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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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MEETING WITH ADVISORY COMMITTEE

ON MEDICAL USES OF ISOTOPES (ACMUI)

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PUBLIC MEETING

Nuclear Regulatory Commission
Room 1F-16
White Flint Building 1
11555 Rockville Pike
Rockville, Maryland

Thursday, May 8, 1997

The Commission met in open session, pursuant to notice, at 9:01 a.m., Shirley A. Jackson, Chairman, presiding.

COMMISSIONERS PRESENT:

SHIRLEY A. JACKSON, Chairman
KENNETH C. ROGERS, Commissioner
GRETA J. DICUS, Commissioner
EDWARD McGAFFIGAN, JR., Commissioner
NILS J. DIAZ, Commissioner

STAFF AND PRESENTERS SEATED AT THE COMMISSION TABLE:

ANNETTA VIETTI-COOK, Assistant Secretary

NAOMI ALAZRAKI, M.D.

JUDITH I. BROWN

DANIEL F. FLYNN, M.D.

JOHN GRAHAM

WIL B. NELP, M.D.

JUDITH ANNE STITT, M.D.

DENNIS P. SWANSON, M.S., B.C.N.P.

LOUIS K. WAGNER, Ph.D.

THERESA WALKUP

JEFFREY F. WILLIAMSON, Ph.D.

ANDREW KANG, M.D.

P R O C E E D I N G S

[9:01 a.m.]

CHAIRMAN JACKSON: Good morning, ladies and gentlemen.

Today, the NRC's Advisory Committee on the Medical Uses of Isotopes will provide the Commission with its annual briefing.

The ACMUI, as its called, last met with the Commission in May of 1996 to discuss the National Academy of Sciences report on the Medical Use Program.

In the intervening year, much has occurred that relates to the medical use program.

Most recently, the Commission directed the staff, in a March 20, 1997, Staff Requirements Memorandum, to develop a program for revising 10 CFR Part 35.

Also within that SRM, the Commission directed the staff to continue to use the Advisory Committee on the Medical Uses of Isotopes and other professional organizations and societies in developing regulatory guides and standards.

Today's presentation provides the Commission with its first formal briefing since the SRM was issued. We look forward to hearing from the advisory committee on its views on achieving the goals of the SRM.

I understand that presentational material is

available at the entrances to the room.

So, unless my colleagues have any opening comments, please begin.

Dr. Stitt, are you the lead?

DR. STITT: I think Don Cool is the lead.

CHAIRMAN JACKSON: Okay.

DR. COOL: Good morning.

The Advisory Committee on Medical Uses of Isotopes is an advisory committee which has been established for a large number of years, going way back to the time of the Atomic Energy Commission.

Its function has changed over the course of time a little bit, as the Commission's involvement in medical regulation has increased, FDA involved that occurred in the '70s occurred. So, it has undergone some transitions.

This group provides the staff with advice in a number of areas in terms of the regulation and guidance documents that are being developed, some instances of particular training and experience where some unique questions come up.

They provide us particular advice on individual cases, provide us advice and a sounding board, if you will, for interactions with other Federal agencies, professional societies, and various groups.

I personally find it very valuable to have these

folks available to me and my staff in trying to work through the program.

The chairman for the committee now is Dr. Judith Stitt from the University of Wisconsin.

The ACMUI met just about a month ago, on April 10th and 11th, and devoted the entirety of that meeting to the issues associated with the revision of Part 35 and the questions and things which the Commission had put forward in the SRM.

That SRM was available to the advisory committee during that briefing.

And at this point, I'm going to turn it over to Dr. Stitt to introduce the committee members and the committee to provide you with their thoughts and views on the subject.

Dr. Stitt?

DR. STITT: Thank you, Don, and good morning. The ACMUI is very pleased to be here, to have this opportunity to meet with the commissioners and to express our opinions and our ideas regarding radiation medicine.

I'd like to introduce three of our members who are seated behind me and are not at microphones but are certainly available for questions.

Theresa Walkup, Certified Medical Dosimetrist and Radiation Therapist. She's at Mercy Health Care in Oklahoma

City.

Andrew Kang, who represents the FDA as a member of our committee.

And Will Nelp, to my far right, who is a Nuclear Medicine Physician at the University of Washington in Seattle.

I'd like to ask my committee members to introduce themselves, starting with Jeff Williamson.

DR. WILLIAMSON: I'm Jeff WIlliamson, a Radiation Oncology Physicist at Washington University School of Medicine in St. Louis.

DR. STITT: Dennis?

DR. WILLIAMSON: And good morning.

MR. SWANSON: Good morning. I'm Dennis Swanson, Nuclear Pharmacist from the University of Pittsburgh.

MR. GRAHAM: John Graham, Director of St. Mary Hospital, an affiliate of the Beaumont Hospital System.

DR. ALAZRAKI: Naomi Alazraki. I'm a Nuclear Medicine Physician at Emery University School of Medicine in Atlanta.

DR. FLYNN: Daniel Flynn, a Radiation Oncologist, Holy Family Hospital in Massachusetts, also Mass General Hospital and Harvard Medical School.

DR. STITT: Thank you, committee members.

We view ourselves as the voice of clinical

medicine. The ACMUI members manage patients, we perform diagnostic tests, and treat cancer patients with radiation procedures.

The ACMUI has been working together effectively for several years and has developed a cohesive style but with plenty of room for different views.

We are now embarking on a new venture that for us started just three weeks ago, when we received direction from the commissioners regarding the IOM report, the elements of DSI-7, and Part 35 changes.

The ACMUI is here today to discuss an overview of these issues and to give the commissioners a sense of our clinical opinion.

I'd like to start with the first slide.

[Slide.]

DR. STITT: Radiation medicine is a small part of the NRC business. It's also a small part of medicine when considered as a whole.

Radiation medicine is a safe process in relationship to the practice of medicine.

We have taken our definition of risk from the documents that we have been reviewing from the NRC staff. Risk is related to the probability of error and the severity of consequences.

CHAIRMAN JACKSON: Let me just ask a question

question. When you speak of risk, are you referring to the worker, the patient, or the public?

DR. STITT: I'm referring to it in the sense of risk as a whole, when you're looking at medical events, human factors in medicine. So, you could use risk in any of those particular subcategories.

The risk is going to then change to some degree, depending on which group of procedures and whether you're looking at workers, patients, or public, and I think those all become important in some categories, and we're going to try to address those as we go through our comments.

One can also think of risk in a little more simpler term, but that is variation around an expectation, and you can consider that variation, again, in all the different walks of life of radiation medicine.

When I think about risk, it's something I do every day.

I talk to patients about what is the risk of you having a bowel injury if we proceed with this radiation and what is the likelihood that radiation treatment to the pelvis is going to keep cancer at bay versus your chance, your risk of developing a bowel obstruction as a consequence?

Next slide, please.

[Slide.]

DR. STITT: Research in risk and event reporting for medicine is relatively new. It's been studied for quite some time in transportation, aviation, and in other industry, but when you look at the literature for medicine, it's really quite new.

It's been said that risk or error just simply doesn't occur in medicine, doctors don't make mistakes, and so it's really not been the subject of much formal research.

There is a growing body of literature about medical events of all nature, and there are some small pockets of research that are actually taking place now in radiation medicine.

In general, there's a very low incidence of error in radiation medicine, and this is not even relating error to consequence or to risk.

We feel that incidence of error is low in all of the radiation modalities because of the elements listed here on this slide.

They include voluntary practice patterns, practice standards among the different groups, staff training standards for dosimetrists, physicians, physicians, and the broad quality improvement patterns, programs that exists in all departments.

In addition, you can look at credentialing and hospital privileges for those procedures that are performed

in hospitals.

COMMISSIONER ROGERS: Excuse me. Just before we leave that slide --

DR. STITT: Sure.

COMMISSIONER ROGERS: The number, 1 times 10 to the minus 4 -- where does that come from? We've had a lot of trouble trying to get numbers like that over the years, and I wondered how you were successful in doing so.

DR. STITT: We did, too. We took it from NRC materials that we were given.

[Laughter.]

DR. STITT: Jeffrey, do you want to make any comments?

DR. WILLIAMSON: Well, it's really hard to defend.

I looked at the numbers of misadministrations that were reported in your evaluation of the QM program, and you actually had the numbers of procedures there, so I looked at that. I looked at the IOM report. I ball-parked the number of procedures that occur over the country and kind of came up with this number.

COMMISSIONER ROGERS: Well, it's always the denominator that gives us the problem, not the numerator.

DR. STITT: Correct.

Dan?

DR. FLYNN: I'll give you an example.

Like maybe 5 or 10 years ago, we estimated the number of brachytherapy procedures in the United States between 30 and 50 thousand.

Now, with prostate seed implants, more than 5,000 a year, and HDR brachytherapy, individual procedures, it's probably closer to 60 to 80 thousand a year.

If you have 8 misadministrations per year and the denominator is 60 to 80 thousand, that would be 1 to the 10 to the minus 4th. That would be a reasonable estimate.

COMMISSIONER McGAFFIGAN: Could I ask a couple of questions?

DR. STITT: Please.

COMMISSIONER McGAFFIGAN: Is it possible that NRC regulation has had something to do with the 1 in 10 to the minus 4th? I mean, you know, you have a list of --

DR. STITT: You notice we left that one out, but it comes up every time we have this discussion, and certainly, the NRC very definitely is of the opinion that radiation -- that events are lower in radiation medicine because of the NRC's presence.

CHAIRMAN JACKSON: Let me rephrase the question, if I may. If NRC removed and replaced its prescriptive regulatory requirements with performance-based, would the low incidence of error remain so based upon these other factors that you talked about?

DR. STITT: I think that is putting it in a little bit different context. I think it's one of the real issues.

We're going to try to at least address -- talk around those issues as we go through our report to see if there's some groundwork, some basis on which to try to answer that question.

Naomi.

DR. ALAZRAKI: Yes.

I would just interject that I think the medical community feels that the errors have been low more because of the training and experience of those working in the field than because of any prescriptive rules from NRC, and I think that the experience -- there is some experience that -- that, in the absence of some of these -- and I can't quote right off the top of my head -- that, in the absence of some of the prescriptive-nature materials, that the error doesn't change, that it's basically the bottom-line human error.

COMMISSIONER McGAFFIGAN: Could I ask another question on voluntary standards? One problem -- the reason your community -- medical community at large, not radiation medicine -- ends up on "60 Minutes" with such regularity is that the -- there are some people who clearly practice medicine and don't practice it well, and you know, you get the horror stories.

I was told last year by a fellow who does New York

City's radiation safety, not just for us but for the whole city, of a person conducting mammographies who, when they finally looked at him, almost everything was wrong about what he was doing, over 100 procedures -- they're just bogus.

Actions had been taken as a result of that. He still hadn't been disciplined by the State medical board. He had moved on to Pennsylvania or something. It was a real horror story. That one hasn't made "60 Minutes" yet.

But how do you deal with the fact that you have -- everybody on the other side of the table practices medicine, practices medicine well, you know that there is an outlier element of your community that doesn't, and you know, does regulation or at least the possibility of enforcement by us or a state body if it's not by-product material keep those people somewhat honest or at least get them off the streets?

DR. STITT: Well, a general response to that would be more like the comments that Stephen Brier made in his book, Breaking the Vicious Cycle. How can you regulate any part of life down to the last 10 percent, 5 percent, 1 percent?

So, I mean I think we have to set standards, whether they're NRC regulations, voluntary standards of hospitals, or national practice groups, and then try to

bring practitioners to those standards.

Were you waving your hand?

DR. WILLIAMSON: Well, I guess I could make some statement. I guess, in my own practice, which focuses largely on brachytherapy, the Commission's rules and so on are sort of an overlay that's imposed on top of already functioning quality assurance program.

You have to remember that brachytherapy in virtually all departments is a relatively small part of the practice, and so, we have, in most institutions, a fairly detailed quality improvement program that encompasses brachytherapy.

So, we kind of have the NRC standards functioning, of course, and we have our quality improvement program functioning, which I'll try and address in my part of the comments.

It is my opinion that the incidence of errors is kept low because of the adherence to voluntary standards rather than compliance with the sort of overlay of regulations, which I think are a fairly incomplete clinical quality assurance program.

CHAIRMAN JACKSON: I think, as we go through -- and I think we should move on -- I think we do have to try to make a distinction between two things.

One is, does the mere existence of regulation

encourage the creation and lay out some baselines for effective quality assurance programs of the type you feel that you have, and the second part has to do with the nature of the regulations and what they can be or need be if we assume that there's an affirmative answer to the first, which is obviously where the Commission, in a certain sense, is coming down, where one can accomplish and ensure that one has the right elements in a program to protect patients, the worker, and the public in a way that's different than the way we've been doing it to this point.

DR. STITT: We'll continue on with slide three.

[Slide.]

DR. STITT: I think the first comments that we have made really lead us to the statement that the ACMUI members have agreed upon, that the low-risk status does justify and move away from prescriptive regulations and toward the development of performance-based regulation of radiation medicine.

So, I think the comments you just made, Commissioner Jackson, put that side of the table and this side of the table on a level where we have several things that we agree upon.

Next slide, please.

CHAIRMAN JACKSON: I haven't made a statement. I asked a question.

DR. STITT: What's that?

CHAIRMAN JACKSON: I said I haven't made a statement relative to prescriptive versus non-prescriptive.

DR. STITT: Okay.

CHAIRMAN JACKSON: I've asked the question, which is what we'd like to hear from you about.

DR. STITT: Next slide.

[Slide.]

DR. STITT: As we said initially, risk is related to the probability of error and the potential for the consequences of those errors.

We, as the ACMUI, have developed a spectrum of radiation procedures that we have begun to look at from one end being high-dose-rate brachytherapy, which is a special form of radioactive isotope therapy, to diagnostic nuclear medicine, which we feel is at the opposite end of the spectrum.

CHAIRMAN JACKSON: Where does gamma teletherapy fit in the spectrum?

DR. STITT: Gamma teletherapy is a specific type of teletherapy, teletherapy referring to cobalt therapy, and it should be on this list and is not.

We felt that it resided toward the bottom, around the level of low-dose-rate brachytherapy and that the gamma stereotactic really refers to very, very focused multiple

beams of radioactive cobalt as the teletherapy unit that is almost exclusively used for treating small brain cancers or AVM malformations in the brain.

It has a risk that's on the higher end of the spectrum because it has multiple fields, it's very high doses, and treatment is given in a single visit.

Dan Flynn will continue with comments on the next slide.

DR. FLYNN: Next slide, please.

[Slide.]

DR. FLYNN: Again, continuing with the risks and the potential, I should say, health consequences of exposure, high-risk procedures, meaning high-risk for health consequences, would be, for example, exposure to large numbers -- I should say large numbers of members of the public to greater than Part 20 limits, deterministic injuries to staff possible or likely, probable serious injury to the patient, and health consequences meaning a low-risk event occurs and it results in a consequence such as harm to the whole body, harm to a part of the body, like an organ system, the kidney or the skin, produces symptoms and injury.

Examples would be, for example, high-dose-rate accident in Indiana, Pennsylvania, where a source is -- lost control.

Not only is the patient severely injured by the accident, but members of the public could be potentially seriously injured as this source is out of control for longer and longer periods of time.

Another example would be in Guyana, Brazil, an uncontrolled teletherapy cesium-137 source, large numbers of people, much bigger accident than even Indiana, Pennsylvania, and with serious consequences.

Next slide.

COMMISSIONER McGAFFIGAN: Could I ask a question on that slide before we go on? Which Part 20 limits are you talking about?

Exposure to the public greater than Part 20 limits. Are you talking about the public release limit, the 100-millirem, the patient release, 500 millirem, the occupational dose?

DR. FLYNN: It's more of a general statement, meaning if -- large numbers of the public, meaning many thousands of individuals -- that would be considered a high-risk procedure if thousands or -- large numbers of the population would be exposed to a dose that's greater than -- much greater than the Part 20 limits, for example, such as in those accidents.

CHAIRMAN JACKSON: Dr. Williamson has a comment.

DR. WILLIAMSON: Yes. This is attempting to

define risk separately for three separate sub-populations. So, for general public, we meant large numbers of people being exposed to even small doses that could have a, you know, calculable epidemiological impact.

COMMISSIONER McGAFFIGAN: But that's 100 millirem.

DR. WILLIAMSON: That's 100 millirem, roughly. I guess we took that as -- one could debate it, but --

COMMISSIONER McGAFFIGAN: Right.

DR. WILLIAMSON: -- for purposes of this discussion, we accepted that.

For members of the staff working with the radioactive sources, we took the end point to be the possibility of some injury.

COMMISSIONER McGAFFIGAN: Greater than 5 rems?

DR. WILLIAMSON: No, much greater than that, an injury, an actual injury, like putting the source in your pocket and getting a skin burn, a skin erythema, or something of that nature, not -- I think we would say medium risk might be for the public where only a relatively small number of persons could be exposed to an epidemiologically significant exposure.

COMMISSIONER McGAFFIGAN: So, for the staff, it's much greater than 5 rems. 50 rems?

DR. WILLIAMSON: Possibly. It would depend on the end point involved. 50 rem to the whole body, I think,

would probably be closer.

DR. FLYNN: The staff is also being monitored, and as radiation workers, of course, we would expect that the limits on them would be different than the limits on the public.

COMMISSIONER McGAFFIGAN: Right. The current limit is 5 rems, isn't it?

DR. WILLIAMSON: Yes.

DR. FLYNN: Yes. 1,250 a quarter.

COMMISSIONER McGAFFIGAN: You're saying, in this case, it's much higher than 5 rems.

DR. WILLIAMSON: Yes. I'm talking about like an actual injury, not the possibility of getting cancer 30 years down the line.

CHAIRMAN JACKSON: Please go ahead.

DR. FLYNN: All right. Next slide, please.

[Slide.]

DR. FLYNN: And then these are general statements now in terms of risk.

Health consequences of exposure, let's say, medium-risk procedures, members of the public and staff exposed to less than Part 20 limits, but if we're talking about very large numbers of the public -- and we'll discuss the ALARA concept separately -- we certainly wouldn't want to see unnecessary radiation exposure to large populations

of people, even if it was below the limits, small numbers of individual staff or public exposed to greater than Part 20.

An example of medium risk might be teletherapy, but not teletherapy in the sense of the Guyana, Brazil, accident, teletherapy in the sense of medical practice.

I think when a source is decommissioned or a radiation oncology facility is abandoned, like in Guyana, Brazil, that that's a different issue, handling sources in transport or sources that have been decommissioned, as opposed to -- we're talking about medical practice, treating patients on a daily basis.

Teletherapy would, in my opinion, be in the medium-risk level.

Whereas in low-risk procedures, exposures to the public and all staff would be less than Part 20 limits, would be, for example, diagnostic nuclear medicine, where if there is a technesium incident of some type, it is unlikely to result in any harm to the public or staff and it only involves one patient to which we would not expect any medical consequence whatsoever and a very low-risk procedure in that particular isotope.

Next slide.

[Slide.]

DR. FLYNN: Again, risk in radiation medicine -- high-risk procedures, the potential for risk based on the

health consequence of errors -- that is, for individual patients or individual staff, we're talking about harm to the body or part of the body, especially when talking about patients.

The probability of occurrence is low given the current standards for both the physician, the physicist, the support staff in terms of education and training, existing quality improvement in practices, safety, regulations within the community, and the delivery practices.

The overall risk is low given the current practice standards, and practice standards normally means professional societies like the American College of Radiology, American College of Radiation Oncology, and other societies, but the process that we're going through in terms of state licensure, credentialing by the hospital, privileging by specialists in the field to make sure that, even though physician is credentialed by the hospital, is that person's background and education and training sufficient to perform this procedure, and national certification boards, which a lot of hospitals now, and insurance companies, are requiring before they will reimburse for that procedure, separate from the hospital privileging process.

I think I'll turn this back to Judy now.

DR. STITT: I'd like to start with the next slide

and spend some time discussing the Medical Policy Statement.

[Slide.]

DR. STITT: The ACMUI at its most recent meeting just three weeks ago spent considerable time discussing the Medical Policy Statement.

We felt this was a very important place to start our comments regarding Part 35 and DSI-7, because the Medical Policy Statement really is the foundation for those other elements.

Number one, the NRC will continue to regulate medical uses of isotopes as necessary to provide for the radiation safety of workers and the general public.

Statement number two, which is the next slide --

[Slide.]

DR. STITT: -- and the slides have modifications and they are named ACMUI modification in that it's in the lighter font -- the NRC will regulate the radiation safety of patients only where justified by the risk to patients and only where voluntary standards or compliance with standards are inadequate.

Our second point is that assessment of the risks justifying such regulations will reference comparable risks and comparable modes of regulation for other types of medical practice -- for example, anesthesia risk, drug administration error.

COMMISSIONER ROGERS: Before you leave it, do you want to discuss these as we go or -- for example, the use of the word "only" --

DR. STITT: Uh-huh.

COMMISSIONER ROGERS: What is that intended to exclude that's a problem right now?

DR. STITT: I think it's intended to be -- to focus on what is included, potentially, more than what is excluded.

I think that you could say that that relates back to low risk of diagnostic procedures -- that is, that only where justified by risk of patient could allow you then to say risk from diagnostic procedures, the consequences are so low that that might not need to be in the regulatory framework.

Other comments from the committee on policy statement two?

CHAIRMAN JACKSON: Dr. Williamson.

DR. WILLIAMSON: Well, I think the underlying concern is that a criterion of risk, like 10 to the minus 6, 10 to the minus 7, or zero, might be imposed, and therefore, even one incident could be cited to trigger, you know, the rulemaking process, and I think what we're trying to suggest is that the baseline for figuring out what an acceptable risk is for threshold of regulation, you know, ought to be

somewhat comparable to what happens in other medical specialties and not orders of magnitude below, you know, what our colleagues deem acceptable.

COMMISSIONER ROGERS: But that could be the interpretation of the statement without the "only," and you know, what I'm trying to get at is there's something that you felt was going to be accomplished by adding the "only," and I'm trying to get at what is that?

CHAIRMAN JACKSON: Mr. Graham?

COMMISSIONER ROGERS: You've already said we're justifying it by the risk to the patients.

MR. GRAHAM: Right.

And I think part of what the ACMUI has discussed over the past several meetings is the concept that, as it's originally defined, as it's originally developed, the regulation may sound very reasonable, that the Medical Policy Statement sounds perfectly adequate, but it's over time, as incidents come up and then additional regulations are applied and then you get into issues of interpretation and enforcement in the field, that we want to assure that the good programs, the majority of the programs out there, have a system of performance-based initiatives in which they're working with the NRC and the staff to get better and yet there are prescriptive regulations that still permit the winnowing-out of the bad players, who are small in number

but who, as you say, garner a lot of the press.

Adding the word "only," in the opinion of the committee, created a perspective of a threshold that you don't write a regulation when it might help you write a regulation only where justified by the risk to the patient, and I think Dr. Stitt's example of diagnostics is a concrete example of, if there's very low risk to the patient, low risk to the public, then regulation related to those diagnostics under a revised policy that has added the word "only" would probably be revised.

COMMISSIONER McGAFFIGAN: I'll tell you my frustration with the focus on the Medical Policy Statement before we redo Part 35 is I think you can -- as Commissioner Rogers was just suggesting, under the current policy statement and the staff's intention as expressed in various papers to you and to us has been that they are going to look in Part 35, they've been wanting to look for three years in Part 35 at less prescriptive regulation on diagnostic medicine, and that's within the spirit of the current policy statement.

My sense is that what you're trying to do here is constrain and work on -- you're really working on other issues through the policy statement when probably the best use of time is to work on Part 35 and see where you get, you know, with the staff in addressing your specific issues on

things like diagnostic medicine.

DR. STITT: I think the committee felt very strongly about the Medical Policy Statement and that we as a group reflect so many backgrounds of clinical medicine that to come up with some sort of idea of where we wanted to start working on this, we had to see if we even had the same philosophy background-wise.

We're all clinicians here, we take the Medical Policy Statement very seriously and feel that that's the foundation upon which 35 needs to be addressed, and that's the reason we spent most of our meeting discussing the Medical Policy Statement.

CHAIRMAN JACKSON: Why don't we go on?

Commissioner Rogers, did you have another comment?

COMMISSIONER ROGERS: Well, I don't want to pursue it too much, but it does -- I tend to have the same response that Commissioner McGaffigan had, namely it's really the implementation of the policy statement that I think is where you're finding problems, and I still haven't heard anything that suggest that, with the addition of the word "only," there's a clear change in policy.

It's a question of how this policy is implemented by the regulators, and so, I don't want to pursue it any further, but so far I haven't heard anything that illuminates that.

DR. STITT: The word "only" appears in -- we haven't made that as an addition, but the second bullet is also our commentary on statement two, and really the "only's" -- actually, there are two; one is missing -- only where justified and only where voluntary standards are inadequate -- relate to the second bullet that tie this into risks that are -- that reference comparable risks in other parts of medicine.

COMMISSIONER ROGERS: So, you really would like to add a second "only." Is that it?

DR. STITT: The second part of that slide is part of our modification to statement two.

COMMISSIONER ROGERS: Well, no, but what you just said now was a second "only" after --

DR. STITT: In the minutes of the ACMUI meeting, there were two "only's," only where justified and only where involuntary standards are inadequate, followed by the second bullet.

COMMISSIONER ROGERS: You're adding a second "only" to the first bullet. I'm just talking about the first bullet.

MR. GRAHAM: Yes. I think we're just trying to clarify which set of slides you have there.

COMMISSIONER ROGERS: Oh, I don't know. I have one that I got the other day.

MR. GRAHAM: Okay.

COMMISSIONER ROGERS: Has it changed?

DR. STITT: The minutes of the ACMUI meeting --

COMMISSIONER ROGERS: Oh, yes. I'm sorry.

COMMISSIONER DIAZ: There's another "only" there.

COMMISSIONER ROGERS: Another "only."

DR. COOL: Commissioner Rogers, we apologize. There was one that was sent up that had that typo, which we tried to fix.

DR. STITT: Statement three is the next slide.

CHAIRMAN JACKSON: He wants to discuss the second bullet.

COMMISSIONER ROGERS: The second bullet also, I think, is a question, and could you just elaborate on that?

It sounds to me as if what you're suggesting here is that we look at what the risks are for anything else, any other practices of medicine, and see that what we do with respect to -- what our expectations are for radiation, medical radiation areas, would be the same, we would have about the same results. Is that what you're saying?

DR. STITT: I think what the committee is saying -- and I'll let this unruly group speak for themselves --

COMMISSIONER ROGERS: In other words, that you tolerate risks in radiation medicine that are comparable to the risks that occur in other practices of medicine.

DR. STITT: Yes.

We think radiation medicine ought to be viewed as part of a whole. It's a relatively small part of medicine. Risks, events in medicine are now starting to be reported, described, and assessed to complete the cycle to decrease those events in all of medicine, and I think we feel that radiation medicine shouldn't be kind of sitting out there on the end of the limb by itself, it ought to be viewed as part of the practice of medicine in the whole.

Does anyone else have a comment?

COMMISSIONER ROGERS: You know, my concern there is that our attention to this area is dictated by the Atomic Energy Act, and I think there is a question about whether that, in fact, is a point of view that is justified under that act. That's a question for OGC to look at.

COMMISSIONER DIAZ: I actually share that concern.

It might be that -- the statement is very broad. It might be that the intent is good, but if you look at the statement, it says "as comparable." It's just very open, and it might not be compatible with the way that the we handle things.

CHAIRMAN JACKSON: I think we need to move on.

[Slide.]

DR. STITT: Let's move to the next slide, which is the third statement under the Medical Policy Statement, and

the Medical Policy Statement three is the NRC, and we have added "will not intrude into medical judgements affecting patients and into other areas traditionally considered to be part of the practice of medicine."

CHAIRMAN JACKSON: Do you have a working definition of what those areas are?

DR. STITT: Certainly, patient-physician interaction. I think this has specifically come up, and Jeffrey will probably address this in his section, the obligation to send a written letter to a patient about an event that's occurred, most people would feel is an intrusion into the practice of medicine, and that tends to come up on a regular basis at ACMUI meetings.

COMMISSIONER McGAFFIGAN: Could I --

DR. STITT: We feel that the risk to the patient in radiation medicine is probably lower than other areas of medicine.

This is what you have addressed in statement two as an area of question, and we feel that there are a variety of reasons that the risk is quite low, including the many factors that we've discussed this morning.

COMMISSIONER McGAFFIGAN: Again, I'll just suggest that the current words are "minimize its intrusion into the medical judgements," etcetera, and "minimize its intrusion," I think, recognizes that there's, you know, always going to

be a balance that has to be struck, we're going to try to minimize, but "not intrude" is such a blanket statement that it is surely intended to be used as a stick against us in any case where any doctor perceives any intrusion into what their definition is of the normal practice of medicine.

So, I think you're taking a balanced statement from 1979 and trying to turn it into a stick that the medical community can use against us.

DR. STITT: Well, it probably reflects the fact that we're clinicians and practice medicine and think pretty strongly about these issues.

COMMISSIONER McGAFFIGAN: Okay.

DR. STITT: Let's move on.

I have a series of slides that try to focus in a little bit more detail on the issues of prescriptive and performance-based, and this has to do with the issue of quality improvement and quality assurance.

[Slide.]

DR. STITT: This slide describes quality assurance which, for any procedure, action is taken only when the process average exceeds a pre-determined threshold. This would be very -- this would be a definition of a prescriptive-based process as we know it.

So, when the process average is under the threshold, no questions are asked; when the threshold is

exceeded, there's commonly panic and finger-pointing.

This is not exclusive to our area of medicine at all. Common examples of traditional QA include the number of C-sections performed at an institution per month, medication errors, and certainly, radioactive isotope events.

Next slide.

[Slide.]

DR. STITT: When you look at quality improvement, the entire output of the process provides a basis for action, not just occurrences that are deemed unacceptable because they exceed a certain threshold or specification.

I'd like to move to the next slide, which is a graphic.

[Slide.]

DR. STITT: So, in the top graph, in the QA process, there are a number of cases -- and you can see that on the vertical axis -- that are evaluated by some sort of a quality measure -- that's on the horizontal axis -- and then when that threshold is exceeded, some sort of action occurs, and that's a fairly common description that's used in manufacturing, business, and in medicine and does describe a prescriptive-based type of process.

If you look at the second diagram, which describes the QI approach and a more performance-based approach, cases

are evaluated also according to a measure, but as you can see, there are more cases that are being evaluated and acted upon, and therefore, you're narrowing that curve.

So, there is a shift in the process and a shift toward the desired direction of quality.

COMMISSIONER McGAFFIGAN: Could I ask, how is that achieved?

I mean how -- if this approach has been used, how do you enforce or -- you know, as a -- if you're the head of the hospital and you want -- you want the whole curve narrowed, you know, do they get a -- if you're the head of the hospital, do you get a monthly report as to whether -- whether things are narrowing and then hold the department head responsible if they aren't and, you know, ultimately fire them or -- I mean how do you -- how do you --

DR. STITT: One issue -- and we'll be getting to enforcement, and I think that is a key, and it's -- this is not a knee-jerk. This is a continuum. It goes on and on and on. And I was hoping our hospital administrator might perk up and contribute.

This is actually a process that JCHO has encouraged for some time and that you find most institutions applying on a broad hospital or out -- now out-patient clinics are starting to come under this JCHO type of process.

So, John, why don't you make some comments?

MR. GRAHAM: Let me give one -- one simple example of how we've converted over the past 10 years from quality assurance to quality improvement, going back to that real simple example of Caesarean-section rate, and then the related event is the attempt, the goal to have a vaginal delivery for later births wherever possible, and under quality assurance, we would track the Caesarean-section rate of a physician.

Those that truly were outliers, we would send a letter to; the chairman would talk to them. It had very little potential affect on practice in a lot of cases.

It was only where it was a very large dramatic variance from the entire group that it became so obvious that we could take some sanctioned action against that individual.

Under quality improvement, we developed a review of the process of how you would take care of that patient in their second delivery, where you're trying to encourage a vaginal delivery, and identify the concerns that had kept practitioners from using the approach -- the time it took to try to educate the mother on getting ready for that attempt -- set up a process with the nursing staff and others that would collaborate so that it became much easier in the overall process to achieve the goal of that vaginal delivery

in the second birth, and all of the statistics moved in the right direction, the C-section rate went down, the V-vac rate went up, because we focused on the process, we identified where the problems were in the system, defined the resources that could improve that process, and without ever going after anyone, all of the numbers simply moved in the right direction.

It became easier from a system and a process standpoint to try to achieve the right outcome than to do it the old way.

CHAIRMAN JACKSON: I think Dr. Flynn wanted to make a comment.

DR. FLYNN: A radiation medicine example would be -- and this is also an example of compliance with voluntary standards by professional societies -- you know, weekly chart rounds where the radiation physicians get together and present cases and show up the films, weekly checks of the patients under treatment, weekly checks of the dose calculations by the physicist, usually a second physicist or a second dosimetrist other than the one who initially did the calculation.

But for example, in port filming -- port filming is whereby a patient is under treatment and we actually take a film of the treatment beam to make sure the patient hasn't -- see how compliant the patient is in not moving, how good

the technologists are in setting up the fields and everything.

Now, if we do port films, let's say -- let's say a practice may choose to do port films once a week. They see that the prostate cancer patients with very stable setups are not moving.

So, the outcome would be that, with all these films that we're looking at, there is no real deviation seen, but with the -- so, instead of doing the port films on those patients every week, it might be every other week.

But on the other hand, the Hodgkin's disease patient, the setup is complex. There a patient may move or cough, and so, those port films, instead of being done once a week, they may be done twice a week.

So, therefore, you are focusing medicine in a cost-effective means on the more error-prone measures of outcome and less focus on the less error-prone procedures. That would be an example of what we actually do today and what most practices do. That's just one example.

DR. STITT: I think one of the points that we would like to make is that this -- these two graphics do describe the QA versus QI type of performance.

The QI is performance-based type of process. It's something that actually goes on in hospitals on a routine basis; this is not research that we've pulled from

something.

So, I just want to make it known that this is something that we're already doing. This may be a way to shift radiation medicine into a process that we're already familiar with.

COMMISSIONER McGAFFIGAN: You said you're going to get back to enforcement?

DR. STITT: Yes. That's coming up.

COMMISSIONER McGAFFIGAN: So, is this enforceable? I mean the statistics that were talked about earlier. Instead of enforcing against the outlier, can you enforce against the whole licensee improving practice, and if that's --

DR. STITT: I think so. Most of us are hospital-based, some or all of our practices.

In order to maintain accreditation for our staff privileges, for the hospitals that we work in to maintain accreditation with JCHO, we're obligated to be able to show that we can work within these boundaries.

Well, I'm going to turn it over to Jeff Williamson, who's going to address more of those issues, and we'll start with our favorite slide of all.

Next slide, please.

[Slide.]

DR. WILLIAMSON: Well, we thought this would be a

good lead-in to the two topics that I want to address.

One is just to review our committee's concerns with what we understand to be the current regulatory approach, especially as it pertains to patient safety as an end point and especially in those areas where continuing regulation -- i.e., the high-risk procedures -- seems likely.

The government-by-yo-yo is kind of -- is an amusing analogy, of course, coined by our previous chairman, Dr. Siegel, and what he's getting at is the consequences of letting the course of rulemaking be charted by single very low-likelihood events.

The consequences I've sort of listed on this next slide.

I think the -- you know, one major result is that you wind up, when you look at the totality of regulations formed in this way, without regard to principles of coherence and completeness and without looking at the place of these events that drive the process in the whole spectrum of potential risks, one winds up with a kind of a quality-improvement fragment that's a very sort of unbalanced and distorted sort of mirror image of what we do every day in clinical practice.

I think two characteristics that it has is that there are a lot of detailed prescriptive rules on some

things that are not very important, and other things that are very important are left unmentioned by the regulations.

A good example might be the excruciatingly detailed regulations regarding quality assurance of dose calibrators used to measure source strength of diagnostic radiopharmaceuticals, whereas the calibration of low dose-rate brachytherapy sources, to my knowledge, is not mentioned anywhere in the regulations or even in the guidance, and brachytherapy is an area where trying to deliver the dose accurately to the patient is, you know, much more important to clinical outcome, I believe you could argue, than it is in diagnostic nuclear medicine.

I think not only in terms of content but style, too -- this is really maybe the -- a major point we're trying to get across is -- is that what we have is basically a set of relatively rigid rule-governed prescriptive things we're supposed to do that are supposed to be applied no matter what the circumstances are, and that's just not how effective functioning quality improvement works in radiation oncology.

Most of our -- the guidance provided by, for example, the AAPM emphasizes the process of adopting and adapting general guidelines to the specific needs of each individual clinical practice.

I think another example I could give -- one might

consider requirements in our license that we have vendor-supplied training for our HDR unit every year. Well, how useful is this, one could ask.

I think for a facility that has a very high frequency of procedures, has a lot of experience using the unit, frequently it's probably a waste of time.

In a practice that has a very low frequency of procedures, the annual training is probably woefully inadequate, and some sort of program, ideally, needs to be set up in order to maintain the competence of the care-givers.

Where exactly this line should be drawn is very difficult. It really boils down to a clinical judgement on somebody's part.

In this particular instance, which is a technical question, it would have to be answered by the physicist; he would be the responsible person for determining this.

I think another example of QI versus QA is, if there is some sort of an event, maybe not even a misadministration but just some concern about the overall delivery process, I think just simply slapping another rule like, uh-oh, better have a second person now come and check the treatment plan if you're concerned about the accuracy of computer treatment planning -- I think, in fact, what we would do is look over the whole process and decide among a

number of different alternatives to try and improve the overall quality of treatment planning.

Some possibilities that we would consider would be more intensive training, perhaps, increased physicist supervision of the dosimetrist in certain types of cases, maybe improved forms for capturing the data that's needed to drive the treatment planning process in a clearer and more accurate form.

So, it's not necessarily adding another sort of formal feedback loop. It's not like we're workers at some machine where we do the same actions all the time.

A great deal of clinical judgement is needed to keep this system going, and as a clinical physicist, much of my time is spent, really, in designing and overseeing a process and trying to make the standard deviation be as small as possible.

I think another really major concern is the way enforcement is done.

I think most of us would agree that the end points mentioned in the regulations are good common sense things and they're incorporated in virtually all voluntary standards, but what really is upsetting and, I think, somewhat counterproductive is the adversarial and punitive enforcement attitude.

The emphasis is on -- during inspections, to this

day, at least in our institution, at least remains on isolated errors and paperwork violations, really, whether or not they are truly representative or descriptive of the overall quality of our program and whether or not these particular paperwork violations, which they are, often, have any real clinical significance.

So, it's sort -- when you make a very rigid rule-based system that relies on sort of automatic fixed punishments, you know, that does not rely -- or leaves out clinical judgement, I think you maybe, we would submit, wind up with something that is not a productive use of either the agency's resources or our time either.

CHAIRMAN JACKSON: Let me ask you a question about this.

DR. WILLIAMSON: Sure.

CHAIRMAN JACKSON: You talk about future patient safety regulations, and your second bullet suggests that -- encourage the acceptance of voluntary practice standards, and with many voluntary standards available to practitioners, how should the NRC determine which ones are acceptable?

DR. WILLIAMSON: Well, I was going to try and address that.

CHAIRMAN JACKSON: Okay. Well, when you do that --

DR. WILLIAMSON: Okay. Yes. I will --

CHAIRMAN JACKSON: -- address the following, also.

DR. WILLIAMSON: Yes. I will try to do that. It's not a simple answer.

CHAIRMAN JACKSON: That's right.

DR. WILLIAMSON: Yes.

CHAIRMAN JACKSON: And there are many industry standards that are actually broad guidelines, that, in fact, require the user or allow the user to modify or tailor those guidelines to his or her economic or staffing situation, and so, to what extent should NRC allow flexibility in interpreting or making a choice?

DR. WILLIAMSON: I'll try to give an answer. I guess, at this point, I would say there are, you know, really three directions maybe the Commission could go in terms of what to do about patient safety in so-called high-risk procedure areas.

One would be to maybe accept the modification we've suggested or accept the implications of our modified Medical Policy Statement, which suggests that things really work quite well by themselves, that the community really has an intensive significant commitment to this type of quality improvement program, as evidenced by our overall good record in unregulated parts of radiation, or at least unevenly regulated parts of radiation medicine.

I think a second option would be to persist with a similar sort of model, which is the threshold-driven, rule-based, punishment-based type of system.

CHAIRMAN JACKSON: Better get to the third.

DR. WILLIAMSON: Okay.

Well, the third -- okay -- I think would be to put aside this whole model of rigid rule-based prescriptions and -- and accept, I think, that clinical judgement and flexibility really are critical elements of a functioning quality improvement process, and if you could come up with a system of writing regulations and enforcing them that was consistent with the actual way most of the community practices quality improvement, I think a lot of the sort of dissonance would go away.

CHAIRMAN JACKSON: But that still begs the question of how does one decide which voluntary standards are acceptable, and how does one decide how to bound flexibility, and what does flexibility mean?

DR. WILLIAMSON: Okay.

CHAIRMAN JACKSON: Then I'm going to defer to Commissioner Dicus.

DR. WILLIAMSON: All right. Okay.

Well, I will -- our suggestion is to go to some type of a system that's more of an overall score-card, like an accreditation process of each practice, that that should

be the enforcement mechanism, rather than punishment related to detailed infractions of prescriptive regulations or even detailed -- even individual treatment errors, there should be a credentialing or accreditation process to which each practice is subjected to periodically, and I think it would be helpful if we had slide 17.

CHAIRMAN JACKSON: Let me let Commissioner Dicus -- I think she had a question.

DR. WILLIAMSON: Okay. I'm sorry.

COMMISSIONER DICUS: Let me pursue the enforcement policy a little bit with you, and I'll be as brief as possible, just a little bit of discussion.

I think you're going to touch on a couple of things I'm bringing up, but -- and I am familiar with accreditation processes from my previous life in the State of Arkansas, and they have a different goal than perhaps the regulatory process, and so, we have to be a little careful there when we try to make these kinds of comparisons, but one of my theories about enforcement policy is basically, in a perfect world or a better world, an enforcement policy should be a very positive process, one that, in effect, encourages, even promotes better performance, a better way of doing business, but also has an element of it that will address the outliers, the 10, 5, 1 percent that you mentioned that don't -- that fall outside the framework.

Given that, given some of the things that you're talking about here and, I think, a couple of things you're going to go into, what I see missing -- I like the idea of QI. That's a positive process. You have that, you have accreditation.

But what is missing, in my view, is the transition and the metrics to really show how we make a positive enforcement policy work, and my question, then, to the advisory committee is, are you prepared to be able to give us some very definitive advice on how we make that transition and what those transition steps are?

It's not an easy thing to do, and we have to go from the words to the reality, and so, I'm asking -- give us a little bit of feedback on that.

CHAIRMAN JACKSON: Don't everyone speak at once.

[Laughter.]

DR. STITT: We love to give you advice. That's one thing we're good at, and certainly, that would be --

COMMISSIONER DICUS: I mean something very definitive.

DR. STITT: That would be part of our continuing discussions as a committee. We have tremendous work that has to be done, and I think what we need is what you're saying.

You're telling us what you would like to hear from

us, and so, that -- what we're putting forth here are some ideas, and you're responding back, and I don't happen to have a list in my pocket, but certainly we can move toward that.

DR. WILLIAMSON: I'll try to give some examples as I go through my last slide.

CHAIRMAN JACKSON: Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: I want to go back -- actually, this may help, it may not -- to the example you gave.

Your license at the moment requires you to provide vendor-supplied training for an HDR unit annually. If we went performance-based, say, and your license instead said, you know, in your case, you believe you don't need it at all, because your unit uses the device.

How does an NRC staffer -- and other units, you said, might -- you know, that use them infrequently -- might need it much more frequently.

Do you want us, in writing licenses, instead of to say annually, to say, in your case, not at all, and in another case, you know, three times a year, or do you want us to say you will get vendor-supplied training on an adequate basis in your clinical judgement, and then how do we enforce against --

One exercise you might go through in terms of

bringing this down to details is each of you look at your licenses and tell us what -- tell Don Cool what your license really should look like and what -- and what it is that -- that he could do, then, to enforce that new license you -- you propose.

But in this particular case, you know -- because if we start doing it, you know, we'll be into clinical judgement all the time as to whether adequately, you know, you took advantage of vendor-supplied training.

DR. WILLIAMSON: Well, you raise a really good general question. If you're going to get into the swamp and swim with us, you have to learn to swim with us, I guess.

CHAIRMAN JACKSON: I think what the commissioner is suggesting is an exercise, which you say you're going to be taking this up in ensuing meetings, is that, you know, at some point the rubber has to meet the road.

DR. WILLIAMSON: Yes, exactly.

CHAIRMAN JACKSON: And you could do this exercise, not a Gdanken experiment, to look at a license and how it would be --

DR. WILLIAMSON: Yes.

CHAIRMAN JACKSON: -- modified and how it would be enforced against -- okay -- because if the enforcement is against a given doctor's judgement as to what is adequate, then you're basically saying we predicate our regulatory

action on the judgement of that person to whom -- you know -- or the institution that hires that person, to whom we're giving the license, and so, that's an interesting concept.

DR. WILLIAMSON: Okay.

CHAIRMAN JACKSON: So, I think it's more than a Gdanken experiment that he's talking about.

So, why don't we move along?

DR. WILLIAMSON: Okay. Okay.

Now, the -- could I have the next slide, please, the next one?

[Slide.]

DR. WILLIAMSON: Well, to continue -- and maybe this is a really good example -- I think, to have a accreditation-based system, you first have to decide what the end points of it are, what indicators are going to be looked at, what sorts of things is this process going to attempt to see that are available in every practice.

As a mechanism, I would suggest close collaboration with the professional organizations that are in the business of attempting to set and codify voluntary standards of practice.

I think the practices that have to be developed maybe fall into three categories.

I think that there are safety standards for -- similar to -- perhaps qualitatively similar to those in the

present regulations for handling and storing and inventorying sources and so on, designed to promote safety of staff and public.

There are essential resources that must be available for any staff or practice to be up to standards. These include not only equipment, such as quality assurance equipment, but appropriately-trained and credentialed staff for handling the kinds of procedures that are done.

This is sort of the really sticky end point, which is these specific quality improvement elements, which are agreed upon are appropriate to be in a accreditation-based regulatory system -- I guess we'd take Commissioner McGaffigan's example -- probably a good end point it would be reasonable to consider would be there has to be some sort of a program which is deemed adequate for ensuring the competency of all staff members using critical treatment delivery equipment -- the treatment planning system, the treatment delivery unit -- and how do you compensate in your individual practice if you have only a few procedures each year to ensure that you maintain competence in that?

The site visit would be, basically, is that a good answer?

Do professionals in the field agree that this is a reasonable approach that this institution has put together in order to assure a minimum -- minimal state of competence

in using the devices which are essential to doing treatment accurately.

So, this is kind of the example.

If I could go to the next slide.

[Slide.]

DR. WILLIAMSON: It's qualitative. It relies on the judgement of some kind of a team -- outside team of experts that comes and visits each institution.

So, this is what this slide attempts to do, is inspections would function like an accreditation site visit. It might helpful to incorporate some clinical professionals as outside reviewers in this periodic process.

Next slide, please.

[Slide.]

DR. WILLIAMSON: I think it would be helpful to study other models of accreditation.

There's the American College of Radiology Accreditation program, which is functioning for radiation oncology.

There's the Mammography Quality Standards Act, which functions somewhat as sort of score-card of overall institutional performance in providing mammography services and, at least ideally, doesn't hit on people for isolated infractions but, you know, presumably, is designed to bring that group of outliers, that 10 or 15 percent, try to

encourage them to stay closer to the mean.

It looks at the end point being, you know, overall conformance with the appropriate quality improvement standards.

I think maybe calibrating this process against a random sample of institutions might be a good way to garner experience and decide the details of where cutoffs should be.

Thank you.

DR. STITT: Dennis Swanson will continue.

MR. SWANSON: Yes. I've been asked to address misadministration medical event reporting.

Next slide, please.

[Slide.]

MR. SWANSON: At the outset, let me state that the commissioners did ask the ACMUI to provide input on the use of terminology "misadministration" versus "medical event," and you'll see that this slide has listed "isotope event."

The ACMUI has not come to any agreement on what terminology should be used, and certainly, "isotope event" is not the final ACMUI terminology.

My personal thoughts on it is that the actual terminology used is probably not nearly as important as the mechanism by which we go about doing event reporting. So, I'm just going to refer to these as events at this point in

time.

The ACMUI has come to some agreement, though, on key points related to event reporting.

The first of these is that there is a need to dissociate the reporting of isolated events from actual or perceived punitive actions, and we feel that one mechanism to approach this -- and I'll come back to this a little bit later on -- is to address reporting at a local level, for example, have regulations that require reporting to the RSO or to the licensee rather than reporting on a national level.

That will take some of the perception of punitive action away from it, I think.

CHAIRMAN JACKSON: Let me ask you a question about that.

MR. SWANSON: Sure.

CHAIRMAN JACKSON: With this focus at the local rather than the NRC level, then to whom should an NRC licensee report, and how will the NRC be made aware of events that affect its overall mandate to protect public health and safety?

MR. SWANSON: Well, certainly, the reporting at the local level is not necessarily in lieu of a central reporting program, and I'll come back to that later on.

When the NRC, in the agreement states, conducted

inspection processes, they certainly have the right to look at the adverse events reporting at the local level and can make judgements at that local level as to were these events appropriately responded to.

They also, I think, would have the opportunity to identify what are potential problem programs and then, with the assistance of consultants, can actually make the final determination of are these or are these not problem programs.

Reporting at the local level -- I mean you still have your inspection processes in place -- doesn't preclude the NRC from ascertaining that that process is taking place.

I'll come back to central reporting program in my next slide.

CHAIRMAN JACKSON: I'm also interested in how the NRC would be made available of events that have generic implications.

MR. SWANSON: Let me come back to that one in the central reporting program, which is in the slide down the road here, okay?

Other key points.

There's certainly a need to dissociate the reporting of events from the patient notification requirements. This gets a little bit into the quality management rule.

As Dr. Stitt said earlier, while the ACMUI recognizes the concerns related to patient notification, patient notification falls into practice of medicine, and really, I think this is beginning to intrude into the practice of medicine.

COMMISSIONER McGAFFIGAN: So, you would have no requirements on patient notification?

MR. SWANSON: Patient notification is taking place at the institutional level. It's part of the patient-physician interaction.

I think that that's an area that the NRC has gotten itself in particular trouble with with the quality management rule in general, if you read the comments of the community.

Third point. There is a need to simplify and harmonize the definitions of isotope events. The current definitions of events, medical misadministration events, are far too complex, far too confusing.

I as a practitioner, when I'm giving presentations on this or discussing this, I have to go back and review the rules every time.

They're very complex definitions, far too complex, and I would personally feel that many of the violations of the quality management rule that have been documented are probably due to just simply the complexity and the confusion

surrounding the definitions.

There is also a need to harmonize the definition. Another factor contributing to the complexity is the difference between state definitions and NRC definitions.

I come from Pennsylvania, which is an NRC state. Our state regulations governing accelerator-produced materials have a totally different set of definitions for misadministrations.

It's already confusing to begin with, and then add a different set of confusion on top of it, it's almost unwieldy to deal with.

Also, when we're talking about harmonization, I think you need to look at, you know, how does the rest of medicine define misadministration medical event reporting, and it's something that we need to take a look at as we evolve these definitions.

Next slide, please.

[Slide.]

MR. SWANSON: As a possible approach in defining the definitions, a couple of points that we need to consider -- if technical data is desired, if that's what we're going after, then we need to define the technical criteria independent of clinical effects.

If what we're trying to go after are patient sequelae data, then we need to define our terminology in

terms of clinical findings and come to some decision on that.

Next slide, please.

[Slide.]

MR. SWANSON: Some possible approaches to this -- as I mentioned earlier, I think we need to look at the development of a performance-based regulation that addresses reporting at the local level, required reporting to the licensee, to the RSOs.

As I said earlier, I still think that this will allow the NRC in agreement states to review medical event reports, the fact that they're taking place. It will allow the NRC and agreement states to identify potentially problem programs.

With regard to centralized reporting, I think -- it's a personal comment; I don't think the ACMUI has come to total agreement on this -- I think there is a need for centralized reporting of misadministration, because if we're ever going to be looking for trends or causes of these events, we need more data that what we'd see at a given institution.

This has actually been a problem with event reporting in medicine in general, is that this information has tended to remain sequestered within the individual institutions, and thereby, the word doesn't get out, and

people aren't aware of problems that other institutions are having.

CHAIRMAN JACKSON: I just wish to point out that, you know, in addition to what you just said -- you were talking a minute ago about harmonizing the definitions of "isotope event" and you talked about the difficulties within a statement between what the agreement state program required versus -- you know, for what it covers versus NRC, but yet, you know, you stress, you know, having local reporting, and you know, is that an oxymoron, that somehow you want harmonization and consistent definitions and so forth, but you want very tailored ways, localized ways of reporting events.

I mean it seems to me that, therein, you offer the opportunity for different definitions to propagate into the mix.

MR. SWANSON: Well, I think what I'm talking about about simplification and harmonization of the definitions -- there probably needs to be somewhere within the new regulations a simplified definition of events with reporting at the local level based upon those regulatory definitions. At least that's my perception of how -- my personal perception of how that would happen.

I don't think it would be wise to allow each institution to define its own definitions of

misadministrations or events, because then you would end up with the scenario that you're describing, a very mixed bag of reporting.

CHAIRMAN JACKSON: I think Commissioner McGaffigan has a comment.

COMMISSIONER McGAFFIGAN: I'll just tell you that the word "voluntary" under voluntary central reporting -- I'm not sure I even buy the notion that you wouldn't -- the reporting at the local level, but voluntary central reporting just strikes me that we're going to end up -- people with good records may voluntarily share their -- share their data, and people with bad records can voluntarily not share their data, and you just said the medical community as a whole has had a problem, not just in this area, knowing what's going on, you don't have good databases.

Are your insurance companies sort of forcing non-voluntary reporting and better databases for their own uses to decide what insurance rates to charge you, or how does all that work?

MR. SWANSON: Well, first of all, I haven't gotten to that yet, and I think the introduction to that will probably address some of your concerns.

I think that, when it comes to centralized reporting, one of the things that's missing now is that

there has to be a clearly defined purpose for the central reporting of medical events, and you know, I might be so radical as to suggest that that purpose may be a cooperative effort of the medical community and the NRC to identify possible causes of events and to document their prevalence. That ought to be the approach that we're taking if we're working together on this.

COMMISSIONER McGAFFIGAN: Right.

MR. SWANSON: Okay? That's not happening. Right now, it's viewed as punitive -- okay? -- and it's based upon isolated events. You have a requirement for reporting only high-consequence events. You've collected minimal amounts of data. It's absolutely serving no purpose, period.

Now, I'm all for central reporting personally -- and I'm speaking personally -- if that's the purpose of the central reporting. I'm 100-percent in favor of it. Okay?

To get to that, though, you've got to take the punitive -- the perceived punitive actions out of this, and that means it needs to be a voluntary, anonymous reporting system, and I can give you some models that work very well.

You can look at the pilot event reporting of the Federal aviation people, the FAA. It works very nicely. It's a voluntary, anonymous reporting system.

If you want to know what happens in traditional medicine now, there's a voluntary reporting system. It's

called the Medical Errors Reporting Program, takes place through the United States Pharmacopeia Convention, Incorporated.

It's a voluntary, anonymous reporting program. The USP is an independent agency. For your information, it's an agency responsible for setting drug standards and has been and is the only agency -- it's one of the oldest agencies in the country.

It's a voluntary, anonymous reporting program for the central collection of information on medical errors for the purpose, as I stated, to identify the possible causes of those errors and to document their prevalence. That's what we need to get to if we're truly going --

COMMISSIONER McGAFFIGAN: How does this deal with the 10 to 15 percent or 1 percent -- why would somebody who is not practicing medicine well submit this information anonymously? Is this another doctor turning in a doctor who they think is not --

MR. SWANSON: No. It's a voluntary reporting program.

Again, you know, I think you're going to have to seek the endorsement of the professional organizations, the practice standards to participate in this program, very important that you get a buy-in of the professional community in doing it, and I think that's easy to do if you

have that stated purpose up front.

Let me ask you the question. What makes you think a regulation is going to make somebody report it? Why do you think a bad person -- isolate a bad person -- will report an event just because a regulation requires it?

COMMISSIONER McGAFFIGAN: I suspect that isolated bad person will get -- I hope get caught and enforced against, having not done it.

CHAIRMAN JACKSON: And if it affects the license of the facility, others have a shared interest.

COMMISSIONER McGAFFIGAN: Right.

CHAIRMAN JACKSON: But I don't think we're here to debate that issue here.

MR. SWANSON: You asked for specific issues and how you might go about doing this. You can have a performance-based regulation that basically addresses people participating in this voluntary reporting program.

Go on to the next slide, please.

[Slide.]

MR. SWANSON: We're talking about philosophies here, a little bit about ALARA. ALARA started out as a philosophy and has gradually evolved into a requirement, and the ACMUI believes that ALARA needs to be a philosophy.

I think here is another area that the NRC can actually become actively involved in this philosophy.

At the last meeting we had with the commissioners, one of the statements I made was I can never understand -- the NRC goes out and sees a lot of these practices and you report the bad things, but we don't see the good things reported.

Here is where the NRC could actually become involved in the ALARA program and letting other people know good things that are happening out there, as a philosophy.

Next slide, please.

[Slide.]

MR. SWANSON: Quality management program.

As per the commissioner's directive that appears in the SRM through the NRC medical program staff, the ACMUI concurs that the useful regulatory end points of the quality management rule are written treatment prescription, review of dose calculations, identification of the patient.

We feel that the quality management regulatory end point should be performance-based and not prescriptive.

I don't care to be cited, for example, if my physicians initial the written prescription rather than sign it, doesn't make a whole lot of sense -- okay? -- and certainly the quality management rule with these end points should focus on the higher-risk procedures, which they do not.

DR. STITT: We have two final speakers.

Dr. Alazraki?

DR. ALAZRAKI: Could I have the next slide, please?

[Slide.]

DR. ALAZRAKI: I'm going to address the NRC and medical expertise.

I've been a practicing physician in nuclear medicine for the past 25, 26 years, and over that period of time, I've witnessed a very painful and sometimes tumultuous relationship between the NRC and the medical community.

Many of the problems can be distilled down to a lack of involvement of the medical community, medical practitioners, in the regulatory process over the years and also a mind-set of punitive consequences for transgressions which are frequently the result of the human element in practicing medicine, and therefore, the ACMUI encourages an enhanced level of medical and clinical input into the regulatory process.

Several years ago, about seven or so years ago, the NRC initiated the Medical Fellows Program. Currently, although there are two slots, only one is filled by Dr. Myron Pollycove, a nuclear medicine physician.

Now, we think it's very important that medical personnel be incorporated into the rulemaking process at the NRC level and that the role of the medical fellows perhaps

be enhanced.

We feel that not only nuclear medicine physicians but radiation oncology physicians, clinical physicists, and nuclear pharmacists should all somehow be incorporated as medical fellows and active in the fundamental process which NRC is now about to embark upon of the revision of regulations.

Further, perhaps a jump, but even further, even though the ACMUI appreciates and is aware that the commissioners take in account the advice of the ACMUI, the medical community is probably not going to be truly satisfied until one of its own, someone involved, who has been involved in the daily medical decision-making process and the care of patients, is on the Commission, even though the activity of the Commission, we understand, only a very small --

CHAIRMAN JACKSON: On the Commission or on the NRC staff?

DR. ALAZRAKI: No, on the Commission.

CHAIRMAN JACKSON: Then you should go to the White House.

[Laughter.]

DR. ALAZRAKI: I'd be very happy to.

But you know, even though the activities of the Commission, probably only a very small part relate to

medical issues, what the Commission does greatly affects the activities in the clinical areas of nuclear medicine and radiation oncology, particularly, and so, we feel that there is perhaps an appropriate rationale for that stand.

Could I have the next slide, please?

[Slide.]

COMMISSIONER McGAFFIGAN: Could I ask a question?

CHAIRMAN JACKSON: Please.

COMMISSIONER McGAFFIGAN: On that last slide, the fellows program, you understand the conflict of interest and salary problems that we get into in trying to recruit fellows from your community.

The highest salary I think that can be offered is $123,000, which oftentimes isn't very attractive, unless somebody comes in under the inter-governmental personnel act, which means people working at state university medical centers or universities, you know, can come in and get paid whatever they're currently getting paid, but then you still have conflict-of-interest issues that arise. Have you thought those through?

DR. ALAZRAKI: This is problematic, we're aware of that, and every other agency which tries to do the same sort of thing -- the FDA and at NIH, in particular -- faces those problems.

There are ways around that or there are ways, I

think, particularly if you deal with people on sabbatical leaves, where these things can be dealt with, and we would encourage that the people who come in under this program be people who are really actively involved in medical practice or medical care, and so, they can't be removed for many years; they have to be current people who really understand what's going on in the current environment in the medical community.

The medical program in Part 35, as you're all aware, the changes are going to be considerable, the deliberations and discussions and the consensus building, and the staff is, I think, embarking on a -- or planning to embark on a program which would involve consensus building through sessions that they would -- briefings they would hold around the country and solicit commentary.

However, when they go back to their room to write the regulations, those are -- somehow become distant and, therefore, very important that not only the Medical Fellows Program but perhaps even the ACMUI be involved at the level of the writing of regulations.

ACMUI will be problematic, we're aware of that, but I think that we probably would be willing to make some sacrifices to help as much as we can, time permitting because of our -- getting harder and harder in the medical world to find time to do voluntary work such as this because

of the pressures of reimbursement and the pressures that are on us.

CHAIRMAN JACKSON: We're doing voluntary work, too.

[Laughter.]

DR. ALAZRAKI: Okay.

So, encourage active input from the regulated medical users -- that's what we've been talking about with the fellows program, with the ACMUI, with the -- also, the professional societies.

Just as we've been talking -- both Dennis and Jeffrey were talking in the past about the programs of the professional societies. They're also volunteers.

But there you have groups who want to contribute meaningfully in the types of programs that you need to have, and frankly, I think that's your best way right now, in the absence of one of you who's really been in the medical practitional world.

That's your best way of effectively instituting good programs which will be satisfactory to the users and also do what you need to do in your regulatory mission.

The Society of Nuclear Medicine, the American College of Nuclear Physicians, the Radiation Oncology Groups, and the American College of Radiology all can help in putting together those types of programs for you, and

then there will not be the same question of intrusion into the practice of medicine, and any quality improvement program can be viewed as an intrusion into the practice of medicine.

DR. STITT: John Graham is our final speaker, to summarize.

MR. GRAHAM: On a bright note, we're done with the slides, so I'll try to keep this brief.

In summary, the Advisory Committee on the Medical Use of Isotopes concurs with the Nuclear Regulatory Commission's preliminary position supporting a combination of two options -- to continue the ongoing program with improvements, which is option two, and to decrease oversight of low-risk activities with continued emphasis on high-risk activities, which was option three.

The advisory committee supports the definition of risk as presented by the International Commission on Radiological Protection in Publication 60.

Risk is the product of the probability that an event occurs and some measure of the potential loss or consequences associated with that event.

Within the context of this definition and based on the NRC's documentation of abnormal events and misadministrations, the actual history of risk from the medical use of isotopes has been very low.

Radiation medicine, in a relationship to the entire practice of medicine, is low risk. The actual history of low risk has been a result of standards, policies, and procedures that have been voluntarily developed by medical practitioners.

The advisory committee believes the most efficient and effective control of risk will be achieved from working with the provider community to further refine those standards, policies, and procedures.

The actual history of low risk also is a result of a portion of the regulations that have been established by the Nuclear Regulatory Commission.

There are areas of radiation medicine that need more surveillance than others for the protection of public safety. The advisory committee is committed to working with the NRC to establish these required regulations.

The advisory committee recommends reconsideration of the Medical Policy Statement of 1979. Every action taken by the NRC on the medical side and every discussion that we have at the ACMUI should be influenced and guided by the Medical Policy Statement.

The advisory committee is encouraged by the Commission's commitment as stated in the Staff Requirements Memorandum for the Materials Medical Oversight to support the use of the ACMUI and professional medical organizations

and societies in developing regulatory guidelines and standards.

The ACMUI represents a focused clinical background and a medical perspective that can support the Commission's responsibility for the public health and safety.

The ACMUI encourages an increased medical perspective through addition of a radiation medicine practitioner to the NRC staff and increased utilization of medical fellows within all of the practical constraints that you identified, Commissioner McGaffigan.

Medical representation within the NRC also could evaluate minor incidents and medically rationalize the enforcement process to avoid some of the reactionary response that is so vocally presented at some of the meetings that we attend.

The advisory committee looks forward to having an opportunity to work with the commissioners, the staff of the NRC, medical professionals, and the general public to revise 10 CFR Part 35.

As discussed in the Staff Requirements Memorandum for Materials Medical Oversight, we agree that revision of Part 35 should emphasize high-risk activities, which was item one in the summary of that memorandum.

We support the development of performance-based initiatives for activities where failure to meet the

performance criteria results in tolerable conditions for which appropriate corrective action will be taken in referenced items two, three, and four of that memorandum.

We support revision of Part 35 to safely introduce new treatment modalities to the American public as quickly as possible while considering the public safety, which was listed in item five.

We recommend that the Quality Management Program should be revised or revoked as a rule since we have not efficacy from the program.

We recommend an emphasis on quality improvement of the processes in the systems, with prescriptive regulations only applied when absolutely necessary, in addressing item six.

We concur with the concept of collaborating with professional organizations to develop practice standards within Part 35. We want to emphasize the role of training and experience in referencing available industrial guidance and standards, as stated in item seven.

We support the concept of a rulemaking process that creates more opportunity for input from potentially affected parties but that is more efficient for timely completion of the process, as outlined in item number eight.

In conclusion, the ACMUI is prepared to work with the Commission and the staff of the NRC to review 10 CFR

Part 35.

You have deliberated on this issue for a few years. There has been a strategic assessment initiative, public comments, the IOM report, and recommendations from the ACMUI.

We believe that, with open communication and feedback from the Commission and staff, the ACMUI can contribute to the public safety and improve the environment for the practice of radiation medicine.

CHAIRMAN JACKSON: Thank you.

DR. STITT: I just wanted to thank my committee, who has put in all sorts of time, late at night, during weekends, and to a man and woman, every single individual has contributed.

So, thank you very much for everything that you have done.

And thank you, the commissioners, for the opportunity for us to be here today.

CHAIRMAN JACKSON: Dr. Cool, I have one question for you. Do you have a patients' rights advocate on the committee?

DR. COOL: Yes, there is, at this time, a patients' rights advocate. Ms. Judith Brown was not able to be in attendance today.

That is one of the positions which will be coming

open come this October. Ms. Brown will have been on the committee for six years, which is the maximum length, and that is one of the positions which has currently been advertised in the Federal Register for replacement.

CHAIRMAN JACKSON: Okay.

Any final comments?

Commissioner Rogers?

COMMISSIONER ROGERS: Yes. There's two points that -- I don't know how far we can get into them today, but I'm just going to raise them with you.

The first is, how is NRC to determine when an isolated event is truly an isolated event? That's a matter of concern to us.

You have emphasized very much in your presentation that there's been too much focus on isolated events.

That's probably true, but how, from the standpoint of a -- of responsible stewardship point of view, is NRC to be able to determine objectively or find out on some objective basis when an isolated event is truly an isolated event and not evidence of something broader?

The second one is really the question that's somewhat connected to this, and that is, should there be a threshold for required corrective actions?

In reading your -- looking over your slide material and trying to understand, you know, what you were

thinking about, it seemed to me that basically you were rejecting the idea that there should be a threshold for any kind of required corrective actions, and I think that's a very fundamental point that somehow is going to have to get thrashed out, because if there is no threshold, then I think -- and a well-defined threshold for required corrective actions -- how do you deal with the situation which is really -- has a significant root cause that just never gets dealt with?

So, those are the two points which I'd like to throw out at you. I don't expect answers right now, but it does seem to me that these are points that you really have to think about, because they're very fundamental to the whole thing.

The other point I'll just touch on, and that is terminology. I would ask you and the NRC staff to try to be as clear as possible on terminology.

When you talk about quality assurance in your slides, you're really talking about what we would call quality control, not quality assurance, and I know that these terms sound and seem as if they mean the same thing. To us, they do not mean the same thing. There's a significant difference between quality control and quality assurance.

In brief, quality assurance relates to the

demonstration that you have done everything that is reasonable, when challenged, after you've, in fact, done the right thing, and quality control relates to the processes that lead you to determine what is the right thing to do.

So, there's a distinct difference there, and when you talk about quality assurance and we talk about quality assurance, maybe we ought to make sure we are talking about the same thing, because you know, it's very, very easy to carry on endless discussions and debates when, in fact, you mean something different by the same words.

So, I would just simply point out to you that there may be a little problem here of terminology and an understanding of what we mean when we're talking about quality assurance. Certainly, in the reactor area, it's very clearly different from what you've outlined here as QA.

So, I would just say, try to make sure that terminology is not an impediment to -- a misinterpretation of terminology is not an impediment to progress.

CHAIRMAN JACKSON: Commissioner Dicus.

COMMISSIONER DICUS: I have a question just for information purposes.

To your knowledge -- and it's on patient notification -- is our rule on patient notification, to your knowledge, the only rule related to medicine by a Federal agency or a state agency or government or law, for that

matter, requiring patient notification? Does anyone know?

DR. STITT: I'll answer for myself. To my knowledge, that is correct.

I think that some of the basic problems are those of communications. The QA would be a standard medical process, and we're not reactor people, and I think that's why there is a lot of difficulty in trying to communicate.

If an individual received the wrong medication, the standard process of dealing with that is formal, it's institutional, it's written, but there's no Federal regulation that requires you to write a letter to the patient.

The patient has to be discussed. You have to fill out the appropriate hospital form. It's reviewed by the QA committee and becomes part of the hospital or clinic's annual report in that particular area.

CHAIRMAN JACKSON: But it doesn't necessarily trigger an automatic notification of the patient.

DR. STITT: No. The patients may have that discussed, but there's nothing that's in the form of --

CHAIRMAN JACKSON: It may or it may not be discussed.

COMMISSIONER McGAFFIGAN: Is this true for the mammography act? I thought that, in the mammography act, there was some requirement for patient notification.

DR. STITT: That's the notification of results of the mammograms.

CHAIRMAN JACKSON: Commissioner Diaz.

COMMISSIONER DIAZ: I personally agree that, you know, we need to look at this on a risk basis. I think we realize that the low risk -- it should be relatively clear.

I do have a concern when we're talking about assessments of risk and trying to make assessments of risk in nuclear medicine comparable to other areas in medicine.

Although it was a long time ago, I did work for hospitals and I did perform as a physicist, and I saw so many differences between these places that I've always kept the concern that what we are trying to do is to minimize the risk to the public. I'm sure you want to do the same thing.

However, to compare to the risk in medicine -- I have a serious concern that that is probably not definable, because there are many procedures in medicine that are very high-risk, and we certainly don't want to elevate the risk from nuclear medicine, especially diagnostics, although, you know, therapeutical procedures are different, to some of the same kind of risk that are associated with some of the medical procedures, and I'm a little bit concerned that we're trying to say we are taking this risk field in nuclear medicine and comparing it to other fields in medicine, and I don't think that that will fly very far. I'm sorry.

I see that as a distinct, you know, for me, a philosophical difference. I would like to keep them in a playing field that is more quantitative, because we have a way of quantifying it and maintain it in a more controllable manner than many other processes in medicine.

CHAIRMAN JACKSON: Commissioner McGaffigan.

COMMISSIONER McGAFFIGAN: I'd again like to ask a point of information.

The rule on patient notification says that you have to notify the patient unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgement, telling the individual would be harmful.

Does that occur, where people use clinical judgement and say no, we won't, and is that enough of an effort to allow clinical judgement to get into the notification process?

DR. STITT: Yes, it does occur where clinicians make a decision.

DR. FLYNN: I've had a number of instances, looking at about 50 or 60 misadministrations as a medical consultant for the NRC, whereby the radiation oncologist notifies the referring physician, the referring physician says I don't want my patient notified.

The referring physician has no idea what NRC

regulations are. They have no idea.

And oftentimes, then, the radiation oncologist reminds the referring physician that they have this regulation, and then it may be that the patient is -- harm won't be brought to the patient, but the patient may be elderly, and whatever you tell them in the nursing home would be confusing to them, you tell their next of kin that some minor event occurred, and some of the referring physicians believe it brings on a psychosis and a radiation phobia, a psychosis of some minor event that they're required to report.

So, it comes into problems with how do you deal with the referring physician if the referring physician is adamant about the patient not knowing.

So, there's some --

CHAIRMAN JACKSON: It strikes me that the regulation has that escape hatch.

DR. WILLIAMSON: It does not have that escape hatch.

We had a case where a 10th of a centigrade was given to the wrong site because of a minor machine malfunction, which, since there's no lower threshold for wrong site, this minor technical error was required to be reported to the patient.

The physician and referring physician did not want

to report it to the physician and we had extensive discussions with your general counsel, and we were forced to report it, to sort of pick out one of the patient's relatives or friends.

So, as the law reads now, you have to report it to somebody.

If you, on medical judgement, decline to report it to the patient, you must then put yourself in the position, as physician, of violating the patient's confidentiality and sort of picking out some friend, associate, or relative. I think the word in the law is "guardian," but it's very broadly interpreted.

COMMISSIONER McGAFFIGAN: This gets down to my earlier point. I think you all have to deal with the words in the regulations and your words in your licenses, and we have to get beyond philosophy in the next year --

CHAIRMAN JACKSON: That's right.

COMMISSIONER McGAFFIGAN: -- to rulemaking, and I appreciate the last speaker's commitment to do that, but that's --

CHAIRMAN JACKSON: That's where the rubber meets the road.

COMMISSIONER McGAFFIGAN: -- where the rubber meets the road, right.

CHAIRMAN JACKSON: And on that note, I'd like to

thank each member of the committee for today's briefing.

It's clear that you've devoted many long hours of thought and consideration to this matter, obviously, in and out of the committee meetings.

And the issue of NRC's regulatory role in the medical use of by-product material is not a simple or a trivial one, and the Commission didn't arrive at its recent decision lightly on this matter.

And the advisory committee's views will be of tremendous benefit to the Commission and the staff as we work to revise the program.

And we'll, of course, always give serious consideration to the views expressed here today, as the staff reviews the program -- its program for completing the revision of 10 CFR Part 35.

And building on what Commissioner McGaffigan said, the Commission would appreciate a more direct and focused look at possible revisions to 10 CFR Part 35, including test cases -- I mean you can take any suggestion or think of your own -- in order to advance the decision-making on this issue.

And as you do that, it's important to address a number of the questions that you've heard put to you today by the Commission, because it's what we are thinking about, and it's going to inform our decision-making.

And so, those two elements of giving a more direct and focused look at possible revisions to Part 35 and, in the process, addressing the questions or types of questions that you have heard put to you today are how you can be of the best help to us as we review the staff's activities on revising Part 35, because that's where we're going.

We're a regulatory agency, and we're focusing on that, and so, unless there are further comments, we're adjourned.

Thank you.

[Whereupon, at 10:51 a.m., the meeting was adjourned.]

CERTIFICATE

This is to certify that the attached description of a meeting of the U.S. Nuclear Regulatory Commission entitled:

TITLE OF MEETING: MEETING WITH ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES (ACMUI) - PUBLIC MEETING

PLACE OF MEETING: Rockville, Maryland

DATE OF MEETING: Thursday, May 8, 1997

was held as herein appears, is a true and accurate record of the meeting, and that this is the original transcript thereof taken stenographically by me, thereafter reduced to typewriting by me or under the direction of the court reporting company

Transcriber: Tamara Sheppard

Reporter: Mark Mahoney

ACMUI Commission Briefing

May 8, 1997

Judith Stitt, M.D.
John Graham
Dennis Swanson, M.S., B.C.N.P.
Jeffrey Williamson, Ph.D.

Risk and Radiation Medicine

- Radiation Medicine is a safe process in relation to the practice of medicine as a whole
- Risk is related to the probability of error and the severity of consequences

Risk and Radiation Medicine

- Low incidence of errors (1×10^{-4}) in all modalities because of:
  - Voluntary practice standards
  - Staff training standards
  - Broad Quality Improvement (QI) programs

Risk and Radiation Medicine

- The low risk status justifies a move away from prescriptive regulations.
- The low risk status justifies the development of performance based regulation of radiation medicine.

Risk in Radiation Medicine

Potential Consequences of Exposure

- Spectrum of radiation procedures
  - HDR brachytherapy
  - Gamma stereotactic therapy
  - Radionuclide therapy
  - LDR brachytherapy
  - Diagnostic nuclear medicine

Risk in Radiation Medicine

Potential Consequences of Exposure

- Higher risk procedures
  - Exposure to public greater than Part 20 limits
  - Deterministic injuries to staff possible
  - Probable serious injury to the patient

Risk in Radiation Medicine
Potential Consequences of Exposure

- Medium risk procedures
  - Public and staff exposures less than Part 20 limits
  - Small numbers of staff & public exposed to greater than Part 20

- Lower risk procedures
  - Public and staff exposures less than Part 20 limits

Risk in Radiation Medicine

- High risk procedure has the potential for risk based on consequences of errors

- Probability of occurrence is low given current standards of
  - Physician, physicist, support staff education and training
  - QI, safety, physics, and delivery practices

- Overall risk is low given current practice standard compliance

Medical Policy Statement

- Statement 1: The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

Medical Policy Statement ACMUI Modification

- **Statement 2: The NRC will regulate the radiation safety of patients only where justified by the risk to the patients, and only where voluntary standards or compliance with the standards are inadequate.**
- Assessment of the risks justifying such regulations will reference comparable risks and comparable modes of regulation for other types of medical practice.

Medical Policy Statement
ACMUI Modification

- **Statement 3: The NRC will** not intrude **into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.**

Radiation Medicine and Quality Improvement

- Quality Assurance: For any procedure, action is taken only when the process average exceeds a predetermined threshold.

- When the process average is under the threshold, no questions are asked. When the threshold is exceeded, there is panic and finger pointing.

Radiation Medicine and Quality Improvement

- Quality improvement: The entire output of the process provides the basis for actions, not just those occurrences that are deemed unacceptable because they exceed a specification limit.

- When a QI approach is taken there are two options for improvement:
  - Reduce the variability in the process &/or
  - Shift the process in the desired direction

Government by Yo-Yo

B. Siegel, M.D.
1996

Current Patient Safety Regulations

- QI program is incomplete and unbalanced
  - Driven by low-probability single events at expense of higher-likelihood processes
    - (Yo-Yo effect)
  - Focuses on excessive documentation
  - Relies on prescriptive rules and threshold events

Current Patient Safety Regulations

- Adversarial with punitive enforcement
  - Emphasis on isolated errors and paper work violations rather than overall QI program
  - Errors result in punishment rather than constructive assistance

Future Patient Safety Regulations

- Do not intrude into medical & physics practice
- Encourage acceptance of voluntary practice standards
- Focus enforcement on substandard practices rather than isolated errors & paperwork infractions by good practices
- Enforcement should be constructive not punitive

Regulatory Program-Practice Standards

- Collaborate with professional organizations (ACR, AAPM, SNM). Develop practice standards for specific areas of radiation medicine
  - Safety standards for public and staff
  - Essential resources - equipment, staff
  - QI program elements for patient safety

Regulatory Program-Enforcement

- Enforcement process guidelines
  - Inspections - function like an accreditation site visit
  - Use clinical professionals as reviewers
  - Emphasize staff credentialing and adherence to practice standards vs. isolated errors

Accreditation Standards

- Goal - Bring sub-standard practices into mainstream without burdening others

- Calibrate inspection process against random sample of practices to ensure reasonableness

- Models to study:
  - ACR accreditation programs
  - Mammography Quality Standards Act
  - JCAH

Isotope Event Reporting

- Dissociate the reporting of isolated events from actual or perceived punitive actions
- Address reporting at the local rather that NRC level

Isotope Event Reporting

- Dissociate the reporting of events from patient notification requirements
- Simplify and harmonize the definitions of isotope events

Isotope Event Reporting - Possible Approaches

- Performance-based regulation that addresses reporting at the local level
  - RSO, licensee, Agreement States
  - NRC review problem programs
- Change the mechanism of centralized reporting
  - Clearly define purpose
  - Voluntary central reporting

Adverse Event Reporting - Possible Approaches

- If technical error data is desired - define technical criteria independent of clinical effects
- If patient sequelae data are sought - define in terms of clinical findings

Quality Management Program

- ACMUI concurs that useful regulatory endpoints include:
  - Written treatment prescription
  - Review of dose calculations
  - Identification of patient

- Regulatory endpoints should be performance-based not prescriptive
  - Focus on procedures with higher risk

ALARA

- Current program imposes 500 mR annual staff exposure limit on procedure and facility design
- Require only compliance with Part 20 limits
- Encourage ALARA as a program philosophy but not a requirement

NRC & Medical Expertise

- ACMUI encourages an enhanced level of medical and clinical input into the regulatory process.
  - Consider medical personnel for NRC staff
  - Increased role of Medical Fellow

Medical Program & Part 35

- Changes will require considerable deliberation, discussion, and consensus building.
- Encourage active input from the regulated medical users
- Use ACMUI as part of the process

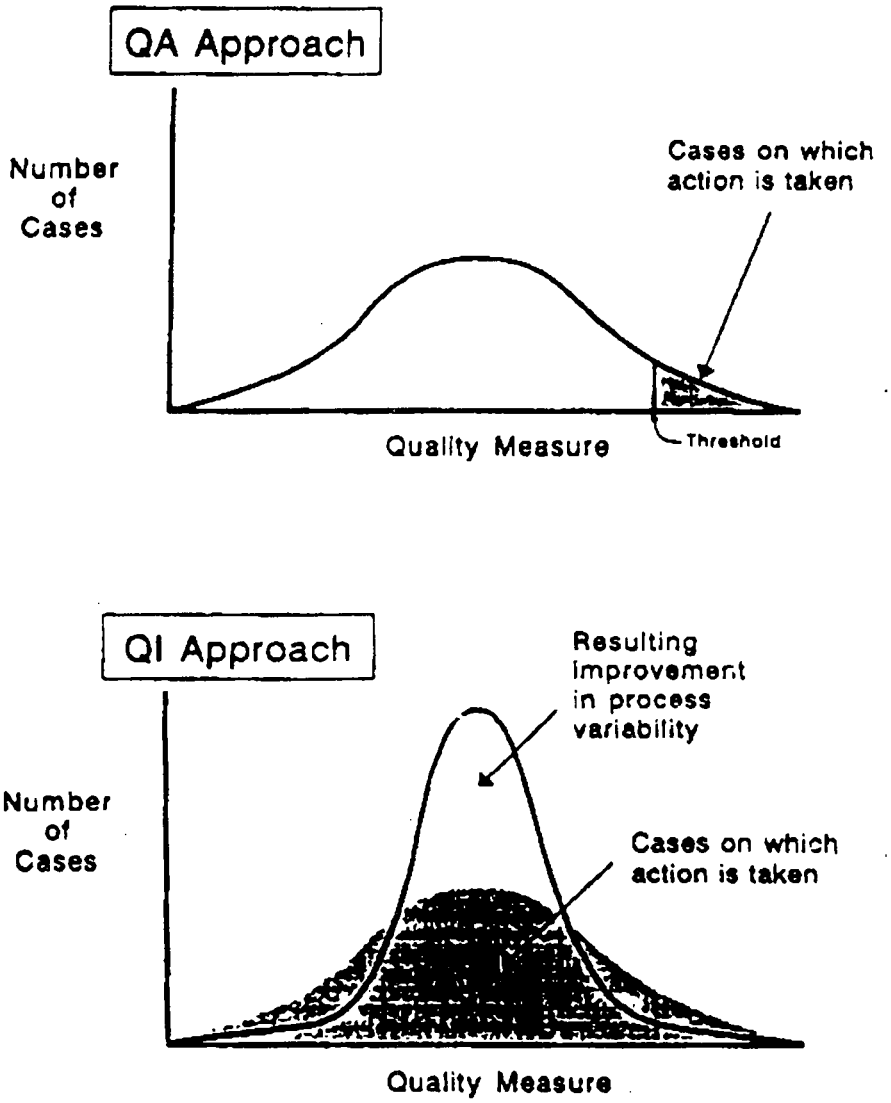

FIGURE 1.1. The difference between quality assurance and quality improvement.

ACMUI Commission Briefing

May 8, 1997

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Risk and Radiation Medicine

- Radiation Medicine is a safe process in relation to the practice of medicine as a whole
- Risk is related to the probability of error and the severity of consequences

Risk and Radiation Medicine

- Low incidence of errors (1×10^{-4}) in all modalities because of:
  - Voluntary practice standards
  - Staff training standards
  - Broad Quality Improvement (QI) programs

Risk and Radiation Medicine

- The low risk status justifies a move away from prescriptive regulations.
- The low risk status justifies the development of performance based regulation of radiation medicine.

Risk in Radiation Medicine

Potential Consequences of Exposure

- Spectrum of radiation procedures
  - HDR brachytherapy
  - Gamma stereotactic therapy
  - Radionuclide therapy
  - LDR brachytherapy
  - Diagnostic nuclear medicine

Risk in Radiation Medicine

Potential Consequences of Exposure

- Higher risk procedures
  - Exposure to public greater than Part 20 limits
  - Deterministic injuries to staff possible
  - Probable serious injury to the patient

Risk in Radiation Medicine
Potential Consequences of Exposure

- Medium risk procedures
  - Public and staff exposures less than Part 20 limits
  - Small numbers of staff & public exposed to greater than Part 20

- Lower risk procedures
  - Public and staff exposures less than Part 20 limits

Risk in Radiation Medicine

- High risk procedure has the potential for risk based on consequences of errors

- Probability of occurrence is low given current standards of
  - Physician, physicist, support staff education and training
  - QI, safety, physics, and delivery practices

- Overall risk is low given current practice standard compliance

Medical Policy Statement

- Statement 1: The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

Medical Policy Statement
ACMUI Modification

- **Statement 2: The NRC will regulate the radiation safety of patients** only **where justified by the risk to the patients, and** only **where voluntary standards or compliance with the standards are inadequate.**
- Assessment of the risks justifying such regulations will reference comparable risks and comparable modes of regulation for other types of medical practice.

Medical Policy Statement
ACMUI Modification

- **Statement 3: The NRC will** not intrude **into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.**

Radiation Medicine and Quality Improvement

- Quality Assurance: For any procedure, action is taken only when the process average exceeds a predetermined threshold.

- When the process average is under the threshold, no questions are asked. When the threshold is exceeded, there is panic and finger pointing.

Radiation Medicine and Quality Improvement

- Quality improvement: The entire output of the process provides the basis for actions, not just those occurrences that are deemed unacceptable because they exceed a specification limit.

- When a QI approach is taken there are two options for improvement:
  - Reduce the variability in the process &/or
  - Shift the process in the desired direction

Government by Yo-Yo

B. Siegel, M.D.

1996

Current Patient Safety Regulations

- QI program is incomplete and unbalanced
  - Driven by low-probability single events at expense of higher-likelihood processes
    - (Yo-Yo effect)
  - Focuses on excessive documentation
  - Relies on prescriptive rules and threshold events

Current Patient Safety Regulations

- Adversarial with punitive enforcement
  - Emphasis on isolated errors and paper work violations rather than overall QI program
  - Errors result in punishment rather than constructive assistance

Future Patient Safety Regulations

- Do not intrude into medical & physics practice
- Encourage acceptance of voluntary practice standards
- Focus enforcement on substandard practices rather than isolated errors & paperwork infractions by good practices
- Enforcement should be constructive not punitive

Regulatory Program-Practice Standards

- Collaborate with professional organizations (ACR, AAPM, SNM). Develop practice standards for specific areas of radiation medicine
  - Safety standards for public and staff
  - Essential resources - equipment, staff
  - QI program elements for patient safety

Regulatory Program-Enforcement

- Enforcement process guidelines
  - Inspections - function like an accreditation site visit
  - Use clinical professionals as reviewers
  - Emphasize staff credentialing and adherence to practice standards vs. isolated errors

Accreditation Standards

- Goal - Bring sub-standard practices into mainstream without burdening others

- Calibrate inspection process against random sample of practices to ensure reasonableness

- Models to study:
  - ACR accreditation programs
  - Mammography Quality Standards Act
  - JCAH

Isotope Event Reporting

- Dissociate the reporting of isolated events from actual or perceived punitive actions
- Address reporting at the local rather that NRC level

Isotope Event Reporting

- Dissociate the reporting of events from patient notification requirements
- Simplify and harmonize the definitions of isotope events

Isotope Event Reporting - Possible Approaches

- Performance-based regulation that addresses reporting at the local level
  - RSO, licensee, Agreement States
  - NRC review problem programs
- Change the mechanism of centralized reporting
  - Clearly define purpose
  - Voluntary central reporting

Adverse Event Reporting - Possible Approaches

- If technical error data is desired - define technical criteria independent of clinical effects
- If patient sequelae data are sought - define in terms of clinical findings

Quality Management Program

- ACMUI concurs that useful regulatory endpoints include:
  - Written treatment prescription
  - Review of dose calculations
  - Identification of patient

- Regulatory endpoints should be performance-based not prescriptive
  - Focus on procedures with higher risk

ALARA

- Current program imposes 500 mR annual staff exposure limit on procedure and facility design
- Require only compliance with Part 20 limits
- Encourage ALARA as a program philosophy but not a requirement

NRC & Medical Expertise

- ACMUI encourages an enhanced level of medical and clinical input into the regulatory process.
  - Consider medical personnel for NRC staff
  - Increased role of Medical Fellow

Medical Program & Part 35

- Changes will require considerable deliberation, discussion, and consensus building.
- Encourage active input from the regulated medical users
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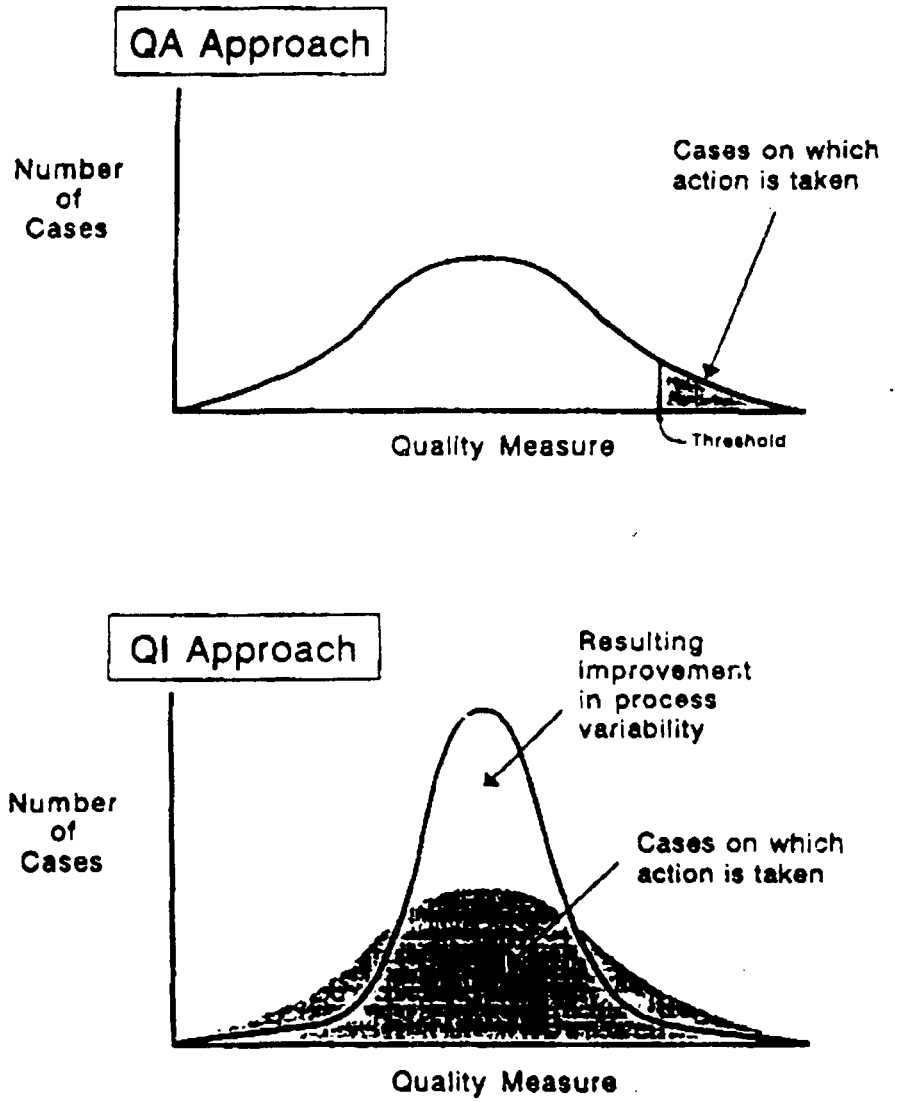

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