U.S. Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Licensing Guidance Alpha Tau Alpha DaRT™ Manual Brachytherapy

Final Report
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The subcommittee thanks the NRC for the opportunity to comment of the Alpha Tau Alpha DaRT™ Manual Brachytherapy Licensing Guidance. All mentions of section numbers refer to this document as shared with the subcommittee.

The subcommittee supports the licensing of Alpha DaRT™ under 35.1000. The diffusion of radioactive particles into the interstitial tissues and blood circulation make this device significantly different from brachytherapy sources such that licensing it under 35.400 would be inappropriate. Similarly, Alpha DaRT™'s delivery via a source placed into tissue differentiates it substantially from radiopharmaceuticals to support not licensing it under 35.300. The subcommittee believes it is appropriate to draw on requirements of 35.400 regarding aspects of Alpha DaRT™ that are similar to brachytherapy and requirements of 35.300 for aspects similar to radiopharmaceuticals.

The subcommittee does not support any specified role for an authorized medical physicist (AMP) in acceptance testing of software for treatment planning (section 6.3). This opinion aligns Alpha Dart™ with brachytherapy treatment planning software requirements in 35.400. However, it should be noted that the subcommittee believes strongly that rigorous acceptance testing of any new software system or modification of existing software system, such as the addition of a new source, be performed by a qualified medical physicist prior to clinical use.

Similarly, the subcommittee does not believe an AMP has any role in training RSOs (section 5.2.2). RSO training should come from the vendor or an RSO already trained in Alpha DaRT™.

Finally, the subcommittee sees no role for an authorized nuclear pharmacist for this device (section 5.2.2). There is no liquid or pill for a pharmacist to manage.

The subcommittee does not support an assessment to assure the sources are not leaking outside the body (section 6.1, 6.5). Since the radioactive particles are traveling through tissue in all directions, it is impossible to assess leakage as opposed to intended radiation distribution from treatment. The concept of leakage does not apply since Alpha DaRT™ is not a sealed source, rather the Ra-224 is adherent to the surface of the source with the Rn-220 gas and subsequent daughters readily diffusing off the device.

Regarding the required surveys required by 10 CFR 35.70 and 35.404 (section 6.5), the subcommittee notes that unlike sealed source brachytherapy, there is a potential of room contamination after the procedure due to the fact that sources are not sealed, but rather, the radioactivity is adherent to the surface of the source and the daughter products diffuse from the source. These two features create the possibility of contamination in the procedure room. Following both the ambient radiation level and contamination survey guidance in NUREG 1556 Volume 9 is recommended. In addition, the subcommittee recommends changing the phrase "survey instrument used" to "radiation detection instrument" to keep this more generic.

The subcommittee does not support assessing the integrity of the source seal (section 6.7). In the subcommittee's opinion, even if the integrity were broken and equilibrium were not reached, the dose delivery would not be affected.

Regarding patient release (section 7.3), the subcommittee recommends changing the following language. Patients should not be released from the licensed facility "if it is *possible* under normal conditions for a seed or seal has a potential to become dislodged" to "if it is *likely* under normal conditions for a seed or seal to become dislodged."

The subcommittee agrees with the definition of Medical Event (section 6.2) for temporary applications of Alpha Dart™. However, if in the future permanent implants are performed, the subcommittee recommends the definition of Medical Event for that application be defined like other permanent brachytherapy as stated in 10 CFR 35.3045.

The requirement that locations where the patient will spend significant time be documented (section 7.4) does add any clear safety benefit. It is unclear what the clinical and safety team at the treating facility will do with this information to enhance radiation safety. The subcommittee recommends removal of the requirement.

Respectfully submitted,

Subcommittee on Alpha DaRT™ Manual Brachytherapy,
Advisory Committee on the Medical Uses of Isotopes,
U.S. Nuclear Regulatory Commission

The ACMUI unanimously approved this report as presented during its public teleconference meeting on December 15, 2021.