



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

July 3, 2025

ALL AGREEMENT STATES
CONNECTICUT, INDIANA, WEST VIRGINIA

NOTIFICATION OF ISSUANCE OF LV LIBERTY VISION CORPORATION YTTRIUM-90 DISC
AND iWAND® OPTHALMIC SYSTEM LICENSING GUIDANCE (STC-25-036)

Purpose: To inform the Agreement States, Connecticut, and Indiana that the U.S. Nuclear Regulatory Commission (NRC) issued the LV Liberty Vision Corporation Yttrium-90 Disc and iWAND® Ophthalmic System Licensing Guidance.

Background: On March 15, 2017, the LV Liberty Vision Model 1 ⁹⁰Yttrium Brachytherapy Source (hereafter the LV Liberty Vision ⁹⁰Yttrium Disc or the LV Y-90 Disc) received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for episcleral brachytherapy of tumors and benign growths and for use within a manual brachytherapy system. The LV Y-90 Disc is a manual brachytherapy source intended to be used within the Liberty Vision iWand® Ophthalmic System.

The LV Y-90 Disc contains a yttrium-90 (Y-90) source with unique properties that merit radiation safety considerations and general licensing considerations beyond those required by Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, Subpart F, "Manual Brachytherapy." The Y-90 source within the LV Y-90 Disc is different than the traditional strontium-90 (Sr-90) sources presently used in standard ophthalmic (eye) applicators for ophthalmic radiotherapy under 10 CFR 35.400, "Use of sources for manual brachytherapy." Traditional ophthalmic radiotherapy, regulated under 10 CFR 35.400, typically involves use of Sr-90 sources, which are actually Sr-90/Y-90 radionuclides in secular equilibrium. Use of the LV Y-90 Disc falls outside of the requirements for physicians authorized under 10 CFR 35.491, "Training for ophthalmic use of strontium-90," which was intended for use of Sr-90 superficial eye applicator sources. The regulations in 10 CFR 35.433, "Strontium-90 sources for ophthalmic treatments," 10 CFR 35.491, and 10 CFR 35.2433, "Records of decay of Strontium-90 sources for ophthalmic treatments," are specific for the use of Sr-90 sources for ophthalmic radiotherapy by physicians other than radiation oncologists. Regulation under 10 CFR Part 35, Subpart F, further does not contemplate use by ophthalmologists, the target user of the LV Y-90 Disc source for ophthalmic treatments. As a result of these differences from the eye applicator sources currently regulated in 10 CFR Part 35, Subpart F, the use of the LV Y-90 Disc is regulated under the provisions of 10 CFR 35, Subpart K, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

Enclosure 1 provides the final 10 CFR 35.1000 licensing guidance for the LV Y-90 Disc and iWand® Ophthalmic System ([ML24274A279](#)). This guidance lists an approved set of regulations and licensing conditions specific to the LV Y-90 Disc and iWand® Ophthalmic System. 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 use of the LV Y-90 Disc and iWand® Ophthalmic System. 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>).

If you have any questions regarding this correspondence, please contact the individual named below:

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Sincerely,



Signed by Giantelli, Adelaide
on 07/03/25

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. LV Liberty Vision Corporation Yttrium-90 Disc and iWand® Ophthalmic System Licensing Guidance
2. Consolidated Technical Analysis Table

Regional Memo and STC-25-036 Agreement State Letter - LV Liberty Vision Y-90 Disc Source DATE July 7, 2025

DISTRIBUTION:

MAYoade, NMSS/MSST/MSEB/MRST

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* via email

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