#### **Consolidated Technical Analysis**

The following table provides a list of 10 CFR Part 35 regulations and conditions the NRC has determined are applicable for use of *Eye90 microspheres*<sup>®</sup>. Licensees shall comply with all regulations which address use of *Eye90 microspheres*<sup>®</sup>. The table also provides specific conditions which the NRC has determined are necessary for the medical use of *Eye90 microspheres*<sup>®</sup>. 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	Use Addressed in Regulation	Guidance	Eye90 microspheres® Guidance Section	Comment
<u>35.1</u>	Purpose and scope	⊠Yes □No	⊠1556 Vol 9		
		□N/A	☐ <i>Eye</i> 90		
			microspheres®		
			□Other		
<u>35.2</u>	Definitions	⊠Yes □No	⊠1556 Vol 9		
		□N/A	□ Eye90		
			microspheres®		
			□Other		
<u>35.5</u>	Maintenance of records	⊠Yes □No	⊠1556 Vol 9		
		□N/A	□ Eye90		
			microspheres®		
			□Other		
<u>35.6</u>	Provisions for the	⊠Yes □No	⊠1556 Vol 9		
	protection of human	□N/A	□ Eye90		
	research subjects		microspheres®		
			□Other		
35.7	FDA, other Federal, and	⊠Yes □No	⊠1556 Vol 9		
	State requirements	□N/A	□ <i>Ey</i> e90		
			microspheres®		
			□Other		

Section	Description	Use Addressed in Regulation	Guidance	Eye90 microspheres® Guidance Section	Comment
<u>35.8</u>	Information collection requirements: OMB approval	⊠Yes □No □N/A	⊠1556 Vol 9  □ Eye90  microspheres®  □Other		

<u>35.10</u>	Implementation	⊠Yes □No	⊠1556 Vol 9	
		□N/A	□ <i>Eye</i> 90	
			microspheres®	
			□Other	
<u>35.11</u>	License required	⊠Yes □No	⊠1556 Vol 9	
		□N/A	□ Eye90	
			microspheres®	
			□Other	
<u>35.12</u>	Application for license,	⊠Yes □No	⊠1556 Vol 9	
	amendment, or renewal	□N/A	□ Eye90	
			microspheres®	
			□Other	
<u>35.13</u>	License amendments	⊠Yes □No	⊠1556 Vol 9	
		□N/A	☐ Eye90	
			microspheres®	
			□Other	
<u>35.14</u>	Notifications	⊠Yes □No	⊠1556 Vol 9	
		□N/A	☐ Eye90	
			microspheres®	
			□Other	
<u>35.15</u>	Exemptions regarding	⊠Yes □No	⊠1556 Vol 9	
	Type A specific licenses	□N/A	☐ Eye90	
	of broad scope		microspheres®	
			□Other	
<u>35.18</u>	License issuance	⊠Yes □No	⊠1556 Vol 9	
		□N/A	☐ Eye90	
			microspheres®	
			□Other	
<u>35.19</u>	Specific exemptions	⊠Yes □No	⊠1556 Vol 9	
		□N/A	□ Eye90	
			microspheres®	
			□Other	

Subpart E	3 – General Administrative F	Requirements			
35.24	Authority and responsibilities for the radiation protection program	⊠Yes □No □N/A	⊠1556 Vol 9 □ Eye90 microspheres® □Other		
35.26	Radiation protection program changes	⊠Yes □No □N/A	⊠1556 Vol 9  □ Eye90  microspheres®  □Other		
35.27	Supervision	⊠Yes □No □N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
35.40	Written directives (WDs)	□Yes ⊠No □N/A	□1556 Vol 9  ⊠ Eye90  microspheres®  □Other	6.2	35.40(b)(6) details written directive requirements for permanent implant brachytherapy. 35.40(b)(6)(ii) requires a record of the number of sources implanted, which is not possible due to the small size and large number of microspheres involved in Eye90 therapy. Therefore there are different items required by the written directive.
35.41	Procedures for administrations requiring a WD	⊠Yes □No □N/A	⊠1556 Vol 9 ⊠ Eye90 microspheres® □Other	6.2	The guidance document provides additional information specific to Eye90 Microspheres.
35.49	Suppliers for sealed sources or devices for medical use	⊠Yes □No □N/A	⊠1556 Vol 9  □ Eye90  microspheres®  □Other		
35.50	Training for Radiation Safety Officer (RSO) and Associate RSO	⊠Yes □No □N/A	⊠1556 Vol 9 ⊠ Eye90 microspheres®	5.2	The guidance document provides additional information specific to Eye90 Microspheres.

			□Other		
<u>35.51</u>	Training for an authorized medical physicist (AMP)	□Yes □No ⊠ N/A	□1556 Vol 9		
	medical physicist (7 tivil )	IN/A	☐ Eye90 microspheres®		
			□Other		
35.55	Training for an authorized	□Yes □No ⊠	□1556 Vol 9		
	nuclear pharmacist	N/A	□ <i>Ey</i> e90		
	(ANP)		microspheres®		
			□Other		
<u>35.57</u>	Training for experienced	⊠Yes □No □	⊠1556 Vol 9		
	RSO, teletherapy or medical physicist, AMP,	N/A	☐ Eye90		
	authorized user (AU),		<i>microspheres</i> ® □Other		
	nuclear pharmacist, and		⊔Other		
05.50	ANP			_	
<u>35.59</u>	Recentness of training	⊠Yes □No	⊠1556 Vol 9	5	The guidance document provides additional information specific to Eye90
		□N/A	⊠ Eye90 microspheres®		microspheres <sup>®</sup> .
			□Other		'
Subpart C	C – General Technical Requi	rements			
35.60	Possession, use, and	□Yes ⊠No □	□1556 Vol 9	6.1	Although Eye90 microspheres® are not
	calibration of instruments	N/A	⊠ Eye90		considered unsealed byproduct material,
	used to measure the activity of unsealed		microspheres®		their pre-treatment activity is measured as per 35.60.
	byproduct material		□Other		per 33.00.
35.61	Calibration of survey	⊠Yes □No	⊠1556 Vol 9		
	instruments	□N/A	□ <i>Ey</i> e90		
			microspheres®		
			□Other		
<u>35.63</u>	Determination of dosages	□Yes ⊠No □	□1556 Vol 9	6.1	Although Eye90 microspheres® are not
	of unsealed byproduct material for medical use	N/A	⊠ Eye90		considered unsealed byproduct material, their pre-treatment activity is measured as
	material for medical use		microspheres®		per 35.60.
			□Other		

and reference	e sources	☐ Eye90 microspheres® ☐Other		
35.67 Requirement possession of sources and brachytherap	of sealed □N/A	□1556 Vol 9  ⊠ Eye90  microspheres®  □Other	6.5	Microspheres are not managed as individual discrete sources and Y-90 is short-lived. 35.406, 20.1906, 20.1904, 35.69, 20.1801, and 35.92 are sufficient.
35.69 Labeling of v syringes	ials and ⊠Yes □No □N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
35.70 Surveys of a radiation exp		□1556 Vol 9  ⊠ Eye90  microspheres®  □Other	6.8	The guidance document provides additional information specific to Eye90 microspheres <sup>®</sup> .
35.75 Release of ir containing upproduct mimplants con byproduct m	nsealed □N/A aterial or taining	□ 1556 Vol 9 □ Eye90 microspheres® □Other		
35.80 Provision of medical serv	1 00 10	□1556 Vol 9 □ Eye90 microspheres® □Other		
35.92 Decay-in-sto	□N/A	⊠ 1556 Vol 9 ⊠ Eye90 microspheres® □Other	7.3	The guidance document provides additional information specific to Eye90 microspheres®, including concerns specific to isotopic impurities inherent in the production of Y-90.

35.400	Use of sources for manual brachytherapy	⊠Yes □No □N/A	□ 1556 Vol 9 □ Eye90 microspheres® □ Other		
35.404	Surveys after source implant and removal	□Yes ⊠No □N/A	☐ 1556 Vol 9  ☑ Eye90  microspheres®  ☐ Other	6.8	The guidance document provides additional information specific to Eye90 microspheres®. Eye90 microspheres® are permanent implants, therefore post-removal surveys are not applicable.
35.406	Brachytherapy sources accountability	□Yes ⊠No □N/A	□1556 Vol 9  ⊠ Eye90  microspheres®  □Other	6.5	The guidance document provides additional information specific to Eye90 microspheres <sup>®</sup> .
35.410	Safety instruction	□Yes □No ⊠ N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
<u>35.415</u>	Safety precautions	□Yes □No ⊠ N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
35.432	Calibration measurements of brachytherapy sources	□Yes ⊠No □N/A	□1556 Vol 9  ⊠ Eye90  microspheres®  □Other	6.1	Microspheres are too small to be calibrated in accordance with 35.432, therefore 35.63 and 35.60 are used for measuring each dosage.
35.433	Sr-90 sources for ophthalmic treatments	□Yes □No ⊠ N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
35.457	Therapy-related computer systems	□Yes □No ⊠ N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		

<u>35.490</u>	Training for use of manual brachytherapy sources	□Yes ⊠No □N/A	□ 1556 Vol 9 □ Eye90 microspheres® □ Other	5	The guidance document provides additional information specific to Eye90 microspheres <sup>®</sup> .
35.491	Training for ophthalmic use of Sr-90	□Yes □No ⊠ N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
Subpart L	. – Records				
35.2024	Records of authority and responsibilities for radiation protection programs	⊠Yes □No □N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
35.2026	Records of radiation protection program changes	⊠Yes □No □N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
35.2040	Records of WDs	⊠Yes □No □N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
35.2041	Records for procedure for administrations requiring a WD	⊠Yes □No □N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials	⊠Yes □No □N/A	□1566 Vol 9 □ Eye90 microspheres® □Other		
35.2061	Records of radiation survey instrument calibrations	⊠Yes □No □N/A	☐ 1556 Vol 9 ☐ Eye90 microspheres®		

			□Other		
35.2063	Records of dosages of unsealed byproduct material for medical use	□Yes □No ⊠N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
35.2067	Records of leaks tests and inventory of sealed sources and brachytherapy sources	□Yes ⊠No □ N/A	□1556 Vol 9  ⊠ Eye90  microspheres®  □Other	4.4, 6.5	Microspheres are not managed as individual discrete sources and Y-90 is short-lived. 35.406, 20.1906, 20.1904, 35.69, 20.1801, and 35.92 are sufficient.
35.2070	Records of surveys for ambient radiation exposure rate	⊠Yes □No □N/A	⊠1556 Vol 9  □ Eye90  microspheres®  □Other		
35.2075	Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material	⊠Yes □No □N/A	⊠1556 Vol 9  □ Eye90  microspheres®  □Other		
35.2080	Records of mobile medical services	□Yes □No ⊠ N/A	□ 1556 Vol 9 □ Eye90 microspheres® □ Other		
35.2092	Records of decay-in- storage	⊠Yes □No □N/A	⊠1556 Vol 9 ⊠ Eye90 microspheres® □Other	7.3	The guidance document provides additional information specific to Eye90 microspheres <sup>®</sup> .
35.2204	Records of Mo-99, Sr-82, and Sr-85 concentrations	□Yes □No ⊠ N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		

35.2404	Records of surveys after source implant and removal	□Yes ⊠No □N/A	□1556 Vol 9  ⊠ Eye90  Microspheres®  □Other	6.8	The guidance document provides additional information specific to Eye90 microspheres® are permanent implants, therefore post-removal surveys are not applicable.
35.2406	Records of brachytherapy source accountability	□Yes ⊠No □N/A	□1556 Vol 9  ⊠ Eye90  microspheres®  □Other	6.5	Microspheres are not managed as individual discrete sources and Y-90 is short-lived. 35.406, 20.1906, 20.1904, 35.69, 20.1801, and 35.92 are sufficient.
35.2432	Records of calibration measurements of brachytherapy sources	□Yes ⊠No □ N/A	□1556 Vol 9  ⊠ Eye90  microspheres®  □Other	6.1	Microspheres are too small to be calibrated in accordance with 35.432, therefore 35.63 and 35.60 are used for measuring each dosage.
35.2433	Records of decay of Sr- 90 sources for ophthalmic treatments	□Yes □No ⊠ N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
Subpart N	M – Reports				
35.3045	Report and notification of a medical event	□Yes ⊠No □N/A	□1556 Vol 9 □ Eye90 microspheres® □Other	6.3	The guidance document provides additional information specific to Eye90 microspheres <sup>®</sup> .
35.3047	Report and notification of a dose to an embryo/fetus or a nursing child	⊠Yes □No □N/A	⊠1556 Vol 9  □ Eye90  microspheres®  □Other		
35.3067	Report of a leaking source	□Yes □No ⊠ N/A	□1556 Vol 9 □ Eye90 microspheres® □Other		
35.3204	Report and notification for an eluate exceeding permissible Mo-99, Sr-	□Yes □No ⊠ N/A	□1556 Vol 9 □ Eye90 microspheres®		

concentrations	
Subpart N – Enforcement	
35.4001 Violations	
□N/A □ Eye90	
microspheres <sup>®</sup>	
□Other	
35.4002 Criminal penalties ⊠Yes □No ⊠1556 Vol 9	
□N/A □ Eye90	
microspheres®	
□Other □	
Additional Considerations	