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Advisory Committee on the Medical Uses of Isotopes Title:

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1	UNITED STATES OF AMERICA
2	NUCLEAR REGULATORY COMMISSION
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4	ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
5	+ + + +
6	TELECONFERENCE
7	+ + + +
8	WEDNESDAY,
9	DECEMBER 12, 2007
10	+ + + +
11	The meeting was convened via
12	teleconference at 12:00 noon, LEON S. MALMUD, M.D.,
13	ACMUI Chairman, presiding.
14	MEMBERS PRESENT:
15	LEON S. MALMUD, M.D. Chairman
16	DARRELL FISHER, Ph.D. Member
17	RALPH P. LIETO Member
18	STEVE MATTMULLER, R.Ph. Member
19	SUBIR NAG, M.D. Member
20	SALLY WAGNER SCHWARZ, R.Ph. Member
21	BRUCE THOMADSEN, Ph.D. Member
22	WILLIAM VAN DECKER, M.D. Member
23	RICHARD J. VETTER, Ph.D. Member
24	JAMES S. WELSH, M.D. Member

	2
1	NRC STAFF PRESENT:
2	CYNTHIA M. FLANNERY (ALT DFO)
3	DONNA-BETH HOWE, Ph.D.
4	ANTHONY HUFFERT
5	DORIS LEWIS
6	ASHLEY TULL
7	SANDRA WASTLER (DFO)
8	DUANE E. WHITE
9	
10	ALSO PRESENT:
11	LYNNE FAIROBENT, AAPM
12	CHRIS GALLAGHER, ASNC
13	EMILY GARDNER, ASNC
14	DEBBIE GILLEY, FL/OAS/CRCPD
15	EUGENIA KRIMER, ACR (FOR GLORIA ROMANELLI, ACR)
16	RICHARD MARTIN, ASTRO
17	MIKE PETERS, SNM
18	DOUGLAS PFEIFFER, AAPM
19	

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

(12:04 p.m.)

MS. WASTLER: Welcome.

CHAIRMAN MALMUD: Good morning. Good afternoon.

MS. WASTLER: Well, I guess we are in the afternoon. Okay. We have everyone now with the exception of Dr. Eggli and Dr. Suleiman, who we knew were not going to be there. So we have a quorum. So I am going to go ahead with the remarks as the designated federal officer. And then I will turn the meeting over to you, sir.

CHAIRMAN MALMUD: Thank you.

MS. WASTLER: All right. As the designated federal officer for this meeting, I am pleased to welcome you to the telephone, I guess I should say, -- I am in Rockville -- for this meeting of ACMUI.

I am Sandra Wastler, the Chief of the Medical Safety and Events Assessment Branch. I have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR part 7.11.

Present today is the alternative designated federal officer, Cindy Flannery. This is

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1	a
2	(Interruption.)
3	MS. WASTLER: Somebody put us on hold.
4	CHAIRMAN MALMUD: Someone has us on hold.
5	MS. WASTLER: Yes. This is an announced
6	meeting of the Committee. It is being held in
7	accordance with the rules and regulations of the
8	Federal Advisory Committee Act and the Nuclear
9	Regulatory Commission.
10	CHAIRMAN MALMUD: Someone just joined us.
11	Hello?
12	MEMBER MATTMULLER: This is Steve
13	Mattmuller listening in.
14	MS. WASTLER: All right. Thank you, Mr.
15	Mattmuller.
16	This meeting was announced in the Federal
17	Register notice on what was the date, Ashley? I
18	have forgotten. I forgot the
19	MS. TULL: November 26th.
20	MS. WASTLER: November 26th. The function
21	of the Committee is to advise the staff on issues and
22	questions that arise on the medical use of byproduct
23	materials.
24	The Committee provides counsel to the
25	staff but does not determine or direct the action or

1 decisions of the staff or the Commission. The NRC solicits the reviews of the Committee, and it values 2 3 their opinions. I request, whenever possible, we try to 4 5 reach consensus on the procedural issue we will be discussing today and would recognize there may be 6 7 minority or dissenting opinions. If you have such an opinion, please allow them to be read into the record. 8 9 At this point I have already gone through and recognized the individuals in attendance at the 10 11 meeting today. With that, Dr. Leon Malmud will chair today's meeting, and I will turn that meeting over to 12 him. 13 14 CHAIRMAN MALMUD: Thank you. MS. WASTLER: Before we do that, I would 15 just like to point out that there are several people 16 17 with me here in the room. And I am going to ask them to go around and introduce themselves. 18 19 MS. HOWE: Donna-Beth Howe. 20 MS. FLANNERY: Cindy Flannery. 21 MS. LEWIS: Doris Lewis. 22 MR. WHITE: Duane White. 23 Tony Huffert. MR. HUFFERT: 24 MS. WASTLER: All right. This is Ashley Tull. I would 25 MS. TULL:

1	also remind anyone who speaks to identify themselves
2	for the court reporter.
3	CHAIRMAN MALMUD: Thank you.
4	MS. WASTLER: Are there any members of the
5	public on the line?
6	MS. KRIMER: Eugenia Krimer is sitting in
7	for Gloria Romanelli.
8	MS. FAIROBENT: Lynne Fairobent, AAPM.
9	MR. PFEIFFER: Doug Pfeiffer, AAPM.
10	MR. MARTIN: Richard Martin with ASTRO.
11	MS. GARDNER: Emily Gardner and Chris
12	Gallagher with ASNC.
13	MR. PETERS: This is Mike Peters from SNM.
14	MS. WASTLER: All right. Thank you very
15	much.
16	Dr. Malmud, I will turn the meeting over
17	to you.
18	CHAIRMAN MALMUD: Thank you. This is Leon
19	Malmud.
20	The past several years the National
21	Academies has been conducting a study of industrial
22	kind of research and commercial uses for radiation
23	sources.
24	In response to this, this is actually in
25	response to congressional concerns that radiation
Į	I and the state of

sources could be purchased or stolen for terrorists by use in dirty bomb attacks on the United States.

Does someone want to say something? Okay.

I'm picking up an echo. All right.

The goal of the study was to identify industrial or other processes that could be replaced with economically and technically equivalent or perhaps even improved process that did not require the use of radiation sources or perhaps using a radiation source that would pose a lower risk in the event of an accident or an intentional attack involving a radiation source. The Energy Policy Act of 2005 actually directed the NRC to enter into an arrangement with the National Academies to conduct that study.

Once the results of that study are issued, the NRC will have only a few days to review the report and to provide comments. The NRC's comments will be focused on the NRC's mission, which is safety and security of radioactive material. The NRC believes that it's vital for Congress to also understand any potential impacts on the practice of medicine, which would result from the report and the recommendations.

In other words, the NRC, quite simply, wants Congress to be aware that any restrictions on existing uses of radioactive material could impact the

actual practice of medicine.

So, in order to provide the NRC with ACMUI's comments in the time frame necessary, we really had to do this, which is a slight change in ACMUI's normal procedure.

Given our own professional schedules, the requirements of a notice of a meeting for the full Committee, meaning the full ACMUI, which requires ten days' notice prior to the meeting, did not really give us time to have a meeting in Rockville, but we could schedule this teleconference.

We need to give the NRC our impressions about what needs to be done in order to assure that whatever changes are made in the availability or restrictions on use of radioactive material do not negatively impact the practice of medicine and the delivery of patient care within the United States.

So, as the Chair of the Committee, I thought that Drs. Vetter and Nag by virtue of their technical expertise would adequately represent the views of the full ACMUI in this particular issue.

It is also, I believe, our opportunity to voice any "practice of medicine" issues directly to Congress. Therefore, we wanted to brief the full Committee regarding the issue. And this needs to be

1 done in a timely fashion so that when we are asked for our opinion, we can respond with the opportunity to 2 3 have given it prior thought. So, basically, the purpose of the meeting 4 5 is to voice our concern on behalf of patients regarding the practice of medicine and possible 6 7 restrictions that might occur to the practice of medicine with tightening of the availability or the 8 use of certain radioactive materials. 9 Is what I have said clear? 10 11 PARTICIPANT: Yes. Dr. Malmud, this is Sandra 12 MS. WASTLER: Could I clarify a couple of points? 13 14 CHAIRMAN MALMUD: Please do. I think what we want to make 15 MS. WASTLER: clear is that because of schedule requirements by FACA 16 with regards to setting up a meeting of the full 17 Committee and to getting it in the Federal Register 18 notice, that it takes like three weeks to schedule a 19 20 full Committee meeting if everybody happens to be 21 available. What we're faced with is that when this 22 report comes out -- and in a minute, I'm going to ask 23 24 Tony Huffert, who is with Research, to give you just

an overview of, you know, the requirements or the

contractual requirements with regards to this document.

But we have only a day or two essentially to turn these comments around. So what Dr. Malmud and what we were trying to come up with was a mechanism by which ACMUI as a body could provide their comments.

And the only way we could figure to do
this was to, as Dr. Malmud said, appoint a
subcommittee and get the full Committee to give the
subcommittee authorization to speak for them so that
when the subcommittee would comment on this report,
those comments would be basically the full ACMUI's
comment. And then after the fact, the full Committee
would be briefed on the report and its
recommendations.

So that is basically the direction that we are trying to go. You know, we want to provide the members with an opportunity to have their voice heard along with ours to Congress essentially on this topic. And we're just trying to figure out a procedural way of doing so. And this was the approach that we had come up with that was really, we felt, the only viable way to proceed.

And, with that, I will ask Tony if he could give you just a very quick overview of the I

guess contractual side of the NAS report. And maybe he can tell us what the latest is on when the report will be issued.

MR. HUFFERT: Thank you, Sandi. I'm Tony
Huffert. I work in the Office of Nuclear Regulatory
Research at the U.S. NRC here in Rockville. And one
thing that the Office of Research does with the
National Academies is enter into these types of
contractual arrangements with a study.

Now, this study was directed by Congress.

And the NRC was directed to work with the National

Academies on this topic. That direction, as Dr.

Malmud said, was from August 2005, the Energy Policy

Act. And since that time, I have been working very

closely with the National Academies in providing them

technical information so they could write a report.

They have about a dozen experts, including someone from the medical community, working on this report. And they are looking at a wide variety of source applications. But these are typically the very high-activity sources, not the lower-activity sources.

What we do with the National Academies is we provide them with as much technical information as they need. And then they go off by themselves and write a report.

After the report is prepared, the NRC is offered an opportunity to review it very quickly for information security purposes. Basically we want to make sure that the report does not contain any information that could be useful to a terrorist organization.

After we conduct that review, the NRC has completed its job of supplying information to the National Academies. And it's up to them to resolve any comments on the report or come up with a publications schedule.

So where we are right now in the process is it's up to the National Academies to prepare a final report and issue it. When they issue it, they would brief the NRC and Congress within 24 hours, and it would be available on their Web site almost immediately.

As far as schedule is concerned, I think the National Academies might be rolling out the report in the next several weeks. I don't think that this will happen before the holidays, but with the National Academies, you never know. They only have to give the NRC a very short time before they go forth with their own independent process.

MS. WASTLER: We only have a very short

1 time to effect any comments on that document to the National Academy and to Congress after they make the 2 report public. And that is the issue that we are 3 trying to deal with. 4 5 MR. HUFFERT: And, again, the National Academies is an independent organization. 6 It is not 7 part of the federal government. They report directly 8 to Congress. And they have their own independent process, and they are very careful not to release 9 10 information about the report prior to briefing the 11 study sponsor, which is the NRC, and Congress. I just wanted to clarify the 12 MS. WASTLER: points from Dr. Malmud and provide you with background 13 14 as to why we have requested this full ACMUI meeting 15 and why Dr. Malmud is proposing a motion, I believe, or will be that the ACMUI give the subcommittee 16 17 authority to speak on his behalf on this issue so that we can in the appropriate timely manner provide both 18 19 ours and your comments on this document when it is 20 released. 21 This is Dr. Naq. May I just MEMBER NAG: interject one comment? 22 23 CHAIRMAN MALMUD: Please do, Dr. Nag. This is Malmud. 24 Basically this is for 25 MEMBER NAG: Yes.

1	my fellow ACMUI members. There are two options. In
2	that short time of one or two days, the whole
3	Committee cannot provide the input because we cannot
4	meet in one or two days.
5	So the options are either for the ACMUI
6	not to have any voice or to have one or two select
7	members of ACMUI be the subcommittee members and talk
8	on behalf of the whole ACMUI. And basically the ACMUI
9	members would have selected the one or two members to
LO	be its voice. I think that is my summary for the rest
L1	of the ACMUI members.
L2	CHAIRMAN MALMUD: Thank you, Dr. Nag.
L3	Are there questions of Dr. Nag or myself
L4	regarding this process?
L5	MEMBER LIETO: This is Ralph Lieto. I
L6	have two questions.
L7	CHAIRMAN MALMUD: Yes, Ralph?
L8	MEMBER LIETO: Is this applying to all
L9	radioactive sources or is this just Category I and II
20	sources? That is my first question.
21	MR. HUFFERT: The answer is yes. The way
22	the Congress set up this particular requirement was
23	that the National Academies would only be able to look
24	at Code of Conduct Category I and II sources.
25	MEMBER LIETO: Okay. Which narrows it

1 down, I think, quite a bit from the medical side. A second question is, was there 2 3 consideration given to other members if other members were interested in viewing this and providing comments 4 5 to the subcommittee? CHAIRMAN MALMUD: Yes, Ralph. 6 This is 7 Malmud again. The turnaround time for us to consider the 8 9 problem was brief. And it seemed to me that given the membership of the Committee, a radiation physicist and 10 11 a radiation oncologist, that we would have adequate coverage within these two disciplines to discuss the 12 impact on clinical medicine. My own background, of 13 14 course, is nuclear medicine. So we add that to it. believed that this small 15 And we subcommittee could deal with the issue on behalf of 16 the whole Committee in the time frame allowed, 17 recognizing that there are security issues involved. 18 19 No member of the Committee was chosen 20 because of his or her security clearance, but we had 21 to keep the number small. And we're discussing a 22 theoretical issue. Does that answer your question, Ralph? 23 24 MEMBER LIETO: Yes. Thank you. Thank you. 25 CHAIRMAN MALMUD:

response to a recommendation that has not yet come forth. And we thought that by addressing it in this manner we could recognize the concerns of all of us, particularly since the radiation physicist crosses disciplines of radiology and nuclear medicine radiotherapy.  MS. WASTLER: Dr. Malmud, did you want t make a motion for the Committee?  CHAIRMAN MALMUD: Yes, I will. In this unusual circumstance, perhaps I should ask either Dr. Vetter or Dr. Nag, who are members of the subcommittee, rather than myself, to make the motion.  MS. WASTLER: That would be fine.	1	Okay. So we understand the process, which
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MEMBER VETTER: This is Dick Vetter. I	22	behalf of the entire ACMUI in terms of the medical
	23	implications of the report.
25 second the motion.	24	MEMBER VETTER: This is Dick Vetter. I
	25	second the motion.

1	CHAIRMAN MALMUD: Thank you, Drs. Nag and
2	Vetter. Is there discussion of the motion?
3	MEMBER SCHWARZ: This is Sally Schwarz.
4	I just wanted to clarify Dr. Nag's motion that it's
5	the National Academy document that we're speaking in
6	reference to.
7	MEMBER NAG: Right.
8	CHAIRMAN MALMUD: That is correct.
9	MEMBER NAG: This is the National
10	Academies document that was endorsed by the NRC in
11	response to the Congress.
12	MEMBER SCHWARZ: Right. I just thought
13	that should be part of the motion,
14	MEMBER NAG: Yes, right.
15	MEMBER SCHWARZ: the name of the
16	document.
17	CHAIRMAN MALMUD: Thank you. The motion
18	will be amended to include that phrase. Any further
19	discussion?
20	(No response.)
21	CHAIRMAN MALMUD: If not, all in favor?
22	I'm sorry.
23	MEMBER THOMADSEN: Yes.
24	CHAIRMAN MALMUD: Who is speaking?
25	MEMBER THOMADSEN: This is Bruce

Thomadsen.

I do have the utmost confidence in that subcommittee. I think that this is a reasonable way to address the issue. If it is going out in the name of the entire ACMUI, I think it would be good if when you get the report that you do send it to the Committee and give them the opportunity should they have it to look at the report and make suggestions to that Committee.

MEMBER NAG: The problem that -- I mean, that is what we would have liked also, but the problem is that we have about 24 hours. And in that 24 hours, to look at it, review it, and then get the concurrence of the entire ACMUI is not possible.

We looked at it at several different ways.

And what you are suggesting would have been the best way, but, unfortunately, this is an unusual circumstance. So we had to find a way to circumvent this unusual circumstance.

This is not the way we normally would do it in ACMUI. And I'm sure the other members of ACMUI realize that this is not the way we have ever done it.

MEMBER THOMADSEN: This is Thomadsen again. I understand everything you have said. I understood that up to this point. And you have

1 changed part of what I was asking. I was not asking for getting any type of 2 3 a concurrence from the members. I am asking that they get the report and if in the time frame allowed they 4 have comments to send to the subcommittee that that be allowed so that we would have that opportunity to be 6 7 able to have the input, whether we take it or not. And the subommittee doesn't have to wait. 8 As a matter of fact, they can't wait. 9 10 MS. WASTLER: Right. Dr. Thomadsen, Dr. 11 Nag, if I could comment? MEMBER NAG: 12 Sure. What Dr. Thomadsen is WASTLER: 13 14 suggesting, if I am understanding him correctly, is 15 that when the report becomes public and it goes up on the web site, the subcommittee would come in, do the 16 review as through the motion, would review the report. 17 But it will be on their public web site. 18 19 And, therefore, if a member chooses, it can read the 20 report and could send comments to you for your 21 consideration. 22 You would not go back to them. You know, if you decide, the subcommittee would decide whether 23 to include those comments or not. But it would be an 24

opportunity at least for them to look at it if they

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1	are able and provide you with some views on the issue.
2	MEMBER NAG: Yes. I think that is
3	MS. WASTLER: That is doable, but it would
4	still be you would only have two days. You know,
5	essentially the subcommittee would, you know, be
6	looking at the report and putting together the
7	document we need to go back to Congress.
8	And if other members can read it and have
9	some comments, they could provide them to you. It's
10	just that the subcommittee would be marching on,
11	speaking for the full Committee, and trying to take
12	comments where and if available members want to make
13	them. I mean, I think that's doable.
14	MEMBER THOMADSEN: This is Thomadsen
15	again.
16	Would the NRC staff be so kind as to send
17	out an announcement to the Committee when the report
18	is released? Otherwise
19	MS. WASTLER: Oh, of course.
20	MEMBER THOMADSEN: we're likely to miss
21	that.
22	MS. WASTLER: That would be very easy for
23	us to do.
24	MEMBER THOMADSEN: Thank you.
25	MS. WASTLER: When it is on the web site,

1	we can send you an e-mail saying it's up, the
2	subcommittee is reviewing it, and if you have
3	comments. I mean, we can give you a single point of
4	contact with us where we could get those comments to
5	Dr. Vetter and Dr. Nag.
6	MEMBER THOMADSEN: Wonderful.
7	CHAIRMAN MALMUD: This is Malmud.
8	Dr. Thomadsen, does that satisfy your
9	request?
10	MEMBER THOMADSEN: Yes.
11	CHAIRMAN MALMUD: Thank you. Any further
12	discussion of the motion?
13	(No response.)
14	CHAIRMAN MALMUD: If not, all in favor?
15	(Whereupon, there was a chorus of
16	"Ayes.")
17	CHAIRMAN MALMUD: Any opposed?
18	(No response.)
19	CHAIRMAN MALMUD: Any abstentions?
20	(No response.)
21	CHAIRMAN MALMUD: Hearing no opposed and
22	no abstentions, the motion is unanimous.
23	MS. TULL: This is Ashley Tull. I just
24	wanted to thank the Committee for doing this within
25	the 30 minutes allotted. I really appreciate it.

1	Those of you that I talked to, I told you it was
2	possible.
3	CHAIRMAN MALMUD: Well, you have a
4	Committee that has made it possible.
5	MS. TULL: Yes. Thank you very much.
6	MS. WASTLER: And I just want to thank the
7	members very much for this. We appreciate it. Thank
8	you, and have a good day.
9	CHAIRMAN MALMUD: We thank you all.
10	(Whereupon, the foregoing matter was
11	concluded at 12:30 p.m.)
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