November 11, 2020

Dear Nuclear Medicine Program Director:

Radionuclide therapy has been an important part of Nuclear Medicine practice since the founding of the ABNM in 1971, and currently accounts for 8% of ABNM diplomate practice hours on average. The ABNM periodically re-evaluates radionuclide therapy requirements for initial certification. There has been an evolution of practice since the requirements were last changed in 2014, resulting in fewer radioiodine therapies for benign and malignant thyroid disorders, and more parenteral therapies. The ABNM is, therefore, proposing to change the requirements, as shown in the Table.

<table>
<thead>
<tr>
<th>ABNM Requirements</th>
<th>Radionuclide Therapy – Current vs Proposed</th>
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<tr>
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<tr>
<td>I-131 ≤ 33 mCi (benign)</td>
<td>10 – 15</td>
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<td>I-131 &gt; 33 mCi (malignant)</td>
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<tr>
<td>Parenteral</td>
<td>5</td>
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<tr>
<td>Total Therapies</td>
<td>35</td>
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* At least 2 different FDA approved radiopharmaceuticals excluding 90Y microspheres

In August of this year, the ABNM asked Nuclear Medicine training program directors for their feedback on the proposal and received a response from the directors of all 38 ACGME accredited programs (100%). Fifty-seven percent supported the proposal unequivocally, and another 34% supported the proposal with reservations. One reservation was concern that radioiodine therapies accounted for the majority of therapies at some hospitals, and that lowering the minimum number of required therapies would lower standards of competency. Another reservation concerned training with at least 2 different FDG approved radiopharmaceuticals given the limited number of FDA approved parenteral therapies commonly used in practice at this time.

Four directors (10.5%) did not support the proposal citing challenges in providing training opportunities for parental therapy due to the cost of the agents and limited or non-coverage by medical insurance companies, limited number of FDA approved radiopharmaceuticals actually used in practice, treatment only being done at dedicated cancer centers, and treatment being done in Radiation Oncology rather than Nuclear Medicine departments.
Suggestions regarding radioiodine therapies included raising the proposed minimum number above 10 (5 for benign plus 5 for malignant thyroid conditions), but a recent SNMMI survey of Nuclear Medicine program directors indicated that several programs were unable to meet current requirements for a minimum number of 20 radioiodine therapies (10 for benign plus 10 for malignant thyroid conditions).

Suggestions regarding parenteral therapies included giving credit for $^{90}$Y microsphere ablation of liver tumors, but the Nuclear Regulatory Commission considers this treatment a form of manual brachytherapy, which is regulated under 10 CFR 35.1000, whereas other parenteral radiopharmaceuticals are considered to be drugs, regulated under 10 CFR 35.396. Another suggestion was to require 10 parenteral therapies with a minimum of one FDA approved radiopharmaceutical (rather than two), or not change the requirements until the FDA approves more agents. An anonymous summary of all the feedback received from Nuclear Medicine program directors, with ABNM response, is attached.

Based on the feedback, the ABNM has decided that candidates for initial certification in 2021 and 2022 can fulfill the requirements using the current criteria in effect since 2014, or the new criteria. The ABNM will require all candidates to submit a training record that includes date of treatment, name of treating facility, radiopharmaceutical, and administered dose. Based on this information and the state of practice in 2022, the ABNM will re-evaluate requirements for radionuclide therapy at that time.

The ABNM believes that the new criteria will improve resident training, give Nuclear Medicine program directors more flexibility in meeting ABNM requirements, and maintain high standards for the specialty.

Thank you for supporting Nuclear Medicine training programs at your institutions, and training young professionals to be the future leaders of our specialty. You may send your questions or comments to abnm@abnm.org.

Sincerely,

Jonathan McConathy, M.D., Ph.D.
Chair

George Segall, M.D.
Executive Director

JEM/GS/mrw
Dear Program Director:

The ABNM is re-evaluating radionuclide therapy requirements for initial certification. There has been an evolution of practice since the requirements were last changed in 2014 resulting in fewer radioiodine therapies for benign and malignant thyroid disorders, and more parenteral targeted radionuclide therapies.

The ABNM is proposing changing the requirements, as shown below.

ABNM Requirements
Radionuclide Therapy – Current versus Proposed

<table>
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<td>5</td>
<td>*10 +</td>
</tr>
</tbody>
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The proposed change would give Nuclear Medicine program directors more flexibility in meeting ABNM requirements and maintain high standards for the specialty while recognizing changes in practice.

The ABNM would like your feedback on the impact the proposal would have on your training program, specifically, if your trainees would be able to meet the proposed requirements. Please provide an explanation for your answer. Additional comments and suggestions are welcomed.

Thank you.

The American Board of Nuclear Medicine
Summary of Program Director Responses (n = 38/38, 100%)

- Unequivocal Support – 20 (53%)
- Do Not Support – 4 (10%)
- Support with Reservations – 13 (34%)
- Support but Program Closed – 1 (3%)

Program #1
It is good to see the evolution of theranostics and the ABNM. Proposed requirements for ABNM eligibility are reasonable and appropriate. I will be participating on the ACGME Milestone Committee and I would like to rationalize training requirements to cover board eligibility and of course NRC AU requirements. I am sure we can all agree that medical knowledge theranostics training should be enhanced. Perhaps there is a role here for SNMMI in developing organized content for residents and MOC.

Regards

Program #2
Such changes will not have a negative impact on our training program. We are doing weekly Luta Thera treatments and Xofigo therapies, both of which already have resident involvement and participation.

I totally support a change in this direction.

Sincerely

Program #3
The reduction in the I-131 requirements I think is appropriate and achievable for both hybrid training residents and dedicated fellows to be able to complete in their training timeframes. Likewise, the 10+ parenteral therapies is also very doable in the same scenarios. All training, programs should be doing at least 2 types (this will only increase in the very near future as you well know) aside from microspheres already, so this also should be easy to complete.

This is a welcomed proposal!

Cheers

Program #4
I like the attached proposal and think it’s much more in line with current day therapy volumes. I do think our trainees would be able to meet them. My colleague recently took over as NM PD so I’ve copied her for her thoughts as well.

Thanks
Hi,

Yes, I totally support the proposed changes. I think they are more in line with the current practice. This will give us more flexibility meeting the requirements, especially for low dose iodine therapies. And I support raising the minimum for parenteral therapies, which are an important part of our field now.

Thank you!

**Program #5:**

I hope all is well with you and with ABNM. Things here are still disrupted, but not a disaster (yet). At present, we have no problem meeting the therapy requirements for our residents. New proposed metrics should not be a problem, as long as we get an approved prostate theranostic soon - otherwise, it may be a challenge to get the required 2 distinct parenteral agents. We virtually never do lymphoma radioimmuno therapy these days. This leaves palliative (and not very) 223RaCl2 and the occasional 131I-MIBG in neuroblastoma. We have a large program in 177LuPRRT

**ABNM response:** Thanks. Getting experience with 2 distinct parenteral agents hopefully won’t be an insurmountable challenge since there is no minimum requirement for a single agent, for example, nine 177LuPRRT and one 223RaCl2 therapies would be fine, although broader experience would be preferred. The idea was to reflect current practice and give program directors maximum flexibility, while maintaining high standards.

**Program response:** Should be fine!

**Program #6**

We are a relatively high volume therapy program. As such, we are not affected. Our thyroid volume is flat, but we will have a high volume of prostate therapies and a small volume of Lutathera.

I wonder whether there could be some sort of video/zoom preceptorship of these therapies to help the smaller and remote programs. I think it may be time to think out of the box.

Best

**ABNM response:** I’m glad that you have a relatively high volume therapy program. I agree it is time to think out of the box, and your idea of video/zoom preceptorship is a good idea. The ABNM wants to support innovation that improves education and training.

**Program response:** Excellent! I am trying to find ways to do video/simulation authorized user work. It is really the only way to get everything done with a rather large Radiology and smaller NM and RadOnc residencies. Inclusion and innovation are what we will be our “thing”.

Best

**Program #7**

I share the thoughts of the ABNM on this topic. My program performs enough cases, either with I-131 in thyroid processes, and parenteral therapy
through Lutathera, MIGB-I131 or Ra223-Dichloride to satisfy the new requirements proposed for the nuclear medicine fellows by the ABNM. Also, I believe the need for significant experience in managing patients with thyroid cancer and the benefits that future consultants in the specialty will obtain by treating a large number of patients. Please do not hesitate to contact me for any additional query.

Best Regards

Program #8
We like the proposal as thyroid therapies are declining and we see few female patients. We do several parenteral therapies so meeting that requirement is not a problem.

Program #9
I support the proposed changes.

Program #10
Our program can meet this requirement, which is more flexible and emphasizing the parenteral therapy.

Thanks

Program #11
Dear ABNM:

Thank you for soliciting our fellowship’s input regarding a proposed change to the radionuclide therapy requirements. In regards to the parenteral therapy changes, it is very difficult to provide meaning feedback without knowing when this proposed change would take place and not knowing for sure when new radionuclide therapies will be approved by the FDA, and hence, when will our training hospital and affiliated training sites begin performing any newly approved therapies.

Our fellows currently rotate at 4 sites during their training. Between those sites, only 2 FDA approved therapies are being performed routinely, Xofigo and Lutathera, with Lutathera only performed at one site. Unfortunately, we may be facing some changes and there has been discussion of referring out our costly Lutathera therapies to other centers. Samarium 153 is available, but has only been used once in the last 3 years and thus cannot be relied upon for meeting the proposed new parenteral therapy training requirements.

Given those challenges, if the proposed changes took effect before one of our sites begins performing an additional FDA approved parenteral radionuclide therapy, and based upon feedback from other NM core faculty, we would consider converting our program to an ABR NM CAQ fellowship or the 16-month alternate pathway, in order to continue providing NM subspecialty training and meeting the NRC requirements for
Authorized User status. Thank you again for providing us the opportunity to provide our input.

Best wishes

**ABNM response:** Thank you for your thoughtful comments. Any change the ABNM might make would not happen immediately. The proposal is based on feedback the board has received from many nuclear medicine programs that do fewer radioiodine therapies compared to past years, and more parenteral therapies.

*Did your trainees in academic year 2018-2019 have any difficulty getting experience with 30 radioiodine therapies, including a minimum of 10 for benign thyroid disease, and a minimum of 10 for thyroid cancer? Based on your experience, will your trainees be able to meet current requirements in the next academic year (i.e. July 1, 2021 - June 30, 2022), excluding COVID-19 considerations?*

**Program response:** Regarding the I-131 experience for benign and malignant thyroid disease, we had to add a training site in order to meet the combined requirements of our fellows and radiology residents, while limiting each case to only two house staff. This frequently entails our fellows and radiology residents needing to leave their assigned training site and travel to the other site in order to participate in a therapy, which is suboptimal, but acceptable. Given the caseload, we anticipate no issues meeting our 30 case minimum for the next few years.

Best wishes

**Program #12**

I just looked at the case logs for one of our residents. Over the last two years he logged over 40 parenteral therapies (Xofigo and Sir Spheres) and about 50 combined benign and malignant thyroid I-131 therapies. He didn’t log any therapies the last few months because of COVID. Our residents could easily meet the minimum requirements if they were to be increased. I would be in favor of increasing the minimum requirement even higher than the proposed number. I see no benefit in reducing the RAI requirement.

Thank You

**Program #13**

We would be supportive of the change. We would readily make the numbers of these therapy experiences as we have seen rises in parenteral therapies and declines in 1-131 usages. Our trainees who rotate through 5 sites of practice will be able to achieve these quota. I would ask, though, that you verify that other programs who may not have our volumes would be able to meet these requirements, as I am sure that you are doing.

Best regards

**Program #14**

This gives greater emphasis on parenteral therapy, which we need, and I welcome the flexibility regarding I131 therapy even as I realize that each
PD and program must take more responsibility for ensuring the quality of I131 therapy participation.

Yes, we will be able to meet above requirements. I131 therapies will be fine for us as before, and there are enough parenteral therapies at DFCI.

I full support your proposed requirement changes, and thank you for them.

**Program #15**

I think we should keep I-131 therapy/ablations at 10 each. Ten low dose <33mCi, and ten high dose >33mCi. Bringing down to 3 each, similar to radiology residents does not make anybody competent enough to practice this discipline. Most radiology residents do 3 each just to comply with ABR requirements. Most of them never practice radionuclide therapies.

Parenteral therapies are rarely being ordered. Lowering it down to 5 will make more sense. Moreover, radiation oncology appears to taking over such therapies such as Lutathera which will make it even harder to comply.

Best regards

**ABNM response:** The total number of required radionuclide cases wouldn’t change. A total of 35 would still be required, with a minimum of 5 (not three) radioiodine therapies for benign thyroid disorders, and a minimum of 5 (not three) radioiodine therapies for thyroid cancer. Many NM programs are having difficulty with providing experience with 30 radioiodine treatments to meet current requirements, so the ABNM is proposing giving PDs more flexibility in meeting the requirement for 35 therapies.

Do expect that your trainees will be able to meet the current requirement for 30 radioiodine therapies in the academic year 2021-2022 if the requirements are not changed?

Am I correct in understanding that your trainees would probably not be able to meet the proposed requirement for 10 parenteral therapies (minimum of 2 different radionuclides) in the academic year 2021-2022 if the requirements are changed?

**Program #16**

I agree to the proposed changes regarding the requirement. I understand the previous requirement regarding radioiodine therapy might be difficult for smaller programs.

Thanks

**Program #17**

We all agree that decreasing the required number of I131 therapy is reasonable – given that 30 cases during one year of training can be challenging. To meet the proposed required number of parenteral cases, we need to implement additional educational modules, such as case-based lectures. Currently, in our institution, these therapies are performed by the radiation oncology department, and we are working towards a system where radionuclide therapy will be a collaborative effort. We estimate that this transition will probably take several years to implement.
Program #18

I appreciate the steps forward the ABNM is taking to address the change in clinical practices. The changes in high dose iodine therapies is a welcome change, as we have moved away from remnant ablations and low stage radioiodine therapies.

Currently we are administering Lutathera and Xofigo at our facility. I anticipate our use of these two agents to expand and in the future, as well as the add new agents as available, and the number of 10 should be achievable. As these therapies expand in use, I anticipate the total of 35 to also be achievable - although we are struggling with this number now with the decline of I131 use.

My only concern is in the immediate future. We provided approximately 12 parenteral therapies in the last year (not including Y90 microspheres) and are right at that cusp for providing the minimum of 10. I believe these therapies are the future of Nuclear Medicine, and the goal of 10 is reasonable.

Please let me know if I can provide any additional information.

Regards

Program #19

Although I agree completely with these proposed changes, I preferred not to vote because my program closed as of 6/30/20. It was the last active program in the entire state!

Program #20

I would support the proposed change. The recent expansion of IV radionuclide therapies makes it imperative that we train our residents adequately.

Please feel free to get back to me for any questions.

Thanks

Program #21

I agree that radionuclide therapy practice is evolving and this should be reflected in updated ABNM requirements. I appreciate you reaching out to us for our feedback on the proposed changes.

I wholeheartedly agree with increasing the requirement for parenteral therapies, as the availability and demand for such therapies continues to
grow, and patient management/ follow-up is often complex. I also agree with decreasing the requirement for RAI treatment of benign disease. Based on the provided table, it seems that the quota for RAI <33 mCi would be increased (currently >=3, proposed >= 5); was this intentional? I’m not quite sure I agree with decreasing the requirement for RAI treatment of malignant disease as this remains an important part of nuclear medicine practice. As an aside, I’ve always found the guidelines on I-131 therapies to be ambiguous and confusing. There also seems to be discrepancy between ABNM and ACGME on these requirements (at least as currently worded). My recommendation would be to get rid of the distinction between benign/ malignant and </> 33 mCi and to simply require 10 or more treatments of I-131 for any disease process.

Finally, our trainees will be able to easily fulfill a total of 35 radionuclide treatments, including >= 10 parenteral with two different FDA approved drugs (e.g. Xofigo, Lutathera).

Best Regards

**ABNM response:** The ACGME NM program requirements, and the ABNM requirements are currently identical. Appearance to the contrary in the Table is due to brevity. The current requirements of both organizations are currently:

- Radiotherapy with I-131 - 30 cases (at least 10 benign plus 10 malignant, including 3 ≤ 33 mCi and 3 > 33 mCi)
- Parenteral therapies requiring a written directive - 5 cases

Regarding your specific comment, “Based on the provided table, it seems that the quota for RAI <33 mCi would be increased (currently >=3, proposed >= 5); was this intentional?”, the NRC regulations regarding AU status for 10 CFR 35.392 requires 3 administrations of I-131 ≤ 33 mCi, but the ACGME NM program requirements require a minimum of 10 administrations for “benign” thyroid disease, which is almost always going to be ≤ 33 mCi. In short, the ABNM proposal does not increase the requirement from 3 to 5 administrations of I-131 ≤ 33 mCi, but effectively lowers the requirement from 10 to a minimum of 5 administrations.

Regarding your specific comment, “I’m not quite sure I agree with decreasing the requirement for RAI treatment of malignant disease as this remains an important part of nuclear medicine practice.”, the minimum requirement would decrease from 10 to 5 administrations, but I think most programs would provide their trainees with more than 5 administrations, and we wanted to give PDs maximum flexibility within the unchanged requirement for a total of 35 therapies (I-131 plus parenteral). I understand your point, however, and it is good to have your perspective.

**Program #22**

With the advent of theragnostic, I believe the proposed change moves us towards the right direction. As such, I fully support it.

We are very well positioned with the new parenteral requirements. I guess you will have to look at the response from smaller institutions to ensure they can meet them.

Thanks

**Program #23**

I presume that this was done in conjunction with the RRC? I don’t know what data they have for what parenteral therapies are being done, but our
trainees log into their ADS, so I know they have ours. Our program will have no problem either way, but I’m curious about smaller programs and their access to parenteral therapy, especially if Y-90 microsphere therapies are excluded.

Another question that I expect you have discussed at the Board or RRC level is the decrease of the I-131 NaI therapies. This decrease seems to give a message that they are less important. I would argue that these are commonly done and require a good deal of experience to be exposed to the different questions that could be raised by patients or other things that can potentially go wrong that intersect with regulations, etc. Have some programs been unable to meet this higher bar? Learning doesn't stop at the NRC minimum of 3 and certainly wouldn't stop at 5. I would favor having them stay at their current level.

I see that the total number of therapies is unchanged, perhaps to not make it so onerous for trainees to log? I still encourage all of our trainees to keep track of all they do so they have good data for future hospital credentialing purposes. If the group wanted to add to the parenteral number only, I would be more supportive of that. We will certainly see even more parenteral therapies coming to use, so I think that would be a logical step.

All in all, I don't want to sound too negative with this, but definitely want to not diminish the importance of the I-131 NaI therapies. I hope that helps.

Take care

Program #24

We still do lots of thyroid therapy, but I can understand that other sites do not due as much. So reducing I 133 to 5 each is not inappropriate in my opinion.

Targeted therapies are only being done at dedicated cancer centers. We luckily have one of our hospitals, so we could meet the increased requirement. However, other programs which have just as valid and effective general Nuclear Medicine training may not be able to meet 15. I do really think the Board is jumping the gun at this point. If we lived in Europe, it would be a different matter, but targeted therapy is now only emerging in the USA. And given the expense of the drugs, it may be forever restricted to cancer centers. The drugs are far more expensive in the USA than they are in Europe, because the EU regulates that. We have no such regulation in the USA. For example, I pay $2600 for ioflupane. The EU pays $1000 for the same drug from the same vendor.

In the spirit of Nuclear Medicine practice for everyone, I am not in favor of increasing the targeted therapy requirement to 10 or 15 at this time.

Program #25

Our trainees would be able to meet these proposed criteria.

Last year our trainee was involved in over 24 parenteral therapies, most of which were Lutathera. He was also able to participate in several thyroid therapies that meets the current requirements, however, as you know, the more difficult procedure for them to participate in are 131-Iodine therapies >33mCi, so this change would be helpful.
Program #26

I write to express my support for the proposed changes to the requirement for Radionuclide Therapy. As the director of the NM training program, I see no problems for our trainees to meet the proposed changes.

Best regards

Program #27

I believe the proposed change is very much in line with the evolving practice of nuclear medicine and, as a program director as well as an ABNM diplomate, would definitely support this change.

Benign thyroid disease is now often treated in the community; while practicing nuclear medicine in the community for 8 years, I treated several individuals with I-131 each week. However, since many nuclear medicine training programs are based at major academic centers, we see a paucity of patients for benign thyroid conditions and it is very difficult for trainees to see the number of required “low dose” I-131 cases during their training. We still treat many thyroid cancer patients in academics, whereas these patients may not be seen very much in the community. Therefore, I would very much support the concept of a total number of therapies to be set at 35 with minimums in each category to allow the greatest flexibility.

I did have one question regarding the parenteral therapies. Excluding 90Y Sirspheres/Theraspheres, these are the parenteral agents of which I am aware:

- Y90 Zevalin (last treated a patient with this in 2015?)
- Sm153 Quadramet (last treated a patient with this in 2014)
- Ra-223 Xofigo (though quite popular initially, we treat one patient per week on average, and we are a referral center for prostate cancer patients)
- Y90 Dotatate (treat about 4 patients per week)
- I131-MIBG (very occasionally we see a pediatric patient for this, but we have not started treated adults for paraganglioma on a regular basis)

I may have forgotten one, but it would seem that the bulk of experience in parenteral therapy will likely come through Lutathera, at least in the short run (until a PSMA agent or other is approved). We will have no problem meeting the parenteral requirement, but I wonder if other programs at other community centers or non-cancer-focused hospitals will have the same opportunity. I’m wondering if the total of 35 should remain but the minimum number of parenteral therapies be set at 5 OR that there not be a minimum of 2 different parenteral therapies used to meet the criteria. Again, I am 100% certain that our program can meet any permutation of the requirements. I am concerned that we might be in the minority.

Finally, in addition to setting the number of therapies, I wondered if the ABNM might consider updating its description of what it means to “perform” a therapy. For example, the ABNM lists the requirement: “30 Oral radiotherapies with sodium I-131 (at least 10 benign plus 10 malignant, including 3 ≤ 33 mCi and 3 > 33 mCi); 5 Parenteral therapies requiring a written directive”. Should the applicant be required to attest
that he/she primarily managed patient care in preparation for, during, and following administration of the therapy, verified the dose, completed dosimetry calculations if required, etc? I realize that the level of involvement is the responsibility of the ACGME-accredited program, but we have a spectrum of nuclear medicine practitioners ranging from those who have abided by the spirit of the requirements (good solid patient care preparation) to those who checked off the boxes.

Best

**ABNM response:** Thank you for your thoughtful comments. The majority of programs that have responded so far have stated their trainees could meet the proposed requirements, but there are some programs that have stated that they could not meet the proposed requirement for 10 parenteral therapies with at least 2 different FDA approved radionuclides excluding Y90 microspheres. I hope we will be able to obtain comments from all 37 NM program directors in order to determine how best to proceed.

I agree it would be a good idea for the ABNM to inform program directors that “required case experience” must fulfill the following ACGME Nuclear Medicine program requirements:

**IV.B.1.b).(1).(a).(ii).(m) therapeutic administration of radioiodine for both malignant and benign thyroid disease, including:** patient selection; evaluating risks and benefits; determining the administered activity; patient identity verification; obtaining informed consent; documenting pregnancy status; using administrative controls to prevent a medical event; complying with federal and state regulations regarding medical use of radiopharmaceuticals; counseling patients and their families about radiation safety issues; and scheduling and performing post-therapy follow-up; (Core)

**IV.B.1.b).(1).(a).(ii).(n) therapeutic administration of other unsealed radiopharmaceuticals for malignant and benign diseases, including:** patient selection; evaluating risks and benefits; determining the administered activity; patient identity verification; obtaining informed consent; documenting pregnancy status; using administrative controls to prevent a medical event; complying with federal and state regulations regarding the medical use of radiopharmaceuticals; counseling patients and their families about radiation safety issues; and scheduling and performing post-therapy follow-up; (Core)

AND

fulfill NRC regulations for supervised work experience for at least 3 administrations of I-131 ≤ 33 mCi, 3 administrations of I-131 > 33 mCi, and 3 administrations of any parenteral therapy, as follows:

Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys

Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters

Calculating, measuring, and safely preparing patient or human research subject dosages
Using administrative controls to prevent a medical event involving the use of unsealed byproduct material
Using procedures to contain spilled byproduct material safely and using proper decontamination procedures
Thanks again for taking the time to respond.

Program #28

We were able to discuss proposed requirements at our faculty meeting. As per discussion-

At our institution, number of RAI as well as parenteral therapies performed annually are fairly large and we understand that we are in a unique position, unlike some smaller programs. We have approximately 4 residents per year and based on the number of treatments we perform at our institution we are able to meet the current requirements of the board. Given the evolution of practice we agree with the proposed changes of reducing the number of RAI treatments and increasing the number of parenteral therapies. With the ongoing development as well as approval of theranostic radiotracers, number of parenteral therapies are on rise. We strongly believe that theranostics should be an essential component of the ABNM curriculum.

We also believe curriculum/webinars/modules related to theranostics should be developed.

One of the concerns/questions I have - will these requirements apply to 1-year training programs (ABR pathway/Alternate pathway candidates)?

Also one of the faculty members had following comments-

As requested, I'm providing a written objection to the ABNM's proposal to cut down the requirement of I-131 radionuclide therapies for ABNM trainees. Whereas there appears to be a practicality of doing so given the significant decrease in the numbers of RAI therapies being done, this should not be done in sacrificing standards of competency. Moreover, there needs to be a comprehensive approach to training in therapeutic Nuclear Medicine, with changes in paradigms on how we set these standards, especially if there is hope that this will rise as a new modality practiced by only well qualified physicians. I will outline some thoughts below:

1) It is understandable that in a single Nuclear Medicine program, the exposure of the trainees to the number of therapies in Nuclear Medicine is becoming almost impossible to meet. In fact, it is also understood that even the minimal 3+3 requirement required by ABR candidates to gain competency to get AU status is limited. In those cases, many housestaff 'double up' on participating in therapies, and such an approach could certainly be taken amongst the Nuclear Medicine candidates. Understandably, this may already be taking place at certain programs and may still not be meeting the mark. I would also point out that many institutions that have ABR Fellowship and Residency training programs continue to have RAI treatments. Moreover, there are many institutions that do not have any training programs at all. Hence, ABNM program directors really do need to make the effort to reach beyond their own institutions and partner with other places, even if there are private community practices, to get the appropriate competency in treatments. It is also worth noting that there are still many Endocrinologists who manage to get certification in...
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the current environment. That getting the currently required number of cases may be difficult, if approached creatively it is not impossible.

2) I am encouraged that the number of parenteral therapy requirements is being increased; however, I would caution a generic categorization of
this area. In this area, both infusion of bone palliation treatments (Quadramet, Xofigo, etc.) and disease treatment modalities (Lutathera, Zevalin,
etc.) are put under the same competency. It is clear that the latter areas are far more complex than the former, including the approach to
evaluation for disease management and therapy. There are also other therapeutics, such as Radiosynovectomy, that are not considered in this
document, but need to be addressed. By the same token, Y-90 microspheres have been deliberately left out of the document, but I believe they
can be considered by an overall approach as suggested below.

3) A proposal I would have is to count the total number of complex therapies one performs. Whereas the total number for I-131 therapies should
remain at the current amount, they can be substituted by more complex therapies (like Xofigo, Lutathera), and even Quadramet could be
substituted by Lutathera, but not vice versa. Whereas each therapy is somewhat unique, being certified in the complexity of therapies should
entitle someone to administer more simpler ones.

4) Ultimately, ABNM needs to create a system closer to EANM and other societies, where a candidate is certified in being able to deliver
radiotherapeutics, and should be reflected by an overall competence in approach. In this scenario, the total number would not be absolutely
deterministic of competency status, but rather a training verification of approach and overall competency. This will also allow a candidate to
‘grandfather in’ to various treatment modalities as they develop into the future, although perhaps some sort of minimum training may still be
required to absorb those therapeutics into their practice (eg. Y-90 microspheres). Having a simple target of total numbers does not cover this
competency, and should be thought of how much complexity the candidate has been able to handle.

These are outline of basic thoughts, the details of which are beyond the scope of this letter as this is supposed to stimulate thought and discussion
within the ABNM- By anonymous faculty.

Thanks

Program #29

The changes you propose would be achievable at our institution at this time. I am in favor of increasing parenteral therapies, as I see that as an
important component of our specialty’s future.

I do have some reservations however about the numbers we have chosen. In particular our volume of 131-I for hyperthyroidism decreased
significantly, and I am concerned that is not unique to us. I am worried that our arbitrary “30” 131-I may be difficult for programs to achieve in the
not-too-distant future. This is especially true considering most places have radiology residents competing for those experiences as well. If we
loosened up the requirement of one resident per therapy (as the ABR did in response to COVID, for example) that might make things easier. Of
course to my mind the actual administration of the dose is probably the easiest step in the therapy procedure; we need to stress that there had to
be meaningful participation throughout the therapy process.

I am also somewhat concerned that smaller programs may have difficulty with 10 parenteral therapies, at least in the short term until PSMA ramps
up. One could make the argument that maybe they shouldn’t be in the business of training residents if they can’t provide that many, but I don’t
think this is the right time to force more contraction of NM programs. Maybe the Society could step in with a clinical experience for programs (have them come to a central place like AFIP, or provide money for a stipend for residents to do a rotation at a “center of excellence”), but that is an interminable email chain topic for another day.

It would be nice if we had a source of reliable data that we could use to come up with to make sure what number we settle on is achievable, as well as meaningful to resident experience and competency. I am worried that the ACGME data is not robust, as we still have the occasional “0” for therapies. I also worry that they stop reporting data when the numbers are achieved, although that is a lesser concern (at least they achieved our arbitrary number in that case). There are a couple of therapy surveys floating out there from the Society (Fred Grant had one, as did the Therapy COE I think). Those may help to inform our decision if we could convince them to allow us access.

Just my $0.02. Sorry for the delay in getting this to you.

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**Program #30**

Thanks for your inquiry regarding our program's ability to comply with the new proposed radionuclide requirements.

In reviewing our case load for radionuclide therapies these proposed thresholds seems reasonable. I have added my comments for consideration by the committee below.

I-131 ≤ 33 mCi (benign) 5+
- Comment: Our residents should be able to achieve this number.

I-131 >33mCi (malignant)
- Comment: Our residents will have no trouble achieving this number

*10+ parenteral therapies (*At least 2 different FDA approved radiopharmaceuticals excluding 90Y microspheres)
- Comment: most of these will be Lutathera until the FDA approves other agents. Requests for Xofigo have declined at our institution, possibly due to the adverse effects when combined with abiraterone which is so commonly used in the metastatic prostate cancer population.
- It is not clear to me why 90Y microspheres are not included among the acceptable parenteral therapies. It seems that ABNM certification in giving broad approval for use of radionuclide therapy would want there to be evidence of training in 90Y microspheres which is a well established modality.
- I would suggest modification to the following: 10+ parenteral therapies (*At least 2 different FDA approved radiopharmaceuticals including no greater than 5 with 90Y microspheres)

Thank you for your inquiry.

Sincerely
ABNM response: Thank you for your comments. Y-90 microsphere brachytherapy is regulated under 10 CFR 35.1000. The training requirements to be an AU for Y-90 microsphere brachytherapy go beyond the requirements to be an AU for parenteral radionuclide therapy, which is regulated under 10 CFR 35.390, and the training requirements for Y-90 microsphere brachytherapy are not included in the ACGME program requirements for Nuclear Medicine.

What is the role of the NM physician for Y-90 microsphere brachytherapy at your program, which is administered by an Interventional Radiologist?

Program response: At our institution nuclear medicine physicians not only review the pretherapy Tc99mMAA scan for lung shunt fraction and extrahepatic activity, but also prescribe the Y90 treatment dose. We have an interdisciplinary conference with interventional physicians to discuss treatment planning and also involve our department physicist as needed in some cases. The Y90 dose that the NM physician prescribes is then administered by the IR physician.

Program #31

The proposed is fine, but I would not exclude Y-90 microspheres. We do Ra-223, our Luta-Thera program is not that active, and our I-131 MIBG program is yet to start. This would not allow our residents to fulfill the requirements.

Best

ABNM response: Thank you for your comments. Y-90 microsphere brachytherapy is regulated under 10 CFR 35.1000. The training requirements to be an AU for Y-90 microsphere brachytherapy go beyond the requirements to be an AU for parenteral radionuclide therapy, which is regulated under 10 CFR 35.390, and the training requirements for Y-90 microsphere brachytherapy are not included in the ACGME program requirements for Nuclear Medicine.

What is the role of the NM physician for Y-90 microsphere brachytherapy at your program, which is administered by an Interventional Radiologist?

Program response: I am the authorized user for Y-90 microspheres here. We do the dose calculations and I go down the IR suite to insure my IR colleagues catheterize the correct vessels feeding the tumor(s), and I administer the dose(s). Our trainees: Nuclear Medicine, Radiology and IR are involved in the process.

Best

Program #32

I have reviewed the ABNM’s proposal of reduced training requirements for radioiodine therapy of benign and malignant thyroid disorders and increased requirements for parenteral targeted radionuclide therapies. These changes are reasonable and reflective of variations in practice that we have experienced since 2014. I believe that our trainees would be able to meet the proposed requirements.

Sincerely
Program #33

After reviewing the new proposed radionuclide therapy requirements for initial certification, I would be in favor of this proposal and we "should" be able to make the requirements easily. We would need to get our NM residents to be involved with a second parenteral therapy but this would help us leverage involvement with resident training in Xofigo/Radium-223 treatment which is currently done by radiation oncology here. My concern is that some sites may not be able to reach this number and 2 different parenteral radiopharmaceutical requirement.

Question: Are parenteral therapy numbers by number of patients OR number of parenteral infusions, since there are multiple administrations per patient? We can meet this number however at UW regardless of how the number is determined.

I-131 <= 33 mCi (benign) of 5+: YES
I-131 > 33 mCi (malignancy) of 5+: YES
Parenteral 10+ (at least 2 different FDA approved radiopharm excluding 90Y): YES (but requires change in NM Resident involvement to including Radium-223 as well as Lutathera)

Thank you

ABNM response: Thank you for your feedback and additional comments. Each radiopharmaceutical administration counts as 1 case experience, so if a trainee participated in 4 Lutathera administrations for one patient, and 6 Xofigo administrations for a second patient, the trainee could claim credit for 10 therapies.

Program response: Thank you for the clarification and response to my question. Dose numbers sound very reasonable.

Best

Program #34:

I am the new program director for the NM and NR training programs. I am in agreement with the proposed changes to the therapies requirements. Our trainees should have no problem meeting the requirements suggested by the ABNM.

Sincerely

Program #35

In relation to the Radioiodine therapies, both above and below 33 mCi, we have an adequate volume of cases to comply with requirements.

That is not the case with parenteral therapies. We have problems to comply with the current requirements. We believe the limited or non-coverage of the radiopharmaceutical by the medical insurance of most of the population and the cost of the radiotracer are related to the low volume of cases.

It will be very difficult for our Program to comply with the proposed number of cases for parenteral therapies.

ABNM response: Thank you for your feedback and explanation. Is your program able to comply with the current requirement for trainees to have
Training and experience with 5 parenteral radionuclide therapies?

Program response: I think for our next graduates we can comply with the five cases in the three year program

Program #36

Thank you so very much for your email. Would you please clarify “the total of 35 therapies”? Since Lutathera and Xofigo need 4 and 6 doses per patient, respectively, should we count ten or two therapies? In other words, if counting doses instead of patients, we can do it.

Thanks. Have a great week!

Best

ABNM response: Each radiopharmaceutical administration counts as 1 case experience, so if a trainee participated in 4 Lutathera administrations for one patient, and 6 Xofigo administrations for a second patient, the trainee could claim credit for 10 therapies.

Program #37

Our trainees have absolutely no problems meeting the current ABNM requirements for Radionuclide therapy.

With regards the new proposals, again our program would have no difficulties meeting the I-131 requirements.

The proposed change to parenteral therapies requiring at 10+therapies with at least 2 different FDA therapies might be a little more challenging but is also achievable. We continue to roll out our Lutathera treatments, although COVID has put a dampener on it so in a post Covid world we expect a much busier practice. We do offer other therapies (Xofigo, Samarium) although our opportunities to treat these patients is not as robust.

For clarification, if a trainee is present for all 4 lutathera treatments on one patient, does it count as 4 or just 1 therapy?

ABNM response: To answer your question, if a trainee fully participates in all 4 Lutathera treatments for one patient, the resident can claim 4 therapies towards the proposed new requirements for 10 parenteral radionuclide therapies.

Program #38

Many thanks for giving me the opportunity to provide a feedback on this very important issue.

I think that we do absolutely need to increase the number of parenteral therapies required and I agree with the numbers. However, I would suggest that we don’t strictly pose the requirement of 2 different parenteral therapies. There are still many places in US where this would be practically impossible to achieve.