U.S. Nuclear Regulatory Commission
Advisory Committee on the Medical Uses of Isotopes

Subcommittee on ADVANCE Act

Interim Draft Report
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Subcommittee Charge: The subcommittee will provide recommendations and advice to support the Nuclear Regulatory Commission's (NRC) implementation of the ADVANCE Act.

Background: The subcommittee was established at the Spring 2025 ACMUI meeting in April 2025. The subcommittee will assist the NRC to develop mission statement implementation guidance as required by Section 501 of the ADVANCE Act.

The subcommittee will focus on the following objectives:

1. Mission Statement Alignment: Evaluate the ADVANCE Act's mission statement and guidance and provide recommendations, if any, to ensure the NRC's medical regulatory framework complies with the mission statement.
2. Efficiency Improvements: Identify recommendations, if any, for the NRC to streamline medical licensing as mandated by the ADVANCE Act.
3. Emerging Issues: Monitor and assess any emerging issues arising from the ADVANCE Act's implementation that may require further ACMUI exploration or the formation of additional subcommittees.

Discussion: The previous NRC mission statement was:

> The NRC licenses and regulates the nation's civilian use of radioactive materials to provide reasonable assurance of adequate protection of public health and safety and to promote the common defence and security and to protect the environment.

In January 2025, the NRC approved an updating mission statement, as directed by the ADVANCE Act. This updated mission statement is:

> The NRC protects public health and safety and advances the nation's common defense and security by enabling the safe and secure use and deployment of civilian nuclear energy technologies and radioactive materials through efficient and reliable licensing, oversight, and regulation for the benefit of society and the environment.

The ACMUI subcommittee found the NRC's medical regulatory framework complies with the updated NRC's mission statement as it protects public health and safety and advances the nation's common defense and security by enabling the safe and secure medical use of

byproduct material through generally efficient and licensing, oversight, and regulation for the benefit of society.

However, in spirit of the updated mission and second charge, the subcommittee examined the NRC's licensing practices in order to determine possible recommendations for improving efficiency, timeliness and effectiveness, without compromising safety for radiation workers or members of the public. All possibilities were encouraged and considered to be inclusive and meaningful. The subcommittee evaluated the ideas based on their importance (likely impact on improved efficiency and reduced waste) and feasibility (the amount of additional effort or potential cost required to make changes in the proposed area and/or other barriers to change). Possible recommendations that met the criteria of importance (relevant and impactful) and feasibility for implementation were included in this report. Proposed recommendations should save the NRC and licensees time and expense thus making the Commission more effective, efficient, timely, and should not compromise the NRC's mission to protect public health and safety.

Summary of Findings

Charge # 1: The updated NRC's mission statement is aligned with the NRC's medical regulatory framework, and the subcommittee has no recommendations regarding this charge.

Charge # 2: The subcommittee has the following recommendations for consideration by the NRC.

The subcommittee met and reviewed aspects of the current regulations and licensing requirements that add significant administrative burden but do not contribute significantly to safety.

Under licensing issues, an inordinate amount of administrative time is spent listing and updating Authorized Users (AUs) for 10 CFR 35.100 and 35.200 or maintaining medical physicists on medical radioactive materials (RAM) licenses. The NRC 313a AUT form has also been noted to be confusing and difficult to complete, and the scope of applications covered by 10 CFR 35.300 and 35.390 is not well understood. Administrative burdens for amendments and renewals have low thresholds and relatively high frequencies which could be adjusted. Emerging technologies often remain covered under 10 CFR 35.1000 and could be moved to intended 10 CFR 35 designations, simplifying ongoing licensing of new AUs.

During the subcommittee evaluation of regulations and oversight, Executive Order 14300 was issued directing the NRC to undertake a review and wholesale revision of its regulations and guidance documents. As staff is actively working on this activity, the subcommittee decided to wait until it could be provided with NRC staff's proposed changes to regulations to avoid conflicts with staff's efforts.

Under administrative issues, an area that needs improvement is medical event reporting. For the ACMUI, comprehensive information is not available, including the total number of cases performed to put the event rate into perspective. This results in a poor understanding of the safety issues and inefficient use of the NRC and ACMUI's time during the review process.

Charge #3: The subcommittee will continue to assess any emerging issues arising from the ADVANCE Act's implementation and NRC staff proposed regulations and guidance in response to Executive Order 14300 and provide recommendations as appropriate. Therefore, the subcommittee proposes to remain active.

Specific Findings for Charge 2: The subcommittee has recommendations in three different categories – Licensing, Inspections and Administrative. Recommendations are provided by importance ranking with feasibility ranking provided.

A. Licensing:

1. **The ACMUI supports eliminating listing individual physician authorized users for 10 CFR 35.100, 35.200 and 35.500 on medical radioactive materials licenses.**

Licensing Ranking: Importance 1, Feasibility 2.

Safety Basis:

A. 35.100, 35.200, and 35.500 authorized users rarely personally handle radioactive material.
B. Administrations of RAM for diagnostic use are low-risk with typical patient doses ranging from 2 to 30 mSv. And for PET typical patient doses ranging 5 to 30 mSv.
C. Diagnostic administrations of RAM are "template procedures" (not customized to individual patients), with standard protocols.
D. Diagnostic radioactive material is rarely associated with medical events.
    - Since January 1, 2015, there have been eight reported medical events with Tc-99m, five of which involved administration of a bulk dose instead of patient unit dose. The other three were skin doses >50 rem for wrong drug or leakage.
    - In addition, since January 1, 2015, there have been two reported medical events with F-18. One was administration of a bulk dose, and other was due to external contamination (part of dose squirted onto patient shirt).
    - Since January 1, 2015, there have been two reported medical events with I-123. Both had wrong activity ordered (approximately an order of magnitude larger than intended).

Administrative Savings: Licensees submit many radioactive materials notifications and amendments for diagnostic physician authorized users. The simplest amendment request involves an estimated four hours of administrative and professional staff time between receiving the mail, logging in licensing database, reviewing the request, drafting the license, writing a transmittal letter, and distributing the final documents. More complex or deficient requests require additional time to process. Additionally, when a hospital system changes the physician group it contracts with, it is common for regulatory agencies to receive numerous simultaneous requests to amend diagnostic authorized users on medical licenses. In these cases, the administrative savings by not listing diagnostic authorized users on medical licenses would be multiplied.

Other Considerations:

A. The Subcommittee discussed whether all physician authorized users should be removed from RAM licenses. However, due to the inherent risks involved with therapeutic material and risks of permanent damage to patient, physician authorized users for 10 CFR 35.300, 35.400, 35.600, and 35.1000 should remain listed on licenses.
B. Licensees would still be responsible to ensure diagnostic authorized users meet training and experience and could maintain a list of approved users, similar to how 10 CFR 34 includes specific training requirements for radiographers and requires radiography licensees to keep a list of approved radiographers.

2. **The ACMUI supports clarification and modification of the NRC 313a Forms, primarily NRC 313a (AUT). Specific recommendations include clarification of Table 3c on NRC 313a AUT forms to make parenteral supervised case requirement more explicit (NRC 313a AUT form – clarify for licensees that only 3 total supervised cases are needed rather than 3 supervised cases per type of parenteral administrations) and draft clearer and streamlined NRC 313a forms to make implementation less challenging for NRC and licensees.**

Licensing Ranking: Importance 2, Feasibility 1.

Safety Basis:

A. Currently the NRC Form 313A (AUT) is complicated to fill out, with multiple possible attestation pathways and multiple steps/sections. This should be simplified to a single acknowledgement of proposed AU training and experience, case requirements, and radiation safety duties, as the proposed AU must meet all of these requirements in any case.

B. An outsized amount of the NRC Form 313A (AUT) is spent on differentiating between I-131 administrations <= 33mCi or >33 mCi and parenteral administration of all other forms of radioactive byproduct material. The distinction between these dose levels should be eliminated as they have no practical impact on safety, only on clinical practice of medicine. The form should be simplified to at most oral and parenteral pathways.

C. For Training and Experience, “clock hours” should be replaced by simple confirmation of whether or not the training was received, as there are no clear specifications for “clock hour” requirements, only the total hours of training.

D. Clarification of licensee requirements for the NRC 313a forms through guidance will streamline the process and ensure that only appropriately trained and credentialed AUs are able to perform the full range of procedures covered by 35.300. Without guidance, AUs may be limited to performing only those administrations in which they had documented training experience, instead of being able to perform administrations of the full range of applications under 35.300, which limits patient access to treatment and clinical research into new applications.

E. Streamlined NRC 313a forms will minimize interpretation errors and improve accuracy in drafting these forms by licensees. The result will be more accurate forms with less licensee queries to the NRC thus making the process more efficient as well as timely. Accurate forms are important to maintaining patient safety.

Administrative Savings: Completing the NRC 313a forms are currently perceived as an arduous and confusing process. Removing these would save time and effort on the part of the applicants, their preceptors/training directors and NRC staff. Medical licensees submit numerous license amendments requesting the addition of Authorized Users (AUs) on their medical licenses. Deficient requests require additional time to process and may result in delays to physician authorization.

Other Considerations:

A. If the recommendation is not implemented, qualified potential AUs may be delayed in their approval to deliver therapies to patients or engage in clinical research to improve patient outcomes.

B. The current NRC 313a Forms are adequate but result in confusion, increased time to complete and ineffective communication to the NRC. This may result in additional time spent by the licensee and NRC to resolve license amendments involving the addition of AUs to radioactive materials licenses.

3. **The ACMUI supports radioactive material activity/possession limits for medical licensees based on the amount a licensee can manage safely and effectively rather than limits based on current need. This would reduce the number of license amendments for NRC and Agreement State regulatory organizations.**

Licensing Ranking: Importance 3, Feasibility 5.

Safety Basis:

A. Licensee activity limits can change rapidly due to the nature of clinical and research treatments (volume and novel clinical medical procedures) being performed.

Administrative Savings: Medical licensees submit license amendments requesting changes in the activity or possession limits of radionuclides listed on their medical license. . The simplest amendment request involves an estimated four hours of administrative and professional staff time between receiving the mail, logging in licensing database, reviewing the request, drafting the license, writing a transmittal letter, and distributing the final documents. More complex or deficient requests require additional time to process.

4. **The ACMUI supports moving appropriate emerging technologies to intended 10 CFR 35 designations. In addition, retiring 10 CFR 35.1000 guidance for systems that are not commercially available in the U.S. (e.g., ViewRay, NorthStar RadioGenix) would eliminate the need to maintain guidance for obsolete devices.**

Licensing Ranking: Importance 4, Feasibility 4.

Safety Basis:

A. Some of the emerging technologies (e.g. microspheres) have become standard of care and are no longer emerging technologies.

B. Assimilation of these emerging technologies into their intended 10 CFR 35 designation will streamline the licensing process,(particularly for adding new physician authorized users).

C. Efficiency may be improved because the emerging technologies will be following the regulations in the intended 10 CFR 35 designations rather than the less defined guidance in 10 CFR 35.1000.

D. Licensees and regulators will benefit from more general regulatory requirements for these well-established “emerging” technologies. The regulations would be able to accommodate new devices without the need for device-specific guidance (e.g., recent efforts to license Eye-90 microspheres).

Administrative Savings: NRC staff will not have to develop device-specific licensing guidance for similar new technologies.

5. **The ACMUI supports decreasing frequency of license renewals. Medical licenses are more frequently amended than other RAM license types, mostly due to authorized user changes. Many medical radioactive materials licenses have few procedural modifications and therefore license amendments, thus performing a license renewal provides minimal benefit with all the necessary effort required by the NRC to renew the license. Instead of performing license renewals on a time period requirement, the recommendation is to renew licenses after 25 amendments or "tie downs".**

Licensing Ranking: Importance 5, Feasibility 3.

Safety Basis:

A. License renewals will be dictated or limited by the number of license modifications to prevent excessive "tie downs". Significant numbers of "tie downs" create unnecessary complexity for the NRC and licensees, and the greater the number of tie-downs, the more difficult it is for regulators and licensees to know what commitments have been superseded.

B. Safety considerations will still be included in the license via amendments or "tie downs".

Administrative Savings: NRC would benefit from reduced time spent processing license renewals because of the lower rate at which renewals would be required. Licensees would not need to complete renewal applications as often.

Other Considerations:

A. Current license renewal is every fifteen years and other frequencies or strategies were considered. Decreased renewal frequencies were not selected due to increased likelihood of disproportionate numbers of "tie downs" and increasing the renewal frequency would create more effort without advantages.

B. Elimination of renewals would create excessive "tie downs" that would make the licensee difficult to inspect.

C. The most significant benefit will be observed by having license renewals required when a certain number of amendments or tie downs are reached rather than requiring then at a specific frequency based on a number of years.

B. Inspections:

The subcommittee will continue to evaluate this area of opportunity and will formulate recommendations as appropriate.

C. Administrative:

1. **The ACMUI supports development of a medical event reporting form to support submission of the appropriate information to evaluate medical events.**

Safety Basis:

A. Complete and more detailed information will enable the NRC and ACMUI to more effectively evaluate medical events, determine safety concerns, decide if corrective action is appropriate and identify trends.

B. Further understanding of medical events will allow the NRC to more effectively manage medical events and provide timely guidance for licensees in order to improve patient safety.

C. Some NMED database submissions lack the necessary information needed to understand the medical event, which may increase the risk of similar future events and jeopardize patient safety.

Administrative Savings: NRC staff must request additional information from licensees via phone or email inquiries. The time invested in this iterative process is inefficient and not timely thus making responses to medical events tardy. Each of these medical events is a different situation and time required is difficult to quantify.

Charge # 3: The subcommittee will continue to monitor and assess any emerging issues arising from the ADVANCE Act's implementation. There are no additional recommendations at this time that require further ACMUI exploration or the formation of additional subcommittees.

Concluding Remarks: The ACMUI subcommittee on ADVANCE Act appreciates the opportunity to provide recommendations and advice to support the NRC's implementation of the ADVANCE Act. The subcommittee welcomes any comments and/or recommendations.

Respectfully submitted, September 30, 2025
Subcommittee on ADVANCE Act
Advisory Committee on the Medical Uses of Isotopes (ACMUI)
U.S. Nuclear Regulatory Commission (NRC)