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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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WEDNESDAY,

AUGUST 10, 2016

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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

Physician

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

LAURA M. WEIL, Patients' Rights Advocate

Non-Voting: RICHARD GREEN

NRC STAFF PRESENT:

MICHAEL FULLER, Acting ACMUI Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Alternate Designated Federal Officer and ACMUI Coordinator

JENNIFER BISHOP, R-III/DNMS/MLB

COLLEEN CASEY, R-III/DNMS/MLB

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

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

SARA FORSTER, R-III/DNMS/MLB

CASSANDRA FRAZIER, R-III/DNMS/MLB

CHRISTINA ENGLAND, OGC/GCLR/RMR

ADAM GENDELMAN, OGC/GCLR/RMR

JOHN GIESSNER, R-III/DNMS

VINCENT HOLAHAN, Ph.D., NMSS/MSTR

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

PENNY LANZISERA, R-I/DNMS/MB

JOHARI MOORE, COMM/OCM

JAN NGUYEN, R-I/DNMS/MB

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

PATTY PELKE, R-III/DNMS/MLB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

TOYE SIMMONS, R-III/DNMS/MLB

MICHELLE SMETHERS, NMSS/MSTR/MSEB

KATIE TAPP, Ph.D., NMSS/MSTR/MSEB

MEMBERS OF THE PUBLIC PRESENT:

ANDREW BROWN, The Ohio State University Wexner Medical Center

STEVE CHILINSKI, PharmaLogic

CASON COAN, Alabama Department of Public Health

JAMES COOK, Advanced Accelerator Applications

HENDRIK ENGELBRECHT, *unaffiliated*

LYNNE FAIROBENT, American Association of Physicists in Medicine

SANDRA GABRIEL, International Atomic Energy Agency

WENDY GALBRAITH, University of Oklahoma College of Pharmacy

DAN HILL, Cardinal Health

AKRAM HUSSEIN, The Ohio State University Wexner Medical Center

THOMAS HUSTON, Veterans Health Administration National Health Physics Program

BRANDON JURAN, Minnesota Department of Health

SCOTT KNISHKA, University of Wisconsin School of Pharmacy

CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging

SAMUEL LEVERITT, Cardinal Health

RALPH LIETO, St. Joseph Health

RICHARD MARTIN, American Association of Physicists in Medicine

STEVEN MATTMULLER, Kettering Health

NEIL PETRY, Duke University Medical Center

ANDREA RAVARD, Cedar Sinai Medical Center

MICHAEL SHEETZ, University of Pittsburgh

JARED THOMPSON, Arkansas Department of Health

CINDY TOMLINSON, American Society for Radiation Oncology

RICHARD VAN SANT, PharmaLogic

JOSEPH WISSING, Veterans Health Administration National Health Physics Program

MELONIE WISSING, Veterans Health Administration National Health Physics Program

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

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

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

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

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

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

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

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

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

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

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

Dr. Pat Zanzonico?

VICE CHAIR ZANZONICO: Present.

MR. FULLER: Mr. Frank Costello?

MEMBER COSTELLO: Present.

MR. FULLER: Dr. Vasken Dilsizian?

MEMBER DILSIZIAN: Present.

MR. FULLER: Dr. Ronald Ennis?

(No audible response.)

MR. FULLER: Dr. Sue Langhorst?

MEMBER LANGHORST: Present.

MR. FULLER: Dr. Darlene Metter?

MEMBER METTER: Present.

MR. FULLER: Dr. Michael O'Hara?

MEMBER O'HARA: Present.

MR. FULLER: Dr. Christopher Palestro?

MEMBER PALESTRO: Present.

MR. FULLER: Dr. John Suh?

MEMBER SUH: Present.

MR. FULLER: Ms. Laura Weil?

MEMBER WEIL: Present.

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

(No audible response.)

MR. FULLER: Or Mr. Richard Green?

(No audible response.)

MEMBER GREEN: Present.

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

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

DR. HOWE: Dr. Donna-Beth Howe.

MS. HOLIDAY: Sophie Holiday.

MR. GENDELMAN: Adam Gendelman.

DR. HOLAHAN: Dr. Vincent Holahan.

MS. SMETHERS: Michelle Smethers.

DR. DAIBES: Dr. Said Daibes.

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

DR. TAPP: Dr. Katie Tapp.

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

MS. NGUYEN: Jan Nguyen.

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

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

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

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

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

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

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

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

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

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

Dr. Tapp?

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

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

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

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

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

After today's meeting from the ACMUI is a

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

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

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

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

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

VICE CHAIR ZANZONICO: Thank you, Mr.

Fuller.

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

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

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

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

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

As was mentioned, as with any generator,

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

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

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

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

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

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

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

compliance with their respective regulations.

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

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

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

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

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

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

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

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

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

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

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

VICE CHAIR ZANZONICO: Yes, Sue?

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

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

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

Are there other comments from the Subcommittee?

(No audible response.)

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

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

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

MR. GREEN: I'd like to thank the

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

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

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

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

VICE CHAIR ZANZONICO: Understood. Thank

you for that as well.

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

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

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

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

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

So thank you, Mr. Green.

Other comments from the ACMUI membership?

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

VICE CHAIR ZANZONICO: Yes, please.

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

VICE CHAIR ZANZONICO: Right.

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

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

for that.

Are there other comments from the ACMUI membership?

(No audible response.)

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

OPERATOR: Thank you.

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

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

One moment as questions register.

(Pause.)

OPERATOR: We have a question from Christina England.

Ma'am, your line is open.

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

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

Your line is open.

(No audible response.)

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

(No audible response.)

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

One moment to see if we have any questions.

(Pause.)

OPERATOR: We have a question from Dan Hill.

Your line is open.

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

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

an exemption being from decommissioning financial assurance?

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

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

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

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

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

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

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

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

OPERATOR: One moment.

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

(Pause.)

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

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

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

MR. HILL: Thank you, everyone.

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

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

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

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

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

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

MR. HILL: Thank you.

VICE CHAIR ZANZONICO: Thank you both.

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

VICE CHAIR ZANZONICO: Yes, Dr. Langhorst?

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

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

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

VICE CHAIR ZANZONICO: Yes, Mr. Costello?

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

VICE CHAIR ZANZONICO: Thank you for that comment.

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

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

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

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

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

VICE CHAIR ZANZONICO: Can I hear a second?

MEMBER COSTELLO: I second.

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

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

(Chorus of aye.)

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

(No audible response.)

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

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

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

Sophie, did you have something?

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

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

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

VICE CHAIR ZANZONICO: Thank you.

(Pause.)

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

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

MR. FULLER: That's okay.

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

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

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

VICE CHAIR ZANZONICO: Yes, thank you very much.

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

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