TRAINING AND EXPERIENCE REQUIREMENTS FOR UNSEALED BYPRODUCT MATERIAL: SUMMARY OF OUTREACH AND COMMENTS

Introduction:

In SECY-18-0084, "Staff Evaluation of Training and Experience Requirements for Administering Different Categories of Radiopharmaceuticals in Response to SRM-M170817" (Agencywide Documents Access and Management System [ADAMS] Accession No. ML18135A276), the U.S. Nuclear Regulatory Commission (NRC) staff concluded that while it may be feasible to establish tailored training and experience (T&E) requirements for categories of radiopharmaceuticals, additional outreach to the medical community was needed. Additional outreach would focus on (1) how to tailor the T&E requirements to establish a limited authorized user (AU) status, (2) the specific T&E requirements that should apply, and (3) how the T&E requirements should be met (e.g., hours of training, demonstration of competency).

After issuance of SECY-18-0084 in late August-2018, a stakeholder outreach plan was developed by staff and approved by Office of Nuclear Material Safety and Safeguards management. The stakeholder outreach plan centered around publication of a *Federal Register* notice (FRN) that asked a series of questions about tailored T&E requirements for administration of unsealed byproduct materials (i.e., radiopharmaceuticals) requiring a written directive, recognition of NRC medical specialty boards, patient access to radiopharmaceuticals, and on other suggested changes to the NRC's T&E requirements. The stakeholder outreach plan initially included a single 90-day public comment period and four public comment meetings.

After evaluation of the comments received during that time, the staff developed draft approaches to address the Commission's directions in the August 2017 staff requirements memorandum (SRM) SRM-M170817.[1] Because some of the draft approaches the staff was considering involved potential regulatory changes not mentioned in the SRM and not envisioned during the initial public comment period, the staff determined that a second public comment period was needed to receive targeted feedback from the medical and regulatory communities on the draft approaches.

This document details the staff's stakeholder outreach efforts related to evaluating T&E for radiopharmaceuticals requiring a written directive, and the key takeaways from stakeholder comments. Written comments were received using the Federal rulemaking Web site, www.Regulations.gov, and oral comments were received during the six transcribed public meetings. The public meeting transcripts, meeting summaries, and all written comment submissions are available on www.Regulations.gov under docket ID number NRC-2018-0230, as well as in the NRC's Agencywide Documents Access and Management System (ADAMS). Enclosures 1 and 2 contain detailed comment summaries and commenter identification tables for the first and second comment periods, respectively.

First Public Comment Period:

On October 29, 2018, the NRC published an initial notice in the *Federal Register* (83 FR 54380) requesting comments on its evaluation of the T&E requirements for all the medical uses authorized under 10 CFR 35.300, "Use of unsealed byproduct material for which a written directive is required." Publication of the FRN opened a three-month public comment period that closed on Tuesday, January 29, 2019. Staff transmitted the FRN to medical and regulatory

[1] SRM-M170817, "Staff Requirements-Affirmation Session, 10:30 A.M., Thursday, August 17, 2017, Commissioners' Conference Room, One White Flint North, Rockville, Maryland (Open to Public Attendance)," dated August 17, 2017 (ADAMS Accession No. ML17229B283).

stakeholders through a number of methods: 1) A November 6, 2018 e-mail using the NRC's Medical List Server (ADAMS Accession No. ML19169A385); 2) A letter dated November 2, 2018 e-mailed or mailed to approximately 100 medical stakeholders including medical specialty boards, medical professional societies, patient advocacy groups, medical colleges offering a nuclear medicine program, and medical industry representatives (ADAMS Accession No. ML18306A926), and 3) A November 1, 2018 State and Tribal Communication (STC) letter to the Agreement States and Vermont (STC-18-065; ADAMS Accession No. ML18297A142). Additional discussion of the staff's coordination with the Agreement States can be found in Enclosure 2 of the staff's rulemaking plan SECY, available at ADAMS Accession No. ML19217A318.

The staff attended two medical conferences to advertise their T&E evaluation effort and encourage conference attendees to submit comments on the FRN: the American Society for Radiation Oncology (ASTRO) 2018 annual meeting and the Society of Nuclear Medicine and Molecular Imaging (SNMMI) 2019 Mid-Winter Meeting.[2] Staff also published a short article in online newsletters of four organizations: ASTRO, the American Association for Physicists in Medicine, the American Brachytherapy Society, and the Conference of Radiation Control Program Directors (ADAMS Accession No. ML19169A383).

During the three-month comment period, the NRC held four transcribed public meetings to accept oral comments on the T&E docket:

Meeting Date	Meeting Type	Meeting Summary	Meeting Transcript
November 14, 2018	Webinar	ML18333A384	ML18330A113
December 11, 2018	In-Person at NRC Headquarters and Webinar	ML19002A614	ML19002A566
January 10, 2019	In-Person at NRC Headquarters and Webinar	ML19019A023	ML19014A270
January 22, 2019	Webinar	ML19058A320	ML19029B476

The NRC received 133 unique written comment submissions during the first public comment period and 28 individuals provided comments during the four transcribed public meetings. Generally, opposition to creating tailored T&E requirements for certain categories of radiopharmaceuticals far out-weighed support. Nuclear medicine physicians, some radiation oncologists, and the related professional societies and medical specialty boards supported maintaining the existing T&E requirements, and these stakeholders strongly opposed any reduction in the T&E requirements that would create new limited authorized user (AU) pathways. Support for creating tailored T&E requirements for specific radiopharmaceuticals or categories of radiopharmaceuticals was heard from the radiopharmaceutical industry, related industry groups, and a small number of non-nuclear medicine and non-radiation oncology physicians that expressed interest in treating their patients with specific radiotherapies but stated that 700 hours of T&E was a barrier. Section A in Enclosure 1 provides detailed summaries of the comments received during the first public comment period and the list of commenters.

[2] The staff's T&E evaluation posters and handouts are available at ADAMS Accession Nos. ML18298A352 and ML18298A354 for the staff's attendance at the ASTRO Annual Meeting and at ML19011A463 and ML19011A464 for the SNMMI Mid-Winter Meeting.

Second Public Comment Period:

On May 2, 2019, the NRC published a second FRN (84 FR 18874) requesting comments on the staff's draft approaches regarding the T&E requirements. Publication of the FRN opened a 30-day public comment period that was originally scheduled to close on Monday, June 3, 2019. Similar to the first FRN effort, staff transmitted the second FRN to medical and regulatory stakeholders through a number of methods: 1) A May 2, 2019 e-mail using the NRC's Medical List Server (ADAMS Accession No. ML19169A386); 2) A letter dated May 2, 2019 e-mailed or mailed to approximately 100 medical stakeholders including medical specialty boards, medical professional societies, patient advocacy groups, medical colleges offering a nuclear medicine program, and medical industry representatives (ADAMS Accession No. ML19123A222), and 3) A May 2, 2019 STC letter to the Agreement States and Vermont (STC-19-023; ADAMS Accession No. ML19120A256). And on May 7, 2019, the NRC staff gave a presentation on the draft approaches for comment at the CRCPD's 2019 National Conference on Radiation.

By letter dated May 13, 2019 (ADAMS Accession No. ML19136A236), the American College of Radiology, ASTRO, and SNMMI jointly requested a 30-day extension to the public comment period. United Pharmacy Partners, Inc. (UPPI) also submitted a request for extension by letter dated May 14, 2019 (ADAMS Accession No. ML19136A238). Additional requests for an extension to the public comment period were also heard during the May 14, 2019, public comment meeting.[3] The NRC granted the request and extended the public comment period until July 3, 2019 (84 FR 23812; May 23, 2019). The NRC notified stakeholders via the Medical List Server on May 23, 2019 (ADAMS Accession No. ML19170A011) and STC letter to the Agreement States and Vermont also on May 23, 2019 (STC-19-029; ADAMS Accession No. ML19137A353).

During the public comment period, the NRC held two transcribed public meetings to accept oral comments on the staff's draft approaches on the T&E docket:

Meeting Date	Meeting Type	Meeting Summary	Meeting Transcript
May 14, 2019	In-Person at NRC Headquarters and Webinar	ML19144A256	ML19141A119
May 23, 2019	Webinar	ML19155A372	ML19149A525

The NRC received 67 unique written comment submissions during the first public comment period and 18 individuals provided oral comments during the two transcribed public meetings. Generally, the nature of comments received during the second public comment period echoed those of the first. The nuclear medicine and radiation oncology communities and their associated medical boards and professional societies opposed any changes to the T&E requirements and strongly supported maintaining the status quo. These groups cited continued protection of public health and safety, and the potential for new AU pathways to dilute or even diminish the field of nuclear medicine. Urologists, some medical oncologists, related healthcare practice administrators, the pharmaceutical industry and related professional societies and industry groups advocated for a more risk-informed approach to T&E for certain patient-ready radiopharmaceuticals that featured lower activity and uncomplicated administration protocols. A handful of commenters plus some Agreement States and the Organization of Agreement States Executive Board supported a more performance-based approach to regulating T&E, relying

[3] See pages 52 and 87 of the public meeting transcript at ADAMS Accession No. ML19141A119.

more on medical specialty boards and nuclear medicine professional societies to develop T&E criteria and credential AUs.

Processing Comments:

At the end of the two public comment periods on the NRC staff's evaluation of training and experience (T&E) requirements for radiopharmaceuticals, individual comments in the meeting transcripts and each of the written comment submissions were identified and grouped according to topic. The grouped comments were then summarized, and those summaries are included Enclosure 1 for the first comment period and Enclosure 2 for the second comment period.

Tables 1 and 2 (in Enclosures 1 and 2, respectively) provide the list of commenters for each comment period, their comment identification (ID) numbers, and the ADAMS accession numbers for their comments. Each comment summary is followed by a list of unique comment identifiers, shown as a set of two or three numbers in parentheses. For example, comment identifier "(4-5-1)" corresponds to "Transcript Number-Commenter ID-Comment Number" for comments spoken at a public meeting, and comment identifier "(8-5)" corresponds to "Commenter ID-Comment Number" for written submissions.

TRAINING AND EXPERIENCE REQUIREMENTS FOR UNSEALED BYPRODUCT MATERIAL:

COMMENT SUMMARIES FROM THE FIRST PUBLIC COMMENT PERIOD

This enclosure summarizes comments received in response to the U.S. Nuclear Regulatory Commission's (NRC's) first *Federal Register* notice (83 FR 54380; October 29, 2018) on the evaluation of training and experience (T&E) for radiopharmaceuticals requiring a written directive. Table 1 on page 14 provides the list of commenters and their comment ID number.

1. General Comments on T&E

Several commenters addressed the general safety history of radiotherapy, saying that the safety record was generally excellent. One commenter suggested that there be an evaluation of all medical events to determine if T&E requirements were adequate. Another commenter said that the NRC's Nuclear Material Events Database (NMED) data was inconsistent due to different levels of input from the Agreement States and noted that the NRC does not make its NMED information available to licensees or authorized users (AUs). The commenter also stated that they had never seen a medical event reported where the T&E of an AU was a major contributing cause. Two commenters suggested reviewing the safety record of physicians who were grandfathered into AU status prior to the 2002 10 CFR Part 35 rulemaking.

One commenter stated that the current T&E requirements were not necessarily germane to today's supplied radiopharmaceutical agents. Another commenter stated that not all radiopharmaceuticals were equally hazardous and that an objective assessment of each agent was needed. A medical device industry representative stated that there were devices that could help identify misadministration of radiopharmaceuticals and reduce their occurrence.

Commenters also raised the issue of needing training requirements related to patient release criteria. One commenter clarified that nuclear medicine technologists administer radiopharmaceuticals under the supervision of an AU, and they also deliver radiation safety education and protection to the patient.

Comments: (1-4-1) (1-5-1) (3-7-1) (4-2-1) (4-3-1) (4-5-1) (8-1) (31-4) (77-1) (83-3) (83-4) (99-1)

2. Comments Supporting Creation of Tailored T&E Requirements/Limited Authorized User Status

Several commenters from the Council on Radionuclides and Radiopharmaceuticals (CORAR), National Rural Health Association, Spectrum Pharmaceuticals, the State of Wisconsin, Nuclear Physics Enterprises and others generally supported the NRC's consideration of alternate T&E pathways and tailoring T&E requirements for physicians wishing to obtain limited AU status for specific categories of radiopharmaceuticals, especially patient-ready unit doses, as it can help to safely expand patient access to medical treatments. A few commenters suggested that the NRC evaluate specific categories of radiopharmaceuticals, specific routes of administration, radiation characteristics, preparation methods, and unique practice setting requirements as part of its decision-making process for potentially revising the T&E requirements.

Many commenters supported the existing tailored T&E pathways for oral Iodine-131 (I-131) and commented that NRC's current requirement mandating 700 hours of T&E was excessive, particularly for radiopharmaceuticals available as patient-ready doses such as Xofigo (Radium-

223). A few commenters proposed that the NRC consider patient-ready doses of Xofigo®, an alpha-emitting therapeutic, as an example of a radiopharmaceutical with less safety concerns than I-131, and a good candidate for limited AU use requiring just 80 hours of T&E, similar to considerations the NRC provided in the past for sodium I-131 use. Commenters suggested that a tailored, reduced training pathway for Xofigo® would be useful for physicians seeking limited authorized use such as hematologists, endocrinologists, oncologists, or urologists and was in keeping with the NRC's regulatory authority.

Several commenters supported the NRC taking a risk-informed approach to unit-dose, patient-ready radiopharmaceuticals, which these commenters stated, "are easy to administer." Several commenters recommended limited AU status be provided for all patient-ready, non-imaging radiotherapies, including alpha-, beta-, or beta-gamma-emitting radiotherapies. CORAR pointed out that the Advisory Committee on the Medical Use of Isotopes (ACMUI) and its Subcommittee on T&E Requirements for All Modalities had acknowledged the past safety record with regard to handling and administration of non-imaging alpha- and beta-emitting radiotherapies, including the limited pathways for I-131.

Several commenters suggested that the NRC should consider specific radiopharmaceuticals rather than specific categories of radiopharmaceuticals and evaluate ease of administration, the "As Low As Reasonably Achievable" (ALARA) pathway, radiation exposure to the public, half-life, route of elimination from the body, waste disposal, potential for internal contamination, and qualifications of the treatment team such as the Radiation Safety Officer and supervising nuclear medical technologist.

Some commenters stated that while creating additional alternate T&E pathways and providing tailored T&E requirements for specific radiopharmaceuticals may increase the complexity of regulatory oversight, by using a risk-informed approach regarding the radiation risks, the benefits of increased patient access justified the increased regulatory complexity.

Comments: (1-2-1) (1-6-1) (1-6-2) (2-3-2) (3-4-1) (3-4-2) (3-5-1) (3-17-1) (4-3-2) (4-6-1) (4-6-3) (4-8-2) (6-1) (7-1) (10-1) (14-1) (14-4) (28-1) (29-1) (31-1) (31-2) (31-3) (32-1) (33-1) (46-1) (47-1) (52-1) (54-1) (67-1) (70-1) (76-1) (76-2) (76-18) (83-1) (83-5) (83-18) (87-1) (92-1) (92-3) (92-4) (92-5) (92-6) (92-7) (92-9) (92-10) (94-1) (112-3)

3. Comments Opposing Tailored T&E/Limited Authorized User Status

Almost 100 respondents including the American Society of Radiation Oncology (ASTRO), American Board of Nuclear Medicine, Nuclear Medicine/Residents Organization, American College of Radiology (ACR), American Association of Physicists in Medicine (AAPM), American Brachytherapy Society, Health Physics Society, Society of Nuclear Medicine and Medical Imaging (SNMMI), American College of Nuclear Medicine (ACNM), Emory University, the University of California in Los Angeles Radiation Safety Committee, Memorial Sloan Kettering Cancer Center, and a variety of individual nuclear medical physicians and educators opposed any reduction in the T&E requirements. The respondents also opposed tailored T&E for specific categories of radiopharmaceuticals and the proposition of providing additional alternate pathways for limited AU status. The commenters communicated concerns regarding the safety of patients, hospital staff, and the public. The commenters also expressed concerns regarding the complexity of radionuclide therapy treatments. Several commenters cited an editorial printed in the *Journal of Nuclear Medicine* (Razmaria et. al) which argued against reducing the T&E requirements needed for administration of radionuclide therapies. The concerns were rooted in the protection of health and safety of patients.

Most respondents believed that the current T&E requirements, pathways, and structure were appropriate, essential, and not burdensome to the medical field. The respondents felt that radiopharmaceutical knowledge was a unique field with little overlap with other areas of medical knowledge. ASTRO stated that it was their belief that the current training requirements were a contributing factor of the excellent safety record of radiopharmaceuticals as well as the rare occurrence of medical events involving radiopharmaceuticals. Other commenters believed that the current T&E requirements (700 hours) were not sufficient to keep up with the ever-evolving field of radionuclide therapies. These commenters felt that the T&E requirements should be revised to require more training, not less. Examples of emerging radionuclide therapies included newly approved radiotherapies such as Lutetium (Lu-177) Dotatate which require a higher level of patient preparation, individualized therapies, and an ability to interpret the follow-up diagnostic scans, as well as monitoring during therapy. One commenter presented several real-life examples of risky decisions made within the current T&E paradigm, illustrating why the NRC should consider expanding the T&E requirements, not decrease them.

Others expressed concern that a regulatory framework focused on reducing T&E requirements was detrimental to the field of nuclear medicine in general, as well as to the quality of patient care. Those concerned indicated that the proposed changes would “dumb down” a “complex, interactive, collaborative” process. The commenters noted that the safe and effective administration of radiopharmaceuticals—in a manner that reduces side effects and minimizes overexposure—requires well-trained experts who are board certified, have clinical “hands-on” continuous experience, scientific understanding of therapeutic radiopharmaceuticals, and prolonged training in nuclear medicine and radiation sciences. These commenters asserted that experts must possess the knowledge base to adequately educate patients on radiation safety precautions. Many commenters added that the safe administration of radionuclides required education and in-depth knowledge in mathematics, radio-physics, material science tumor biology, normal and compromised physiology, radiation physics, radiation biology, chemistry, instrumentation, and radiation protection. One commenter added that appropriate “advanced” infrastructure and setting (i.e. lead shielding, fume hoods, calibration and contamination instruments, and waste storage) were important considerations for the safe administration of radionuclides.

Some commenters also thought that a reduction in T&E requirements was of particular concern, given the emerging new therapeutic procedures that are becoming more complex and individualized (i.e., theranostics). Additional examples of the complexity in the process provided by commenters included accurate screening, determination of radioactivity that can be safely administered, knowledge about waste management, preparation and handling, treatment toxicities, and other special protections. Other commenters expressed concern that changes would turn the NRC regulatory framework “upside down” by undermining the role of the physician involved, particularly from the perspective of overseeing both diagnostic and therapeutic treatment, which would be a disservice to patients. The concerns included the consideration of potential contamination issues, the ability to knowledgeably educate the patient on radiation safety, and accurately and effectively administer the radionuclide such that the therapeutic effect is achieved. Concerns about the ability of a limited AU to knowledgeably handle issues of misuse, unexpected events, patient complications, and diagnosing and managing adverse effects were communicated.

Some commenters believed that the NRC’s concern about patient access as a reason for reducing T&E requirements was misplaced and influenced by radiopharmaceutical companies who were motivated by financial gain and not safety. The commenters noted a lack of evidence that current regulations limited patient access. One commenter suggested that NRC was

motivated by its own financial gain, as NRC would financially benefit from an increase in licensed AUs through licensing fees. A few commenters expressed concern that a reduction in T&E requirements for specific categories of radiopharmaceuticals would result in changes in the direction and cost of medicine. One commenter compared this to what happened when NRC allowed cardiologists to become AUs, the commenter said this change resulted in an overutilization of nuclear cardiac diagnostic scans, presumably because cardiologists could self-refer and were increasingly motivated by financial gain and not patient safety or need.

The ACR communicated the need for a qualified physician to administer radiopharmaceuticals due to co-morbidity concerns and other complexities in treatment. The ACR among others also cautioned that changes in regulations would result in costly regulatory complexities requiring the NRC to make continuous administrative rulemaking changes, including updates to inspection protocols, which could result in decreased flexibility, have disruptive effects on NRC-recognized certification boards, associated training programs, and the Agreement States, and reduce public trust in the NRC's ability to oversee the safe administration of radiopharmaceuticals. Commenters also believed that rulemaking changes would also lead to an increase in annual fees, adversely affecting the licensee community and patient access. The ACR and others also stated that the current AU T&E framework (i.e., the NRC-recognized board certification paradigm) and its inherent flexibility allows the Accreditation Council for Graduate Medical Education (ACGME), boards, and programs to evolve and address new agents and evolving subtopics. The ACR and others expressed concern that a reduction in the T&E requirements could lead to increased medical events and that the NRC should determine if T&E was a causal factor in past medical events.

One commenter expressed concern about the possibility of providing alternate T&E for just Xofigo®. In this scenario, the limited AU would not be knowledgeable about other therapeutic isotopes, their side effects, or issues that arise when therapies are administered in combination, and the limited AU would have "limited value." Some commenters stated that pre-packaged doses carry similar concerns, as they may have multiple emissions (both alpha and beta), which can raise concerns for safety and security. One commenter suggested that the NRC expand treatment availability by investing in and promoting outreach in the nuclear medicine community, rather than focusing on reducing T&E requirements.

A comment was received which suggested that the NRC focus on tightening requirements for a changing field given the new radionuclide therapies and associated complexities for safe handling and administration. Nuclear Medicine Residents Organization (NMRO) noted that the regulatory requirements outlined in 10 CFR 35.490 ("Training for use of manual brachytherapy sources") and 35.690 ("Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units") do not provide for either alternate pathways or limited authorizations, and regulatory standards should be equally stringent in the case of radiopharmaceutical therapies. Two commenters expressed concern about how these changes could increase availability of radioisotope/radiopharmaceuticals such that terrorists could access them.

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4. Comments on Fundamental Training Needs

Some commenters stated that it was not reasonable to have a quantitative requirement for training (700 hours) and that the NRC's T&E requirements should be qualitative. Those that did not support a tailored T&E alternate pathway stated that an AU needed a holistic understanding of radionuclide therapy, competency in radiation safety, radiobiology, dosimetry, instrumentation, radionuclide diagnostics, tumor biology, oncology, and a background in radiation protection, radiation physics, or nuclear medicine. In order to be qualified, the commenters stated that at minimum, one year of formal training in an ACGME-accredited nuclear medicine program which includes extensive lab experience, physics training, and radiation safety knowledge should be required. These new requirements would be in addition to the current requirement of 700 hours and nuclear medicine board certification. The commenters stated that an AU must have familiarity with waste management procedures, clinical experience in dosing and delivery, years of experience in safely administering radiopharmaceuticals, and established competency. The SNMMI, ACNM, and ASTRO opposed reducing T&E requirements and submitted a list of the basic science and clinical training and experience necessary to have as part of the total training for 10 CFR 35.390 (most of which would be obtained within the context of nuclear medicine training programs but would be useful for physicians wishing to provide radionuclide therapy) which included background in radiation physics, mathematics, biochemistry, molecular biology, pharmacology, radiation biology, familiarity with instrumentation used in detection, measurement, and imaging, radionuclide production and quality control, radiopharmacy, radiation protection, and the ability to demonstrate compliance with radiation safety rules, as well as specific clinical requirements for radionuclide therapy covering all aspects of patient oversight.

A few commenters (CORAR, Advanced Accelerator Applications, and Spectrum Pharmaceuticals) stated that they thought the current 700 hours of T&E for alternate pathway for physicians to become an AU was excessive, especially when considering the administration of a unit-dose, patient-ready radiopharmaceutical. The administration of a patient-ready dose would not require the full knowledge currently mandated in the 700-hour requirement but should focus on radiological safety profiles, including non-imaging radiotherapy doses of alpha-, beta- and beta/gamma-emitting isotopes. CORAR recommended a needs-based T&E that would also consider the limited handling required of patient-ready radiopharmaceuticals and existing training and experience a physician may already have in handling toxic non-radioactive

chemical therapies. CORAR attached an outline (originally submitted to the NRC on April 27, 2018) providing specific feedback on fundamental knowledge required by a physician. This feedback assumed that the radiopharmaceuticals were prepared by licensed nuclear pharmacists or under the supervision of an AU and delivered in patient-ready doses. CORAR further commented that the training should be: (1) contingent upon the radiopharmaceutical and its characteristics (for example, low-risk agents such as alpha-emitters should have reduced training requirements), (2) should include training in safety hazard experience, and (3) should include didactic instruction that could be covered in 40–80 hours focused on patient safety, dose calculations, administration and post-administration procedures, and patient monitoring. CORAR further stated that clinical experience should consist of experience with more than three patients if didactic hours were reduced, e.g. three observations and at least five patients treated under supervision. Advanced Accelerator Applications and Spectrum Pharmaceuticals supported CORAR's recommendations.

Another commenter thought training could be accomplished within three months, but it would have to be rigorous, with training in radiobiology and radiation safety. A few commenters thought that in the future, training would have to be expanded from the current extensive background requirements to address new radiopharmaceuticals that would be developed, with one commenter focused on the need to have familiarity with radiopharmaceutical-image-based dosimetry. Another commenter recommended that the NRC work with professional physician organizations to ascertain what the supervised work experience requirement should be and the number of required supervised procedures. Another commenter disagreed with the current 80-hour training program for I-131 and did not support a similar "quickie" course for other radiopharmaceuticals. Another commenter who helped develop Nuclear Education Online (www.nuclearonline.org) thought that their online training could be used as an easy platform for training on the administration of radiotherapies in a way that would impart competencies and balance the protection of the public and the needs of patient access. One commenter stated that they believed that the current requirement of 200 hours of classroom and laboratory hours prescribed under the alternate pathway was reasonable to acquire fundamental knowledge that an AU would need to administer any radiopharmaceutical.

Comments: (1-1-2) (1-1-4) (1-3-1) (2-3-3) (3-1-1) (4-1-2) (12-2) (15-1) (16-2) (17-2) (18-1) (18-2) (22-1) (22-2) (34-1) (35-2) (42-1) (50-1) (51-1) (53-1) (56-1) (62-7) (63-4) (76-12) (76-13) (76-14) (76-16) (77-5) (77-7) (78-7) (79-1) (83-2) (83-6) (83-7) (84-1-19) (92-8) (96-10) (96-11) (98-7) (98-8) (103-2) (105-7) (106-2) (110-1) (112-5) (117-2) (118-1-12) (118-1-13) (126-4) (129-4)

5. Comments on Competency

Several commenters supported proficiency testing by examination administered by a medical specialty board recognized by the NRC. The State of Wisconsin supported a standardized competency assessment but said that periodic assessment was not necessary. One commenter suggested that the cost to initiate and maintain an exam program would be prohibitive. Several commenters mentioned that an exam is only a "snapshot in time" and that it would not be a good indicator of competency. Commenters generally expressed that competency should be a certification that is periodically renewed and that requires a threshold of number of administrations over time to maintain the certification. However, one commenter stated that such an assessment program should not be onerous to the AUs. One commenter stated that the NRC should require specialized training tailored to each therapeutic radiopharmaceutical that the AU is approved to administer. One commenter suggested that the manufacturer could train the AU while other commenters suggested that there was a conflict of

interest in the manufacturer providing certifications and attestations. The State of Wisconsin said that manufacturers were not in a position to adequately attest to all of the qualifications of an AU. Many commenters stated that manufacturers should not be allowed to provide preceptor attestation. CORAR supported both an exam and an in-hospital laboratory training program supervised by an AU or authorized nuclear pharmacist (ANP). Several commenters suggested that training programs, including their proficiency testing, and not individuals, should be certified by the NRC.

Comments: (4-1-4) (4-1-5) (4-10-2) (9-1) (9-2) (23-2) (27-1) (39-2) (48-8) (48-9) (48-10) (56-5) (59-4) (62-8) (76-7) (76-17) (77-8) (81-1-18) (81-2-1) (81-2-2) (81-2-3) (81-2-4) (84-1-18) (84-2-1) (84-2-2) (84-2-3) (84-2-4) (91-5) (91-6) (91-8) (96-12) (99-2) (103-1) (112-6) (112-7) (112-8) (112-9) (112-10) (116-5) (118-1-14) (118-1-16) (118-1-17) (118-1-18) (118-1-19) (126-6) (126-7) (126-8)

6. Comments on Medical Specialty Boards

Almost all commenters responded that no other certification boards should be considered, noting that the current boards were satisfactory, ensured that all AUs were adequately trained, and protected patient safety. Commenters found that aside from the boards already recognized by the NRC for 10 CFR Part 35, Subpart E [American Board of Nuclear Medicine (ABNM), American Board of Radiology (ABR), American Osteopathic Board of Radiology, and the Certification Board of Nuclear Endocrinology for I-131], no others had sufficient expertise within the specialty to provide T&E recognition for medical uses under Subpart E. A few commenters offered additional input on what they viewed as the most appropriate medical specialty boards to assess skill. One commenter concluded that ACGME provided the best ability to train and assess skills, while a few others noted that only American Board of Medical Specialties medical specialty boards should be recognized, such as the ABNM and the ABR. Some commenters suggested the inclusion of specialty board requirements for oncology and the ABR subspecialty in nuclear radiology to be recognized.

Most respondents commented that the current NRC medical specialty board recognition criteria were sufficient, as evidenced by the long record of patient and public safety. A few commenters noted that as more advanced radiotherapies were developed, more stringent criteria may be needed to cover new therapies or specialized training. One commenter noted that the criteria should require a medical specialty board to demonstrate the ability to develop training guidelines, certify AUs, and facilitate continued competency. Of those who found the criteria adequate, a few commenters noted however that it was not adequate for radiologists who had only minimal training in nuclear medicine. Alternatively, one commenter thought that the current criteria may be more restrictive than necessary and offered that the NRC could consider “non-binary” recognition of medical specialty boards where the board could be evaluated on only the T&E requirements that it satisfied. Of those commenters who offered suggestions for additional criteria, one noted that the ABR completion letter with a statement of AU eligibility should be recognized by the NRC, while another maintained that only training accredited by ACGME and the successful passing of a board certification exam through the ABNM provided enough assurance of adequate training for an AU.

One commenter expressed concern that the NRC's procedures were focused only on the radiation safety aspect of patient care, which overlooks comprehensive patient care. This commenter noted that basing recognition of specialty boards solely on compliance with radiation safety processes does not necessarily safeguard adequate qualification. Furthermore, this commenter found that the NRC does not have actionable mechanisms in place to control and

examine recognized specialties and whether minimum requirements were being met. Additional commenters expressed similar concerns with and noted that the NRC must do a better job of monitoring those not in compliance. Commenters observed that many practitioners may not necessarily be receiving the T&E they claim to receive. One commenter noted that inspectors may not directly ascertain whether the 200 hours of lecture and laboratory experience are met with the 500 hours of supervised experience, instead relying on assurances from residency program directors or preceptor letters. This commenter emphasized the importance of independent verification by the NRC.

Comments: (1-9-1) (12-3) (13-1) (13-2) (23-3) (23-4) (48-11) (48-12) (56-3) (60-6) (60-7) (63-6) (63-7) (66-6) (66-7) (73-6) (73-7) (76-5) (77-9) (77-10) (78-8) (78-9) (78-10) (80-6) (80-7) (81-2-5) (81-2-6) (83-8) (83-9) (84-2-5) (84-2-6) (91-9) (98-9) (98-10) (103-5) (103-6) (105-4) (108-2) (112-11) (112-12) (116-6) (116-7) (117-6) (117-7) (118-1-20) (118-2-2) (126-9)

7. Comments Suggesting AU Shortage and a Patient Access Issue

Some commenters observed that an AU shortage in rural areas existed. Commenters cited the general shortage of physicians in rural areas and noted that specialized medical services were in even shorter supply. Still others noted that there was a shortage in therapy, but not in diagnostics. Commenters expressed concern that additional T&E requirements would further limit access and that the development of new therapies would further "tax the system." A few commenters cited the example of issues with patient access to Xofigo® as illustrative of their concerns. Some commenters stated that there were additional barriers to access in rural areas, including: insurance coverage or network issues, travel time, cost, compensation for nuclear medicine physicians, the time required to prepare, administer, and follow through with patient care, lack of adequate facilities to support radiopharmaceutical work flow, and lack of availability of patient-ready radiopharmaceuticals (i.e., supply-demand issues). One commenter noted that the scarcity of new treatments in nuclear medicine that physicians are uniquely qualified to perform has contributed to the perceived shortage, noting that the lack of new procedures creates difficulty in recruiting new physicians.

Concerns about patient access were voiced mainly by pharmaceutical industry groups, but some patient and citizen advocacy groups also noted a shortage, and a couple of commenters also expressed concern based on their own personal experiences. Numerous commenters requested that the NRC make efforts to find AU geographic distribution data, noting that it was unfair to place the burden of finding that information on respondents and that it should instead be an NRC priority.

Comments: (2-1-3) (3-4-3) (3-9-1) (4-6-2) (4-8-1) (14-3) (14-5) (14-6) (14-8) (24-1) (29-2) (57-4) (58-3) (70-2) (74-3) (76-4) (76-8) (83-11) (83-12) (83-13) (92-2) (100-13) (100-14) (129-3)

8. Comments Suggesting No Evidence of AU Shortage or Patient Access Issue

Most respondents noted that there was no credible evidence of an AU shortage, nor any evidence that NRC regulations limited patient access or impacted geographic disparity. Commenters noted that the current training pathways were more than enough to provide an adequate number of trained AUs, citing ABNM numbers of nuclear medicine diplomates as remaining constant or growing. Such comments were voiced largely by national medical board organizations, hospitals, and physicians. Furthermore, commenters maintained that the perceived shortage was not based on data (or was based on inaccurate data presented at the SNMMI Annual Meeting) and instead based on anecdotal industry stakeholder

concerns. A couple commenters cited the example of Lutathera's quick implementation and distribution as an example of the adequate existing network of AUs and its ability to quickly respond to new therapies.

Other respondents noted that the availability of AUs was the same as other treatments where patients travel to regional centers for procedures. These commenters noted that while disparities may exist in treatment due to geographic, economic, or social factors, these factors affect general access to medical care and do not specifically limit access to procedures involving radiopharmaceuticals. One commenter observed that since almost every radiopharmaceutical therapy requires imaging studies, patients would likely have to travel to imaging centers closer to metropolitan areas anyway, so increasing the number of AUs in rural regions would help patient access if done in isolation. Commenters provided examples of other issues more likely to impact access or interest in new therapies, including the lack of insurance coverage, economic viability of new therapies, availability of infusion spaces and technical nursing support, complexity of the therapy, or availability of other treatments to fill the clinical need. Commenters felt that in cases where patient access was an issue, it was not a result of access to trained AUs or NRC T&E regulations.

Some commenters stated that they would prefer to travel for treatment if they knew it meant they were being treated by an adequately trained team. Numerous respondents observed that even if there was evidence supporting a shortage, compromising patient care, safety, and public safety by reducing training was not the answer. In that case, traveling to a medical center to ensure that complex treatments are performed by trained physicians (and support staff) was preferred to revising the NRC T&E regulations. Multiple commenters stated that if a shortage was found to exist, the responsible approach would be consultation with the national medical board organizations to determine responsive actions. Additionally, one commenter noted that if more licensed facilities with more AUs were created, this could potentially tax the NRC, the National Health Physics Program, and the Agreement State regulatory agencies.

Comments: (3-10-1) (4-1-3) (4-4-2) (4-7-2) (23-5) (34-3) (57-2) (57-3) (59-1) (60-8) (60-9) (60-10) (62-4) (62-9) (63-8) (63-9) (63-10) (64-3) (65-2) (65-3) (66-8) (66-9) (66-10) (69-2) (73-8) (73-9) (73-10) (74-1) (77-2) (77-11) (77-13) (77-14) (77-16) (78-11) (78-12) (78-13) (79-2) (80-8) (80-9) (80-10) (81-1-12) (81-1-19) (81-1-20) (81-2-7) (81-2-8) (81-2-9) (81-2-10) (81-2-11) (82-2) (83-10) (84-1-5) (85-2) (85-3) (86-5) (91-11) (91-13) (91-15) (93-2) (96-3) (96-4) (96-7) (96-8) (98-11) (98-12) (98-13) (103-7) (105-5) (109-3) (110-2) (112-13) (112-14) (113-4) (116-8) (116-10) (117-1) (117-8) (117-9) (117-10) (118-1-3) (118-2-5) (122-5) (122-8) (122-12) (123-2) (124-11) (125-2) (126-10) (126-11) (126-12) (129-2) (129-7) (131-2)

9. Comments on Patient Access

Numerous commenters observed that they could not adequately answer the NRC's questions regarding patient access without additional data. Commenters responded that there was an overwhelming need to find trustworthy AU data because no reliable, actionable, NRC-curated data exists on the total number of AUs in the U.S. Respondents emphasized that no changes in the T&E requirements should be made until comprehensive AU data is made available and that data must include information from all NRC and Agreement State licensees. Multiple commenters felt that the NRC was the only reliable entity that could provide such data. In addition, a few commenters expressed concern at what they perceived was the use of anecdotal evidence by industry to claim that there is a shortage of AUs.

Multiple commenters offered the suggestions that information gathered by the NRC should include geographic or zip code data (such as the number and location of AUs), the type of training the AU received, the distribution of AUs by category (include therapy uses in 10 CFR 35.200, 35.400, and 35.600), the availability of current and future AUs to administer current or future agents, and data should cover an extended period of time (ideally this would be a multi-year data collection effort). Multiple commenters noted that the NRC could work with existing boards and professional societies, including SNMMI and ACR, to gather data and determine if there is a shortage of AUs and what the proper response should be. One commenter stated that the NRC could look at comments received for the revisions to 10 CFR Part 35 (67 FR 20250, April 24, 2002).

Comments: (1-7-1) (2-1-4) (48-13) (77-12) (84-1-6) (84-2-7) (84-2-8) (91-12) (91-14) (108-3) (112-14) (113-5) (116-9) (118-1-10) (118-2-3) (118-2-4)

10. Comments Addressing if Current T&E Requirements Limit Research and Development in Nuclear Medicine

The majority of respondents commented that the NRC regulations on T&E requirements did not unnecessarily limit research and development in nuclear medicine, with a handful of commenters noting a resurgence in nuclear medicine research and funding in recent years. One commenter maintained that current T&E requirements stimulated research by outlining training requirements for research projects, creating availability of a greater volume of clinical material, and facilitating access to clinical research personnel. Yet another commenter suggested that a more comprehensive, multi-year training requirement could contribute to research and development, since limited training could discourage hospitals and physician groups from hiring nuclear medicine specialists (instead relying on existing radiologists and radiation oncologists to run nuclear medicine services).

Conversely, a couple industry commenters noted that current NRC requirements discouraged clinicians from learning about non-imaging radiotherapies, thereby limiting clinical participation in research and development. A few commenters found that the U.S. lagged in research and development in comparison with other countries. Citing this lag, another commenter also observed that radiologists in the U.S. had to cover multiple modalities, which limited their time to take on research, and that there was not an emphasis in the U.S. to train and encourage radiologists to explore various avenues for doses, continued learning, and taking on new projects. Additionally, one commenter found that the U.S. lagged significantly behind other countries in delineating T&E requirements and suggested that the U.S. examine how Europe handled such requirements. This commenter also offered that the U.S. must increase its training and clinical expertise, commenting that by focusing too much on radiation safety, the U.S. had overlooked the clinical expertise of using radiopharmaceuticals for therapeutic purposes. However, a different commenter stated there was no clear evidence that NRC regulations contributed to any potential limitations in research.

Comments: (1-8-1) (1-8-3) (2-6-2) (60-11) (63-11) (66-11) (73-11) (76-9) (77-16) (78-14) (80-11) (81-2-12) (83-14) (84-2-10) (91-16) (98-14) (103-8) (112-15) (116-11) (117-11) (118-2-6)

11. General Comments on the NRC's Medical Regulations

Commenters offered input regarding whether the NRC should regulate the T&E requirements of physicians for medical uses, with nearly all commenters supporting periodic review of regulations by the NRC. Most commenters supported the NRC’s regulation of T&E

requirements of physicians, citing the NRC's ability to serve as a system of "checks and balances" to regulate patient safety. A few commenters cautioned that periodic review should focus on issues of compliance and issues identified by medical use licensees. One commenter noted that physicians were already closely monitored by professional affiliations.

Respondents elaborated on how the NRC could best regulate requirements. A few commenters noted that the NRC's role was to establish parameters while simultaneously relying on the knowledge and skills obtained from specialty board certified residency training programs. These commenters cautioned against highly prescriptive T&E requirements, offering the example of training regulations set forth in 10 CFR 35.490 and 35.690. One commenter proposed that the NRC limit its role to ensuring, once a prescription for a radiopharmaceutical is written, that the licensee has a strong program in place to ensure the written directive is carried out accordingly. One respondent opposed the NRC regulating T&E requirements in favor of the NRC relying on established medical specialty boards certifying physicians as AUs, noting that the NRC staff were not health professionals and that the tasks being regulated were the responsibility of medical specialty boards. This commenter supported the NRC following recommendations from organizations such as the Advisory Committee on Medical Use of Isotopes and the National Academy of Sciences Institute of Medicine.

Regarding non-safety-related T&E requirements, nearly all commenters stated that there were no additional requirements to consider and that the current requirements were adequate. One respondent expressed that additional regulations were unnecessary and possibly contradicted Occupational Safety and Health Administration requirements. However, a couple commenters explained that the current framework focused entirely on radiation safety, which they felt implied that radiation safety was all-encompassing, when in fact elements such as experience in patient care should be considered. Still another respondent observed that the requirements for 700 hours of radiation safety T&E were unlikely to be devoted solely to radiation safely and likely included clinical training.

Respondents also provided feedback on how the NRC could transform its regulatory approach for T&E while ensuring protection of patients, workers, and the public. Commenters proposed that the NRC should continue to monitor the nuclear medicine field as it evolves. In particular, commenters stated that the NRC should monitor theranostics as image-guided individual dosimetry increases, use evidence-based medicine, consult with existing AUs and medical organizations to consider developing individualized T&E, make NMED medical event reports publicly available to educate medical licensees, coordinate with groups who provide input into guidance documents for ACGME-approved residency programs, and consider establishing T&E requirements for technologists administering radiopharmaceuticals.

Multiple commenters supported adding requirements for quantitative and image-guided individual dosimetry as it becomes common practice. Commenters noted that any change in approach should involve the recognized medical specialty boards. One commenter offered that the NRC should transfer responsibility of T&E regulation to medical specialty boards, while another felt that the NRC should transform its approach by following the NRC's Medical Policy Statement. This commenter offered the example of requirements in 10 CFR 35.490 and 35.690 which require a minimum of three years of residency training.

Comments: (23-6) (60-12) (60-13) (60-14) (63-12) (63-13) (63-14) (63-15) (63-16) (63-17) (63-18) (66-12) (66-13) (66-14) (73-12) (73-13) (73-14) (76-10) (77-15) (77-17) (77-18) (78-15) (78-16) (78-17) (80-12) (80-13) (80-14) (81-1-1) (81-2-14) (83-15) (83-16) (84-2-11) (84-2-12) (84-2-13) (91-10) (98-15) (98-16) (98-17) (105-6) (108-5) (112-15) (113-6) (113-7) (113-8)

(116-12) (116-13) (116-14) (117-12) (117-13) (117-14) (118-1-1) (118-2-8) (118-2-9) (118-2-10) (118-2-11) (126-13)

12. Comments on Nuclear Medicine Advanced Associates (NMAAs)

Multiple commenters expressed support for maintaining current T&E requirements while adding NMAAs as AUs. Commenters explained that NMAAs are mid-level providers who are board certified, complete the same training and education as AUs, complete a two-year internship under the supervision of a physician, and who practice under physician supervision. Therefore, they stated that NMAAs already meet the current T&E criteria required for AUs by the NRC. One respondent suggested that an NMAA should only gain AU status if they were supervised by an AU who was trained in therapeutic nuclear medicine (versus general training in clinical or imaging). Those who supported NMAAs gaining AU status responded that this could improve patient access to healthcare while increasing efficiency, throughput, and patient safety. A few commenters stated that while they did not support limited AU status for ANPs, they did support NMAAs being recognized as AUs. One commenter offered that a clinic that was interested in administering radiopharmaceuticals could develop procedures and team up with an AU and file an application with their regulator.

However, numerous commenters opposed the idea of NMAAs gaining AU status, stating that it undermined the role of the physician and could compromise patient care. Some commenters who opposed NMAAs as AUs were unclear as to whether there would be a supervising physician on-site. Other commenters noted that if NMAAs were practicing under the supervision of a physician, the physician should perform the procedure, obviating the need for the NMAA. Furthermore, one respondent pointed out that the written directive requirements for administration of unsealed byproduct materials were beyond the abilities of an NMAA. Commenters also expressed general concern with NMAAs, citing the possibility of errors, unforeseen medical issues that may arise during an administration (heart attack, etc.), confusion over the ultimate responsibility if an issue were to arise, and concerns that dose administration could not be separated from other aspects of patient care.

Comments: (3-2-1) (3-3-1) (3-8-1) (3-12-1) (3-13-1) (3-14-1) (3-16-1) (3-16-2) (3-16-3) (4-9-1) (4-12-1) (19-1) (20-1) (21-1) (26-1) (37-1) (48-5) (59-6) (72-3) (81-2-13) (83-17) (91-3) (101-1) (101-2) (101-3) (101-4) (115-2) (115-4) (118-2-1) (122-9)

13. Comments on Authorized Nuclear Pharmacists (ANPs)

Multiple respondents provided comments about teaming ANPs with limited-trained AU physicians. A small number of these commenters supported the idea of an alternate pathway that provided a mechanism to partner ANPs with limited-trained AU physicians. They noted that the number of required training hours to become an ANP is the same as for physicians to become an AU. Those in support commented that providing such an option would expand service areas, particularly for those in rural locations. Furthermore, commenters stated that the need for new therapies would continue to grow, underscoring the demand for such a program. It was noted that the precedent already exists outside of nuclear medicine for pharmacists to have provider status. However, others in opposition to this idea commented that an ANP is not in the practice of prescribing radiopharmaceuticals.

Commenters provided options for how such a partnership could work, such as teaming an onsite ANP with a specialist physician, oncologist, hematologist, or urologist, allowing an ANP on-site to serve in the nuclear safety role, creating patient-specific doses that would be

delivered to a clinic, scheduling therapies on certain days of the week, and/or bringing a health physicist onsite to help monitor the patient. Commenters in support of this option stated that an ANP has received 700 hours of training in their specialty, and in these scenarios, the limited-trained AU would provide direct supervision and handling expertise before, during, and after administration. Other commenters encouraged the NRC to consider expanding successful dual AU programs, while others felt confident that the NRC could establish effective training criteria that would allow such a team approach.

Multiple commenters expressed concern with the idea of teaming ANPs with limited AUs, noting that the person signing the written directive must be the AU, that teaming would not work in situations where an issue arose, and that an AU could not be geographically separated from their patient if a problem occurred. Commenters voiced concerns with teaming ANPs with limited AUs, citing concern over the impacts to patient safety and the lack of training that may be required of the AU. Others described how AU physicians do not operate independently and that a limited AU physician without the appropriate support staff may lead to dosing errors or lack of attention to radiation regulatory requirements. One commenter noted that ANPs do not necessarily possess an understanding of bio-distribution and altered bio-distribution secondary to pathology.

Comments: (2-1-1) (2-1-2) (2-2-1) (2-3-1) (2-4-1) (3-5-2) (3-5-3) (3-11-1) (4-4-1) (4-11-1) (4-13-1) (4-14-1) (11-1) (14-2) (14-7) (24-2) (59-2) (76-3) (76-6) (76-11) (76-15) (100-3) (100-4) (100-5) (100-6) (100-7) (100-8) (100-9) (100-10) (100-11) (100-12) (100-15) (100-16) (100-17) (100-18) (100-19) (100-20) (106-3)

14. Comments on Public Participation

One commenter expressed general appreciation for the public participation process. Several commenters recommended additional ways to connect to knowledgeable individuals for input, and one commenter recommended a list of specific individuals to whom the NRC should reach out.

Comments: (64-5) (64-7) (89-3) (100-1) (100-2)

15. Comments on Issues Out of Scope

The NRC received one comment encouraging the use of appropriate nomenclature for radiopharmaceuticals. One respondent submitted comments concerning the demand for targeted radionuclide therapies in Sub-Saharan Africa and their interest in the NRC's evaluation. Another comment was received discussing whether radiologists in charge of nuclear medicine should supervise wipe tests for sealed sources. One commenter submitted comments explaining that the NRC should be viewed as facilitators, in addition to regulators, and that radiation oncology's growth as a specialty was a result of its practice model and independence.

Comments: (2-5-1) (5-1) (104-1) (116-1)

Table 1. Individuals Providing Comments During the First Comment Period (83 FR 54380)

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Aaron, Vasantha		reg.gov (ML19029B442)	0080
Allen-Auerbach, Martin	UCLA Radiation Safety Committee	reg.gov (ML19030B574)	0090
Allio, Theresa	Advanced Accelerator Applications, USA	reg.gov (ML19029B447)	0083
Anonymous, Anonymous		Meeting Transcript (1)	0001-9
Anonymous, Anonymous		reg.gov (ML19003A241)	0016
Anonymous, Anonymous		reg.gov (ML19011A050)	0025
Anonymous, Anonymous		reg.gov (ML19016A083)	0034
Anonymous, Anonymous		reg.gov (ML19016A085)	0035
Anonymous, Anonymous		reg.gov (ML19023A394)	0039
Anonymous, Anonymous		reg.gov (ML19025A131)	0043
Anonymous, Anonymous		reg.gov (ML19025A132)	0044
Anonymous, Anonymous		reg.gov (ML19029B389)	0061
Anonymous, Anonymous		reg.gov (ML19029B412)	0066
Anonymous, Anonymous		reg.gov (ML19029B419)	0069

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Anonymous, Anonymous		reg.gov (ML19029B423)	0071
Anonymous, Anonymous		reg.gov (ML19029B438)	0079
Anonymous, Anonymous		reg.gov (ML19031B147)	0114
Anonymous, Anonymous		reg.gov (ML19031B155)	0115
Anonymous, Anonymous		reg.gov (ML19031B217)	0120
Anonymous, Anonymous		reg.gov (ML19031B219)	0121
Anonymous, Anonymous		reg.gov (ML19031B223)	0123
Anonymous, Anonymous		reg.gov (ML19031B228)	0125
Anonymous, Anonymous		reg.gov (ML19031B249)	0128
Anonymous, Anonymous		reg.gov (ML19031B257)	0129
Anonymous, Anonymous		reg.gov (ML19031C62)	0117
Anonymous, Anonymous		reg.gov (ML19046A008)	0048
Anonymous, Anonymous	Kettering Health Network	reg.gov (ML19030B659)	0095
Anonymous, Anonymous	Memorial Sloan Kettering Cancer Center	reg.gov (ML19030B685)	0097
Arey, Steve		reg.gov (ML18310A183)	0005
Ashlock, Robert		reg.gov (ML19030B648)	0089

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Bailen, James		reg.gov (ML19025A136)	0047
Banks, Kevin		reg.gov (ML19030B736)	0103
Batra, Jaspreet		reg.gov (ML19029B432)	0075
Baxter, Michael	American Pharmacists Association	reg.gov (ML19030B734)	0106
Beckly, Karen	Conference of Radiation Control Program Directors	reg.gov (ML19031C710)	0083
Burpee, Dave		Meeting Transcript (4)	0004-6
Burpee, Dave	Bayer Pharmaceuticals	Meeting Transcript (3)	0003-17
Burpee, Dave	Bayer Pharmaceuticals	Meeting Transcript (3)	0003-4
Byrd, Bill		reg.gov (ML19010A322)	0021
Campbell, Janice	Beaumont Hospital	reg.gov (ML19030B733)	0105
Cook, Barbara		reg.gov (ML19023A393)	0038
Courtines, Michel		reg.gov (ML19030B577)	0080
Crowley, Dave		Meeting Transcript (1)	0001-4
Crowley, James		reg.gov (ML19025A125)	0040
Czernin, Johannes		Meeting Transcript (3)	0003-10
Czernin, Johannes		Meeting Transcript (3)	0003-15

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Czernin, Johannes		Meeting Transcript (3)	0003-18
Czernin, Johannes		Meeting Transcript (3)	0003-6
Czernin, Johannes		reg.gov (ML19010A316)	0018
de la Guardia, Miguel		Meeting Transcript (4)	0004-11
de la Guardia, Miguel		Meeting Transcript (4)	0004-8
Degenhardt, Scott		Meeting Transcript (3)	0003-12
Degenhardt, Scott		Meeting Transcript (3)	0003-2
Degenhardt, Scott		Meeting Transcript (4)	0004-12
Degenhardt, Scott		reg.gov (ML19010A318)	0019
Dickey, Olivia		reg.gov (ML19018A194)	0024
DiPietro, Allegra		reg.gov (ML18352A692)	0011
Djang, David		reg.gov (ML19029B456)	0088
Egle, Lisa		reg.gov (ML19029B418)	0068
Fabrizio, Michael		reg.gov (ML19029B416)	0067
Francisco, John		reg.gov (ML19025A135)	0046
Froelich, Jerry	University of Minnesota	reg.gov (ML19031B225)	0124

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Galt, James	Emory University School of Medicine	reg.gov (ML19030B738)	0108
Gardner, Linda		reg.gov (ML19030B730)	0102
Gartmann, Jeannine		reg.gov (ML19031B201)	0119
Gayed, Isis		reg.gov (ML19025A140)	0051
Gerard, Stephen		reg.gov (ML19031B264)	0130
Gervasi, Lawrence		reg.gov (ML19029B455)	0087
Ghesani, Munir		Meeting Transcript (1)	0001-3
Gleason, Shaemus	Bayer Pharmaceuticals	Meeting Transcript (3)	0003-9
Graham, Michael		reg.gov (ML19030B694)	0098
Greenspan, Ben		Meeting Transcript (4)	0004-1
Greenspan, Ben		Meeting Transcript (4)	0004-7
Greenspan, Bennett		reg.gov (ML19029B375)	0056
Guastella, Michael	Council on Radionuclides and Radiopharmaceuticals	Meeting Transcript (3)	0003-1
Guastella, Michael	Council on Radionuclides and Radiopharmaceuticals	Meeting Transcript (3)	0003-7
Guastella, Michael	Council on Radionuclides and Radiopharmaceuticals	reg.gov (ML19025A141)	0076
Horman, Lisa		reg.gov (ML19030B631)	0093

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Jadvar, Hossein		reg.gov (ML19025A138)	0049
Jafari, Lida		reg.gov (ML19029B394)	0063
Jafari, Mahnoosh		reg.gov (ML19031B237)	0127
Jayaram, Nagesh		reg.gov (ML19025A142)	0052
John, J		reg.gov (ML19029B373)	0055
Johnson, Darrin		reg.gov (ML19029B359)	0054
Johnson, Darrin		reg.gov (ML19029B378)	0054
Kahn, Ahsan		reg.gov (ML19030B748)	0111
Kahn, Mubeen		reg.gov (ML19008A027)	0017
Klitzke, Alan		reg.gov (ML19030B676)	0096
Kozlov, Andrew		reg.gov (ML19031B210)	0117
Krishnananthan, Ruben		reg.gov (ML19025A145)	0053
Kubler, Caitlin	Society of Nuclear Medicine and Molecular Imaging	reg.gov (ML19029B435)	0077
LaRue, Vicki		Meeting Transcript (3)	0003-13
LaRue, Vicki		Meeting Transcript (3)	0003-8
LaRue, Vicki		reg.gov (ML19010A320)	0020

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
LaRue, Vicki		reg.gov (ML19030B729)	0101
Lattanze, Ron	Lucerno Dynamics	reg.gov (ML19025A137)	0099
Lattanze, Ron	Lucerno Dynamics	reg.gov (ML19030B706)	0099
Lebel, Francois	Spectrum Pharmaceuticals, Inc	reg.gov (ML19031B185)	0092
Leito, Ralph		reg.gov (ML19031B226)	0118
Lieto, Ralph		Meeting Transcript (1)	0001-5
Lieto, Ralph		Meeting Transcript (1)	0001-7
Lieto, Ralph		Meeting Transcript (4)	0004-10
Lieto, Ralph		Meeting Transcript (4)	0004-14
Lieto, Ralph		Meeting Transcript (2)	0004-2
Liu, Frank		reg.gov (ML19016A087)	0036
Mahgerefteh, Samuel		reg.gov (ML19029B437)	0078
Mailman, Josh	NorCal CarciNET Community	reg.gov (ML19029B379)	0058
Mankoff, David		reg.gov (ML19025A130)	0042
Manzone, Timothy		reg.gov (ML19032A015)	0057
Marcus, Carol S.	University of California, Los Angeles	reg.gov (ML18344A607)	0013

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Marcus, Carol S.	University of California, Los Angeles	reg.gov (ML18355A535)	0012
Marcus, Carol S.	University of California, Los Angeles	reg.gov (ML18355A537)	0013
Marcus, Carol S.	University of California, Los Angeles	reg.gov (ML19011A054)	0012
Mehr, Samuel		reg.gov (ML19029B424)	0072
Meltzer, Carolyn	Emory Radiology	reg.gov (ML19029B450)	0085
Mirhadi, Amin	American Society of Radiation Oncology	Meeting Transcript (1)	0001-1
Morgan, Alan	National Rural Healthcare Association (NRHA)	reg.gov (ML18362A094)	0014
Morgan, Rustain		reg.gov (ML19029B427)	0073
Nelson, Kasey		reg.gov (ML19023A351)	0037
Norenberg, Jeff		Meeting Transcript (2)	0002-4
Norenberg, Jeff	National Association of Nuclear Pharmacies	Meeting Transcript (2)	0002-3
Norenberg, Jeff	National Association of Nuclear Pharmacies	Meeting Transcript (2)	0002-5
Norton, Blaine		reg.gov (ML19030B573)	0059
Opila, Jennifer	Organization of Agreement States	reg.gov (ML19030B764)	0113
Orunmuyi, Akintunde		reg.gov (ML19030B732)	0104
Pachynski, Russell		reg.gov (ML19016A076)	0028

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Palmer, Edwin	Massachusetts General Hospital	reg.gov (ML19030B740)	0109
Panichi, Michele		Meeting Transcript (4)	0004-4
Panichi, Michele		Meeting Transcript (4)	0004-9
Peters, Michael	American College of Radiology	reg.gov (ML19029B444)	0081
Peters, Tricia		reg.gov (ML19031B229)	0126
Peterson, Charles		reg.gov (ML19029B397)	0064
Phillips, William		reg.gov (ML19030B731)	0103
Puritty, Twila		reg.gov (ML19016A078)	0029
Quon, Andrew		reg.gov (ML19010A323)	0022
Rajendran, J		reg.gov (ML19031B163)	0116
Razmaria, Aria		Meeting Transcript (1)	0001-8
Razmaria, Aria		Meeting Transcript (2)	0002-6
Razmaria, Aria		Meeting Transcript (3)	0003-16
Razmaria, Aria		reg.gov (ML19030B667)	0063
Reimer, Sarah		reg.gov (ML19029B445)	0082
Reindl, David	Wisconsin Department of Health Services	reg.gov (ML19030B750)	0112

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Rubin, Joseph	United Pharmacy Partners	Meeting Transcript (2)	0002-1
Schuster, David		reg.gov (ML19029B398)	0065
Schuster, David	Emory Radiology	reg.gov (ML19029B450)	0085
Segall, George		reg.gov (ML19029B392)	0062
Semon, Rachel		Meeting Transcript (4)	0004-13
Sheikh, Arif		reg.gov (ML19030B575)	0122
Sheikh, Arif		reg.gov (ML19031B222)	0122
Sieber, Paul		reg.gov (ML19016A081)	0032
Siegel, Jeffry		Meeting Transcript (1)	0001-2
Siegel, Jeffry		Meeting Transcript (1)	0001-6
Siegel, Jeffry		Meeting Transcript (4)	0004-3
Siegel, Jeffry		Meeting Transcript (4)	0004-5
Siegel, Jeffry A.	Nuclear Physics Enterprises	reg.gov (ML19016A080)	0031
Siegel, Jeffry A.	Nuclear Physics Enterprises	reg.gov (ML19016A082)	0033
Singh, Amolak		reg.gov (ML19003A238)	0015
Siska, Richard		Meeting Transcript (3)	0003-14

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Siska, Richard		Meeting Transcript (3)	0003-3
Siska, Richard		reg.gov (ML19011A052)	0026
Slabach, Brock	National Rural Health Association (NRHA)	reg.gov (ML18354A678)	0014
Soman, Prem	American Society of Nuclear Cardiology	reg.gov (ML19011A053)	0027
Steinbock, Greg		reg.gov (ML19030B652)	0094
Sullivan, Glenn		reg.gov (ML19029B421)	0070
Tann, Mark		reg.gov (ML19029B385)	0060
Thevenot, Laura	American Society for Radiation Oncology	reg.gov (ML19030B576)	0091
Thomadsen, Bruce	Joint comments submitted by the following organizations: American Association of Physicist in Medici	reg.gov (ML19029B449)	0084
Thompson, Holly		reg.gov (ML19029B454)	0086
Toney, Lauren		reg.gov (ML19016A079)	0030
Tulchinsky, Mark		reg.gov (ML19029B381)	0080
Villanueva-Meyer, Javier		reg.gov (ML19018A059)	0023
Virgolini, Irene	World Association of Radiopharmaceutical and Molecular Therapy	reg.gov (ML19030B747)	0110
Wagner, Robert		reg.gov (ML19029B428)	0074

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Wan, David		reg.gov (ML19025A139)	0050
Witkowski, John	United Pharmacy Partners	Meeting Transcript (2)	0002-2
Witkowski, John	United Pharmacy Partners	Meeting Transcript (3)	0003-11
Witkowski, John	United Pharmacy Partners	Meeting Transcript (3)	0003-5
Witkowski, John	United Pharmacy Partners	reg.gov (ML19030B712)	0100
Wong, Terrence	Duke University	reg.gov (ML19030B737)	0107
Yu, Jian		reg.gov (ML19025A134)	0045
Zarnegar, Kousha		reg.gov (ML19029B434)	0063
Zuckier, Lionel		reg.gov (ML19025A129)	0041

TRAINING AND EXPERIENCE REQUIREMENTS FOR UNSEALED BYPRODUCT MATERIAL: COMMENT SUMMARIES FROM THE SECOND PUBLIC COMMENT PERIOD

This enclosure summarizes comments in response to the U.S. Nuclear Regulatory Commission's (NRC's) second *Federal Register* notice (84 FR 18874; May 2, 2019) regarding the staff's draft approaches for training and experience (T&E) for radiopharmaceuticals. Table 1 on page 19 provides the list of commenters and their comment IDs.

1. Comments Expressing General Opposition to Changes to the T&E Requirements

A large number of commenters opposed changing, particularly reducing, the T&E requirements for administering radiopharmaceuticals. The primary reasons given were the difficulty and added complexity of establishing new requirements, that a change or reduction could compromise proper training to deal with unusual occurrences or adverse radiological events, and increased potential to compromise patient and medical staff health and safety. A few commenters noted that a change in T&E requirements could result in deviation from international standards for nuclear medicine training, and that even more training should be required than at present. Most commenters expressed support for the current level of T&E and indicated that it provides the best option for access to radiopharmaceuticals while preserving public health and safety. Several commenters also noted that the current practice accommodates new and emerging radiopharmaceuticals.

Comments: (1-3-4) (1-3-9) (1-5-1) (4-1) (7-1-1) (7-3-1) (17-1) (28-1) (29-1) (30-1) (32-1) (34-1) (35-1) (35-21) (37-16) (37-17) (46-1) (47-1) (49-2) (49-18) (52-11) (52-16) (53-1) (53-17) (53-21) (55-16) (56-1) (63-1) (65-1) (65-15)

2. Comments Expressing General Support for Changing the T&E Requirements

A smaller number of commenters expressed general support for a tailored approach to T&E requirements, specifically supporting tailored T&E requirements for patient-ready doses of alpha- and beta-emitters (more detailed comments on tailored T&E requirements for alpha- and beta-emitters and patient-ready doses are summarized in Sections 5 and 6). Several commenters acknowledged issues to be addressed such as increased complexity, importance of providing appropriate requirements, balancing patient access to radiopharmaceuticals and appropriate levels of T&E, and safety.

Comments: (1-3-1) (7-2-1) (15-1) (23-16) (36-1) (48-6) (58-4-12)

3. Comments on Status Quo

General Comments on the Status Quo Approach

The majority of commenters including the American Medical Association (AMA), Nuclear Medicine Technology Certification Board, American Association of Physicists in Medicine (AAPM), American College of Radiology (ACR), American College of Nuclear Medicine (ACNM), the Society of Nuclear Medicine and Molecular Imaging (SNMMI), and the States of Utah and North Carolina advocated maintaining the status quo based largely on concerns that any reduction in T&E requirements would result in impacts to patient safety, access to quality care, and would jeopardize safety and effectiveness of treatments. Additional concerns

included the need to maintain requirements because emerging radiopharmaceuticals are more complex and require adequate training and education to ensure a thorough understanding of radiation safety. Some commenters expressed concerns about regulatory burden and that tailored requirements would be difficult to regulate. One commenter suggested that a reduction in T&E would erode public confidence in radiation safety and may lead to less experienced providers under-reporting medical events. Other commenters pointed out that maintaining the status quo was supported by most of the nuclear medicine and larger medical community because the current regulatory framework has proven to work well and to provide protection of health and safety of the public.

United Pharmacy Partners, Inc. (UPPI) expressed concern about a "looming AU shortage" and patient access to authorized users (AUs) and radiopharmaceutical treatments (particularly in rural areas), and the need for the NRC to tailor T&E requirements to help address this shortage. A few commenters including both those that support the status quo and those that do not recommended that prior to the NRC making any rule changes, the NRC should complete a more comprehensive study on AUs and patient access, as the data collected thus far is inconsistent and conflicting. One anonymous commenter thought that the current T&E criteria is excessive particularly because AUs operate within teams consisting of radiation safety officers, nuclear medicine technicians, "regulators and administrators" for NRC or State compliance.

***Federal Register* Notice (FRN) Question 1: If status quo is maintained, how should the NRC ready itself for the expected increase in number and complexity of future radiopharmaceuticals?**

Consistent with the comments provided on the status quo approach, most of the commenters that advocated maintaining the status quo also believed that the existing credentialing mechanisms (i.e., NRC-recognized boards ABNM, ABR, AOBR and the alternate pathway) were robust enough to address the expected increase in number and complexity of future radiopharmaceuticals.

UPPI expressed concern about the pending increase in several new and complex radiopharmaceuticals that are expected to receive U.S. Food and Drug Administration approval in the near future (including Lu-177 which is already approved and several radioisotopes that are being researched for use in radiotherapy) and the inability of the "already overburdened AU community" to adequately dispense the new radiopharmaceutical treatments.

Several recommendations were made to improve and strengthen the NRC's current framework:

The State of Wisconsin's response to this question focused on improving and increasing transparency in the regulatory categorization of new therapeutic drugs (10 CFR 35.1000 versus 10 CFR 35.300), suggesting that the NRC should consider developing a framework to decide how drugs are categorized in order to maintain consistency. But Wisconsin also indicated that they support the current broad categorizations for diagnostic radiopharmaceuticals "since they do not present the same hazards as therapeutic drugs." Related to this, the State of North Carolina suggested that the National Materials Program have an increased role and that the NRC develop guidance documents, conduct periodic re-evaluation of rulemakings and effective procedures for moving technologies out of 10 CFR 35.1000.

A few commenters including AAPM suggested that there be greater collaboration between NRC guidance and FDA approval of drugs such as a concurrent review, to enable the NRC to decide

the regulatory category for a new radiopharmaceutical prior to its medical release. AAPM also recommended that each radiopharmaceutical be evaluated on a case-by-case basis and if they feature complexity that precludes being regulated under 10 CFR 35.300, be regulated under 10 CFR 35.1000 unless the NRC modifies the radiopharmaceutical categories already established. AAPM expressed concern about how future radiopharmaceutical complexities will make it difficult to create tailored T&E categories to address the range of variables that may be present within each future radiopharmaceutical.

One commenter recommended that the NRC continue to seek input from medical specialties and stakeholders to incorporate knowledge topics from current alternate pathways in residency programs so that residents-in-training could be recognized within a specialty board—this would ensure that the status quo is maintained while looking ahead.

One commenter recommended that the NRC investigate how these issues have been addressed by radiologic and nuclear medicine physicians and physician training institutions in the past, in particular "the ever-changing fields of imaging diagnosis and therapies" and the manner in which they have met these challenges.

One commenter recommended that the NRC avoid over-regulation by relying on the experts in the field of nuclear medicine for self-regulation. The AMA suggested that the NRC work with the Accreditation Council for Graduate Medical Education (ACGME) to transform criteria developed in consultation with existing medical specialty boards into T&E programs.

With regard to the status quo regulations, one commenter expressed a concern about inadequate oversight of the administration of complex future radiopharmaceuticals when the AU is not on-site. Another commenter suggested that the NRC should require prospective monitoring of medicine injection to avoid infiltration.

FRN Question 2: Is there a challenge with the current T&E requirements?

The responses to this question fell into the following broad categories:

1. Comments stating there are no challenges or changes needed because there is no AU shortage, but there may be treatment access issues that are not related to the NRC's regulation of T&E and should not be a driving factor behind rule change. Associated comments included a request for the NRC to complete a thorough study on the issue of an AU shortage and patient access prior to considering any reduction of T&E.
    a. Delays in treatment are related to insurance coverage and referrals, clinician decision-making, availability of preferred non-radioactive alternative therapies, Center for Medicaid Services requirements, a practice bias for other therapies, schedule problems, competing forces, and geographic limitations.
2. Comments stating that AU shortages and patient access issues in rural areas are driven by the T&E requirements and that a change in T&E regulations is needed to resolve these issues. Associated comments include those questioning the validity of the Advisory Committee on the Medical Uses of Isotope's (ACMUI's) determination regarding an AU shortage and an inadequate assessment by the NRC of the geographic distribution of AUs.
    a. Specifically, UPPI stated that radiopharmaceuticals "with documented clinical impact are not being used because they are not readily available in physician treatment regimens (i.e. Xofigo®, Zevalin®) and that regulatory restrictions on

access drive oncologists to use less effective chemotherapy regimens. No quantification was completed of measuring of the geographic distribution of AUs or if sufficient in all areas. Rural challenges were dismissed. NRC should undertake to raise the number of AUs regardless—find a way to safely increase the AUs."

3. Comments acknowledging limitations of patient access in rural areas as a common reality across many medical disciplines but a relaxation in T&E will not solve this issue and instead will result in diminished quality of care in those areas. There are other drivers of patient access that have more to do with social and economic factors and not T&E requirements.
    a. Patients must travel more-than-average distances to obtain access to new treatments and emerging technologies, and people living in these rural areas are accustomed to traveling for complex medical treatments including brain and heart surgery. Lessening T&E requirements for AUs would not do anything to change or upgrade that reality and requiring less T&E for professionals treating in rural areas which would result in a lesser standard of care in those areas.
4. Comments indicating that there are multiple challenges associated with the current T&E requirements including:
    a. A concern regarding the ability of regulating agencies (i.e., the National Materials Program) to evaluate AU competency and the inherent flaws of preceptor attestations including that physicians do not want the burden of being responsible for attestations which means that oftentimes attestations are signed by senior staff who are not medically trained or competent. A request for the National Materials Program to seek a more objective method for confirming competency and that it not be a part of the National Materials Program's regulations or oversight activities.
    b. The NRC should focus T&E on the radiation safety competence of those handling and administering radiopharmaceuticals on a daily basis (several commenters including the States of Wisconsin, Colorado, and North Carolina supported this idea).
    c. The State of Colorado would like the National Materials Program to focus on the causal link of medical events to AU competency and enhance requirements as needed if links are shown.

Comments: (1-1-1) (1-4-1) (1-5-2) (1-13-1) (1-14-2) (1-16-1) (1-16-3) (5-1) (6-1) (8-1) (12-1) (12-2) (15-3) (19-1) (23-1) (23-10) (31-1) (33-1) (33-9) (35-2) (35-3) (35-4) (35-5) (35-6) (35-19) (35-22) (37-1) (37-2) (37-20) (39-1) (39-2) (39-4) (39-5) (39-8) (40-1) (41-2) (42-2) (43-1) (44-1) (45-4) (47-2) (47-3) (47-13) (47-18) (49-5) (49-6) (49-26) (50-1) (51-1) (52-1) (52-2) (52-17) (53-2) (53-3) (53-19) (55-1) (55-2) (55-20) (57-2) (57-3) (58-1-1) (58-1-2) (58-1-3) (58-1-4) (59-1) (60-4) (60-5) (62-1) (62-2) (62-3) (63-2) (63-3) (63-18) (65-3) (65-4)

4. Comments on Tailored T&E Requirements

FRN Question 3: How should the complexity of the radiopharmaceutical administration protocol be considered in establishing tailored T&E requirements?

Commenters answered FRN Question 3 within the context of whether they supported or opposed tailored T&E, or they offered specific answers. Some supporters of the tailored approach recommended that the NRC allow for multiple medical specialists to be able to administer radiopharmaceuticals and that the NRC partner with National Institutes of Health,

Department of Health and Human Services to set up protocols as well as utilize Euratom to understand differences between US and international standards. Lucerno Dynamics, which has developed a technology for monitoring the administration of radiopharmaceuticals for infiltrations, recommended that the NRC rely on this technology to improve the overall safety and quality of radiopharmaceutical administration. UPPI recommended that tailored training rely on existing and emerging standards and focus only on alpha- and beta-emitting therapies, and pointed out the successful tailoring of T&E for oral administration of Iodine-131. Others recommended that the NRC should allow diagnostic radiologists to be AUs within 10 CFR 35.396, and that their T&E be limited for the administration of Xofigo®. The American Society of Hematology (ASH) supported a tailored T&E approach for administration of patient-ready doses of alpha- and beta-emitting radiopharmaceutical treatments, noting that a 400-hour T&E requirement would appeal to practitioners that would like to offer such treatments but consider the 700-hour requirement to be too onerous. The Organization of Agreement States (OAS) Executive Board and Agreement States opposed tailored approaches. The State of Wisconsin described the ideal new approach as one that is adaptable to future radiopharmaceuticals without additional rulemaking action, establishes competency with respect to the mission of radiation safety, and focuses on an "authorized administrator" (who may or may not be physician). The State of Wisconsin was supportive of alternative T&E pathways if they focused on individuals handling the radioactive material, indicating that such focus could relieve regulatory burden.

Commenters that opposed tailored T&E believe that the current pathways and T&E requirements are best for patient and public safety, that there is no shortage of AUs, that a change or reduction in the T&E requirements is unnecessary and disruptive to existing training programs, that patient access would not increase, and that changes could result in unintended national or regional security consequences. Some commenters stated that a reduction in T&E could result in an increase in medical events or under-reporting of medical events. Commenters expressed concern that tailored approaches would not consider the complexity of the radionuclide, emission, administration, clinical scenarios, and public perception of radiation hazards. Other commenters remarked that the tailored approaches could result in unwanted and unnecessary burden on regulators and licensees and eventually create new barriers in getting radiopharmaceuticals on the market. Other commenters thought that the current T&E is necessary regardless if the radiopharmaceutical was a patient-ready, unit dose as it provides the basic fundamentals for radiation protection and safety. The State of Illinois pointed out that some of the most significant medical events in the past ten years have involved beta-emitters and that the NRC should look at the level of supervision or training requirements for supervised individuals. Other commenters expressed concern about the possibility that these therapies would be administered in clinical settings without appropriate infrastructure in place to manage radiation safety issues and medical complications. The State of Utah expressed concern about the possibility that altering T&E would result in significant training needs for the NRC, the Agreement States, and licenses, and that it could result in inconsistencies across different facilities or different states.

One commenter recommended that NRC consider risk evaluation to determine tailored T&E for alpha-and beta-emitters. Another commenter recommended that NRC evaluate prior violations and citations to determine appropriate qualifications for administering alpha and beta emitting radiopharmaceuticals. One commenter recommend that preceptor attestation should be required but not by the manufacturer, but by medical specialty boards. The State of Utah expressed concern that if a competency-based evaluation was required for an AU approval, then there might be an issue with finding a sufficient number of preceptor physicians willing to sign a statement of competency (especially for small facilities or establishment of new

facilities). The OAS recommended that NRC consider taking a risk-informed, performance-based approach to radioactive materials regulation and to reevaluate the National Materials Program's role and focus on radiation safety and not on the practice of medicine. Other commenters recommended that an independent review be completed of the NRC's medical use program before making any changes.

Comments: (1-3-3) (1-3-10) (1-6-1) (1-17-1) (1-17-2) (2-1) (7-1-2) (7-4-1) (7-4-2) (11-1) (15-2) (15-4) (21-1) (23-2) (35-7) (35-16) (35-23) (37-3) (37-10) (37-11) (37-13) (38-1) (38-15) (39-3) (39-6) (39-7) (39-9) (41-1) (42-1) (45-1) (47-4) (47-11) (47-12) (47-14) (47-20) (48-3) (49-7) (49-10) (49-19) (49-21) (49-24) (49-25) (52-3) (52-10) (52-13) (53-4) (53-11) (53-12) (53-18) (55-3) (55-10) (55-11) (55-12) (55-13) (55-17) (55-18) (55-19) (57-1) (57-4) (58-1-5) (58-1-8) (58-4-2) (60-1) (60-3) (60-6) (60-13) (60-14) (60-18) (61-1) (63-4) (63-7) (63-19) (63-20) (63-22) (63-24) (64-1) (64-2) (64-3) (64-4) (64-5) (65-2) (65-5) (65-12) (65-13) (65-16)

Comments on Limited AU for Alpha- or Beta-Emitting Radiopharmaceuticals

Some of the commenters that support a limited, tailored AU pathway for alpha- or beta- emitters provided examples of specific radiopharmaceuticals such as Xofigo® and Zevalin® that would readily fall into this category. Specifically, Acrotech BioPharma (the commercial license holder for Zevalin®) recommended a tiered approach by tailoring T&E based on the complexity, risk, and safety associated with the administration of the radiopharmaceutical. Some commenters linked their support of this pathway as a way to resolve perceived issues regarding patient access. Another commenter pointed out that tailored, limited pathways already exist requiring 80 hours of T&E for I-131, and that this pathway could be used for Xofigo® which they believe is much less complex than I-131. This commenter pointed out that radiation safety for administration of I-131 has been protected due to other NRC requirements such as licensing and inspection and the radiation safety officer requirements. In addition to the T&E recommended for this pathway, this same commenter recommended that NRC also require the manufacturers' training certification as part of the training requirement. UPPI suggested an authorized nuclear pharmacist (ANP) be present during the administration of alpha and beta emitters by limited-trained AUs to make sure they are administered safely.

Commenters that opposed this approach expressed concern about the varying secondary emissions resulting from alpha and beta emitters and the need for T&E to be comprehensive enough to address such issues as improper use, storage, and long-half lives. Similarly, the ACR expressed concern that this approach overlooks other medical radiation safety considerations because it ignores the complexity of the physical and biological properties of different radionuclide agents. The American Society for Radiation Oncology (ASTRO) noted that comprehensive knowledge like that gained by the current AU T&E requirements was necessary for the safe administration of alpha and beta emitters in particular "knowledge of radiobiology, radiation physiology, radiochemistry, dosimetry (when available), ability to perform radiation activity assays, and appropriate handling of spills and intravenous infiltration". The American College of Radiation Oncology also supported comprehensive T&E (especially in nuclear medicine) for the administration of alpha and beta-emitters as without this, issues such as radiation spills and unused material handling would not be safely managed. The American College of Radiation Oncology provided an example of Lutetium-177 as an example of a beta-emitter that also emits a 208 keV gamma energy emission which is of greater concern for safety and security.

FRN Question 4: How should the NRC categorize radiopharmaceuticals with mixed emissions?

Several commenters recommended not changing the way radiopharmaceuticals are categorized on the basis of emissions and that they should be categorized under already existing categories outlined in 10 CFR 35.300. The AAPM recommended that mixed emitters and single emitters be categorized together and should require the same level of training. The State of Utah recommended that mixed emitters be evaluated on a case-by-case basis. ACR recommended that any attempt by NRC to classify radiopharmaceuticals should account for factors such as half-life of the agent(s), energy levels (typically multiple), type of emission (alpha, beta, gamma, or mixed), chemical properties, etc., and would be inordinately burdensome to maintain on an ongoing basis by the NRC and/or the Agreement States as new agents are introduced. UPPI recommended that the NRC separately review each radiotherapeutic radiopharmaceutical to make sure that long-lived decay issues are addressed (because they effect handling, disposal, and patient release criteria).

Comments: (1-12-1) (12-3) (12-5) (18-1) (20-1) (23-3) (26-1) (35-8) (37-4) (47-5) (48-1) (49-8) (52-4) (53-5) (55-4) (58-1-6) (63-5) (65-6)

Comments on Limited AU for Unit-Dose, Patient-Ready Radiopharmaceuticals

Many commenters advocated that a limited AU approach be developed for Xofigo® such that urologists located in under-served areas could treat their prostate cancer patients. One such provider indicated that they had limited access to a qualified AU resulting in the inability and/or delay in being able to treat patients locally or those living in rural areas, as well as burdening these patients with added costs and travel needs. This commenter stated that urologists have extensive training in handling biological and chemically hazardous materials. Commenters believed that the 700-hour training requirement to be excessive for the administration of Xofigo®. Others advocated a general approach to simplifying the way that patients can access radiopharmaceuticals like Xofigo®. Acrotech BioPharma indicated that the risks are much reduced as the doses are prepared by a licensed radiopharmacy and delivered to the physician on the day of administration in a pre-filled syringe, thus avoiding the need for direct handling of radioactive isotopes by the administering physician. UPPI supports a limited AU pathway but believes that a physician with a limited 400 hours of T&E be teamed with an ANP to administer patient-ready radiopharmaceuticals. The Council on Radionuclides and Radiopharmaceuticals (CORAR) provided specific input on a reduction of training requirements for limited AUs to administer intravenous, non-imaging, patient-ready radiopharmaceuticals.

The commenters that opposed this approach expressed concern about radiation safety and unforeseen complications. Specific concerns expressed by a consortium of private individuals who are nuclear medicine physicians or trainees include the possibility of “radiopharmaceutical infiltration, carcinoid crisis, hypertensive crisis, contaminations due to urinary incontinence, lack of appropriate thyroid blockade, or more long-term side effects including renal toxicity, hematologic toxicity, gastrointestinal toxicity, or salivary gland toxicity.” This same commenter warned of the need to consider the multidisciplinary context of radiopharmaceutical therapy. ACR asked that the NRC refrain from using the term “patient-ready,” as it serves to simplify and diminish the responsibility of the AU and ignores the unique physical characteristics of each individual patient being treated.

FRN Question 5: Under what conditions should a radiopharmaceutical be considered ''patient ready'' such that the T&E requirements could be tailored?

Many commenters (including ACR, ASTRO, and private individuals) didn't think there should be any other conditions than the ones that currently exist which is that they be overseen by a fully trained AU. These commenters stated that radiopharmaceuticals should not be considered "patient-ready" as the treating AU must make sure that all aspects of the administration of a radiopharmaceutical are suitable for the patient. ASTRO noted that administering radiopharmaceuticals is not as simple as ordering it from a radiopharmacy and injecting it into a patient—it comes with a need to have specific nuclear medical training, responsibility and experience, and should only be carried out by a fully trained AU with a high level of knowledge such that all of the steps in the administration process, including unexpected situations, are handled correctly and safely. The AAPM echoed these concerns noting that Zevalin®, Lu-177 and Xofigo® ("patient-ready" radiopharmaceuticals) each have different administration methods (pump infusion, hand pushed-IV, and gravity drip method) and each also has its own radiation safety issues. While the training can be categorized together, the administration of the radiopharmaceutical cannot and requires a highly-trained person.

Other commenters such as the State of Utah stated that radiopharmaceuticals that should be considered "patient-ready" should follow the Board of Pharmacy requirements for labeling patient doses. UPPI recommended that the T&E requirements be tailored based on the risk associated with the radionuclide (alpha- or beta-emitter) and not based on being "patient-ready." The State of Wisconsin also recommended that NRC take a risk-informed approach, by taking into consideration emission type, physical form, administrative technique, dose preparation and annual limit on intake. CORAR recommended that a patient-ready dose is an individual (single) dose that is prepared by a licensed nuclear pharmacist in a licensed nuclear pharmacy or received directly from the manufacturer in a patient-ready dose container, and the patient-ready dose is dispensed for an individual patient pursuant to a prescription order.

Comments: (7-5-1) (10-1) (12-4) (12-6) (13-1) (14-1) (16-1) (23-4) (24-1) (25-1) (27-1) (35-9) (37-5) (38-2) (38-3) (38-7) (47-6) (48-2) (49-9) (52-5) (53-6) (55-5) (58-1-7) (60-7) (63-6) (65-7)

5. Comments on the Emerging Radiopharmaceuticals Approach

Two commenters supported individual reviews of emerging pharmaceuticals to determine T&E requirements specific to each (the context for these comments being that a reduced T&E, limited pathway is preferable for emerging pharmaceuticals [including alpha- and beta-emitters] in patient-ready doses). Four other commenters were strongly opposed to individual reviews of new radiopharmaceuticals, arguing that such individual reviews would result in significant negative impacts: confusion over multiple pathways for different pharmaceuticals; increased time and cost for rulemaking, guidance development, license amendments; increased burden on specialty boards, training programs, and administration (including ongoing T&E and competency documentation); increased licensing fees; and further fragmentation of the already highly-specialized nuclear medicine T&E requirements.

Comments: (35-24) (49-11) (53-14) (58-1-9) (61-2) (63-8)

6. General Comments on the Performance-Based Options

Comments were divided on the issue of removing prescriptive T&E requirements in favor of licensee-developed performance-based T&E as part of the licensee's medical program for

administration of radiopharmaceuticals. Nonnuclear medicine and nonradiation oncology commenters considered performance-based options a "viable alternate pathway" for certain categories of radiopharmaceuticals or "better suited to assessing training and experience than a strict hours-based requirement." One of these entities noted that a self-determined performance-based program would allow licensees to develop risk-informed policies and procedures based on radiotherapy characteristics (e.g., emission profile, amount of activity administered, routes of administration and elimination) and would allow licensees to achieve compliance with 10 CFR 35.41 and 10 CFR Part 20. The other noted that a competency-based framework was presented at the October 2016 meeting of the ACMUI. The OAS noted that any approach that allowed regulators to focus on the radiation protection (vs. patient care) aspects of radiopharmaceutical administration rather than on credentialing and verification would be an advantage, despite higher initial rulemaking costs. However, OAS also noted that regulators could be overwhelmed by license amendment requests as licensees add radiopharmaceutical treatments. Several groups objected to removing the existing T&E requirements and allowing licensees to develop their own T&E requirements. The primary objections were that minimum qualifications would become deregulated, that the NRC would have difficulty overseeing licensee-determined programs consistently, that the NRC should rely on the nuclear medicine societies and boards that set the current training requirements, and that the cost and liability of self-regulation would become a burden on licensees. The ACR elaborated that the licensee burden issue might actually reduce patient access, claiming that only large institutions with sufficient available staff and resources would be able to develop and implement a performance-based T&E program.

Comments: (35-10) (35-15) (38-4) (38-9) (48-4) (57-5) (57-9) (63-9)

7. Comments on Competency-Based Evaluation

A number of commenters either expressed support for a competency-based evaluation approach, or at least suggested that the approach had merit. However, several Agreement States and most of the nuclear medicine groups (ACR, American College of Radiation Oncology, APPM, and ASTRO) expressed opposition to changing the T&E requirements to a competency-based evaluation approach. Most of these organizations believed that the current T&E approach (board certifications, facility accreditation, and required periodic reassessments by the boards) would be the best way to create and maintain appropriate AU T&E. Several noted that competency is established by years of T&E that include medical residency and management of adverse circumstances, initial certification, and continued maintenance of certification requirements. Utah noted that a competency-based evaluation would not ensure that T&E was appropriate for administering pharmaceuticals unless a standardized examination could be developed by the relevant professional organizations. ASTRO also noted that an examination or other competency evaluation might not "assure the depth of knowledge" that comes with the current prescriptive T&E requirements and that there are sufficient alternative pathways to becoming an AU.

FRN Question 6: How could a competency-based evaluation ensure appropriate training and experience for AUs administering radiopharmaceuticals?

CORAR interpreted the goal of a competency pathway as providing a means for licensed medical specialists to gain the "…skills necessary to effectively and safely prescribe and administer specific non-imaging radiotherapies," stating that the T&E should be contingent on the non-imaging radiotherapy characteristics and usage, and that low-risk agents should have reduced T&E requirements compared to higher risk pharmaceuticals. CORAR also suggested

that a competency-based assessment include an examination and a hands-on training component (in a hospital, radiopharmacy, or manufacturer-provided location) that is completed under the supervision of and assessed by a preceptor (AU, authorized nuclear pharmacist, radiation safety office, or health physicist). UPPI felt that a competency-based evaluation would provide a means of peer review and updating the evaluations to keep up with current practices and new radiopharmaceuticals (alpha- and beta-emitters). Another industry commenter noted that competency-based evaluation should include objective measurement of an AU's radiopharmaceutical administration skills that would allow licensees to demonstrate quality of administrations, and that the technology exists to provide such objective evidence. Several Agreement States favored incorporating a form of competency-based assessment of radiation safety knowledge (e.g., material security, labeling and posting, reporting events, medical event identification, obligations to patients), such as an examination and periodic re-examinations. One state suggested that such a requirement could replace preceptor attestation. Another state suggested that core competency areas for different modalities (e.g., diagnostic, therapeutic, unsealed) be established. Most States remain focused on radiation safety and support changes that would better address the actual hazards associated with medical use of radiopharmaceuticals, e.g., approaches that focus on the individuals shipping, handling, and administering the radiopharmaceutical, and not just the AU. The OAS reiterated that a competency-based examination should be required at an interval determined by the NRC and the nuclear medicine specialty boards, adding that such evaluations be done at the national rather than State level. The organization representing nurse practitioners supported a pathway to becoming an AU that relied on meeting consistent T&E and competency requirements and standards rather than the licensed physician requirement.

As noted above, nuclear medicine professional organizations were generally of the opinion that a competency-based evaluation would be similar to the existing board certification structure and that there would be no point in creating a different system. One commenter noted that competency evaluations for specific radiotherapies not currently covered by certification boards could be added by contracting with those same boards. Another noted that maintaining facility accreditation was important to demonstrate competency, and that the existing boards could also provide a radiation safety examination. The ACR repeated several of its arguments against tailored and/or licensee-determined T&E approaches: that it is not clear whether there would be minimum T&E requirements (e.g., to sit for an examination), the T&E requirements in 10 CFR 35.390 are intended to avoid requiring an NRC-specific examination, and that any licensee-directed and/or limited pathway would require constant updates and would increase regulatory and administrative costs.

Comments: (1-2-2) (1-3-5) (12-7) (15-5) (23-5) (35-25) (37-6) (38-5) (47-7) (49-12) (51-3) (52-6) (53-7) (54-1) (55-6) (57-6) (58-1-10) (60-8) (60-12) (63-10) (65-8)

8. Comments on Credentialing Authorized Users

Most commenters provided a direct answer to FRN Question 7, "How could physicians in small practices be credentialed (e.g., physicians not associated with hospitals or other large institutions and their credentialing boards)?" CORAR commented that demonstration of didactic knowledge could be evaluated through an exam administered in an online AU education program, and that a hands-on laboratory training component for a limited AU T&E program could be completed at a radiopharmacy, hospital nuclear medicine department, or manufacturer-provided location. UPPI commented that ANPs should be considered in the credentialing AUs discussion, noting that UPPI and its members could work with "appropriate

disinterested third parties" to develop and apply a credentialing standard to assure its members' competency in radiotherapeutic applications. However, its response to the question about credentialing physicians in small practices was that the concern could be addressed by making such credentialing mandatory, did not really address the question of how physicians at small practices become credentialed AUs in the first place.

The general sentiments of the agreement states that provided comments were that competency requirements should not be different for small vs large practices, that credentialing should be performed on a national level by existing medical specialty boards (and this would not put smaller practices at a disadvantage), and that licensee-directed and/or limited-training pathways would increase the burden on both licensees and regulators. Several states pointed out that past experience has shown that licensee-developed T&E programs can take weeks to months to resolve training issues, and that this requires a much more regulatory review time than is typically available during inspections.

Most of the nuclear medicine professional organizations also commented that AUs should have consistent training and certification regardless of size or location of practice. Like the competency-based evaluation question, these organizations responded that the current system of [nuclear medicine] board certifications, facility accreditation, and required periodic reassessments would be the best way to create and maintain appropriate AU credentials. Several commenters argued that smaller practices in general would either not have or not want to acquire the infrastructure and staff teams necessary to provide radiopharmaceutical treatments, or to develop, implement, and monitor their own training and experience programs. ACRO noted the relative infrequency at which radiopharmaceutical treatment was incorporated into a patient's overall plan of care, and that larger institutions are better suited to providing comprehensive complex care, whereas smaller practices would incur significant burden to provide such an expensive treatment at such a low frequency. ACRO and several other organizations noted that adding limited-scope treatments at smaller practices would not improve patient access to comprehensive care. A number of organizations (ASTRO, U.S. Oncology Network, ACR) shared the concern that the licensee self-determination approach to credentialing physician AUs would result in inconsistent requirements among licensees, which could compromise patient care and result in disparate outcomes.

ABNM commented that the results of examinations and reports showed that trainees often do not meet all of the 10 CFR 35.390 requirements, but that program directors are under pressure to attest to T&E that trainees do not have. ABNM was concerned that the situation of false attestation would be exacerbated if licensees were allowed to develop their own T&E policies and procedures. Another commenter questioned what NRC's consideration of Part 35 Subpart N ("Enforcement") was, and how the public would be assured that the NRC is providing adequate oversight to prevent submittal false information. Yet another responded that the boards such as ABNM and ABR have developed very specific and rigorous documentation requirements for hours, training, and testing, so continuing to rely on such boards for credentialing was preferred and that the requirements should not be left to industry. This commenter mentioned current NRC enforcement and how that is "enforcement after the fact" even with the current system, so that any new system would rely greatly on *how* the documentation of credentialing would be implemented.

Many nuclear medicine professionals and their organizations repeated arguments in general opposition to limited-training and/or licensee-directed AU T&E requirements: that new methods of credentialing AUs would not necessarily establish new facilities willing and able to provide

radiopharmaceutical treatments (e.g., patient access would not be improved), that different standards at different facilities could create hazardous situations and compromise patient care, and that variability between licensees and between states would add complexity to regulation and burden on licensees (e.g., for developing and renewing training programs, board programs, accreditations, license amendments). Several individual commenters noted that small practices are more limited by their lack of a radiopharmaceutical team, rather than AU T&E requirements. One added that if a practice does not have the infrastructure to handle radiopharmaceutical therapies, then its physician(s) probably should not be credentialed. Another thought the definition of "small practice" would probably exclude a physician in small practice from being credentialed without association with a larger institution, as only larger institutions would have the necessary infrastructure and personnel to appropriately train AUs, monitor and document their training programs, and ensure compliance.

Comments: (1-2-1) (1-3-6) (1-3-8) (1-7-1) (1-8-1) (1-9-1) (1-16-2) (12-8) (23-6) (35-11) (35-26) (37-7) (38-6) (44-3) (45-2) (47-8) (49-13) (52-7) (53-8) (55-7) (57-7) (57-12) (58-1-11) (60-9) (63-11) (63-12) (65-9)

9. General Comments on the Team-Based Approach

The majority of comments in this category indicated that a team-based approach to treatment was not only typical for contemporary or complex health care but that the current regulations allow for it. However, most also noted that a team should require a fully trained and experienced AU to lead the team (some specified present or on-site), that the responsibilities of the AU should not be delegated, and that going outside an AU's scope of practice raises liability issues. Although outright opposition to team-based T&E requirements was not always stated, these comments implied that using such an approach for T&E requirements was neither necessary nor preferable. Commenters directly stating opposition to an approach to team-based T&E requirements also argued that a change would be unnecessarily complex, that patient access to radiopharmaceutical therapy would not be improved, and that any complications that arise could undermine public confidence in radiopharmaceutical therapy. A number of nuclear medicine professional organizations (e.g., ACR, ASTRO, ACRO, U.S. Oncology Network) were concerned that patient safety could be put at risk because an AU with limited training might not be qualified to deal with administration incidents; with "indications, contraindications or toxicities to patients and staff;" or with long-term implications of radiopharmaceutical treatment, especially if combined with non-radiopharmaceutical treatment. OAS also argued that there is little justification for an "arbitrary" team-based approach to T&E. In direct response to FRN Question 8, some commenters noted that clear documentation of radiation safety responsibilities for each team member would be necessary, indicating current practice is clear regarding responsibilities of the radiation safety officer (RSO) vs all other responsibilities which fall to the AU. One commenter described the specific roles of team members who, in addition to an onsite AU, need to understand radiation safety procedures: authorized nuclear pharmacist (ANP) prepares material and performs official activity assay; authorized medical physicist (AMP) performs dose calculations and establishes safety procedures, and checks assays; ANP or AMP responsible for radiation surveys even if means supervising performance by another trained staff member. The State of Colorado Radiation Control Program stated that the AU's radiation safety responsibilities "must be delineated in writing and acknowledged by the AU's signature. The same approach must be used for each team member responsible for radiation safety duties. The Medical Director and the RSO would need to work together to develop the duties and responsibilities for each team member. When completed, the listed duties and responsibilities for each team member would need to be approved by the RSO, the Medical Director, and the Radiation Safety Committee, if

a Radiation Safety Committee is required. The duties and responsibilities of each team member should be included in the licensee's radioactive materials license and changes to the listed duties should require a license amendment." UPPI expressed support for a team-based approach that could remove prescriptive T&E requirements for AUs, indicating that such an approach could increase patient access to treatments while maintaining safety and training. UPPI favors an approach in which a fully-trained ANP would team with a limited-trained AU, wherein the AU would not have to complete 700 hours of T&E in order to be qualified to 'ensure patient and radiation safety,' but that an ANP or other authorized individual with 700 hours of T&E would be present for radiation safety purposes. UPPI stopped short of supporting "entire team" competency, indicating that it implied a team would work together multiple times, whereas UPPI's team-based approach would define specific responsibilities each team member, and that those individuals should be appropriately trained to perform those responsibilities. For example, UPPI pointed out that many ANPs are RSOs at a nuclear pharmacy, but that if an ANP were teamed with a limited AU and the therapy is administered at a different site, the team should include an RSO with responsibility at the licensed site, and that the responsibilities of each member of the team with respect to the licensed site should be explicitly stated.

Comments: (1-3-7) (1-10-1) (1-10-2) (7-2-2) (23-7) (35-12) (37-8) (44-2) (44-4) (45-3) (47-9) (49-14) (51-2) (52-8) (53-9) (55-8) (57-8) (58-1-12) (60-10) (63-13) (65-10)

10. Comments on Radiopharmaceutical Team

Two organizations had supportive comments on the radiopharmaceutical team approach, but most commenters leaned away from team performance-based T&E requirements, indicating that one fully trained and experienced nuclear medicine physician AU should be responsible for all aspects of treatment and that the AU's authority should not be 'diluted' by increasing the 'weight' of the rest of the team in a performance-based T&E approach. The Organization of Nurse Practitioners' position is that nurse practitioners who have met the T&E and competence requirements should be authorized to fill the AU role, and UPPI reiterated its position that an ANP should be able to serve alongside an AU. However, several nuclear medicine and radiation oncology professional societies argued that ultimate responsibility for both medical treatment and radiation safety should lie with the AU regardless of team composition; the group of nuclear medicine trainees and recent graduates stated that any team would need a responsible leader that is "…a nuclear medicine physician with expertise in various internal radiation-specific effects of radiopharmaceutical therapies, who is present during all stages of the therapy, [and] can recognize these complications and immediately react accordingly." This group provided specific examples of radiopharmaceutical treatments (e.g., Lutathera™, Azedra™) that can have immediate medical complications during radiotherapy. Several commenters, mostly from nuclear medicine and radiation oncology professional societies, expressed concern that performance-based team T&E policies and procedures determined by each individual licensee was not sensible and would be impractical to implement. ACR did not see any advantages to this approach and offered a number of disadvantages and potential consequences. For example, only larger licensees would be able to bear the cost, administration, and legal burdens of determining performance-based T&E and authorization requirements, which would reduce patient access if fewer licensees were able to provide treatment. Besides the added burden on licensees, another example was that a performance-based team approach would be difficult to implement consistently across institutions and State lines, which could complicate regulatory oversight by the NRC and the Agreement States, as

well as complicate practice for insurers and nuclear medicine practitioners who provide contract radiation safety services or who wish to relocate.

Comments: (12-9) (35-27) (49-15) (54-2) (58-1-13) (63-14)

11. Comments on Teaming AUs with Authorized Administrators

This approach received cautious support from some commenters, primarily because they felt it could improve patient access to radiopharmaceuticals yet could be implemented with less disruption to existing T&E and certification requirements. The Nuclear Medicine Technology Certification Board would support a current physician extender such as a Nuclear Medicine Advanced Associate (NMAA) becoming an authorized administrator on such a team-based approach, as long as the authorized administrator was supervised by a nuclear medicine physician or radiologist. One Agreement State favored the focus, with respect to radiation safety, on the individual administering the radiopharmaceutical. United Pharmacy Partners, Inc. expressed concern that teaming AUs with authorized administrators would not improve access to radiopharmaceutical therapies unless the approach were clarified with regard to specific training requirements and if the team ANP could be the authorized administrator. One commenter stated that a fully-trained AU should still be responsible for safety, appropriate use, and compliance, while the group of medical professionals/recent trainees stated that a fully-trained physician AU should still bear responsibility for an entire radiopharmaceutical treatment. The ACR repeated its concerns regarding the disadvantages and potential consequences of a team-based approach in which licensees determine and implement training and authorization requirements, e.g., that only larger institutions could afford the time and resources to implement such an approach, that patient access could be reduced rather than improved, and that deferring so much development and oversight responsibility to the licensees would complicate both nuclear medicine practice and regulatory oversight by NRC and Agreement States.

Comments: (12-10) (12-12) (33-7) (35-28) (58-1-14) (59-2) (60-11) (63-15)

12. Comments on Partnering Limited-Trained AUs with ANPs

The nuclear medicine and radiation oncology professional societies and boards opposed this approach, for the same reasons as they opposed other changes to T&E requirements (fully-trained AUs should lead both patient care and radiation safety, responsibilities are currently clearly delineated, adds unnecessary complexity, patient access would not be improved, patient and worker safety could be put at risk). Specific comments in opposition to partnering a limited-trained AU with an ANP noted the following with regard to patient and worker safety: ANPs are not trained to work with individual patients, radiation safety responsibility lies with the AU and licensed facility and should not be designated to an ANP, and ANPs are typically located in populated areas so this approach would not improve patient access in rural areas. The Agreement States had a limited number of comments regarding responsibilities for radiation safety-related duties, but ultimately, they opposed any team-based approaches.

The vast majority of comments on this topic were from one organization, UPPI. This group predicts that the rising use of current radiopharmaceutical treatments as well the number of new and emerging radiopharmaceuticals will create a demand for AUs to administer these treatments that is beyond current AU availability. They also posit that the NRC desires to expand access to radiopharmaceutical treatments without sacrificing radiation safety. UPPI proposed partnering limited-trained AUs with ANPs, and developing tailored T&E requirements

based on the AU's required competencies. The tailored T&E requirements would require strict training (possibly in excess of 400 hours) and preceptor attestation. In all cases, the partnership would involve at least one party with a full 700 hours of T&E. UPPI claims that ANP and AU training can be considered equivalent in terms of radiation safety regulation, thus positioning the ANP to serve in a radiation safety role. However, UPPI proposes that the ANP would have the primary responsibility for radiation safety requirements "that are not patient specific," and the facility would have "an accessible RSO [radiation safety officer]" to work with the ANP. UPPI believes its approach would improve treatment availability and patient safety, claiming that the limited AU training pathway would increase the number of physicians pursuing nuclear medicine.

UPPI stated that a fully-trained ANP could be qualified to fulfill radiation safety responsibilities during radiopharmaceutical administration by a limited-trained AU, because ANPs have more experience with day-to-day handling of radiopharmaceuticals, and an ANP's radiation safety training is essentially equivalent to an AU's with regard to material receipt, dose preparation and calibration, dispensing, radiation monitoring, and waste disposal. Objectors argue that ANPs are generally not trained to perform these radiation safety duties in a patient care setting with other health care workers, and that adding this responsibility could pose risk to patient and worker safety. Comments in opposition to UPPI's proposal, particularly from ACR, claim that radiation safety responsibility lies with the licensed facility and the fully-trained physician AU, and that changing facility operations to allow for an offsite ANP to take on that responsibility adds unnecessary complexity with respect to scope of practice, facility accreditation, facility liability, and payer (insurance) requirements. UPPI countered that such risks can be identified and mitigated. UPPI also noted that the risk to patients' lives from having to forgo optimum radiopharmaceutical treatment because it is not available to them should be considered in the analysis of patient access and patient safety.

UPPI noted that because the current ANP footprint already reaches to locations up to 4 hours away from a centralized nuclear pharmacy, ANPs have a broader "reach" than a medical facility's resident AU; and an ANP could physically deliver the radiopharmaceutical and be present during administration to address radiation safety (in partnership with a facility RSO). ACR countered that most of UPPI's centralized nuclear pharmacies are located in urban areas and thus would not substantially increase treatment availability or patient access in rural areas by partnering with a medical facility's AU. With regard to added regulatory and operational complexity, ACR added that the 10 CFR 35.27 supervisory requirements would require revision, liability could increase if licensed facilities grant access to offsite ANPs, changes to current accreditation and billing requirements would be costly, and implementation and regulation would likely differ in Agreement States vs. non-Agreement States. As noted above, UPPI argued that the program could be developed in such a way that identified risks would be mitigated, for example through additional training and guidance, vetted protocols, standard operating procedures, and information on packaging inserts.

Comments: (1-11-1) (3-1) (7-2-3) (12-11) (23-8) (35-13) (35-29) (37-9) (47-10) (49-16) (49-17) (52-9) (53-10) (55-9) (58-1-15) (58-2-1) (58-2-2) (58-2-3) (58-2-4) (58-2-5) (58-2-6) (58-2-7) (58-2-8) (58-2-9) (58-2-10) (58-2-11) (58-2-12) (58-2-13) (58-2-14) (58-2-15) (58-2-16) (58-2-17) (58-2-18) (58-2-19) (58-3-1) (58-3-2) (58-3-3) (58-3-4) (58-3-5) (58-3-6) (58-3-7) (58-3-8) (58-3-9) (58-3-10) (58-3-11) (58-3-12) (58-3-13) (58-3-14) (58-3-15) (58-4-1) (58-4-3) (58-4-4) (58-4-5) (58-4-8) (58-4-9) (63-16) (63-17) (65-11)

13. Comments Suggesting Other Approaches

Most commenters indicated that the current approach, perhaps combined with competency examinations, was the best approach for dealing with future radiopharmaceuticals. The AAPM recommended incorporating ACMUI guidance into the current approach and requesting assistance from professional societies and existing certification boards for developing and implementing competency-based requirements for specific radionuclide treatments. The group of nuclear medicine trainees and recent graduates also proposed that the NRC use the expertise and experience of the nuclear medicine specialty boards and societies when deciding how to regulate new radiopharmaceuticals.

Comments: (38-8) (38-10) (38-11) (38-14) (48-5)

14. Comments on Patient Access

Two commenters supported changes to T&E requirements that would improve patient access to radiopharmaceuticals; one specifically noted that the current applicability of 10 CFR 35.396 only to certain radiation oncologists limits patient access. That commenter also noted that many patient access limitations were due to factors other than the T&E regulations (e.g., insurance network limitations, practice bias for other therapies, geographic limitations). Three commenters, all representing nuclear medicine and radiation oncology professional societies, noted that patient access to radiopharmaceuticals is not limited by the NRC's current T&E requirement or a shortage of AUs. One of these commenters listed a number of other market-related factors that limit patient access to radiopharmaceuticals; the others noted that radiopharmaceuticals are not different than other specialized therapies in terms of patient access, adding there is no factual evidence that patient access to radiopharmaceuticals is particularly limited.

Comments: (9-1) (22-1) (35-14) (53-13) (60-15) (63-21)

15. Comments on Regulatory Burden

Most of the comments on regulatory burden came from the State agencies involved in regulating radioactive material licenses, with additional comments from the OAS and two radiation oncology organizations. While one commenter noted that a performance-based approach with AU competency examinations could reduce burden by creating a less arbitrary, more objective means of assessing competency, the majority of commenters indicated that most of the draft approaches would increase the regulatory burden associated with rulemaking and processing license amendment requests, particularly if regulatory agencies are staff-limited. One commenter noted that an increased number of non-compliance actions could be an unintended consequence of tailored T&E requirements, which would result in additional regulatory burden.

Comments: (23-11) (23-12) (33-2) (33-3) (33-4) (33-5) (33-6) (37-12) (47-17) (49-20) (52-12) (57-11)

16. Comments on Radiation Safety Competency Assessments

Commenters were generally in support of initial and ongoing radiation safety competency assessments administered by medical specialty boards or professional societies. However, there were differences of opinion regarding the question of whether such a competency assessment should be formally included by the NRC for any of the draft approaches. Five

nuclear medicine organizations indicated that the current assessment tools for certification and maintenance of AU status by NRC-recognized specialty boards was appropriate and sufficient such that further NRC consideration of competency was not required; these organizations support the current T&E approach and oppose the draft approaches to tailoring or reducing T&E requirements. A group of nuclear medicine trainees and recent graduates pointed out that focusing on radiation safety could give a false sense of [medical] competency, noting that the current T&E standards are much less than the minimum requirements of the ABNM as well as international standards. Four other commenters specifically answered that yes, the NRC should consider inclusion of formal radiation safety competency assessments for the draft approaches, to be administered by professional organizations or medical boards. The State of North Carolina suggested objective initial and recurring competency assessments rather than the existing preceptor attestation requirement, suggesting that certifying entities could be professional organizations or medical boards, established by implementing a standard or method developed by the National Materials Program. UPPI commented that AUs, ANPs, and limited AUs should all be subject to the same competency criteria. The OAS commented that the performance-based options should include a competency assessment that is developed by the NRC and the Agreement States, and administered by the NRC.

Comments: (23-9) (23-13) (23-14) (35-17) (37-14) (38-12) (47-15) (49-22) (52-14) (53-15) (55-14) (57-10) (58-4-6) (60-16) (63-23) (65-14)

17. Comments on Impacts to Medical Organizations

One commenter felt that the draft approaches involving limited AUs for certain specialties would encourage the formation of new medical societies in those specialties; another commenter did not think there would be a negative impact on medical societies that would use limited T&E requirements as a basis for their training programs. Yet another noted that organizations could adapt to a performance-based approach under which they would have more flexibility, adding that the National Materials Program should focus on radiation safety and regulatory compliance rather than medical competency. However, the majority of comments described negative impacts anticipated to result from alternative T&E pathways: numerous amendment requests to revise training programs would be burdensome, new training programs could be confusing and of variable quality, non-compliance actions could increase, nuclear medicine research and development could decrease, medical student interest in comprehensive training could decrease, licensee self-determination of AU status could ‘dilute’ or undercut the organizations that currently maintain T&E standards and quality, and the potential for discrepancy in the level of NRC oversight for 10 CFR 35.300 material uses vs. other Part 35 materials could increase. Most of the commenters pointing out negative impacts represented nuclear medicine professional societies and boards that support maintaining the current T&E requirements.

Comments: (23-15) (35-18) (37-15) (38-13) (47-16) (49-23) (52-15) (53-16) (55-15) (58-4-7) (60-17)

18. Comments on the Best Approach for the Future

Most commenters indicated that the current approach, perhaps combined with competency examinations, was the best approach for dealing with future radiopharmaceuticals. The APPM recommended incorporating ACMUI guidance into the current approach and requesting assistance from professional societies and existing certification boards for developing and implementing competency-based requirements for specific radionuclide treatments. The group of nuclear medicine trainees and recent graduates also proposed that the NRC use the

expertise and experience of the nuclear medicine specialty boards and societies when deciding how to regulate new radiopharmaceuticals.

Comments: (23-17) (37-18) (38-16) (44-5) (58-4-10) (60-19) (63-25)

19. Comments on the NRC's Role in T&E

Nearly all commenters supported a continued role for the NRC in review and approval of AUs. Several noted the need for consistency of AU T&E or another agency to pursue training issues and corrective actions. Several commenters representing Agreement States maintained that the NRC's role should be limited to regulating T&E for public health, safety, and security, and should not reach beyond requiring physicians be certified by medical specialty boards. A few commenters noted that the present NRC role should not preclude implementing a limited AU T&E pathway. Several other commenters reiterated that NRC should seek advice from nuclear medicine specialty boards such as the ABR and ABNM with respect to regulating new or emerging radiopharmaceutical treatments. OAS recommended ensuring that radiation protection practices are adhered to by auditing the specialty boards and related examination development and administration procedures. The group of nuclear medicine trainees and recent graduates suggested that NRC's medical use program be subject to an independent review before implementing any changes to T&E requirements.

Comments: (15-6) (23-18) (33-8) (35-20) (37-19) (38-17) (39-10) (47-19) (49-27) (52-18) (53-20) (55-21) (57-13) (58-4-11) (60-20) (63-26) (65-17)

20. Comments on Public Participation

The NRC received several comments requesting an extension of the comment period or expressing appreciation that a 30-day extension was granted. Several organizations referenced comments submitted in response to NRC's request for public input dated October 29, 2018 (83 FR 54380); others noted that their future activities related to the process of care and workflow for radiopharmaceuticals would be shared with the NRC when finalized.

Comments: (1-3-2) (1-14-1) (49-1) (49-4) (59-3)

21. Comments on Issues Out of Scope

One commenter requested a change to a Wisconsin administrative code, one commenter described an upcoming radiopharmaceutical workshop, one commenter expressed support for conforming changes to medical modalities other than radiopharmaceuticals.

Comments: (21-2) (49-3) (60-2)

Table 2. Individuals Providing Comments During the Second Public Comment Period

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Adams, Mark		reg.gov (ML19190A190)	0062
Agarwal, Ankit		reg.gov (ML19190A190)	0062
Akaike, Gensuke		reg.gov (ML19190A195)	0063
Allen-Auerbach, Martin		reg.gov (ML19190A190)	0062
Anderson, Thomas		reg.gov (ML19190A190)	0062
Anonymous, Anonymous		reg.gov (ML07143A075)	0010
Anonymous, Anonymous		reg.gov (ML19130A176)	0003
Anonymous, Anonymous		reg.gov (ML19141A248)	0008
Anonymous, Anonymous		reg.gov (ML19162A004)	0020
Anonymous, Anonymous		reg.gov (ML19165A043)	0022
Anonymous, Anonymous		reg.gov (ML19183A333)	0036
Anonymous, Anonymous		reg.gov (ML19183A337)	0040
Anvekar, Ashish	Acrotech Biopharma	reg.gov (ML19184A607)	0048
Apiah-Kubi, Emmanuel		reg.gov (ML19190A195)	0063
Avram, Anca		reg.gov (ML19190A190)	0062

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Bahri, Shadfar		reg.gov (ML19190A195)	0063
Baldwin, Jon	Nuclear Medicine Technology Certification Board	reg.gov (ML19184A592)	0059
Barron, Bruce		reg.gov (ML19190A190)	0062
Batra, Jaspreet		Meeting Transcript (ML19149A525)	0007-3
Batra, Jaspreet		reg.gov (ML19190A195)	0063
Baxter, Michael	American Pharmacists Association	Meeting Transcript (ML19141A119)	0001-6
Becker, Murray		reg.gov (ML19190A190)	0062
Bennet, K		reg.gov (ML19190A190)	0062
Bjorklund, Jay		reg.gov (ML19147A051)	0011
Blankenship, Beth		Meeting Transcript (ML19141A119)	0001-13
Blue, Carla	CSA Urology Division	reg.gov (ML19157A053)	0013
Brown, Jamie		reg.gov (ML19165A041)	0021
Byun, John		reg.gov (ML19176A426)	0028
Chin, Bennett		reg.gov (ML19157A052)	0012
Colletti, Patrick		reg.gov (ML19190A190)	0062
Collins, Denise		reg.gov (ML19190A190)	0062

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Coury, David	Specialty Networks	reg.gov (ML19172A005)	0024
Crowley, David	North Carolina Department of Health and Human Services	reg.gov (ML19170A073)	0023
Czernin, Johannes		reg.gov (ML19183A344)	0046
Dadparvar, Simin		reg.gov (ML19190A190)	0062
Daignault, Cory		reg.gov (ML19190A190)	0062
Dillehay, Gary		reg.gov (ML19190A190)	0062
Dodd, Gerald		reg.gov (ML19135A009)	0004
Esposito, Giuseppe		reg.gov (ML19190A190)	0062
Flynt, Lesley		reg.gov (ML19190A190)	0062
Franc, Benjamin		reg.gov (ML19190A190)	0062
Galinsky, Dennis		reg.gov (ML19183A340)	0043
Galinsky, Dennis		reg.gov (ML19190A190)	0062
Gershenson, Jonathan P.		reg.gov (ML19190A195)	0063
Ghesani, Munir		Meeting Transcript (ML19141A119)	0001-5
Gleason, Shaemus	Bayer Pharmaceuticals	Meeting Transcript (ML19141A119)	0001-12
Golshan, Kellie		reg.gov (ML19157A188)	0014

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Gould, Kyle		reg.gov (ML19130A175)	0002
Grady, Erin		Meeting Transcript (ML19141A119)	0001-14
Grady, Erin	American College of Nuclear Medicine	reg.gov (ML19183A336)	0039
Greenspan, Bennett		Meeting Transcript (ML19141A119)	0001-3
Greenspan, Bennett		reg.gov (ML19184A081)	0051
Gribbin, Christopher		reg.gov (ML19190A190)	0062
Grice, James	State of Colorado Radiation Control Program	reg.gov (ML19177A330)	0033
Guastella, Michael	Council on Radionuclides and Radiopharmaceuticals	reg.gov (ML19183A335)	0038
Hahn, Kristian		reg.gov (ML19176A423)	0026
Hayrapetian, Artineh		reg.gov (ML19190A195)	0063
Hebert, David	American Association of Nurse Practitioners	reg.gov (ML19184A587)	0054
Heron, Dwight	American College of Radiation Oncology	reg.gov (ML19184A082)	0052
Hertel, Nolan	Health Physics Society	reg.gov (ML19198A315)	0065
Hertzberg, Todd		reg.gov (ML19190A190)	0062
Hille, Kathy		reg.gov (ML19176A425)	0027
Hope, Thomas		reg.gov (ML19190A190)	0062

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Houston, Carol	American Osteopathic College of Radiology	reg.gov (ML19158A454)	0019
Howard, Ty L.	State of Utah Department of Environmental Quality	reg.gov (ML19184A588)	0055
Humphrey, Brad		reg.gov (ML19135A010)	0005
Jadvar, Hossein		reg.gov (ML19190A190)	0062
Jaffe, Robert		reg.gov (ML19190A190)	0062
Jahromi, Amin		reg.gov (ML19176A435)	0032
Jones, Ben	The US Oncology Network	reg.gov (ML19183A342)	0045
Kahn, Mohamed		reg.gov (ML19190A190)	0062
Kempf, Jeffrey		reg.gov (ML19190A190)	0062
Klitzke, Alan		reg.gov (ML19190A190)	0062
Kramer, Brad		reg.gov (ML19176A430)	0031
Lattanze, Ron	Lucerno Dynamics	reg.gov (ML19157A190)	0015
Litvack, Bonnie		reg.gov (ML19190A190)	0062
Lu, Yang		reg.gov (ML19190A190)	0062
Lubin, David		reg.gov (ML19184A080)	0050
Lubin, David		reg.gov (ML19190A195)	0063

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Madara, James	American Medical Association	reg.gov (ML19183A338)	0041
Mahajan, Sonia		reg.gov (ML19190A195)	0063
Mahgerefteh, Samuel		Meeting Transcript (ML19149A525)	0007-1
Mahgerefteh, Samuel		Meeting Transcript (ML19149A525)	0007-4
Mahgerefteh, Samuel		reg.gov (ML19190A190)	0062
Mahgerefteh, Samuel		reg.gov (ML19190A195)	0063
Marchese, Michael		reg.gov (ML19176A429)	0030
Marcus, Carol		reg.gov (ML19157A195)	0017
McCollough, Cynthia H.	American Association of Physicists in Medicine	reg.gov (ML19184A586)	0053
McGinty, Geraldine	American College of Radiology	reg.gov (ML19183A332)	0035
Miletich, Robert		reg.gov (ML19190A190)	0062
Minoshima, Satoshi	Society of Nuclear Medicine and Molecular Imaging	reg.gov (ML19183A336)	0039
Molchanova-Cook, Olga		reg.gov (ML19190A190)	0062
Morrison, Greg	American Society of Radiologic Technologists	reg.gov (ML19183A339)	0042
Neal, Katie	Nuclear Medicine Technology Certification Board	reg.gov (ML19184A592)	0059
Ng, David		reg.gov (ML19190A190)	0062

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Niederkohr, Ryan		reg.gov (ML19190A190)	0062
Odom, Carl		reg.gov (ML19190A190)	0062
Opila, Jennifer	Organization of Agreement States	reg.gov (ML19184A590)	0057
Pace, Michelle	American Osteopathic Board of Radiology	reg.gov (ML19183A341)	0044
Patel, Vijay		reg.gov (ML19157A196)	0018
Peacock, Justin		Meeting Transcript (ML19141A119)	0001-15
Peters, Michael	American College of Radiology	Meeting Transcript (ML19149A525)	0007-5
Pieters, Richard		reg.gov (ML19190A190)	0062
Puritty, Twila		reg.gov (ML19143A074)	0009
Quon, Andrew		reg.gov (ML19190A190)	0062
Ravizzini, Gregory		reg.gov (ML19190A190)	0062
Razmaria, Aria		reg.gov (ML19190A190)	0062
Razmaria, Aria		reg.gov (ML19190A195)	0063
Rege, Sheila		reg.gov (ML19190A190)	0062
Rege, Shiela	American College of Radiation Oncology	reg.gov (ML19184A082)	0052
Reindl, David	Wisconsin Department of Health Services	reg.gov (ML19184A593)	0060

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Richardson, Tim		reg.gov (ML19176A422)	0025
Rubin, Joseph	United Pharmacy Partners	Meeting Transcript (ML19141A119)	0001-11
Savir-Baruch, Bital		reg.gov (ML19190A190)	0062
Schuster, David		reg.gov (ML19135A011)	0006
Schwarzbach, Mitchell		reg.gov (ML19157A194)	0016
Segall, George		Meeting Transcript (ML19141A119)	0001-2
Shariftabrizi, Ahmad		reg.gov (ML19184A589)	0056
Shariftabrizi, Ahmad		reg.gov (ML19190A195)	0063
Sheikh, Arif		Meeting Transcript (ML19141A119)	0001-10
Shuster, David		Meeting Transcript (ML19141A119)	0001-4
Shuster, David		Meeting Transcript (ML19141A119)	0001-8
Siegel, Jeffry		Meeting Transcript (ML19141A119)	0001-16
Silverman, Daniel		reg.gov (ML19190A190)	0062
Silverstein, Roy	American Society of Hematology	reg.gov (ML19190A189)	0061
Smith, Mary		reg.gov (ML19176A427)	0029
Strahle, Brook		reg.gov (ML19183A331)	0034

Commenter	Affiliation (if stated)	Comment Source and Document ID	Correspondence ID
Thevenot, Laura	American Society for Radiation Oncology	reg.gov (ML19184A079)	0049
Thomadsen, Bruce	Joint comments submitted by the following organizations: American Association of Physicist in Medici	Meeting Transcript (ML19141A119)	0001-1
Thomadssen, Bruce		reg.gov (ML19183A334)	0037
Tulchinsky, Mark		reg.gov (ML19190A190)	0062
Tulchinsky, Mark		reg.gov (ML19192A005)	0064
Vinson, Charles	State of Illinois	reg.gov (ML19183A346)	0047
Walter, Steven		Meeting Transcript (ML19141A119)	0001-7
Walter, Steven		Meeting Transcript (ML19141A119)	0001-9
Wang, Steven		reg.gov (ML19190A190)	0062
Witkowski, John	United Pharmacy Partners	Meeting Transcript (ML19149A525)	0007-2
Witkowski, John	United Pharmacy Partners	reg.gov (ML19184A591)	0058
Zhuang, Hongming		reg.gov (ML19190A190)	0062