U.S. Nuclear Regulatory Commission
Advisory Committee on the Medical Uses of Isotopes
Subcommittee on LV Liberty Vis Disc and iWand® Ophthalmic System

Subcommittee Review and Comments on:
LV LIBERTY VISION CORPORATION YTTRIUM-90 DISC AND IWAND® OPHTHALMIC SYSTEM DRAFT LICENSING GUIDANCE

Final Report
Submitted on: April 24, 2024

Subcommittee Membership:
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Subcommittee Charge:

To review the Liberty Vision technology and comment on the NRC staff's draft licensing guidance for the LV Liberty Vision Corporation Yttrium-90 Disc and iWand® Ophthalmic System. This subcommittee was established by the Advisory Committee on the Medical Use of Isotopes (ACMUI) Chair, Dr. Darlene Metter, during the ACMUI's Fall 2021 Meeting on October 4, 2021. Note that implementation of the subcommittee charge was deferred while the NRC staff focused on high priority rulemaking and NRC-recognized specialty board efforts.

Introduction

The LV Liberty Vision ^{90}Yttrium Disc Source (LV Y-90 Disc Source) is a new eye applicator brachytherapy source for episcleral tumors and benign growths. The episcleral tissue is a thin layer of connective tissue in the eye that lies between the sclera (the white of the eye) and the conjunctiva (transparent membrane). This is a temporary brachytherapy procedure. The source manufactured by LV Liberty Vision Corporation has a sealed source and device certificate with the state of New Hampshire. Each source with activity up to 20 mCi (range of 10-20 mCi) is designed for a single use. The treatment time with such activity is in the order of 3-7 minutes. The NRC has determined that this product needs to be listed under 10 CFR 35.1000 and has developed the draft licensing guidance for this device.

This Subcommittee endorses the proposed draft licensing guidance, subject to the specific changes provided below.

Discussion

A) Specific comments

1) In section 1, the subcommittee recommends the deletion of the statement comparing the beta energy between the LV Y-90 and the Sr-90 sources.

2) In section 3, first paragraph: Recommend changing “upgraded” to “other.” The licensee, if authorized by the license, may possess other approved source models as they become available. These are not necessarily upgraded sources but simply with different diameters etc.
3) In section 5.2, the Subcommittee recommends stating clearly the two different training pathways, depending on whether the treatment is prescribed for the surface or prescribed at depth (below the surface).
4) Section 5.2.2 should clearly describe that there are different training requirements for AUs treating superficial lesions versus AUs treating at depth (below the surface).
5) In section 5.2.2.D, the Subcommittee strongly disagrees with requiring a written attestation statement for “involved non-AUs (i.e., an ophthalmologist).” Non-AUs are supervised individuals and do not require preceptor attestations.
6) In section 5.2.3, the Subcommittee recommends that this procedure be performed in the presence of an AMP. The use of Ophthalmic physicist should be deleted.
7) In section 6.1, the Subcommittee recommends requiring the presence of both the AU and the AMP. This is similar to other procedures, such as Intravascular brachytherapy etc. where the AU and the AMP are present.
8) In section 6.4, as per the manufacturer’s recommendation and other AAPM reports, the calibration of the LIV source must be performed by the user prior to its use and compared to the manufacturer’s stated activity. Any discrepancies must be resolved according to the AAPM guidelines related to source calibration and manufacturer’s recommendations (±5%).
9) In section 6.5, service and maintenance is not needed as this is a single use device. Recommend deleting this section.
10) In section 6.6, the committee recommends replacing “returned to the safe shielded position” with “returned to the shielded container”.

B) General comments

The Subcommittee recognizes that the LV Disc and iWand system present challenges in accounting for anisotropy of the source, properly positioning and orienting the iWand, dispensing sterile adhesive, and allowing the adhesive to cure. Members of the treatment team should take precautions to assure that their use of the source is in accordance with the manufacturer’s instructions.”

Respectfully submitted, March 11, 2024
Subcommittee on LV Liberty Vision Y-90 Disc and iWand® Ophthalmic System.
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The ACMUI unanimously approved this report as presented during its public meeting on April 8, 2024