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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

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
Subpart A – General Information					
35.1	Purpose and scope	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2	Definitions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.5	Maintenance of records	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.6	Provisions for the protection of human research subjects	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		

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Section	Description	EMT Use Addressed in Regulation	Guidance	[LV Guidance] Guidance Section	Comment
35.7	FDA, other Federal, and State requirements	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.8	Information collection requirements: OMB approval	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.10	Implementation	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.11	License required	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.12	Application for license, amendment, or renewal	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.13	License amendments	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		

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35.14	Notifications	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.15	Exemptions regarding Type A specific licenses of broad scope	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.18	License issuance	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.19	Specific exemptions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
Subpart B – General Administrative Requirements					
35.24	Authority and responsibilities for the radiation protection program	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.26	Radiation protection program changes	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other	Section 6.2	<ul style="list-style-type: none"> - 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.

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35.27	Supervision	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other	Section 6.1	<ul style="list-style-type: none"> - This is a new technology that requires additional operational experience. - Precedence with NeoVista Epi-Rad₉₀™ 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)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other	Section 6.3	<ul style="list-style-type: none"> - 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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.49	Suppliers for sealed sources or devices for medical use	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		

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35.50	Training for Radiation Safety Officer (RSO) and Associate RSO	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other	Section 5.2	<ul style="list-style-type: none"> - 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)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other	Section 5.2	<ul style="list-style-type: none"> - 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)	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.57	Training for experienced RSO, teletherapy or medical physicist, AMP, authorized user (AU), nuclear pharmacist, and ANP	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.59	Recentness of training	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		

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Subpart C – General Technical Requirements					
35.60	Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.61	Calibration of survey instruments	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.63	Determination of dosages of unsealed byproduct material for medical use	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.65	Authorization for calibration, transmission, and reference sources	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.67	Requirements for possession of sealed sources and brachytherapy sources	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.69	Labeling of vials and syringes	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		

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35.70	Surveys of ambient radiation exposure rate	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		<ul style="list-style-type: none"> - 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	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.80	Provision of mobile medical service	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.92	Decay-in-storage	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
Subpart F – Manual Brachytherapy					
35.400	Use of sources for manual brachytherapy	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		

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35.404	Surveys after source implant and removal	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other	Section 6.5	<ul style="list-style-type: none"> - 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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.410	Safety instruction	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.415	Safety precautions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		

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35.432	Calibration measurements of brachytherapy sources	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other	Section 6.4	<ul style="list-style-type: none"> - 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other	Section 6.4	<ul style="list-style-type: none"> - 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.

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35.457	Therapy-related computer systems	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.490	Training for use of manual brachytherapy sources	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other	Section 5.2	<ul style="list-style-type: none"> - 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	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other	Section 5.2	<ul style="list-style-type: none"> - 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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2026	Records of radiation protection program changes	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		

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35.2040	Records of WDs	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2041	Records for procedure for administrations requiring a WD	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2061	Records of radiation survey instrument calibrations	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2063	Records of dosages of unsealed byproduct material for medical use	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2067	Records of leaks tests and inventory of sealed sources and brachytherapy sources	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2070	Records of surveys for ambient radiation exposure rate	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		

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35.2075	Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2080	Records of mobile medical services	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2092	Records of decay-in-storage	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2204	Records of Mo-99, Sr-82, and Sr-85 concentrations	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2404	Records of surveys after source implant and removal	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2406	Records of brachytherapy source accountability	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.2432	Records of calibration measurements of brachytherapy sources	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		

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35.2433	Records of decay of Sr-90 sources for ophthalmic treatments	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input checked="" type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		<ul style="list-style-type: none"> - 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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.3047	Report and notification of a dose to an embryo/fetus or a nursing child	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.3067	Report of a leaking source	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		

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35.3204	Report and notification for an eluate exceeding permissible Mo-99, Sr-82, and Sr-85 concentrations	<input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A	<input type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
Subpart N – Enforcement					
35.4001	Violations	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
35.4002	Criminal penalties	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	<input checked="" type="checkbox"/> 1566 Vol 9 <input type="checkbox"/> [LV Guidance] <input type="checkbox"/> Other		
Additional Considerations					