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on the Medical Uses of Isotopes

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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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MONDAY,

JUNE 8, 2026

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The meeting was convened via
videoconference, at 12:30 p.m. EDT, Hossein Jadvar,
ACMUI Chair, presiding.

MEMBERS PRESENT:

HOSSEIN JADVAR, M.D., Ph.D., Chair

RICHARD L. GREEN, Vice Chair

ANDREW EINSTEIN, M.D., Ph.D., Member

JOANNA R. FAIR, M.D., Ph.D., Member

MICHAEL R. FOLKERT, M.D., Ph.D., Member

RICHARD HARVEY, DrPH, Member

JOSH MAILMAN, Member

MELISSA C. MARTIN, Member

MICHAEL D. O'HARA, Ph.D., Member

ZOUBIR OUHIB, Member

MEGAN L. SHOBER, Member

HARVEY B. WOLKOV, M.D., Member

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NRC STAFF PRESENT:
CHRISTIAN EINBERG, Designated Federal Officer
JENNIFER DALZELL, Region III
SARAH HOENIG, NMSS
KATHERINE TAPP, NMSS

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

12:30 p.m.

1
2
3 MR. EINBERG: Okay, good morning. As the
4 designated federal officer for this meeting, I'm
5 pleased to welcome you to the public meeting of the
6 Advisory Committee on the Medical Uses of Isotopes.
7 My name is Chris Einberg. I am the Chief of the
8 Medical Safety and Events Assessment Branch, and I've
9 been designated as the federal officer for this
10 advisory committee in accordance with 10 CFR Part
11 7.11.

12 This is an announced meeting of the
13 committee. It is being held in accordance with the
14 rules and regulations of the Federal Advisory
15 Committee Act and the Nuclear Regulatory Commission.
16 This meeting is being transcribed by the NRC, and it
17 may also be transcribed or recorded by others. The
18 meeting was announced in the May 21, 2026 edition of
19 the Federal Register, volume 91, pages 29990-29991.

20 The function of the ACMUI is to advise the
21 staff on issues and questions that arise with the
22 medical use of byproduct material. The committee
23 provides counsel to the staff, but does not determine
24 or direct the actual decisions of the staff or the
25 commission. The NRC solicits the views of the

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1 committee and values their opinions.

2 I request that whenever possible, we try
3 to reach a consensus on the various issues that we
4 will discuss today, but I also recognize there may be
5 minority or dissenting opinions. If you have such
6 opinions, please allow them to be read into the
7 record. At this point, I would like to perform a roll
8 call of the ACMUI members participating today. Dr.
9 Hossein Jadvar, Chair, Nuclear Medicine Physician.

10 CHAIR JADVAR: Present.

11 MR. EINBERG: Mr. Richard Green, Vice
12 Chair, Nuclear Pharmacist.

13 VICE CHAIR GREEN: Present.

14 MR. EINBERG: Dr. Michael Folkert,
15 Radiation Oncologist.

16 MEMBER FOLKERT: Present.

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

19 MEMBER MARTIN: Present.

20 MR. EINBERG: Mr. Zoubir Ouhid, Therapy
21 Medical Physicist. Mr. Zoubir -- Mr. Ouhid, are you
22 here?

23 MEMBER OUHIB: Yes, present. I didn't
24 hear you the first time, sorry.

25 MR. EINBERG: Okay. Yeah, we missed it,

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1 thank you. Ms. Megan Shober, Radiation -- I mean,
2 sorry, Agreement State Representative.

3 MEMBER SHOBER: Present.

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

6 MEMBER WOLKOV: Present.

7 MR. EINBERG: Dr. Richard Harvey,
8 Radiation Safety Officer.

9 MEMBER HARVEY: Present.

10 MR. EINBERG: Dr. Andrew Einstein, Nuclear
11 Cardiologist.

12 MEMBER EINSTEIN: Present.

13 MR. EINBERG: Dr. Joanna Fair, Diagnostic
14 Radiologist.

15 MEMBER FAIR: Present.

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

18 MEMBER O'HARA: Present.

19 MR. EINBERG: Josh Mailman, Patients'
20 Rights Advocate.

21 MEMBER MAILMAN: Present.

22 MR. EINBERG: I confirm that we have a
23 quorum. Dr. John Angle, who's our Interventional
24 Radiologist Consultant to the ACMUI, may participate
25 in today's discussion, but does not have voting rights

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1 for any actions requiring a vote. But I don't believe
2 that he's participated today. All members of the
3 ACMUI are subject to federal ethics laws and
4 regulations and receive annual training on these
5 requirements.

6 If a member believes that they may have a
7 conflict of interest, as that term is broadly used
8 within 5 CFR Part 2635, with regard to an agenda item
9 to be addressed by the ACMUI, this member should
10 divulge it to the chair and to the DFO as soon as
11 possible before the ACMUI discusses it as an agenda
12 item. ACMUI members must recuse themselves from
13 participating in any agenda item in which they may
14 have a conflict of interest, unless they've received
15 a waiver or prior authorization from the appropriate
16 NRC official.

17 We are using Microsoft Teams, and so that
18 the members of the public and other individuals can
19 watch online or join via phone. The phone number for
20 the meeting is 301-576-2978. The phone conference ID
21 is 549512836#. The handouts and agenda for this
22 meeting are available on the NRC's ACMUI public
23 website.

24 Members of the public who notified Ms.
25 Hoenig that they would be participating via Microsoft

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1 Teams will be captured as participants in the
2 transcript. Those of you who did not provide prior
3 notification, please contact Ms. Hoenig by email at
4 sara.hoenig@nrc.gov at the conclusion of this meeting.

5 Today's meeting is being transcribed by a
6 court reporter. We are utilizing Microsoft Teams for
7 the audio of today's meeting and to view presentation
8 material in real time. The meeting materials and
9 agenda for this meeting can be accessed from the NRC's
10 public meeting schedule. For the purpose of this
11 meeting, the chat feature in Microsoft Teams has been
12 disabled. Dr. Jadvar, at his discretion, may
13 entertain comments or questions from members of the
14 public who are participating today.

15 Individuals who would like to ask a
16 question or make a comment when Dr. Jadvar opens it
17 up, comments or questions may use the raise hand
18 function to signal our Microsoft Teams host, Ms.
19 Hoenig, that you wish to speak. If you have called
20 into the Microsoft Teams using your phone, please
21 ensure you have unmuted your phone. When you begin
22 your comment, please clearly state your first and last
23 name for the record.

24 Comments and questions are typically
25 addressed by the committee near the end of the

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1 presentation after the committee has fully discussed
2 the topic. We will announce when we are ready for the
3 public comment period portion of the meeting and Ms.
4 Hoenig will assist in facilitating public comments.
5 At this time, I ask that everyone who is not speaking
6 to please mute your Teams microphones or phone. I
7 will now turn over the meeting to Dr. Jadvar.

8 CHAIR JADVAR: Thank you very much, Mr.
9 Einberg, and good morning and welcome everyone to the
10 June 8, 2026 meeting of the Advisory Committee on
11 Medical Uses of Isotopes. And with that, let's get on
12 with our agenda. The first agenda item is some old
13 business that Dr. Tapp is going to go over with us.
14 Dr. Tapp?

15 DR. TAPP: Yes. Next slide, please. This
16 is a follow-up from the April meeting. We have the
17 recommendations and action items that ACMUI is
18 tracking. In this list, it has been updated since
19 April to include the recommendations through your
20 subcommittee reports that were provided at the spring
21 meeting. Those actions are still ongoing and we're
22 working on those for the fall. However, at that
23 meeting, we had four topics that were discussed that
24 I have here to propose to close.

25 The first was the Subcommittee on ACMUI

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1 Generic Reporting Process. That subcommittee provided
2 their report and recommendations at that April
3 meeting. The second, the Subcommittee on Potential AI
4 Deep Learning Applications for NRC Medical Enterprise.
5 Again, that subcommittee provided their report and
6 recommendations. The Subcommittee on Modernizing
7 Requirements Related to Physical Protection of
8 Category 1 and Category 2 Quantities of Radioactive
9 Material Rulemaking. Again, that subcommittee
10 provided its report.

11 And then finally, we have the Subcommittee
12 on Modernizing NRC Regulations for Byproduct Material
13 Use Rulemaking. That subcommittee is providing its
14 report now. Lastly, the Subcommittee on Giving Advice
15 in the ADVANCE Act of July 2024 Mission Statement.
16 That subcommittee did provide its report, but at the
17 discretion of the ACMUI, you wanted to do that as an
18 interim report. So that subcommittee is still taking
19 actions on that item. So that one is remaining open.
20 So I'm going to turn it over to you, Dr. Jadvar, to
21 see if the ACMUI would like to close these items and
22 move to do that or turn it over to you.

23 CHAIR JADVAR: Okay. Thank you, Dr. Tapp.
24 So may I have a motion from the committee to close
25 these four items, number 2, 3, 4, and 5 as a

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1 conglomerate? Can I have a motion?

2 MEMBER WOLKOV: Harvey Wolkov, so moved.

3 PARTICIPANT: Second.

4 CHAIR JADVAR: Thank you. Any opposed?

5 Any abstention? None heard. So, Dr. Tapp, all these
6 four items, 2, 3, 4, and 5 are now closed officially.

7 DR. TAPP: Thank you.

8 CHAIR JADVAR: Thank you. All right. We
9 move on now to the third item on the agenda, which is
10 Overview of the Modernizing NRC Regulation for
11 Byproduct Material Use Proposed Rule. And this will
12 be presented by Ms. Jennifer Dalzell. Ms. Dalzell?

13 MS. DALZELL: Hello. Hopefully, you can
14 all hear me. We can go to the next slide. For the
15 Modernizing Energy Regulations for Byproduct Material
16 Use, we have published the proposed rule as of May
17 18th. So it is open now for public comment. That
18 public comment period ends on July 2nd. Some
19 highlights of the proposed rule. There's some changes
20 being proposed to the financial assurance regulations
21 for both sealed and unsealed radioactive material.
22 This includes the germanium-gallium generators.

23 The rule also would create a new class of
24 general licenses called the standard general license.
25 This would be a hybrid between a specific license and

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1 a general license. And another change that helps the
2 medical community is allowing radio pharmacies to
3 prepare and distribute the microspheres in addition to
4 other radioactive drugs without needing additional
5 program codes.

6 Next slide, please. So a little bit more
7 on the standard general license. This is going to
8 offer an optional new class of licenses that is taking
9 some of the lower risk diagnostic medical use cases to
10 the standard general license. The requirements for
11 licensing will remain the same. Training and
12 experience, all of that will remain the same. The
13 difference is going to be in the application process.

14 You would not need to provide any of this
15 information. It will be reviewed instead during our
16 regular inspection program. So inspections would stay
17 the same. The licensing would be significantly
18 reduced. And if needed, the current licensing options
19 are available for the high risk activities or if it
20 makes more sense for your particular organization to
21 have a specific license going forward.

22 Next slide, please. So, as I mentioned,
23 the proposed rule has been published for public
24 comments. If you are interested in providing any
25 comments on the proposed rule, you will need to do

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1 that through the Federal Register. And you can do
2 that by searching for the NRC docket number 2005-1205.
3 And again, those comment period ends on July 2nd. So
4 there's not a lot of time left in the comment period.
5 That's all I have. Turn it back over to you.

6 CHAIR JADVAR: Thank you very much, Ms.
7 Dalzell. So now we move on to Dr. Harvey, who is
8 going to present a subcommittee report and
9 recommendations on the NRC's proposed rulemaking
10 entitled Modernizing NRC Regulations for Byproduct
11 Material Use. Dr. Harvey?

12 MEMBER HARVEY: Thank you very much, Dr.
13 Jadvar. Again, so I'll present that report for the
14 ACMUI. As Dr. Jadvar said, Modernizing Regulations
15 for Byproduct Material Use Rulemaking Proposed Rule.
16 Next slide, please. Subcommittee members were Dr.
17 Jadvar and myself, and the NRC staff resources was Dr.
18 Katie Tapp and Ms. Elizabeth Tindall Engelmann.

19 Next slide, please. Our charge. The
20 Subcommittee on Modernizing NRC Regulations for
21 Byproduct Material Use Proposed Rule was established
22 by the NRC staff on November 11, 2025. The
23 subcommittee was to provide ACMUI review and comments
24 on the Modernizing Regulations for Byproduct Material
25 Use Proposed Rule.

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1 Next slide, please. Our findings on the
2 Standard General Licensing. The Standard General
3 Licensing establishes a low-burden regulatory by-rule
4 pathway for common, low-risk medical uses of byproduct
5 material. Standard General Licensing creates a more
6 predictable and streamlined licensing environment for
7 medical institutions by replacing repetitive licensing
8 correspondence with standardized commitments and
9 inspection-based oversight without reducing the level
10 of safety expected on medical use licensees. The
11 ACMUI subcommittee supports this proposed rule.

12 Next slide, please. Our findings with
13 regards to microsource distribution. The proposed
14 rule also addresses emerging clinical practices by
15 expanding microsource distribution options. The ACMUI
16 subcommittee supports this proposed rulemaking. Next
17 slide, please. Our findings on 10 CFR 30, the
18 definition of a physician. The proposed rule removes
19 the definition of physician from 10 CFR 30.4 because
20 the term is already fully defined in 10 CFR 35.2. The
21 ACMUI subcommittee supports this proposed rulemaking.

22 Next slide, please. Our findings with
23 regards to financial assurance. These revisions
24 modernize decommissioning financial assurance
25 thresholds by incorporating updated radionuclide

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1 values, adding isotopes not previously listed, such as
2 for gallium-germanium generators, and resolving overly
3 conservative default values that have created
4 licensing inefficiencies for medical and industrial
5 users.

6 The ACMUI previously reviewed a draft
7 regulatory basis document for this rulemaking and
8 provided its recommendation in its final report dated
9 August 29, 2024, ML24254A315. The ACMUI subcommittee
10 supports the NRC's continued efforts in this area and
11 endorses moving forward with the updates to financial
12 assurance regulations.

13 Next slide, please. In summary, the ACMUI
14 subcommittee on the modernizing NRC regulations for
15 byproduct material use rulemaking recommends that the
16 proposed rule be made final as proposed. Next slide,
17 please. And this just wraps up with our acronyms, and
18 I would turn this back over to Dr. Jadvar. Thank you.

19 CHAIR JADVAR: Thank you. Thank you very
20 much, Dr. Harvey. So I want to open it up to the
21 ACMUI members for any comments or questions. Okay,
22 none heard. Looks like it was very clear. So also,
23 I want to open it up to any NRC staff who wants to --
24 I'm sorry, Ms. Megan Shober just raised her hand.

25 MEMBER SHOBER: Zoubir was ahead of me.

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1 CHAIR JADVAR: Okay. Zoubir, please go
2 ahead.

3 MEMBER OUHIB: Yes. Sorry, it took me
4 time to undo. Just a brief comment. Should
5 microsource be defined in this document or in this
6 proposal?

7 CHAIR JADVAR: Dr. Harvey, do you want to
8 make a comment on that?

9 MEMBER HARVEY: Well, my first question
10 would be, is it defined already? Does the NRC staff
11 know?

12 DR. TAPP: So this is Dr. Tapp. The
13 medical definitions for like brachytherapy and
14 sources are generally defined in Part 35. I cannot
15 talk about an upcoming rulemaking, but as you're
16 aware, there is a Part 35 rulemaking undergoing right
17 now. So I would think that Part 35 would be a place
18 to put the microsource definition. And these rules
19 are going to be running pretty parallel in the future.

20 MEMBER OUHIB: So I assume that will be
21 referenced in this proposal?

22 DR. TAPP: I cannot talk about the
23 proposed rule yet because it's not out for public
24 comment, but emerging medical technologies is part of
25 that rulemaking.

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1 MEMBER OUHIB: Okay.

2 DR. TAPP: But you could give a
3 recommendation to have a definition, but, yeah,
4 usually that would go in Part 35, not Part 30.

5 MEMBER OUHIB: Right. Okay.

6 DR. TAPP: And this rule doesn't touch
7 Part 35. It only touches Part 30 and 32, and yeah,
8 but doesn't touch Part 35.

9 MEMBER OUHIB: Okay. I do have another
10 question on the draft report that we received. It
11 says license amendments are replaced by simple
12 notifications, basically reducing administrative
13 delays, and so on and so forth. I'm just curious, how
14 will these notifications be acknowledged? So in other
15 words, somebody doesn't think that, well, I don't know
16 if they got it, I don't know if they didn't, I'm not
17 sure what's going to happen, and so on. And there are
18 potentially some ramifications if indeed that
19 communication got lost somewhere.

20 DR. TAPP: It's the rulemaking -- go
21 ahead.

22 CHAIR JADVAR: No, I'm just wondering if
23 Dr. Tapp has a comment on that feedback mechanism.

24 DR. TAPP: Yes, that acknowledgement
25 letter and then the WBL controls are being updated for

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1 implementation of the rulemaking. There would be a
2 location where you can verify that they do have the
3 appropriate licensing to receive and use the material.
4 So the implementation would make sure that you can
5 confirm that they have the license to use and receive
6 the material they're requesting, like if you're
7 distributing.

8 MEMBER OUHIB: Okay, thank you.

9 CHAIR JADVAR: Okay. Thank you, Mr.
10 Ouhib. Okay. We move on to Ms. Shober, please.

11 MEMBER SHOBER: Hi, thank you. I have a
12 couple of comments and a couple of questions as well.
13 So my first comment is with regard to including Moly
14 tech generators in the standard general license
15 framework. Those Moly tech generators do have a
16 potential for high extremity doses and the risk
17 profile for using generators is much different from
18 the other types of radioactive material that's
19 proposed for use via standard general license. So I
20 don't support having the Moly tech generators within
21 the standard general license framework.

22 I do have a concern in general about small
23 medical consultants that have consultant radiation
24 safety officers. In my experience, those are the
25 diagnostic medical sites that tend to have the most

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1 compliance issues. So I have some concerns about the
2 standard general license framework would exacerbate
3 those issues by reducing regulatory interaction prior
4 to those sites receiving byproduct material.

5 I do -- okay. I guess I have a question
6 for the NRC, if there's any timeline for publishing
7 the standard general license proposed fee schedule.
8 It's been -- it's impossible for us to evaluate cost
9 savings if that fee schedule is not available. I
10 don't know if someone has an answer for that.

11 CHAIR JADVAR: Okay. Thank you. Dr. Tapp
12 or anyone from NRC want to address these comments or
13 their last question?

14 MS. DALZELL: Hi, this is Jenny Dalzell.
15 For the fees for the standard general license, it's
16 still in the development phase. We won't be able to
17 publish that rule until we do the FY27/28 fee rule.
18 So it's not going to be until next fall that we would
19 be able to publish that.

20 MEMBER SHOBER: Okay. So I guess I'll
21 also just throw out there that this whole rule is
22 predicated on saving money and it's real hard to
23 assess that. I do want to just speak a little bit to
24 -- on the issue of cost savings because although there
25 are perhaps reduced licensing costs associated with

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1 the standard general license framework, there will be
2 significantly increased inspection costs for the NRC
3 due to the types of information that are currently
4 reviewed during licensing which will now have to be
5 reviewed on inspection.

6 And so, that is a pretty significant
7 increase on the inspection effort to review both users
8 and a large number of standard facility procedures
9 which are currently, again, that's all currently
10 addressed in licensing. So that effort is going to be
11 -- would have to be pushed into inspections and that
12 would increase training costs for any agency that
13 separates where inspectors and license reviewers are
14 distinct sets of people.

15 So that's my biggest concern with the
16 standard general license framework is with increased
17 costs for having duplicative licensing pathways and
18 increased inspection effort to manage the information
19 that's currently handled during licensing. I do want
20 to say that I support excluding PET and mobile
21 medicals from the standard general license framework
22 and I also support the changes to the financial
23 assurance table. Thank you.

24 CHAIR JADVAR: Thank you, Megan. Any
25 comments by NRC staff in the final comments by Ms.

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1 Shober?

2 DR. TAPP: No, I didn't know if the ACMUI
3 had comments on the Mali tech or the consultant RSO,
4 but I heard this.

5 CHAIR JADVAR: Thank you. And I see Mr.
6 Richard Green has his hand up. Mr. Green, please.

7 VICE CHAIR GREEN: Thank you, Dr. Jadvar.
8 I agree with Megan. I was on a subcommittee that
9 looked at breakthrough testing and looked at the
10 distribution of Moly generators, and they are very
11 predominantly in centralized radio pharmacies. And I
12 would agree that they probably should be excluded from
13 the standardized general licensing framework as it
14 does out of the ordinary now. It may have been in the
15 past, but it is not common at all today.

16 I'm in favor of the proposed changes with
17 the exception of that standardized inclusion of the
18 Mo-99 generators. I guess the other question I have
19 is more transactional. So there are several hundreds
20 of licensed facilities, whether they're radio
21 pharmacies or hospitals, that now have surety bonds,
22 \$1.1 million or so per facility for germanium-gallium
23 generators.

24 So when the table values are changed,
25 up-dyed radionuclide values, what's the action to be

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1 taken by licensees? Do they need to continue to renew
2 these surety bonds until they renew their license? Do
3 they have to do a license amendment to remove the need
4 to continue the existing surety bonds, or is it just
5 wiped off immediately and they don't have to renew
6 them with their financial institutions?

7 DR. TAPP: That is a good question, Mr.
8 Green. And it is something that could be dependent on
9 the way the license is structured. The regulation
10 will have an implementation date, and at the date of
11 that implementation for the NRC licensees, that will
12 go into effect. Then the agreement states may have a
13 separate implementation date. So if you are an
14 agreement state licensee, you need to know that
15 agreement state licensee.

16 And then next, it depends on the way the
17 license is written. If it's tied in that license,
18 it'll have to be an amendment. But if it's not,
19 you're following just the regulations. That's
20 different. And I'm sure Megan has more advice here.

21 CHAIR JADVAR: And her hand is up. So
22 Megan?

23 VICE CHAIR GREEN: That's helpful. Thank
24 you.

25 MEMBER SHOBER: Yeah, so my understanding

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1 of the new proposed value for the germanium-68 in that
2 financial assurance table is that the financial
3 assurance mechanisms that are in place would continue
4 to be required and stay in place. So currently, all
5 licensees that have those generators are granted an
6 exemption from the decommissioning funding plan
7 requirements.

8 And in lieu of submitting a
9 decommissioning funding plan, which has to cover the
10 entire radioactive materials license, so we've been
11 exempting the decommissioning funding plan. And in
12 lieu of that, licensees have been providing financial
13 assurance instruments, or they can provide financial
14 assurance instruments. And that level that we've been
15 requiring financial assurance was based on the value
16 that is now being proposed to add to the table.

17 So in practical terms, the financial
18 assurance that's currently in place would still be
19 required under the proposed regulations, but we would
20 no longer need the exemption from the decommissioning
21 funding plan requirements. That's my understanding of
22 it, and NRC can speak to that if I'm mistaken.

23 VICE CHAIR GREEN: If I may, is this the
24 time to re-look at that? I mean, to remove a spent
25 germanium generator from my license, all I have to do

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1 is pay a \$75 Federal Express fee and send it back to
2 the manufacturer who built it. It's very simple. So
3 I don't know why that, you know, needs a \$1.1 million
4 surety bond. So I appreciate your information, Megan,
5 that it doesn't change the value, but still, does that
6 make sense today for that device?

7 CHAIR JADVAR: Any comments from NRC staff
8 on this last issue? Okay. And any more comments from
9 the committee members, ACMUI committee members?

10 MEMBER HARVEY: Dr. Jadvar, Dr. Harvey, if
11 I could?

12 CHAIR JADVAR: Yeah, please.

13 MEMBER HARVEY: Just the Moly tech
14 generators, I mean, I understand I've heard lots of
15 concerns from many places about that. If the
16 shielding is standardized and the number is so few,
17 I'm not sure how impactful this really is. Also, all
18 the other regulations would still be in place to make
19 sure that people use those Moly tech generators
20 safely. I think we're just really changing some of
21 the licensing requirements. That might be very
22 generalized and maybe I might be missing something,
23 but that's all I really wanted to say. Okay, thank
24 you.

25 CHAIR JADVAR: Thank you, Dr. Harvey. Any

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1 additional comments by the ACMUI members? All right.
2 Let's give a chance to NRC staff if they want to make
3 any more clarifications, comments, anything else?
4 Okay. So --

5 DR. TAPP: I don't see --

6 CHAIR JADVAR: Okay. What was it?

7 DR. TAPP: I said I don't see any. I was
8 looking for a hand.

9 CHAIR JADVAR: Okay, thank you. All
10 right. So at this point, I'm going to ask Ms. Hoenig
11 to navigate us to open up to the public comment for
12 brief comments if there is any.

13 MS. HOENIG: All right, great. If you're
14 interested in commenting, for the ACMUI direction,
15 please keep your comments to be less than two minutes
16 and go ahead and unmute your mic and raise your hand
17 to note that you want to make a comment, and please
18 fully identify yourself with your full name and your
19 affiliation. Thank you.

20 CHAIR JADVAR: I see Mr. Bryan Lemieux.

21 MR. LEMIEUX: Thank you. Bryan Lemieux,
22 Lexington, Kentucky. I'm an RSO and health physicist.
23 Thank you for letting me speak really quick. My only
24 comment and concern really has to do with in the
25 general license process for the mechanism, which if

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1 I'm understanding correctly, for a general license or
2 registering use of a general license, that authorized
3 user validation, that RSO validation mechanism that
4 these people really meet sort of the NRC standards and
5 requirements for qualifications up front kind of goes
6 away, right?

7 And those of us that, you know, have to
8 navigate RSO requirements and have to navigate, you
9 know, vetting authorized users, sometimes that can get
10 confusing and sometimes it can be a little challenge
11 figuring out, hey, does this guy really qualify? Does
12 this person really meet the requirements? Are they in
13 their seven years? Do they meet all of these
14 specifications to qualify under Part 35 for whatever
15 uses they're wanting?

16 And so when I think about the low volume
17 small licensees that this general license is pointed
18 at, especially for them, and especially if they're
19 just naming somebody as an RSO who may or may not be
20 qualified because they're not getting double checked
21 by somebody, who's validating these people? Who's
22 validating these positions? We're just going to take
23 it on faith until NRC gets over there to inspect them.
24 And then we're talking about people who are
25 responsible for patient care, right? And so that's

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1 really the only concern I have with this set of
2 changes.

3 But if you were going to say, hey, you're
4 in charge of a change here, I would say, you know,
5 force some sort of independent verification of at
6 least the RSO making the submissions or, you know,
7 maybe the AUs or something. Like, I want to know that
8 that person is actually qualified that's making that
9 assessment, that there is some level of compliance
10 with somebody that's doing patient care like that and
11 has that level of responsibility. So that's it.
12 Thank you so much.

13 CHAIR JADVAR: Thank you for your comment.
14 It has been noted. I'm not sure if NRC wants to
15 respond to that at this time, but certainly it has
16 been noted.

17 MEMBER HARVEY: Dr. Jadvar, if I could?

18 CHAIR JADVAR: Yes. Oh, please go ahead.

19 MEMBER HARVEY: I think that the training
20 and experience requirements are still in place. So
21 that still has to be done, or am I understanding this
22 incorrectly?

23 DR. TAPP: No. Just for Dr. Harvey's
24 awareness, it would still be in place, but they would
25 not be confirmed at time of licensing, but they are

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1 still in place. And if someone would like to come in
2 for a traditional licensing pathway, that option is
3 still available as well. But it would be checked at
4 time of oversight for just the diagnostic uses at
5 these SGLs.

6 MEMBER HARVEY: So, Dr. Tapp, to Mr.
7 Lemieux's point, everything is still in place for
8 training and experience, but the issue is when are
9 they reviewed and checked?

10 DR. TAPP: That's correct.

11 MEMBER HARVEY: Okay. All right, that's
12 the way I understood it. So is there, I guess, are we
13 comfortable with that?

14 CHAIR JADVAR: All right. Well, I see
15 that Mr. Ouhib has his hand up, probably comment on
16 this. Mr. Ouhib?

17 MEMBER OUHIB: Yes, I think Mr. Lemieux
18 brings up a very important point. And the key item
19 here is that, yes, NRC or the state, whatever, will
20 look --

21 CHAIR JADVAR: You got cut off.

22 MEMBER OUHIB: -- has treated some
23 patients. So it is not prior to, but it's at some
24 point, and that person might have already treated some
25 patient. I think Mr. Lemieux brings up a very

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1 important point.

2 MEMBER HARVEY: If I could, so I think
3 that we still have to do this at the licensee level.
4 You know, so we still have to check the training and
5 experience. I'm certain, if I was the RSO at these
6 licensees -- as one of these licensees, I would
7 certainly do that before I let somebody, you know,
8 perform any of the activities under that license.

9 DR. TAPP: I also just want -- for
10 clarification, making sure it's clear. Treated, this
11 only applies to 100 and 200 uses excluding PET at this
12 time. So I just want to make sure I heard the word
13 treated. Okay. Yes, diagnostic only.

14 CHAIR JADVAR: Diagnostic, yes. Okay.
15 And I see Mr. Matt Wait.

16 MR. WAIT: Hi, good morning. Can you hear
17 me?

18 CHAIR JADVAR: Yes.

19 MR. WAIT: Hi, good morning. My name is
20 Matt Wait. I'm a diagnostic and nuclear medicine
21 physicist with Kaiser Permanente in Los Angeles. I
22 want to echo Mr. Lemieux's concern and also kind of,
23 to kind of follow up on Mr. Richard Harvey, you know,
24 I think the question is who is watching the watchmen,
25 right? If you have an unvetted RSO approving NRC, you

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1 know, authorized users, again there's a theoretical
2 possibility of harm if that RSO is also not qualified,
3 right?

4 So if no one is verifying that the RSO is
5 qualified and they are potentially approving
6 authorized users that are also not verified, then
7 that's -- then the concern is that there's a potential
8 for harm in the interim between when those -- when
9 those authorized users are added and, you know, when
10 there's an actual enforcement inspection. So that's
11 my first point.

12 My second point is, you know, I work for
13 a large hospital system in an agreement state, so, you
14 know, the managing authorized users for large
15 facilities and in particular, our license is unique
16 because it covers many different facilities. So, you
17 know, this has the potential to reduce a lot of the
18 burden because right now our state regulators take a
19 very long time to even assign license amendments for
20 review, let alone reviewing and approving the license
21 amendments.

22 But that brings the second concern that
23 another speaker, who I'm unfortunately forgetting,
24 brought up, which is that this then moves the burden
25 to inspections. So if our state is already struggling

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1 to approve routine license amendments, is it really
2 reasonable to expect that our state is going to be
3 able to perform inspections at the required rate given
4 all of these additional verifications that are going
5 to need to happen?

6 CHAIR JADVAR: Thank you, Mr. Wait. Your
7 comments have been noted. I just want to give the
8 folks or NRC any opportunity if they want to respond
9 at this time. Okay. I see another hand, Ms. Michelle
10 Egberts. Please.

11 MS. EGBERTS: Hello. Thank you for
12 letting me ask my question. So I'm assuming that the
13 need for Moly tech generator training for authorized
14 users is not going away either. Yes or no?

15 MEMBER HARVEY: My understanding is yes,
16 it's not going away.

17 MS. EGBERTS: It's going away.

18 MEMBER HARVEY: No, it's not going away.

19 MS. EGBERTS: Oh, it's not going away, all
20 right. So then part two is, and I don't know if I'm
21 getting ahead of everybody here, there's a rumor out
22 on the street that radiation oncologists are going to
23 be granted 100, 200 without having previous training
24 in, you know, basically liquid radioactive materials,
25 which alone is frightening to me. Will they be

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1 exempted from Moly tech generators?

2 MEMBER HARVEY: This is Dr. Harvey. I
3 have not heard that. I am not aware of that in any
4 way, shape, or form, but maybe somebody else can
5 comment.

6 MS. EGBERTS: Great, thank you.

7 CHAIR JADVAR: Dr. Tapp has her hand up.

8 DR. TAPP: Yes. This rulemaking here
9 today that we're discussing does not make any changes
10 to Part 35 or the training and experience
11 requirements. The rulemaking is on the standard
12 general licensing and Part 30, 32, and some others
13 that aren't as impactful to medicine. But Part 35 is
14 not changed in this rulemaking.

15 MS. EGBERTS: Thank you.

16 DR. TAPP: Thank you.

17 CHAIR JADVAR: Okay. Any other comments?

18 MEMBER HARVEY: Dr. Jadvar, Dr. Harvey.
19 I just, if I could.

20 CHAIR JADVAR: Please.

21 MEMBER HARVEY: I don't know if the NRC
22 can answer, but how do they feel about the shifting
23 burden from, you know, license generation or license
24 renewal to the inspections? There's been a number of
25 comments where there's concerns that the inspection

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1 process will be slowed down and be more costly. Does
2 the NRC share that viewpoint, or do they -- are they
3 comfortable with moving the licensing, some of the
4 licensing aspects over to the inspection process?
5 Thank you.

6 DR. TAPP: That is a fair question. I
7 will say this is going to be an answer for NRC. With
8 the proposed rule, we did the evaluation for these
9 lower risk activities that are standardized. The
10 standard general license was looking at things that in
11 general come in and there's a standard application,
12 and that the license reviewers do not have to have a
13 lot of back and forth with. So moving for these
14 activities proposed in this rulemaking for standard
15 general licenses, we were comfortable with the switch
16 over to inspection and in that area.

17 But I should point out that this is an
18 NRC. The standard general licenses is a compatibility
19 D, which means agreement states can choose, depending
20 on their processes, if they want to use standard
21 general licenses or stay with the traditional
22 licensing pathway. And because we recognize the
23 states operate so differently, just there's so many
24 different ways of operation and how they're going to
25 do their inspections and licensing. So for NRC, we

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1 were comfortable. But I see Megan's hand up.

2 CHAIR JADVAR: Yeah, Ms. Shober.

3 MEMBER SHOBER: Yeah, so my main comment
4 with that is that these licenses are only standard
5 when the applicants commit to model procedures that
6 are in the NUREG-1556 volume. And if you don't have
7 a mechanism for licensees to commit to those standard
8 procedures and instead the rule requires them just to
9 develop, implement, and maintain, they're not standard
10 anymore. So that's one of the things that I don't
11 know how to reconcile with this format.

12 CHAIR JADVAR: Okay. Ms. Martin?

13 MEMBER MARTIN: Yes. I was just wondering
14 if the NRC could give us some examples as to what is
15 considered a standard procedure. That's what I was
16 looking for and I didn't find what type of activities
17 are considered standardized to the point where they do
18 not need specific instructions.

19 DR. TAPP: Sure. An example in the
20 medical realm would be a small clinic that uses only
21 Tc-99m. You know, one authorized user, one RSO. They
22 submit this registration for a standard general
23 license. All the regulations that we can
24 traditionally be in a licensed condition are now
25 contained in the regulation itself. It's listed out

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1 -- you know, the conditions are listed in that
2 proposed rule. And then you would be committing
3 yourself to those regulations in that proposed rule
4 for those uses, and that would be a standard general
5 licensee.

6 So we don't -- you would have the facility
7 location address still on your registration, but
8 there's no other additional information that would
9 need to be submitted for those uses.

10 CHAIR JADVAR: Thank you. Dr. Tapp.

11 DR. TAPP: I should say the draft form is
12 with the rule for a review and comment. So that draft
13 form of what you need to fill out to receive a
14 standard general license is also available for review.

15 CHAIR JADVAR: Very good. I see another
16 hand by Mr. Matthew Williams. You want to make your
17 comment, please?

18 MR. WILLIAMS: Yeah. My comment, it kind
19 of goes back to a combination of Melissa's and
20 Bryan's, is that --

21 CHAIR JADVAR: Please say where you're
22 from.

23 MR. WILLIAMS: Sorry, I'm Matt Williams.
24 I'm from Children's National in DC. Yeah, I think
25 that the concern that I have is that in some of these

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1 small clinics that we see, you have the attending
2 that's also the RSO. So you can have someone that is
3 putting themselves as the RSO and as the AU for 100 and
4 200 and not actually validating that they fit either
5 criteria until the third year when the inspection
6 comes.

7 It just, it seems like a very delayed
8 process that you could actually see a lot of patients
9 in that timeframe before actually validating that this
10 person should be practicing. So I just want to,
11 again, kind of reiterate that point that Bryan made
12 earlier. It just seems like a long period of time
13 before validation of someone's ability, especially the
14 fact that someone could be an RSO and then also make
15 themselves an authorized user. Ultimately, they would
16 have to validate that, but it just feels way down the
17 line.

18 CHAIR JADVAR: Thank you for that comment.
19 Any comments on this comment at this time? Thank you,
20 but it's been noted. Any other questions or comments
21 from the public? All right, I see no more. Is that
22 what you see, Ms. Hoenig?

23 MS. HOENIG: Yes, I don't see any more
24 hands. Mr. Williams still has his hand up. I'm
25 assuming that's from his comment.

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1 CHAIR JADVAR: Okay. Very good. All
2 right, thank you very much. Very robust discussion.
3 So I guess at this time, I want to move this for a
4 motion for a vote of the subcommittee report. Do I
5 have a motion for a vote on it from the ACMUI members?

6 MEMBER EINSTEIN: So moved, Andrew
7 Einstein.

8 CHAIR JADVAR: Any seconds?

9 MEMBER HARVEY: Dr. Harvey, I'd be happy
10 to second.

11 CHAIR JADVAR: Okay, thank you. Any
12 opposed to the subcommittee report?

13 MEMBER SHOBER: I'm opposed. This is
14 Megan Shober.

15 CHAIR JADVAR: Okay, thank you. Any
16 abstentions?

17 MEMBER OUHIB: Yes, this is Zoubir Ouhib.
18 Abstain.

19 CHAIR JADVAR: Okay, Mr. Ouhib is
20 abstaining. Thank you. Any recusals? Any deferring
21 or dissenting views at this time? All right. So the
22 subcommittee report passes with one opposed by Ms.
23 Shober and one abstention by Ms. Ouhib. Thank you.
24 I'm sorry, Mr. Ouhib. All right. At this time, I
25 don't have anything else on my agenda items. Let me

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1 just go back to NRC and make sure that everything is
2 okay or if there is anything else they want to discuss
3 at this time before we adjourn.

4 DR. TAPP: Just like last time, Megan,
5 with an opposed, you have an option to write a
6 dissenting opinion, which will be attached to the
7 report. I believe you read what I'm assuming would be
8 similar to that. Up to you, Ms. Shober, if you'd like
9 to do that for the report. But I think it's an
10 abstention or an opposal versus a differing or
11 dissenting opinion. But you still have an option to
12 write, to add, to amend to the report if you'd like
13 to.

14 MEMBER SHOBER: This is Megan Shober. I
15 guess, I'm not really sure what the difference is
16 between an opposal and dissenting opinion. It sounded
17 like there was a difference there. Can you clarify?

18 DR. TAPP: An opposal is a little bit more
19 you're opposed to the entirety. And dissenting
20 opinion is, you know, dissenting opinion too. This is
21 the rate I take it, but a dissenting opinion is a part
22 dissenting. But I think it's very similar. You're
23 going to write a dissenting opinion for your -- that
24 is more your formal written dissenting opinion. And
25 I didn't know if you wanted to read anything now for

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1 that or if you just want to write it and append it to
2 the report.

3 MEMBER SHOBER: I can write that and
4 append it to the report.

5 DR. TAPP: Thank you.

6 CHAIR JADVAR: Okay, thank you. All
7 right, anything else, Dr. Tapp, or anyone from NRC
8 before we adjourn?

9 DR. TAPP: I just want to thank the ACMUI
10 and the subcommittee for the time you took to review.
11 I know this is a lot of information and I thank you
12 guys for the meeting today, taking time out of your
13 busy schedules and providing us your recommendations.

14 CHAIR JADVAR: Thank you. Well, I just
15 want to thank also you, Dr. Tapp and Mr. Einberg and
16 Ms. Hoenig and everybody else at the NRC for all the
17 great work you do. And of course, my colleagues in
18 the ACMUI membership who joined today and for the
19 robust discussion. And with, that I believe we can
20 adjourn the June 8, 2026 meeting of the ACMUI. Thank
21 you so very much again.

22 (Whereupon, the above-entitled matter went
23 off the record at 1:22 p.m.)

24

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