



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

November 25, 2024

MEMORANDUM TO:

Anne DeFrancisco, Chief  
Medical and Licensing Assistance Branch  
Division of Nuclear Materials Safety  
Region I

Bob Orlikowski, Chief  
Materials Licensing Branch  
Division of Nuclear Materials Safety  
Region III

Neil F. O'Keefe, Chief  
Materials Licensing Branch  
Division of Nuclear Materials Safety  
Region IV

FROM:

Chris Einberg, Branch Chief  
Medical Safety and Events Assessment Branch  
Division of Materials Safety, Security, State  
and Tribal Programs  
Office of Nuclear Materials Safety  
and Safeguards

A handwritten signature in blue ink, appearing to read "Chris Einberg".

Signed by Einberg, Christian  
on 11/25/24

SUBJECT:

NOTIFICATION OF ISSUANCE OF EYE90 MICROSPHERES®  
LICENSING GUIDANCE

The Eye90 microspheres® Licensing Guidance ([ML24247A254](#)) was published on September 27, 2024.

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 35.1000, 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](#)).

My staff developed licensing guidance for the Eye90 microspheres. This licensing guidance is available under Medical Licensee Toolkit/Emerging Medical Technologies at

<https://www.nrc.gov/materials/miau/med-use-toolkit/emerg-licensed-med-tech.html>. 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. 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.

Memorandum: NOTIFICATION OF ISSUANCE OF EYE90 MICROSPHERES® LICENSING GUIDANCE  
DATE November 26, 2024

## DISTRIBUTION:

SSpence, NMSS/MSST/MSEB

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OFFICE	NMSS/MSST/MSEB	NMSS/MSST/MSEB		
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DATE	Nov 22, 2024	Nov 25, 2024		

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