UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 14, 2025

ALL AGREEMENT STATES, CONNECTICUT, INDIANA, WEST VIRGINIA

NOTIFICATION OF ISSUANCE OF ALPHA DART REVISION 1, MANUAL BRACHYTHERAPY LICENSING GUIDANCE (STC-25-009)

Purpose: To inform the Agreement States, Connecticut, and Indiana that the U.S. Nuclear Regulatory Commission (NRC) issued the Alpha DaRT Revision 1 Licensing Guidance.

Background: In 2018, the U.S. Food and Drug Administration conditionally approved the Alpha DaRT™ Model series device for temporary implant therapy. The approval was granted under Investigational Device Exemption number G180076. The initial Alpha Tau Alpha DaRT™ Manual Brachytherapy Licensing Guidance (LG) was issued on March 10, 2022.
Due to recent findings related to the sterile packaging, the LG has been updated to address potential risks of radium-224 (Ra-224) and decay progeny contamination within the sealed applicator assembly. Illustrations of the applicator packaging can be reviewed in SS&D MA-1426-D-101-S, published on September 20, 2024.

Revision 1 to Alpha DaRT™ Licensing Guidance was released on February 4, 2025. This document outlines a set of approved regulations and licensing conditions specific to Alpha DaRT™. The revision includes updates to the following sections: (1) device description, (2) surveys, and (3) contamination control.

Enclosure 1 provides the final 10 CFR 35.1000 licensing guidance for Alpha Tau Alpha DaRT™ (ML24324A33). This guidance lists an approved set of regulations and licensing conditions specific to Alpha DaRT™. This guidance should be used in concurrence with NUREG-1556, Volume 9, Revision 3, “Consolidated Guidance About Material Licenses: Program-Specific Guidance about Medical Use Licenses,” which provides overall licensing guidance for all medical uses of byproduct material. Enclosure 2 provides a supporting technical analysis table which includes a list of 10 CFR Part 35 regulations and conditions the NRC has deemed acceptable for the use of Alpha DaRT™. However, as stated in the licensing guidance, applicants may submit alternative list of regulations and specific conditions to be reviewed on a case-by-case basis.

The attached licensing guidance has been posted on NRC’s Medical Licensee Toolkit/Emerging Medical Technologie public website at https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html.

If you have any questions regarding this correspondence, please contact me at (301) 415-3521 or the individual named below:

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Sincerely,


Signed by Giantelli, Adelaide
on 03/14/25

Adelaide S. Giantelli, Branch Chief
State Agreement and Liaison Programs Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety and Safeguards

Enclosures:
1. Alpha DaRT™, Revision 1 Licensing Guidance (ML24324A33)
2. Consolidated Technical Analysis (ML24338A041)

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