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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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THURSDAY,

APRIL 30, 2020

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The meeting was convened via teleconference, at 2:00 p.m. EDT, Dr. A. Robert Schleipman, ACMUI Vice Chairman, presiding.

MEMBERS PRESENT:

DARLENE F. METTER, M.D., Chairman

A. ROBERT SCHLEIPMAN, Ph.D., Vice Chairman

GARY BLOOM, Member

VASKEN DILSIZIAN, M.D., Member

RONALD D. ENNIS, M.D., Member

RICHARD L. GREEN, Member

HOSSEIN JADVAR, M.D., Ph.D., Member

MELISSA C. MARTIN, Member

ZOUBIR OUHIB, Member

MICHAEL SHEETZ, Member

MEGAN L. SHOBER, Member

HARVEY B. WOLKOV, M.D., Member

NRC STAFF PRESENT:

CHRIS EINBERG, Chief, Medical Safety and Events Assessment Branch (MSEB), Designated Federal Officer

LISA DIMMICK, Medical Radiation Safety Team Leader, MSEB

KELLEE JAMERSON, Designated Federal Officer, ACMUI Coordinator

DARRELL ADAMS, OCA

MARYANN AYOADE, NMSS/MSST/MSEB

DAVID BROWN, COMM/OCM

COLLEEN CASEY, R-III/DNMS/MLB

LAURA CENDER, R-III/DNMS/MLB

SAID DAIBES-FIGUEROA, Ph.D., NMSS/MSST/MSEB

SARA FORSTER, R-III/DNMS/MLB

CASSANDRA FRAZIER, R-III/DNMS/MLB

VINCENT HOLAHAN, Ph.D., NMSS/MSST

SOPHIE HOLIDAY, NSIR/DPR

ESTHER HOUSEMAN, OGC/GCLR/RMR

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

IAN IRVIN, OGC/GCLR/RMR

JANELLE JESSIE, COMM/OCMJB

CYNTHIA JONES, COMM/OCMAC

ERIN KENNEDY, R-III/DNMS/MLB

MICHAEL LAFRANZO, R-III/DNMS/MCID

PENNY LANZISERA, R-I/DNMS/MLAB

OLIVIER LAREYNIE, NRR

SAMANTHA LAV, COMM/OCMDW

CHRISTINE LIPA, R-III/DNMS

SARAH LOPAS, NMSS/MSST/MSEB

KATHY MODES, NMSS/MSST/SLPB

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

ROBERT ORLIKOWSKI, R-III/DNMS/MLB

BRYAN PARKER, R-III/DNMS/MLB

DARREN PICCIRILLO, R-III/DNMS

VERED SHAFFER, RES/DSA/RPB

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

GEOFF WARREN, R-III/DNMS/MIB

DUNCAN WHITE, NMSS/MSST/SLPB

IRENE WU, NMSS/MSST/MSEB

ALSO PRESENT:

CHRISTINA ARENAS, SNMMI

REX AYERS, AAPM

SUKHJEET AHUJA, SNMMI

ROLAND BACKHAUS, Morgan Lewis

JAIME BARNES, Cook Children's Medical Center

JANET BUKOVCAN, Boston Scientific

MARY BURKHART, Illinois Emergency Management Agency

WHITNEY COX, Illinois Emergency Management Agency

ELAINE CRESCENZI, Pennsylvania Department of Environmental Protection

DAVID CROWLEY, North Carolina Department of Health and Human Services, Radiation Protection Section

LEWIS CSEDRIK, Morgan Lewis

ARIEL DOUCET, Virtua Health

MICHELE EGBERTS, Nuclear Diagnostic Products

BRIAN ERASMUS, Boston Scientific

SANDY GABRIEL, Unaffiliated

IRA GOLDMAN, Lantheus Medical Imaging

ERIN GRADY, M.D., Emory University School of Medicine

MIGUEL DE LA GUARDIA, Cook Children's Medical Center

STANLEY HAMPTON, Eli Lilly

JAMES HARVEY, NorthStar Medical Technologies

JOSEPH KOSHY, Pennsylvania Department of Environmental Protection

TYLER KRUSE, Minnesota Radioactive Materials Unit

RALPH LIETO, Unaffiliated

WILLIAM LORENZEN, Boston Children's Hospital

CINDI LUCKETT-GILBERT, Unaffiliated

CAROL MARCUS, Ph.D., M.D., UCLA

RICHARD MARTIN, AAPM

CANDI MCDOWELL, University of Pennsylvania

MAHTA MCKEE, Wake Forest Baptist Health

VANESSA MONGEON, Boston Scientific

NIKI NOLL, Pennsylvania Department of Environmental Protection

MICHAEL PETERS, American College of Radiology

GLORIA ROMANELLI, American College of Radiology

KATIE SCOTT, Pennsylvania Department of Environmental Protection

TRACY SCHERER, Pennsylvania Department of Environmental Protection

TIM SHOWALTER, University of Virginia

DIANA THOMPSON, Sirtex

CHRISTOPHER TIGHE, University of Pennsylvania

CINDY TOMLINSON, American Society for Radiation Oncology

JEFF WAGNER, UCSD

BRADLEY WILLIAMS, U.S. Senate Committee on Environment and Public Works

JOHN WITKOWSKI, United Pharmacy Partners

PAT ZANZONICO, Ph.D., Memorial Sloan Kettering Cancer Center

C O N T E N T S

P R O C E E D I N G S

2:16 p.m.

OPERATOR: Welcome. And thank you for standing by. All participants are in a listen only mode until the question and answer session of today's call.

If you anticipate asking a question during the Q&A period, please press star one at your earliest convenience.

I would now like to turn the call over today to our host, Chris Einberg. Sir, you may begin.

MR. EINBERG: Okay. Well, thank you. Good afternoon everyone. Sorry for the delay.

So, I'm going to go ahead and open up the meeting and read the Designated Federal Officer remarks here. So, as the Designated Federal Officer for this meeting, I am pleased to welcome you to the public meeting of the Advisory Committee on the Medical Uses of Isotopes.

My name is Chris Einberg. I'm the Chief of the Medical Safety and Events Assessment Branch. And I've been designated as the Federal Officer for this Advisory Committee in accordance with 10 CFR, Part 7.11.

Participating today, we have Lisa Dimmick,

our Medical Radiation Safety Team Leader, and Kellee Jamerson, our ACMUI Coordinator as Designated Federal Officers for this meeting.

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.

The meeting was announced in the April 16, 2020 addition of the Federal Register, in Volume 85, page 21273.

Due to the immediate need to receive recommendations from the ACMUI, develop and provide guidance to medical use licensees due to the COVID-19 pandemic, the NRC recognizes that this meeting was noticed less the 15 calendar days in the Federal Register.

The purpose of this meeting is to discuss the draft recommendations of the ACMUI COVID-19 subcommittee. The subcommittee's recommendations will include its review of the impact of COVID-19 on the medical use community, and potential regulatory relief measures as it relates to medical uses of radioactive

material.

The function of the ACMUI is to advise the staff on issues that relies on the medical uses 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 that whenever possible, we try to reach a consensus on the various issues that we will discuss today.

But I also recognize that 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. Darlene Metter, Chairman Diagnostic Radiologist.

CHAIRMAN METTER: Present.

MR. EINBERG: Dr. A. Robert Schleipman, Healthcare Administrator.

VICE CHAIRMAN SCHLEIPMAN: Present.

MR. EINBERG: Mr. Gary Bloom, Patient's Rights Advocate.

MEMBER BLOOM: Present.

MR. EINBERG: Dr. Vasken Dilsizian,

Nuclear Cardiologist.

MEMBER DILSIZIAN: Present.

MR. EINBERG: Dr. Ronald Ennis, Radiation Oncologist.

MEMBER ENNIS: Present.

MR. EINBERG: Mr. Richard Green, Nuclear Pharmacist.

MEMBER GREEN: Present.

MR. EINBERG: Dr. Hossein Jadvar, Nuclear Medical Physician.

MEMBER JADVAR: Present.

MR. EINBERG: Ms. Melissa Martin, Nuclear Medicine Physicist.

MEMBER MARTIN: Present.

MR. EINBERG: Dr. Michael O'Hara, FDA Representative.

Mr. Zoubir Ouhib, Radiation Therapy Physicist.

MEMBER OUHIB: Present.

MR. EINBERG: Mr. Michael Sheetz, Radiation Safety Officer.

MEMBER SHEETZ: Present.

MR. EINBERG: Ms. Megan Shober, State Government Representative.

MEMBER SHOBER: Present.

MR. EINBERG: Dr. Harvey Wolkov, Radiation Oncologist.

MEMBER WOLKOV: Present.

MR. EINBERG: I confirm that we do have a quorum. I would add that all members of the ACMUI are subject to Federal Ethics Laws and Regulations to receive continuing training on these requirements.

If a member believes that he or she may have a conflict of interest and that term is broadly used within 5 CFR, Part 265 with regard to an agenda item to be addressed by the ACMUI, this member should divulge it to the Chair and the DFO as soon as possible before the ACMUI discusses it as an agenda item.

ACMUI members must recuse themselves from participating in any agenda item in which they may have a conflict of interest unless they received a waiver or prior authorization from the appropriate NRC official.

The NRC is operating in a maximum telework status where we all are working remotely, and each individually calling into this meeting. I now ask NRC staff members who are participating by phone to identify themselves.

We'll start with the medical team.

DR. HOWE: Dr. Donna-Beth Howe.

(Simultaneous speaking.)

MR. EINBERG: I heard Dr. Katie Tapp and --

MS. AYOADE: Maryanne Ayoade.

MR. EINBERG: Dr. Said Daibes, and Maryanne Ayoade.

MS. LOPAS: Sarah Lopas.

MR. EINBERG: Okay. Thank you. Any other NRC staff participating on the call right now?

MS. HOUSEMAN: Esther Houseman, Office of the General Counsel.

MR. IRVIN: Ian Irvin, Office of the General Counsel.

MR. EINBERG: Okay. Thank you. Members of the public who notified Ms. Jamerson that they would be participating on the teleconference will be captured as participants in this transcript.

Those of you who did not provide the prior notification, please contact Ms. Jamerson by email at kellee.jamerson@nrc.gov. That's K-E-L-L-E-E dot J-A-M-E-R-S-O-N at NRC dot GOV, at the conclusion of this meeting.

This meeting is also using the Webex application to view presentation handouts in real

time. You can access this by going to USNRC.webex.com, USNRC.webex.com, and searching for the event number 908709487. Once again, the event number is 908709487.

Individuals who would like to ask a question or make a comment regarding a specific topic the Committee has discussed, should dial star one to signal the operator that you wish to speak. Please clearly state your first and last name for the record.

Comments and questions are typically addressed by the Committee near the end of a presentation after the Committee has fully discussed the topic. We will notify the operator when we are ready for the public commentary of the meeting.

I would also add, like to add that the handouts and agendas for this meeting, are available on the NRC's public website.

At this time, I ask that everyone on the call who is not speaking, to please place your phone on mute. If you do not have the capability to mute your phone, please press star six to utilize the conference line mute and unmute functions.

I would also 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 this large.

At this point I'd like to turn the meeting over to Dr. Schleipman, who will be chairing the meeting for Dr. Metter today. Thank you. Dr. Schleipman?

VICE CHAIRMAN SCHLEIPMAN: Thank you, Mr. Einberg. And thanks to all who are attending today. It's a pleasure to chair this panel while Dr. Metter is working diligently in the emergency radiology reading rooms. And I welcome her to join our discussions as she is able.

As a younger man I never quite understood the epithet, may you live in interesting times. Certainly, I've come to understand its depths as we are now in very interesting times, with lives, schedules, and routines turned upside down.

And I'm sure each of us know those facing the anxieties and dislocations of the pandemic, and perhaps also the manifestations and related illnesses of SARS-CoV-2 infection. With that in mind, I would invite us all to observe a moment of silence to honor the thousands of individuals worldwide who have succumbed to this illness.

(Moment of silence.)

VICE CHAIRMAN SCHLEIPMAN: Thank you.

Well, we're here today at the Commission's request to offer suggestions and guidance relative to regulatory relief during the pandemic, and I welcome Dr. Jadvar to begin.

MEMBER JADVAR: Thank you, Dr. Schleipman. I'm pleased to be on this call. I want to thank every -- the COVID-19 Subcommittee was formed on March 30, 2020 by Dr. Darlene Metter, Chair of the Advisory Committee on the Medical Uses of Isotopes.

I want to thank all the subcommittee members who participated and shared their knowledge and expertise, Dr. Vasken Dilsizian, Mr. Richard Green, Ms. Melissa Martin, Ms. Megan Shober, and Dr. Harvey Wolkov.

I also want to thank the subcommittee consultants, Mr. Gary Bloom, Mr. Zoubir Ouhib, and also our NRC staff resource, Ms. Lisa Dimmick.

The charge of the subcommittee is to propose potential options for regulatory relief for licensees of the Nuclear Regulatory Commission because of, and during the COVID-19 pandemic.

The emergence of the COVID-19 outbreak has prompted many changes in everybody's personal and professional life. Mitigation through physical distancing and focus of hospitals and clinics on

caring for patients with suspected or known COVID-19 has led to a new environment in which individuals and organizations operate.

The subcommittee received information from a number of stakeholders, including the American College of Radiology, the American Society of Radiation Oncology, the Society of Nuclear Medicine and Molecular Imaging, the American College of Nuclear Medicine, American Board of Nuclear Medicine, Council on Radionuclides and Radiopharmaceuticals, Incorporated, and also reviewed ancillary information that has been released by various governmental entities, including the Food and Drug Administration, and the Centers for Medicare and Medicaid Services.

The following proposed regulatory relief options are a brief review of the result of an amalgamation of this information in consultation with the NRC staff.

General comments. It is clear that in view of major changes in the operations of the hospitals and medical clinics prompted by the COVID-19 outbreak and the general decree for physical distancing, including shelter in place and work from home to the extent feasible, telehealth, and postponement of many non-urgent and elective

diagnostic and therapeutic procedures, licensees may be unable to meet a specific regulatory requirement in a timely manner.

However, the licensees may consider alternative pathways in actively managing and meeting the requirements safely to the extent feasible, and in keeping with local guidelines and conditions.

If delays are anticipated for regulatory relevant activities, licensees should contact the NRC or regional regulatory office via phone, email, or letter, and express their need for temporary exemption requests.

NRC has provided a temporary exemption template for medical use licensees during the COVID-19 pandemic on April 10, 2020. Questions can also be referred to MedicalQuestions.Resource@nrc.gov.

The subcommittee came up with seven specific comments. Number one, Training and Education. Currently due to COVID-19 pandemic, there has been a major decline in elective and procedural cases.

In compliance, with local regulations, if and when an AU cannot be physically present, then the AU can participate remotely via secure virtual platform for radiotherapeutic administration such as

radioiodine I-131, Radium-223 dichloride, or Lutetium-177 Dotatate, if the procedure is clinically indicated and cannot be postponed.

Moreover, the American Board of Nuclear Medicine has notified the nuclear medicine program directors in a letter dated 25 -- March 25, 2020, announcing a one-time modification of case experience requirements in 2020 for all COVID-19 related reasons.

In situations where hands on training, for example, hot lab is not feasible, then virtual observational training may be considered. Similarly, when work experience cannot be met in person, then virtual training may be considered.

Item Number Two, Regulatory Reporting. If delays are anticipated for relevant regulatory reporting, licensees should contact the NRC or regional regulatory office via phone, email, or letter, to express their need for temporary exemption requests.

Delay in non-urgent reporting requirements is reasonable and the proposal is for 90 days. Reporting deadline in 10 CFR 20.2206, Reports of Individual Monitoring, and the NRC Form 5, Occupational Dose Records for a Monitoring Period, can be considered to be changed from April 30, 2020 to

July 31, 2020, which is analogous to the postponed IRS tax filing date.

Licensees should refer to the COVID-19 Regulatory Activities for Nuclear Materials' webpage for the most up to date NRC recommendation.

Item Number Three, Medical Events Reporting. Only if specifically requested by the licensee, it is reasonable to allow variance on written reporting requirements for an initial report and ameliorating plan of the incident to the NRC or regulatory agency within 15 days, and the full incident report in 30 days, versus prior 15 days.

If further delays are anticipated, licensees should contact the NRC or regional regulatory office via phone, email, or letter, in expressing their need for temporary exemption request.

Item Number Four, Radiation Safety Activities. Delay, and the proposal is for 90 days, in regular radiation safety activities by the radiation safety officers may be reasonable.

However, licensees should consider alternate methods of meeting requirements prior to requesting an exemption. For example, if a radiation safety officer typically travels to a clinic to perform calibration or inventory activities, licensees

should evaluate whether technologists onsite can perform the required task.

The proposal does not apply to urgent situations such as major radioactive spills. All local regulations should be followed for the safety of the RSO and others involved.

AUs may participate remotely via secure virtual platform to supervise, review, and approve treatment plans, and sign the written directive. Any annual refresher training required for the radiation safety program should be postponed up to 90 days during the public health emergency.

Item Five, Physical Presence. The ACMUI recommends no change to the physical presence requirements for HDR or Gamma Knife Stereotactic Radiosurgery.

These are high risk procedures that require physical presence of the AMP and AU as outlined in Part 35 and appropriate guidance documents.

Item Number Six, Inspections. Any inspections that require inspectors and licensees to be physically present and/or in the same room, should be postponed up to 90 days.

Item Number Seven, Regulatory Fees. Due

to significant decline in radiology practice volume and other economic ramifications of COVID-19 pandemic, ACMUI supports delaying payment of all relevant fees for fiscal year 2020. For a specified period, the proposal is for 90 days.

Moreover, review of medical use license amendment requests related to COVID-19 can be considered for expedited review.

This is the conclusion of the subcommittee report. Thank you.

VICE CHAIRMAN SCHLEIPMAN: Thank you, Dr. Jadvar. Are there additional comments from the subcommittee members?

I'd like to open this up to the full ACMUI committee. But first, mention that on Monday, an additional two questions came via email from Ms. Jamerson, which I believe you've at least partly discussed in the setting of training and experience, and also in another section.

But I wasn't sure if we've completely addressed those in that facilities' AUs or AMPs, if they could not enter the hospital, what would happen?

And if they were in turn considered a vulnerable population, what would happen if they were not there? And it looks like you've addressed that

through telecommunication or some sort of remote process.

So, I'm not sure if those were fully answered.

MEMBER JADVAR: I think you're correct. That the -- first of all, I think that, I personally think these are very rare situations.

But, if that happens, as we suggested in our report, that the NRC or the regional office should be contacted via phone, or email, or which would be faster, and try to discuss it case by case. And then, of course, seek their advice.

And that perhaps there also has to be in coordination with the leadership of the medical facility and the -- to see if the case -- the treatment needs to be done or cannot be delayed.

And if it has to be done, then all the precautions can be taken into account to do it properly.

VICE CHAIRMAN SCHLEIPMAN: Great. Thank you. So, I'd welcome any of the other members of the ACMUI to feel free to ask questions or speak up.

It sounds like we have a consensus.

MEMBER ENNIS: Hi, this is Ron, Ron Ennis. I just want to congratulate the subcommittee. I

think it's very thoughtful, well done. And I have no issues with any of the recommendations.

A very minor emendation I'd like to suggest just for accuracy in number seven. Decline in radiology and radiation oncology practice.

MEMBER JADVAR: Okay. Thank you.

MEMBER SHEETZ: This is Mike Sheetz.

VICE CHAIRMAN SCHLEIPMAN: Yes?

MEMBER SHEETZ: Thank you for the subcommittee, for all of this work. I agree with everything.

But I do have a different opinion on number five with respect to physical presence. And in respect to the particular situations that Dr. Schleipman described, where maybe the AU or the AMP would be COVID positive, and they would not be able to enter the hospital.

And so, I feel it would be appropriate in those unique special circumstances to only have one of the required individuals physically present in order to be able to complete the patient treatments.

In all of the other regulatory requirements there are routine safety checks and training. And they really have little impact on safety.

But, to deny a patient treatment because both individuals cannot be present, I think creates a significant negative impact on patient care. And so, I would suggest that that be looked at in a different light.

In my 30 years of experience with HDR units and all models of the Gamma Knife, I've never seen a situation where it requires two people to respond in an emergency. These events are very rare.

And so I think one individual should be able to respond to an emergency. Again, these are unique situations we're under right now.

And to deny patient care because both individuals could not be present, I think is doing greater harm then what it may prevent. Thank you.

VICE CHAIRMAN SCHLEIPMAN: Okay.

MEMBER SHOBER: This is Megan Shober.

VICE CHAIRMAN SCHLEIPMAN: Yes, go ahead.

MEMBER SHOBER: I'm going to comment on that as well. I think it's easier to consider a situation where the authorized user is participating remotely, like through some kind of video conference, because the regulations already allow for the quote/unquote continuation of patient treatment having another physician present who is not an authorized

user.

So, I think it's a shorter step to -- for the authorized user to participate remotely. The regulations are not set up as well to have a back up to the authorized medical physicist however.

And so, that is a little harder for me to wrap my head around. But I guess I do want to at least throw out there for discussion.

That if you're talking about the authorized user not being physically present, you're not saying the physician role is absent, because you could sub -- you could then as the regulations already largely allow, have a physician under the authorized user's supervision who is physically present.

I just want to throw out that, that it's not an all or nothing for the physician presence.

VICE CHAIRMAN SCHLEIPMAN: Thank you, Ms. Shober. Other comments related to this?

MEMBER ENNIS: This is Ron. So, I'm more comfortable with the recommendation as written. And I think when we say the physician is an authorized user, it's a bit of a shorthand for the expert in executing a whole variety of activities.

And many of which could not be done without physically being present, like putting on the

frame in Gamma Knife, for example. And making sure that's proper, inserting the brachytherapy device for HDR, et cetera.

And, it's not quite the same as once treatment is all set, stepping away and asking a colleague to be there and text you, you know, if something comes up.

So, although it's a shorter step perhaps, it's to me a dangerous step. And although I appreciate Mr. Sheetz' comments, it would be quite problematic to deny patient care.

I think though, the risk benefit seems to me to fall on the side of being safe. The likelihood of AMP and AU being infected, and that delaying treatment so much that there's no other AU or AMP available, and they're not recovered in time, I suppose it's possible.

But I think the risk is too great.

VICE CHAIRMAN SCHLEIPMAN: Thank you. This is Robert Schleipman. I think I also saw in the supporting materials that this was the same recommendation of ASTRO or the AAPM.

In that they felt this was enough of a high-risk procedure that the physical presence requirement should not be altered in this case.

MEMBER WOLKOV: This is Harvey Wolkov. That statement is correct. And it was from ASTRO.

VICE CHAIRMAN SCHLEIPMAN: Thank you. Should we open this up now to members in the room? The virtual room? The NRC staff?

MR. EINBERG: Well, yes. That will be fine. Well, actually why don't you open it up to NRC staff first.

VICE CHAIRMAN SCHLEIPMAN: Right.

MR. EINBERG: And see if NRC staff have any questions.

DR. TAPP: And this is Dr. Tapp. To continue on the physical presence question, I believe I was looking through ASTRO's recommendation.

Would there be any case where you would feel maybe a COVID-19 positive patient might need to be treated, and in that case maybe have the AU train another physician. And then not be physically present if they're a vulnerable AU?

I'm just trying to see if there's anything there. Or if that's just not really feasible with the types of treatments that HDR and Gamma Knife really provide.

MEMBER ENNIS: This is Ron. So, I think it's an interesting question. And, of course, there

are precautions that could be done to, you know, for a COVID patient.

So, to minimize any transmission to anyone, because obviously everyone needs to be protected. But, of course, that concern would be a little bit higher if you're someone who might be in a high-risk group.

But I still can't see how that training could be adequate in such a short period of time to be able to do the treatment, you know, up to the level that we would want. It's not a simple thing obviously, as our T&E spells out, it's not simple to learn how to do these kinds of tasks.

DR. TAPP: Thank you.

MEMBER JADVAR: Ron, this is Hossein Jadvar. Just for my information, but is this -- I mean, this is probably a very rare situation, right?

When you have, you cannot delay the HDR or Gamma Knife treatment until the COVID is passed and taken care of. I mean, is that really a potential situation that happens?

That do we -- I mean, I'm not familiar with HDR or Gamma Knife sufficiently to know if that's really an emergency situation, that you have to treat the patient before you take care of an acute

infection.

MEMBER ENNIS: Right. So, I mean, we're all actually, you know, in the field trying to figure this out now. And deciding who to treat, you know, right away, who to delay when they're infected.

And it's an evolving situation. I would think that this could happen. There are some situations, not common. So, for Gamma Knife especially, the most -- if it's a very urgent situation, it would usually be treated with a simpler form of radiation, you know, more quickly.

And Gamma Knife is usually reserved for patients for whom we have at least a little bit of time. But, not impossible.

And same for HDR. The vast majority of those situations, while not elective, a week's delay, let's say, to allow it -- or even two weeks, for an infection to clear if that was necessary, would not be out of the question.

But, there could again occur in HDR, these situations for example, a bleeding cervical tumor. And again, would usually be dealt with more quickly with a simpler form of treatment.

But, so it's not like a common scenario for sure that this would happen. But, also to be

fair, I do think this could come up -- very rarely, but occasionally it could happen.

MEMBER JADVAR: Thank you.

MEMBER WOLKOV: Yes, Harvey Wolkov once again. Gamma Knife is really an elective procedure. It's going to be an exceptionally unusual situation that would require very prompt, if not emergent treatment.

Again, typically an elective procedure, one can generally wait two to three weeks for some conditions. Others you can actually wait months.

MEMBER JADVAR: Thank you.

VICE CHAIRMAN SCHLEIPMAN: This is Robert Schleipman.

MEMBER SHOBER: Very helpful.

VICE CHAIRMAN SCHLEIPMAN: Yes. I would suggest that given the rarity of that, and the -- still the options to use PPE aggressively, perhaps -- I don't know if we need to vote on changing this or not.

But I think it looks okay as is. But, do we need to -- Chris, perhaps you can help me. Do we need to have other people weigh in yet?

MR. EINBERG: So, you can have a motion to modify this. But, before doing a final vote on the

revised document, you may want to open it up to the public and hear the input from members of the public as well.

VICE CHAIRMAN SCHLEIPMAN: And not this specifically, but on the whole report?

MR. EINBERG: On the whole report.

VICE CHAIRMAN SCHLEIPMAN: Right. Does anyone else --

MR. EINBERG: And Dr. Schleipman, it's up to you actually. You have the latitude to do it either way.

VICE CHAIRMAN SCHLEIPMAN: Okay. All right. Is there a motion for changing this or accepting it as is?

MEMBER WOLKOV: Move acceptance as is. Harvey Wolkov.

VICE CHAIRMAN SCHLEIPMAN: Thank you. Is there a second for that?

(Simultaneous speaking.)

MEMBER MARTIN: Melissa Martin, second.

VICE CHAIRMAN SCHLEIPMAN: Great. Shall we state our names where we vote? Or does it -- should I just ask is there anyone who --

MR. EINBERG: Yes. You can get it.

VICE CHAIRMAN SCHLEIPMAN: -- wishes to

recuse or -- not approve of it?

MS. JAMERSON: Dr. Schleipman, this is Kellee Jamerson.

VICE CHAIRMAN SCHLEIPMAN: Mm-hmm.

MS. JAMERSON: I just have a question. Is the motion specifically for number five?

VICE CHAIRMAN SCHLEIPMAN: This is for number five. Yes.

MS. JAMERSON: Okay.

VICE CHAIRMAN SCHLEIPMAN: Well, I'll say it then. All in favor?

(Chorus of aye.)

VICE CHAIRMAN SCHLEIPMAN: Anyone opposed?

Anyone recused?

Great. Thank you all very much. I think then, I had a few other questions which may be for the staff. Maybe that should wait until later, but I'm not sure.

But I'll just throw them out there. One was that, I was able to listen as were several others on the April 22 teleconference, where it seemed that several callers asked for blanket exemptions. That is some publicly distributed waivers or regulatory relief categories that would not require individual licensee exemption requests.

And I wondered if those, if there will be additional populated tables akin to the generic exemptions that are -- which are currently listed?

MS. DIMMICK: Hi, this is Lisa Dimmick, Medical Radiation Safety Team Leader. So, we are planning to continue developing the table as NRC staff continues to evaluate other potential exemption requests or other exemptions.

So, we're reviewing the public meeting from last week. And then from the meeting today, we'll evaluate where we could consider adding some additional exemptions, areas to that table.

VICE CHAIRMAN SCHLEIPMAN: Great. Thank you. Robert Schleipman again. On the current list there are posted several extension time frames. Some were discussed here as well.

And I presume this may be revisited as we have very much non-uniform and perhaps reversals and opening of states, counties and cities. So, might those time frames be revisited as well?

MS. DIMMICK: So, this is Lisa Dimmick. So, those were time frames that we evaluated. If a licensee has a different time frame needed, that would be something that they would, you know, include in their request for that exemption if they have a

different time frame.

VICE CHAIRMAN SCHLEIPMAN: So, --

MS. DIMMICK: So again, when we developed those tables, it was to facilitate the review on the part of the NRC staff processing exemption requests. So, those were times that we had evaluated.

But again, if there is a different need for a different time period, the supporting basis for why a different time is needed is what the licensee would just need to include.

VICE CHAIRMAN SCHLEIPMAN: I see. Thank you. Thanks again to the subcommittee for a great report. I think at this time we could then open it up for public discussion.

MR. EINBERG: Operator, can you open up the lines there for public comment?

OPERATOR: Yes, sir. We will now begin questioning. For questions or comments, please press star one. Make sure you unmute your phone and record your name.

Again, star one for questions. One moment while we collect questions.

(Pause.)

OPERATOR: And our first question today comes from William Lorenzen. Your line is now open.

MR. LORENZEN: Hello. And thank you for taking my question. My question is around the process for regulatory relief.

And my understanding is that the NRC indicated last week that there were some obstacles as to why they could not issue blanket exemptions rather than having every licensee submit a request for relief.

Can someone explain what those barriers are? And is there a way to overcome those barriers to make this process more user friendly and expeditious?

Thank you.

MR. EINBERG: Yeah, this is Chris Einberg.

VICE CHAIRMAN SCHLEIPMAN: Can someone -- go ahead.

MR. EINBERG: Oh, I'm sorry. Yeah, again Chris Einberg. Yeah, as you heard in last week's meeting, there are barriers, for the NRC's process do not easily allow for us to issue blanket exemptions.

Having said that, you know, we are looking at different mechanisms for granting exemptions. But what the best and most expeditious thing that we've come up with right now is to develop these templates where we have evaluated where exemptions maybe warranted.

And so, while we've heard the comments from the last week's meeting on the need for blanket regulatory relief, we're exploring options in that area. But currently our processes do not allow that in an expeditious manner.

VICE CHAIRMAN SCHLEIPMAN: This is Robert Schleipman. I just want to say thank you Mr. Lorenzen for the question. [and thank you] For the question for Chris as well, for Mr. Einberg.

We -- I think that many people are going to be asking sort of follow up questions from last week's meeting.

But we really are probably trying to focus on this report, right?

MR. EINBERG: That's correct.

VICE CHAIRMAN SCHLEIPMAN: Okay.

MR. EINBERG: And we're happy to take comments and feedback. But --

VICE CHAIRMAN SCHLEIPMAN: Okay.

MR. EINBERG: You know, the focus is on this report.

VICE CHAIRMAN SCHLEIPMAN: All right. Thank you.

OPERATOR: Thank you. Our next question comes from Pat Zanzonico. Your line is now open.

DR. ZANZONICO: Thank you. Pat Zanzonico, Memorial Sloan Kettering in New York City. And I too want to congratulate the Committee. Very thoughtful report.

One issue I did want to raise was the issue of release criteria for radionuclide therapy patients. As I'm sure everyone knows or suspects, the number of radiopharmaceutical therapies has decreased dramatically during the COVID-19 outbreak.

But, I wanted to raise the possibility of waiving of the 500 millirem projected dose limit for release of patients. Not only would that require in some unusual instances nowadays, for a patient to remain in the hospital for non-medical reasons, and thereby be exposed to a possibility of infection, but it also diverts hospital beds and hospital staff who are more than fully occupied with the onslaught of infected patients.

And it just seems that such diversion of resources and exposure to risk of treated patients for non-medical reasons, for a hypothetical radiation risk, is really not justified in this setting of the very real risks of infection that we're all witnessing.

And so I want to at least raise the

possibility of addressing that in the Subcommittee's report. Some form of waiving of current release criteria that would allow patients who receive radionuclide therapy under the current circumstances to be treated exclusively as outpatients in those rare instances where the regulations might require that they be hospitalized.

Thank you.

VICE CHAIRMAN SCHLEIPMAN: Thank you, Dr. Zanzonico. It's great to hear you again. Would anyone on the Committee, perhaps someone related, who treats these patients, care to answer?

MEMBER JADVAR: Well, this is Hossein Jadvar. I think in general, this is probably going to be a rare situation given the dramatic decline in these types of treatments at this time.

And I think the final discussion or consensus was to contact their regional office and discuss it on a case by case basis. But, I mean, I guess I'll open it to the rest of the Subcommittee members if they want to also chime in.

DR. ZANZONICO: If I might just -- this is Pat Zanzonico again. Yes, I agree completely. It is a rare instance.

But, we are already ramping up at Sloan

Kettering to treat a number of patients whose treatments were deferred. And Governor Cuomo here at New York has imposed a 70 percent capacity limit on hospital beds.

And again, there does seem to be a competition that could arise in a place such as ours, where we will be treating many patients in the very near future whose treatments have been deferred. And yet maintain that 70 -- not exceed that 70 percent capacity limit.

I don't really anticipate that will happen, just because so many of our patients now can compliantly be treated as outpatients. But, it seems like one less consideration, one less complexity that could be eliminated as medical centers ramp up and begin treating patients not only with radiopharmaceutical therapy, but certainly in radiation oncology as well.

MEMBER OUHIB: This is Zoubir. I think Pat Zanzonico raises a very good point here. And I fully understand the situation.

I think what might be possible, and I'm just thinking aloud here, is that prior to treating the patient, perhaps the physician and the family, or the physician and the patient, could provide some sort

of a radiation safety plan. I hate to call it a plan.

But, how they would -- I mean, I understand that they're going to be provided with some, with instructions. But perhaps it will be, this might be different, because the patient is going to be discharged a little bit earlier than it should.

So, maybe if the patient has some sort of a plan. And then the physician will approve that. And then maybe that would be practical perhaps.

MEMBER ENNIS: This is Ron. Great to hear from you, Pat. You know, it's really a very valid point.

I guess the only thing I would say for consideration is, what's going on in Manhattan is so different from even New Jersey, where I am. Which is also so different from my colleagues in the rest of the country that this, I think is really a New York City or Metropolitan New York issue rather than a national issue.

DR. ZANZONICO: Good to hear you, Ron, as well. And so many other people at the NRC and on the ACMUI. The only -- and I agree completely. I think here in New York, especially in Manhattan we live in a somewhat unique situation.

What I think the, many of the agreements

state, and in our case the city regulated would take a very serious cue from the NRC if they were to take a position on this issue.

MEMBER OUHIB: This is Zoubir. Just to comment on what Dr. Ennis just said. While this might be a New York issue, a Manhattan issue, we don't know what tomorrow might have, you know, surprises elsewhere.

VICE CHAIRMAN SCHLEIPMAN: This is Robert Schleipman. Question for the staff, I guess. That would you perhaps consider some discretion and flexibility there?

Or does that need to come into this report for you to do so?

(Simultaneous speaking.)

MS. DIMMICK: I think my --

MR. EINBERG: So, Chris Einberg --

MS. DIMMICK: So -- oh, go ahead, Chris.

MR. EINBERG: No, I was going to ask you to opine.

MS. DIMMICK: Sure. We're -- NRC staff is present on the call. We're listening to the public comment and the feedback. And so, we're -- I'm hearing the comments.

So, it's really, you know, does the

Committee want to incorporate a recommendation on this topic in your report, you know, or take a position with it?

That's really up to you. But, NRC staff is hearing the comments on this particular topic. So, we're treating these comments just like we did the public comment period from last week.

So, I know it's our opportunity to hear as well what stakeholders are interested in with regard to relief.

VICE CHAIRMAN SCHLEIPMAN: Thank you.

MS. DIMMICK: So, bottom line. It's up to you if you -- the Committee needs to determine if it wants to incorporate something in its report topic.

VICE CHAIRMAN SCHLEIPMAN: Dr. Jadvar, I think given that the NRC staff are looking at this, I don't know if that's a necessity.

But I would welcome you and your Subcommittee to consider that.

MEMBER JADVAR: Well, we did -- we did have a paragraph before. But, which you know, it's not in the final report.

I mean, we could -- as a subcommittee we can decide if we like to put it back. But we essentially said that, you know, that this is a rare

situation.

And in exceptional cases or situations when these treatments cannot be postponed, and also hospitalization, as was mentioned, is not feasible to do this, specifically due to COVID-19, then the treatment can be done as an outpatient again, with either personal or visual presence of the AU.

But, the physician or the AU has to, and I think Zoubir also mentioned this a little bit earlier, kind of be cognizant with the personal and family condition. And see if there is anything that can be modified in that situation to minimize potential exposure, radiation exposure, to the other individuals or family members.

There are also some exceptional again, situations when the patient may be incontinent or things of that sort, which really, should -- needs to be taken into account in those cases.

So, I guess I'll leave it up to the Subcommittee. If they want, we can add something like that into our report. Or maybe what I just said, is sufficient and as was said earlier before, the staff is quite aware of these potential questions.

VICE CHAIRMAN SCHLEIPMAN: Thank you. Certainly, one can't envision and write out all of the

exceptions in this report.

Is there -- are there other Committee members who think that we should add something here?

MEMBER GREEN: This is Richard Green. I think it was wise to take that patient release criteria paragraph out.

I think the unique circumstances of patients and family issues and housing, and you know, all of the incontinence and all those issues is still addressed adequately in the general comments to approach your NRC regulator at the regional office with email, phone call, and ask for individual relief.

I think it's still covered under that category.

VICE CHAIRMAN SCHLEIPMAN: Thank you, Mr. Green. I would agree with that. And there's still the flexibility of, as you mentioned, sites calling their regional regulator and lobbying for change as needed.

Are there any other comments on that issue specifically?

I suppose then we're ready to entertain the next question.

OPERATOR: Our next question will come from Karen Grady. Your line is now open.

DR. GRADY: This is Erin Grady. I'm the -- or you said Karen Grady. I don't know if this is the right --

OPERATOR: My apologies. It's Erin Grady. You're sure -- you're fine.

DR. GRADY: All right. Great. Well, my name is Dr. Erin Grady. I'm the Director of Nuclear Medicine Education at Emory University in Atlanta.

And I have a question about the use of Zoom or similar platform for observing radionuclide therapy. Some of our therapies are ongoing due to severe disease or as part of a clinical trial where timing is important.

And we have a very small treatment room. And for the purposes of social distancing, we'd really like to have fewer people involved in a therapy at a time.

Many of the trainees are also rotating in other locations and could be exposed to some COVID patients. And I'd really like to protect the patients.

The trainees, you know, that would be participating with the therapy will have participated in the telemedicine consult. All of our consults are now being done remotely, performed ahead of time.

And that's where we discuss the radiation precautions and safety measures that the patient should take. We also answer patient questions, family member questions, et cetera.

We've really only requested this for the remainder of the academic year. And to try to better accommodate procedures for graduating trainees who are really motivated to complete the requirements.

So, we have a limited number of therapies since a lot of them have been rescheduled due to COVID.

VICE CHAIRMAN SCHLEIPMAN: Thank you, Dr. Grady.

DR. GRADY: So, I guess, what would be the thought of the Committee on using Zoom or similar platform?

VICE CHAIRMAN SCHLEIPMAN: This is Robert Schleipman. I believe that's actually addressed in Item One, where it states, in situations when hands on training, in parentheses, hot lab.

But, I think perhaps that could be extended to other.

DR. GRADY: Okay.

VICE CHAIRMAN SCHLEIPMAN: And maybe it was meant to consider this. But, I will let Dr.

Jadvar expound on that.

MEMBER JADVAR: Yeah. I think that's correct. It is basically handled in that particular sentence.

And --

DR. GRADY: Okay. Well, when I have read that, I even took a picture of it so I could keep it in my head when I was thinking about the question.

It seems like it wasn't quite addressing that. So, great. Thank you for the clarification.

MEMBER JADVAR: Yeah.

OPERATOR: And as a reminder, if you have a question, please press star one and record your name. If you have a question or a comment, please press star one and record your name.

(Pause.)

OPERATOR: I am showing no questions at this time.

VICE CHAIRMAN SCHLEIPMAN: All right. This is Robert Schleipman. Can we then entertain a motion to accept the report?

MEMBER SHEETZ: So moved.

VICE CHAIRMAN SCHLEIPMAN: I didn't hear that.

MEMBER SHEETZ: Move acceptance.

VICE CHAIRMAN SCHLEIPMAN: That was Mr. Scheetz, I believe. Is there a second?

MEMBER MARTIN: Second. Melissa Martin.

VICE CHAIRMAN SCHLEIPMAN: Thank you. All in favor?

(Chorus of aye.)

VICE CHAIRMAN SCHLEIPMAN: Any opposed?

Any recused?

It sounds like the motion carries. Thank you once again to the Subcommittee for this excellent and comprehensive report.

Thanks to all of the participants today as well. Mr. Einberg, I turn it back to you.

MR. EINBERG: Okay. Thank you, Dr. Schleipman. I wanted to also thank you, thank the Subcommittee as well as the full Committee.

I know we made a big ask of the Subcommittee during this public health emergency here. And all of you are busy healthcare professionals, and so your time is very valuable.

But the recommendations that you have provided will be seriously considered. And it's a very valuable input as well as the public participation that we've received from the public today.

So, I once again thank everybody and congratulate you on an excellent report. But with that then, Dr. Schleipman, I'll turn it back to you if you care to adjourn the meeting.

VICE CHAIRMAN SCHLEIPMAN: I'd be happy to adjourn the meeting. Thanks to all. And thanks for your great work.

And I think we'll see you in September, right?

MR. EINBERG: Thank you.

OPERATOR: That concludes today's conference. Thank you for participating. You may disconnect at this time.

(Whereupon, the above-entitled matter went off the record at 3:10 p.m.)