: Therefore, you would categorize those and you would know what to expect when you get to a center that's got --

DR. McMANUS: And using the same set of standards, you could serve the 30-bed vis-a-vis the 800-bed, using the same standards, if you have robust standards, which we feel they are, and you ask the right questions -- you don't even have to be a nuclear medicine physician -- you would come out with a pretty good evaluation of their nuclear medicine setup.

MR. TELFORD: Okay.

DR. McMANUS: The basis for that would be the scoring guidelines and the standards. You would score it. The report comes back to the Joint Commission; it's analyzed to put into the form of a report. I mentioned a grid, and I brought a grid down with me. So that you would see what they get. And don't look at -- oh, this is okay to look at, because it's not even in the United States. But that's the grid. And there's nuclear medicine there, there's diagnostic radiology. And there may or may not be radiation oncology, yes.

MR. TELFORD: So your basis for acceptance of

their program is based on your survey.

DR. McMANUS: Right.

MR. TELFORD: So if your survey is good, you've got a good test.

DR. McMANUS: Right.

MR. TELFORD: If your survey is sketchy, you've got a sketchy basis for acceptance.

DR. McMANUS: So as Bill Jessee said this morning, there are four decisions that have to be made: does the organization get a letter of commendation; do they get accredited with a focus survey or written progress; do they get conditional accreditation; do they get non-accredited?

And it's based on the survey of the team. That's a team survey. If you look at it, there are 56 elements for the usual survey of the hospital.

MR. TELFORD: Okay. Then let me suggest we move to inspection, then. Because that's the --

DR. McMANUS: Now, inspection is the part we've been trying to get away from for 20 years.

MR. TELFORD: Your survey, our inspection.

Our inspector might go to a nuclear medicine department and spend three-quarters of the day or all day there, probably at the very least, a half day, and go through the whole program. And if we add this QA rule to their requirements, it might be another two hours that the

guy is going to spend there.

DR. McMANUS: Right. And our focus survey, a survey that's done in between the three-year, is much like his. It focuses on the three problem areas.

We would spend a half a day or maybe three-quarters of a day there, and not only resurvey it for correction, but give consultation and education in those areas, just those problem areas --

MR. TELFORD: That you identified last time.

DR. McMANUS: -- that we identified during the full survey.

MR. TELFORD: Okay. So every three years, --

MR. Van SCHOONHOVEN: There's a full survey.

MR. TELFORD: -- you do a full survey. But then you follow up after that, if you identify problem areas.

DR. McMANUS: Right.

MR. TELFORD: And the followup could be an all-day session?

DR. McMANUS: The follow-up could be an all-day session, depending again on the elements.

If you see on the grid there, there are 4s and 5s and 3s. That hospital is going to get a focus survey, and we'd follow up on those.

MS. CARROLL: Question, please. I forgot to ask.

In your inspection trips, do you provide

consultation and suggestions for corrective action, that kind of thing?

MR. WIEDEMAN: Yes, we do.

MR. KLINE: It's somewhat a mixed bag in the sense that you can provide what should be done, but we don't provide consultation services, because we're more of a compliance regulatory organization.

MS. CARROLL: I just meant, you know, in the course of your work at the facility.

MR. KLINE: That's a very good question.

MS. CARROLL: I did not mean as a personal enterprise.

MR. KLINE: I know you didn't.

MR. WIEDEMAN: There is that thin line between being a regulator and a consultant.

MS. CARROLL: Right.

MR. WIEDEMAN: Now, if a licensee should ask us, you know, how can I best comply with this regulation, you can make suggestions on how other facilities have complied.

MS. CARROLL: That's what I was talking about, that kind of thing.

MR. CAMPER: There's a question that I wanted to ask that I think is a crucial question as we look at this and how JCH might fit in.

A couple of things have come up in discussions

with physicians or with participants in our pilot program.

One is that could we or shouldn't we be able to submit to NRC our JCAHO program as being acceptable as required under your rule and have that be sufficient, and I think, as we have gone through this process, we have looked at your standards and done some of this cross-walking, if you will, having looked at it, and I think that most licensees, with some adjustments to their JCAHO program, could submit to an NRC inspector or an NRC license reviewer a program that the agency would probably find acceptable. I think that's a fairly easy thing to do.

What I am troubled by, though, is when we get to an inspection/enforcement issue. If this rule becomes a regulation, it's going to be a regulation that is enforceable. It's going to be a regulation that we would inspect against. It's going to be a regulation, I can envision, there would be violations that would be citable. Okay? Conceivably, there could be violations that could result in a civil penalty.

Now, it is a performance-based rule, and it is a rule which we intend to develop inspection guidance for our inspectors, in which, generally speaking, we're going to instruct them to look to see if major program elements are met. Do they have these things in place? As opposed to getting into some of the nit-picking that I think a lot of

the physicians and a lot of the medical community are concerned about, where inspectors are going to go out there and make judgement calls about: Did we do this adequately? Or we didn't do this in one instance. Ours is going to be guidance, on the other hand, to try to look at a performance-based program.

But I guess what I'm really looking at, having said all that, just to give you some backdrop, philosophically, is I am wondering how comfortable the JCAHO would be with inspecting against an NRC regulation during your JCAHO accreditation process.

Is that feasible? Is that workable?

MR. TELFORD: Mr. Camper, this is a very important question. I'd like to suggest that we take a break and we find out if the people that were here this morning, like Bill Jessee -- what I think we're doing, I think we've moved through -- we're now down to the 2 p.m. item.

MR. CAMPER: Not really. Perhaps you can draw that conclusion, but I'm asking in the context, primarily, in terms of inspection -- NRC regulation and inspection steps, and I'm trying to draw the relationship between the inspection steps as it ties back to NRC regulations and what some of the implications are. But if you want to do it under the 2 p.m. context, that's fine.

MR. TELFORD: Let's take about a five-minute

break.

[Brief recess.]

MR. TELFORD: Let's go back on the record.

MS. CARROLL: I thought it would be a good idea, even in the absence of Dr. Jessee, if we talked about feasibility.

MR. CAMPER: If I may, let me set the stage for discussing feasibility by bringing to bear certain concerns or issues that are important and germane to that discussion.

We have spent a great deal of time talking about JCAHO accreditation process might work to address NRC's concerns about the quality-assurance area, and the discussion we're about to go into now would focus upon the diagnostic aspect, not therapeutic, but I think it's important to put a few things on the table that you need to be aware of as you ponder the feasibility, and that is recognize that we're presently on course for a rulemaking to require a quality-assurance program or something of that nature that's designed to prevent misadministrations.

NRC regulations are inspected against, and they are enforced. In some cases, these enforcement actions involve escalated enforcement actions, including civil penalties; orders being issued, licenses being removed, and those types of things.

Now, I think that it's unlikely that those severe

steps would be taken as it relates to this quality-assurance program, and I certainly wouldn't rule that out.

Now, as I said a few moments ago, also, we have had some individuals in our pilot program, and what have you, bring up the fact that JCAHO accreditation issues could probably be modified and submitted to our agency for review, and we could take a look at that, the NRC could take a look at that, and see if, indeed, this is going to satisfy our review process, our licensing review process.

I don't think we are too troubled with that aspect of it.

My concerns, though, really deal with the inspection and enforcement process.

For example, JCAHO, if it were inspecting against this rule, would find itself in the position, during its accreditation inspection process, in the role of identifying the bad players and referring them to the Nuclear Regulatory Commission, at which point we would take steps, as we would normally in the inspection and enforcement process.

The question of up to what degree JCAHO would be comfortable with that role should be explored.

I know that you indicated, now, when you see problems, you refer them to OSHA, for example, but this is distinctly different in the sense that a specific regulation would be on the books that you would be inspecting against,

for lack of a better term.

So, I am interested in knowing how something like that might work, if it would work, and to what degree the organization would be comfortable with that.

MR. TELFORD: If I could add a couple of thoughts here, we've been talking about a comparison on three levels.

On the regulation level, our regulations versus your standards, I think the conclusion we have come to collectively here is that, with a little bit of modification, we could certainly achieve equivalence there.

The second level being what we call inspection -- I'm sorry -- what we call licensing, that you call accreditation, it seems clear that you delay the decision of acceptance until you get to what we call inspection, which you call survey, so that the equivalence at the licensing level doesn't exist, but it's open to discussion as to whether or not there should be equivalence or whether or not you could rely on your surveys.

The third level of what we call inspections and what you call surveys, we see a difference in how much attention is devoted to the nuclear medicine department, but to me, it's certainly theoretically possible that we could achieve equivalence there. It's just a question of how much effort do you devote to the nuclear medicine department upon your survey?

There's sort of - larger question here that Mr. Camper is asking.

Let's assume for a moment that we could achieve equivalence on all three levels and assume that we said to all licensees: You have your choice. You can send in your application to the NRC and get licensed and inspected by the NRC for nuclear medicine departments. Or you can get accredited through the Joint Commission, and your surveys, then, would -- assuming we had achieved equivalence on the three levels, your surveys would go in place of our inspections, but as was indicated earlier today, something less than five percent get to these sort of six-month probationary periods and something around one percent get rejected. Those guys are going to occur.

It would be almost as if the NRC has had a report of a misadministration, and also, keep in mind that the reporting and recordkeeping requirements that would be contained in this rulemaking would still apply to all licensees, so that they would have to report misadministrations to us, but if they're nuclear medicine diagnostics, then it could be that you're the identifier of the poor players.

So, the question is: Does that bother you?

MS. CARROLL: No. I don't think it would.

DR. McMANUS: No. I think, the way I envisage it,

if this is a choice situation for hospitals to undergo Joint Commission survey for continuation of NRC licensure or NRC inspection for continuation of licensee, and we went into a hospital that elected the Joint Commission way that we would then review those areas that we had equivalence with the NRC, in our standards, and that if we found -- and we would have to agree on what that consisted of in terms of what should be reported to the NRC in terms of poor performance, we would have to agree on a certain threshold.

If we found that to be, I would have no qualms about identifying that at the exist conference, at the time of the survey, or subsequently, to NRC for further action.

In other words, I would presume that there would be identified some poor players and that NRC would take, then, their people, as a secondary situation, and say, now, look, the Joint Commission identified these things; I am here to find out how bad it is and whether certain penalties have to be levied.

I don't think we would be linked to the penalty itself. We'd be identifying it to the NRC.

Is that how you envisage it?

MR. TELFORD: Well, Darrel, remember this case over in Indiana, the authorized user that was doing the brachytherapy procedures? Let's use that as an example, as to what could happen to these folks; you know, the real poor

players.

MR. WIEDEMAN: Which case are we talking about?

MR. TELFORD: St. Mary.

MR. WIEDEMAN: St. Mary's Medical Center?

MR. TELFORD: Yes. Is that a good example? Or could you pick an example?

MR. WIEDEMAN: I know a case of a misadministration in two months.

MR. TELFORD: This is worse.

MR. WIEDEMAN: This is worse?

MR. TELFORD: This guy is worse, I think.

MR. WIEDEMAN: That one is still under review.

MR. TELFORD: Okay. Let's not talk about the details on it, then.

Let's pick one where you have -- just picture a very poor department that has several misadministrations, let's say.

DR. McMANUS: Okay.

MR. TELFORD: And the Joint Commission goes in, and you do your survey, and it's pretty obvious to you that that department doesn't deserve accreditation. So, you withdraw accreditation immediately.

DR. McMANUS: The department does not govern the accreditation decision unless there is an immediate threat to life or safety.

MR. TELFORD: All right.

DR. McMANUS: There has to be, across all disciplines, real severe problems. You're focusing in one the NRC aspects of it.

The Joint Commission has, let's say, 50 elements, nurse, administrator, and physician to survey. Those 50 contribute to the accreditation decision.

MR. TELFORD: Let me withdraw what I said.

Let's just say that you identified a nuclear medicine department, that it alone looked like a poor player, a poor performer, but the rest of the hospital was okay, and you identify that department to the NRC, saying we're very suspect about those folks.

DR. McMANUS: Right. That's an agreement with the hospital, before we even get there, that if we find these problems, the information would go to the NRC.

MS. CARROLL: The carrot for the hospital is it saves them an extra inspection. Right? Wouldn't that be the incentive?

MR. van SCHOONHOVEN: Who is going to license them? We're not going to license them.

MR. TELFORD: No. You're going to accredit them.

MR. CAMPER: They currently have a license with us. All they would do is they would submit to us that they're going to participate in the JCAHO accreditation

process in the area of quality assurance, as opposed to submitting to us --

DR. McMANUS: But they still have other obligations to the NRC. This is only the Qe QA piece of it.

MR. CAMPER: That's correct.

MR. van SCHOONHOVEN: There is another alternative. You could have it as an understanding that the hospital shares with you any Type 1 recommendations on nuclear medicine.

DR. McMANUS: That's what we thought.

MR. van SCHOONHOVEN: Make the hospital do it.

DR. McMANUS: Either way.

MR. van SCHOONHOVEN: Rather than us do it.

DR. McMANUS: Either way.

MS. CARROLL: It's easier for us to control, though. These are options.

MR. CAMPER: Clearly, there are those who would characterize us as police.

DR. McMANUS: I don't mind that if it's in advance, an agreement with the hospital.

MR. van SCHOONHOVEN: If it's understood, yes. But there could be one of two understandings. Either we're going to do it, or the hospital is going to have to do it every time they are surveyed, any form of a contingency type reg comes up.

MS. CARROLL: But those are tactical matters that I think, you know, can be deferred, don't you think?

DR. McMANUS: Sure.

MR. van SCHOONHOVEN: The decision doesn't have to be made now.

MS. CARROLL: That's what I mean.

MR. TELFORD: Let's say that the hospital has the choice going in, and they elect Joint Commission accreditation, with the understanding that if that Department is identified as a poor player, the report goes to the NRC.

DR. McMANUS: Right.

MR. TELFORD: The NRC would then send an inspector.

DR. McMANUS: Right.

MR. TELFORD: Investigate as to what's really happening, and if warranted, then we would say -- we might go to the enforcement step, enforcement conference, escalation to a civil penalty.

DR. McMANUS: Okay. If loss of license occurs and they are required to provide for nuclear medicine services, then they would have to contract through some other organization for that provision.

MR. TELFORD: Yes, as far as you're concerned.

DR. McMANUS: As far as we are concerned. And

they would still be eligible for survey.

MR. KLINE: Contract in the sense that they could not provide that service if they had their license removed.

DR. McMANUS: They provide for it. They don't provide it.

MR. van SCHOONHOVEN: They may have to transport the patients to another hospital.

MR. CAMPER: So, if all licensees were to choose to indicate to us the use of the JCAHO accreditation process in lieu of submitting to us the quality-assurance program, am I hearing from you, then, that JCAHO would be prepared to modify its accreditation process to look for and evaluate those kinds of items that we have expressed an concern about in our quality-assurance program?

We think that there is a close fit.

DR. McMANUS: Yes. We do, too.

MR. CAMPER: But if we identify, after getting back and looking at this, a few areas where we say you ought to put a little more emphasis here, fine-tune this or what have you --

DR. McMANUS: I think it would be a good idea fo. you to identify one or two or both indicators that you want ongoing and evidenced at the time of the survey. It would not be up to the hospital to look at that or not. It would be up to the NRC. They'd say these are indicators that will

be shown to the Joint Commission surveyor when the Joint Commission surveyor comes, just like you would now.

When you go there, how do you know they are doing what's going to be here? Are you going to tell them that that's what you want monitored?

MR. KLINE: Well, under current conception, they would have their license, and they would have these regulations.

DR. McMANUS: So, the QA program would be obligatory if you were doing it. It would be the identical program if we were doing it. I guess that's what we would like to see.

MR. KLINE: Well, there we get into this thing of licensing. If they submit their license application addressing this QA program to the NRC, we will have a rapport back and forth with the licensee to make sure they're doing the deficient areas, that we understand that they are going to meet our criteria, because along with this set of rules, we have licensing.

DR. McMANUS: Let's divorce the licensing for a minute.

MR. KLINE: The other would be your standards that they would address.

DR. McMANUS: Let's just stick to the QA program.

You envisage the QA program that you're going to

look at pretty much the same as we're going to look at, because there has to be commonality there.

MR. KLINE: That's a good question. That's correct.

We have developed inspection guidance on it that breaks down these categories and talks about what the inspector should look at.

MS. CARROLL: Like our scoring guidelines.

MR. KLINE: That's correct. And that is based, also, on a prior breakdown by the license reviewer of that program.

MS. CARROLL: Yes.

MR. KLINE: But we do have criteria which we want the inspectors to be trained and knowledgeable in prior to going into a QA program and evaluating the program, and this is the sort of question, at the inspector level, whether or not your review process would be equivalent in quality and time that we would involve our inspectors in during the evaluation of that QA program.

MS. CARROLL: We might have to incorporate some of your provisions into the process.

MR. TELFORD: I think we could achieve equivalence fairly easily on the regulatory level. On these kind of things, we would rewrite these. You would say, well, we'll make some of these mandatory indicators. Okay. You would

create indicators that would be mandatory to monitor progress here.

DR. McMANUS: But would the NRC make them mandatory?

MR. TELFORD: We will identify them for you, but it's your accreditation process.

DR. McMANUS: Suppose a hospital chooses not the Joint Commission but chooses NRC.

MR. TELFORD: It's worse.

DR. McMANUS: But are the indicators there, those indicators?

MR. TELFORD: Yes, definitely.

DR. McMANUS: Okay. That's all I wanted to know.

MR. TELFORD: More so.

DR. McMANUS: So, we could say as required by the NRC, the following indicators will be looked at.

MR. TELFORD: Yes. In other words, if they didn't choose accreditation, they would certainly have to adhere to those same objectives.

DR. McMANUS: That's all I asked.

MR. TELFORD: Okay.

MR. van SCHOONHOVEN: Keep in mind, too, Jim and Jean, we, hopefully in the next year or year and a half, are going to convene a task force on imaging, diagnostic imaging.

MS. CARROLL: In a couple of years, '93.

MR. van SCHOONHOVEN: Are you sure it's going to be that long?

This is where specialists are brought together, and you know, the state of the art is changing all the time, but the intent would be to be hospital-wide on these, not just nuclear medicine, diagnostic radiology, and that type of thing.

That's the whole intent of any of the performance indicators we're trying to develop for organizations to use themselves, to compare themselves with others, as well as address possible times when they can improve on the quality of care.

So, I can see some rather specific ones popping in there, if they're related to lower radiation, that type of thing, which is more likely to occur in the imaging than in some of the others, by a long shot.

MS. CARROLL: We live with that today. It's the same tune.

MR. TELFORD: What you're saying, I think -- if I am hearing this correctly -- is that the optimal set of indicators may change in future years. We can work with that. The question is how to get started.

MR. van SCHOONHOVEN: The indicators that I'm referring to -- these are all in developmental and some are

in field testing and other subjects or other specialty areas, but the intent is that all of these that they come up with and agree upon, the Board of Commissioners, hospitals will have to address those.

DR. McMANUS: To get back to one of your concerns about licensing, where do you place that? I don't place that with us at all. The hospital has to be licensed to provide nuclear medicine services before we would even survey it.

For six to eight months, they would be doing nuclear medicine procedures and they may not even have Joint Commission accreditation.

MR. CAMPER: What would happen, I think, is that during the licensing process, again, for diagnostic uses, the licensee would submit to us -- let's assume this rule becomes effective, they would submit to us a statement that they are following -- they will conduct their quality assurance program under their existing JCHO accreditation process. That's it.

For those who chose not to do that, they would submit to us their quality assurance program. We would not inspect against that aspect of their program when our inspectors went out into the field; rather, the JCHO accreditation process would do that.

MR. TELFORD: The JCHO survey, in our language,

would inspect the diagnostic program.

MR. CAMPER: The diagnostic quality assurance program would be looked at during your accreditation survey.

MR. TELFORD: Okay.

MR. CAMPER: In those cases where you identified problems, you would refer them to the NRC, at which point an inspector would go out. The licensing part of it would be entirely our agency's responsibility.

MS. CARROLL: The relationship with you continues through your inspection process.

MR. TELFORD: For the therapy part. Now, if they're only doing nuclear medicine diagnostics, then we might only see them if they're identified as an bad actor.

DR. McMANUS: So you're going to restrict your role routinely to therapeutic nuclear medicine.

MR. TELFORD: That's under discussion. That's what we're talking about.

MR. CAMPER: We're saying that in those cases where the hospital chose to indicate the JCHO accreditation process for its program, we would not be involved with that. Therapy, if they're doing therapy, we would. They're going to have to give us a QA program for therapy as well.

DR. McMANUS: Mandatory?

MR. CAMPER: Sure. However, I would think, just talking off the cuff, I would think that the majority of

them would indicate the use of -- for diagnostic, would indicate the use of JCHO. That's my guess.

Consequently, we find our greatest emphasis being placed on therapeutic area which is the area we have the most concern about anyway, which is healthy.

DR. McMANUS: Would you estimate that half of nuclear medicine departments also treat, especially with radioactive iodine?

MR. TELFORD: Radiopharmaceutical therapy?

DR. McMANUS: Yes. Do you have any idea about that?

MR. KLINE: The questions comes up as to what is defined as a therapy procedure and in the --

DR. McMANUS: If it's under 30.

MR. KLINE: Well, if we're looking at pharmaceuticals greater than 30 microcurie, of Iodine-131 and Iodine-125, then we get into a criteria by which they establish level as an action level, then that would be, I guess, the therapy.

MR. CAMPER: It's certainly half.

MR. van SCHOONHOVEN: Remember we've got MN 1.1.1; am I wrong? Appropriate institutional licenses and/or applicable law and regulations. We cover ourselves, even organizational-wide in that management and administrative because that's one of the early standards there that the

hospital must be in compliance with applicable laws.

MS. CARROLL: It's in the general administrative, too.

MR. CAMPER: Well, that argues for making the fit easier.

MR. van SCHOONHOVEN: I thought I better bring it up when I thought of it.

DR. McMANUS: It tends to make the fit look more easily achieved. I think I'm also hearing something encouraging in that the JCHO would be prepared to look at its process and make some adjustments in this area to accommodate what NRC is looking for and that's a very crucial point.

MR. TELFORD: As long as it doesn't require change in the standards. What Dr. Tse and I were talking about takes about two years.

DR. TSE: Yes.

DR. McMANUS: To get something out is easier, but to change it or to put something in is --

MR. van SCHOONHOVEN: Well, we could maybe drop it under editing, editorial change.

MS. CARROLL: We have a lot of levels of --

DR. McMANUS: I'm going to bring up the written prescription --

MR. TELFORD: The written referral?

DR. McMANUS: The written referral and the written prescription and see how that will balance.

MR. TELFORD: How easy is it to change the indicators that you look at?

MR. van SCHOONHOVEN: Easy. That's why you don't see any specific ones here, you see.

MR. KLINE: The indicators appear to be the ones where the greatest modification --

DR. McMANUS: Well, it's a sentinel event indicator or a rate-based indicator and we look at these under sentinel events -- if the following sentinel events will be monitored and evaluated.

MS. CARROLL: You don't have to worry about reliability?

MR. van SCHOONHOVEN: It's a zero occurrence.

MR. TSE: The hospital has to make a choice either they do the NRC inspection or they will say, we're going to follow the JCHO, so they voluntarily choose either NRC or JCHO.

DR. McMANUS: Right. We'll be going there anyway, but whether we do the NRC piece is up to them. You're saying that for all diagnostics, we might be doing it?

MR. CAMPER: For diagnostics only, yes.

DR. McMANUS: Okay.

MR. CAMPER: I would point out though that with

the diagnostics, the 30 microcurie issue is something we have to take a look at.

MR. van SCHOONHOVEN: That's editorial.

MR. TELFORD: So it's all diagnostics and any Iodine radiopharmaceutical less than 30 microcurie?

MR. TSE: Also, only applicable to -- we are thinking about it, but limiting it to the iodine which therapy which is more than 30 microcurie.

DR. McMANUS: Right.

MR. TELFORD: That would be considered a diagnostic procedure. In other words, that would be exempt from that less than 30 because it's a routine procedure in a lot of hospitals.

In other words, any procedure with Hipuran would be included as if it were a diagnostic procedure and would be under Joint Commission survey, rather than NRC inspection.

MR. CAMPER: I have another question for you regarding timing. We're currently working against a March '91 publication date for the rule.

DR. McMANUS: To the Commission?

MR. CAMPER: To the Commission, right.

DR. McMANUS: To your Commission?

MR. CAMPER: Right. Of course, the Commission will then review it, make adjustments and what have you, and

the theory will be published sometime next year.

DR. McMANUS: We have Perspectives.

MS. CARROLL: Perspectives is a publication.

DR. McMANUS: Perspectives comes out every two months.

MR. van SCHOONHOVEN: It's a companion to our standards.

MR. TELFORD: Let me put it this way: we have a schedule that we're marching to, and we're marching next year and we will present our draft final rule to our Commission, which you can think of as our board of directors.

Typically, they consider a rulemaking for about a month. Between -- let's see, very recently, like in this year, we've conducted our pilot program with 60 odd volunteers that went all the way through. We've met with -- back in March, we met with representatives of four agreement states. In the summer, we met with ACNP and SNM. We met with five societies; recently, the AAPM, the ACMP, the ACR, the AES and Astro. We met with that group for a total of two days.

Tomorrow and Wednesday, we're going to be meeting with representatives of approximately 10 agreement states and we've met with JCHO. We're talking to everybody and we're just about to complete the circuit since we have

talked to virtually everybody that has any interest in this area.

We'll take the information that we've gotten from the workshops, from the pilot program, from the public comments and we will draft the final rule and reporting requirements. So, for planing purposes, you could assume that, come March, we will have our final rule before the Commission.

So, if we are trying to move along together here, there may be some questions that are still in your mind that you want to ask internally and --

MS. CARROLL: During the next few weeks, the next four or five weeks, I'm sure we'll have to have --

MR. CAMPER: That's precisely what I was talking about a moment ago. I'm sensing that there are some things that we need to go back and begin to look at, now that we have established this general understanding today. I think that it's going to necessitate sometime after the first of the year, the organizations getting together to further --

MS. CARROLL: Drafting a proposal.

MR. CAMPER: -- identify and solidify these issues.

DR. McMANUS: We will have to have our own meeting.

MR. CAMPER: Of course. Also, I would like to

point out that on the 14th and 15th of January, in Washington -- actually in Alexandria, Virginia -- there's going to be a meeting of the Advisory Committee meeting on the medical uses of isotopes.

At that time, our staff is going to present to that advisory committee, our findings relative to the pilot program, a summary of our findings with the various meetings we've had with these different organizations that Mr. Telford identified and to discuss with the ACUI, a staff level version of the final rule. I would encourage a representative of JCHO to attend so as to be able to stay aware.

MR. TELFORD: That's January 14 and 15 in Rockville, Maryland.

MR. CAMPER: If you like, you may contact me directly. My number is 301-492-3417. We'll be happy to provide you with copies of the information.

MR. TELFORD: Following that, we will get some advice from the ACMUI. I would suspect that sometime in February would be a good time for a second meeting in which we could discuss the questions that are in your mind and to see how close we can get to an agreement.

MS. CARROLL: We will be in touch before that, probably with memoranda, some kind of a -- thing, maybe.

MR. TELFORD: You may want to follow up with a

letter to me saying, we had the meeting and we came to this sort of tentative conclusion. We'll resolve certain questions and try to meet sometime in February.

DR. McMANUS: If you get this through in March and envision finalizing it in April or May, will your inspections start in July, mid-year? Have you ever done mid-year?

MR. TELFORD: What you are really asking is what we call the effective date of the rule.

DR. McMANUS: Right.

MR. TELFORD: Let me look into my crystal ball. If we take it to the Commission in April, typically -- in March -- sometime in April, we'll get a decision on the rule. We'll get what is called a Staff's Requirement Memorandum. It will tell us how to fine-tune what we've presented and the changes that the Commissioners want.

We'll make those changes and then a few weeks later, it will be published in the Federal Register as a final rule. Now, that could be May; that could be June.

Six months later, it could be effective.

DR. McMANUS: December or January?

MR. TELFORD: November of December.

DR. McMANUS: At this time, the inspectors would be --

MR. CAMPER: In the meantime, we will be

developing the inspection guidance. We will prepare that in draft. We sent that out to our regional offices.

DR. McMANUS: All the surveyors come in each January. This is an ideal time to --

MR. TELFORD: The six month period is really to allow the licensees to get ready. They can develop their programs to get ready to submit a statement to us on the effective date; that they have implemented their program.

The way we phrased it in the proposed rule was that we would review their application at time of license renewal. That's once every five years, basically, so that they would be required to have a program on the effective date. We would review it on their license renewal date.

We only have to review 20 percent of them per year.

DR. McMANUS: If we went into a hospital -- let's say the effective date, the survey effective date was December 1st, if we went in there on December 5th, you would expect to see how much?

MR. TELFORD: Their program should be in place, effective and implemented.

MR. CAMPER: They're going to be required to send to us a letter certifying that they have put in place, quality assurance programs.

DR. McMANUS: That meets our timetable.

MR. CAMPER: I would suspect that during that six month period that we were just discussing, as we're developing inspection guidance, there would be the need, again, to interface with JCHO was we go through that process.

Although, while we are clearly developing inspection guidance for NRC inspectors, given the role that, at least as we talk at this point, theoretically, that JCHO would play, there would be a need for some communication and interaction there to make sure that everything is in order.

MR. TELFORD: Mainly the indicators. The indicators that you would use, definitely, and the kind of resources that you would devote during your survey to the nuclear medicine department, the minimum that you would devote to each and every hospital's nuclear medicine department --

MR. KLINE: The indicators would also be a function of time and how much time is spent per indicator or what indices we're looking for in those particular areas. That could all be discussed.

MS. CARROLL: You'd have to develop some possible scenarios.

DR. McMANUS: You might have to say, in addition to the NRC indicators, because we're looking at the 98 percent of the care that's already given that could be

improved.

MR. CAMPER: Another point about the advisory committee meeting in January and another reason why I mention it -- and I think that someone being there is good -- we are going to present the staff's version to the ACMUI. We have some concerns about the degree of detail that we can discuss with regards to specific language in the staff version because it is a public meeting. We have a difficult task.

On the one hand, we want to inform our advisory committee and they will receive a copy of the document. On the other hand, the degree to which we can discuss it in a public forum has to be somewhat guarded because it is pre-decisional.

I think that the important point, having given that caveat, your being there -- you will become well aware of the fact that there are going to be significant changes, we think, in the final version of the rule, as compared to the proposed rule that was published several months ago. Those changes result from interactions with the various organizations that Mr. Telford identified.

MR. TELFORD: There will be a lot of polishing.

MR. CAMPER: A lot of polishing.

MR. TELFORD: We've indicated so far, like medical use; we wouldn't say that. Prescription; we wouldn't say

that. There's going to be a lot of that.

DR. McMANUS: It's ongoing. Even after you get it right, there's something you should have changed.

MR. CAMPER: We have been very encouraged by the interactions thus far with these groups. They have been extremely helpful and we just feel that in the final analysis, what will end up as a rule will be a lot better product than it was.

MR. TELFORD: I think we're at the point of summary and conclusions. Can we summarize that we've examined the three different levels of comparisons or equivalents: the regulation level, the licensing level and the inspection level. Those are our terms.

It looks as if we could achieve equivalence theoretically, and with a little work, we could achieve equivalence in a practical sense. We've explored the feasibility of using JCHO accreditation in lieu of the regulations in licensing.

We've determined that there were certain questions that the Joint Commission has to ask itself internally and it seems fruitful to have a second meeting sometime in February of next year. It seemed important that the Joint Commission send at least one person to the ACMUI meeting in January to -- that will at least get you an update of where we are and what we're thinking at that point and at our

meeting in February, we can further update you as to what we're doing.

For those areas that are of practical nature of significant in that, if you are going to carry this out and you would need certain details, I believe we can do that. I've been very encouraged by this meeting. I'm leaving with a lot more than I expected to.

I want to thank you for having had this meeting with us and all these discussions. I look forward to our next meeting.

MS. CARROLL: Thank you. I do, too. Speaking for Dr. Jessee and those who are not here, we're very glad to have had this opportunity to learn about the project, what's going on and to discuss the areas of agreement. I think I can say for all of us that we look forward to continuing this relationship. Thank you very much.

MR. TELFORD: Anything anyone else would like to say?

DR. McMANUS: I enjoyed it very much. I'm sorry I wasn't here for the whole time, but we had a visitor from England who is starting up a Joint Commission over there. Every week, somebody's coming from another country, practically.

So, as far as the surveyor is concerned, we'll have to see how much additional time -- I don't think

there's any problem relative to the philosophy. I think that clearly the field knows about it before we get there and that will take care of your concerns. It's just a question of time and training and the training, it looks like we'll have time to do between now and January or December or the first of 1991.

We'll try to get somebody there in January and we look forward to meeting with you February.

MR. TELFORD: Okay.

MS. SCHUMACHER: I thought the meeting was very good. Paul Mullen is the Director of Government Relations. I'll pass the issues on to him. He'll be delighted that we pretty much are in agreement. If he has questions, I'll have him contact you.

MR. TELFORD: Okay. That bring us to an item on the agenda which is questions and comments from members of the public.

DR. HENKIN: I would like to take this opportunity to make some comments. First of all, I think you need to understand that this meeting arose from a meeting last spring between Peter, Dr. O'Leary and myself at which we urged that the Joint Commission take a role in this process, because we feel that it is a process of medical quality assurance and that it's an important place for the Joint Commission to be.

However, in looking at the issues, I sat here today feeling like a kid at a table while mom and dad discuss what it is that he's going to be when he grows up. Participation of the nuclear medicine community has really been minimal as to what we think is important, what, as practitioners, we think is important and that has unfortunately been the history of this process.

It's one that's led to an adversarial relationship between nuclear medicine and the NRC because they published the material without consultation first and then only later did consultation come. We hope, as the process goes forward, that there is much more consultation with the nuclear medicine specialists based in hospitals as to what Joint Commission thinks is important in developing these procedures as well, since we have had little luck with NRC at the present time.

There are some things that bother me about what went on today. One of them is the exclusion of I-131 from [illegible] quality assurance. There is no reason that I-131 should not fall under Joint Commission in terms of therapeutics; there really isn't.

First of all, you're talking about a relatively low frequency procedure compared to the diagnostics. We do not want to live in the setting of having two masters. That's one of the things that really is a potential problem

for us. That is, if we are to be inspected by Joint Commission and then our program is to be reinspected by NRC because we use Iodine-131, that is not a desirable situation. There really should be, if at all possible, one inspection that encompasses quality for both of them. It doesn't seem to be logical to split that off.

MR. TELFORD: May I ask a question at that point?

DR. HENKIN: Sure.

MR. TELFORD: Let's take your suggestion for a moment. Let's say that you have a nuclear medicine department that does both radiopharmaceutical diagnostics and therapy.

We would define the things we would call misadministrations or some other term, those are reportable events that are bad enough that you still have to report to us.

What if we relied on the joint commission for all of the departments? That's what you're suggesting?

DR. HENKIN: What I am suggesting is that if we are talking about some sort of quality program that develops, a program within the department to handle patients, that in fact that program should be a single unified program with one group inspecting it rather than, say, okay, the diagnostics we can opt to have JCHO examine but the therapeutics are still going to have NRC examine.

I say this because Iodine 131 is not likely to continue to be the only therapeutic.

MR. TELFORD: If I understand your point correctly, you are saying that it would be effective because you would have the joint commission surveys and you would have the reporting requirements, so therefore if somebody were really messing up badly with Iodine-131 we could send our inspector anyway.

DR. HENKIN: I have my reasons for broadening it beyond I-131. By law you are restricted to byproduct material. A number of the potential therapeutics are not byproduct material so that from the point of view of patient quality and patient service it makes it logical that things you cannot regulate might still be covered by joint commission from poor patient quality point of view.

MR. TELFORD: Or if I could put it in NRC terms and protection of the public, you are saying that if we let joint commission oversee these other radiopharmaceuticals that are not byproduct material then we are in effect ensuring protection of the public through the joint commission.

DR. HENKIN: I guess if you want to look at it that way you could. I am looking at it as the fact that joint commission would be the responsible agency to make sure that there is an effective program in place and that

for those things that are legally reportable to NRC they would still be reported to NRC and that I don't see a problem conceptually with that.

I do see a problem conceptually with the two master scenario.

We used to have it before we were an Agreement state in Illinois where half of our inspection was state and half of our inspection was federal and it always caused problems because what pleased one didn't always please the other, so that from a hospital point of view administratively a single program with a single audit or survey or whatever you want to call it is the most desirable thing to have happen.

Now I think you clearly need to understand that the therapeutic issue relates to something like six patients a year for nuclear medicine nationwide, so that we are indeed putting in a lot of effort for this and everybody has put in a lot of effort to it.

It appears to be the desire of NRC to have it. There appears to be no way to stop them from doing it. Therefore, let's do it in a way that works out the best for everybody involved.

Let me deal with a couple of points that came up today.

The issue that Larry raised of decreased staff and

increased isotope procedures is a key issue that worried nuclear medicine greatly. It is related to the certification of medical professionals. It's also non-physician medical professionals.

It's also related to what we have observed on our own and that is that we have a decreasing supply of ancillary staff in all areas to carry out procedures that are continually going up.

We find it in clinical laboratories. We find it among profusionists in the operating room. We find it in a number of places. You just don't have the people pool to handle it.

MR. TELFORD: How can we help?

DR. HENKIN: I have a naive suggestion. My naive suggestion is that we need to return to the system we had ten or fifteen years ago where hospitals either got credit for operating ancillary schools -- they could pass the cost through to HCFA, which is no longer the case -- or that we have some sort of active lobbying by everybody involved for all of ancillary medicine, not just nuclear medicine.

This is a problem throughout radiology. It is a problem throughout -- how could NRC help? I think NRC can identify this as a problem and as an agency make recommendations within the federal government to appropriate agencies.

MR. TELFORD: May I add something here? It may be of interest to you, Dr. Henkin, to know that in one of the reports to Congress on abnormal occurrences, I believe it was this year, I can call you and tell you which volume, which page, it was an inspection which the NRC did so identify that there was a shortage of qualified personnel at this licensee facility.

We asked the licensee to address that so we share your concern and we have so identified.

DR. HENKIN: I'm sure you do. I think what we need is in addition to a program that looks at quality in addition something to bring people into the field.

Now exactly how that should be structured is unclear at the moment.

Let me go on to a couple of others.

One is that in looking and creating a program you should be aware that ACNP has an active practice audit program which in contrast to everybody else's contains about 80 pages of standards, very much along the structure of JCHO standards and that having done a number of inspections I can tell you that there are a lot of things that are not covered in anybody else's program that are covered in this particular program.

I think some of that ought to be looked at in creating standards to find out what it is that the joint

commission might like to adopt from that program for its own standards and that material is freely available so that is not a problem.

MS. CARROLL: How can you get it?

DR. HENKIN: Oh, I can get it for you.

MS. CARROLL: Why don't you do that?

DR. HENKIN: Just give me your card before we leave and I'll have it sent to you but NRC has copies of it, has seen it and it is a peer-created manual that says what it is it's supposed to be to be a quality practice.

We just now I think we have finally gotten a contract from the Army to inspect their hospitals, nuclear medicine facilities, for compliance with that and what we also call accreditation in our system.

The issues that were discussed with written referrals are particularly troublesome issues. They work fine, written referrals, when you have a full-time geographic staff located in your hospital or nearby.

They work fine at my hospital because 90 percent of my patients come from people who are on campus.

However, when you deal in the setting of particularly smaller hospitals the issue of the written referral becomes a nightmare rather than an assistance because what you have is you have a system where first of all the referring physician and patient may travel quite a

distance. The patient may travel quite a distance to get to the institution. That's number one.

Number two, when these written referrals are handed to the patient in the office to give to the physician quite commonly they are misplaced, lost, or not understood as to what they are.

Thirdly, the transmission by fax sounds wonderful. We found out recently not as many people have faxes as we thought they did. All the big guys have got them. It's the little guys that don't have them at the moment, so that this whole issue needs to be examined I think quite carefully as to what appropriate referral is.

There isn't a knee jerk answer that I think will work for all institutions.

I think it is a concern to us at our institution, we use 100 percent written referral, but we can carry it off. I am not sure everybody else can carry it off successfully and it may actually at night and on the weekend result in delayed and denied care in the emergency situation, if that is an absolute requirement because it is not uncommon for the physician not to have seen the patient in the middle of the night but order a lung scan on him based on clinical findings.

I know -- you are going to say there's an exception to that, that you create an exception to that, but

if JCHO does it, it's harder for them to create exceptions at times so that the issue of what appropriate referral is I think needs to be -- we agree it needs to be dealt with. I mean think that appropriate referral is a key process. It's a mechanism that we worry -- what is the mechanism that is going to serve the patient best and not have him sitting around four hours while you try and dig up his doc to get the prescription faxed to you.

That's a real key issue.

Another key issue we deal with is the issue of patient identify. Now again patient identity is more or less a problem between different hospitals.

In some hospitals where you have an affluent population everybody knows who he is and everybody will tell you who he is.

In county hospitals or poorer sections, first of all, they may not use the same name every time they come to the hospital. This is a particular problem in that population. They may, you may have other people who are trying to beat the system, change their names, so that the billing office can't catch up with them, things of that sort.

This identity problem -- in some populations they don't have two things to give you for identity.

MR. TELFORD: How about a photo?

DR. HENKIN: Photograph of whom?

MR. TELFORD: Photograph of the patient.

MR. HENKIN: Who is going to have the photograph and who is going to know that the photograph is that patient?

MR. TELFORD: Of the initial visit you're saying.

DR. HENKIN: He comes back the next time as a different name. What are you going to do? What is your photograph worth?

Your photograph is only as good as the name on it.

MR. KLINE: How many people are coming in using false names?

DR. HENKIN: In L.A. County a significant number of people, at Cook County a significant number of people.

MR. KLINE: How about nationwide?

DR. HENKIN: I can't tell you because the only people who are concerned about it, we know in our emergency room, we are an affluent hospital if you want, that we have somewhere, maybe 5 or 6 percent of the people who aren't using correct names because somebody remembers them from the time they were there before with another name.

MR. KLINE: No doubt that's another problem. We try to work toward the objective of preventing individuals who have the wrong name -- but there can always be unique situations that people can get around regulations and

deliberately trying and we account for that.

DR. HENKIN: But when you put a regulation in place which puts the onus on the hospital and physician, that means that we are in violation --

MR. KLINE: But I don't think the NRC is going to come in if a patient lies and tells you deliberately he's a different person and you have redundantly checked him and he has a false ID but the NRC is going to levy a penalty --

DR. HENKIN: There are many people you cannot redundantly check either. There are many people who do not have two forms of identification, et cetera.

MR. TELFORD: Dr. Henkin, I hear you saying that you really agree with what we are trying to do. You are just pointing out that --

DR. HENKIN: I'm pointing out mechanistic problems that are significant.

MR. TELFORD: Are they significant?

DR. HENKIN: I think there's good data to show they are significant.

MR. TELFORD: Do you have suggestions for how to address this issue?

DR. HENKIN: Well, they exist within joint commission standards already, and that patient identity is an issue in all joint commission. We're supposed to make what amounts to a reasonable effort to identify this patient

as far as if the patient is semi-conscious and can't respond to get somebody down from the floor who knows that patient and ask that person to identify the patient.

I am not worried about the inpatient setting. I have great worries about the outpatient setting.

MR. TELFORD: In other words, if we said "to the greatest extent possible" redundantly identify --

DR. HENKIN: I would want to see implementation guidelines for how such a thing might be implemented before I would comment on them

MR. TELFORD: Or am I going in the right direction?

DR. HENKIN: Yes, you are going in the direction that says if it's possible, do it; if it's not possible you can't do it but then how do you document it is impossible.

MR. TELFORD: We can write guidance on that.

DR. HENKIN: These issues are, even as I say, even in our population we have people answer to the wrong names. We have -- I may have told you the story of the patient who intentionally answered to the wrong name because they felt they had been sitting out there too long and didn't want anybody to go ahead of them!

MS. CARROLL: Excuse me. You started to say that you had great worries? About what?

DR. HENKIN: The identity issues.

MS. CARROLL: No, when -- you started on something else. You had grave worries. I lost you. I am trying to keep notes on this.

DR. HENKIN: I think it was the issues about the issue of written referrals. I have real worries about the mechanisms again associated with written referrals.

Do not misunderstand me. I am not against any of these things. I want to make sure that nothing simplistically gets written that can't be done.

It's very easy to put a regulation in place that says "thou shalt" and try as you can, you can't satisfy that particular "thou shalt."

Those are the concerns I am voicing, that if this were a perfect world, all these things would run fine.

MR. TSE: In your example if a patient specifically, purposefully answers their wrong name then if somebody have a second check --

DR. HENKIN: Well, not necessarily, because they are likely to continue to say -- if you say "Let me see some ID?" "No, I don't have any with me." What are you going to do?

There are --

MR. TELFORD: Did this patient come in without a referral?

DR. HENKIN: No. This patient, you know, it's the

classic situation. You have got six patients sitting out there in the waiting area while you get their doses ready, okay, for different procedures.

As it turns out, patients one, two and three -- well, patient six was there ahead of patient one but because of department operations patients one, two and three go first because their stuff was ready first.

Now patient six is all perturbed because these people who came in after him have gone ahead of him. The next that is called, patient five was in the bathroom, patient six -- nobody responds, looks around and says "That's me, I'm going to go now" and he continues to answer to that name.

MR. TELFORD: Does this patient who came in? You know, it seems to be that you almost have a case, your example here of where the authorized user has decided that this patient should get this byproduct material --

DR. HENKIN: Well, that the exam is just the part that the patient indicated, okay?

MR. TELFORD: Yes, but you in the joint commission terminology, a qualified physician has decided that this patient should get the byproduct material --

DR. HENKIN: Sure. We reviewed the history on that patient, the exam is appropriate to the clinical condition.

MR. TELFORD: So if you had taken a picture of that patient, then you would not that it is patient six instead of patient five.

DR. HENKIN: John, it's not. The picture system is not going to work. I'm going to get a file -- I do 14,000 people a year, 14,000 studies a year. I have a lot of those people with similar names, some of whom could be one letter off or one middle initial off. How much time is it going to take me to sort through those photographs to find which John Jones is here today? Is it John J. Jones? John A. Jones? Is this the right photograph to go with John Jones?

Also there are I think questions of evasion of privacy when you get to photography as well because it is not necessary to the therapeutic procedure. The patient can refuse to have his photograph taken.

Radiotherapists routinely photograph patients for reasons of documentation for malpractice but some patients refuse to be photographed.

MR. TELFORD: We are also determining some treatments by a number of factors related to the alignment and the treatment processing.

DR. HENKIN: Well, it depends. Look at some of the photographs that you can't tell much about anything except the pre- and post- therapy appearance in the patient.

MR. KLINE: If you have an individual who comes in and they respond a name and you believe it is not the person, that's different. If you believe it is not the person, that's another issue.

DR. HENKIN: Well, let's say it's undefined and the person says "I'm Mr. Jones" and he jumps out of line.

You have the patient's chart, "Mr. Jones." I don't have the patient's chart in an outpatient setting.

MR. WIEDEMAN: But you do have, if I remember right, the ALO issues a little plastic card like a credit card for each outpatient.

DR. HENKIN: Oh, yes, but the number of people who show up without that card is significant.

MR. WIEDEMAN: But I understand that they don't even -- you go over to the lab, they will not give you anything at the lab.

DR. HENKIN: They will look you up in the computer but that's --

MR. WIEDEMAN: They send you back to billing and then say, well, you go down and talk to Administration and fill out another form and get a brand new card.

DR. HENKIN: It is as much honored in the breach as it is in the practice because of the long line, okay? They'll say, okay, we'll look you up in the computer, get your medical record number, find your name and address.

MR. TELFORD: Seems like that card would be essential for identification of the patient throughout your system so you would insist on him having it. Sounds like that is what you would do.

DR. HENKIN: It's not as big a problem in our system as it is in some other systems.

MR. TELFORD: I think you solved it.

DR. HENKIN: No. We haven't solved it by any means because we can look at our bad bills and tell you we haven't solved it.

MR. TELFORD: Well, that's just they don't pay it when you send it -- they gave you the wrong address, but you can certainly identify the patient while the patient is there.

MR. KLINE: Will your hospital treat a patient or accept a patient for a diagnostic procedure if all they can give you is their name?

DR. HENKIN: If they give us a name and address, sure.

MR. KLINE: That's it?

MR. WIEDEMAN: If there is a medical record that matches that, then --

DR. HENKIN: If there is none, then a new one will be created and we periodically have to go through and clean out the bad medical records from folk who come in and lie.

It is not an uncommon occurrence.

MR. TELFORD: Yes, but the identification of that patient that day, you solved that issue with your card. The only time we have identification is when they show up with Medicare or Medicaid. Then we have identification because we need those cards.

MR. CAMPER: But I think though, I think I have heard you say though, the idea as an objective of redundantly identifying a patient prior to the administration of a --

DR. HENKIN: I think it is the redundant part that gets me, that identification of a patient, okay, the way joint commission specifies it, is do-able, okay, within the limits of patient veracity.

The onus is on the patient to know who he is unless he is unconscious, okay?

Now if you have a question for an inpatient, there it is real straightforward. There is no problem because they are banded, at least in theory they are banded. You know who everybody is.

It is the outpatient setting that creates grief and the outpatient private office setting creates even more grief.

MR. WIEDEMAN: I'm not so sure. I mean the inpatient you admit is not a problem because they have

armbands.

The outpatients, they have their little plastic cards.

DR. HENKIN: In some systems and not all. If you go over to other places --

MR. WIEDEMAN: I am talking about Loyola.

DR. HENKIN: At Loyola the little plastic card is not universally present, even though it looks on paper like it is. If it were, we wouldn't run the bad bill rates that we run.

I mean we know that's a check on it.

MR. WIEDEMAN: Well, let's assume that a patient came in and they'll at least have something from their referring physician or you are expecting John Doe to walk in.

DR. HENKIN: But the paper gets separated from the patient when they show up and they get reunited at the time of injection.

The paper goes over to a physician to verify that it is an acceptable procedure based on the history, from the physician to the hot lab to get a dose drawn, okay, and actually in our system the dose sheet is part of the requisition so that they stay together forever because they are on clip-sides of a page. They can't get separated.

That paper then is reunited with the patient at

the time that the patient is taken back for injection.

It is possible to change that system.

MR. KLINE: Dr. Henkin, you might have a good point here. The reason for the objective is we had misadministrations related directly with misidentification of patients by which they could have been resolved by a second identification process of which often the remedial action taken by the licensee after a misadministration is to make a double-check.

I think we are focusing on the area that, yes, there could be problems here, but the total picture it appears an effective means for fixing that problem.

We need to concentrate on the moral majority. There can be cases where people try to get around the laws, where people try to sneak in, try to get free treatment, but the majority of hospitals at least with my dealings in talking with people has not been the problem.

The problem that we get reports on, again voluntary reports, has been with misidentification -- nobody trying to trick anybody, nobody trying to get free treatment, just, boy, I got Mr. Jones and there is a John Jones instead of Fred Jones. There's Fred -- oh! We're sorry, we missed him.

MR. WIEDEMAN: If I was at the Loyola University Medical Center and I had my card and I had a requisition

that's been stamped with this card, I could verify that I am Darrel Wiedeman by my birthdate. I could ask the patient what is your birthdate and look at it on the card. Can I see a copy of your card? Now I have verified two things.

I could ask what is your home address and it is on my card.

DR. HENKIN: I guess I have a problem with that being an in-depth responsibility of nuclear medicine. I think we have a responsibility to make a reasonable effort to see that it is the right patient. To cross-examine patients becomes another issue: Are you really who you say you are?

MR. TELFORD: I don't think Mr. Wiedeman said that, Dr. Henkin. I think he said if you have the card you just -- you can easily go up in a very friendly manner and say, you know, my name is John Telford, I am the technologist who is going to treat you today. Would you please tell me your name?

DR. HENKIN: If you don't have the card, what do you do?

MR. WIEDEMAN: Well, that's the part I am having a problem with because -- you work there day in and day out but every time I have gone to Loyola no card -- it's like the old thing, "No tickee, no takee."

They will send you back to Administration to get a

new card and fill out all the forms all over again.

You have to show them your driver's license. You have to verify who you are at that point.

MR. KLINE: Doing the pilot study when you get into identification questions in order to evaluate the programs, and often people that were in the interview they said the chief technologist or the administrator or physician in the hospital would say yes, we have a billing system and oh, yes, that's a redundant mechanism because we require everybody to check in at our front desk. Everybody has to get a receipt. Everybody has to be billed accordingly or else we don't treat.

It appears that they are very concerned that they get their payment, whether it be Medicaid, whether it be from the patient or whoever, before they treat a patient.

The misadministration question of course is relevant --

DR. HENKIN: You guys have seen the letters --

MR. KLINE: -- money.

DR. HENKIN: -- letters from Dr. Marcus at UCLA which describe the level of the problem at that particular hospital, okay?

There are similar problems we're aware of in other hospitals. That's not a unique occurrence.

What I am saying is it's a desirable goal. What

is the mechanism that allows it to operate, okay?

I am not sure I know beyond having the patient truly identify himself.

Now the only situation I think that presents a problem in is an inpatient setting where there is a mechanism in place already for that, that everybody has the same mechanism basically for identifying inpatients who can't identify themselves.

That one I'm not worried about.

I am worried about again the situation of nuclear medicine being a policeman on who's who because there is no other hospital department required to do that.

The Department of Radiology doesn't have to do that. They'll take their word for it.

MR. KLINE: How about blood doning?

DR. HENKIN: Blood donating is hardly done in hospitals anymore. It's done in blood centers and that, you know, that I think that there's really not another -- another parallel setting in a hospital for that at the moment, unless you write it in for radiotherapy, in which case it will be there as well for radiotherapy.

MR. TELFORD: If I understand your point, Dr. Henkin, you agree that it's a very good idea to -- to identify the patient, but when we say redundantly identify the patient, you're saying for some small percentage of the

patients, it may be difficult and, therefore, we shouldn't write it as if it's an absolute thing.

DR. HENKIN: We've just agreed that we have a significant staffing shortage in ancillary medicine, okay. To impose requirements that tie up ancillary staff, is not something that is desirable. It takes them away from patient care settings to do something that may or may not benefit the patient population as a whole.

So that, if you wanted to re-emphasize somehow the importance of identifying patients, yes, I agree with that. I think, however, if we're going to have even one setting a day where 15 or 20 minutes is devoted to this, I think that's not a good idea. I don't have the people to do that. I'm chronically 3 people short.

MR. TELFORD: Okay. We understand your point.

MS. CARROLL: Yes, I've got it.

DR. HENKIN: I don't have anything else to say, except that we, you know, we believe that -- that, as I opened with, a joint commission is the appropriate place for this vehicle to run through, because we do have to comply with so many joint commission standards that are a part from these, but that are important to quality care. So, this is, I think, the right way to go about doing it, and I'm very supportive of the concept of doing it through joint commission, as the nuclear medicine community.

Again, if it mechanistically works right, it will be very good for everybody.

MS. CARROLL: Thank you very much.

MR. CAMPER: We appreciate you coming.

MS. CARROLL: It's great to be considered the lesser of 2 evils.

[Laughter.]

DR. HENKIN: Actually, we deal in the State of Illinois, that for us --

MR. CAMPER: It's a feeling that we haven't had the experience.

DR. HENKIN: -- yes, the lesser of 3 evils then.

MR. TELFORD: Okay. Well, if that's all the comments and the questions, let the meeting be adjourned.

[Whereupon, at 4:13 o'clock p.m. the meeting was adjourned.]

REPORTER'S CERTIFICATE

This is to certify that the attached proceedings before the United States Nuclear Regulatory Commission

in the matter of:

NAME OF PROCEEDING: Joint Commission On Accreditation of Healthcare Organizations on the Proposed QA Rule and Reporting Requirements

DOCKET NUMBER:

PLACE OF PROCEEDING: Oakbrook Terrace, Illinois

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.

Official Reporter
Ann Riley & Associates, Ltd.

Comparison Between JCAHO Standards

and Proposed 35.35 Objectives - for Nuclear Medicine

Section 35.35 Objective	JCAHO Standards
(1) Ensure that any medical use is indicated for the patient's medical condition.	NM. 1.1 NM. 1.3.9 NM. 2.2.2
(2) Ensure, prior to any medical use, that a prescription is made for any therapy procedures and any diagnostic radiopharmaceutical procedure involving more than 30 microcuries of I-125 or I-131. and (3) Ensure, prior to any medical use, that a prescription or a diagnostic referral is amde for any diagnostic procedure not involving more than 30 microcuries of I-125 or I-131.	NM. 1.3.2 NM. 2.2.1 NM. 2.2.3 NM. 2.2.4
(4) Ensure, prior to any medical use, that the prescription or the diagnostic referral and clinical procedures manual is understood by the responsible individuals.	NM. 1.3.1 NM. 1.3.3 NM. 1.3.7 NM. 2.2.4 NM. 2.2.7 NM. 2.2.20
(5) Ensure that any medical use is in accordance with a prescription or a diagnostic referral and clinical procedures manual.	NM. 2.2.10 NM. 2.2.10.1.3 NM. 2.2.14 NM. 2.2.14.2 NM. 2.2.14.4
(6) Ensure, prior to any medical use, that the patient's identity is verified as the individual named on the prescription or the diagnostic referral.	NM. 2 NM. 2.2.8 NM. 2.2.10.1.3
(7) Ensure that any unintended deviation from a prescription or a diagnostic referral and clinical procedures manual is identified and evaluated.	NM. 1 NM. 1.3.9 NM. 4 NM. 4.1

DRAFT

QUALITY ASSESSMENT AND IMPROVEMENT

PROPOSED REVISED STANDARDS

Preamble

This chapter--formerly called "Quality Assurance" -- describes the activities of the hospital that are designed to assess and improve the quality of patient care. The chapter includes revisions and additions to the 1991 standards which are intended to assist hospitals in performing these activities more effectively. The standards revisions are focused on two areas:

- placing greater emphasis on the role of the hospital's leaders -- governance, managerial, medical, nursing, and other clinical leaders -- in assessing and improving patient care, and

- shifting the emphases and further clarifying certain steps in the monitoring and evaluation process.

In addition, in an effort to simplify the Manual, some standards related to quality assessment and improvement that were repeated in numerous other chapters of the Manual have been consolidated into this chapter (and deleted from the others).

The revised standards are based on the following principles:

- A hospital can improve patient care quality -- i.e., increase the probability of desired patient outcomes, including patient satisfaction -- by assessing and improving those governance, managerial, clinical, and support processes that most affect patient outcomes.

- Some of these processes are carried out by medical, nursing and other clinicians, some by governing body members, some by managers, and some by support personnel; some are carried out jointly by more than one of these groups.

- Whether carried out by one or more groups, the processes must be coordinated and integrated; this coordination and integration requires the attention of the managerial and clinical leaders of the hospital.

- Most governance, managerial, medical, nursing, other clinical, and support staff are both motivated and competent to carry out the processes well. Therefore, the opportunities to improve the processes -- and, thus, improve patient outcomes -- are much more frequent than are mistakes and errors. Consequently, without shirking its responsibility to address serious problems involving deficits in knowledge or skill, the hospital's principal goal should be to help everyone improve the processes in which he/she is involved.

These principles underlie the continual assessment and improvement of quality. For hospitals, the natural next step in the steady progression of approaches from implicit peer review, to medical audits, to systematic quality assurance (QA), is to continual improvement of quality.

Beginning with this 1992 Manual, and progressing over the next few years, the Joint Commission is incrementally revising the standards on quality assessment and improvement to help hospitals use their current commitment, resources, and approaches to improving patient care quality more effectively and efficiently. The revisions in this Manual are designed to emphasize the role of hospital leaders in these quality improvement activities, to encourage hospitals to evaluate their current activities in light of the above principles, and to assist those hospitals that are already moving toward the continual improvement of quality. In subsequent Manuals, the standards revisions will begin to establish expectations for all hospitals to continually improve quality.

New to the chapter this year is a series of standards (QA.1 through QA.1.5.1) that addresses the important role that the hospital's leaders play collectively and individually in assessing and improving patient care quality. These standards emphasize the governance, managerial, medical, nursing, and other clinical leaders' responsibilities to set expectations for quality assessment and improvement, to provide the resources and training needed for these activities, to foster communication and coordination, and to personally participate in improvement activities.

The revisions in the monitoring and evaluation standards are intended to shift some emphases of the previous standards in order to help many hospitals avoid those weaknesses in their current practices of quality assurance that can inhibit the development of an approach to continually assessing and improving quality. These weaknesses in current practice include:

- an almost exclusive focus on the clinical aspects of care (e.g., what the doctor and nurse do with the patient), rather than on the full series of interrelated governance, managerial, and support, as well as clinical, processes that affect patient outcomes;

- an almost exclusive compartmentalization of QA activities in accordance with hospital structure (e.g., by department, by discipline) rather than organizing quality improvement activities around the flow of patient care, in which the interrelated processes are often cross-disciplinary and cross-departmental;

- an almost exclusive focus on the performance of individuals, especially on problem performance, rather than on how well the processes in which they participate are performed, how well the processes are coordinated and integrated (e.g., the "handoffs"), and how the processes can be improved;

- initiating action only when a problem is identified, rather than also trying to find better ways to carry out processes; and

- separating the appropriateness ("Was the right thing done?") and effectiveness ("Was it done right?") of care from the efficiency of care, rather than integrating efforts to improve patient outcomes with those to improve efficiency (i.e., improving value).

In addition, because of its almost exclusive focus on individual performance -- especially problem performance -- for many health care professionals QA has a negative persona which can deaden their instinct to pursue lifelong self-assessment and constant personal growth.

The changes in the monitoring and evaluation standards are designed to shift the emphases of quality assessment and improvement activities away from an exclusively department -- and discipline-specific, exclusively direct care focused, and exclusively individual problem oriented approach to an approach that reflects the principles discussed above -- an approach that will harness the professional instinct for continual improvement.

STANDARD

QA.1 The organization's leaders* set expectations, develop plans, and implement procedures to assess and improve the quality of the organization's governance, management, clinical, and support processes.

REQUIRED CHARACTERISTICS

QA.1.1 The leaders set priorities for organizationwide quality improvement activities that are designed to improve patient outcomes.

QA.1.2 The leaders allocate adequate resources for assessment and improvement of the organization's governance, managerial, clinical, and support processes, through

QA.1.2.1 the assignment of personnel, as needed, to participate in quality improvement activities;

QA.1.2.2 the provision of adequate time for personnel to participate in quality improvement activities; and

QA.1.2.3 information systems and appropriate data management processes to facilitate the collection, management, and analysis of data needed for quality improvement.

QA.1.3 The leaders assure that organization staff are trained in assessing and improving the processes that contribute to improved patient outcomes.

QA.1.4 The leaders individually and jointly develop and participate in mechanisms to foster communication among individuals and among components of the organization, and to coordinate internal activities.

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* The leaders responsible for performing the identified functions include at least the leaders of the governing body; the chief executive officer and other senior managers; the elected and/or appointed leaders of the medical staff and the clinical departments, and other medical staff members in hospital administrative positions; the nursing executive and other senior nursing leaders; and other clinical leaders.

QA.1.5 The leaders analyze and evaluate their personal involvement in quality improvement activities and the effectiveness of their contributions to improving quality.

QA.1.5.1 This analysis and evaluation is performed at least annually, and is based upon an assessment that involves the application of prospective criteria that have been agreed on by the leaders.

QA.1.6 There is a written plan for the program to assess and improve quality that describes the program's objectives, organization, scope, and mechanisms for overseeing the effectiveness of monitoring, evaluation, and improvement activities.*

Standard

QA.2 The scope of the program to assess and improve quality includes at least the activities listed in Required Characteristics QA.2.1 through QA.2.4.2 and described in other chapters of this Manual.

Required Characteristics

QA.2.1 The following medical staff functions are performed:

QA.2.1.1 The monitoring and evaluation of the quality of patient care and the clinical performance of all individuals with clinical privileges through

QA.2.1.1.1 participation by members of each department/service in intra- and/or interdepartmental/service monitoring and evaluation of care; periodic review of the care; and communication of findings, conclusions, recommendations, and actions to members of the department/service.

QA.2.1.1.2 surgical case review;

QA.2.1.1.3 drug usage evaluation;

QA.2.1.1.4 the medical record review function;

QA.2.1.1.5 blood usage review; and

QA.2.1.1.6 the pharmacy and therapeutics function.

QA.2.2 The quality of patient care, including that provided to specific age groups, in all patient care services are monitored and evaluated.*

QA.2.2.1 The services in which care is monitored and evaluated include at least:

QA.2.2.1.1 Alcoholism and other drug dependence services, when provided;

QA.2.2.1.2 Diagnostic radiology services;

QA.2.2.1.3 Dietetic services;

QA.2.2.1.4 Emergency services;

QA.2.2.1.5 Hospital-sponsored ambulatory care services, when provided;

QA.2.2.1.6 Nuclear medicine services, when provided;

QA.2.2.1.7 Nursing services;

QA.2.2.1.8 Pathology and medical laboratory services;

QA.2.2.1.9 Pharmaceutical services;

QA.2.2.1.10 Physical rehabilitation services, when provided;

QA.2.2.1.11 Radiation oncology services, when provided;

QA.2.2.1.12 Respiratory care services, when provided;

QA.2.2.1.13 Social work services;

QA.2.2.1.14 Special care unit services, when provided; and

QA.2.2.1.15 Surgical and anesthesia services, when provided.

QA.2.2.2 The director of each department/service is responsible for including the department's/service's activities in the monitoring and evaluation process.*

QA.2.2.2.1 The department/service participates in: *

QA.2.2.2.1.1 the identification of important aspects of care relevant to the department/service;

QA.2.2.2.1.2 the identification of indicators used to monitor the quality of the important aspects of care; and

QA.2.2.2.1.3 the evaluation of the quality of care.

QA.2.2.3 When an outside source(s) provides patient care services, or when there is no designated department/service in the hospital that provides a patient care service, the organization's leaders are responsible for implementing the monitoring and evaluation process.*

QA.2.3 The following hospitalwide functions are performed:*

QA.2.3.1 Infection control (Standards IC.1 and IC.2);

QA.2.3.2 Utilization review (Standard UR.1); and

QA.2.3.3 Review of accidents, injuries, patient safety, and safety hazards ("Plant, Technology, and Safety Management" Standard PL.1, Required Characteristics PL.1.3.1.2, PL.1.3.1.3, and PL.1.3.1.4, and PL.1.4.3).

QA.2.4 Relevant results from the quality assessment activities listed in Required Characteristics QA.2.1 through QA.2.3.3:

QA.2.4.1 are used primarily to study and improve processes that affect patient care outcomes, and

QA.2.4.2 if relevant to the performance of an individual are used as a component of the evaluation of individual capabilities. ("Medical Staff" Required Characteristics MS.5.3.1 and MS.5.3.1.5, and "Governing Body" Required Characteristic GB.1.15).*

STANDARD

QA.3 Monitoring and evaluation activities, including those described in Standard QA.2, Required Characteristics QA.2.1 through QA.2.4.2.3, reflect the activities described in Required Characteristics QA.3.1 through QA.3.2.8.*

Required Characteristics

QA.3.1 There is a planned, systematic, and ongoing process for monitoring, evaluating, and improving the quality of care and of key governance, managerial, and support activities that has the characteristics described in Required Characteristics QA.3.2 through QA.3.2.8.*

QA.3.2 Those aspects of care that are most important to the health and safety of the patients served are identified.*

QA.3.2.1 These important aspects of care are those that

QA.3.2.1.1 occur frequently or affect large numbers of patients;

QA.3.2.1.2 place patients at risk of serious consequences or of deprivation of substantial benefit when

QA.3.2.1.2.1 the care is not provided correctly; or

QA.3.2.1.2.2 the care is not provided when indicated; or

QA.3.2.1.2.3 the care is provided when not indicated; and/or

QA.3.2.1.3 tend to produce problems for patients or staff.

QA.3.2.2 Indicators are identified to monitor the quality of important aspects of care.*

QA.3.2.2.1 The indicators are related to the quality of care and may include clinical criteria (sometimes called "standards," "guidelines" or "parameters" of care or "practice").

QA.3.2.2.1.1 These indicators are

QA.3.2.2.1.1.1 objective;

QA.3.2.2.1.1.2 measurable; and

QA.3.2.2.1.1.3 based on current knowledge and clinical experience.

QA.3.2.2.1.2 These indicators reflect structures of care (for example, resources), processes of care (for example, procedures, techniques), or outcomes of care (for example, complication rates).

QA.3.2.3 Data are collected for each indicator.*

QA.3.2.3.1 The frequency of data collection for each indicator and the sampling of events or activities are related to

QA.3.2.3.1.1 the frequency of the event or activity monitored;

QA.3.2.3.1.2 the significance of the event or activity monitored; and

QA.3.2.3.1.3 the extent to which the important aspect of care monitored by the indicator has been demonstrated to be problem-free.

QA.3.2.4 The data collected for each indicator are organized so that situations in which an evaluation of the quality of care is indicated are readily identified.*

QA.3.2.4.1 Such evaluations are prompted at least by

QA.3.2.4.1.1 important single clinical events; and

QA.3.2.4.1.2 levels, patterns, or trends in care or outcomes that are at variance with predetermined levels, patterns, and/or trends in care or outcomes.

QA.3.2.5 When initiated, the evaluation of an important aspect of care

QA.3.2.5.1 includes analysis of trends and/or patterns in the data collected on the indicators;*

QA.3.2.5.2 includes review by peers when analysis of the care provided by a practitioner is undertaken; and*

QA.3.2.5.3 identifies opportunities to improve, or problems in, the quality of care.*

QA.3.2.6 When an important opportunity to improve, or problem in, the quality of care is identified,*

QA.3.2.6.1 action is taken to improve the care or to correct the problem; and*

QA.3.2.6.2 the effectiveness of the action taken is assessed through continued monitoring of the care.*

QA.3.2.7 The findings, conclusions, recommendations, actions taken, and results of the actions taken are

QA.3.2.7.1 documented; and*

QA.3.2.7.2 reported through established channels.*

QA.3.2.8 As part of the annual appraisal of the hospital's program to assess and improve quality, the effectiveness of the monitoring and evaluation process is assessed.*

Standard

QA.4 The administration and coordination of the hospital's overall program to assess and improve quality are designed to assure that the activities described in Required Characteristics QA.4.1 through QA.4.5 are undertaken.*

Required Characteristics

QA.4.1 Each of the monitoring and evaluation activities outlined in Standards QA.2 and QA.3 is performed appropriately and effectively.*

QA.4.2 Necessary information is communicated among departments/services and/or professional disciplines when opportunities to improve patient care or problems involve more than one department/service and/or professional discipline.*

QA.4.2.1 There are operational linkages between the risk management functions related to the clinical aspects of patient care and safety and quality assessment and improvement functions.*

QA.4.2.2 Existing information from risk management activities that may be useful in identifying opportunities to improve the quality of patient care and/or resolve clinical problems is accessible to the quality assessment and improvement function.*

QA.4.2.3 Information from departments/services and the findings of discrete quality assessment and improvement activities are used to detect trends, patterns, opportunities to improve, or potential problems that affect more than one department/service and/or professional discipline.*

QA.4.3 The status of identified opportunities or problems is tracked to assure improvement or resolution.*

QA.4.4 The objectives, scope, organization, and effectiveness of the program to assess and improve quality are evaluated at least annually and revised as necessary.*