Appendix

LV Liberty Vision Corporation Yttrium-90 Disc and iWand® Ophthalmic System

Consolidated Technical Analysis

Emerging Medical Technology (EMT): LV Liberty Vision Corporation Yttrium-90 Disc and iWand® Ophthalmic System
Guidance Version: Original / Revision 0
Determination: 35.1000
Completed by: Maryann Ayoade
Reviewed by: Maryann Ayoade
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The following table provides a list of 10 CFR Part 35 regulations and conditions the NRC has determined are applicable for use of the LV Liberty Vision Corporation Yttrium-90 Disc and iWand® Ophthalmic System. Licensees shall comply with all regulations which address use of the LV Liberty Vision Corporation Yttrium-90 Disc and iWand® Ophthalmic System. The table also provides specific conditions which the NRC has determined are necessary for the medical use of the LV Liberty Vision Corporation Yttrium-90 Disc and iWand® Ophthalmic System. In addition, the table lists where licensees and applicants can find additional guidance. Applicants may submit alternative list of regulations and specific conditions to be reviewed on a case-by-case basis by NRC staff.

Section	Description	EMT Use Addressed in Regulation	Guidance	*[LV Guidance]* Guidance Section	Comment
35.1	Purpose and scope	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2	Definitions	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.5	Maintenance of records	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		

35.6	Provisions for the protection of human research subjects	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.7	FDA, other Federal, and State requirements	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.8	Information collection requirements: OMB approval	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other	Section 9	

35.10	Implementation	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.11	License required	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.12	Application for license, amendment, or renewal	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.13	License amendments	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.14	Notifications	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.15	Exemptions regarding Type A specific licenses of broad scope	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐ *[LV Guidance]* ☐Other		
35.18	License issuance	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.19	Specific exemptions	☒Yes ☐No ☐N/A	☒1566 Vol 9		

			☐*[LV Guidance]* ☐Other		
Subpart B – General Administrative Requirements					
35.24	Authority and responsibilities for the radiation protection program	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.26	Radiation protection program changes	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other	Section 6.2	- Parts of 10 CFR 35.26 can be met with modifications provided in the guidance. - The guidance document provides additional information specific to LV Liberty Vision use. - The guidance may be revised as the regulator, manufacturer, and industry gains more experience more about the technology.
35.27	Supervision	☐Yes ☒No ☐N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other	Section 6.1	- This is a new technology that requires additional operational experience. - Precedence with NeoVista Epi-Rad$_{90}$™ System and Intravascular Brachytherapy System Licensing Guidance that both have consultation and physical presence criteria. - ACMUI recommended physician presence of both the AU and AMP.
35.40	Written directives (WDs)	☐Yes ☒No ☐N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other	Section 6.3	- Parts of 10 CFR 35.40 can be met with modifications provided in the guidance. - The guidance document provides additional information specific to LV Liberty Vision use. - 10 CFR 35.40(b)(7) describes written directive requirements for all other

					brachytherapy. This requirement does not include the source activity as part of the written directive, which is essential for determining the treatment times, similar to the requirement for Sr-90 sources in accordance with 10 CFR 35.433.
35.41	Procedures for administrations requiring a WD	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other		
35.49	Suppliers for sealed sources or devices for medical use	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.50	Training for Radiation Safety Officer (RSO) and Associate RSO	☐Yes ☒No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other	Section 5.2	- Parts of 10 CFR 35.50 can be met with modifications provided in the guidance. - The guidance document provides additional information specific to LV Liberty Vision use. - Similar criteria are needed for training in the use of the LV Y-90 Disc source for the AU.
35.51	Training for an authorized medical physicist (AMP)	☐Yes ☒No ☐ N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other	Section 5.2	- Parts of 10 CFR 35.51 can be met with modifications provided in the guidance. - The guidance document provides additional information specific to LV Liberty Vision use. - Similar criteria are needed for training in the use of the LV Y-90 Disc source for the AU.

35.55	Training for an authorized nuclear pharmacist (ANP)	☐Yes ☐No ☒ N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.57	Training for experienced RSO, teletherapy or medical physicist, AMP, authorized user (AU), nuclear pharmacist, and ANP	☒Yes ☐No ☐ N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.59	Recentness of training	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
Subpart C – General Technical Requirements					
35.60	Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material	☐Yes ☐No ☒ N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.61	Calibration of survey instruments	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.63	Determination of dosages of unsealed byproduct material for medical use	☐Yes ☐No ☒ N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.65	Authorization for calibration, transmission, and reference sources	☒Yes ☐No ☐ N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		

35.67	Requirements for possession of sealed sources and brachytherapy sources	☐Yes ☐No ☒ N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.69	Labeling of vials and syringes	☐Yes ☐No ☒ N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.70	Surveys of ambient radiation exposure rate	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		Parts of 10 CFR 35.70 can be met with modifications provided in the guidance. The guidance document provides additional information specific to LV Liberty Vision use. The requirement for surveys related to unsealed byproduct materials use is not needed as the LV Liberty Vision Y-90 Disc source is not unsealed materials.
35.75	Release of individuals containing unsealed byproduct material or implants containing byproduct material	☐Yes ☐No ☒ N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.80	Provision of mobile medical service	☐Yes ☐No ☒ N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.92	Decay-in-storage	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]*☐ Other		

Appendix

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Subpart F – Manual Brachytherapy					
35.400	Use of sources for manual brachytherapy	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.404	Surveys after source implant and removal	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other	Section 6.5	Parts of 10 CFR 35.404 can be met with modifications provided in the guidance. The guidance document provides additional information specific to LV Liberty Vision use. 10 CFR 35.404(a) is not needed. 10 CFR 35.404(b) is needed. The licensee needs only to perform surveys following removal of the implant to confirm that the source has been removed. The licensee does not need to perform surveys to locate and account for sources not implanted as this is a temporary brachytherapy treatment that uses a single source for a one-time/single use.
35.406	Brachytherapy sources accountability	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other		
35.410	Safety instruction	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other		
35.415	Safety precautions	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☒*[LV*		

			Guidance] ☐Other		
35.432	Calibration measurements of brachytherapy sources	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other	Section 6.4	- Includes commitment for the licensee to commit to following 10 CFR 35.432 and 35.2432. - Also includes recommendation that the licensee should— in alignment with manufacturer recommendation and published protocols by American Association of Physicists in Medicine, perform measurements to confirm the manufacturer measurements of source activity. Any discrepancies should be resolved according to the AAPM guidelines related to source calibration and manufacturer's recommendations.
35.433	Sr-90 sources for ophthalmic treatments	☐Yes ☒No ☐ N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other	Section 6.4	- Parts of 10 CFR 35.433 can be met with modifications provided in the guidance. - The guidance document provides additional information specific to LV Liberty Vision use. - Similar to 10 CFR 35.433, but specific for use of the LV Y-90 Disc source. - Similar criteria are needed for use of Y-90 sources for ophthalmic treatments and to allow for the AMP or ophthalmic physicist to perform the required calculations for a Y-90 source to determine treatment times and for the development of written directive procedures for the LV Y-90 Disc.
35.457	Therapy-related computer systems	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV*		

			Guidance] ☐Other		
35.490	Training for use of manual brachytherapy sources	☐Yes ☒No ☐N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other	Section 5.2	- Parts of 10 CFR 35.490 can be met with modifications provided in the guidance. - The guidance document provides additional information specific to LV Liberty Vision use. - Similar criteria are needed for training in the use of the LV Y-90 Disc source for the AU.
35.491	Training for ophthalmic use of Sr-90	☐Yes ☒No ☐ N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other	Section 5.2	- Parts of 10 CFR 35.491 can be met with modifications provided in the guidance. - The guidance document provides additional information specific to LV Liberty Vision use. - Similar criteria are needed for training in the use of the LV Y-90 Disc source for the AU.
Subpart L – Records					
35.2024	Records of authority and responsibilities for radiation protection programs	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2026	Records of radiation protection program changes	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2040	Records of WDs	☒Yes ☐No ☐ N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		

35.2041	Records for procedure for administrations requiring a WD	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials	☐Yes ☐No ☒ N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2061	Records of radiation survey instrument calibrations	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2063	Records of dosages of unsealed byproduct material for medical use	☐Yes ☐No ☒N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2067	Records of leaks tests and inventory of sealed sources and brachytherapy sources	☐Yes ☐No ☒ N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2070	Records of surveys for ambient radiation exposure rate	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2075	Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material	☐Yes ☐No ☒ N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		

35.2080	Records of mobile medical services	☐Yes ☐No ☒ N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2092	Records of decay-in-storage	☒Yes ☐No ☐ N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2204	Records of Mo-99, Sr-82, and Sr-85 concentrations	☐Yes ☐No ☒ N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2404	Records of surveys after source implant and removal	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2406	Records of brachytherapy source accountability	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2432	Records of calibration measurements of brachytherapy sources	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.2433	Records of decay of Sr-90 sources for ophthalmic treatments	☐Yes ☒No ☐ N/A	☒1566 Vol 9 ☒*[LV Guidance]* ☐Other		- Although use of the LV Y-90 Disc is not addressed in this requirement (because it is specific for Sr-90 sources and not Y-90 sources), this requirement is not needed. - This requirement to maintain records of activity for the life of the source is not

					needed for use of the LV Y-90 Disc. Due to the much shorter half-life of Y-90 – 64.2hrs as compared to Sr-90 – 28.8yrs (10 half-lives is about 26 days for Y-90 vs. 290 years for Sr-90) and the single use of the source, the requirement to maintain records of activity for the life of the source will be a much shorter timeframe, and is not needed.
Subpart M – Reports					
35.3045	Report and notification of a medical event	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.3047	Report and notification of a dose to an embryo/fetus or a nursing child	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.3067	Report of a leaking source	☐Yes ☐No ☒ N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
35.3204	Report and notification for an eluate exceeding permissible Mo-99, Sr-82, and Sr-85 concentrations	☐Yes ☐No ☒ N/A	☐1566 Vol 9 ☐*[LV Guidance]* ☐Other		
Subpart N – Enforcement					
35.4001	Violations	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV*		

			Guidance] ☐Other		
35.4002	Criminal penalties	☒Yes ☐No ☐N/A	☒1566 Vol 9 ☐*[LV Guidance]* ☐Other		
Additional Considerations					