# POLICY ISSUE
## (Information)

August 28, 2018 SECY-18-0084

FOR: The Commissioners

FROM: Marc L. Dapas, Director
Office of Nuclear Material Safety and Safeguards

SUBJECT: STAFF EVALUATION OF TRAINING AND EXPERIENCE REQUIREMENTS FOR ADMINISTERING DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS IN RESPONSE TO SRM-M170817

PURPOSE:

This paper provides the initial results, status, and next steps related to the U.S. Nuclear Regulatory Commission (NRC) staff's evaluation of training and experience (T&E) requirements for administering different categories of radiopharmaceuticals for which a written directive is required in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material," Subpart E, "Unsealed Byproduct Material—Written Directive Required." This paper also presents the results from outreach conducted to date with medical and regulatory stakeholders, including licensees, Agreement States, and the Advisory Committee on the Medical Uses of Isotopes (ACMUI). This paper does not address any new commitments or resource implications.

SUMMARY:

In the August 17, 2017 staff requirements memorandum (SRM) approving the final rule revising 10 CFR Part 35, the Commission directed the NRC staff to evaluate: (1) whether it makes sense to establish tailored T&E requirements for different categories of radiopharmaceuticals, (2) how those categories should be determined (such as by risks posed by groups of radionuclides or by delivery method), (3) what the appropriate T&E requirements would be for each category, and

CONTACTS: Irene Wu, NMSS/MSST
(301) 415-1951

Maryann Ayoade, NMSS/MSST
(301) 415-0862

(4) whether those requirements should be based on hours of T&E or focused more on competency.[1]

In response to the SRM, the NRC staff evaluated the knowledge topics that should be covered by the T&E requirements in 10 CFR Part 35 Subpart E and then solicited feedback from medical and regulatory stakeholders in that regard. The NRC staff determined from this evaluation that it may be feasible to establish tailored T&E requirements for categories of radiopharmaceuticals under 10 CFR Part 35 Subpart E. This could be accomplished by creating an alternative means of approving the limited administration of certain categories of radiopharmaceuticals (i.e., limited authorized user (AU) status). The NRC staff also considered some initial options for how these categories could be determined and what the appropriate T&E requirements could be for each category. The NRC staff also determined that a competency-based approach to the T&E requirements for a limited AU should be considered. The NRC staff plans to conduct more extensive outreach with the medical community focused on how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, and how the T&E requirements should be met (e.g., hours of training, demonstration of competency). As part of that outreach, the NRC staff will consider whether a competency-based approach makes sense for 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."

BACKGROUND:

Four groups of T&E requirements currently exist under 10 CFR Part 35 Subpart E: (1) use of all unsealed byproduct material for which a written directive is required (10 CFR 35.390); (2) oral administration of less than or equal to 33 millicuries of sodium iodide I-131 requiring a written directive (10 CFR 35.392); (3) oral administration of greater than 33 millicuries of sodium iodide I-131 requiring a written directive (10 CFR 35.394); and (4) parenteral administration of any radiopharmaceutical requiring a written directive (10 CFR 35.396). The T&E requirements in 10 CFR 35.390 provide three ways that a physician may be authorized to administer unsealed byproduct material or radiopharmaceuticals requiring a written directive. A physician may: (1) be certified by a medical specialty board, whose certification process is recognized by the NRC or an Agreement State; (2) satisfy the T&E requirements via an alternate pathway; or (3) be previously identified as an AU on an NRC or Agreement State license or permit. The board certification pathway requires that the physician successfully complete residency training and pass an examination that tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required. The alternate pathway consists of completing a structured educational program and supervised work experience (i.e., seminars, online training, vendor training) totaling 700 hours, including a minimum of 200 hours of classroom and laboratory training and 500 hours of supervised work experience. The alternate pathway requires that a proposed AU receive a preceptor's attestation that the proposed AU has satisfactorily completed the T&E requirements and has demonstrated the ability to function independently as an AU for the medical uses authorized under 10 CFR 35.300. Preceptor attestation is *not* required if the

[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 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML17229B283). The 10 CFR Part 35 rule addressed by this SRM was provided to the Commission in SECY-16-0080, "Final Rule: Medical Use of Byproduct Material—Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-A163)," dated June 17, 2016 (ADAMS Accession No. ML16123A342).

physician is certified by a medical specialty board or has been previously identified as an AU for medical uses authorized under 10 CR 35.300 on an NRC or Agreement State license or permit.

Since the T&E requirements were amended in 2002 (67 FR 62872; October 9, 2002) and subsequently in 2005 (70 FR 16336; March 30, 2005),[2] stakeholders have raised concerns about the effects of T&E requirements in 10 CFR 35.390 on patient access to certain therapeutic radiopharmaceuticals.[3] Specifically, some stakeholders have asserted that the 700-hour requirement is overly burdensome for physicians who are not certified by a medical specialty board and that the extensive requirements have resulted in a shortage of AUs.[4] As a result, from 2015 to 2016, in separate efforts, the NRC staff and the ACMUI independently reviewed the T&E requirements for the medical uses authorized under 10 CFR 35.300. Specifically, the NRC staff reviewed the regulatory basis and comments received on past rulemakings related to the medical use of byproduct material and did not identify any new information that would call into question the basis of the existing requirements.[5] As a result, the NRC staff did not propose any changes to the regulations at the time.

The ACMUI, in its final report "ACMUI Sub-Committee Final Report on Training & Experience for Authorized Users of Alpha and Beta Emitters under 10 CFR 35.390," dated March 16, 2016 (ADAMS Accession No. ML16089A271) in relation to its effort to evaluate T&E requirements, concluded that no change to the requirements was warranted and that the current requirement of 700 hours for AUs does not adversely affect patient access to therapeutic radiopharmaceuticals. Moreover, the ACMUI noted in that report that even in large metropolitan areas and large medical centers, both of which have large numbers of AUs, certain therapeutic radiopharmaceuticals were used infrequently, indicating that factors other than the availability of AUs were dictating choices of treatment. In that report, the ACMUI recommended that a subcommittee be formed with the specific charge of periodically reviewing the T&E requirements currently in effect and making recommendations for changes as warranted.

In 2016, the ACMUI formed a subcommittee to periodically review the T&E requirements for all medical modalities (unsealed and sealed byproduct material) in 10 CFR 35.100, 35.200, 35.300,

---

[2] In 2002, the Part 35 rule was amended in its entirety (the rule was published on April 24, 2002 (67 FR 20249), and was superseded by an amended rule that corrected typographic and editorial errors on October 24, 2002 (67 FR 62872). The changes included, among other things, establishment of new T&E requirements (e.g., 700 hours of combined classroom/lab training and supervised work experience for modalities requiring a written directive) and provisions for recognition of medical and other specialty boards. In 2005, the rule was amended to change provisions related to the use of preceptor attestations and certain specialty boards' certifications: specifically, attestations were separated from the board certifications as a means of demonstrating proficiency, and most board certified individuals (except board certification processes recognized under 10 CFR 35.392 and 35.394) were required to provide documentation of clinical experience and attestations in addition to their board certifications. No changes were made to the minimum hours required for classroom and lab training or supervised work experience that were established in the 2005 rule.

[3] Stakeholders raised concerns in the petition for rulemaking submitted by William Stein III, M.D. (PRM-35-19) (71 FR 34285; June 14, 2006) and in the comments on the proposed rule to amend the regulations related to the medical use of byproduct material (79 FR 42410; July 21, 2014). The NRC responded to those comments in the Denial of Petition for Rulemaking (72 FR 60285; October 24, 2007) and in the final rule (83 FR 33046; July 16, 2018), respectively.

[4] These concerns were also raised by stakeholders during the ACMUI meetings held on March 10, 2016 (transcript can be found in ADAMS Accession No. ML16109A042) and on October 7, 2016 (transcript can be found in ADAMS Accession No. ML16357A688).

[5] The T&E requirements in 10 CFR Part 35 related to radiopharmaceutical therapies were amended in 1998 (63 FR 43516; August 13, 1998), 2002 (67 FR 20249; April 24, 2002), 2005 (70 FR 16336; March 30, 2005), and 2018 (83 FR 33046; July 16, 2018). Comments were received and reviewed in response to these rulemaking efforts.

35.400, 35.500, 35.600, and 35.1000, beginning with review of 10 CFR 35.300, and determine if changes are needed. As noted in its status report dated September 16, 2016 (ADAMS Accession No. ML17066A442), this subcommittee was formed in response to: (1) continued concerns raised by stakeholders regarding patient access to radiopharmaceuticals, (2) development of new radiopharmaceuticals since the T&E requirements, which included the 700 hours, went into effect on October 24, 2002 (67 FR 62872; October 9, 2002),[6] and (3) a shift in the educational paradigm in the medical specialty training infrastructure from hours and experience to one that is more competency-based. The subcommittee provided the NRC staff with its draft interim report (ADAMS Accession No. ML18051A725) dated February 19, 2018, and discussed the report with the full committee in a public teleconference on March 1, 2018. In its report, the subcommittee expressed concerns about the decrease in the number of nuclear medicine physicians in recent years,[7] noting that this could be a problem in the future. The subcommittee also indicated that while it is difficult to judge the effect of this decline on patient access, there is no data to suggest that "there is a surplus [of AUs], nor have future needs been addressed." Therefore, the subcommittee concluded that the creation of a new alternative approach for AUs under 10 CFR 35.390 should be reconsidered, and the subcommittee committed to continue its work in this area.

DISCUSSION:

To conduct the evaluation directed by the Commission in SRM-M170817, the NRC staff first evaluated the knowledge that an AU needs to possess to safely administer any radiopharmaceutical, developed a list of knowledge topics based on the outcome of this evaluation, and then conducted outreach with various medical and regulatory stakeholders to confirm the accuracy and validity of the knowledge topics as well as to assess if the scope of the topics was adequate. The stakeholder feedback was used to inform the NRC staff's analysis of whether the classroom/laboratory portion of the current T&E requirements (200 hours) was appropriate for administering any radiopharmaceutical, regardless of how a radiopharmaceutical might be categorized (i.e., based on risk factors; delivery method; type of emission including alpha, beta, gamma, and low energy photon; and preparation method such as single-unit or multiple dose).[8]

In developing the list of knowledge topics, the NRC staff used, as a starting point, the specific areas listed in 10 CFR 35.390 (radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, chemistry of byproduct material for medical use, and radiation biology) and considered additional topics pertaining to the depth of knowledge that AUs need to possess to safely administer radiopharmaceuticals.[9] The NRC staff then developed a questionnaire covering four main areas: (1) the fundamental knowledge necessary for administering any radiopharmaceutical under 10 CFR 35.390, (2) the

---

[6] This *Federal Register* Notice (FRN) corrects typographic and editorial errors found in the final rule appearing in the *Federal Register* on April 24, 2002 (67 FR 20249).

[7] The American Board of Nuclear Medicine (ABNM) provided a comment letter (ADAMS Accession No. ML18221A170) in response to the March 1, 2018, ACMUI public meeting. In that letter, ABNM indicated that the number of certificates issued each year had been relatively constant from 1977 to 2015. The average number of certificates issued each year was 72 during this time (range 50 – 107). The ABNM noted that it had issued 43 initial certificates in 2016, and 49 certificates in 2017. No data is available for 2018 since the certification examination will not be administered until October.

[8] The NRC staff determined that there was a minimum set of knowledge topics required for the administration of radiopharmaceuticals, and concluded that this knowledge could not be reduced for limited uses of radiopharmaceuticals.

[9] These additional topics included general patient release determination, medical events, and other NRC requirements.

additional specific knowledge necessary for administering specific types of radiopharmaceuticals under 10 CFR 35.390, (3) how best to acquire this knowledge, and (4) how this knowledge and ability to function independently should best be evaluated. The NRC staff sent the questionnaire (ADAMS Accession No. ML18108A266) to nine non-Federal stakeholders (a professional medical society, a medical specialty board, a trade association, five licensees, and an Agreement State) and seven Federal licensees in the medical community. The NRC staff received responses from six of the non-Federal medical stakeholders including three medical licensees, one Agreement State, a professional society, and a trade organization, and received responses from three of the seven Federal licensee stakeholders. The comments are summarized below and can be found in ADAMS (Accession No. ML18130A786).

*Fundamental Knowledge for Administering Any Radiopharmaceutical and Specific Knowledge for Administering Specific Types of Radiopharmaceuticals*

Most stakeholders responded that the list of knowledge topics included in the questionnaire was appropriate and that the majority of these topics are covered in sufficient depth during a physician's residency program for a specialty board certification. Several stakeholders stated that the detailed list of knowledge topics should not be incorporated into the T&E regulations and instead should be provided in guidance documents.

The NRC staff also received comments on whether and how the T&E requirements for administration of radiopharmaceuticals should be categorized. One stakeholder suggested creating an alternative means by which a limited AU status could be obtained for specific radiopharmaceuticals. Similarly, another stakeholder suggested that training should be contingent upon the characteristics and use of the radiopharmaceutical and balancing safety and risk to patients, workers, and the public. Specifically, this stakeholder suggested that radiopharmaceuticals that are of lower risk should have reduced training requirements as compared to radiopharmaceuticals that are of higher risk. Another stakeholder suggested that the NRC adopt a specific provision for administering intravenous therapeutic radiopharmaceuticals containing alpha- and beta-emitting radioisotopes that have been prepared by a licensed nuclear pharmacist in a state-licensed radiopharmacy and dispensed to physicians as patient-ready doses.

*Means of Acquiring Knowledge*

For this question, the responses by stakeholders were more varied. Some stakeholders indicated that the knowledge would mostly be acquired in a physician's residency or fellowship program or through a combination of classroom and laboratory training and hands-on experience, and thus, no change to the T&E regulations is needed. Two stakeholders indicated that the NRC and Agreement State regulators should not focus on how to best acquire the necessary knowledge; rather, they should focus on whether or not physicians possess that knowledge. Two stakeholders suggested that the alternate pathway provision that exists in the current T&E requirements should be eliminated and that the NRC should require board certification, with the T&E gained through medical school and a residency program, as the only method of becoming an AU. Another stakeholder stated that the alternate pathway should be maintained to provide flexibility due to the length of the board certification process. One stakeholder indicated that the requirement of supervised clinical experience with at least three administrations of each type of therapy is reasonable. Another stakeholder indicated that the current number of cases (three) required for iodine-131 is too few.

*Evaluation of Knowledge, Skills, and Abilities*

Stakeholder responses to the question about how knowledge, skills, and abilities should be evaluated also varied. Some stakeholders suggested that the medical specialty boards create and administer an examination to test competency; specifically, one of those stakeholders suggested that the American Board of Nuclear Medicine have that responsibility. One stakeholder stated that the alternate pathway involving preceptor attestation that currently exists in the T&E requirements should be maintained. While most of the stakeholders offered that a written examination would be an appropriate method to determine if a physician has demonstrated the ability to function independently as an AU, one stakeholder was not sure if a written examination was a reliable evaluation by itself. In addition, another stakeholder did not support a practical examination because these examinations are difficult to standardize on a national basis. Another stakeholder suggested that the professional medical societies may be able to administer an examination as a method to evaluate knowledge, skills, and abilities, and a different stakeholder suggested that the NRC could administer such an examination. The overarching comment made by most of the stakeholders was that the NRC should collaborate with knowledgeable external entities to determine how the knowledge and ability to function independently as an AU should best be evaluated.

*Staff Analysis*

In addition to considering the potential means of categorizing radiopharmaceuticals identified by the Commission in its SRM (i.e., risks posed by groups of radionuclides and delivery method), the NRC staff evaluated two additional categorization approaches: type of emission and preparation method. The staff also considered combinations of these categories. In addition, the staff evaluated radiopharmaceuticals that are currently available and those known to be under development within the scope of 10 CFR Part 35 Subpart E, and determined that several of these radiopharmaceuticals possess unique characteristics and/or would fall under multiple categories. For example, lutetium-177 dotatate, which was approved by the U.S. Food and Drug Administration in January 2018, is a single-dose radiopharmaceutical used primarily for its beta emission, is delivered parenterally, and has some unique radiation properties that require specific knowledge. Its properties include a high-energy gamma emission in addition to the beta emission, and its administration process is unique in that it requires administration of a dose-blocking agent to prevent overexposure to the kidneys, and involves the potential for the presence of a long-lived radionuclide impurity. These elements present complexities in developing categories and demonstrate the unique factors that need to be considered in establishing categories.

As a benchmark for the appropriate content and number of hours of classroom training for authorization of physicians to administer radiopharmaceuticals, the NRC staff consulted with the Technical Training Center staff who develop courses with similar content. Through those discussions, the NRC staff estimated that it would take approximately 90 to 300 hours of classroom training to cover the knowledge topics developed by the NRC staff, and endorsed by the stakeholders that the NRC staff engaged. This estimate was based on existing NRC courses that mostly cover the fundamental knowledge topics. However, the estimate did not take into account the redundancies in the training topics that exist between many of these courses. In addition, the estimate only included classroom training and limited hands-on exercises that can be conducted in a classroom or typical training facility setting, and did not include the hours for applicable laboratory training involving patient administrations that would have to be accomplished in a clinical setting. Based on the NRC staff's evaluation of the current T&E requirements in combination with the responses to the questionnaire, the NRC staff

determined that the number of classroom and laboratory training hours under the alternate pathway in the current T&E requirements (200 hours) is reasonable to acquire the fundamental knowledge that an AU would need to administer any radiopharmaceutical, regardless of its category.

Additionally, the NRC staff considered the appropriate number of hours of work experience beyond the classroom and laboratory training that an AU would need to safely administer radiopharmaceuticals by category and determined that for a limited AU, it may be possible to tailor the number of hours of work experience by category. The rationale for this conclusion was based on the range of work experience that is currently applied to AUs of all modalities, and the fact that a limited scope of work experience could reasonably be applied to limited uses (e.g., an AU administering only a certain category of radiopharmaceuticals would only need work experience in relation to that specific category, whereas an AU administering multiple types of radiopharmaceuticals that collectively fall under more than one category would need work experience in all of the relevant categories).

In addition to evaluating the comments received from external stakeholders with respect to how a physician's knowledge and ability to function independently should be evaluated, the NRC staff considered how the NRC administers the reactor operator licensing program and whether certain aspects of that program could be used to inform the development of a competency-based approach for the T&E requirements for a limited AU. Specifically, the NRC staff considered the relevant requirements and guidance, how operator license examinations are developed and administered, and how the NRC qualifies examiners. The staff noted that the operator licensing program was developed with substantial input from the regulated community, including the Institute of Nuclear Power Operations and the Nuclear Energy Institute. The staff also considered the resources necessary to implement the NRC's operator licensing program in assessing the potential for a similar program to approve a limited AU.

The comments received from external stakeholders coupled with an understanding of the reactor operator licensing program helped to inform the approaches considered by the NRC staff for a limited AU to demonstrate the knowledge, skills, and abilities to function independently. One option is to require a written examination to demonstrate competency, in lieu of classroom and laboratory training, combined with preceptor attestation for work experience. This examination could be developed by medical specialty boards, professional medical societies, or other experienced training professionals, then reviewed and approved by the NRC. Another option is to require a written examination developed and administered by the NRC. This option was not supported by the various stakeholders that the NRC staff has engaged to date and would require additional resources for the NRC staff to create the infrastructure, processes, and procedures to write and administer the examinations. The staff also discussed the option of the medical industry developing new medical specialty boards for the NRC to consider for recognition and certification under 10 CFR Part 35. Finally, the NRC staff considered the possibility of a hybrid approach where the number of classroom and laboratory training hours could be reduced when combined with a competency demonstration (i.e., an examination and demonstration of work experience). In considering an examination in lieu of hours of classroom and laboratory training, the NRC staff recognized that this could be used for all AUs.

In summary, based on the information considered to date, the NRC staff has concluded that it may be feasible to establish tailored T&E requirements for the limited administration of certain categories of radiopharmaceuticals (i.e., a limited AU status). In establishing these categories, care would need to be taken to ensure that the unique risks of various radiopharmaceuticals are

fully considered, and that the categories established are distinct enough that a specific radiopharmaceutical does not fall under more than one category. Several options for developing categories of radiopharmaceuticals are feasible, and the NRC staff intends to further engage a wider range of stakeholders to develop a preferred option. In considering the appropriate T&E requirements, the NRC staff has identified an initial list of knowledge topics that were mostly supported by the stakeholders engaged to date. Based on the NRC staff's initial outreach, it appears that a competency-based approach to the T&E requirements for a limited AU may be feasible.

The NRC staff plans to conduct further outreach with the medical community, focused on how to tailor the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, and how the T&E requirements should be met (e.g., hours of training or demonstration of competency). As part of that outreach, the staff will consider whether a competency-based approach makes sense for the T&E requirements for all the medical uses authorized under 10 CFR 35.300, including for limited AU uses. That outreach, at a minimum, will include a *Federal Register* notice with specific questions, several public meetings and webinars, and presentations to professional medical societies. These outreach activities will be conducted in accordance with budgeted resources and agency priorities. If, based on this feedback, the NRC staff proposes to revise the T&E requirements in 10 CFR Part 35 Subpart E, the staff will provide a rulemaking plan to the Commission. These activities will also be informed by input from the ACMUI, including the results of its independent assessment of the T&E requirements for the medical uses authorized under 10 CFR 35.300, which is expected to be completed in Spring 2019.

*Agreement State Coordination*

The NRC staff solicited and received feedback on the initial outreach questionnaire from one Agreement State. The staff also solicited feedback from the Agreement States and the Organization of Agreement States (OAS) board on the preliminary results and conclusions drawn from the staff's evaluation, and received comments from six Agreement States and the OAS board. One Agreement State supported the NRC staff's conclusion that it may be feasible to establish tailored T&E requirements for the limited administration of certain categories of radiopharmaceuticals. The OAS board and five Agreement States did not support the idea of creating another subcategory of AUs because it would likely add another layer of complication when approving AUs. The OAS board and five Agreement States indicated that the focus of the NRC and Agreement States as regulators should be on radiation safety and protection, and that the regulatory agencies should not allow the oversight approach to impinge on the practice of medicine.

*Advisory Committee on Medical Uses of Isotopes Coordination*

Based on the ACMUI's assessment of the staff's preliminary evaluation of T&E requirements, the Committee agreed with the NRC staff's conclusion that a limited AU status for radionuclide therapy is possible, but that there must be a clear outline for the individual's scope of practice (Enclosure 1). The ACMUI also agreed that additional stakeholder outreach is needed. The ACMUI recommended that the NRC staff conduct ongoing monitoring for the potential incidence of an AU shortage for the medical uses authorized under 10 CFR 35.300. The staff will consider this recommendation as part of its planned outreach activities.

CONCLUSION:

The NRC staff concluded that it may be feasible to establish tailored T&E requirements for different categories of radiopharmaceuticals under 10 CFR Part 35 Subpart E and to create a means of authorizing the administration of certain categories of radiopharmaceuticals (i.e., limited AU status). In addition, the staff concluded that there are viable options for creating a competency-based approach to demonstrate acceptable T&E for limited AUs. The staff plans to conduct more extensive outreach with the medical community focused on assessing options related to tailoring the T&E requirements to establish a limited AU status, the specific T&E requirements that should apply, and determining how the T&E requirements should be met (e.g., hours of training, demonstration of competency, or some combination of the two). As part of that outreach, the staff will consider whether a competency-based approach makes sense for demonstrating the requisite knowledge level with respect to the T&E requirements for all the medical uses authorized under 10 CFR 35.300. These outreach activities will be conducted in accordance with budgeted resources and agency priorities. The staff will continue to engage the ACMUI and will keep the Commission informed of its outreach efforts through the semiannual updates directed by SRM-M170817. The staff will raise any policy issues to the Commission in a timely manner, and will provide a rulemaking plan if the staff determines, based on its assessment, that it is appropriate to propose changes to the current T&E requirements.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objections.

Marc L. Dapas, Director
Office of Nuclear Material Safety
and Safeguards

Enclosure:
Advisory Committee on the Medical Uses of
Isotopes Comments on the Draft SECY Paper
Subcommittee Final Report

SUBJECT: STAFF EVALUATION OF TRAINING AND EXPERIENCE REQUIREMENTS FOR ADMINISTERING DIFFERENT CATEGORIES OF RADIOPHARMACEUTICALS IN RESPONSE TO SRM-M170817

**ML18135A276(P)**

| **OFFICE** | NMSS/MSST | NMSS/MSST | NMSS/MSST | NMSS/MSST | NMSS/MSST |
|---|---|---|---|---|---|
| **NAME** | IWu | MAyoade | LDimmick | DBollock | AKock |
| **DATE** | 05/15/18 | 05/15/18 | 05/15/18 | 05/16/18 | 05/31/18 |
| **OFFICE** | OGC | NMSS/MSST | NMSS | | |
| **NAME** | TCampbell | SAtack for DCollins | MDapas | | |
| **DATE** | 08/24/18 | 08/14/18 | 08/21/18 | | |

**OFFICIAL RECORD COPY**