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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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General Comment

Please see the attached PDF.

Attachments

Response to NRC, Kousha Zarnegar MD

Response to NRC T&E Questions

A. Tailored Training & Experience Requirements The NRC is requesting comments on whether it should establish tailored T&E requirements for different categories of radiopharmaceuticals for physicians seeking AU status for the medical use of specific categories of radiopharmaceuticals requiring a written directive under 10 CFR 35.300 (i.e., a limited AU status). This would be for physicians seeking AU status via the alternate non-board-certified pathway, and for physicians certified by a medical specialty board that is not currently recognized by the NRC under 10 CFR 35.390, 35.392, 35.394, or 35.396 (Unsealed Byproduct Material- Written Directive Required).

1. Are the current pathways for obtaining AU status reasonable and accessible? Provide a rationale for your answer.

The current pathways to obtain AU status are too loose and too easily accessible. The requirements bypass the in-depth training curriculum established by the American Board of Nuclear Medicine, which consists of several years of training in an ACGME-accredited nuclear medicine training program and board certification.

2. Are the current pathways for obtaining AU status adequate for protecting public health and safety? Provide a rationale for your answer.

Public health and safety can be divided in this context into radiation safety and safety in terms of having a guarantee of high quality of medical care. By reducing protection of public health and safety to radiation safety only which the existing alternate pathways in 10 CFR 35.390, 35.392, 35.394, or 35.396 in essence do, public health and safety is jeopardized. These aforementioned regulatory pathways suggest that having a minimal training of 2 weeks (80 hours) or at best 4 months (700 hours) is equal to several years of nuclear medicine training and sufficient to practice nuclear medicine. According to current regulatory framework any physician would be licensed and endorsed by NRC to administer a highly specialized radionuclide therapy like I-131 after taking a 2 weeks course and after observing 3 cases. Nuclear medicine specialists attain the same privilege after several years of dedicated nuclear medicine specialty training, experience with dozens of cases, and after undergoing rigorous board certification by the American Board of Nuclear Medicine. By this virtue, the current regulatory pathways endorse substandard training and practice of nuclear medicine and are therefor not sensible and dangerous.

3. Should the NRC develop a new tailored T&E pathway for these physicians? If so, what would be the appropriate way to categorize radiopharmaceuticals for tailored T&E requirements? If not, explain why the regulations should remain unchanged.

The answer to this question is an unequivocal "No". Creating new "tailored T&E pathways" would mean to cut the specialty of nuclear medicine in pieces. This would be akin to having a non-surgeon physician taking a quick course and learn to perform cholecystectomies (surgical removal of the gall bladder) another non-surgeon to perform appendectomies or another non-surgeon physician learn to perform hernia repairs, instead of having a surgeon trained in all aspects of surgery carry out these procedures. This practice might even go well for a while if patients are uncomplicated and everything is ideal. But what happens if there are complications like patients who had prior surgeries with significant adhesions, or in case of intraoperative complications bowel or vascular injuries, or patient has bowel obstruction

after surgery? This is the time when the value of a fully trained surgeon knowledgeable in all aspects of surgery becomes crucial. Another example would be to have the high blood pressure of a patient treated by one physician, the high cholesterol by another, and the irregular heart rate by yet another physician and none of these physicians is facile in the other treatments. This is not how medicine is practiced. These considered tailored pathways are poorly conceived, appear to follow economic perspective of radiopharmaceutical manufacturers, endanger patient safety, and do not have any parallels anywhere else in the world.

4. Should the fundamental T&E required of physicians seeking limited AU status need to have the same fundamental T&E required of physicians seeking full AU status for all oral and parenteral administrations under 10 CFR 35.300?

Yes. High standard of training and quality of care in all aspects of nuclear medicine therapies guaranteed by a comprehensive curriculum including radiation safety but above and beyond that emphasizing all clinical aspects of practicing nuclear medicine as outlined by the American Board of Nuclear Medicine and board certification in nuclear medicine for all AU's, is the only way that patient safety and highest quality of patient care can be guaranteed.

5. How should the requirements for this fundamental T&E be structured for a specific category of radiopharmaceuticals? a. Describe what the requirements should include:

Dividing the specialty of nuclear medicine by category of radiopharmaceutical is unheard of anywhere else in the world. This would be to the detriment of the specialty of nuclear medicine and as a consequence compromising significantly quality of patient care. The NRC does not have the necessary access to medical knowhow to structure training programs. It has to rely on medical specialty boards and base any regulatory considerations on the medical specialty guidelines of training and experience. In this case it is the American Board of Nuclear Medicine and its guidelines. Not relying on medical specialty training requirements and instituting arbitrary number of hours of training is contrary to common sense, undermines the authority of medical specialties, and ultimately promotes poor quality of patient care.

B. NRC's Recognition of Medical Specialty Boards the NRC is requesting comments on its recognition of medical specialty boards. The NRC's procedures for recognizing medical specialty boards are located on the Medical Uses Licensee Toolkit website (https://www.nrc.gov/ materials/miau/med-use-toolkit/certifprocess-boards.html). The NRC staff periodically reviews information to determine a board's continued eligibility for recognition.

1. What boards other than those already recognized by the NRC (American Board of Nuclear Medicine [ABNM], American Board of Radiology [ABR], American Osteopathic Board of Radiology [AOBR], Certification Board of Nuclear Endocrinology [CBNE]) could be considered for recognition for medical uses under 10 CFR 35.300?

At the current time only a specialty training in a nuclear medicine training program, or a combined nuclear medicine and radiology training program, accredited by ACGME and successful passing of board certification examination through American Board of Nuclear Medicine provides sufficient assurance of adequate training in using therapeutic radiopharmaceuticals.

2. Are the current NRC medical specialty board recognition criteria sufficient? If not, what additional criteria should the NRC use?

The NRC's procedures for recognizing medical specialty boards as specified on the Medical Uses Licensee Toolkit website: www.nrc.gov/materials/miau/med-use-toolkit/... are focused on radiation safety aspect of patient care only and require the above-indicated 2 weeks – 4 months (80 hours – 700 hours) of T&E in radiation safety and equate these radiation safety requirements to a complete nuclear medicine specialty training of 3 years. What this approach of recognition employed by NRC however overlooks is that practice of nuclear medicine and high quality of patient care is much more than only radiation safety requirements. Therefore basing recognition of specialty boards solely on compliance with radiation safety processes doesn't safeguard adequate qualification. In addition, NRC does not have any actionable mechanism in place to control and examine different recognized specialties whether even the minimum radiation safety requirements in training are truly complied with. Furthermore, some of the specialties mentioned among the currently already recognized specialty boards by the NRC are not even listed as medical specialties/subspecialties registered with the American Board of Medical Specialties (ABMS). That means that these specialties/subspecialties have not undergone the scrutiny and rigorous evaluation of ABMS.

C. Patient Access the NRC is requesting comments on whether there is a shortage in the number of AUs for 10 CFR 35.300.

1. Is there a shortage in the number of AUs for medical uses under 10 CFR 35.300? If so, is the shortage associated with the use of a specific radiopharmaceutical? Explain how.

There is no indication that there is a shortage of AUs for medical uses under 10 CFR 35.300. The original concerns voiced by NRC regarding a shortage of AUs was related to NRC's perception of a decreasing Nuclear Medicine workforce. However, based on American Board of Nuclear Medicine (ABNM) annually published data, there have been on average 67 new Nuclear Medicine diplomates per year in the last ten years (2008-2017). This number appears to plateau at about 50 diplomates per year in most recent years (63 in 2015, 43 in 2016, and 49 in 2017). Additionally, in the last 5 years, 568 diplomates have taken the ABNM maintenance of certification examination with their licenses being still active for at least another 5 years at the current time (1). This means that at the present time based on conservative estimates a work force of at least more than 1200 board-certified nuclear medicine physicians across the US are available. Based on projections of future needs in radionuclide therapies, approximately 150 new theranostic centers across the US would be needed to deliver approximately 150 000-200 000 treatment cycles (assuming 4 cycles/patient for up to 50 000 patients). This estimate is extrapolated from the experience at a tertiary care academic center, considering expanded access use for patients with neuroendocrine tumors as well as endstage prostate cancer patients which are being currently entered into clinical trials for PSMA radioligand therapy. Each of these sites would treat 1000-1250 patients/year or 5-7 patients/day. Based on information published by The Carcinoid Cancer Foundation (2), 62 such centers have already been established across US for administration of PRRT for neuroendocrine tumors since the FDA approval of Lu-177 Dotatate (Luthathera ™) in January 2018 within less than 1 year of time. The vast majority of these sites are nuclear medicine departments/divisions. This indicates that the current ABNM-certified work force in the US and the expected addition of new ABNM-certified physicians in the upcoming years of approximately 50-60 ABNM diplomates per year will easily meet the above-mentioned demand of new therapy centers.

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) in its advisory role to NRC also refuted in its report from July 5, 2018 the assumption of a shortage of authorized users (3). Thus, the argument of an AU shortage is simply not supported by data!

[1] The American Board of Nuclear Medicine. www.abnm.org/index.php/docs/newsletters Accessed: November 16, 2018

[2] The Carcinoid Cancer Foundation. www.carcinoid.org/2018/07/26/... Accessed: December 30, 2018

[3] The Nuclear Regulatory Commission: www.nrc.gov/docs/ML1818/ML18186A517.pdf Accessed: December 30, 2018

2. Are there certain geographic areas with an inadequate number of AUs? Identify these areas.

The NRC as a licensing entity for non-agreement states and with its supervising function for agreement states would be best placed to provide accurate statistics on number and location of authorized user licenses issued for individual physicians and also medical institutions and the scope of each of these licenses.

What is clear though is that all tertiary level and many secondary level medical care centers/ facilities have a nuclear medicine service/division and hence presence of authorized users. Thereby a wide net of authorized users across the country is existent. As it is well known, medical service in general is scarce in some mainly rural regions of the country and nuclear medicine coverage is not exempt from this general problem. In general, patients who live in small villages or towns may not have access to most medical specialties and are used to traveling to a larger town or city for non-emergency specialist care. That larger town or city will have physicians licensed to perform radiopharmaceutical therapy based upon the requirements of 10 CFR Part 35.390. For example, patients are ready to travel longer distances to the nearest specialized centers to receive complex procedures like CABG (coronary artery bypass surgery), brain surgery, organ transplantation, new chemotherapies, or PRRT (peptide receptor radioligand therapy) knowing that they will receive at these centers the best and highest level and quality of care. To receive all possible medical care in a local community hospital is not feasible and not necessarily in the best interest of the patient.

Radioligand therapies are highly specialized treatments requiring several years of training and experience that guarantees in-depth knowledge and expertise in all aspects of these therapies. Many of these new therapeutic agents are part of clinical trials and can only be offered at specialized centers. These therapies cannot be offered in a primary care setting or at the local CVS and Walgreens stores as some recent discussions have suggested as possible solutions.

3. Do current NRC regulations on AU T&E requirements unnecessarily limit patient access to procedures involving radiopharmaceuticals? Explain how

Patient access is not an issue. Based on information presented by the radiopharmaceutical industry (Advanced Accelarator Applications) at the most recent Society of Nuclear Medicine and Molecular Imaging (SNMMI) annual meeting in Philadelphia in June of 2018, after the recent FDA approval of Lu-177-Dotatate (Luthathera ™) approximately 60 therapy centers across US have been established. This quick implementation occured within a time frame of only six months after FDA approval of Lu-177-Dotatate (Luthathera ™) in January 2018. This fact demonstrates that the current existing network of authorized users is able to quickly respond to needs and use of new therapeutic radiopharmaceutical FDA approvals.

4. Do current NRC regulations on AU T&E requirements unnecessarily limit research and development in nuclear medicine? Explain how.

The broad licensure approach of NRC in the last 15 years requiring only 2 weeks or maximum 4 months (80 hours to 700 hours) of training as defined in 10 CFR part 35.390, 35.392, 35.394, and 35.396 instead of a comprehensive 3 years long nuclear medicine training for administration of radiopharmaceutical therapies has significantly undermined the foundations of nuclear medicine as a specialty. By resorting to NRC's regulation and minimal requirements, hiring managers in hospitals and large physician groups do not see the necessity to hire nuclear medicine specialists. They burden their existing radiologists or radiation oncologists to run the nuclear medicine service on the sideline without their radiologists or radiation oncologists being nuclear medicine board-certified. This fact has led in many instances to suboptimal use of nuclear medicine studies and more importantly to a decline in research and new developments. The radiologists and radiation oncologists who are busy with running their own services do not have the time, resources, or the necessary background to carry out time and resource consuming tasks like devising new clinical trials, developing new imaging probes, or promoting research for new therapeutic agents. As a result nuclear medicine has experienced stagnation in US in the last 15 years where as the specialty has flourished in the rest of the world. What we are witnessing today is that vast majority of cutting-edge research, new introduction of imaging probes, new development of therapeutic radiopharmaceuticals are coming from outside US from countries like Germany, France, or Australia. It should be kept in mind that nuclear medicine was first introduced and invented in US with pioneering work coming from institutions like University of Berkeley. US used to be the world leader in nuclear medicine just a couple decades ago.

D. Other Suggested Changes to the T&E Regulations In 2002, the NRC revised its regulatory framework for medical use. The goal was to focus the NRC's regulations on those medical procedures that pose the highest risk to workers, the public, patients, and human research subjects and to structure the regulations to be more risk-informed and more performance-based. The 2002 rule reduced the unnecessary regulatory burden by either reducing or eliminating the prescriptiveness of some regulations. Instead, the rule provided for a performance-based approach that relied on the training and experience of the AUs, authorized nuclear pharmacists, and radiation safety officers. The NRC is requesting comments on whether there are any other changes to the T&E regulations in 10 CFR part 35 that should be considered. Please discuss your suggested changes.

1. Should the NRC regulate the T&E of physicians for medical uses?

The response to this question has to be a clear "No" based on the following reasons:

- NRC has to rely on established boards of medical specialties and their training and experience guidelines to practice the respective recognized medical specialty. More than 80% of the time and energy of NRC's employees is directed to regulating nuclear power plants. The overwhelming majority of the NRC's professional staff are not health professionals but their expertise is oriented toward technical and engineering skills. The staff of NRC has no full-time physician and no infrastructure to create comprehensive training and experience guidelines for physicians let alone the capability to set up mechanisms for testing and assessment of competency. These tasks are responsibilities of medical specialties boiled down in training requirements in ACGME accredited training programs and board certification process. The mere fact that the NRC is currently requesting "public" comments in terms of content and extent of training and experience requirements to practice nuclear medicine is testimony to this lack of expertise in the medical field. As a consequence the training and experience guidelines pertaining to radiation safety put forward by NRC have to be looked at as a small component of the training needed to become a board certified nuclear medicine physician and not be conceived as a replacement of the specialty training in nuclear medicine.
- The Advisory Committee on the Medical Uses of Isotopes (ACMUI) which has an advisory role to NRC and is comprised of nuclear medicine physicians, radiologists, radiation oncologists, radiation physicists among others, has only a limited role in NRC regulatory decisions. As an example, the current 80-hour training requirement defined in 35.392, 35.394, and 35.396 for administration of I-131 and parenterally administered therapeutic radiopharmaceuticals can be used. This amount of training is grossly insufficient to educate physicians in all the aspects of the use of I-131 NaI or parenterally administered therapy radiopharmaceuticals. In 1994, going into a revision of Part 35, the ACMUI voted unanimously to recommend that NRC rescind the 80-hour training program which was started by the Atomic Energy Commission after World War II and which had long outlived its usefulness. The NRC did not follow the ACMUI recommendation. This indicates that not only does NRC lack access to in-house medical expertise but also its rulemaking is non-receptive to external medical advice and recommendations!
- The training and experience requirements as put forth by NRC in 10 CFR Part 35 Subpart E (35.390, 35.392, 35.394, 35.396) as well as Subpart D (35.190, 35.290) set the extent of needed training in nuclear medicine between 60 hours to 700 hours which equates to 1 week to 4 months of training. This is in astonishing contrast to specialty training in nuclear medicine with 3 years or 5500 hours of training in an ACGME approved residency training program as required by the specialty board. These above-mentioned regulations have unequivocally undermined the authority of nuclear medicine as a medical specialty and its licensing specialty board. As a consequence the NRC as an agency tasked with safeguarding patient and public safety has accommodated poor practice of nuclear medicine by endorsing substandard training.

As a notable exception, the training regulations set forth in Subpart F pertaining to manual brachytherapy sources as defined in 35.490 and in Subpart H pertaining to teletherapy and stereotactic radiotherapy units as defined in 35.690 can be reviewed. In this instance the training requirements clearly outline a minimum of 3 years of residency training in a radiation oncology program approved by the Residency Review Committee of the ACGME and passing of an examination, administered by diplomates of the specialty board (Board certification).

The question that poses itself is why there is a discrepancy in how the training and experience requirements are regulated in Subparts F and H as compared to Subpart E? Why are sealed

brachytherapy sources for example treated differently than high dose unsealed sources that can distribute throughout the whole body? Why is a minimum of 3 years residency training in a nuclear medicine program approved by the Residency Review Committee of the ACGME and passing of board examination (board certification) not anchored in 35.390? These inconsistencies in the regulatory body of 10 CFR Part 35 require urgent revision and transfer of responsibility of delineating and ensuring adequate training to medical specialty boards. A minimum of 3 years of residency training in a nuclear medicine program approved by the Residency Review Committee of the ACGME and passing of board examination (board certification) have to be unambiguously incorporated in all aspects of 10 CFR Part 35 Subpart E (35.390, 35.392, 35.394, 35.396) similar to Subparts F and H to guarantee highest standard of patient care!

- In the last 15-20 years there has been a continuous weakening of nuclear medicine as a specialty in US. Signs of this weakening are the fact that vast majority of cutting-edge research in nuclear medicine is coming from outside of US, new development and clinical introduction of targeted radiotracers as well as new therapeutic approaches including theranostics are pioneered in Europe and Australia, there have been fewer hiring opportunities for new nuclear medicine trained graduates in US, and nuclear medicine technologist training programs run by nuclear medicine departments in hospitals are closing. This is despite the fact that nuclear medicine was invented in US and has been very strong previously. Currently nuclear medicine as an independent specialty is flourishing everywhere but in US. As a cardinal reason for this development the regulatory framework in this country has to be held accountable.
- In 1995 the National Academy of Sciences Institute of Medicine (NAS-IOM) charged and paid by NRC itself conducted a thorough and independent external evaluation of NRC's medical use program. In this report significant inefficiencies and undue interference with practice of medicine were demonstrated. The NAS-IOM study detected such insufficiencies that it recommended that Congress remove NRC's statutory authority in all of medicine and medical research (4).

NRC's 2002 revision of its regulatory framework for medical use with the intention of the rule making to reduce or eliminate prescriptiveness has failed to achieve its goals and has not been a success story. This regulatory framework has directly and indirectly pushed back nuclear medicine as a specialty and its research and development behind many other countries in the world, and by that not served patients or the American public at large. It's time that the accurate perceptions of the NAS-IOM were followed.

[4] Gottfried KD, Penn G: Radiation in medicine. A need for regulatory reform. National Academy Press. Washington DC. 1996. ISBN-13: 9780309053860

2. Are there requirements in the NRC's T&E regulatory framework for physicians that are non-safety related?

NRC's T&E regulatory framework focuses only on radiation safety. The way the regulatory T&E requirements are formulated, they suggest that mere compliance with radiation safety guidelines is all

encompassing and provides legitimation of practicing all aspects of nuclear medicine. This is the fundamental problem of this regulatory framework.

3. How can the NRC transform its regulatory approach for T&E while still ensuring that adequate protection is maintained for workers, the public, patients, and human research subjects?

NRC needs to transfer the responsibility of T&E regulation to medical specialties. In case of 10 CFR part 35.900 the respective medical specialty board is the American Board of Nuclear Medicine. NRC does not have access to medical personnel with expertise in all aspects of clinical practice of nuclear medicine. The radiation safety guidelines by NRC are just a small component of safe and competent practice of nuclear medicine. This approach would be also more in line with NRC's Medical Policy Statement, which favors minimum regulatory intrusion into practice of medicine.

As a good example the T&E requirements outlined in 10 CFR part 35.490 and 35.690 pertaining to manual brachytherapy sources and teletherapy or stereotactic radiation therapy units used in radiation oncology can be viewed. Here, the T&E requirements clearly ask for a minimum 3 year-long training in an ACGME accredited radiation oncology training program and board certification. There are no provisions for alternate pathways or limited authorized users in this regulation. The same standard and rigor in regulatory framework needs to be applied to radiopharmaceutical therapies, which require specialized training. A clear and unambiguous requirement of dedicated nuclear medicine training in an ACGME accredited training program and board certification has to become quintessential part of this regulation. Radionuclide therapeutic agents distribute throughout the whole body and can have significant side effects comparable to if not more deleterious than brachytherapy sources or teletherapy treatments.

In an era of sub-specialization in medicine having regulations that encourage practice of a medical specialty by non-subject matter experts irresponsible and puts patients and public at risk.