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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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WEDNESDAY,

APRIL 26, 2006

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The meeting was convened in Conference Room E in the Natcher Conference Center, Natcher Building (Building 45), National Institutes of Health, Bethesda, Maryland, at 8:00 a.m., Leon S. Malmud, M.D., Chairman, presiding.

MEMBERS PRESENT:

LEON S. MALMUD, M.D.	Chairman
EDGAR BAILEY	Member
DOUGLAS F. EGGLI, M.D.	Member
RALPH P. LIETO	Member
SUBIR NAG, M.D.	Member
SALLY WAGNER SCHWARZ	Member
ORHAN SULEIMAN, Ph.D.	Member
WILLIAM VAN DECKER, M.D.	Member
RICHARD J. VETTER, Ph.D.	Member
JEFFREY F. WILLIAMSON, Ph.D.	Member

SPEAKERS AND PARTICIPATING NRC STAFF:

DONNA-BETH HOWE, NRC

LYDIA CHANG, NRC

THOMAS H. ESSIG, Designated Federal Official, NMSS/IMNS/MSIB

CYNTHIA M. FLANNERY, NMSS/IMNS/MSIB

ANGELA McINTOSH, NMSS/IMNS/MSIB

CHARLES MILLER, Ph.D., NMSS/IMNS

MOHAMMAD SABA, NRC

RONALD ZELAC, Ph.D., NRC

I-N-D-E-X

P-R-O-C-E-E-D-I-N-G-S

(8:04 a.m.)

CHAIRMAN MALMUD: Okay. We'll start. The first item on the agenda is the ACMUI Review of Medical Events Involving I-131, and Dr. Eggli is making a presentation.

MEMBER EGGLI: Good morning. This is an ACMUI Subcommittee report. Subcommittee members were me, Ralph Lieto, Sally Schwarz, and Dick Vetter.

The charge from NRC staff was to review the I-131 administration incidents to determine if there were any patterns to the errors, and, secondly, to determine whether there was any way to further reduce the iodine administration errors. And since several of the incidents were initially intended to be less than 30 microcuries, which would not have required a written directive, but ended up being larger administrations, if there were any recommendations that could be made to prevent these sort of conversion errors, converting a low dose into a higher dose administration.

So what I thought we would do is essentially review the incidents one by one and look for the common threads. What I have done here is I have simply cut and pasted the description of the

incident out of the NMED database, so that I had reliably represented the information that was available.

In the first incident, it was -- a thyroid uptake dose of approximately one millicurie, .98 millicuries, was administered instead of the prescribed dose of approximately 15 microcuries. The event occurred due to the prescription being made incorrectly, with no subsequent verification by the technologist.

So if you look at sort of what were the errors that occurred, first, the dosage was ordered incorrectly. And then, we're going to make some assumptions, because, again, the NMED database contains summary reports, and we're assuming that unless a specific error was mentioned in the database it probably didn't occur.

So that we're going to assume here that when the -- that the dosage was actually labeled properly with the activity that it actually contained. Then, if the dose had been verified in a dose calibrator, which is not required, but, nonetheless, if a dose had been verified in a dose calibrator, they would have been able to confirm that the dose was outside of the written range.

The other thing is that if the technologist even looked at the label on the capsule, they would have noted that the amount of iodine contained within the capsule was greater than 30 microcuries and required a written directive. So there are two issues. One is the initial order didn't require a written directive, but the amount of iodine that was actually administered would have required a written directive, and the tech did not look for a written directive.

So this is effectively an error in following procedure, that if a technologist had verified the written directive, which would have been required for the dose they were administering, they would have -- or had attempted to verify that, they would have discovered that, in fact, the dosage was in error.

The lack of a written directive for a roughly one millicurie dose of I-131 should have been a big red flag to the technologist, and apparently it wasn't. So this is an error in confirming that presence of a written directive on a dose that the technologist knew was in the range requiring a written directive at the time the dose was administered. This is going to be a recurring theme throughout this

process.

The second event was the patient was administered approximately 500 microcuries of radioactive iodine instead of a prescribed five microcurie uptake dose. This was a verbal order from an authorized user for the five microcurie dose that was misunderstood, and 500 microcuries were ordered.

Again, we are doing the same -- we have the same category of error: a dosage of 500 microcuries was ordered incorrectly based on a misunderstood verbal order for five microcuries. The technologist should not have accepted a verbal order for a dosage in the range requiring a written directive. Again, although the doctor intended to order a dose that did not require a written directive, the dose that the technologist understood and ordered did require a written directive, and the technologist did not pursue either looking at or verifying that a written directive for that order existed.

Again, likewise, the administering technologist went ahead and administered the dose without verifying the written directive. So we have two people who administered dose -- one who ordered and one who administered a dose which would have required a written directive.

The assumption is that the technologist knew how much activity was being administered to the patient, and, therefore, should have known that that amount of activity would have required a written directive. Once again, we have a failure of a technologist to follow procedure, which is to verify the presence of a written directive.

Event 3, wrong patient was administered two millicuries of I-131 for a thyroid cancer workup instead of 200 microcuries of I-131 -- of I-123 for an uptake and scan. The patient apparently responded to the name that the technologist called in the waiting room, and the technologist didn't use any further procedure to verify the identity of the patient.

Basically, this was an error in identification. I've seen this actually happen before, it turned out, with a tagged red cell administration many, many years ago while I was in training. A patient was here for -- was here for -- was in our clinic for bloodwork, and there was another patient who had the last name of Blood who was having a tagged red cell study. And the technologist went in and called the name for blood, and the patient who was here to have their blood drawn got up and got injected with the blood of the patient whose last name was

Blood.

So if you don't verify the name of the patient, you can have all sorts of interesting errors occurring.

Basically, JCAHO requires that you have two ways of independent -- of identifying the patient. What the technologist should have done in this case, and what our technologists routinely do, is when they bring the patient into the dose room, in spite of the fact that they went out into the waiting room, called the patient's name and the patient followed them into the dose room and sat down, the technologists are required to ask the patient to state their full name and their date of birth, which the technologists then verify. This procedure would have prevented this administration error.

Likewise, in therapeutic administrations, using two people to identify the patient, much the same as is required for blood administration, where two people have to identify that it is the same patient. For a therapeutic administration, we are going to -- we recommend that the committee consider endorsing a requirement of two people identifying -- positively identifying the patient for a therapeutic administration.

Jeff?

MEMBER WILLIAMSON: Isn't there already a requirement in Part 35 for redundant identification?

MEMBER EGGLI: I believe the requirement is a JCAHO requirement, and the requirement for -- the JCAHO requirement says you have to use two means of identifying the patient. And what we are using is asking the patient to state their full name and to tell us their date of birth, which we have on the paperwork. But I'm not aware of a specific requirement in Part 35.

MEMBER NAG: But at least for -- at least for 400 and 600 use, require two methods of identification.

MEMBER EGGLI: I think that for -- I don't think that -- Donna-Beth, do you know, in 200, is there a -- because these are all 200, most of these are 200 errors. Is there a requirement in Part 35 for 200?

DR. HOWE: When we had the quality management rule, which we don't use that name anymore, when we revised it in 2002, the committee believed that requiring two methods of identification was overly prescriptive. And so the requirement now is that you have procedures in place to identify the

patient, but it does not specify how you identify the patient.

MEMBER EGGLI: Okay.

DR. HOWE: So it's a performance-based rule now.

MEMBER EGGLI: Essentially, we're governed by many regulators in clinical nuclear medicine, one of which is JCAHO, which requires two methods of positive patient identification. Again, what we are using in our practice is name and date of birth. And the subcommittee may be suggesting a more rigorous approach for known therapeutic doses.

Okay. Event 4, the patient received roughly a millicurie of I-131 for a thyroid uptake study instead of the intended dose of 10 microcuries. The root cause of the event was a lack of adequate doublechecking of the I-131 uptake prior to dose administration. This is a unique case where a pipette -- where an institution actually pipetted liquid doses, and they reused a pipette that had been used for a high dose therapy for a low dose uptake, and the residual activity in the pipette brought the activity up over the top.

This is I think a unique error, not likely to be repeated. The site has corrected that error by

not allowing any pipette to be reused. The pipette had to be disposed of after each use, which should solve that problem. But, again, looking at the dose in a dose calibrator also would have solved that problem as well.

So this is a unique incident. No real theme associated with the rest of our incidents.

Incident 5, a 19-year old patient was diagnosed with Grave's Disease and was administered a 12.5 millicurie dose instead of the prescribed dose of 12 microcuries. However, the clear intent of the procedure was to ablate the thyroid gland. And, actually, the physician who wrote the prescription wrote "microcuries" instead of the intended "millicuries." So the patient actually got the intended dose, but it wasn't the dose that was actually ordered.

So the right thing happened essentially for the wrong reason here. So in this case, again, a physician ordered a dose a thousand-fold smaller than the intended dose. The tech actually gave the intended dose. However, again, right outcome, wrong reason. If the tech had compared the dosage ordered with the dose administered, again, the ordering error would have been detected.

And the technologist again administered a dosage greater than 30 microcuries, and should have reviewed a written directive before administering the dose but did not. And the tech would have detected on the written directive that the order was in error, and could have asked the physician to correct the order before administering the radioactive iodine to the patient.

Event 6, patient received 2.8 millicuries of I-131 instead of a prescribed two millicurie dose. This is a vendor problem. This is a problem we see every day where the vendors send us capsules that are out of range for the dose that we ordered. Again, we measure all of these in our -- in my site, we measure all of these capsules in a dose calibrator and determine that the dose is within our prescribed and our policy error range allowed.

But, again, the assumption is that the capsule was properly labeled. And the technologist, again, did not verify the activity listed on the capsule label with a written directive. And the -- nor did the technologist review the order with the authorized user who ordered it.

So, again, what we have is a failure to follow a simple, straightforward process of verifying

a dose that would require a written directive when you know the dose is above the 30 microcurie range.

In Event 7, a licensee reported that the patient received three millicuries of I-131 for the assessment of metastatic thyroid disease instead of the prescribed dose of 25 microcuries. This prescribed dose was prescribed by a requesting physician, and it appears to be practice in some locations that requesting physicians can specify the dose, and the Nuclear Medicine Department simply delivers the dose requested. And an authorized user did not -- did not approve that particular order.

So the bottom line is a dosage of 25 microcuries for the evaluation of metastatic thyroid cancer is both inappropriate and ineffective. I don't think that any iodine should ever be ordered at the direction of a referring physician, who is not an authorized user without the knowledge and approval of a responsible authorized user.

The dosage actually administered would have required a written directive, which, again, was not reviewed by the administering technologist. Again, the amount ordered is inconsistent with good, clinical practice, and, in fact, a three millicurie dose is an appropriate dose -- dosage for evaluating

thyroid cancer metastasis, assuming that a patient has been properly prepared for the study.

So I think we have a couple errors here. One error is ordering an iodine dosage at the request of a physician who is not an authorized user. The second, again, is not reviewing a written directive, which apparently didn't exist in this case, not reviewing a written directive when administering a dose that the technologist was aware was greater than 30 microcuries.

Event 8, the licensee reported that the patient received about 100 millicuries of I-131 instead of a prescribed dose of 17 millicuries. Multiple patients were scheduled on the same day, and there was an error in administration. I mean, it's not uncommon for a busy patient -- a busy clinic to treat multiple patients with radioactive iodine in the same day, and to have multiple doses of radioactive iodine on hand.

Our supplier gets very grumpy when we bring the doses in one at a time when we have three in a row, and we bring all the doses in at the same time. And this is simply an issue of both accurate patient identification and review of the written directive for the appropriate patient resulted in this error.

So now we've got two themes going, one of them a minor theme and one of them a major theme. The major theme, again, is failure to review a written directive for a dosage that would require a written directive, regardless of how the case started out. But if the technologist sees that a dosage is greater than 30 microcuries, they certainly should be reviewing a written directive before administering that dosage. And then, again, we have our second error in patient identification.

Okay. In this case, in Event 9, the licensee reported that a patient was administered four millicuries of I-131 without a written directive. Again, several patients were scheduled to receive a dose of four millicuries, but one of the patients did not have a written directive, so the technologist simply went ahead and administered this dose to a patient. It was subsequently determined that the patient was supposed to have a 150 millicurie therapeutic dose instead of a four millicurie dose for a whole body scan.

I believe that the dose was subsequently boosted up to the 150 millicurie range, and the patient subsequently received the correct total treatment. But, again, what we have is a failure to

review a written directive. And in this case, actually, the technologist knew there was no written directive at the time of administration of the radioactive dosage, so this was essentially a clear and willful violation of the regulation.

But, again, an unambiguous policy of requiring the technologist to have the written directive in hand prior to administration of any dose greater than 30 microcuries would have presented this. And this is an issue that, as you deal with basically a well understood and routinely enforced policy, is likely to be followed by the technologist than a sort of haphazardly enforced administration policy.

So if you're really serious about this, and you require that this be done every time, the technologists are more likely to do it, because it's hard to expect a technologist to make a judgment when they have to do what they're supposed to do and when they don't have to do what they're supposed to do, when there is not a clear-cut culture of always doing it the right way.

Event 10, patient was scheduled to receive two millicuries of I-131, and was instead administered a dose of 15 millicuries. The patient's thyroid was surgically removed previously due to cancer, and the

patient had also previously received an ablative dose. The patient was scheduled to receive a two millicurie dose as a diagnostic procedure, as a followup to verify the effectiveness of the previous therapy.

Unfortunately, there was not enough detail in the NMED database to determine whether or not a written directive existed for the dose. But if we assume that a written directive existed, and that the dosage was properly labeled with the correct activity, then the technologist must not have reviewed the written directive prior to administering the dosage. And, again, so we have a failure to match a dose administered greater than 30 microcuries with a written directive for that dosage.

And again, as we go back and look over the events, it doesn't matter what dose was ordered. If the technologist knows at the time of administration that the dosage they are administering is greater than 30 microcuries, based on a label, based on putting it in a dose calibrator, based on whatever reason the tech knows that the dose is greater than 30 microcuries, then they have an obligation to verify the written directive.

The final event that was in the date range that we reviewed was a patient received 5.6

millicuries of I-131 instead of the prescribed two millicuries for a -- again, for a followup scan on a thyroid cancer patient. The prescribing physician discovered the error subsequent to the administration when the patient underwent a scan. The patient had a useful scan, nonetheless.

The amount of iodine used for neck and chest scanning varies widely around the country, from as low as one millicurie to as high as 10 millicuries. And depending on how much you're worried about studying the patient, and how much thyroid bed you think the patient is likely to have, there is a wide range of iodine used.

So, again, this did not result in harm to the patient, but it was not a dose -- dosage to the patient that was in compliance with the directive.

Again, we don't know whether a written directive exists, but if a written directive existed the technologist did not verify the dosage against that written directive. And the technologist clearly knew how much activity they were administering. What they didn't do was verify the order for that dosage.

So overall, we reviewed 11 iodine incidents in the NMED database for the period which was considered, which was about a year and a half.

There are actually tens of thousands of both diagnostic and therapeutic administrations in the United States every year. So assuming that we're capturing the vast majority of these incidents, the -- which Orhan shakes his head and said we're not capturing the vast majority of the incidents.

But probably, nonetheless, the numerator is fairly small compared to the denominator. I think that's probably safe to say. Of the 11 incidents reported, four involved intended therapeutic dosages, two involved dosages that were intended to be greater than 30 microcuries, and five involved dosages that were intended to be less than 30 microcuries and would not have required a written directive.

Actually, I have an error here. Two cases involved incorrect patient identification. And the subcommittee essentially recommends that two positive methods of patient identification be adopted as good practice. Again, whether the regulation is prescriptive or not in that case, at least hospital facilities have to deal with JCAHO, which is prescriptive about identifying -- positively identifying patients.

In nine of the 11 cases, the dosage administered was in the range that would have required

a written directive with the technologist knowing the dosage they were administering. And it's hard to believe that the tech didn't actually know what dosage they were administering, since there is no evidence that any of these dosages were incorrectly labeled or incorrectly calibrated, although in one case the technologist didn't believe the dose calibrator and had a decimal placement error.

Five of the six administrations, again, were intended to be under 30 microcuries. There is no reason to believe that the administering technologist was unaware that the dosages were in the range requiring a written directive. The subcommittee's recommendation is that the written directive must be reviewed with the authorized user by the administering technologist whenever the dosage is greater than 30 microcuries, and that would have prevented all of these errors.

The only two errors that would not have been prevented by enforcing a policy of at least validating that a written directive exists, and comparing the written directive against the dose being administered, only the two cases of incorrect patient identification would have been missed by this procedure. So it would have taken an N of 11 and

reduced that N to two by simply making sure that the technologists follow a standard procedure.

In two of the cases, in spite of erroneous orders, the patient received the medically appropriate dose. However, doing the right thing for the wrong reason doesn't necessarily keep you out of trouble. In both cases, the iodine dosages were in the range that would have required a written directive, and, again, the technologist did not pursue the written directive.

The absence of a written directive in an iodine dosage greater than 30 microcuries should be a big red flag to the individual administering the dose.

And so the -- as a final conclusion, the subcommittee on I-131 administration incidents reaffirms the recommendations from April 2005, which are probably impossible to read because I stuffed them all into one slide.

But the bottom line is sort of it's impossible to entirely eliminate all human errors from any process. However, verification procedures similar to blood administration could be considered for therapeutic administration, since the risk there is greater that the burden to make sure that it's done correctly can be greater.

Verbal orders should not be permitted at any step in a therapeutic process or for dosages greater than 30 microcuries. Verbal orders should not be permitted. They should -- a written directive is required, and the individual should validate that written directive.

One of the, again, recurring common themes here were communication errors or communication breakdowns. And those links between the authorized user and the administer -- and the individual administering the dosage should be strengthened. One of the ways to do that is to have -- require the technologist to review the written directive. Another is to require the technologist to review the written directive with the authorized user prior to administration.

The second one imposes a greater burden. If the first was done routinely, again, all but two of these errors would have been prevented.

Reverifying therapeutic dosages in a dose calibrator onsite prior to administration might have prevented a couple of the therapeutic administration errors. And, again, more detailed documentation in the NMED database might help in data analysis, but a lot of these come from agreement states and the NRC

doesn't control what actually ends up in the NMED database. But more data in the database, or encouraging a more complete description of the event, might assist in the evaluation of root causes of these events.

But let me go back. I'm a firm believer in the Will Rogers School of Public Speaking, which says you tell people what you're going to tell them, you tell them what you're telling them, and then you tell them what you told them. So what I'm going to do one more time is that a big root cause here is failure to require the technologist to verify the dosage against a written directive when the technologist knows that the dose is in the range that would require a written directive.

And, secondly, positive patient identification is a standard practice required by JCAHO in hospitals. It should be extended to outpatient clinics as well.

And, thirdly, communications links between authorized users and individuals administering radioactive materials need to be strengthened. And that's -- again, this is a subcommittee report to the entire ACMUI, so the rest of the committee needs to decide what to do with this.

CHAIRMAN MALMUD: Thank you, Dr. Eggli, for a very thorough and informative review.

It appears that Dr. Williamson has a comment or question.

MEMBER WILLIAMSON: Yes. I guess the two cases of patient identification were those in the requiring or not requiring written directive category?

MEMBER EGGLI: Effectively, the doses -- dosages administered were both in the therapeutic range and required a -- would have required a written directive.

MEMBER WILLIAMSON: Now, in looking at 35.41, it appears that procedures need to be in place -- it's not specified exactly what -- for identifying the patient or human subject. In the case where a written directive is required, but there are no -- there is no such requirement for the standard 35.200 cases where a written directive is not required.

So is it the recommendation of the subcommittee that the rule be changed, and this requirement --

MEMBER EGGLI: No.

MEMBER WILLIAMSON: -- imposed on 35.200?

MEMBER EGGLI: No. Because the dosages administered greater than 30 microcuries require a

written directive. And so it doesn't really matter whether the dose ordered was under 30 microcuries, the technologists knew they were administering a dose greater than 30 microcuries. A written directive was required. So there is no change in regulation.

But, again, what we're talking about I think predominantly is a culture issue. And if the culture is such that you verify the written directive on any dose you are administering that you know is greater than 30 microcuries, then these errors, with the exception of the erroneous patient identification -- two errors -- nine out of the 11 errors would have been prevented, because all nine of those doses, whether they started that way, at the time of administration were greater than 30 microcuries and would have required a written directive which was not verified by the technologist.

So I don't think any regulation change is required. What is required is rigorous compliance with the existing regulation for administrations greater than 30 microcuries.

CHAIRMAN MALMUD: Dr. Miller.

DR. MILLER: Dr. Eggli, thank you. I think that that was a great presentation, and I guess what I'd like to do is offer some thoughts for the

committee to ponder in providing advice to the staff to try to see if we can get a dialogue going.

First, one of the things that the staff looks at when we review events ourselves are: is there a recurring theme? And, you know, are there enough of these events that something needs to be done? Okay. Many times what we do is we put out some generic communication to remind people of what they should be doing.

And I guess that's one thing I would ask the committee to consider. Were there enough instances here that the staff should consider some kind of generic communication?

Dr. Eggli, what did you say the period of --

MEMBER EGGLI: It was approximately a year and a half worth of data that we looked at.

DR. MILLER: About a year and a half, okay.

MEMBER EGGLI: So we're looking at 11 reported incidents over about a year and a half. But, again, nine of them had a common theme --

DR. MILLER: Right.

MEMBER EGGLI: -- of failing to review a written directive in a case where the dosage

administered was in a range that required a written directive. And I would think that reminding licensees that any dose that a technologist administered that is over 30 microcuries requires a written directive, with the advice that that directive should be reviewed prior to administration is potentially effective and certainly cost effective. It just simply reminds people of that obligation.

DR. MILLER: Okay. So that consideration in place, I mean, for the full committee to ponder. The second thing that caught my attention that I would be interested in your reaction to is, given the fact that most if not all of these fell on the shoulders of the technologist, is there something in technologist training that should be enhanced that would address this, or do you not see it as a training issue rather, you know, an individual lack of attention issue.

MEMBER EGGLI: As a working day nuclear medicine doc, I can tell you our techs are trained for this. It's usually the pressure of being busy, and there's always -- the rule is there is never time to do it right, but there's always time to do it again. You know, so the technologists sense -- artificially sense pressure to get things done, and they devise in their own workflow shortcuts that don't necessarily

comply with departmental policy.

And I think the issue to encourage is that the technologists need to feel free to communicate with the authorized user, and that they just have to stop and verify the written directive. They have to stop, and they have to find it.

But then, what they need is a workflow that makes it easy for them to find the written directive. I mean, I -- you know, I can't speak to what other -- all practices do, but typically when I write a written directive for a dose that's going -- dosage that's going to be administered today, I personally carry it back to the radiopharmacy and hand it to the technologist.

I don't think that that extreme is necessary, but the technologist has to feel free to go back to the authorized user and say either, "I don't have the written directive," or "I don't understand the written directive" or "there is a disconnect between the written directive and the dosage that I have in the hot lab ready to administer to the patient."

So the culture needs to be that the technologist feels free to ask questions. Or maybe in a more direct fashion, to challenge the authorized

user on the dosage ordered.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER EGGLI: In a couple of cases, the tech did the right thing without challenging the authorized user, and it became an incident, even though the right thing was done.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I agree completely on everything that has been said. Supporting your Will Rogers theme, I think human errors are common. They happen all the time. I don't think it would hurt -- you don't need a 10 percent error rate reported real or whatever. I think this is an ongoing thing. It's not unique to radioactive dosages. And I think to sort of remind people about this wouldn't hurt.

I don't know -- we're not there now. I wonder if we'll ever get to a culture where people consider reporting errors as part of doing business. You know, baseball players miss, you know, two-thirds of the time, and they accept that. Nobody is perfect. And when people make errors, reporting that information back is very important to identifying a trend and remediating it. But society just -- you don't want to admit that you made a mistake.

But how we change that is a different

issue. But I think communicating this I don't think would hurt. I don't think you need a higher number to support that. And this sort of thing happens with drugs across the board.

One thing, though, to encourage standard units. I think sometimes the millicurie/microcurie business, the becquerals, does cause confusion. You were saying 30 millicuries for therapeutic. I think that would be appropriate for I-131. But I wouldn't separate the two; maybe put a quantity so it would trigger, you know, the technologist that may not be aware of that.

But I pretty much agree. I think it's a nice presentation, and I think we don't need any more justification that, you know, this sort of thing happens. And, again, this is the cream of the crop. These are the self-reporters. Trust me, there are people out there who make mistakes, and they don't report them.

CHAIRMAN MALMUD: Dr. Vetter was next. Dr. Vetter.

MEMBER VETTER: A number of years ago, the NRC put out -- I think it was an information notice addressing this issue, saying that the primary cause was inattention to detail. And I think since then the

error rate has gone way down. Now, whether or not we can attribute it to that information notice, or a lot of other things, I'm not sure.

But I agree with Orhan. I think it would be appropriate to -- I don't know if it's information notice or how you communicate this, but I think it would be appropriate to focus in on this particular issue, the written directive and needing to pay attention to it -- attention to detail, review with the authorized user, etcetera, to get out to the nuclear medicine community, and then ask inspection and enforcement to ask the question when they are inspecting: did you receive this information notice, has it been reviewed with you, etcetera, to sort of focus on that.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Yes. We have a policy in our Department -- and I don't know whether it's like a state -- like the JCAHO, that we have a timeout for any procedure. That before any procedure is done using the HDR or gamma knife, there's a timeout, and the timeout includes identification of the patient by two methods and ensure that the procedure that is scheduled is the procedure that is given for that patient. Is that something we can incorporate here?

MEMBER EGGLI: Yes. That is a JCAHO regulation. Unfortunately, that does not drift down to the level of Part 200 or Part 300 uses of radioactive iodine.

MEMBER NAG: Yes. But, you know, if you have a rule for that, even if it's not there in Part 200 or Part 300, it's something your hospital has to do.

MEMBER EGGLI: And I think that our recommendation on these issues of both verifying the written directive and positively identifying the patient approaches that type of a timeout requirement for the -- that JCAHO requires for other procedures.

You know, it does a couple of things. It identifies the patient correctly. It makes sure that you're doing the right procedure on the right patient, and that everything you have is what you're supposed to have for that procedure. And I think the recommendations for positive patient identification and reviewing the written directive with the authorized user really meets the spirit of that timeout concept.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: Yes. I don't think recommendations to do this are necessary, because

35.41 requires both things. It's a requirement whenever more than 30 microcuries is given. I think the recommendation has to focus on the issues of attention to detail, being able to recognize when the unexpected occurs, when -- that may be another aspect, that it might not be willful negligence.

It might be that if you're expecting a very low dose case to occur, you're not necessarily neurologically receptive to evidence indicating the contrary possibility. That often happens.

MEMBER EGGLI: I think the issue here is not that we're recommending that there be any new rulemaking or any new policy. I think the recommendation is that people are reminded of their existing obligations under the regulation.

CHAIRMAN MALMUD: Mr. Essig.

MR. ESSIG: Yes. Two things. First, I wanted to respond to Dr. Vetter's observation about the use of information notices. And he's right, that we have done that in the past and that's normally the appropriate vehicle for calling attention to the licensee community of this -- these types of events.

And we also have the additional mechanism of the NMSS quarterly newsletter for licensees. And so depending on the nature of the event, we could put

it in either or both of those.

And then, I wanted to address Dr. Eggli, if I might. The events that were of particular interest to me that you reviewed were those where -- that were intended to be or thought to be diagnostic and ended up being therapeutic.

MEMBER EGGLI: Right.

MR. ESSIG: And it seems to me that a simple reinforcement of the use of a dose calibrator could have at least put up the red flag that you said was -- should have been apparent. But if someone doesn't verify that they, in fact, are confronted with a therapeutic dose, and they believe they actually have a diagnostic, and they just blindly follow what the piece of paper says, then it seems like those kind of things could be maybe not entirely prevented, but at least an awareness that the technician would have.

MEMBER EGGLI: I personally wouldn't run a clinic without a dose calibrator, but there are a lot of places who unit dose out of central pharmacies who do not have a dose calibrator. I think the dose calibrator serves as an extra reminder to the patient -- or to the clinic. However, there is no evidence in NMED that these doses were not properly labeled, so there should have been no problem for the

administering individual to know how much radioactivity they were actually administering.

Sally has been waiting for a long time to make a comment.

CHAIRMAN MALMUD: Yes. Dr. Schwarz.

DR. SCHWARZ: I just wanted to make a comment in regard to administration within our Department, something that doesn't have to be done but that we do, is once the physician writes the written directive, and then the dose is assayed in the dose calibrator, it is written on the lower part of the prescription, and then the physician, who is then responsible to administer the dose -- actually, he doesn't give it, but he comes in and sees the dose and dose calibrator, signs off a second time on that dose, and then it's administered by the technologist to the patient.

So it's kind of a confirmation, of course none of which is required in the regulation, but it is certainly the verification with the dose calibrator and the second check by the physician who has written the directive. And even if we wouldn't have a directive, we're always measuring the doses as you're mentioning that. So if it is a diagnostic dose, and a therapeutic dose is received, again, it's noticed

with that dose calibrator.

But that second measurement on the written directive, the second signature that we ask for, really is a help, because it does confirm that in fact what they wrote for is what they are getting in the dose calibrator.

CHAIRMAN MALMUD: Dr. Howe.

DR. HOWE: I think it might help if you look at our regulations. And Jeff is right, we do have current regulations in place for the greater than 30 microcurie requirements for written directives. But perhaps the focus needs to shift to 35.27, which is supervision. And I think in my mind many of these that were supposed to be diagnostic, they were given therapeutic.

I think the individuals were probably thinking diagnostic, and the red flag that should have been there, that should have said, "Oh, I need a written directive," maybe they don't handle many written directives. So that red flag wasn't really there. So maybe it is a focus on ensuring that under supervision, even if you don't give many written directives, all of the personnel are aware of and trained on the fact that there should be a written directive greater than 30 microcuries. So that red

flag does become a red flag.

MEMBER EGGLI: And I think that's the issue of the culture of following the regulation. And if it -- in truth, it is at the leadership level in the Department. If that's not enforced from top down, it doesn't happen. The culture has to -- it has to be there, that you do this every time. And even if you only do it infrequently, it has to be reinforced. Particularly if you do it infrequently, it has to be reinforced with your annual technologist retraining or whatever your frequency is, that there are some things you have to do.

And so I think it is -- it's a top-down culture issue. If it isn't enforced from the leadership of the Department, that the technologists don't take it seriously.

CHAIRMAN MALMUD: Mr. Bailey.

MEMBER BAILEY: On the analysis, you turned up with most of them, the vast majority of them being a technologist problem. And yet Part 35 is totally silent with regard to technologists. And I think back when Part 35 was being put in place, with the RSO qualifications and the medical physicists, the agreement states in particular were concerned that there was no addressing of technologists, not even

saying what the minimal training of a technologist had to be, much less saying they had to be certified.

I think that's something that needs to be reexamined at some point. I would like to have seen in the analysis whether or not -- the training level of the technologist. Were they a certified nuclear medicine technologist? Were they licensed by the state in which they were operating? And so forth.

MEMBER EGGLI: And that data is not available.

MEMBER BAILEY: Right. But I think that's something that, you know, we ought to start looking at if, in fact, it is really the technologists' fault, if you want to put it that way, that these things occurred.

Now, I would play devil's advocate a bit and say that there had -- if there was a culture there that said, "Hey, you see this, you go question the nuclear medicine doctor," we might have seen some different results. There was mention of putting out an information notice, and another piece of information that would have been interesting to have from my perspective was, how many of these 11 occurred in agreement states, and how many in non-agreement states? Because an information notice in effect only

reaches 20 percent of the licensees in the United States. They are not mailed to agreement state licensees routinely.

So I think if we're having the problems in the agreement states, then we need to look at it and focus on it. On the other hand, if it's, you know, going to be addressed by an information notice, then we need to make sure that everybody gets a copy of it.

I would say that one thing that we have required in California for years other than having state licensed nuclear med techs is that on the administration of therapeutic doses the physician has to be physically present in the room when the dose is administered. And in my however many years in California, the only two cases I can remember of a therapeutic misadministration occurred when the physician was not physically present.

CHAIRMAN MALMUD: Thank you, Mr. Bailey.

This is Malmud speaking as a member of the committee. I have a couple of questions which will precede my statement. Number one, how often is I-131 used today in quantities of less than 30 microcuries? And what is it used for?

MEMBER EGGLI: In my practice, it's used for measuring iodine uptake by the thyroid gland. We

do seven to ten a week.

CHAIRMAN MALMUD: How many microcuries do you use for uptakes?

MEMBER EGGLI: Seven to ten.

CHAIRMAN MALMUD: Okay. You've answered that question. It occurs to me that the additional training of technologists is always valuable, but it won't be the solution, because the most frequent errors that occur in the United States, according to the literature that's produced, are medication errors which are distributed by RNs who are well trained and retrained periodically, so that these kinds of errors will occur. They are human errors.

The issue of the written directives is an important one. The reason I question the number of times that one uses I-131 is that we don't use it at all for uptakes at our institution. We use I-123 now. And I was wondering whether a written directive might be appropriate for the use of I-131, period. That would lead to a less thoughtful consideration of whether or not a written directive was required, because a written directive would be required for each use of I-131 for diagnostic or therapeutic purposes.

But that would be burdensome to a Department such as yours which is still using I-131

for uptakes, I assume.

MEMBER EGGLI: Actually, our Department is unique. We do a written directive on every radiopharmaceutical ordered, whether it's a Part 200 or a Part 300 use. So it would pose no additional burden. It's just that for us it's a different form, but not -- but for Departments who don't use written directives for Part 200 uses, it would probably be seen as burdensome.

CHAIRMAN MALMUD: So that it would not be an additional burden, in your particular situation.

MEMBER EGGLI: No, it would not.

CHAIRMAN MALMUD: Because you already are using written directives for all diagnostic and therapeutic doses.

MEMBER EGGLI: For every dose that comes out of the radiopharmacy.

CHAIRMAN MALMUD: Do you also require that the patient have identification, such as a bracelet, which is done at the time of registration?

MEMBER EGGLI: Not for outpatients. We use the JCAHO requirement for using two pieces of information to identify.

CHAIRMAN MALMUD: We've gone to using the bracelet even for outpatients, and the reason is that

we have a multilingual patient population. And often asking if the patient is who we think it is, the patient says yes, comes in, only for us to discover it is not the patient that we thought that it was. And we check this in two ways -- by asking for the patient's name, which often gets a positive response whether or not the name is correct, and then check the patient's birthday, and that often results in the patient saying, "No, that's not my birthday."

MEMBER EGGLI: What we do -- we don't allow the technologist to offer a name to the patient. The patient has to state their full name, which is slightly different. You can't have the error of a patient misunderstanding and saying, "Yes, that's my name," when you ask the patient, "Please tell me your full name."

CHAIRMAN MALMUD: The third issue that was mentioned, of course, is the issue of the dose calibrator. I can't imagine running the Department without a dose calibrator. We have gone to unit doses a long time ago, but we still check them with a dose calibrator. Since we are the final individual who hands the dose to the patient, we feel it's our responsibility whether or not a certified nuclear pharmacy has previously calibrated the material or

not.

MEMBER EGGLI: And I agree with you, because if I get a bad dose from my central radiopharmacy, I still do the paperwork. I have to explain to the patient and the referring physician that an incorrect dosage was administered, so I would not personally practice without a dose calibrator. But there are a lot of -- there are a lot of practices who, in fact, just do not use them.

CHAIRMAN MALMUD: Dr. Suleiman.

MEMBER SULEIMAN: I have a question. What's the uncertainty in dose delivery, in terms of the dose calibration, how much of the drug actually gets into the patient. What are we talking about, five percent, 20 percent? Is there a number out there? Does anybody know?

MEMBER EGGLI: For a lot of the radiopharmaceuticals, it depends on how long it sits in the syringe before administration and how much of the dose sticks to the plastic of the syringe. But in general, if you rinse the syringe well, you get -- and the dose is freshly prepared, you get virtually all of it into the patient.

CHAIRMAN MALMUD: But if I may, the other answer to your question is, after we give a

therapeutic dose, we measure the syringe again in the well, in the scintillation counter, to see how much of the activity remains in the syringe.

MEMBER EGGLI: And we do that with diagnostic doses as well.

DR. SCHWARZ: Sally Schwarz. I think if you don't flush the syringe, you still get about three percent left in the syringe, unless it has been sitting maybe possibly -- there are those that are greater, but on average probably three or four.

CHAIRMAN MALMUD: Okay. Aside from those errors, what about the accuracy of the dose calibrators themselves? I understand that these -- they are not as calibrated for the different radionuclides as one would expect. A lot of them are calibrated using cesium.

DR. SCHWARZ: Well, I think the dose calibrator is very accurate at measurement of doses for all of the radiopharmaceuticals that we routinely use, yes.

MEMBER EGGLI: I think the reliability of the dose calibrator is far greater than 10 percent.

CHAIRMAN MALMUD: So you have given us a lot to think about, Doug.

MEMBER EGGLI: Ralph has a comment.

CHAIRMAN MALMUD: I'm sorry?

MEMBER EGGLI: Ralph has a comment.

CHAIRMAN MALMUD: Ralph. Excuse me.

MEMBER LIETO: Actually, I'm going to answer a question you asked some time ago about uses of I-131 over 30 mics. We do a lot of cancer ablations at our facility, so we routinely do a lot of the three to five millicurie whole body studies. So, and I would say there is probably at least three to five of those a week that we do. So it's a fairly common procedure for those types of activities.

CHAIRMAN MALMUD: Thank you.

My question had been about doses of 30 microcuries or less, because I was wondering whether, given the availability of I-123, if I-131 was being used very much any longer in doses of 30 microcuries or less. And if it had not been continued to be used, then perhaps we should just have a blanket rule for I-131, which would be a less challenging rule for those to interpret who dispense I-131. But it's still being used for uptakes in small doses, and, therefore, that would be burdensome, except in a Department such as Dr. Eggli's, where he is using written directives routinely anyway.

I was just trying to think of how we could

simplify this for those who are dispensing the pharmaceutical.

So, in conclusion, then, what are your -- what is the recommendation?

MEMBER EGGLI: Again, I think the recommendation is to remind the licensees that they have an obligation under the current regulations to verify any dose of greater than 30 microcuries against a written directive, and strongly recommend an effective positive approach to identify patients. And then, thirdly, to encourage free communication between the authorized user and the administering technologist.

CHAIRMAN MALMUD: Thank you, Dr. Eggli.

Dr. Williamson?

MEMBER WILLIAMSON: I would suggest adding to this, if we're making up a motion, that there be a reminder, even in the diagnostic cases, to be aware of the possibility of erroneous delivery of a larger dose, and to examine the label before administering to ensure that it's less than 30 microcuries.

CHAIRMAN MALMUD: I'm not sure whose arm it was. Mr. Lieto.

MEMBER EGGLI: Mine is over here.

(Laughter.)

CHAIRMAN MALMUD: We had this problem yesterday. I kept moving your extremities from one person to another. Ralph?

MEMBER LIETO: I would like to see that the recommendations -- that the committee make a recommendation that the subcommittee's recommendations be put into an informational mechanism to be decided by NMSS staff as to which is the best, whether it's the information notice or the newsletter or both. Or possibly a third is to incorporate some of these into the NUREGs which are guidance for licensees, and proceed from there.

MEMBER EGGLI: Could I make a suggestion on that distribution as well? Mr. Bailey's point that direct NRC mailings get a small portion of the technology group, one of the other approaches might be to actually send the information letter to the two main certifying boards for technologists -- AART and CNMT -- and ask them to distribute this information to their memberships along with their newsletters.

CHAIRMAN MALMUD: Thank you. That's a good idea.

Dr. Miller.

DR. MILLER: I have a question for Mr. Bailey. Ed, when we put out information notices,

don't copies go to the agreement states? So the agreement state regulator does get a copy to do with as they choose, right? Donna-Beth is waving her head yes.

MEMBER BAILEY: I was going to answer if you want me to.

CHAIRMAN MALMUD: You're on.

DR. MILLER: I do.

MEMBER BAILEY: Yes. We get -- I would say we get at least one copy --

DR. MILLER: Okay.

MEMBER BAILEY: -- because there are several different mailing lists. What happens from that point on, though, is very variable.

DR. MILLER: Depending on the state.

MEMBER BAILEY: Okay. First of all, if you're talking about the newsletter, it's four pages long generally, you hit it like this and pass it on to somebody who passes it on. An example -- my notebook. Came into the office, it was passed on to someone who passed it on to the head of licensing, who passed it to a medical licensing guy. So it took me about two days to find it.

There is not a set routine, particularly in a large state program.

DR. MILLER: Okay.

MEMBER BAILEY: But I think the -- there does need to be some better way of communicating these generic type issues to the agreement state licensees, and I don't know how that's going to occur, really, unless we have a national database of licensees.

DR. MILLER: Right. But I do think the suggestion about having copies go to the boards is a good one. That would be an enhancement at least to get it in the boards.

MEMBER BAILEY: Yes, that seems to be a very effective way of getting the word out, assuming that the majority of technologists are certified by one or more of those bodies.

MEMBER EGGLI: I think the reality is that the vast majority of technologists are certified by one of those two bodies. In most hospital-based practices, again, to be JCAHO-compliant, the technologists are certified. The outpatient freestanding clinics -- still the vast majority of those technologists, at least in our area, although Pennsylvania has no licensure for technologists, most -- virtually all of the technologists are certified by one of those two boards.

DR. MILLER: Okay.

CHAIRMAN MALMUD: Thank you again.

If we may, we'll move on to the next item on the agenda, which is the status of -- which is Mr. Essig.

MR. ESSIG: Was there an item that hasn't been finished? Had Ralph made a motion that -- a general recommendation? Okay.

CHAIRMAN MALMUD: The committee supports the recommendation. Did you want an actual formal motion? Is it required?

MR. ESSIG: I don't know that it's necessarily required. I wasn't sure if it was just a recommendation or a motion.

CHAIRMAN MALMUD: All right. Dr. Eggli, would you like this to be in the form of a motion?

MEMBER EGGLI: I think that that would probably be useful, to put it in the record and it makes it an action item if it's --

CHAIRMAN MALMUD: Thank you, Mr. Essig, for bringing that to our attention.

So the motion has been made by Mr. Lieto. Is there a second to the recommendation?

MEMBER WILLIAMSON: Second.

CHAIRMAN MALMUD: Dr. Williamson. Any further discussion?

(No response.)

All in favor?

(Chorus of ayes.)

Any opposed?

(No response.)

Any abstentions?

(No response.)

It's unanimous. Thank you very much.

Mr. Essig.

MR. ESSIG: One other point, if I may. I know Dr. Howe is at the podium, and we're about ready to begin her presentation, which was originally well over an hour. She has slides in the notebook, and we've condensed it down to 15 minutes. And I would offer that we could go ahead with that as planned -- in other words, the 15-minute presentation.

The thing that we have to be sure to do, and that is to allow the one hour that we've allocated for Mr. Lieto. And I notice that we have an error on the agenda. It's not Dr. Howe that's going to present it, it's Mr. Lieto that -- from 9:00 until 10:00. And we have to be sure to get that done out of fairness to Mr. Lieto and to allow the committee to provide any input that they may have.

So we can either go ahead with the

presentation, keeping it to 15 minutes if at all possible, then go on to the session where we review Ralph's slides, or we can just not do the 15-minute presentation, recognizing that there are some detailed slides in the notebook. So I would just offer that as a timesaver, if -- whatever the committee would prefer.

CHAIRMAN MALMUD: We'll move ahead with Dr. Howe, if you're ready, for 15 minutes, and we will -- we appreciate your having concentrated so much material into a briefer presentation.

MR. ESSIG: And, I'm sorry, I misspoke. The 9:00 to 10:00 was what I remembered I had written down yesterday. And, actually, Ralph's session is at 10:15, and I just wanted to make sure that we did that. So --

CHAIRMAN MALMUD: Thank you.

DR. HOWE: What I did was I took a look for half a year. Normally, I give a presentation in October for the complete fiscal year, and so what I've done is I've used the first half of a year. I have given you printouts of the NMED reports for all of the reportable medical events, and some of the other reportable events, but not necessarily medical events, behind that.

I have organized them by regulation, so you have the 200 events together, the 300, the 400, the 600, so that they should be easy for you to review and identify any common factors.

I'm going to give just a summary presentation. One of the -- so far we've had 12 medical events in the first half of the year, and I've given a breakdown of where they are. You'll see that we don't have any 200 events, so at this particular point we aren't having diagnostic I-131 and therapeutic doses delivered.

300 are two iodine-131 events. In both cases multiple capsules were intended, and the total number of capsules administered to the patient were less than those that were sent by the pharmacy, and 35.400 -- we've had gynecological ones in addition to prostate cancer, and in 600 most of ours are HDR units. We've also had a yttrium 90 microsphere medical event.

One of the things that we looked at last time was to see if there was a problem with delay in reporting medical events. I'm pleased to -- last time we had events that were not reported for up to about two years, and those were things that were identified during inspection, and the licensee had to go back and

find other cases.

We aren't seeing the same length of time, but we're still having events, especially in the two months and the four months, that are identified at inspection but not by the licensee themselves. And a number of the events coming out at these later dates are where we have asked the licensee to go back and review their records to see if there weren't other medical events that weren't reported.

For 35.300, we had essentially one capsule left in the vial. It's the root cause for both of the events, and one of the factors is that at least in one of them they didn't identify that the capsule was left in the vial until seven to ten days later. And it -- you would think that if they were measuring and checking the vials and checking things before they put them into waste, that they would have identified this much earlier on.

In our brachytherapy medical events, we've had five of them. Three of them were gynecological events. You'll only see that I have causes for two. The third one was fairly recently reported and very sketchy, so I don't have full information on that. In one case, they selected the wrong seed activity to put into a tandem, and they gave an overdose in that case.

In another case, which we ended up with several medical events -- and I think this is the one that I don't have a lot of information on also. The licensee had different size sources from buckets, and they were not checking to make sure that the sources were compatible with the buckets, so the sources weren't going in the bucket and they were giving treatment to the wrong location.

In the prostate, we had a broken source. In this case, the source was identified. It was a mic applicator. The applicator was jamming. They recognized that one of the sources was broken. They lost more sources when they tried to remove some of the sources from the applicator. They did not end up with an I-125 exposure to the patient, because they did not give the broken source to the patient. So they avoided that error.

And in another case, we saw where the licensee ordered the activity of prostate sources in air kerma, and what the manufacturer delivered was in millicuries. And it wasn't until a day or two afterwards that the licensee recognized that they had used the wrong activity sources.

For HDR, we had four events. In one case, the licensee should have calculated the dose to two

centimeters. Instead, they did it to one centimeter, so the patient received half the dose they were supposed to get. There was another unspecified error. I'm not sure what happened there.

We did have two lung cases, one in which the catheter moved between the positioning and the actual delivery. In the other, there was not a cap at the end of the catheter, and so the source was not delivered to the location that it was supposed to be at. So we don't normally see a lot of lung cases, but we did see two this time.

Dr. Nag.

MEMBER NAG: Yes. The lung catheter moving, that is a -- that's something that's done by the patient. And from what I remember, if there is a movement that you -- an intentional act of the patient, that's not supposed to be a misadministration.

DR. HOWE: Patient movement is not necessarily misadministration. In this case, the tape became loosened. It wasn't the patient doing anything. It was that the tape was loose. And when they came out to observe, to remove the -- to take the catheter out, they realized the catheter was out further from the nose than it was supposed to be.

So patient movement in itself is not patient intervention. You have to be careful on that.

Yttrium-90 microspheres -- in this case we had a nuclear medicine physician who was delivering the dose, believed that the administration had gone in, and after the administration was over realized there was still liquid in the V-vial. Ended up 45 percent of the dose was still in the V-vial. There was also leakage I believe around the catheter going into the patient, so there was some leakage at that point, too.

So we had multiple points with problems, but the patient only received probably about 50 percent of the dose, somewhere between 60 and 50 percent of the dose. And so there are difficulties in delivering these microspheres to the patient, and it is -- it's not a trivial exercise to get them in. And there is also beads that get stuck up in the stock cocks.

Now, we had other reportable events. These would have been reported under Part 30 or Part 21. And in this case, we had a cesium-131 source that was identified at delivery that there was -- they saw that the source was not in the container. The source had been damaged; there was contamination at

the licensee's facility.

I think this particular event points out the importance of doing your surveys when radioactive materials come in, and in this particular case the physicist didn't wear gloves, contaminated himself, and there was also an assistant technologist that also got some hand contamination. So in this particular case the licensee did not have good procedures on bringing incoming packages, and you never know when there's going to be a problem. So it's kind of a -- yes, Jeff.

MEMBER WILLIAMSON: What form is the cesium-131?

DR. HOWE: It's in a sealed source for brachytherapy.

MEMBER WILLIAMSON: What chemical form?

DR. HOWE: I don't think I know that. But I do know that they had contamination, so it was in a readily spreadable form.

MEMBER NAG: I think the new cesium source for prostate implant.

DR. HOWE: Yes. And we had an I-131 in which we had the -- no written directive, but four millicuries was given to the patient. It ended up that that was what the patient should have gotten, but

the physician did not write a written directive. So this is kind of in a similar thing as to what Dr. Eggli looked at.

It's not a medical event, because we currently have a loophole in the regulations that if there should have been a written directive, but there was no written directive, and material was given that required a written directive, it's not a reportable event. And we'll be talking about that in my next talk.

We had a prostate therapy, administration with strands, and we've had a similar one at the same facility a couple of years ago, and it's not a medical event because the physician revised the written directive prior to completion. Since it's a permanent implant, they could revise the written directive any time, so he changed the written directive from 90 seeds to 45 seeds.

But we also found out something new in this case. And the reason they were so few seeds that were implanted is because they were using strands. And when they identify one of the sources going into the bladder, they remove the entire strand. So instead of removing one or two seeds, if you weren't using a strand system, because that one or two seeds

got into the bladder, then the whole strand comes out, and so the total number of seeds that are being implanted is drastically reduced. And this was a case that we saw earlier.

And I'm not sure we were aware of the fact that that is one of the consequences for strand use, if they're not positioned properly. So I thought that was an important piece of information.

We also had an HDR equipment failure in which they tried to give an HDR procedure. The equipment indicated a failure. They were able to get the source back. They went to give another treatment. The treatment was given correctly, but when they went to get the source back they still had additional problems with error messages.

They finally called the manufacturer. The manufacturer corrected the problem, and then realized there was another problem. And they sent it back to the factory for further evaluation and found that there was a problem in the original manufacture of this particular device.

So I think one reason I'm presenting this kind of information is because we focus on reportable medical events. These are our precursor issues where the patient wasn't involved, but they have equally

important things for us to think about and keep in mind when we're looking at medical regulation and sealed sources and devices and other considerations.

So that concludes my presentation. Dr. Vetter?

CHAIRMAN MALMUD: Thank you, Dr. Howe.

Dr. Vetter?

MEMBER VETTER: Thank you. Excellent report. I think your report reflects -- or one of the problems that you have in collecting the data and analyzing it reflects the same problem that Dr. Eggli's subcommittee did, and that is that the NMED database doesn't always contain enough information to really get at what's going on.

And I don't know -- for instance, a number of these say corrective actions taken by licensee include modifying the procedures, or something of that sort. That doesn't tell us anything. It may be that what they did was very good and very appropriate, but we can't tell from the database.

I'm wondering -- I have two questions. The first one is, I'm wondering whether or not NRC can't do something to get that database cranked up in terms of the level of information that's in there that would help us to analyze what really is happening in

these instances. And I don't know that you can answer that, but that's a concern I have, because Dr. Eggli's subcommittee had the same problem. We just can't quite get to the information that we need.

DR. HOWE: Well, one of the things that I've had the NMED people do is develop a new report format, and you see it in your books. And if you'll notice at the bottom you have reference documents. If there's something that is of particular interest, we can go back and retrieve those reference documents, which may give us additional information.

For the agreement state reports, there is not a lot of information there. It's generally normally a sentence that says that this is a reported event. But we can also for things that are of great interest to the committee, or -- we could also go back to the licensee and try to get additional information.

And I think maybe one of the things that I'm doing is presenting you with an overview, kind of a quick summary. And if there are areas that you would like to pursue further, then we can try to get additional information, because we do have access.

MEMBER VETTER: That may be the answer to my second question as well, and that is that the root cause really isn't presented here. For instance, on

the item capsules, a capsule being left behind is not the root cause; that's the error. So what is it that they did or didn't do that caused them to miss the fact that they didn't give all the capsules to the patient?

And maybe it's in those supporting documents. I don't know.

Thank you.

DR. HOWE: I know one description of the I-131 was that they gave the patient the vial, and the patient tipped the vial up and took the pills, but yet one was still in the vial, so it must have stuck to the vial. But there also didn't appear to be any routine for them to check the vials afterwards to see if there was anything left in them.

MEMBER VETTER: Right. I mean, that was -- is more like the root cause. They need to fix their procedure, so that they can check. And after it's administered, make sure it has all been administered.

DR. HOWE: Dr. Nag?

MEMBER NAG: Yes. I have a feeling that what we see in the NMED report is that initial report. And, you know, after you have the initial report, after maybe 30 days or whatever -- whenever the

investigation is done, and then you have the full report. So what you're seeing is the initial report done by the licensee, which really didn't identify everything. But usually when the case is closed, you know, there is a full report. So is there any way of getting the final report rather than the initial report?

DR. HOWE: I think it also may be a little early on. The six-month one that -- there isn't enough time to complete the entire inspection. If it's a reactive inspection, to complete all of the written reports. So it may be a little early on this one, but we should be able to go back and get a final report from -- and that should be in the reference sections. So we can -- we can try to make sure that we do get final reports.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

May we move on? If so, you're on again.

DR. HOWE: Now, the next presentation is going to be about potential changes to Part 35 or Part 32 that we'd like to bring before the ACMUI to get your recommendation on whether it would be a good potential change or not. This does not mean that we will have rulemaking anytime in the near future.

So I have a long laundry list of things to

go. Some of them are very simple, very short. Some of them are going to be a little bit more complicated. And we're not really looking for exact rule text, just to explain the issue and what we think might be a possible change. If it does go to rulemaking, then you will see these in more detail at some later point.

Okay. And what I've done is I've ordered these in terms of the regulation, so I've just gone pretty much in numerical sequence. There will be a little bit of out-of-sequence information if things are grouped together.

The first issue was essentially I think an oversight. When we revised Part 35 in April of 2005, there was not an attempt to go back and bring 32.72, which is the authorized nuclear pharmacist requirements for the commercial nuclear pharmacy, up to date with the authorized nuclear pharmacy requirements in Part 35. In this case, it's a notification issue.

Now, if you're board certified, you have to, in 35, present the attestation in addition to the board certification, and we need to revise 32.72 so that that attestation is also provided when the commercial nuclear pharmacy notifies the NRC that they have now put a pharmacist in.

CHAIRMAN MALMUD: Does anyone wish to make that a motion? Dr. Schwarz.

DR. SCHWARZ: I would move that it is recommended that the pharmacist present the attestation at the same time that they present their board certification to the Commission.

CHAIRMAN MALMUD: Thank you, Dr. Schwarz. Is there a second to the recommendation?

MEMBER LIETO: Second.

CHAIRMAN MALMUD: It has been seconded. All in -- any discussion?

(No response.)

All in favor?

(Chorus of ayes.)

Any opposed?

(No response.)

Any abstentions?

(No response.)

It carries unanimously. Oh. Dr. Williamson?

MEMBER WILLIAMSON: Sorry. I was not physically present to hear the motion.

CHAIRMAN MALMUD: Oh, you're abstaining?

MEMBER WILLIAMSON: Yes.

CHAIRMAN MALMUD: Thank you. For the

record, Dr. Williamson abstains because he was absent when the motion was discussed. Otherwise, there was unanimity.

Thank you.

Dr. Howe?

DR. HOWE: Okay. The next one is in the definitions of 35.2, and you'll find this is another theme in here. It's the greater than or equal to, and whether we have an equal sign. We have defined a medium dose rate after loader in relationship to 12 gray, and the high dose rate, but in neither case do we have one of them equal to 12 gray. And so we're recommending that we add the equal to for the medium dose rate remote after loader.

CHAIRMAN MALMUD: Would someone care to make that a motion?

MEMBER WILLIAMSON: So moved.

CHAIRMAN MALMUD: We have a motion. Let's second the motion, if someone would.

MEMBER VETTER: Second.

CHAIRMAN MALMUD: Dr. Vetter seconds the motion. Now it's open for discussion. Dr. Nag.

MEMBER NAG: Sure. Just a practical problem. I know that the ICIU defines medium dose rate as greater than two, but less than or equal to 12

gray per hour. However, when you are doing high dose rate or medium dose rate brachytherapy, it's difficult to say exactly what the dose rate is, because the dose rate will depend on the distance you are prescribing.

So for all practical purposes, most dose rate for high dose rate show high, well beyond 12 gray per hour, so practically it doesn't matter. But for the medium dose rate, that can be very tricky, because, you know, you are trying to stay equal to or less than 12 gray per hour when if you prescribe it half -- it can be in the order of, you know, two or three times more or less.

So that's a practical problem there. But for the definition, I have no problem looking at greater than two and less than or equal to 12. But that is for definition's sake. But for practical point of view, I think it's very difficult.

CHAIRMAN MALMUD: Thank you, Dr. Nag. So you're in agreement with the motion, but explaining why you are concerned about it.

MEMBER NAG: Yes.

CHAIRMAN MALMUD: Thank you.

Mr. Bailey.

MEMBER BAILEY: I would like to offer just a friendly amendment that after the two gray,

parentheses 200 rads, that "per hour" be added.

CHAIRMAN MALMUD: Yes, I understand what you're saying. For consistency --

DR. HOWE: Yes, that should have "per hour."

CHAIRMAN MALMUD: -- that the two words "per hour" be inserted.

DR. HOWE: That's a typo.

CHAIRMAN MALMUD: Dr. Howe indicates that's a typographical error. And will the motion and the seconder to the motion accept the typographical error correction?

MEMBER WILLIAMSON: Yes.

MEMBER VETTER: Yes.

CHAIRMAN MALMUD: Any further discussion of the issue?

(No response.)

All in favor?

(Chorus of ayes.)

Any opposed?

(No response.)

Any abstentions?

(No response.)

It carries unanimously. Thank you, Dr. Howe. Move on. You're two for two so far.

DR. HOWE: Okay. This is one of a clarification. In 35.12(d), which is emerging technologies, licensees are required to meet the requirements in 35.12(b) and (c), and (b) and (c) talk about submitting applications using a Form 313, and also providing -- and it goes into providing the training and experience in the site diagram, etcetera, in (b).

But when you go to (c), it just says you can also submit the information -- you can submit a letter. So it does not make it clear that you need to -- if you're applying for a new amendment to use an emergent technology that you need to submit essentially the same information whether you use a 313(a) form or you use a letter format. And so this would be to clarify that the same information is needed regardless of the format that you use.

CHAIRMAN MALMUD: Is there a motion?

MEMBER EGGLI: So moved.

CHAIRMAN MALMUD: Is there a second to the motion?

MEMBER VETTER: Second.

CHAIRMAN MALMUD: The motion has been moved and seconded. Any further discussion?

MEMBER VETTER: Yes. I'm not real clear.

I mean, it seems like such a minor thing, but if you think it's necessary, then I would support it.

DR. HOWE: It just clarifies that the -- the minimum information needed.

CHAIRMAN MALMUD: Dr. Miller.

DR. MILLER: If you will permit me, Mr. Chairman, I would like to ask a question of my staff.

(Laughter.)

CHAIRMAN MALMUD: Please do.

DR. MILLER: Donna-Beth, is this of the nature that we can't handle this through guidance, that it would require a regulation change?

DR. HOWE: It would, because if you're submitting a letter, then they will go back and say, "Well, I don't need to provide the information that is clearly delineated up in (b)." We can also talk about if we ever do get to rulemaking, it can be thoroughly vetted and discussed then, too.

DR. MILLER: Okay.

DR. HOWE: Ralph?

CHAIRMAN MALMUD: We have a motion, moved and seconded. All in favor?

(Chorus of ayes.)

Any opposed?

(No response.)

It's unanimous again, Dr. Howe.

DR. HOWE: No, I'm not sure it's unanimous. There are hands being raised.

CHAIRMAN MALMUD: I didn't see the hand.

DR. HOWE: Ralph has been raising his hand.

CHAIRMAN MALMUD: Ralph? All right.

MEMBER LIETO: I am still unclear as to what we're trying to fix here. And when you're -- is it the form of what -- that the information has to be submitted on? Or would --

DR. HOWE: No, it's the content of the information. When you look at 35.12(b), it says you use Form 313, and you provide the following information. And it makes it clear, some key pieces of information that are needed. When you go to 35.12(c), it says that when you're submitting an application for an amendment or a renewal you can use a letter, and it doesn't really address the information that may be required for the emerging technology.

And so we're just making it clear that the information that is needed for the emerging technology is needed whether you submit a 313 or you submit, at time of renewal or amendment, a letter.

CHAIRMAN MALMUD: Does that answer your question, Mr. Lieto?

MEMBER LIETO: I guess I don't see what the difference is there, but I guess if -- I'm assuming that this has created a problem with the regions in terms of what's being submitted.

DR. HOWE: Yes, and developing the guidance.

MEMBER LIETO: All right.

DR. HOWE: And keep in mind that we are not making these rule changes at this point. If we get an opportunity, when they rise up to a level to go to rulemaking, you will see this more extensively.

CHAIRMAN MALMUD: Mr. Bailey, do you want to comment?

MEMBER BAILEY: Yes. Doesn't the same problem exist if you use the application form?

DR. HOWE: No, because you have the additional text in there that indicates the information that's provided.

MEMBER BAILEY: But --

DR. HOWE: But you don't have that text in (c).

MEMBER BAILEY: But to me, it's just one of them saying "submit this form or submit the

letter." Neither one of those statements says "and submitting procedure dah, dah, dah, dah."

DR. HOWE: You include the training and experience up in (b), and you've got the site diagram and you've got the equipment I think up in (b) also. I don't have my regulations in front of me right now.

MEMBER BAILEY: That's what I'm looking at. (b) says file the original and one copy of 313 and submitting procedures required, so and so. (c) says request an amendment, submitting an original and one copy of Form 313 or a letter. So it would seem that if the letter lacks the specificity of requiring those additional things, then so does the Form 313, because 313 and procedures are not the same as --

DR. HOWE: If you look at (b), it says an application for a license is made by filing the original and one copy of 313(a). That includes and it's that text --

MEMBER BAILEY: No.

DR. HOWE: -- that that includes that --

MEMBER BAILEY: No.

DR. HOWE: -- I'm trying to make sure is clear is also needed when you submit a letter.

MEMBER BAILEY: But I agree that if you

take (1) and (2), if you take (b), you've got both of them included. You've got procedures and you've got the form. But when you go to (c), it doesn't say the form and the procedures. It says the form or a letter. So both of them --

DR. HOWE: The problem is that the letter does not necessarily include the information that's in the text up in (b)(1) and (b)(2).

MEMBER WILLIAMSON: I believe Mr. Bailey is correct that I don't see that there's any implication that it -- if you want to do Part C, any of the requirements in Part B apply to Part C. There is no requirement that says you have to put all of that information in the Form 313. So I think you should take the whole thing back to your General Counsel and come up with a better fix.

DR. HOWE: You know, my point is a fix a needed. That may not be the best fix, but a fix is needed.

Dr. Malmud.

CHAIRMAN MALMUD: The motion has passed.

DR. HOWE: Did we have a record of how many were for and how many were against?

MEMBER WILLIAMSON: I retract my pass.

CHAIRMAN MALMUD: Ralph?

MEMBER LIETO: I guess there wasn't really any discussion on it. I mean, it was basically the motion was made and then the vote, because my hand was raised from the get-go. So, and I'm only the one that had a -- you know, an opportunity to discuss this. And I think ever since I started there has been more objection.

So I guess, how can you vote before you've had the discussion? As a point of Roberts Rules or whatever, the parliamentarian.

CHAIRMAN MALMUD: Was it your motion, Ralph?

MEMBER EGGLI: It was actually my motion.

CHAIRMAN MALMUD: Oh, it's that arm again.

MEMBER EGGLI: Yes.

(Laughter.)

CHAIRMAN MALMUD: Dr. Eggli, it was your motion. Do you care to withdraw the motion?

MEMBER EGGLI: Given the discussion, I'll withdraw it.

CHAIRMAN MALMUD: Thank you. Who seconded your motion?

MEMBER EGGLI: I have no idea.

MEMBER WILLIAMSON: I believe I did, and I agree with --

(Laughter.)

DR. HOWE: So we'll table this one.

CHAIRMAN MALMUD: Yes. You may want to review that, and then bring it back after you've had a chance to review it.

DR. HOWE: Okay.

CHAIRMAN MALMUD: All right. Oh, Dr. Miller.

DR. MILLER: I guess I would like to maybe reconsider how the motion can get made. Donna-Beth has offered that this part needs some kind of fixing, such that we get the information that we need or by letter or on the form. Is that a fair assessment?

DR. HOWE: That's correct.

DR. MILLER: So could there perhaps be a motion of agreement from the committee that we need to go look at that and fix it?

CHAIRMAN MALMUD: May we have such a motion?

MEMBER BAILEY: So moved.

CHAIRMAN MALMUD: Mr. Bailey makes the motion. Is there a second to the motion?

MEMBER WILLIAMSON: Second.

CHAIRMAN MALMUD: Dr. Williamson seconds the motion. Any further discussion of this motion?

(No response.)

Hearing none, all in favor?

(Chorus of ayes.)

Any opposed?

(No response.)

Any abstentions?

(No response.)

It carries unanimously. Dr. Howe, you're three for three now.

(Laughter.)

DR. HOWE: Moving right along, it came to our attention that in the definition sections -- a member of the public is standing up. On this one. It came to our attention that in the definition sections we have a standard format for how to identify an authorized user, an authorized medical physicist, an authorized nuclear pharmacist. And in each case once you are board certified or you are listed on the license, you are automatically an authorized user, nuclear pharmacist, medical physicist, and can use the notification process to begin working before you have to submit information to the NRC.

And what we realized is that the RSO is a different animal. You cannot have an RSO work before you notify the NRC and get the RSO added to the

license. You can have a temporary RSO under the provisions of notification, and there are other requirements for this.

So what we're proposing is that we revise the definition to the RSO to really describe what -- who is an RSO, and the RSO essentially is someone who meets the requirements of being grandfathered as an RSO, or meets the training and experience requirements, regardless of whether it's board certification or the alternate pathway, and is identified as an RSO on any of the instruments listed below. And that's who an RSO is.

So this definition is different because this is a case where the individual has to be approved by the NRC before they're put on a license, and you do not use the notification process for an RSO. But you can have a temporary RSO under 35.26, and so this is not negating that.

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Is the major change to replace an "or" with an "and" so --

DR. HOWE: That's correct.

MEMBER WILLIAMSON: -- it's meeting all of these requirements and being identified on a license?

DR. HOWE: That's correct.

CHAIRMAN MALMUD: I believe we have a comment from a member of the public.

MS. FAIROBENT: Lynne Fairobent, AAPM. Donna-Beth, could you clarify for me, because it's not in this change, but when I read the complete slide, I have a question, because when we look at what is -- follows text-wise under sub-item (2) it says identified as an RSO on first case, a specific medical use license issued by the Commission or the agreement state or a medical use permit issued by a Commissioner master material licensee.

Aren't we missing broad scope license?

DR. HOWE: No, because the broad scope license is a specific license issued by the NRC. It's either a limited specific or a broad scope, and we did not use the -- either one of those designations. So the original terminology in Part 1 covers both the broad scope and the limited specific.

I'm pulling up the definition now. "A specific medical use license issued." Now, if it was a limited specific, it would be a specific medical use license of limited scope. If it was a broad scope, it would be a specific medical use license of broad scope. And by not putting "of limited scope" or "of broad scope," then you mean all NRC medical use

licenses.

So you have captured your broad scope RSO in addition to your limited specific.

MS. FAIROBENT: Okay. I just -- in reading it today, it was not clear that broad scope was even covered in this definition. So I'm not so -- do we define -- because I don't have my regs with us -- do we define a specific medical use license further in the definitions to both mean limited scope and broad scope? I just think there could be potential confusions. That's all.

DR. HOWE: No, we do not. But it is a term of art to have to write it all out if you're meeting limited or you write it all out if you meet broad scope.

MS. FAIROBENT: My only concern was that with 30 years working, since starting with NRC in '77, when I read this today "broad scope" did not appear in my mind at all to be included in this definition.

DR. HOWE: Okay. We can make that clear.

CHAIRMAN MALMUD: Lynne, is your concern satisfied?

MS. FAIROBENT: Yes.

CHAIRMAN MALMUD: Thank you. The answer was yes. Thank you.

MEMBER BAILEY: May I? My concern is why this definition is expanded over the definition we see in other parts of the regulation, which in general says that a radiation safety officer means an individual with responsibility for the overall radiation safety program at the facility.

And I -- I'm not sure why that definition needs to be broadened to be so specific for this part of the regs as compared to other parts of the regs. What has happened is what the radiation safety officer is is defined as what document they are listed on, rather than what their responsibilities are, what their job is.

DR. HOWE: I think it's more of an issue of defining how the individual is a radiation safety officer, not his task. And it's kind of a parallel construction to who an authorized user is, and who is a medical physicist.

I toyed with the idea of defining the RSO based on this task, and I'm not sure I wanted to go there because I wasn't clear we could get all of the tasks listed, and then someone would come up and say it's not complete. But this identifies an individual, so this is the person who carries this title as opposed to saying this is what his tasks are.

CHAIRMAN MALMUD: Please.

MEMBER BAILEY: To me it is putting requirements in definitions, rather than describing what the individual is as is done in all of the other sections, which says they are responsible for the radiation safety program.

DR. HOWE: But this also --

MEMBER BAILEY: As opposed to putting it here, what the requirement is to be a radiation safety officer. A requirement in a definition to me is always a little funny.

DR. HOWE: I think one of the other things which I didn't mention just a few minutes ago is it clarifies who a radiation safety officer is, the individual, so that when you get to the question of a preceptor radiation safety officer you can identify the individual that meets those -- that is that. And it's the same as an authorized user.

We do not give the task of an authorized user. We define the requirements that are needed to be the authorized user in the definitions.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: Yes. I guess one thing, that we are not setting ourselves up for a catch 22 situation, because you are saying that the radiation

safety officer is someone who meets these requirements, and it already identifies your RSO in the license.

Now, to be on the license as the RSO you must first be an RSO. But then, I mean, it -- it's like a catch 22 situation to me. Maybe I am not getting things correctly. But, you know, you have to be an RSO or be identified to be an RSO. That's like a catch 22 situation.

CHAIRMAN MALMUD: Dr. Williamson.

MEMBER WILLIAMSON: Well, I actually think that the language manages to avoid the paradox of self-reference, but it's close. I would like to comment on what Dr. Bailey -- Mr. Bailey has just said. I mean, he has raised a fundamental concern about the entire structure of the definitions of these categories.

So my question to him is: how is the suggested state regulations structured along this line? And do they provide a different alternative?

DR. HOWE: They are identical.

MEMBER BAILEY: May I respond to that?

CHAIRMAN MALMUD: Please do.

MEMBER BAILEY: I'll have to admit total ignorance on how this specifically is done. But what

I would have bet is since the suggested state regs have to have the concurrence of NRC before we publish them, there would be a push to make them. Right now, RSO is defined as it is for well logging and irradiators, and so forth, talking about the individual responsible for the radiation safety program.

And I might add, to get around the problem of the preceptor, the RSO is named on each of these licenses. So it is an individual. It's not some mystical person who does or does not have these qualifications.

CHAIRMAN MALMUD: Dr. Williamson?

MEMBER WILLIAMSON: Yes. I would just, then, add as a final comment on the matter, I don't think it's completely inappropriate to define a group of persons in terms of their qualifications, you know, as opposed to their essential job. So I think, you know, one could define an architect not based on what an architect does but on the required educational and licensure credentials if one wanted to, and thereby define a pool of people.

CHAIRMAN MALMUD: Thank you.

I'm not certain I understood what the purpose of your statement, though, was. Are you

supportive or not supportive of --

MEMBER WILLIAMSON: I think in the end I am not supportive of Mr. Bailey's concern, and I am supporting the -- my comment was intended to support the way the regulations or definitions are structured currently in Part 35.

CHAIRMAN MALMUD: Thank you, Dr. Williamson, for clarifying that for me at least.

So, therefore, we have a motion to -- Dr. Vetter.

MEMBER VETTER: Just as the RSO representative, I just wanted to go on record as supporting the proposed change.

CHAIRMAN MALMUD: Thank you, Dr. Vetter.

And will you be willing to make the motion, therefore?

MEMBER VETTER: So move.

CHAIRMAN MALMUD: Dr. Vetter makes the motion. Is there a second to the motion?

MEMBER LIETO: Second.

CHAIRMAN MALMUD: It was seconded by Mr. Lieto.

(Laughter.)

Is there any further discussion?

(No response.)

If not, all in favor?

(Chorus of ayes.)

Any opposed?

(No response.)

Any abstentions?

(No response.)

We have two opposed? Thank you. It carries.

DR. HOWE: Okay. The next one is also concerning the radiation safety officer, and Dr. Zelac yesterday explained a change that we made to the criteria for a radiation safety officer that added (c)(2) into the preceptor attestation. And what we found is that we have a number of licensees who are new licensees, and they are new authorized users, or we have licensees that want to put a new medical physicist or a new RSO on a license.

And in order to come through the (c)(2) pathway, the person already has to be identified on the licensee's license. And so, therefore, if it's a new person, they aren't identified on the license. So the licensee cannot apply at one point to have the new person on the license and also become the RSO.

And so we're trying to look at, is there a way to solve this problem, and you have to keep in

mind what the preceptor RSO can attest to. He can't attest that the person is on the license, because they're not on the license yet. And it would only be on the licensee's license, so it couldn't be somebody coming over from another license.

So we're recommending that the attestation be identified, that (c)(2) be changed to something -- and this is just a first approximation -- will be identified as an authorized user, authorized medical physicist, or a nuclear pharmacist on the licensee's license.

So that means you could have a new person coming in, you could have a person coming from another license. And then, we still have the part of the attestation that has experience with radiation safety aspects of similar types of use, byproduct material for which the individual has radiation safety officer responsibility. We could say "will have radiation safety officer responsibility." And the other attestations will stay the same.

CHAIRMAN MALMUD: Thank you, Dr. Howe.

Is there a motion to support this change?

MEMBER VETTER: So move.

CHAIRMAN MALMUD: Dr. Vetter makes the motion. Who seconds it?

MEMBER NAG: Second.

CHAIRMAN MALMUD: Dr. Nag seconds it. Any discussion?

(No response.)

Hearing no discussion, all in favor?

(Chorus of ayes.)

Any opposed?

(No response.)

Any abstentions?

(No response.)

It carries unanimously. Thank you.

Dr. Howe?

DR. HOWE: Okay, in 35.65 we essentially have authorization that any medical use licensee without providing additional information can possess calibration transmission and reference sources if each source is below a certain activity. Well, we have a manufacturer out there that wants to use an array of these sources, like 28 of them. Each one of them is right at the level of this authorization and we believe that this is not what was meant by this particular regulation, so we're recommending that we address the issue of aggregates. And that the automatic authorization, 35.65 should be for the activity level, whether it's an individual source or

you have an aggregate of sources in one particular device or place and so that's the recommended change. And if it's not an aggregate -- if it goes beyond the aggregate then it would be listed on the license.

CHAIRMAN MALMUD: Mr. Lieto.

MEMBER LIETO: Thank you. I have some real strong difficulties with this because this aggregate of 30 millicaries for sealed sources would create some significant problems with cobalt 57 flood sources. They're in the range of 15 to 20 millicaries each and I know hospitals have multiples of this, not to include -- you know, also including your dose calibrator sources and so forth. So I could see easily, you know, exceeding -- or this aggregate being a problem.

DR. HOWE: In that particular case, we -- I think the solution is to improve the wording of the aggregate because in this case we're talking about using all of the sources at one time, not having all of the sources at your facility but using them in a device, like this device that has 28 of these sources.

MEMBER LIETO: I understand your concern with the single source but I think what you're trying to do is you're trying to look at one problem an solving that issue but the effect that you're going to

have on everybody, I think, is going to be to the negative and so I guess I would like to suggest that this -- that staff take this back and revisit this.

CHAIRMAN MALMUD: This is Malmud. I have a question for both Mr. Lieto and Dr. Howe. Would both parties be satisfied if the word "simultaneously" were inserted in the last sentence on that slide "when used simultaneously as an aggregate"? That would take care of the --

DR. HOWE: That would certainly -- that would be a good description of what we're trying to get to.

CHAIRMAN MALMUD: And that would also not create the problem that Mr. Lieto is referring to, since it would not use all the cobalt sources simultaneously.

MEMBER LIETO: I'm just trying to think if this would be a -- what problems this might create for like uniformity correction sources and which are larger activities.

DR. HOWE: And I'll remind you that --

MEMBER LIETO: But I guess that would be a licensing --

DR. HOWE: -- if we do go to rulemaking, you will see it again and you'll have plenty of time

to discuss and change wording.

CHAIRMAN MALMUD: Dr. Vetter wishes to make a motion.

MEMBER VETTER: I move that the committee support this change with the word "simultaneously" inserted as Dr. Malmud suggested, so "when used simultaneously as an aggregate.

CHAIRMAN MALMUD: I'll second the motion to bring it to discussion.

MEMBER NAG: One question.

CHAIRMAN MALMUD: Dr. Nag.

MEMBER NAG: If it is required that you do need to use several sources in aggregate, how could you do that under this rule? Do you have to ask for special permission or what?

DR. HOWE: You would include it in your application that you were going to use -- say in this example, you were going to use an array of 28 sources, and then we would list that on the license as a separate line element. We are not prohibiting you from using but we are considering that now to be one device or one source.

CHAIRMAN MALMUD: Thank you. Any further discussion of this item? All in favor? Any opposed? Any abstentions? It carries unanimous. We have one

abstention, otherwise carries unanimously. Thank you, Dr. Howe. We have a question from Mr. Essig.

DR. HOWE: Mr. Essig, yes.

MR. ESSIG: Just a point regarding the schedule. It's now 10:00 o'clock. We're on item -- we've just completed Item Number 6 of 17. I would suggest that this discussion would take quite a bit longer than the time that we've allocated for it. We have already planned a committee conference call, a noticed conference call to discuss the bylaws. My suggestion would be that we, at some point, take either at the halfway point or now, take the rest of these and include them in the conference call so that we can stay reasonably close to the agenda because we do need to be out of there by noon. And I want to make sure that we have -- the committee has adequate time to focus on Mr. Lieto's presentation. Just a suggestion.

CHAIRMAN MALMUD: Those who would participate in the conference call would each have these printouts already in the book.

MEMBER VETTER: Yes.

CHAIRMAN MALMUD: So that would be an efficient way of dealing with it if that's acceptable to Dr. Howe.

DR. HOWE: I would recommend that we finish number 7 and that could be the cutoff point.

MEMBER VETTER: Okay.

MALE PARTICIPANT: I would recommend that we stop now so that we can have our break and get some coffee.

DR. HOWE: Well, we really have an extreme interest in this and if we have the ability to go forward with anything, this is the one we'd want to go forward with.

CHAIRMAN MALMUD: Let's finish with Item number 7 and then we'll take a coffee break.

MEMBER EGGLI: Dr. Malmud, as a technical request could we get these slides in a different format because in the format we have, we cannot see the yellow which represents the changes to review. So if we could get these slides sent to us in maybe a pure black and white format with the changes bolded or something so that in the format that we have we can actually see the changes?

DR. HOWE: Now I also want to point out the behind your slides, you have the more detailed description of the problem for each and the recommended change. So the slides are kind of -- but we can also give you new slides.

MEMBER EGGLI: That's fine. On the lazy side to see it quickly, it's nice to have the slides.

MEMBER LIETO: But it is a fair request and we can certainly accommodate that, but as Dr. Howe points out, there is the detail that follows the slide.

CHAIRMAN MALMUD: Dr. Eggli, I will ask Mr. Saba to e-mail these as an attachment to the memo regarding the meeting in a format that would be the one that you suggested. And let's move on with item number 7 to completion, Dr. Howe.

DR. HOWE: Item number 7 is another one of these less than or equal tos. When they revised the rule in 2002, they upped the days to 120 but they said less than 120. It didn't say less than or equal to. It ends up we have a standard license condition for all other licensees, gauges, industrial, research development, everybody else that we put less than or equal to 120 days for holding for waste into storage. We tried to get this in under an administrative change this year and OGC believed this was a significant change and will have to -- and could not be done during the administrative change. So the change appears trivial.

CHAIRMAN MALMUD: Your recommendation

would make this consistent with the other regulations.

DR. HOWE: That's correct.

CHAIRMAN MALMUD: In the interest of consistency, do we have a motion?

MEMBER BAILEY: I move.

MEMBER VETTER: Second.

CHAIRMAN MALMUD: Mr. Bailey makes the motion, seconded by Dr. Vetter. Any further discussion?

MEMBER NAG: One question. Is there any radio isotope that has a half life of exactly 120 days?

DR. HOWE: Selenium, yes, and it's a medical use one. We did check into that. Okay, then I complete my --

CHAIRMAN MALMUD: All in favor of the motion? Opposed, any abstentions? It carries unanimously, Dr. Howe.

DR. HOWE: Okay.

CHAIRMAN MALMUD: We will now take a break for coffee. Dr. Williamson (inaudible) We'll return in 10 minutes.

(Whereupon, a short recess was taken.)

CHAIRMAN MALMUD: We have a briefing presentation with first some introductory remarks by

Mr. Essig. Mr Essig?

MR. ESSIG: Thank you, Mr. Chairman. We are going to be in a few minutes walking through Mr. Lieto's slides and at that time solicit the views of the committee members as to what changes they would like to see since Ralph will be representing the committee as a whole. I wanted to give just a little context for this. On May 15th, starting at 1:00 p.m. there will be a Commission briefing on the status of the implementation of the Energy Policy Act of 2005.

It's a public meeting, again, May 15th. It's a Monday in the afternoon and there will be two panels at the meeting. The first panel will be talking about the -- basically three sections of the statute, Section 651E, which is the one that's of most interest to this committee because it focuses on the accelerator produced and the other by-product material that we now regulate, and then Section 656 which is titled "The Secure Transfer of Nuclear Materials, and then Section 652 which relates to fingerprinting and a criminal history record. Those latter two sections, I don't believe, are of particular interest to this committee. So Mr Lieto will focus on Section 651 of the -- 651E of the Act when it comes time for his presentation.

So the Panel 1 will be NRC staff. They will do a presentation starting at 1:00 p.m. and then there will be questions and answers from the Commissioners and then there will be a break, and then Panel 2, which consists of stakeholders, as follows; the Organization of Agreement States, the Conference of Radiation Control Program Directors, and the Council on Radionuclides and Radiopharmaceuticals, Mr. Roy Brown whom we heard from yesterday and the --

The process of getting Mr. Lieto to where he is now entailed our revisiting the question of the prior meeting in November where we had a public workshop and we -- for that particular occasion, the committee chose Ms. Sally Schwarz and Mr. Ralph Lieto to represent the committee. At this juncture we have only a spot for one and so when I conversed with DR. Malmud prior to this meeting trying to decide which of the two -- first of all, we agreed that it probably should be the two for continuity purposes. And if we couldn't support two, which it turns out we can't, then which one should it be and the broader issue that's before the committee, DR. Malmud had suggested for the broader issue probably we should go with Mr. Lieto. If it was narrowly focused more on PET, that we should go with Sally Schwarz. So that's kind of

how we got where we are.

And so Ralph has 10 minutes and it will be -- no for the slides on the Commission meeting on the 15th and that we must strictly adhere to. So if the committee feels that the volume of material that Ralph has put together in draft form cannot be presented by him in 10 minutes, you know, moving at a reasonable pace, then we need to provide comments on areas that can be trimmed because he probably has, just my quick read of it, there may be too much there for 10 minutes, but we'll let you come to your own conclusion and offer any necessary changes.

So with that, I'll turn back to the chair or to Ralph.

MEMBER LIETO: Thank you. Can everybody hear me? As Tom pointed out, all this really kind of took place since the latter part of last week and so since then, I tried to put together some slides that would be presented to the Commission as Tom said, within the very narrow scope of time of 10 minutes. So basically, kind of figuring out that I probably would not have more than four slides and if you figure in the manner of presentation that's required for the format, maybe at max three bullets per slide to discuss.

And so a lot of this has been put together based on some discussions that I had with Tom and staff in our teleconference. A lot of it is also based on the summary report of comments on the proposed rule that Sally Schwarz put together and submitted to staff in, I believe, it as late January regarding the proposed rules that we had in terms of the pre-decisional information.

So you should have a copy of the slides and also that report that went to staff regarding the comments on the proposed rules. So that kind of gives you a background that I kind of based things on in putting this together. So you know, a lot of credit goes to Sally also in the information that's presented here. The first two slides will deal with the accelerator produced radioactive material comments that we had, basically, endorsing the proposed categorization of the particle accelerators and agreement not to regulate the medical therapy linacs in terms of the incidental radioactivity that they would produce. This, I think, will be a tremendous benefit and well-received by the medical community.

That there needs to be a high compatibility across state lines. This is really critical in the areas of mobile PET, the centralized

radio-pharmacies, and the training and experience requirements because these are the main factors that will be involved in crossing departmental lines. There was a question and it's still a little bit unclear as to the incidental radioactivity, where that's going to be regulated at. It's sort of been agreed that the incidental radioactivity that is produced in these accelerators that are not for radionuclide production how are they going to be addressed. They seem to kind of -- should they be addressed as an exempt format or are they going to kind of fall into an orphan type of radioactivity that needs to be addressed by the licensees.

Now, as far as, you know, comments, I guess I'm looking for constructive criticism, so if people think that something should not be on the slide, some wording should be changed, I'm -- as I said, most of this has been put together -- well, actually, this was put together over the weekend, so it kind of gives you some idea that I'm looking for some help on this.

So if there are things that you don't think belong in there, things that aren't on there that should be as major points, because I'm presenting this as the committee and so I've got to believe that

there's got to be some concerns or issues that need to be clarified or whatever. But --

CHAIRMAN MALMUD: DR. Vetter.

MEMBER LIETO: -- the cryptic nature of the wording is mainly because of the format.

MEMBER VETTER: I looked real hard at this and have one major suggestion, minor, actually, changing "radiopharmacies" to "nuclear pharmacies".

DR. SCHWARZ: I agree with that. I also have another comment. On the incidental radioactivity, if you're speaking about the medical linac, you need to state that because otherwise it infers that you are talking about the accelerators for production purposes and -- or it's not clear. I think they are regulating the activation products from causing exposure to the personnel.

MEMBER LIETO: You want me to just strike that bullet all together then?

DR. SCHWARZ: No, I think you just need to clarify that incidental radioactivity from the medical linac. Therapy --

CHAIRMAN MALMUD: DR. Williamson?

MEMBER WILLIAMSON: I thought that the way that the regulation was structured is that that was specifically excluded from this regulation. That

unless the accelerator were used for producing radionuclides, that any incidental radioactivity produced by virtue of operating it for some other purpose would not fall under the purview of this regulation; is that not correct?

MEMBER LIETO: So --

DR. SCHWARZ: No.

MEMBER WILLIAMSON: So this needs to apply to PET and other production facilities like if you produce three radionuclides and you're trying to extract one, how do you deal with the other two? I think that would be an appropriate question.

MEMBER LIETO: Should I keep the other comment there about orphan and exempt or not?

DR. SCHWARZ: Probably not.

CHAIRMAN MALMUD: The recommendation is that it not be left there. Another comment?

DR. CHANG: Can I just make a clarification?

CHAIRMAN MALMUD: Yes.

DR. CHANG: I guess within the norm rulemaking it is not our intention to regulate the medical linacs but it is to individuals who have linacs, it is a question who will be regulating. Without our structure, we do not think we have the

authority since those incidental material within the linacs machines, it's not really for medical commercial research purposes. You know, so therefore, we don't feel that we have that kind of authority to regulate that. So the point that we need to make clear is that even though NRC does not feel that we have the authority to regulate that, when the linacs is in use, the state, the special agreement state they are currently regulating such instrument and also the fact that once you decided to decommission your linacs once the life is spent, 30, 40 years from now, the waste that you'd be generating it will be however, considered radioactive material. You do need to dispose of appropriate such.

MEMBER LIETO: Would you like to then bring this up as a point of concern, then?

MEMBER VETTER: Personally, I would stay away from the linacs all together. We support not regulating the linacs, period.

DR. SCHWARZ: I agree with that. I do have a question though. Is there going to be regulation regarding the by-products from the production, then maybe that can then be switched in terms of -- I mean, do they know how they're going to regulate that? They do?

CHAIRMAN MALMUD: All right, Mr. Bailey?

MEMBER BAILEY: I think the regs that the handed out to us do address that issue, that the waste from those would be eligible to go not only to a low level site but to a RCRA site or whatever.

CHAIRMAN MALMUD: If I may, Ralph, I'd make a couple of suggestions. Number 1, I would say you're speaking for ACMUI. So I would just say in bullet number 1, "ACMUI endorses the proposed categorization of accelerators". Next line, "ACMUI supports not regulating linacs". I mean, that's two very clear statements.

The next line, state should have a small S on it. It's not a state. The Federal Government uses a capital S on state?

MR. ESSIG: Yes, we do.

CHAIRMAN MALMUD: All right, can't argue with the Federal Government, not successfully anyway. My English teacher would not approve but she's not here today. And the other points, you have. So you actually would have four bullets, wouldn't you, four bullets. The first one is, "ACMUI endorses the proposed categorization of accelerator". Second bullet, "ACMUI supports not regulating linacs". The third one is as stands and the fourth one as stands.

Mr. Essig?

MR. ESSIG: I would offer on this slide that the first bullet, if we're going to say the proposed categorization, you're speaking to the Commission. If it's not yet been proposed to them, then they won't know what you're meaning by proposed. Proposed by whom? And Lydia, the status is it has not yet gone to the Commission?

DR. CHANG: It's with the Commission.

MR. ESSIG: It's with the Commission, okay. So then proposed would be okay. All right. I stand corrected. And I would not use the acronym TX or the abbreviation.

MEMBER LIETO: Spell it out?

MR. ESSIG: Spell it out. And lastly, I would not raise an issue in the form of a question to the Commission. I would phrase it as an issue that remains open or that -- something but make it in the form of a statement rather than a question.

CHAIRMAN MALMUD: DR. Williamson?

MEMBER WILLIAMSON: Yeah, I guess just for my not being so familiar with this process, have we disposed of the third bullet, the incidental radioactivity or is that still a serious issue that needs to be questioned?

DR. SCHWARZ: Sally Schwarz. I think it should probably be deleted, I mean, because it's really not part of this legislation and when we're encouraging the states to -- or at least not this legislation to regulate that radioactivity.

CHAIRMAN MALMUD: So the recommendation is that we delete the third bullet which begins with "incidental radioactivity". All right, do you want to go to the next slide, Ralph?

MEMBER LIETO: There was a question.

CHAIRMAN MALMUD: Who? Oh, DR. Zelac.

DR. ZELAC: Ron Zelac, one suggestion for the first bullet, I think it might be unnecessarily limiting to the say "medical therapy linacs", because there clearly are other accelerators that are used for medical therapy purposes, not a lot, but some. Do you get what I'm saying? I would just replace the word "linacs" with "accelerators".

MEMBER SULEIMAN: I would say accelerators that are not used to produce radionuclides.

MEMBER LIETO: Wouldn't therapy accelerators be sufficiently clear?

MEMBER SULEIMAN: What about non-medical?

MEMBER NAG: Would that include things like cyclotron that is used for (indiscernible) and so

on?

MEMBER WILLIAMSON: Yes.

MEMBER NAG: Would that be included in your new (indiscernible) would cyclotron be in there?

MEMBER WILLIAMSON: Yes, good point.

CHAIRMAN MALMUD: The answer to your question, Dr. Nag, was yes from Drs. Vetter and Williamson. Dr. Miller?

DR. MILLER: Yes, I'd like to point out on the second bullet, this is so that the committee can fully arm Ralph when he's at the table, although Ralph's presentation will be limited to 10 minutes, the Commission can take whatever time they want to ask questions. And one of the things I'd like to point out is, and I'm not whatsoever taking a position on this, is that your second bullet is calling for a high level of compatibility across straight lines. Another panel member representing OAS or CRCPD is likely to say that they would like to have a low level of compatibility given the information that they've supplied to the Commission, so recognizing that there's going to be a diverse opinion or a diverse number of views at the table, I can see the Commission challenging both parties on the basis for their views.

So I think he would want to be prepared to

be able to address that. Mr. Bailey, I knew that this would activate a question on your part.

MEMBER BAILEY: Yeah, I --

CHAIRMAN MALMUD: Mr. Bailey.

MEMBER BAILEY: Thank you. The difference on high level of compatibility, I don't think the states will mind most of the things you're talking about. The things we're talking about, a low level of compatibility on are sort of nuances. One of the things that came up were the definitions of by-product material. And what we've discovered is that about 30 -- maybe not 30, 28 of the states would have to go back and change their legislation if NRC maintained that there had to be a high level of compatibility on the definition of by-product material. The definition that we'd normally use is radioactive material which we feel adequately encompasses all four types of by-product material that we now have.

So that is the sticking point with the states on the lower level of compatibility. I don't think it has anything to do with the operation of a PET facility or the distribution of PET drugs or pharmaceuticals or whatever. So that's more background information to you and I would encourage you and I will talk to the people who are going to be

representing those two organizations to make sure that there's an understanding of when you talk about high level of compatibility, you're talking about operationally not the nuances that have got the agreement states sort of up in arms on definitions again.

CHAIRMAN MALMUD: DR. Williamson?

MEMBER WILLIAMSON: Well, I'm speculating that actually what the ACMUI position means is probably a lot of the issues raised by the CORAR representative yesterday having to do with basically a streamlined process for introducing drugs and devices to market.

CHAIRMAN MALMUD: Thank you. Mr Lieto, would you like to move on?

MEMBER LIETO: Yes. The next points were to address some of the -- and I'll take that question mark out of there -- come from some of the comments in the report that was submitted for ACMUI to staff and earlier in the year. It has to do with the importance of maintaining availability of radiopharmaceutical production. The accelerator production methods of radioisotopes are done largely in the United States, in terms of the PET facilities, as well as the non-PET pharmaceuticals, and that that the loss of the

availability of a linear accelerator for this purpose may entail the loss of availability of these radiopharmaceuticals either on a local scale or on a much larger scale.

And so it's very important that licensees and the -- both from the production side as well as on the receipt side do not lose the availability of these radiopharmaceuticals from those methodologies. One of the other issues that was brought up is that the proposed regulations address the concept of non-commercial distribution. And that there needs to be, I think, further clarification of that, what that entails and what that allows in the -- in the regulations as well as the implementation.

And the third point has to do, although I know yesterday Mr. Brown indicated that decommissioning financial assurance requirements were not an issue for accelerators, although our input during the report phase to the NRC staff is that this will be a new requirement and will require the licensees in terms of production especially putting forth financial assurance for the waste disposal of the activated components and both from the machine and building and the decommissioning of these accelerators.

DR. SCHWARZ: Sally Schwarz. There's one point on the decommissioning financial assurance, I know Roy Brown was mentioning that it really is no longer an issue because the 11 MEV machines Siemens produces is right at the level of neutron activation, so that they're really not a problem. But there are a number of centralized pharmacies and other older facilities that have other types of machines. We have to positive ion machines. They're old, 16 MEV machines and they will definitely require this type of funding assurance, and as well the larger the GE machine is a 16 MEV machine. It's a new negative ion machine.

There's an ABCO machine out there. There's also higher energy, I think it's 16 or 17 MEV but again, there is one segment of the production population that will be in a reasonable area, but there are others that will have to deal with the decommissioning funding.

MEMBER LIETO: I have a question that maybe Jeff and DR. Vetter, some of these newer like proton facilities and so forth, would those facilities, those seem to be sort of the newer cutting edge types of accelerators. Is this going to be an issue for them as they -- in the long term in terms of

decommissioning?

MEMBER WILLIAMSON: From what I understand, since they are medical treatment accelerators, they are exempt from this regulation. Is that correct? I'll ask the staff.

CHAIRMAN MALMUD: DR. Vetter?

MEMBER VETTER: That's my understanding, too, but I --

MEMBER LIETO: But not the decommissioning.

MEMBER VETTER: Sorry?

MEMBER LIETO: They wouldn't be exempt from the decommissioning, right, or am I wrong? I guess I'm -- because I'm under the impression that the decommissioning applies regardless. It's just the incidental radioactivity during the use.

DR. CHANG: If we're talking about the accelerator, that does not produce material. We are not regulating until the waste is produced. So therefore, in my opinion, I don't think the decommissioning financial assurance will apply because that's part of the licensing.

MEMBER SULEIMAN: So then the decommissioning financial assurance only applies to --

DR. CHANG: To the production accelerator.

MEMBER SULEIMAN: -- the production facilities where the beam is higher than 11 MEV.

DR. CHANG: Correct.

MEMBER SULEIMAN: So it's those accelerators that Sally was talking about.

MEMBER LIETO: So this would be a non-issue. I should strike this bullet.

MEMBER SULEIMAN: I think so, unless the older facilities think this is a major issue for them.

DR. SCHWARZ: It will be a major consideration for older facilities. It will amount in our facility to about a million dollars in financial assurance for our two positive ion machines.

MEMBER VETTER: Now that is an issue because not the -- they don't have to come up with a million dollars, but they have to go to a bank and they have to pay that bank, five or $10,000.00 a year for nothing, for a letter that they send to the regulator that says, "Yeah, we'll make sure there's money there". So it's not a trivial issue. I mean, that's a lot of money for a nuclear medicine department to come up with.

MEMBER LIETO: So for medical production, facilities which are largely located at medical centers, universities, research -- medical research

centers, this is going to be an issue. Okay, so I'll leave it in.

DR. SCHWARZ: Yes, because we're not -- I think we're not the only old facility out there. I'm not sure how many old facilities are non-agreement states but I know that we are not the only one.

CHAIRMAN MALMUD: Thank you, Dr. Schwarz. Dr. Williamson.

MEMBER WILLIAMSON: I would like to make a general suggestion for this and other slides, that you try to cast this as a declarative sentence. Like maintaining availability of PET radionuclides is essential. Non-commercial flexibility to distribute non-commercially is essential to -- you know, make it sort of a little more clear why these points are important and I'd say try to even on the slides, convert them to declarative sentences and I'd say, "Decommissioning financial assurance places a burden on older PET licensees that does not serve public safety". Whatever, you know, that's an example, but there's a certain vagueness to your style of presentation which I, as an observer, not having delved deeply into this, find a little frustrating. It detracts from the effectiveness of your presentation.

MEMBER LIETO: Jeff, I would never want to frustrate you and the cryptic nature was sort of intentional to try to, you know, get a flavor from the committee as a whole. So I appreciate that.

DR. SCHWARZ: And I do have another comment along that line. Really PET is a new progressive field. And at this point, it's very vulnerable to regulation and you know, the increased cost to maintain PET is really -- we don't want to destroy this field. It has tremendous implications for diagnostic purposes and really, as far as nuclear medicine as a whole is concerned, it really is moving toward PET. So to put regulation on board or, you know, financial assurances on board that will prevent PET from moving forward is really a travesty.

I mean, it's something already the Commissioners have acknowledged that they, themselves, have had relatives, you know, who've been involved with PET studies and the actual fabulous information that's available. You know we don't want to stifle research at this point, too. We also financially are in a difficult period with NIH funding, you know, for all of our research that's ongoing. Certainly it's not just PET. But you know, at the point of life, where all this money becomes the most important issue,

you know, science stops moving fiord and we don't want to stifle this field. I mean, it really is very critical and a very vulnerable point.

CHAIRMAN MALMUD: Ralph, if I may, I would suggest that you insert a slide here which essentially summarizes that which Sally has said and I would put it in the following way if you would agree. I'd make a declarative statement that PET radiopharmaceuticals are rapidly advancing. Medicine's understanding of the diagnosis and treatment of the three most prevalent diseases in the United States, the most prevalent causes of death in the United States; number 1, cardiovascular disease, number 2, cancer, number 3, stroke. Those are from the public -- those data are available publicly as well as an understanding of brain disorders including Alzheimers, Parkinsons -- or Alzheimers and movement disorders. Those are -- that's a factual statement and it's very often useful to remind the Commissioners of the role that PET is taking in each of these areas.

Oh, I'd also include psychiatric disorders, the brain, the two plus psychiatric disorders. And there's no family that isn't touched by one of these disorders or more than one.

MEMBER LIETO: I'll make those points and

I'll expand it under the first bullet.

CHAIRMAN MALMUD: I would make it a separate slide, a declarative slide as an introduction to the next slide. Then I would put this slide which says that we are concerned about maintaining availability of PET radiopharmaceuticals without -- without creating dis-incentives.

MEMBER LIETO: Okay.

CHAIRMAN MALMUD: Then make your other two points on this slide. But I think that the introduction is critically important because the statistics are there and the rapid advances are being made and the understanding of certain diseases would not have occurred and will not occur without the use of PET pharmaceuticals, even the newer technologies, the functional MRI are really developing because of what preceded them with PET radiopharmaceuticals and brain research. So that -- brain and heart research, so I think that the statement is worthy of being made and reiterating. Dr. Williamson.

MEMBER WILLIAMSON: I think that is an excellent idea on the part of our Chairman. I would not -- just remind you, don't forget the point that Sally made about financial vulnerability and this is a young and growing research oriented field. I think

that provides then a whole structure for these points to make some sense.

MEMBER LIETO: Okay.

DR. SCHWARZ: Excuse me, one thing there, you're non-commercial distribution, you can refer again to research purposes, you know, because this is the non-commercial distribution involved in the research development of PET and as DR. Malmud mentioned, MRI is being used also in conjunction with PET as well as CT in conjunction with PET to do the fused imaging so that they're essentially a more precise science. It's really at its beginning point, clinically.

CHAIRMAN MALMUD: And if I may, the reason I made the point is that this is not pie in the sky distant future. This is now. These developments are occurring now and nothing should be done to slow down the momentum of the progress. Yet, we want to phrase things positively. So we first make a statement about what's happening currently. This is real, this is not a dream. And number 2, that in creating these regulations that we strive to maintain the availability of these pharmaceuticals, these radionuclides and radiopharmaceuticals without creating -- unintentionally creating disincentives to

the advancement of this research. Lydia.

DR. CHANG: Yes, DR. Lieto, I guess what a second bullet -- within the NAM proposal, we did try to attempt to allow non-commercial distribution of medical use facilities among themselves. I think that's very important to bring it to the Commission's attention, and if the ACMUI believe it's not gone further enough, then perhaps, you should highlight the non-commercial distribution should perhaps go to include the research and development type of activity as well.

CHAIRMAN MALMUD: DR. Miller.

DR. MILLER: I'd like to amplify on what Lydia said so that Ralph is fully armed to defend your honor. The Commission's probably -- you know, when he presents that slide the Commission in their Q and A may take him to please tells us ACMUI's view regarding is the proposed regulation sufficient or does it need to be modified to address the issues that you're bringing to us today? They had this before them and that's what their focus is going to be with regard to the proposed rule.

MEMBER LIETO: Because one of the points under the non-commercial distribution I was going to make is that this is really a new concept that's being

put forth in terms of availability of radiopharmaceuticals, so -- in terms of it being recognized in the regulations. So do we feel that it -- as it's proposed, is adequate or do we think that it needs to be broadened in its scope?

CHAIRMAN MALMUD: You may want to make a statement which says that a number of the advances have occurred because -- as a result of the non-commercial distribution of these products. It is our belief that the momentum of that activity needs to be maintained without creating obstacles to the non-commercial distribution.

DR. SCHWARZ: DR. Malmud, excuse me.

CHAIRMAN MALMUD: Yes, Dr. Howe.

DR. HOWE: Dr. Schwarz was first.

CHAIRMAN MALMUD: Oh, I'm sorry.

DR. SCHWARZ: And in combination with that, that's okay, hands. If you could mention within that sentence also the fact of research, you know, essentially providing materials for research and development.

CHAIRMAN MALMUD: So what you'd be saying is a statement, Ralph, that the non-commercial distribution of these products has been and continues to be essential for continued -- for research and what

was the other term you used?

DR. SCHWARZ: Development.

CHAIRMAN MALMUD: Research and development. Again, I'd reinforce the currency of it in this cutting edge research, because it's occurring now. It's not some -- you know, in the 1980s we talked about the decade of the brain would be the 1990s. And it turned out that well, it wasn't quite the 1990s but it extended into the first decade of this century and in truth, it's happening. One-third of us, if we live long enough, will develop some form of Alzheimers before we die and that's a frightening prospect both for the economy of the country as well as for the personal suffering that's engendered by families.

And everyone is touched by it and advances and understanding of brain physiology are really largely coming from this type of research and now function MRI. Dr. Van Decker, I didn't mean to ignore the heart. I'm sorry.

MEMBER VAN DECKER: No, I was just going to make the side comment, DR. Malmud, is cardiology to blame or to be thanking for having people -- for allowing people to live long enough to come -- to have to come and deal with this stuff? If you'd like,

we'll put this on our plate also.

CHAIRMAN MALMUD: Well, I would imagine that depends whether or not with the blame comes funding. DR. Suleiman.

MEMBER SULEIMAN: There are three things. One, you may want to have a picture of a PET scan, I don't know. Number 2, I have some data that shows, in terms of research under RDRC you know, 20, 30 years ago, a very small percentage was PET and recently as much as -- much larger, 70, 80 percent, I don't remember the numbers, is PET research. And the third thing, you can provide some of the research applications have now worked their way into the clinical, you know, a lot of the neuro-receptor brain imaging studies. You're seeing a lot of cardiovascular, cancer, a lot of applications that have gone from research, whatever. And what you really can't say is that, you know, the community has finally got FDA to smooth things along to get PET GNPs and other things, and so now the NRC is coming in with this whole new set of regulations, so we're really concerned that things don't get bogged down, you know, because I think there's been a change of attitude the last few years regarding, you know, PET radionuclide manufacturing processes.

CHAIRMAN MALMUD: Thank you. Dr. Howe, I didn't mean to ignore you. I'm sorry.

DR. HOWE: Okay. When we were working on this as a working group, I guess my thought was that most of the non-commercial distribution would be from the medical centers, the big medical centers that would have the PET scanners, that they'd want to use internally or share with their contemporaries or even in a consortium. Is there something outside of the medical centers that you see? Would it be the universities? We don't necessarily need to address non-commercial distribution for other licensees, because we don't have prescriptive regulations for them. So we could accept it as a policy and move forward with it, but for the medical we had to put specific regulations in to allow non-commercial distribution because we had 32.72 which was pharmaceutical distribution and we figured there was only commercial.

Do you guys see something other than the medical centers for this?

CHAIRMAN MALMUD: DR. Vetter?

MEMBER VETTER: Well, it's conjecture but I think that's an excellent foresight because there could be -- you know, a medical center could go to a

university or a national laboratory and say, "We would like you to produce this brand new radioisotope, radionuclide, excuse me, that we might be able to use for a new medical procedure. So I think it's entirely possible that that could happen.

DR. HOWE: Okay.

CHAIRMAN MALMUD: Mr. Bailey.

MEMBER BAILEY: Is the concern about the non-commercial distribution because you would have to pay an extra fee or what, because I know in a lot of the agreement states, it's already in the same license fee so there's no real concern about whether you add the distribution --

DR. HOWE: The non-commercial distribution for us was a problem because the way a medical use licensee gets materials, it comes through 32.72 or it comes through some other manufacturer or distributor and then the commercial -- and then the pharmacist or physician can convert it into a radionuclide. So we believe this was a different mechanism for getting the material and we had to be able to authorize the medical use licensee to use the material and to share the material.

MEMBER BAILEY: Okay, just one comment on that; at some point with regard -- I've heard the

phrase research and development used several times here. But strictly speaking, you can't do research and development in the medical field because it's excluded by Part 30. So at some point the NRC needs to take a look at that and change research and development definition.

DR. HOWE: Well, research and development, as defined in Part 30 does not include the use on human beings but when you go into research and development in the medical arena, we cover that in Part 35 and that's covered in 35.6 which is research involving human subjects. So the idea was that you could not give an authorization separate from a medical use authorization to use materials on people. That's why the definition in 30 excludes human use. But that does not exclude research and development involving human subjects. It just means, you need either a Part 35 license or a Part 35 authorization so Eli Lilly would have a Part 35 authorization.

CHAIRMAN MALMUD: DR. Williamson?

MEMBER WILLIAMSON: Well, if I could follow up on Mr. Bailey's concern, I think the issue is that there may be non-human research that has to be -- clinical research that has to be conducted in a medical center on animal systems or perhaps even in

vitro studies. That is included now in a broad scope medical license.

DR. HOWE: That's in the Part 30 authorization for those licensees.

MEMBER WILLIAMSON: But this is important for the development of PET radionuclides. It's not all clinical. There's a huge pre-clinical array of research applications that has to be recognized. I do think, and again, making this point, if you can be -- when you say non-commercial distribution, if you can be specific what's wrong with the current wording, you know, or what the concerns are because they'll ask you what do you want us to do to fix it. They're going to -- so there has to be some specificity to this.

DR. SCHWARZ: At our institution we provide -- we produce radionuclides, PET radionuclides and distribute them across the United States. And it's not for human use. It's just for research to various hospitals and I mean, university settings typically. So just the concern that, you know, this -- excuse me, this type of distribution is allowed, that it wouldn't be problematic for those who receive it or for those of us who are shipping it.

MEMBER LIETO: So a declarative statement to the fact that non-commercial distribution of PET

and accelerator produced radioactive materials for human and non-human applications needs to be maintained in -- I won't say its current format but something to that effect, needs to be maintained.

DR. SCHWARZ: For research as well. I mean, you mentioned it is for research.

MEMBER LIETO: Yes.

CHAIRMAN MALMUD: Mr. Essig?

MR. ESSIG: The only comment I wanted to make on the declarative statements in the slides to speak to Dr. Williamson's recommendation, is that the Commission prefers not having a complete -- and I think that's the approach that you started. You have to have enough of a message, but it isn't something -- what they don't enjoy hearing is where I have a bullet point on the slide that's a complete sentence and the presenter then merely reads it to the Commission, because they have reacted very negatively to that in the past saying, "Well, I can read, you don't need to sit there and read the point to me".

And so you have to have this balancing of a complete enough thought but yet, not something that's a -- you don't strive to have a complete sentence there. Or if you do end up with a complete sentence, such as the slide that DR. Malmud was

recommending, that you can show the slide but then merely summarize some of the elements of that, that additional slide.

CHAIRMAN MALMUD: You amplify it.

MR. ESSIG: You amplify, yes. You recognize that they can read it and then you just amplify some of the points that you want to make.

CHAIRMAN MALMUD: Ralph, it may be helpful, therefore, to maintain the bullet point of non-commercial distribution and to amplify it by saying, "For example, at the Mallinckrodt Institute at Washington University in St. Louis they produce these materials and ship them nationally currently for research purposes to other institutions. And it's essential that we maintain that availability without encumbering unnecessary expense or restrictions into the future. Sally, would that --

DR. SCHWARZ: I agree, that sounds good.

CHAIRMAN MALMUD: DR. Suleiman?

MEMBER SULEIMAN: I really need to clarify a couple of things. PET manufacturing was so in disarray in terms of how it was regulated that the -- one of the laws the FDA Modernization Act of `97 basically adopted U.S. Pharmacopeia standards until FDA came out with what they require of the PET

manufacturers. And so recently FDA has come out with guidance, spelling out and so the Pharmacopeia standards are going to go away two years after that guidance comes out.

FDA considered -- now, they're not so concerned -- we're not so concerned about the radiation safety issue as much as everything else. And they're very aware of the pharmacy issue and the compounding of drugs but up until the point that the product is released to the pharmacist or whatever, FDA considers it a PET production facility and the term I think we've used is "graded response", depending on if it's a large scale manufacturing facility. FDA really is concerned about manufacturing and production always. And so the problem with PET has always been it's such a small quantity that's being produced, you know. How can you apply broad GNP, you know, manufacturing standards to it.

So we've taken the -- we've come out with a proposed draft but at some point -- this is all in play, so I think you just need to be aware of it. I don't think the Commission needs to know that FDA has some changing guidelines on this thing, but it's being addressed. The feedback I've been getting, it's been well-received by the community but the intent really

is to look at every one of these facilities, some way, somehow in the near future. But that doesn't -- we're really not addressing the radiation safety issue. I think we actually say we defer to other authorities to address that along with the drug quality and purity issues.

CHAIRMAN MALMUD: DR. Sulieman, is it the issue that we're discussing now, for example, the products that are being produced at Washington University, those are not being produced to be administered to patients as pharmaceuticals, currently. They're being produced for research purposes. Is that not true, Dr. Schwarz?

DR. SCHWARZ: That's correct.

MEMBER SULEIMAN: But they're still being administered to subjects. Now, there's --

DR. SCHWARZ: No, no, they're being administered to animals.

MEMBER SULEIMAN: Oh, okay.

DR. SCHWARZ: These are not human use.

CHAIRMAN MALMUD: These are not for human use.

DR. SCHWARZ: No, that's what I'm saying, that this type of research involves production of isotopes that are not going into humans. We do do

clinical research. That's a separate issue but the radioisotopes that we're talking about are not going into humans.

CHAIRMAN MALMUD: So that to try again to be helpful to you, Ralph, it might be useful to continue to use the term non-commercial distribution and then without having too much -- without having additional material on this slide, amplify that by saying, "Well, for example", I'll say it again, "At the Mallinckrodt Institute at Washington University in St. Louis PET products are produced for shipment to various other research and development centers throughout the United States where they are doing research including animal studies in the course of developing products which will eventually be used in humans but are not yet being used in humans". Will that summarize it well? Does that satisfy both DR. Sulieman's concern and Dr. Schwarz?

DR. SCHWARZ: DR. Malmud, I think too the PET -- rather than saying "PET products", the PET radionuclides would probably be --

CHAIRMAN MALMUD: PET radionuclides.

DR. SCHWARZ: -- be preferred.

CHAIRMAN MALMUD: The term PET radionuclides is preferred to PET products, otherwise

we'll be thinking of Hartz Mountain or something. Dr. Miller.

DR. MILLER: In the interest of continuing -- to look at the time and in the interest of continuing to advance us through his presentation, I just would like to follow up a little on what Mr. Essig said and maybe relieve a little anxiety of the committee, the bullets that Ralph will have on his slides, I mean, the way the Commission does business, it will help tee up the issue. What he says to those bullets is what's important and I remind everybody al Commission meetings are transcribed, so everything he says will become a matter of public record.

MEMBER LIETO: Everything here is.

DR. MILLER: Just as it is here, yes.

DR. SCHWARZ: Not to make you nervous, Ralph.

DR. MILLER: No, it's not to make him nervous but I think the important thing is if he talks to the bullets and gets these points out, then I think your views will be a matter of record.

MEMBER LIETO: Is everybody comfortable then with these bullets and then I guess I'll, for the sake of time, move onto the next one?

MEMBER SULEIMAN: You might also want to

write out what you're going to say and -- but not -- have it different from what the bullets are.

MEMBER LIETO: Yeah, yeah, that's going to be part of the preparation, yeah. Now, this next slide addressed some concerns that were raised regarding this very aggressive implementation schedule for formulating the regulations in an 18-month period and that the time period that's available for licensees to submit new licenses and NRC regions to review these will effect almost every location that has mobile PET facilities because this will now be a new area of regulatory use by licensees so there will be a large number of license amendments that will be coming in to the regions.

And I have a sub-bullet on here which I think I'll strike and just include in the amplification that because of the non-agreement states that have not been regulated -- excuse me, non-agreement states with PET facilities that have not been regulated, there's going to have to be licensing guidance developed and that really needs to be available at the effective date of the rules so that the licensees can implement this.

The other bullet is that I think needs to be made -- the Commission needs to be made aware of is

that there's going to be a real paradigm shift at the inspection and enforcement levels especially in non-agreement states. The agreement states probably have seen this, in terms of the much higher hand and body doses from PET use. And I think routinely, for non-PET facilities, staying below the 10 percent dose limits has not been a difficulty, even in very large and busy nuclear medicine facilities. But with increased PET use that we're now seeing the above 10 to 30 percent range in terms of doses to nuclear medicine personnel and research personnel, dealing with PET pharmaceuticals so -- and drugs.

So that was a point to make the Commission aware of. This is more a question for the committee in terms, is there other issues in terms of, you know, maybe unforeseen major conflicts with the proposed rules that anybody on the committee here thinks needs to be put into this last slide for the --

CHAIRMAN MALMUD: DR. Vetter?

MEMBER VETTER: Ralph, I'm not sure why you're bringing that second point to the Commission's attention. Why would they need to know about that? That's something, Inspection and Enforcement is aware of, I think, and it's important for them but I don't know, why would the Commission need to know that?

MEMBER LIETO: I think just in terms of -- because something that is not routinely seen in the -- by Inspection and Enforcement in the non-agreement states. In the agreement states where PET is being used, you know, this is pretty well recognized but they haven't been looking at this in their inspection and enforcement in the non-agreement states.

MEMBER VETTER: So what's the Commission going to do about it?

MEMBER LIETO: I think it's just a matter of letting them know that you're going to start seeing the bar in terms of doses to workers from these activities in terms -- that they're going to start regulating be higher.

CHAIRMAN MALMUD: Malmud. If I may, it might be best to focus more on the material that you presented earlier and not bring in this topic at all at this meeting, so that the emphasis which you developed so well in the first several slides can be maintained on the availability of PET radionuclides for the continued research and development with continued flow from both commercial and non-commercial producers to those organizations that are advancing the science.

MEMBER LIETO: I guess, does NRC -- I

guess I'd ask the NRC staff. Is this something that they think the Commission would want to be made aware of or not?

CHAIRMAN MALMUD: DR. Miller?

DR. MILLER: Yeah, just an observation. If you present that, the next question they're going to ask you is, then is the proposed regulation flawed or should there be some other feature added to it to address this concern, because the focus, the focus of the meeting is going to be on the Energy Policy Act and the specific focus here is going to be on an ARM regulation that we're proposing. So that's where they're going to go with that.

MEMBER LIETO: So I'll strike it.

DR. MILLER: Yeah, I mean, if you do believe as a committee that that's something that's flawed in the proposed rule that needs to be addressed, that's one thing. If not, it may be best to address it in some other form.

CHAIRMAN MALMUD: Thank you. Dr. Williamson?

MEMBER WILLIAMSON: If memory serves, I think the regulatory guide for the -- that talks about the ALARA program has been liberalized or made more flexible so I think one is not restricted to the 10

percent level for ALARA. Is that correct? Because obviously, 10 percent is not going to work in this field. That's the underlying concern I'm sure that Ralph has.

MEMBER LIETO: That is correct.

DR. SCHWARZ: I think one of the -- I think exactly, this is a problem with PET because it is a new field and as far as enforcement and inspection, this will be something that they will see that it's certainly different than traditional nuclear medicine. As far as the Commission, they probably don't particularly care about this. I mean, it's not that they don't care, but that they are more interested in licensing these facilities and the overall impact of that licensing phenomenon that has not happened before. That's probably a more important area for us to discuss.

MEMBER LIETO: Are there other issues then, that any of the committee would like --

CHAIRMAN MALMUD: DR. Williamson, were you going to raise another issue?

MEMBER WILLIAMSON: Well, I was thinking, perhaps what Ralph could say is that this isn't having -- you know, acknowledge that this is not in the regulation space but that if Inspection and

Enforcement, you know, proceeds with the same attitude and practices as in the non-PET arena, that could cause substantial difficulties, you know, in the regulated community that might you know, hinder the delivery of medical services or research without any concomitant gain in public safety, that it is so different that there's really going to be a learning curve here for NRC and they should be prepared.

CHAIRMAN MALMUD: DR. Vetter?

MEMBER VETTER: Personally, I do not think this belongs in the discussion with the Commissioners. I don't disagree with what Jeff's saying but I think that's a different subject all together and the NRC will learn about it and if there's problems, we'll deal with it at that time, but I don't think it belongs here.

MEMBER LIETO: Okay. Then I guess, not hearing any other issues are thoughts to be made then, on the accelerator?

CHAIRMAN MALMUD: I didn't hear the last part of what you said, Ralph, I'm sorry.

MEMBER LIETO: I'll strike that second bullet that's up there and I don't -- I don't see any other hands for any other issues to add to this slide in terms of other points to be made on the --

CHAIRMAN MALMUD: I think that the committee agrees with you.

DR. SCHWARZ: Ralph, maybe what you want to do is instead of having that license guidance in the indentation, make it a bullet point because that, I see, as a huge issue. We really do need guidance. Possibly this is available through agreement states, that they have guidance on licensing these facilities because it's not clear that this is going to be an easy thing to do, asking questions, I have been asking questions and certainly we need guidance and I'm hoping that that could be kind of a bigger focus.

MEMBER LIETO: All right, the next slide had to do with the Energy Policy Act regarding discrete sources. And radium has a very long medical history and so I was asked to address the discrete sources in terms of medical -- from a medical perspective and basically I was going to make the comment that Radium 226 discrete sources are obsolete for medical clinical use. This is cited in American College of Radiology Policy Statements and reaffirmed. I've got a copy of what the statement actually states and I can actually put that forth in terms of the expansion on that point.

And that to address a potential question

by the committee, are there any other expected naturally occurring radioactive materials discrete sources that present a similar hazard as Radium 226 on the horizon for medical or clinical use? That there are not any such sources in the foreseeable or probable future. So the next point would go to discrete --

CHAIRMAN MALMUD: Excuse me, I think Dr. Nag wanted to make a comment.

MEMBER NAG: Yeah. Although it's true that Radium 226 is obsolete, there are still some centers that may have old Radium 226, so you're not totally (indiscernible).

MEMBER LIETO: That's in my next slide. That the quantity is right now unknown what the quantity in terms of number and activity.

CHAIRMAN MALMUD: You need to use the microphone.

MEMBER LIETO: Oh, I'm sorry. In the next slide under discrete sources in general, the quantity of unknown radium sources is -- in terms of activity and number is unknown because these fall far below that IAEA Code of Conduct inventory thresholds and they fall also below the DOE disposal thresholds for disposal at these sites. There are a large number of

unwanted brachytherapy sources. These are sealed sources of -- including cesium, strontium-90 as well as other radium sources and that this problem may need some type of increased funding so that in the aggregate they might be collected under the DOE collection and disposal mechanism. And so that there is in terms of the medical side, in terms of both the discrete sources under the Energy Policy Act as well as an increasing number of unwanted sealed sources needing disposal but because of cost and it's sometimes just a lot easier to inventory and store these that licensees are having difficulty getting rid of them.

CHAIRMAN MALMUD: DR. --

MEMBER WILLIAMSON: Jeff Williamson here. I don't see -- this legislation or regulation has no impact on materials currently defined as by-product materials. So while this may be a problem, I think it's -- I wonder if it's not irrelevant to the topic at hand, and so the only issue is the additional cost burden imposed by new requirements possibly for the disposal of radium sources, right?

MEMBER NAG: Yeah, I had the same comment, that this second part has no relevance to the presentation for today.

CHAIRMAN MALMUD: DR. Vetter?

MEMBER VETTER: Yes. I agree with those last two comments entirely.

CHAIRMAN MALMUD: Mr. Bailey?

MEMBER BAILEY: I don't think the Energy Policy Act is going to effect either the availability or the cost of disposing of radium. So, it's sort of neutral. Right now you can't dispose of it but at one place and since they've got the corner on the market, they charge what they feel is appropriate. So whether or not this act is ever passed or not I don't think has any impact on the cost of radium disposal.

MEMBER LIETO: Well, I don't think it's intended to effect the cost. The comment is meant to address the fact that there are there sources out there. We don't know how many there are. Even if we find out how many there are and where they're at, they probably cannot get rid of them, okay, and that if you look at that as a discrete source in addition to from the medical perspective other unwanted sealed sources in the aggregate, this may be a larger issue that needs to be addressed in terms of getting these to be -- to fall into a mechanism for DOE disposal.

CHAIRMAN MALMUD: Ralph, the feeling that seems to be coming from members of the Committee is

that it may be better to spend the majority, if not all the time, in a discussion of the issues of PET radiopharmaceuticals because that is the most pressing issue at the moment and that to bring other issues into the Commission at this time would detract from what is obviously a major concern of all people in nuclear medicine at the moment regarding these new regulations.

MEMBER LIETO: Do you want me then to strike this second bullet and move the first one up to the other slide?

CHAIRMAN MALMUD: I would strike the subjects other than those related to PET radiopharmaceuticals completely and focus on that. I meant, this is our opportunity. This is our opportunity to make our presentation and least from the phone calls and the discussions that have been coming my way, everyone seems most concerned about PET radiopharmaceuticals, their availability, and interest in not creating regulations which would slow down research and development and which would create burdensome, expensive procedures which are unnecessary for their regulation. And those are the expressions that are coming to me

So the anxiety is that nothing occur which

interferes with this very productive area of research and development.

MEMBER LIETO: I don't think this would effect anything with the PET. I think it addresses a part of the Energy Policy Act that I've been asked to address and it does include these discrete sources for radium. So if I don't address it, there's no one else that's going to be addressing it and it's going to probably come up. That's why it's on there.

CHAIRMAN MALMUD: All right, well, obviously, Mr. Bailey has something to say.

MEMBER BAILEY: Yeah, I think you're right and I would ask, you know, NRC staff. I think one of the concerns, at least at the staff level at NRC is how many of these sources are there still out there? Are we going to have a problem regulating radium sources. While they feel they know radium use an agreement states NRC really didn't have a handle on it. So I think the first two bullets would be very informative for the Commission that --

CHAIRMAN MALMUD: The previous slide.

MEMBER BAILEY: Yeah, the previous slide, that, hey, this is an obsolete practice and you don't expect any other norm sources and maybe the first bullet here on the last slide that the inventory is

unknown.

CHAIRMAN MALMUD: Let's say that -- for the purpose of discussion let's say that this is going to come forward. What are we really recommending? We're stating number 1, that these sources are no longer clinically relevant. That they exist and that we don't know how many there are. So we would recommend, therefore that they be inventoried and an estimate be made of the cost of recovering them. Is that a fair summary?

MEMBER BAILEY: That's taking it on, yeah.

CHAIRMAN MALMUD: Tom?

MR. ESSIG: Or you could argue that the committee doesn't have a position at all because it's an old -- it's an outmoded technology and -- but I think Ralph is -- the reason that he has this on here is for completeness. If the committee was silent on radium, then the Commission would wonder if you just hadn't -- if you had inadvertently not -- you know, left it off the agenda or didn't understand that you were supposed to address the complete suite of radioactive material that's in the Energy Policy Act. So I think for completeness, it's not to dwell on it but just to recognize that it's small. It's not even on the committee's radar screen, is I think the point

you want to make. Not in those terms but in essence that the committee doesn't have any concern.

So you don't even have to necessarily formulate a recommendation would be my thought but just recognize --

CHAIRMAN MALMUD: The committee wants to alert the commission to the fact that Radium 226 is no longer used clinically. There are a number of discrete sources out there. We don't know what the inventory is. The Commission may be interested in this, period.

MR. ESSIG: And I think one other fine point there is that if you can say this, that you believe that the -- although the inventory is unknown, you believe most of the sources, the individual sources in the inventory to be less than IAEA Category 2 or that most of them are in the Category 3 to 5 range.

CHAIRMAN MALMUD: So then on one slide we say it's a matter of information. We'd like to inform the Commission that there are a number of obsolete Radium 226 discrete sources which are of unknown quantity but whose activity is below regulatory --

MR. ESSIG: The Commission is attuned to the Code of Conduct, so I would work that into your --

I'd say IAEA Code of Conduct less than -- you can either say less than Category 2 or you can say are in the Category 3 to 5 range.

CHAIRMAN MALMUD: All right, and not even suggest that they may want to inventory them, just to inform them that we're aware that they exist.

MR. ESSIG: Right, you don't even have to use the word "Inventory".

CHAIRMAN MALMUD: Okay, so it's just a one slide matter of information. So it's a -- it's almost like a sidebar note.

MR. ESSIG: Yes, yes, just for completeness.

CHAIRMAN MALMUD: We'd like to inform the Commission of the presence of a number of obsolete Radium 226 discrete sources, period. Now, it looks as if the majority of the presentation is going to be focused on the issue of PET pharmaceuticals. Ralph, do you have direct experience with PET pharmaceuticals? Are you a hands-on person with them?

MEMBER LIETO: Well, yeah, but not probably in the quantities and number that probably Sally is.

CHAIRMAN MALMUD: Is any of the institutions you're covering actually producing any --

MEMBER LIETO: No, we don't have production facilities, just use.

CHAIRMAN MALMUD: It seems to me -- I'm a little embarrassed by this because I've created this situation but it seems to me if that's going to be the major focus, would we have more credibility having a representative to the NRC discussing this issue who's actually hands-on producing it and could answer questions that might come up which others of us might have knowledge of but be totally inexperienced with?

What do you think about it, Ralph? Would you be more comfortable that way?

MEMBER LIETO: I have no problem with that.

CHAIRMAN MALMUD: Sally, would you be comfortable feeling with this?

DR. SCHWARZ: (Nods head)

CHAIRMAN MALMUD: Perhaps after this meeting, the two of you can get together and switch roles in this capacity, and I say it not because Ralph in particular or any of us could not address this issue from an intellectual standpoint, but there's a distinct advantage to having someone who's actually hands-on working with the subject which will be the major focus of discussion being there as the front

person for this subject.

I must apologize for having asked you to do all this work which you have done very well.

MEMBER LIETO: Paybacks are going to be a bummer, DR. Malmud.

CHAIRMAN MALMUD: I beg your pardon?

MEMBER LIETO: Paybacks will be a bummer.

(Laughter)

CHAIRMAN MALMUD: We'll have to figure out something that's affordable.

MR. ESSIG: And DR. Malmud, just to put you a little at ease, when we had a phone conversation to this effect, I believe that we thought it would be a broader issue --

CHAIRMAN MALMUD: Yes, we did.

MR. ESSIG: -- and it was very instructive to walk through these slides and get the committee's view so that we can see that it was really narrowed to the main concern being PET. So --

CHAIRMAN MALMUD: It wasn't that in the beginning.

MR. ESSIG: No.

CHAIRMAN MALMUD: Because I remember discussing it in the beginning and saying, "Well, you know, if it's going to be PET then we really should

ask Sally but it turns out that it really is PET. All right, I thank -- first of all, I humbly thank Ralph and secondly, I appreciate your willingness, Sally, to transition this with Ralph. Thank you.

MR. ESSIG: Is Sally available on the 15th of May?

DR. SCHWARZ: I will be available and I appreciate the offer actually to talk to the Commission. I really look forward to it.

CHAIRMAN MALMUD: DR. Miller.

DR. MILLER: To maybe set the committee further at ease, or to set you further at ease, if you remember yesterday in the presentation on the Energy Policy Act and our rulemaking, we said that there would be another public meeting at some future date in the near future. That could also be an opportunity, if the committee wants to, to have a representative or more than one or the whole committee if you want to come, available to make any comments that you want to make in that forum also.

So if something comes up in the Commission meeting that perhaps falls outside of the realm of what Sally has presenting, that's another opportunity we can take to tell the Commission, you know, we'll make sure that ACMUI addressed that at the public

meeting, if that's okay.

CHAIRMAN MALMUD: Thank you. Mr. Essig.

MR. ESSIG: And one more comment, if I may regarding the schedule.

CHAIRMAN MALMUD: I'm still pondering what the payback is going to be to Ralph.

MR. ESSIG: We have -- Item 17, which is our last item, we had allocated 45 minutes and in my off-line discussion with Mr. Saba, he informs me that he only needs 10 or 15 minutes and he doesn't have much more than that, which is a good thing.

MR. SABA: I have only a few items to discuss with you. The first item is to highlight all the items that I could put together, the actions and recommendations. The first action was the committee action on the by-laws. The by-laws, you suggested some of the -- thank you. You suggested some of the changes. The changes would be incorporated in the by-laws and be ready for the next meeting to be voted on.

The second action was on the Dr. --

MR. ESSIG: Mohammed, before we leave that item, we should decide before we leave today on a date for a telephone conference call to discuss the by-laws, plus the Part 35 rulemaking activities we didn't get to. So if people would have their calendars ready

before we adjourn. And I'm thinking that we ought to maybe set it for maybe sometime maybe a month hence, one month hence. We have to have maybe a couple week lead time to get the notice in the Federal Register but something on the order of a month from now is what I would be thinking to discuss the by-laws and the Part 35.

And we would -- and in response to Dr. Nag's suggestion, we would certainly allow enough time in the call to make sure that we can cover everything.

CHAIRMAN MALMUD: A two-hour conference call?

MR. ESSIG: As a minimum.

MEMBER NAG: I think while we are working on that, we should also work on our fall meeting when (indiscernible) because that's always a problem.

MR. ESSIG: Yes, and then we'll propose a couple of different dates say in October. Okay.

MR. SABA: Okay, the second action was on the risk -- it was decided Mr. Lieto would work with DR. Sharbiti (phonetic) to --

DR. SCHWARZ: Excuse me, could you use the microphone?

MR. SABA: Sorry, to guidelines in the risk regarding minor and pertinent women acting as

caregivers to hospitalize therapy patients. The third action was regarding training and experience in -- authorized for an authorized user who is seeking sole status. We sent two letters to the ABR, one for the diagnostic ABR and one for the oncology section to address this and before we sent the letter, we give it to -- we sent it to DR. Malmud and DR. Diamond to be reviewed.

The third -- the fourth --

CHAIRMAN MALMUD: DR. Williamson has something to say about that.

MEMBER WILLIAMSON: If memory serves, the issue was not just the authorized user becoming an RSO but I think to point out to them that none of the diplomates of the American Board of Radiology and Radiation Oncology could use their -- prior to what is it July 1, 2007, could use their certificates to become an authorized anything. That they would all have to go through the alternative pathway and did the ABR understand the implications of the way they answered the NRC's questions.

MEMBER EGGLI: DR. Malmud, I would actually like to see the one for diagnostic radiology. I think David Diamond's primary interest was for radiation oncology and although diagnostic radiology

isn't represented on this committee, I'm as close as it comes being both a nuclear medicine physician and a diagnostic radiologist.

CHAIRMAN MALMUD: And we will share that with you. Mohammed, would you also copy DR. Eggli when you communicate with Dr. Diamond and with me.

MR. SABA: Sure.

CHAIRMAN MALMUD: Thank you. It shall be done.

MR. SABA: The next action was on the ACMUI review of medical inventory of Iodine -- I'm sorry, involving Iodine 131, DR. Eggli's presentation. The Stafford Center and I answered them with this regard. Is there anything else that should be done, something mentioned about Nuclear Medicine Society or --

CHAIRMAN MALMUD: I didn't hear the last several sentences.

MR. SABA: Oh, something else was said, I don't remember exactly.

MALE PARTICIPANT: That was, I believe an outreach to the certified technicians.

MEMBER EGGLI: Right, to the certification board which is the American Registry of Radiology Technologists for Nuclear Medicine and the

certification board for Nuclear Medicine wants AART(n) and the second one is NMTCB.

MR. SABA: Thank you. That there were a few actions on Dr. Howe's presentation on potential to 10 CFR Part 35, potential changes. All of them -- not all, most of them have been approved by the committee. That's all I remember. And in terms of recommendations, there is only one I have no my list as regarding training and experience for microsphere for the use of microsphere.

CHAIRMAN MALMUD: Yes.

MR. SABA: For therapy, revised guideline to permit 35.390 physicians as authorized users for Y-90. If you don't have anything on this, I'll go to the next item which is the dates for the next meeting.

DR. ZELAC: Excuse me.

CHAIRMAN MALMUD: DR. Zelac.

DR. ZELAC: If I can make one change to one of the items you mentioned and mention another which I believe you skipped, concerning the regulatory information summary, there was a motion, my notes say, that was approved which provided six elements that ought to be included and that was not simply for pregnant women and minor caregivers but for any caregivers and that's the distinction I'm making.

CHAIRMAN MALMUD: DR. Zelac is correct.

DR. ZELAC: Secondly, we had the presentation from North American Scientific. I believe there was a formal motion, it was approved that it would be all right for a device of that type to file a 35.75 guidelines.

CHAIRMAN MALMUD: That is correct also. Thank you, DR. Zelac.

MR. SABA: Okay, for the next -- for the fall meeting, I have a few days; October 17th, October 18th, that's one, 17th and 18th.

CHAIRMAN MALMUD: 17th and 18th, what days of the week is that?

MR. SABA: Tuesday and Wednesday.

DR. ESSIG: And Dr. Miller just informed me that he'll be in Vienna that week, so that probably won't work for him.

MR. SABA: Okay.

MR. ESSIG: And not Vienna, Virginia.

DR. MILLER: I'm the United States representative to IAEA's radiation safety committee so that's the -- we have a meeting every six months and that's the week that they've picked for the meeting. I know several good restaurants, yes.

MR. SABA: How about the 24th and 25th.

Are you going to be here?

DR. MILLER: Yes.

MR. SABA: Is that a good date, the 24th and 25th.

CHAIRMAN MALMUD: October 24th and 25th. Is there anyone on the committee for whom the dates of October 24th and 25th is not convenient? It looks as if you have a date. Excuse me.

MR. ESSIG: And we need to be mindful of an alternate date so that in the event that the chosen facility is not available on the 24th and 25th that we have a backup date. How does the week of the 9th of October.

CHAIRMAN MALMUD: 24th and 25th is okay for me.

MEMBER NAG: What about just (indiscernible) either later in the week, you know, 24th, 25th, 26th, 27th?

MEMBER NAG: Normally when the facility is unavailable to us the other advisory committee typically has it for the week.

MEMBER NAG: Oh, for the whole week?

CHAIRMAN MALMUD: Yeah, for the whole week.

MR. ESSIG: October 10th and 11th would be

two weeks prior.

CHAIRMAN MALMUD: Yes. 10 and 11 okay?

MEMBER NAG: I don't know how many people are going but the radiation -- the European Radiation Oncology meeting is on those days.

CHAIRMAN MALMUD: The European meeting. You're attending that?

MEMBER NAG: Probably, yes, maybe.

CHAIRMAN MALMUD: So our first preference is October 24/25. And it looks as if we're squeezed with respect to other dates.

MR. ESSIG: Or the first week in October, is that --

CHAIRMAN MALMUD: The first week in October would be the 10th and 11th.

MR. ESSIG: No, that's the week we were just talking about. It would be the week of the 2nd. Yom Kippur is on a Monday so we would want to maybe have it later in the week if that week is -- I'm just looking for alternatives.

DR. MILLER: I don't like that first week.

CHAIRMAN MALMUD: No, the first week won't work.

DR. MILLER: One of the hardest things that we have is getting everybody to find a date that

works.

CHAIRMAN MALMUD: Well, the 24th and 25 works.

DR. MILLER: Works, now the question then becomes --

CHAIRMAN MALMUD: Is the NRC building available.

DR. MILLER: Yeah, and why don't we look into it and see if it's available.

FEMALE PARTICIPANT: (Inaudible)

DR. MILLER: Yeah, what we find sometimes is that even though it's available sometimes things happen anyway and like this time, they decided to do construction on the room, that's why we couldn't get in there this week. They're doing some remodeling.

CHAIRMAN MALMUD: If the NRC facility is not available, wold it be possible to use the Marriott across the street? Getting into this facility took 27 minutes in line yesterday through security. For some reason, this morning was much more efficient, but I would prefer to remain off of this campus, if possible.

DR. MILLER: We could look into it. One of the dilemmas that we have being federal officials are we have to look for the cost effective way and if

there's something that's more economical, then we'll push our administrative groups to do that and --

CHAIRMAN MALMUD: We understand.

DR. MILLER: I know we had it there at one point in time.

MR. ESSIG: And it was very pricey.

DR. MILLER: And it's pricey yeah, and we have to look into it, but we could look into an alternative venue that's in that very near vicinity maybe that's not pricey and so you don't have to go through the long security lines.

I mean, it's a disadvantage for us, too, because a lot of times the staff or the Commissioner's staff like to come down and hear certain sessions and when we have to do it too far removed from the NRC building, that makes the commute a little bit more troublesome. It also inhibits the same problem. We want to make sure the venue is completely accessible to the members of the public.

MR. ESSIG: And the other consideration, incentive for us to have it in our facility is that then we can video conference with our regions, which we had told them we would do whenever possible and when we meet here, we can't.

MALE PARTICIPANT: When will you inform us

of this date?

MR. ESSIG: We'll go to work on that right away.

CHAIRMAN MALMUD: We'll keep the 24th and 25th blocked out.

DR. MILLER: We should be able to get you an answer within a week.

MEMBER NAG: If it would help, I mean, (indiscernible) I'm willing to skip the European meeting.

DR. MILLER: Okay, and the week of the 24th and 25th, are there any blackout dates that week or, you know, if the room is available later in the week versus early. We try to avoid Mondays and Fridays for you but --

CHAIRMAN MALMUD: Very good. Any other housekeeping items?

MEMBER NAG: The telephone conference call?

CHAIRMAN MALMUD: Yes, the telephone conference call, are there -- that we would propose within the next month or so, a month from today. So are there -- it has to be at least two weeks from now but --

MR. ESSIG: The 25th and the 26th of May?

CHAIRMAN MALMUD: Friday is not a good day for me for a conference call. Tuesday or Thursday would be better.

MR. ESSIG: Tuesday or Thursday so it would be the 23rd or the 25th?

CHAIRMAN MALMUD: 23rd or 25th, which one?

MR. ESSIG: How does that sound for --

MALE PARTICIPANT: Depending on the time of day.

CHAIRMAN MALMUD: It's the afternoon as a rule.

MR. ESSIG: Which is better for the committee, morning or afternoon?

CHAIRMAN MALMUD: Afternoon.

MEMBER NAG: Probably afternoon because the West Coast will be three hours behind so afternoon here would be morning over there for you.

CHAIRMAN MALMUD: 4:00 o'clock? The meeting may run long, so you would prefer, perhaps 2:00 o'clock.

MR. ESSIG: 2:00 o'clock if we could, yes.

CHAIRMAN MALMUD: 2:00 o'clock Eastern whatever time it is then. It's still daylight. 2:00 o'clock on what date?

MALE PARTICIPANT: Could we do 3:00 as a

compromise?

CHAIRMAN MALMUD: 3:00 o'clock, what date?

MALE PARTICIPANT: The 23rd or the 25th.

MR. ESSIG: Does the 25th work better for you because everybody else was okay with either date?

MALE PARTICIPANT: The 25th is really bad.

MR. ESSIG: Really bad, okay.

CHAIRMAN MALMUD: 5/23 at 2:30? Ralph, how is that for you?

MEMBER LIETO: I'm at the Committee's pleasure.

MALE PARTICIPANT: So how much time should I allocate for it, two hours?

MR. ESSIG: I would say let's allocate three and maybe not have to use it all, from 2:30 to 5:30.

CHAIRMAN MALMUD: Two hours is long enough.

MR. ESSIG: Or let's compromise and say 2:30 to 5:00.

CHAIRMAN MALMUD: Two and a half hours.

MR. ESSIG: 2:30 to 5:00. So on the 23rd, 2:30 to 5:00 Eastern time.

CHAIRMAN MALMUD: So we have two meetings tentatively set up. One is a telephone conference

call May 23rd at 2:30 and the next is the tentative next scheduled meeting for October 24th and 25th, hopefully at the NRC headquarters, if not somewhere else in the Washington area.

MR. ESSIG: Yes.

CHAIRMAN MALMUD: Any other items?

MR. SABA: Just to remind you to give me the time sheets and travel expenses.

CHAIRMAN MALMUD: Will do. We are asked to turn in our time sheets. We shall. Any other items?

MEMBER BAILEY: That's it.

MR. ESSIG: Let me just, also in the way of housekeeping activity or bookkeeping activity, when a time sheet is turned in more than six weeks after the end of the pay period, we have to provide additional justification as to why it's late. Now, I realize in some instances it may not be the particular individual's fault and the fax maybe didn't come through or something, but that is a goal that we try to adhere to where we have it within six weeks of the close.

I mean, ideally, if you can give it the next pay period, it would be great, but we try to have it not more than six weeks because then I have to

write a memo to fairly high level.

CHAIRMAN MALMUD: Mr. Lieto?

MEMBER LIETO: Is there some way that we can --when we submit this is getting a confirmation that it's been received? Because I sent something in both via fax and hard copy mail and it didn't get processed. And I think the assumption is we faxed this in and it's getting handled and so forth. Is there some mechanism so that, you know, either via e-mail or some type of -- something that, you know, "Got your information", because if we don't get it, we can then assume you didn't get it and then follow up on it. But right now the assumption is no news is good news and I think that's not a very safe assumption.

DR. EGGLI; I have an even more interesting situation. Since we've gone to direct deposit, not a penny has been deposited in my checking account. However, I did get a W-2 and had the privilege of paying income tax on the money I did not receive.

MEMBER BAILEY: I've got one better, I got a W-2 and didn't receive any money, period.

MEMBER EGGLI: Well, that's exactly what happened to me, I got no money but I had to pay taxes on the money I didn't get.

CHAIRMAN MALMUD: Thank you all for the time, the effort and for being here and participating and we wish you a safe trip home and look forward to speaking to you on the conference call in May and seeing you well, and well-rested after the summer at the meeting in October. Thank you all.

(Whereupon, at 12:02 p.m., the above-entitled matter concluded.)

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