



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

December 10, 2024

ALL AGREEMENT STATES, CONNECTICUT, AND INDIANA

SUBJECT: NOTIFICATION OF ISSUANCE OF EYE90 MICROSPHERES® LICENSING GUIDANCE (STC-24-065)

**Purpose:** To inform the Agreement States, Connecticut, and Indiana that the U.S. Nuclear Regulatory Commission (NRC) issued the Eye90 microspheres® Licensing Guidance.

**Background:** On May 30, 2023, ABK Biomedical, Inc. announced it had received Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) for Eye90 microspheres®. Eye90 microspheres® are radiopaque yttrium-90 (Y-90) glass microspheres used for treatment of conditions of the liver. Similar to existing microsphere technologies, Eye90 microspheres® are licensed under Title 10 of the Code of Federal Regulations (10 CFR) Part 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material." Like other Y-90 microsphere technologies, Eye90 microspheres® are delivered under fluoroscopy guidance. The radiopacity of the microspheres allows for imaging under fluoroscopy during treatment or after treatment using any X-ray imaging technique. As the use of Eye90 microspheres® requires use of non-licensed sources of radiation, licensees should remain aware of the occupational monitoring requirements for exposure from licensed and non-licensed sources. More information can be found in IN 2021-02 ([ML21152A239](#)).

Enclosure 1 provides the final 10 CFR 35.1000 licensing guidance for Eye90 microspheres® ([ML24247A254](#)). This guidance lists an approved set of regulations and licensing conditions specific to the Eye90 microspheres®. 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 Eye90 microspheres®. 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 will be posted on NRC's public Web site (<https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>).

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

Sincerely,



Signed by Giantelli, Adelaide  
on 12/10/24

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

Enclosures:

1. Eye90 microspheres® Licensing Guidance
2. Consolidated Technical Analysis

STC 24 065 Notification Eye90 microspheres Licensing Guidance DATE December 12, 2024

DISTRIBUTION:

ADAMS Accession No.: ML24325A436; Ltr ML24325A439

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| NAME   | SSpence        | SS | KTapp           | KT             | CEinberg    | CE             | AGiantelli AG |
| DATE   | Dec 2, 2024    |    | Dec 4, 2024     |                | Dec 5, 2024 |                | Dec 10, 2024  |

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