

Official Transcript of Proceedings
NUCLEAR REGULATORY COMMISSION

Title: Meeting of the Advisory Committee
on the Medical Uses of Isotopes

Docket Number: (n/a)

Location: teleconference

Date: Wednesday, August 10, 2016

Work Order No.: NRC-2542

Pages 1-36

NEAL R. GROSS AND CO., INC.
Court Reporters and Transcribers
1323 Rhode Island Avenue, N.W.
Washington, D.C. 20005
(202) 234-4433

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

+ + + + +

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

TELECONFERENCE

+ + + + +

WEDNESDAY,

AUGUST 10, 2016

+ + + + +

The meeting was convened by
teleconference, at 1:32 p.m., Pat B. Zanzonico, ACMUI
Vice Chairman, presiding.

MEMBERS PRESENT:

PAT B. ZANZONICO, Ph.D., Vice Chairman

FRANCIS M. COSTELLO, Agreement State
Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

SUSAN M. LANGHORST, Ph.D., Radiation Safety
Officer

DARLENE METTER, M.D., Diagnostic Radiologist

MICHAEL D. O'HARA, Ph.D., FDA Representative

CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine

1 Physician

2 JOHN H. SUH, M.D., Radiation Oncologist

3 LAURA M. WEIL, Patients' Rights Advocate

4 Non-Voting: RICHARD GREEN

5

6 NRC STAFF PRESENT:

7 MICHAEL FULLER, Acting ACMUI Designated Federal
8 Officer

9 SOPHIE HOLIDAY, ACMUI Alternate Designated
10 Federal Officer and ACMUI Coordinator

11 JENNIFER BISHOP, R-III/DNMS/MLB

12 COLLEEN CASEY, R-III/DNMS/MLB

13 JACKIE COOK, R-IV/DNMS/NMSB-B

14 SAID DAIBES FIGUEROA, Ph.D., NMSS/MSTR/MSEB

15 SARA FORSTER, R-III/DNMS/MLB

16 CASSANDRA FRAZIER, R-III/DNMS/MLB

17 CHRISTINA ENGLAND, OGC/GCLR/RMR

18 ADAM GENDELMAN, OGC/GCLR/RMR

19 JOHN GIESSNER, R-III/DNMS

20 VINCENT HOLAHAN, Ph.D., NMSS/MSTR

21 DONNA-BETH HOWE, Ph.D., NMSS/MSTR/MSEB

22 PENNY LANZISERA, R-I/DNMS/MB

23 JOHARI MOORE, COMM/OCM

24 JAN NGUYEN, R-I/DNMS/MB

25 DENNIS O'DOWD, R-III/DNMS/MIB

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 PATTY PELKE, R-III/DNMS/MLB
2 GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB
3 TOYE SIMMONS, R-III/DNMS/MLB
4 MICHELLE SMETHERS, NMSS/MSTR/MSEB
5 KATIE TAPP, Ph.D., NMSS/MSTR/MSEB
6

7 MEMBERS OF THE PUBLIC PRESENT:

8 ANDREW BROWN, The Ohio State University Wexner
9 Medical Center
10 STEVE CHILINSKI, PharmaLogic
11 CASON COAN, Alabama Department of Public Health
12 JAMES COOK, Advanced Accelerator Applications
13 HENDRIK ENGELBRECHT, *unaffiliated*
14 LYNNE FAIROBENT, American Association of
15 Physicists in Medicine
16 SANDRA GABRIEL, International Atomic Energy
17 Agency
18 WENDY GALBRAITH, University of Oklahoma College
19 of Pharmacy
20 DAN HILL, Cardinal Health
21 AKRAM HUSSEIN, The Ohio State University Wexner
22 Medical Center
23 THOMAS HUSTON, Veterans Health Administration
24 National Health Physics Program
25 BRANDON JURAN, Minnesota Department of Health

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 SCOTT KNISHKA, University of Wisconsin School of
2 Pharmacy

3 CAITLIN KUBLER, Society of Nuclear Medicine and
4 Molecular Imaging

5 SAMUEL LEVERITT, Cardinal Health

6 RALPH LIETO, St. Joseph Health

7 RICHARD MARTIN, American Association of
8 Physicists in Medicine

9 STEVEN MATTMULLER, Kettering Health

10 NEIL PETRY, Duke University Medical Center

11 ANDREA RAVARD, Cedar Sinai Medical Center

12 MICHAEL SHEETZ, University of Pittsburgh

13 JARED THOMPSON, Arkansas Department of Health

14 CINDY TOMLINSON, American Society for Radiation
15 Oncology

16 RICHARD VAN SANT, PharmaLogic

17 JOSEPH WISSING, Veterans Health Administration
18 National Health Physics Program

19 MELONIE WISSING, Veterans Health Administration
20 National Health Physics Program

21

22

23

24

25

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

T-A-B-L-E O-F C-O-N-T-E-N-T-S

Welcome and Opening Remarks

Pat Zanzonico.....7

Michael Fuller.....8

Background on Draft Licensing Guidance

Katie Tapp.....13

Summary of the Subcommittee Report on the Working Group's Licensing Guidance

Pat Zanzonico.....16

Opportunity for Questions and Comments.....22

Closing Remarks

Michael Fuller.....35

Adjournment.....37

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

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

1:32 p.m.

OPERATOR: Welcome and thank you for standing by. At this time all participants are in a listen-only mode. During the question and answer session please press star, one on your touch-tone phone if you'd like to ask a question.

I'll turn the meeting over to Ms. Sophie Holiday.

Ma'am, you may begin.

MS. HOLIDAY: Thank you. I'm going to turn it to Dr. Zanzonico to open up the meeting.

VICE CHAIR ZANZONICO: Okay. Thank you, Sophie.

Pat Zanzonico. And this is a meeting of a Subcommittee of the Advisory Committee on Medical Uses of Isotopes, which considered and generated a report on the license guidance for germanium-68/gallium-68 generators.

The purpose of this meeting is to just basically summarize the salient features of that report and to discuss it and then consider a vote by the full ACMUI to adopt that report.

And before we get into the actual substance

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 of the meeting, I'd like to turn the meeting over to Mr.
2 Mike Fuller of the NRC for additional opening remarks.

3 MR. FULLER: Thank you, Dr. Zanzonico. As
4 the designated federal officer for this meeting I'm
5 pleased to welcome you to this public meeting of the
6 Advisory Committee on the Medical Uses of Isotopes. My
7 name is Mike Fuller and I am the medical team leader of
8 the Medical Radiation Safety Team at the NRC and I have
9 been designated as the federal officer for this advisory
10 committee in accordance with 10 CFR Part 17.11.

11 Present today as the alternate designated
12 federal officer is Sophie Holiday, ACMUI Coordinator.

13 This is an announced meeting of the
14 Committee. It is being held in accordance with the
15 rules and regulations of the Federal Advisory Committee
16 Act and the Nuclear Regulatory Commission.

17 This meeting is being transcribed by the
18 NRC and it may also be transcribed or recorded by others.
19 This meeting was announced in the July 18th, 2016
20 edition of the *Federal Register*. That's volume 81,
21 page 46716.

22 The function of the Committee is to advise
23 the staff on issues and questions that arise on the
24 medical use of byproduct material. The Committee
25 provides counsel to the staff, but does not determine

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 or direct the actual decisions of the staff or the
2 Commission. The NRC solicits the views of the
3 Committee and values their opinions.

4 I request if possible we try to reach a
5 consensus on the issues that we will discuss today, but
6 I also recognize there may be minority or dissenting
7 opinions. If you have such opinions, please allow them
8 to be read into the record.

9 At this point I would like to perform a roll
10 call of the ACMUI members participating today.

11 Dr. Pat Zanzonico?

12 VICE CHAIR ZANZONICO: Present.

13 MR. FULLER: Mr. Frank Costello?

14 MEMBER COSTELLO: Present.

15 MR. FULLER: Dr. Vasken Dilsizian?

16 MEMBER DILSIZIAN: Present.

17 MR. FULLER: Dr. Ronald Ennis?

18 (No audible response.)

19 MR. FULLER: Dr. Sue Langhorst?

20 MEMBER LANGHORST: Present.

21 MR. FULLER: Dr. Darlene Metter?

22 MEMBER METTER: Present.

23 MR. FULLER: Dr. Michael O'Hara?

24 MEMBER O'HARA: Present.

25 MR. FULLER: Dr. Christopher Palestro?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MEMBER PALESTRO: Present.

2 MR. FULLER: Dr. John Suh?

3 MEMBER SUH: Present.

4 MR. FULLER: Ms. Laura Weil?

5 MEMBER WEIL: Present.

6 MR. FULLER: Okay. I've confirmed that a
7 quorum has been met by the presence of at least seven
8 members. On the phone do we have Mr. Zoubir Ouhib?

9 (No audible response.)

10 MR. FULLER: Or Mr. Richard Green?

11 (No audible response.)

12 MEMBER GREEN: Present.

13 MR. FULLER: Mr. Zoubir Ouhib has been
14 selected as the ACMUI therapy medical physicist. Mr.
15 Richard Green has been selected as the ACMUI nuclear
16 pharmacist. Mr. Ouhib and Mr. Green are pending
17 security clearance, but may participate in this
18 meeting, however, they do not have voting rights.

19 I now ask NRC staff members who are present
20 to identify themselves. I'll start with individuals in
21 the room here.

22 DR. HOWE: Dr. Donna-Beth Howe.

23 MS. HOLIDAY: Sophie Holiday.

24 MR. GENDELMAN: Adam Gendelman.

25 DR. HOLAHAN: Dr. Vincent Holahan.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MS. SMETHERS: Michelle Smethers.

2 DR. DAIBES: Dr. Said Daibes.

3 MR. FULLER: Okay. Now we will go to NRC
4 Headquarters employees on the phone. Please identify
5 yourself.

6 DR. TAPP: Dr. Katie Tapp.

7 MR. FULLER: And do we have any members of
8 the working group present on the phone?

9 MS. NGUYEN: Jan Nguyen.

10 MR. FULLER: Okay. Thank you. Members
11 of the public who notified Ms. Holiday that they will
12 be participating on the teleconference will be captured
13 in the transcripts. Those of you who did not provide
14 prior notification, please contact Ms. Holiday at
15 sophie.holiday@nrc.gov or call 301-415-7865.

16 We have a bridge line available and that
17 phone number is 888-469-2036. The pass code to access
18 the bridge line is 7557476#.

19 This meeting is also using the GoToWebinar
20 application to view presentation handouts real time.
21 You can access this by going to www.gotowebinar.com and
22 search for meeting ID 131-635-875.

23 The purpose of this meeting is to discuss
24 the draft report of the ACMUI Germanium-68/Gallium-68
25 Generator Subcommittee. Individuals who would like to

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 ask a question or make a comment regarding a specific
2 issue the Committee has discussed should request
3 permission to be recognized by the ACMUI Vice
4 Chairperson Dr. Pat Zanzonico.

5 Dr. Zanzonico, at his option, may entertain
6 comments or questions from members of the public who are
7 participating with us today. Comments and questions
8 are usually addressed by the Committee near the end of
9 the meeting after the Committee has fully discussed the
10 topic.

11 I would also like to add that the handouts
12 and agenda for this meeting are available on NRC's
13 public web site.

14 For everyone's awareness, NRC staff has
15 recently taken an action that is related to the topic
16 being discussed today, but not the subject of today's
17 meeting. On July 29th NRC issued a memo to our regional
18 administrators authorizing them to grant an exemption
19 to the Decommissioning Funding Plan requirements and 10
20 CFR Part 35.35 -- I'm sorry, Part 30.35 for the
21 possession and use of germanium-68/gallium-68
22 generators will be questioned and under certain
23 circumstances. Those circumstances involve the
24 existence of a legally binding agreement between the
25 licensee and the manufacturer or the distributor of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 generator, that the generator or generators will be
2 returned to the manufacturer or the distributor when the
3 generator expires or is no longer in use.

4 At this time Dr. Katie Tapp is going to
5 provide a little bit of background information on behalf
6 of the working group that developed the Draft Guidance,
7 Licensing Guidance that will be discussed today by the
8 ACMUI.

9 Dr. Tapp?

10 DR. TAPP: Thank you, Mike. The NRC and
11 the Agreement States formed a working group earlier this
12 year to evaluate the use of germanium-68/gallium-68
13 generators to produce gallium-68 for
14 radiopharmaceuticals. Based on the evaluation the
15 working group has made the recommendation that the use
16 of these generators should be under 10 CFR 35.1000
17 because of the potential for germanium-68 breakthrough.

18 Since 10 CFR 35.204 does not have the
19 maximum germanium-68 concentration as it does for other
20 types of generators for the breakthroughs of their
21 parents, the working group has made the recommendation
22 for the use of the generators to be licensed under 10
23 CFR 35.1000. The working group has made a Draft
24 Licensing Guidance that the ACMUI will be effecting the
25 recommendations on today.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 The working group wanted to provide a
2 little overview of what was contained in this Licensing
3 Guidance of background information for those listening
4 on the phone. So the germanium-68 and gallium-68
5 generators are expected to be used both at hospital
6 facilities and at commercial nuclear pharmacies.
7 Because of this, the Licensing Guidance both for medical
8 facilities and for commercial nuclear pharmacies is
9 licensed under Part 32.

10 Example commitments that are currently in
11 the Draft Licensing Guidance include the breakthrough
12 limits set by the manufacturer, but the commitment to
13 test the breakthrough of the generator once the
14 generator is in use and to elute the generator at a
15 frequency set in accordance with manufacturing and
16 operating procedures because the germanium-68
17 breakthrough can increase if elution is not done at a
18 regular frequency.

19 In addition, currently there's a draft
20 commitment for the licensee to provide training for the
21 individuals who are using the gallium-68 -- the
22 germanium-68/gallium-68 generators. Those are
23 examples of draft commitments that the working group is
24 recommending in this Draft Licensing Guidance.

25 After today's meeting from the ACMUI is a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 recommendation on the document as formed. The working
2 group will reconvene to go over this recommendation and
3 the comments received as well as comments received from
4 the states and NRC regions on the draft document. The
5 working group will then issue a final Licensing Guidance
6 document and provide that to the NRC management for
7 final review, and at that time the document will be
8 issued as final and will be posted on our web site with
9 our other 10 CFR 35.1000 documents.

10 With that, I'd like to turn it back to Mike
11 Fuller for his remaining remarks.

12 MR. FULLER: Okay. Thank you. Thank
13 you, Katie.

14 Okay. So at this time I ask that everyone
15 on the call who is not speaking please place their phones
16 on mute. If you do not have the capability to mute your
17 phone, please press star, six to utilize the conference
18 line mute and un-mute functions. I would ask everyone
19 to exercise extreme care to ensure that the background
20 noise is kept at a minimum as any stray background sounds
21 can be very disruptive on a conference call as large as
22 this one.

23 Okay. At this point I would like to turn
24 the meeting back over to Dr. Zanzonico.

25 VICE CHAIR ZANZONICO: Thank you, Mr.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Fuller.

2 As was mentioned I think, I serve as both
3 the Vice Chairman of the ACMUI as well as Chairman of
4 this Subcommittee, so I'm feeling fairly omnipotent
5 today. But in any case, I'll be presiding over the
6 meeting and will be presenting a summary of our
7 subcommittee report on the working group's Licensing
8 Guidance. And as was alluded to, the Food and Drug
9 Administration recently approved a gallium-68
10 radiopharmaceutical, specifically gallium-68
11 DOTATATE, which is a proprietary name NetSpot for
12 diagnostic imaging by positron emission tomography or
13 PET of somatostatin receptor positive tumors.

14 And unlike more conventional PET
15 radiopharmaceuticals like F-18 labeled fludeoxyglucose
16 or FDG, gallium-68 used to prepare DOTATATE can be
17 produced from a generator similar to the more familiar
18 molybdenum-99/technetium-99m generator. But it is a
19 new clinical application of this generator, and the NRC
20 in conjunction with the Agreement State representatives
21 therefore directed guidance to provide applicants with
22 an acceptable means of satisfying the regulatory
23 requirements for a license for the use of the generator
24 for producing gallium-68 to be used in the preparation
25 of gallium-68 labeled radiopharmaceutical.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Our Committee, the ACMUI, subsequently
2 convened a subcommittee to review and comment and offer
3 recommendations on this Draft Licensing Guidance, and
4 the report we prepared and are discussing today
5 represents the Subcommittee's report on this guidance.

6 We included in our report a general
7 background on imaging of neuroendocrine tumors and the
8 clinical challenge that that presents. And we also
9 briefly reviewed and discussed the value, the improved
10 diagnostic capability offered by gallium-68 DOTATATE
11 and related somatostatin receptor
12 radiopharmaceuticals. And that information of course
13 is available in the literature.

14 And as you know, the gallium-68 is a
15 short-lived radionuclide with a physical half-life of
16 68 minutes with a positron emitting radiometal that can
17 be labeled to the radiopharmaceutical via agents such
18 as DOTA. And the gallium-68 is obtained from the
19 generator we're discussing. It can also be used to
20 label any one of other types of radiopharmaceuticals
21 such as antibodies and antibody fragments, and so
22 gallium-68 in the generator can have wide applicability
23 in diagnostic imaging well beyond that of
24 neuroendocrine tumors.

25 As was mentioned, as with any generator,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 the parent, germanium-68 can break through in the eluate
2 and result in an unnecessary or avoidable additional
3 radiation to patients receiving the gallium-68
4 radiopharmaceutical with any germanium-68
5 radio-contaminant.

6 As we reviewed in our report, based on data
7 available in the literature, the additional dose to
8 patients from any such germanium-68 breakthrough will
9 frankly be trivially low. Nonetheless, it's important
10 to regularly assay breakthrough from a regular user to
11 evaluate the health and wellbeing of the generator and
12 so forth. So all of this was discussed in the
13 introduction to our report and is available of course
14 for anyone to read should they be interested in it.

15 The next component of our report was
16 recommended changes to the Licensing Guidance, and
17 actually they were relatively limited, our
18 recommendations. No change to the title was
19 recommended. Really no change to the table of contents
20 other than to bring it into consistency with other
21 changes recommended in our comments.

22 We did recommend that a specific section
23 entitled, "Purpose" be included in the Licensing
24 Guidance. We realize that there's a certain format
25 that is typically used in Licensing Guidance, but we

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 felt that would -- as with any such document it would
2 be helpful to explicitly state what the purpose of this
3 document, the Licensing Guidance is and so had some
4 specific recommendation basically to simply
5 rearranging some of the content of the Licensing
6 Guidance to identify it explicitly as the purpose. But
7 those are fairly minor issues.

8 The main issue the Subcommittee had with
9 the Licensing Guidance was the use of the generators
10 under CFR 35.200 versus 35.1000, and therefore its
11 applicability to commercial nuclear pharmacies which
12 would be possessing these generators and providing
13 gallium-68 to prospective users. As we heard and as we
14 discussed at length by our Subcommittee, such
15 commercial nuclear pharmacies are actually regulated
16 under Part 32. And so, there was a question of the
17 applicability of this Licensing Guidance to commercial
18 nuclear pharmacies given that difference in the part of
19 the CFR that licensed authorized uses and medical uses
20 of byproduct materials versus commercial nuclear
21 pharmacies.

22 Now, it was stated in the Licensing
23 Guidance that this guidance would provide a compliant
24 means of both hospital-based generators and authorized
25 users as well as commercial nuclear pharmacies to be in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 compliance with their respective regulations.

2 We recommended some revised language to
3 hopefully clarify that point and to make it more
4 explicit. And there's a fairly extensive section in
5 our report dealing with that specific issue. And
6 again, that was our main concern, was the range or scope
7 of applicability of the Licensing Guidance to ensure
8 that it covered commercial nuclear pharmacies as well
9 as hospital-based generator systems. Again, it was
10 stated originally in the Licensing Guidance. We felt
11 it could be made more explicit and more emphatic and
12 suggested language, revised language to hopefully
13 accomplish that.

14 We also had a number of other less
15 significant, but noteworthy editorial revisions that we
16 suggested, and one additional issue that was alluded to
17 and that we think may require some expansion in the
18 Licensing Guidance is the issue of leakage of the
19 generators. It is stated at one point in the Licensing
20 Guidance that generators should be evaluated for
21 leakage, but we think that perhaps that should be
22 broadened a little, expanded a bit to provide a
23 compliant means of evaluating leakage.

24 Another issue that was weighed was the
25 meaning of the word or the term "different locations."

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 There was a reference made in the Licensing Guidance to
2 retest and evaluate and so forth if a generator would
3 move to a different location. That term was undefined
4 originally in the guidance, and we subsequently learned
5 it was not intended to apply for example to different
6 areas of the same room, for example, or even different
7 rooms in the same facility building. But we think that
8 a more explicit definition of what that term, the term
9 "location," was meant to imply should be included.

10 Again, we also had a number of other less
11 significant, but noteworthy editorial revisions that
12 were included in our report, but I think those are the
13 main features, the main points and recommendations of
14 our report.

15 And with that, I'll conclude my opening
16 remarks and now ask if any members of the Subcommittee
17 have comments or questions.

18 Before I do, however, I should recognize
19 the other members of the Subcommittee, all of whom put
20 in a lot of time and effort and thought into this report.
21 And I know you want to acknowledge and recognize all of
22 them for their contributions. And they include: Mr.
23 Frank Costello, Dr. Sue Langhorst, Dr. Darlene Metter,
24 Dr. Chris Palestro, as well as myself. I think we
25 crafted an excellent report, if I do say so myself, and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 hopefully it will be of value not only to the working
2 group that prepared the Licensing Guidance, but
3 ultimately to end users.

4 So with that, I would open it up to comments
5 and questions, first by the Subcommittee members, then
6 to the full ACMUI, and finally a time allowed to members
7 of the general public who may be on the line.

8 So if anyone on the Subcommittee would like
9 to make a comment, please identify yourself and go
10 forward.

11 MEMBER LANGHORST: Dr. Zanzonico, this is
12 Sue Langhorst.

13 VICE CHAIR ZANZONICO: Yes, Sue?

14 MEMBER LANGHORST: I'd like to emphasize
15 something, some of the wording that we suggested for the
16 Draft Licensing Guidance in that the use of the
17 germanium/gallium generator to make gallium-68
18 radiopharmaceuticals is the portion that is under
19 35.1000. The use of the gallium-68
20 radiopharmaceuticals remains under 35.200. So for
21 instance, if a hospital gets a germanium/gallium
22 generator, the authorized user who in charge of that
23 elution and production of the radiopharmaceutical has
24 to go through the training requirements listened in the
25 Draft Licensing Guidance, but those authorized users

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 who are only just getting the gallium-68
2 radiopharmaceutical and using it as a diagnostic tool
3 don't have to do any additional training. They're
4 already approved under 35.200 use. Thank you.

5 VICE CHAIR ZANZONICO: Thanks very much.
6 That was a very good point and an omission on my part.
7 I think that's a very important distinction. And
8 again, in our report we endeavored to add language to
9 further qualify and emphasize that point, because it's
10 an important one. So thank you, Dr. Langhorst, for that
11 comment.

12 Are there other comments from the
13 Subcommittee?

14 (No audible response.)

15 VICE CHAIR ZANZONICO: Hearing none at
16 this point, I would then solicit comments from other
17 members of the ACMUI, those not on the Subcommittee that
18 drafted the report. So again, if there any members of
19 the ACMUI who would like to make a comment, please do
20 so and identify yourself.

21 MR. GREEN: Good afternoon, Dr. Zanzonico.
22 This is Richard Green.

23 VICE CHAIR ZANZONICO: Yes, Mr. Green,
24 please.

25 MR. GREEN: I'd like to thank the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 Subcommittee for a very thorough and thoughtful report.
2 I would just like to mention in the paragraph on page
3 1 under "Background" the manufacturer identified as the
4 manufacturer of NetSpot is incorrect. It's listed as
5 Eckert & Ziegler, Berlin, Germany. The FDA-approved
6 kit that is radiolabeled is manufactured by Advanced
7 Accelerator Applications, New York City. So there's a
8 manufacturer of the generator; that is Eckert & Ziegler
9 in Germany, but the pharmaceutical kit labeled with the
10 eluate is Advanced Accelerator Applications.

11 VICE CHAIR ZANZONICO: Thank you, Mr.
12 Green, for that correction.

13 I'm sorry. Did you have a further comment?
14 I didn't mean to interrupt, Mr. Green.

15 MR. GREEN: No, that's fine. Just a note
16 on page 2 in the first paragraph. It reads, "Until the
17 approval of NetSpot and gallium-68 DOTATATE." I'd
18 recommend that the "and" be struck and that the
19 gallium-68 DOTATOC, which is -- okay, my -- so NetSpot
20 is the FDA-approved drug. Gallium-68 DOTATATE is the
21 generic name of the product. And I think the "and" is
22 confusing us, leading people to believe that they're two
23 different products. One is the brand name; one is the
24 generic name.

25 VICE CHAIR ZANZONICO: Understood. Thank

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 you for that as well.

2 MR. GREEN: And the last item is on page 3,
3 and this has to deal a little bit with physics, so I'm
4 getting a little bit outside my area. But on the very
5 last paragraph towards the bottom there's an example of
6 mathematics. It starts off with "The qualitative
7 elution of a 50 millicurie generator." And so, a 50
8 millicurie germanium-68 generator will yield
9 approximately a 60 percent yield, so you would receive
10 an elution of around 30 millicuries of gallium-68. And
11 in this example mathematics I believe was a one-to-one
12 100 percent yield, 50 millicuries of germanium yielding
13 50 millicuries of gallium. And the physics actually
14 would be a 60 percent yield, or 30 millicuries.

15 VICE CHAIR ZANZONICO: Understood. Thank
16 you, Joe. We ought to endeavor to be correct.

17 MR. GREEN: That's it. Thank you very
18 much.

19 VICE CHAIR ZANZONICO: Thank you. I may
20 say there will likely be -- in addition to the
21 corrections Mr. Green identified, there will likely be
22 additional editorial, for lack of a better term,
23 corrections before the report is actually finalized. I
24 don't think any of those would impact the approvability
25 of the report, but in the interest of full disclosure,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 as I said, there will likely be certain editorial
2 corrections. No matter how many people and how often
3 these sets of documents are vetted, there's always
4 another error to find. But again, I don't think any of
5 those at this point will impact the approvability of the
6 report.

7 So thank you, Mr. Green.

8 Other comments from the ACMUI membership?

9 MR. GREEN: I'm sorry. This is Richard
10 Green again.

11 VICE CHAIR ZANZONICO: Yes, please.

12 MR. GREEN: On page 4 the footnote
13 reference No. 14 --

14 VICE CHAIR ZANZONICO: Right.

15 MR. GREEN: -- references a Danish health
16 and nursing authority 2014 product, -- similar product
17 characteristics for the germanium GalliaPharm
18 Generator. Since this NetSpot has been FDA approved,
19 Eckert & Ziegler has released GalliaPharm
20 pharmaceutical GMP grade germanium-68/gallium-68
21 instructions for use, document published May 27th,
22 2016. And we can make that available if you would like.

23 VICE CHAIR ZANZONICO: That would be
24 great. If there's a more pertinent or more up-to-date
25 reference, we should certainly include that. Thank you

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 for that.

2 Are there other comments from the ACMUI
3 membership?

4 (No audible response.)

5 VICE CHAIR ZANZONICO: Hearing none and
6 seeing that we have ample time, to put it mildly, is
7 there anyone on the line from the general public that
8 would like to make a comment or ask a question?

9 OPERATOR: Thank you.

10 VICE CHAIR ZANZONICO: So now is your
11 opportunity to do so. Please identify yourself.

12 OPERATOR: Participants on the phone, if
13 you'd like to ask a question, please press star, one and
14 record your name.

15 One moment as questions register.

16 (Pause.)

17 OPERATOR: We have a question from
18 Christina England.

19 Ma'am, your line is open.

20 MS. ENGLAND: I withdrawn. I was trying
21 to log in earlier when participants were requested.

22 OPERATOR: Thank you. Our next question
23 is from Nawali.

24 Your line is open.

25 (No audible response.)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 OPERATOR: Again, caller, please check
2 your mute button. Your line is now open.

3 (No audible response.)

4 OPERATOR: As a reminder, participants, if
5 you'd like to ask a question, please press star, one and
6 record your name.

7 One moment to see if we have any questions.

8 (Pause.)

9 OPERATOR: We have a question from Dan
10 Hill.

11 Your line is open.

12 MR. HILL: Hi, this is Dan, also working
13 with Richard Green. In the call today there was mention
14 of a memo sent to the NRC regional administrators on July
15 29th, 2016. I believe that it was mentioned that the
16 requirements for the exemption of the gallium-68
17 generator involved one requirement that I heard of
18 specifically, an agreement with the manufacturer for
19 the return of the generator to the manufacturer at the
20 expiry or after the useful life of the generator.

21 Can you tell us on the phone if this means
22 a specific agreement with each and every customer or a
23 general form letter or acknowledgement from the
24 manufacturer, or if this is currently in place and
25 available to all licensees as a single requirement for

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 an exemption being from decommissioning financial
2 assurance?

3 VICE CHAIR ZANZONICO: This is Pat
4 Zanzonico again, and I will in a moment defer to Dr. Tapp
5 to answer that point more explicitly.

6 My reading of the Licensing Guidance is
7 that this agreement must be a legally binding document.
8 And my interpretation of that, and I'm not a legal person
9 by any means -- but my interpretation of that is that
10 there must be a specific letter between a named
11 customer; that is, the hospital or clinic or whatever,
12 and the named manufacturer. I would think that to make
13 that legally binding the party to this agreement must
14 be explicitly identified and there would need to be a
15 separate agreement letter for each customer and each
16 manufacturer. That's my uneducated interpretation of
17 that language.

18 Dr. Tapp, would you care to comment on that?

19 MR. FULLER: Yes, thank you, Dr.
20 Zanzonico. This is Mike and I think I can take this on.

21 Yes, that's correct. The expectation at
22 least for now is that each one of -- each time the
23 licensee is -- or each time one of our licensees requests
24 an amendment to add this to their license, we will need
25 to review that legally binding agreement. We also have

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 an attorney here, Adam Gendelman, who's here with us
2 today. And so this is really more of a legal question
3 I think, and so perhaps he might want to weigh in as well.

4 But, yes, our expectation is that each time
5 someone applies for the authority or the permission to
6 possess and use one of these generators, as part of that
7 review of that application in order to be able to exempt
8 that person or that licensee from the requirements for
9 a Decommissioning Funding Plan, that legally binding
10 agreement is something that would need to be reviewed.

11 MR. GENDELMAN: And this is Adam
12 Gendelman. Operator, if you could open Christina
13 England's line, she has some experience on this as well.

14 OPERATOR: One moment.

15 Ms. England, would you please press star,
16 then one for your question?

17 (Pause.)

18 OPERATOR: Thanks. Ms. England, your
19 line is now open.

20 MS. ENGLAND: Hi, everyone. This is
21 Christina. Yes, what you described is correct. A
22 legally binding agreement will be required between the
23 licensee and the manufacturer or the distributor that
24 is supplying the generator. The agreement itself would
25 be determined -- well, confirmed to be legally binding

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 by an attorney in the regions or an attorney at
2 headquarters, but I haven't heard anything, I don't
3 think, that is exactly what we're expecting and what is
4 anticipated by the exemption.

5 MR. HILL: Thank you, everyone.

6 VICE CHAIR ZANZONICO: Thank you. Mr.
7 Hill, does that answer your question?

8 MR. HILL: Yes, and of course if that is the
9 only requirement or if there's other criteria you could
10 explain.

11 VICE CHAIR ZANZONICO: Well, again, my
12 reading of the document, of the Licensing Guidance and
13 obviously we can only interpret what's on paper, so to
14 speak, is that that's the sum and the substance of the
15 requirements for the exemption. Again, NRC staff could
16 correct me if I'm wrong, but based on what's in black
17 and white in the Licensing Guidance, that's my
18 interpretation.

19 MR. HILL: Agreed. Keeping in mind that
20 for patient care licensees may request permission to
21 have two generators, therefore after six months and
22 return of the first generator they will be able to
23 receive one ahead time as a replacement while the other
24 one is being returned. So I presume there is
25 consideration in Licensing Guidance for having two

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 generators -- permission for two generators when only
2 one generator is actually being used.

3 MS. ENGLAND: Christina again, if my line
4 still open. It's also important to note that the
5 licensee would need to request this exemption, as it is
6 with any exemption. But this isn't something that is
7 on the onus of the NRC to do. The agreement will have
8 to be presented for analysis by the NRC. It's not
9 something the NRC will need to request.

10 MR. HILL: Thank you.

11 VICE CHAIR ZANZONICO: Thank you both.

12 MEMBER LANGHORST: Dr. Zanzonico, this is
13 Sue Langhorst.

14 VICE CHAIR ZANZONICO: Yes, Dr. Langhorst?

15 MEMBER LANGHORST: I also wanted to
16 clarify that licensees that already possess a
17 Decommissioning Funding Plan will not have to request
18 this exemption and will not have to have this legally
19 binding agreement either. Thank you.

20 VICE CHAIR ZANZONICO: Thank you, Dr.
21 Langhorst, for that clarification. I think that that
22 is essentially stated in the Licensing Guidance, but I
23 appreciate the -- clarifying that point.

24 MEMBER COSTELLO: Dr. Zanzonico, this is
25 Frank Costello.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 VICE CHAIR ZANZONICO: Yes, Mr. Costello?

2 MEMBER COSTELLO: Yes, I will point out
3 that most licensees I think who need this exemption or
4 another generator reside in Agreement States. And if
5 that would happen, then they would have to request the
6 Agreement State for the exemption. I don't think the
7 process would be much different, but that's how it would
8 work. You have to request the Agreement State rather
9 than the NRC.

10 VICE CHAIR ZANZONICO: Thank you for that
11 comment.

12 Further comments from the public at this
13 point, or really from anyone who would like to offer one?

14 OPERATOR: I have to remind our
15 participants, if you'd like to ask a question, please
16 press star, one and record your name.

17 At this moment, speakers, I'm showing no
18 questions in queue.

19 VICE CHAIR ZANZONICO: Thank you very
20 much. At this point therefore, since there appear to
21 be no further questions or comments to consider, I
22 believe someone other than myself would need to make a
23 motion to approve the Subcommittee's report, the
24 Subcommittee's draft report on the working group's
25 Licensing Guidance.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MEMBER LANGHORST: This is Sue Langhorst.
2 I'll make such a motion.

3 VICE CHAIR ZANZONICO: Can I hear a second?

4 MEMBER COSTELLO: I second.

5 VICE CHAIR ZANZONICO: So I think at this
6 point the entire Subcommittee -- I'm sorry, the entire
7 Committee, the ACMUI, needs to vote on that motion,
8 which is to approve the Subcommittee's report on the
9 working group's Licensing Guidance and to therefore
10 make it an ACMUI report.

11 So we'll just take a voice vote. All in
12 favor, say aye?

13 (Chorus of aye.)

14 VICE CHAIR ZANZONICO: All those opposed,
15 please say nay?

16 (No audible response.)

17 VICE CHAIR ZANZONICO: The motion is
18 therefore carried unanimously and the Subcommittee's
19 report on the working group's Licensing Guidance is
20 approved unanimously.

21 I think therefore that concludes the
22 business of today's meeting. And I would therefore,
23 before formally closing the meeting, ask if Mr. Fuller
24 or anyone else from the NRC has a closing comment to
25 make.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 MR. FULLER: Thank you, Dr. Zanzonico.
2 No, we really don't have any further comments or so
3 forth. We'd like to thank you and the Committee and
4 especially the Subcommittee's time and effort.

5 Sophie, did you have something?

6 MS. HOLIDAY: I'd just like to ask the
7 operator if anybody else has pressed star, one asking
8 staff a question.

9 OPERATOR: Again, participants, if you'd
10 like to ask a question, please press star, one and record
11 your name.

12 One moment to see if we have additional
13 questions in the queue.

14 VICE CHAIR ZANZONICO: Thank you.

15 (Pause.)

16 OPERATOR: At this time I'm showing no
17 questions.

18 MS. HOLIDAY: Thank you so much. Sorry,
19 Mike.

20 MR. FULLER: That's okay.

21 All right. Well again, thank you everyone
22 for your time and your attention to this matter. I know
23 we got some questions on the Decommissioning Funding
24 Plan, which was really not the purpose of this meeting.
25 I mention that just so that folks would know that we have

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701

1 done that. That document should be publicly available
2 we found out today in a matter of a few days at which
3 time it will be available on our web site.

4 So with that, Dr. Zanzonico, I'll turn it
5 back over to you if you wish to go ahead and adjourn.

6 VICE CHAIR ZANZONICO: Yes, thank you very
7 much.

8 So with that, the meeting is formally
9 adjourned. I thank all of the participants and also
10 again thank the members of the Subcommittee who drafted
11 this report. Thank you all. The meeting is hereby
12 adjourned.

13 (Whereupon, the above-entitled matter went
14 off the record at 2:19 p.m.)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS
1323 RHODE ISLAND AVE., N.W.
WASHINGTON, D.C. 20005-3701