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UNITED STATES OF AMERICA

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

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SPEAKERS AND PARTICIPATING NRC STAFF:

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I-N-D-E-X

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Adjourn	

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

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

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

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

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

1 The other thing is that if the
2 technologist even looked at the label on the capsule,
3 they would have noted that the amount of iodine
4 contained within the capsule was greater than
5 30 microcuries and required a written directive. So
6 there are two issues. One is the initial order didn't
7 require a written directive, but the amount of iodine
8 that was actually administered would have required a
9 written directive, and the tech did not look for a
10 written directive.

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

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

1 process.

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

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

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

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

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

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

1 Blood.

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

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

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

1 Jeff?

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

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

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

15 MEMBER EGGLI: I think that for -- I don't
16 think that -- Donna-Beth, do you know, in 200, is
17 there a -- because these are all 200, most of these
18 are 200 errors. Is there a requirement in Part 35 for
19 200?

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

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

3 MEMBER EGGLI: Okay.

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

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

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

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

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

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

8 Incident 5, a 19-year old patient was
9 diagnosed with Grave's Disease and was administered a
10 12.5 millicurie dose instead of the prescribed dose of
11 12 microcuries. However, the clear intent of the
12 procedure was to ablate the thyroid gland. And,
13 actually, the physician who wrote the prescription
14 wrote "microcuries" instead of the intended
15 "millicuries." So the patient actually got the
16 intended dose, but it wasn't the dose that was
17 actually ordered.

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

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

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

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

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

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

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

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

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

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

3 So I think we have a couple errors here.
4 One error is ordering an iodine dosage at the request
5 of a physician who is not an authorized user. The
6 second, again, is not reviewing a written directive,
7 which apparently didn't exist in this case, not
8 reviewing a written directive when administering a
9 dose that the technologist was aware was greater than
10 30 microcuries.

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

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

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

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

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

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

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

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

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

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

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

15 And again, as we go back and look over the
16 events, it doesn't matter what dose was ordered. If
17 the technologist knows at the time of administration
18 that the dosage they are administering is greater than
19 30 microcuries, based on a label, based on putting it
20 in a dose calibrator, based on whatever reason the
21 tech knows that the dose is greater than 30
22 microcuries, then they have an obligation to verify
23 the written directive.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

12 MEMBER WILLIAMSON: Now, in looking at
13 35.41, it appears that procedures need to be in place
14 -- it's not specified exactly what -- for identifying
15 the patient or human subject. In the case where a
16 written directive is required, but there are no --
17 there is no such requirement for the standard 35.200
18 cases where a written directive is not required.

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

22 MEMBER EGGLI: No.

23 MEMBER WILLIAMSON: -- imposed on 35.200?

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

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

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

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

22 CHAIRMAN MALMUD: Dr. Miller.

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

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

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

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

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

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

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

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

23 DR. MILLER: Right.

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

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

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

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

1 comply with departmental policy.

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

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

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

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

1 user on the dosage ordered.

2 CHAIRMAN MALMUD: Dr. Suleiman.

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

7 CHAIRMAN MALMUD: Dr. Suleiman.

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

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

25 But how we change that is a different

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

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

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

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

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

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

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

16 CHAIRMAN MALMUD: Dr. Nag.

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

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

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

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

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

23 CHAIRMAN MALMUD: Dr. Williamson.

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

1 35.41 requires both things. It's a requirement
2 whenever more than 30 microcuries is given. I think
3 the recommendation has to focus on the issues of
4 attention to detail, being able to recognize when the
5 unexpected occurs, when -- that may be another aspect,
6 that it might not be willful negligence.

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

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

16 CHAIRMAN MALMUD: Mr. Essig.

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

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

1 it in either or both of those.

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

7 MEMBER EGGLI: Right.

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

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

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

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

5 CHAIRMAN MALMUD: Yes. Dr. Schwarz.

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

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

1 with that dose calibrator.

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

7 CHAIRMAN MALMUD: Dr. Howe.

8 DR. HOWE: I think it might help if you
9 look at our regulations. And Jeff is right, we do
10 have current regulations in place for the greater than
11 30 microcurie requirements for written directives.
12 But perhaps the focus needs to shift to 35.27, which
13 is supervision. And I think in my mind many of these
14 that were supposed to be diagnostic, they were given
15 therapeutic.

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

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1 flag does become a red flag.

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

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

17 CHAIRMAN MALMUD: Mr. Bailey.

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

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

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

9 MEMBER EGGLI: And that data is not
10 available.

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

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

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

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

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

18 CHAIRMAN MALMUD: Thank you, Mr. Bailey.

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

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

1 do seven to ten a week.

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

4 MEMBER EGGLI: Seven to ten.

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

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

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

1 for uptakes, I assume.

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

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

12 MEMBER EGGLI: No, it would not.

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

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

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

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

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

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

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

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

1 not.

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

10 CHAIRMAN MALMUD: Dr. Suleiman.

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

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

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

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

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

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

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

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

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

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

25 MEMBER EGGLI: Ralph has a comment.

1 CHAIRMAN MALMUD: I'm sorry?

2 MEMBER EGGLI: Ralph has a comment.

3 CHAIRMAN MALMUD: Ralph. Excuse me.

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

12 CHAIRMAN MALMUD: Thank you.

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

25 I was just trying to think of how we could

1 simplify this for those who are dispensing the
2 pharmaceutical.

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

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

14 CHAIRMAN MALMUD: Thank you, Dr. Eggli.
15 Dr. Williamson?

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

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

24 MEMBER EGGLI: Mine is over here.

25 (Laughter.)

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

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

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

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

23 Dr. Miller.

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

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

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

7 CHAIRMAN MALMUD: You're on.

8 DR. MILLER: I do.

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

11 DR. MILLER: Okay.

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

15 DR. MILLER: Depending on the state.

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

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

1 DR. MILLER: Okay.

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

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

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

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

25 DR. MILLER: Okay.

1 CHAIRMAN MALMUD: Thank you again.

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

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

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

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

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

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

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

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

23 MEMBER WILLIAMSON: Second.

24 CHAIRMAN MALMUD: Dr. Williamson. Any
25 further discussion?

1 (No response.)

2 All in favor?

3 (Chorus of ayes.)

4 Any opposed?

5 (No response.)

6 Any abstentions?

7 (No response.)

8 It's unanimous. Thank you very much.

9 Mr. Essig.

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

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

25 So we can either go ahead with the

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

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

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

17 CHAIRMAN MALMUD: Thank you.

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

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

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

12 300 are two iodine-131 events. In both
13 cases multiple capsules were intended, and the total
14 number of capsules administered to the patient were
15 less than those that were sent by the pharmacy, and
16 35.400 -- we've had gynecological ones in addition to
17 prostate cancer, and in 600 most of ours are HDR
18 units. We've also had a yttrium 90 microsphere
19 medical event.

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

1 find other cases.

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

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

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

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

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

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

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

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

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

12 Dr. Nag.

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

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

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

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

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

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

1 the licensee's facility.

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

12 MEMBER WILLIAMSON: What form is the
13 cesium-131?

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

16 MEMBER WILLIAMSON: What chemical form?

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

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

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

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

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

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

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

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

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

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

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

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

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

4 So that concludes my presentation. Dr.
5 Vetter?

6 CHAIRMAN MALMUD: Thank you, Dr. Howe.

7 Dr. Vetter?

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

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

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

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

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

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

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

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

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

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

8 Thank you.

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

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

21 DR. HOWE: Dr. Nag?

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

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

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

17 CHAIRMAN MALMUD: Thank you, Dr. Howe.

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

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

25 So I have a long laundry list of things to

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

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

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

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

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

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

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

9 MEMBER LIETO: Second.

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

12 (No response.)

13 All in favor?

14 (Chorus of ayes.)

15 Any opposed?

16 (No response.)

17 Any abstentions?

18 (No response.)

19 It carries unanimously. Oh. Dr.
20 Williamson?

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

23 CHAIRMAN MALMUD: Oh, you're abstaining?

24 MEMBER WILLIAMSON: Yes.

25 CHAIRMAN MALMUD: Thank you. For the

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

4 Thank you.

5 Dr. Howe?

6 DR. HOWE: Okay. The next one is in the
7 definitions of 35.2, and you'll find this is another
8 theme in here. It's the greater than or equal to, and
9 whether we have an equal sign. We have defined a
10 medium dose rate after loader in relationship to
11 12 gray, and the high dose rate, but in neither case
12 do we have one of them equal to 12 gray. And so we're
13 recommending that we add the equal to for the medium
14 dose rate remote after loader.

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

17 MEMBER WILLIAMSON: So moved.

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

20 MEMBER VETTER: Second.

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

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

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

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

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

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

21 MEMBER NAG: Yes.

22 CHAIRMAN MALMUD: Thank you.

23 Mr. Bailey.

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

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

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

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

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

8 DR. HOWE: That's a typo.

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

13 MEMBER WILLIAMSON: Yes.

14 MEMBER VETTER: Yes.

15 CHAIRMAN MALMUD: Any further discussion
16 of the issue?

17 (No response.)

18 All in favor?

19 (Chorus of ayes.)

20 Any opposed?

21 (No response.)

22 Any abstentions?

23 (No response.)

24 It carries unanimously. Thank you, Dr.

25 Howe. Move on. You're two for two so far.

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

9 But when you go to (c), it just says you
10 can also submit the information -- you can submit a
11 letter. So it does not make it clear that you need to
12 -- if you're applying for a new amendment to use an
13 emergent technology that you need to submit
14 essentially the same information whether you use a
15 313(a) form or you use a letter format. And so this
16 would be to clarify that the same information is
17 needed regardless of the format that you use.

18 CHAIRMAN MALMUD: Is there a motion?

19 MEMBER EGGLI: So moved.

20 CHAIRMAN MALMUD: Is there a second to the
21 motion?

22 MEMBER VETTER: Second.

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

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

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

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

5 CHAIRMAN MALMUD: Dr. Miller.

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

8 (Laughter.)

9 CHAIRMAN MALMUD: Please do.

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

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

19 DR. MILLER: Okay.

20 DR. HOWE: Ralph?

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

23 (Chorus of ayes.)

24 Any opposed?

25 (No response.)

1 It's unanimous again, Dr. Howe.

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

4 CHAIRMAN MALMUD: I didn't see the hand.

5 DR. HOWE: Ralph has been raising his
6 hand.

7 CHAIRMAN MALMUD: Ralph? All right.

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

12 DR. HOWE: No, it's the content of the
13 information. When you look at 35.12(b), it says you
14 use Form 313, and you provide the following
15 information. And it makes it clear, some key pieces
16 of information that are needed. When you go to
17 35.12(c), it says that when you're submitting an
18 application for an amendment or a renewal you can use
19 a letter, and it doesn't really address the
20 information that may be required for the emerging
21 technology.

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

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

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

7 DR. HOWE: Yes, and developing the
8 guidance.

9 MEMBER LIETO: All right.

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

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

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

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

21 MEMBER BAILEY: But --

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

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

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

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

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

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

20 MEMBER BAILEY: No.

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

22 MEMBER BAILEY: No.

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

25 MEMBER BAILEY: But I agree that if you

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

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

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

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

20 Dr. Malmud.

21 CHAIRMAN MALMUD: The motion has passed.

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

24 MEMBER WILLIAMSON: I retract my pass.

25 CHAIRMAN MALMUD: Ralph?

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

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

11 CHAIRMAN MALMUD: Was it your motion,
12 Ralph?

13 MEMBER EGGLI: It was actually my motion.

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

15 MEMBER EGGLI: Yes.

16 (Laughter.)

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

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

21 CHAIRMAN MALMUD: Thank you. Who seconded
22 your motion?

23 MEMBER EGGLI: I have no idea.

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

1 (Laughter.)

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

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

6 DR. HOWE: Okay.

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

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

14 DR. HOWE: That's correct.

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

18 CHAIRMAN MALMUD: May we have such a
19 motion?

20 MEMBER BAILEY: So moved.

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

23 MEMBER WILLIAMSON: Second.

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

1 (No response.)

2 Hearing none, all in favor?

3 (Chorus of ayes.)

4 Any opposed?

5 (No response.)

6 Any abstentions?

7 (No response.)

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

10 (Laughter.)

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

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

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

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

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

19 CHAIRMAN MALMUD: Dr. Williamson?

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

22 DR. HOWE: That's correct.

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

25 DR. HOWE: That's correct.

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

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

12 Aren't we missing broad scope license?

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

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

1 licenses.

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

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

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

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

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

21 CHAIRMAN MALMUD: Lynne, is your concern
22 satisfied?

23 MS. FAIROBENT: Yes.

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

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

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

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

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

1 CHAIRMAN MALMUD: Please.

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

7 DR. HOWE: But this also --

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

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

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

22 CHAIRMAN MALMUD: Dr. Nag.

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

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

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

10 CHAIRMAN MALMUD: Dr. Williamson.

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

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

21 DR. HOWE: They are identical.

22 MEMBER BAILEY: May I respond to that?

23 CHAIRMAN MALMUD: Please do.

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

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

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

13 CHAIRMAN MALMUD: Dr. Williamson?

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

23 CHAIRMAN MALMUD: Thank you.

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

1 supportive or not supportive of --

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

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

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

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

14 CHAIRMAN MALMUD: Thank you, Dr. Vetter.

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

17 MEMBER VETTER: So move.

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

20 MEMBER LIETO: Second.

21 CHAIRMAN MALMUD: It was seconded by Mr.
22 Lieto.

23 (Laughter.)

24 Is there any further discussion?

25 (No response.)

1 If not, all in favor?

2 (Chorus of ayes.)

3 Any opposed?

4 (No response.)

5 Any abstentions?

6 (No response.)

7 We have two opposed? Thank you. It
8 carries.

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

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

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

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

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

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

21 CHAIRMAN MALMUD: Thank you, Dr. Howe.

22 Is there a motion to support this change?

23 MEMBER VETTER: So move.

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

1 MEMBER NAG: Second.

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

4 (No response.)

5 Hearing no discussion, all in favor?

6 (Chorus of ayes.)

7 Any opposed?

8 (No response.)

9 Any abstentions?

10 (No response.)

11 It carries unanimously. Thank you.

12 Dr. Howe?

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

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

5 CHAIRMAN MALMUD: Mr. Lieto.

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

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

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

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

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

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

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

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

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

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

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

1 to discuss and change wording.

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

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

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

10 MEMBER NAG: One question.

11 CHAIRMAN MALMUD: Dr. Nag.

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

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

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

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

3 DR. HOWE: Mr. Essig, yes.

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

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

22 MEMBER VETTER: Yes.

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

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

3 MEMBER VETTER: Okay.

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

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

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

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

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

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

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

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

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

25 CHAIRMAN MALMUD: Your recommendation

1 would make this consistent with the other regulations.

2 DR. HOWE: That's correct.

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

5 MEMBER BAILEY: I move.

6 MEMBER VETTER: Second.

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

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

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

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

19 DR. HOWE: Okay.

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

23 (Whereupon, a short recess was taken.)

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

1 Mr. Essig. Mr Essig?

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

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

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

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

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1 how we got where we are.

2 And so Ralph has 10 minutes and it will be
3 -- no for the slides on the Commission meeting on the
4 15th and that we must strictly adhere to. So if the
5 committee feels that the volume of material that Ralph
6 has put together in draft form cannot be presented by
7 him in 10 minutes, you know, moving at a reasonable
8 pace, then we need to provide comments on areas that
9 can be trimmed because he probably has, just my quick
10 read of it, there may be too much there for 10
11 minutes, but we'll let you come to your own conclusion
12 and offer any necessary changes.

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

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

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

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

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

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

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

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

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

3 CHAIRMAN MALMUD: DR. Vetter.

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

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

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

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

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

22 CHAIRMAN MALMUD: DR. Williamson?

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

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

6 MEMBER LIETO: So --

7 DR. SCHWARZ: No.

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

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

15 DR. SCHWARZ: Probably not.

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

18 DR. CHANG: Can I just make a
19 clarification?

20 CHAIRMAN MALMUD: Yes.

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

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

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

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

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

1 CHAIRMAN MALMUD: All right, Mr. Bailey?

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

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

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

16 MR. ESSIG: Yes, we do.

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

1 Mr. Essig?

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

9 DR. CHANG: It's with the Commission.

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

14 MEMBER LIETO: Spell it out?

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

20 CHAIRMAN MALMUD: DR. Williamson?

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

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

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

10 MEMBER LIETO: There was a question.

11 CHAIRMAN MALMUD: Who? Oh, DR. Zelac.

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

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

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

23 MEMBER SULEIMAN: What about non-medical?

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

1 on?

2 MEMBER WILLIAMSON: Yes.

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

5 MEMBER WILLIAMSON: Yes, good point.

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

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

25 So I think he would want to be prepared to

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

3 MEMBER BAILEY: Yeah, I --

4 CHAIRMAN MALMUD: Mr. Bailey.

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

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

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

7 CHAIRMAN MALMUD: DR. Williamson?

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

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

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

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

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

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

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

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

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

1 decommissioning?

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

6 CHAIRMAN MALMUD: DR. Vetter?

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

9 MEMBER LIETO: But not the
10 decommissioning.

11 MEMBER VETTER: Sorry?

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

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

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

25 DR. CHANG: To the production accelerator.

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

3 DR. CHANG: Correct.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4 CHAIRMAN MALMUD: Ralph, if I may, I would
5 suggest that you insert a slide here which essentially
6 summarizes that which Sally has said and I would put
7 it in the following way if you would agree. I'd make
8 a declarative statement that PET radiopharmaceuticals
9 are rapidly advancing. Medicine's understanding of
10 the diagnosis and treatment of the three most
11 prevalent diseases in the United States, the most
12 prevalent causes of death in the United States; number
13 1, cardiovascular disease, number 2, cancer, number 3,
14 stroke. Those are from the public -- those data are
15 available publicly as well as an understanding of
16 brain disorders including Alzheimers, Parkinsons -- or
17 Alzheimers and movement disorders. Those are --
18 that's a factual statement and it's very often useful
19 to remind the Commissioners of the role that PET is
20 taking in each of these areas.

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

25 MEMBER LIETO: I'll make those points and

1 I'll expand it under the first bullet.

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

8 MEMBER LIETO: Okay.

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

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

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

3 MEMBER LIETO: Okay.

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

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

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1 the advancement of this research. Lydia.

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

12 CHAIRMAN MALMUD: DR. Miller.

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

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

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

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

13 DR. SCHWARZ: DR. Malmud, excuse me.

14 CHAIRMAN MALMUD: Yes, Dr. Howe.

15 DR. HOWE: Dr. Schwarz was first.

16 CHAIRMAN MALMUD: Oh, I'm sorry.

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

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

1 was the other term you used?

2 DR. SCHWARZ: Development.

3 CHAIRMAN MALMUD: Research and
4 development. Again, I'd reinforce the currency of
5 it in this cutting edge research, because it's
6 occurring now. It's not some -- you know, in the
7 1980s we talked about the decade of the brain would be
8 the 1990s. And it turned out that well, it wasn't
9 quite the 1990s but it extended into the first decade
10 of this century and in truth, it's happening. One-
11 third of us, if we live long enough, will develop some
12 form of Alzheimers before we die and that's a
13 frightening prospect both for the economy of the
14 country as well as for the personal suffering that's
15 engendered by families.

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

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

1 we'll put this on our plate also.

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

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

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

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

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

22 CHAIRMAN MALMUD: DR. Vetter?

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

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

6 DR. HOWE: Okay.

7 CHAIRMAN MALMUD: Mr. Bailey.

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

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

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

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

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

20 CHAIRMAN MALMUD: DR. Williamson?

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

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

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

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

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

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

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

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

7 MEMBER LIETO: Yes.

8 CHAIRMAN MALMUD: Mr. Essig?

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

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

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

4 CHAIRMAN MALMUD: You amplify it.

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

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

18 DR. SCHWARZ: I agree, that sounds good.

19 CHAIRMAN MALMUD: DR. Suleiman?

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

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

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

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

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

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

14 DR. SCHWARZ: That's correct.

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

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

19 MEMBER SULEIMAN: Oh, okay.

20 DR. SCHWARZ: These are not human use.

21 CHAIRMAN MALMUD: These are not for human
22 use.

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

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

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

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

22 CHAIRMAN MALMUD: PET radionuclides.

23 DR. SCHWARZ: -- be preferred.

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

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

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

14 MEMBER LIETO: Everything here is.

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

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

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

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

25 MEMBER SULEIMAN: You might also want to

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

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

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

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

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

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

19 CHAIRMAN MALMUD: DR. Vetter?

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

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

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

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

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

25 MEMBER LIETO: I guess, does NRC -- I

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

4 CHAIRMAN MALMUD: DR. Miller?

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

14 MEMBER LIETO: So I'll strike it.

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

20 CHAIRMAN MALMUD: Thank you. Dr.
21 Williamson?

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

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

5 MEMBER LIETO: That is correct.

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

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

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

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

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

9 CHAIRMAN MALMUD: DR. Vetter?

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

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

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

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

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

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

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

25 And that to address a potential question

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

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

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

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

17 CHAIRMAN MALMUD: You need to use the
18 microphone.

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

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

14 CHAIRMAN MALMUD: DR. --

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

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

1 CHAIRMAN MALMUD: DR. Vetter?

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

4 CHAIRMAN MALMUD: Mr. Bailey?

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

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

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

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

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

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

25 So the anxiety is that nothing occur which

1 interferes with this very productive area of research
2 and development.

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

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

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

21 CHAIRMAN MALMUD: The previous slide.

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

1 unknown.

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

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

12 CHAIRMAN MALMUD: Tom?

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

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

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

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

12 MR. ESSIG: And I think one other fine
13 point there is that if you can say this, that you
14 believe that the -- although the inventory is unknown,
15 you believe most of the sources, the individual
16 sources in the inventory to be less than IAEA Category
17 2 or that most of them are in the Category 3 to 5
18 range.

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

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

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

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

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

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

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

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

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

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

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

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

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

13 MEMBER LIETO: I have no problem with
14 that.

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

17 DR. SCHWARZ: (Nods head)

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

1 person for this subject.

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

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

6 CHAIRMAN MALMUD: I beg your pardon?

7 MEMBER LIETO: Paybacks will be a bummer.

8 (Laughter)

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

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

15 CHAIRMAN MALMUD: Yes, we did.

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

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

22 MR. ESSIG: No.

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

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

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

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

10 CHAIRMAN MALMUD: DR. Miller.

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

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

1 meeting, if that's okay.

2 CHAIRMAN MALMUD: Thank you. Mr. Essig.

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

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

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

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

20 The second action was on the Dr. --

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

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

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

11 CHAIRMAN MALMUD: A two-hour conference
12 call?

13 MR. ESSIG: As a minimum.

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

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

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

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

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

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

9 The third -- the fourth --

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

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

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

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

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

7 MR. SABA: Sure.

8 CHAIRMAN MALMUD: Thank you. It shall be
9 done.

10 MR. SABA: The next action was on the
11 ACMUI review of medical inventory of Iodine -- I'm
12 sorry, involving Iodine 131, DR. Eggli's presentation.
13 The Stafford Center and I answered them with this
14 regard. Is there anything else that should be done,
15 something mentioned about Nuclear Medicine Society or
16 --

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

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

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

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

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

3 MR. SABA: Thank you. That there were a
4 few actions on Dr. Howe's presentation on potential to
5 10 CFR Part 35, potential changes. All of them -- not
6 all, most of them have been approved by the committee.
7 That's all I remember. And in terms of
8 recommendations, there is only one I have no my list
9 as regarding training and experience for microsphere
10 for the use of microsphere.

11 CHAIRMAN MALMUD: Yes.

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

16 DR. ZELAC: Excuse me.

17 CHAIRMAN MALMUD: DR. Zelac.

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

1 CHAIRMAN MALMUD: DR. Zelac is correct.

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

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

9 MR. SABA: Okay, for the next -- for the
10 fall meeting, I have a few days; October 17th, October
11 18th, that's one, 17th and 18th.

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

14 MR. SABA: Tuesday and Wednesday.

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

18 MR. SABA: Okay.

19 MR. ESSIG: And not Vienna, Virginia.

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

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

1 Are you going to be here?

2 DR. MILLER: Yes.

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

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

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

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

16 MEMBER NAG: What about just
17 (indiscernible) either later in the week, you know,
18 24th, 25th, 26th, 27th?

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

22 MEMBER NAG: Oh, for the whole week?

23 CHAIRMAN MALMUD: Yeah, for the whole
24 week.

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

1 two weeks prior.

2 CHAIRMAN MALMUD: Yes. 10 and 11 okay?

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

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

8 MEMBER NAG: Probably, yes, maybe.

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

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

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

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

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

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

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

1 works.

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

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

6 CHAIRMAN MALMUD: Is the NRC building
7 available.

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

10 FEMALE PARTICIPANT: (Inaudible)

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

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

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

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

3 CHAIRMAN MALMUD: We understand.

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

6 MR. ESSIG: And it was very pricey.

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

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

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

25 MALE PARTICIPANT: When will you inform us

1 of this date?

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

4 CHAIRMAN MALMUD: We'll keep the 24th and
5 25th blocked out.

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

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

11 DR. MILLER: Okay, and the week of the
12 24th and 25th, are there any blackout dates that week
13 or, you know, if the room is available later in the
14 week versus early. We try to avoid Mondays and
15 Fridays for you but --

16 CHAIRMAN MALMUD: Very good. Any other
17 housekeeping items?

18 MEMBER NAG: The telephone conference
19 call?

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

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

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

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

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

7 MR. ESSIG: How does that sound for --

8 MALE PARTICIPANT: Depending on the time
9 of day.

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

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

14 CHAIRMAN MALMUD: Afternoon.

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

18 CHAIRMAN MALMUD: 4:00 o'clock? The
19 meeting may run long, so you would prefer, perhaps
20 2:00 o'clock.

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

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

25 MALE PARTICIPANT: Could we do 3:00 as a

1 compromise?

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

3 MALE PARTICIPANT: The 23rd or the 25th.

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

6 MALE PARTICIPANT: The 25th is really bad.

7 MR. ESSIG: Really bad, okay.

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

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

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

14 MR. ESSIG: I would say let's allocate
15 three and maybe not have to use it all, from 2:30 to
16 5:30.

17 CHAIRMAN MALMUD: Two hours is long
18 enough.

19 MR. ESSIG: Or let's compromise and say
20 2:30 to 5:00.

21 CHAIRMAN MALMUD: Two and a half hours.

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

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

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

5 MR. ESSIG: Yes.

6 CHAIRMAN MALMUD: Any other items?

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

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

12 MEMBER BAILEY: That's it.

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

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

1 write a memo to fairly high level.

2 CHAIRMAN MALMUD: Mr. Lieto?

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

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

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

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

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

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

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