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

Licensing Guidance

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U.S. Nuclear Regulatory Commission
Maryann Ayoade | (301) 415-0862
MedicalQuestions.Resource@nrc.gov

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1. 10 CFR 35.1000 APPLICABILITY AND USE

The LV Liberty Vision ^{90}Yttrium Disc (hereafter 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 source has 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 LV Y-90 Disc is an yttrium-90 (Y-90) source with higher energy beta radiation compared to the beta radiation energy that is present in the traditional strontium-90 (Sr-90) sources, which are presently used in standard eye applicators for ophthalmic radiotherapy under 10 CFR 35.400, "Use of sources for manual brachytherapy." Furthermore, 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," for 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. 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."[1]

2. DEVICE DESCRIPTION AND USE

The LV Y-90 Disc and iWand® Ophthalmic System are a source and eye applicator system that use high dose rate beta radiation from Y-90 for episcleral brachytherapy of tumors and benign growths. The LV Y-90 Disc is temporarily positioned on the treatment area using the LV Liberty Vision Corporation iWand® applicator series – iWand® Anterior (A) for anterior placement or iWand® Posterior (P) for posterior placement. The applicator systems have operational commonality with the source affixed to the applicators and the applicator handles allowing for manipulation of the source. The source is comprised of a single solid metal cylindrical disc of Y-90 encapsulated in titanium. Y-90 has a half-life of 2.67 days or 64.1 hrs., and decays by beta emission with average energy of 934 keV (max energy 2,280 keV). Both the source and the iWand® applicators are single or one-time use and the source can be disposed of by decay-in-storage or by return to manufacturer or authorized recipient.

The LV Y-90 Disc was approved by the U.S. Food and Drug Administration with the trade/device name – "LV Liberty Vision Model 1 ^{90}Yttrium" (in a Section 510(k) Number K163571 premarket notification of intent to market, dated March 15, 2017), for episcleral brachytherapy of tumors and benign growths and for use within a manual brachytherapy system. The Sealed Source and Device (SS&D) registration certificate for the source includes a source model – "Model 1 ^{90}Yttrium Brachytherapy Source" with a source diameter size of 6.0 millimeters (mm). More information about the source can be found in its SS&D registration certificate, NH-1501-S-101-S. This licensing guidance is applicable to the Model 1, 6 mm source that was approved in the SS&D registration certificate at the time of issuance of the guidance.

[1] 10 CFR 35.1000 is designated as Compatibility Category D. Agreement States are not required to adopt these regulations for purposes of compatibility but are not prohibited from adopting Compatibility Category D regulations if they so choose. If Agreement States choose to adopt this licensing guidance, references to 10 CFR should be changed to the equivalent Agreement State regulations.

3. LICENSING GUIDANCE

The license conditions in this guidance provide applicants with one acceptable means of satisfying the requirements for a license to authorize the use of the LV Y-90 Disc in the manufacturer's iWand® applicator device/system. This information is not intended to be the only means of satisfying the requirements. While the guidance refers generically to the LV Y-90 Disc, under 10 CFR 30.33(a)(3), the applicant or licensee must document the model that will be possessed and used, but the NRC will not include the model number on the license. There are provisions and commitments in sections 5, 7 and 8 of this guidance that if authorized on the license, will permit the licensee to possess and use upgraded source models, as appropriate.

The applicant must submit the information required by 10 CFR 30.33, "General Requirements for Issuance of Specific Licenses," and 35.12, "Application for License, Amendment, and Renewal," as described below. The applicant should submit additional information and commitments requested below or may, unless the information is specifically required by regulation, submit alternative information and commitments for review by the U.S. Nuclear Regulatory Commission (NRC) staff to make a licensing determination. The commitments incorporated by license condition into the applicant's license will be reviewed during routine inspections. If an applicant commits to the guidance provided below, the applicant must follow commitments described with the use of the word "should." This guidance may be revised as additional experience is gained regarding the medical use of the LV Y-90 Disc.

Applicants should also refer to NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Material Licenses: Program-Specific Guidance about Medical Use Licenses," as it provides overall licensing guidance for all medical uses of byproduct material, including applicable model procedures for audits, occupational dose monitoring program and surveys. Guidance specific for the use of the LV Y-90 Disc under 10 CFR 35.1000, "Other medical uses of byproduct material or radiation from byproduct material" are contained herein.

4. REQUIREMENTS NOT SPECIFIC TO 10 CFR 35.1000 USE

In addition to meeting the applicable regulation in Subpart F – Manual Brachytherapy, applicants must commit to meet the general requirements in 10 CFR Part 35, Subpart A — General Information; Subpart B —General Administrative Requirements; Subpart C —General Technical Requirements; Subpart L —Records; and Subpart M —Reports; except as specified in this guidance. Additionally, applicants must meet applicable requirements of 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations;" Part 20, "Standards for Protection Against Radiation;" Part 30, "Rules of General Applicability to Domestic Licensing of byproduct material," and Part 71, "Packaging and Transportation of Radioactive Material." The enclosed consolidated technical analysis table provides guidance on applicable requirements.

5. SPECIFIC LICENSING GUIDANCE FOR THE LV LIBERTY VISION YTTRIUM-90 DISC

5.1. Radionuclides, Form, Possession Limits, and Purpose of Use

Pursuant to 10 CFR 35.12(c), the applicant must identify the radionuclide, chemical/physical form, requested maximum possession limit, and purpose of use. The NRC Form 313, "Application for Materials License," may be used to submit this information. The information in the table below provides the suggested format and information for completing Item 5 (Radioactive Material) and Item 6 (Purpose of Use) on the NRC Form 313, "Application for Materials License."

Radionuclides: (NRC Form 313 Item 5a)	Yttrium-90 permitted by 10 CFR 35.1000
Chemical/Physical Form: (NRC Form 313 Item 5b)	Sealed sources (Manufacturer and Model Number, e.g., LV Liberty Vision Corporation, LV Model 1 Y-90 Disc)
Maximum Possession Limit: (NRC Form 313 Item 5c)	___ mCi[2]
Purpose of Use: (NRC Form 313 Item 6)	For medical use in the Liberty Vision iWand® Anterior Applicator or iWand® Applicator Posterior permitted by 10 CFR 35.1000.

5.2. Training and Experience

Licensees must have at least one Authorized User (AU), one Authorized Medical Physicist (AMP), and one Radiation Safety Officer (RSO) for medical use of the LV Y-90 Disc for the source to be added to the license. The NRC has determined that individuals meeting the training and experience (T&E) criteria below will be considered qualified and can be authorized for use of the LV Y-90 Disc within the Liberty Vision iWand® Applicator Systems, for episcleral brachytherapy of tumors and benign growths or for superficial episcleral brachytherapy (i.e., ophthalmic radiotherapy that is not beyond the surface or at a depth beyond the surface). Applicants must submit documentation showing these criteria are met. Alternatively, applicants may also submit alternative T&E commitments to be reviewed on a case-by-case basis by NRC staff. The commitments should include an explanation of why the applicant believes the alternative T&E commitments demonstrate that the individual is qualified to be an authorized individual.

5.2.1. Grandfathering

If the NRC revises the T&E criteria (i.e., in subsequent revisions to this guidance), individuals previously considered to be qualified and authorized for use of a specific

[2] Maximum limit for the LV Model 1 Y-90 Disc as listed in SS&D registration certificate (20 millicuries at time of treatment and 80 millicuries at time of shipment to treatment facility).

model of the LV Y-90 Disc and Liberty Vision iWand® Applicator Systems do not have to meet the revised criteria for that model.

5.2.2. Authorized User (AU)

Applicants and licensees should identify each AU and provide documentation of T&E in the use of the LV Y-90 Disc within the Liberty Vision iWand® Applicator Systems. The NRC Form 313A (AUS), "Authorized User Training, Experience, and Preceptor Attestation (for uses defined under 10 CFR 35.400 and 35.600) [10 CFR 35.57, 35.490, 35.491, and 35.690]," or other formats which capture equivalent information may be used to document this T&E.

The NRC has determined that there are two categories of AUs for the medical use of the LV Y-90 Disc within the Liberty Vision iWand® Applicator Systems.

A. An AU for medical use of the LV Y-90 Disc for episcleral brachytherapy, including superficial ophthalmic radiotherapy. This AU is a physician:

   ~~1.~~ Currently identified as an AU for— (i) medical use permitted by 10 CFR 35.400 or 35.600, or (ii) medical use of the LV Y-90 Disc permitted by 10 CFR 35.1000; AND meets the additional device and clinical use T&E criteria in Item C;

   OR

   2. That meets the T&E requirements in 10 CFR 35.490, "Training for use of manual brachytherapy sources," or 10 CFR 35.690, "Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units," or 10 CFR 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist;" and meets the additional T&E criteria in Items C and D.

B. An AU for medical use of the LV Y-90 Disc for superficial episcleral brachytherapy (i.e., superficial ophthalmic radiotherapy that is not beyond the surface or at a depth beyond the surface). This AU is a physician:

   1. Currently identified as an AU for— (i) medical use permitted by 10 CFR 35.400 or 35.600, or (ii) medical use of the LV Y-90 Disc permitted by 10 CFR 35.1000, or (iii) medical use of the LV Y-90 Disc for superficial ophthalmic radiotherapy permitted by 10 CFR 35.1000; AND meets the additional training criteria in Item C;

   OR

2. That meets the T&E requirements in 10 CFR 35.490, “Training for use of manual brachytherapy sources,” or 10 CFR 35.57, “Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist;” and meets the additional training criteria in Item C and as applicable in Item D;

OR

3. Listed on an NRC or Agreement State license (or NRC Master Materials License) as an AU for – Strontium-90 for ophthalmic radiotherapy permitted by 10 CFR 35.400; and meets the additional training criteria in Items C and D;

OR

4. That meets the T&E requirements in 10 CFR 35.491, "Training for ophthalmic use of strontium-90,” by successfully completing the minimum number of hours of classroom and laboratory training and the supervised clinical training to include all the topics described in paragraphs (b)(1) and (b)(2), but specifically for use of the LV Y-90 Disc; and meets the additional training criteria in Items C and D.

C. Both categories of AUs and involved non-AUs (i.e., an ophthalmologist) should receive and successfully complete additional training in the hands-on device operation, safety procedures, and clinical use for the same model of the LV Y-90 Disc and the LV iWand® Applicator Systems (i.e., iWand® A and iWand® P) for which authorization is sought. This training may be satisfied by completing training provided by the LV Y-90 Disc vendor; or by completing training that is supervised by an AU or authorized medical physicist (AMP), as appropriate, who is authorized for use of the same model of the LV Y-90 Disc and the LV iWand® Applicator Systems for which the individual is seeking authorization.

D. Both categories of AUs and involved non-AUs (i.e., an ophthalmologist), except the individuals listed in Items A.1. and B.1., should obtain a written attestation affirming that the individual has satisfactorily completed the above training and is able to independently fulfill the radiation safety-related duties as an AU for applicable use of the LV Y-90 Disc and the LV iWand® Applicator Systems. The written attestation must be signed by a preceptor AU who is authorized for use of the same model of the LV Y-90 Disc and the LV iWand® Applicator Systems that is being requested or a residency program director, similar to that in 10 CFR 35.490, but with the faculty member physician that is an AU for the same model of the LV Y-90 Disc and the LV iWand® Applicator Systems for which the individual is seeking authorization. The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for use of another manual brachytherapy source under 10 CFR 35.400.

5.2.3. Authorized Medical Physicist (AMP)

Applicants and licensees should identify each AMP and provide documentation of T&E in the use of the LV Y-90 Disc and the LV iWand® Applicator Systems. The NRC Form 313A (AMP), "Authorized Medical Physicist Training, Experience, and Preceptor Attestation [10 CFR 35.51, 35.57(a)(3), and 35.433]," or other formats which capture equivalent information may be used to document this T&E.

An AMP for medical use of the LV Y-90 Disc is an individual:

1. Currently identified as an AMP for— (i) medical use of the LV Y-90 Disc and iWand® Applicator Systems permitted by 10 CFR 35.1000; or (ii) meets the T&E requirements in 10 CFR 35.51, "Training for an authorized medical physicist;" or the definition of *authorized medical physicist* in 10 CFR 35.2, "Definitions;" or the requirements in 10 CFR 35.57;

   AND

2. That has received and successfully completed additional training in the hands-on device operation, safety procedures, and clinical use of the LV Y-90 Disc and the LV iWand® Applicator Systems (i.e., iWand® A and iWand® P). This training may be satisfied by completing training provided by the LV Y-90 Disc vendor, or by completing training that is supervised by an AMP authorized for use of the same model of the LV Y-90 Disc and iWand® Applicator Systems for which the individual is seeking authorization.

   AND

3. That has obtained a written attestation affirming that the individual has satisfactorily completed the above training and is able to independently fulfill the radiation safety-related duties as an AMP for use of the LV Y-90 Disc and iWand® Applicator Systems. The written attestation must be signed by a preceptor AMP that is authorized for the use of the same model of the LV Y-90 Disc and the LV iWand® Applicator Systems that is being requested. The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for use of the LV Y-90 Disc.

The applicant must submit documentation for all of the above T&E for each AMP of the LV Y-90 Disc and the applicable LV iWand® Applicator System. The NRC Form 313A (AMP), "Authorized Medical Physicist or Ophthalmic Physicist, Training, Experience and Preceptor Attestation [10 CFR 35.51, 35.57(a)(3), 35.433]," or other formats which capture equivalent information may be used to document T&E.

5.2.3. Ophthalmic Physicist

An ophthalmic physicist for medical use of the LV Y-90 Disc is an individual:

1. Listed on an NRC or Agreement State license (or NRC Master Materials License) as an AMP for medical use of the LV Y-90 Disc and iWand® Applicator Systems; or meets the T&E criteria 10 CFR 35.51, “Training for an authorized medical physicist;” or the definition of *authorized medical physicist* in 10 CFR 35.2, “Definitions;” or the requirements in 10 CFR 35.57;

   AND

2. That has received and successfully completed additional training in the operation, safety procedures, and clinical use of the LV Y-90 Disc and the applicable LV iWand® Applicator Systems. This training should include hands-on device operation commensurate with the individual’s duties. This training may be satisfied by completing training provided by the LV Y-90 Disc vendor; or by completing training that is supervised by an AMP authorized for the LV Y-90 Disc and iWand® Applicator Systems.

   AND

3. That has obtained a written attestation that the individual has satisfactorily completed these requirements and is able to independently fulfill the radiation safety-related duties as an AMP for use of the LV Y-90 Disc and iWand® Applicator Systems. The written attestation must be signed by a preceptor AMP that is authorized for the use of the LV Y-90 Disc and the LV iWand® Applicator Systems that is being requested. The written attestation is not required for individuals who hold certification by a recognized specialty board or are already authorized for use of the LV Y-90 Disc.

The applicant must submit documentation for all of the above T&E for each AMP of the LV Y-90 Disc and the applicable LV iWand® Applicator System. The NRC Form 313A (AMP), “Authorized Medical Physicist or Ophthalmic Physicist, Training, Experience and Preceptor Attestation [10 CFR 35.51, 35.57(a)(3), 35.433],” or other formats which capture equivalent information may be used to document T&E.

5.2.4. Radiation Safety Officer (RSO) and Associate Radiation Safety Officer

An RSO with responsibility for the LV Y-90 Disc within the LV iWand® Applicator Systems is an individual:

a. Listed as an RSO on an NRC or Agreement State license (or NRC Master Materials License) for the LV Y-90 Disc and iWand® Applicator Systems; or that meets the T&E criteria in 10 CFR 35.50, "Training for Radiation Safety Officer;” or the definition of Radiation Safety Officer in 10 CFR 35.2, “Definitions;” or the requirements in 10 CFR 35.57;

AND

That has received and successfully completed additional training in the radiation safety, regulatory issues, and emergency procedures of the LV Y-90 Disc and IiWand® Applicator Systems. This training requirement may be satisfied by completing training provided by the LV Y-90 Disc vendor or by completing training that is supervised by an individual (AU, AMP or RSO, as appropriate) who is authorized for the LV Y-90 Disc.

The applicant must submit documentation for all the above T&E for the RSO of the LV Y-90 Disc. NRC Form 313A (RSO), "Radiation Safety Officer Training and Experience and Preceptor Attestation [10 CFR 35.50]," or other formats which capture equivalent information may be used to document T&E.

6. LICENSE CONDITIONS

The applicant or licensee shall commit to follow all applicable requirements in 10 CFR Part 35 for brachytherapy sources and manual brachytherapy use. The table contained in the appendix to this licensing guidance document provides more details on applicable 10 CFR Part 35 requirements. If this authorization is approved, these conditions will be incorporated as license conditions in the licensee's license. This may be done by incorporating the commitments in the tie down condition. The applicant or licensee shall commit to the following licensing commitments.

6.1. Physical Presence

1. Use of the LV Y-90 Disc for superficial episcleral brachytherapy (i.e., ophthalmic radiotherapy that is not beyond the surface or at a depth beyond the surface) will be conducted in the physical presence of an:

    a. AMP authorized for use of the LV Y-90 Disc and iWand® Ophthalmic System; or

    b. AU authorized for episcleral brachytherapy, including superficial episcleral brachytherapy; or

    c. RSO authorized for the LV Y-90 Disc and iWand® Ophthalmic System (except an RSO who is an AU authorized only for superficial episcleral brachytherapy).

2. For all procedures beyond superficial episcleral brachytherapy, the AU will consult with the ophthalmologist and an AMP authorized for use of the LV Y-90 Disc and iWand® Ophthalmic System before initiating treatment. The procedures will be conducted in the physical presence of either the AU authorized for procedures beyond superficial episcleral brachytherapy, or AMP authorized for the LV Y-90 Disc and iWand® Ophthalmic System.

6.2. Radiation Protection Program Changes

The above licensing guidance may be revised as additional experience is gained regarding medical use of the LV Y-90 Disc by the regulator or manufacturer. Therefore, in contrast with 10 CFR 35.26, a licensee already authorized to use the LV Y-90 Disc and that has committed, by license conditions, to follow the provisions in this guidance existing at the time of commitment, must apply for and receive an amendment to its license prior to making changes to conform to the revised guidance and additional radiation safety recommendations.

An applicant initially applying for authorization for medical use of LV Y-90 Disc (or a licensee applying later for an amendment to conform to revisions in this guidance) may request authorization to allow future changes to its radiation safety program, provided the following conditions are met:

1. The revision is in compliance with the regulations of the NRC or Agreement State;

2. The revision is based on the current licensing guidance for the LV Y-90 Disc under 10 CFR 35.1000 use posted on the NRC Web site;

3. The revision has been reviewed and approved by the licensee's RSO and management;

4. The affected individuals are instructed on the revised program before the change is implemented;

5. The licensee will retain a record of each change for five years; and

6. The record will include a copy of the appropriate NRC Web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee's management representative who reviewed and approved the change.

6.3. Written Directives

The licensee should complete a written directive in accordance with 10 CFR 35.40, "Written directives." In addition, the applicant or licensee should commit to including the source activity as part of the written directive. As the intended use of the LV Y-90 Disc is similar to Sr-90 sources used for ophthalmic radiotherapy under 10 CFR 35.400, the activity of the Y-90 source should also be calculated to determine the treatment times, similar to the requirement for Sr-90 sources in accordance with 10 CFR 35.433. For use of the LV Y-90 Disc, the written directive shall, before treatment, be signed and dated by an AU, and contain the patient or human research subject's name, treatment site, radionuclide, source activity, and total dose.

6.4. Calibration

Licensees shall commit to following 10 CFR 35.432, "Calibration measurements of brachytherapy sources," and 10 CFR 35.2432, "Records of calibration measurements of brachytherapy sources," for calibration and recordkeeping. In accordance with 10 CFR 35.432, licensees may use measurements provided by the source manufacturer.

The activity of each Y-90 source that is used to determine the treatment times for brachytherapy treatments will be calculated by either an AMP authorized for the LV Y-90 Disc and iWand® Ophthalmic System or another individual whose calculation will be reviewed by the AMP authorized for the LV Y-90 Disc and iWand® Ophthalmic System. If an individual other than an AMP authorized for the LV Y-90 Disc and iWand® Ophthalmic System calculates the activity of the Y-90 source, the AMP will review the calculated activity within 15 days prior to the first post-calculation treatment utilizing the source. The records will include the name of the individual who performed the activity calculation, the signature of the AMP who reviewed the calculation, and the date of the AMP's review. The decay will be based on the activity determined under 10 CFR 35.432.

6.5. Service and Maintenance

Service and maintenance will be performed only by the manufacturer or persons specifically licensed by NRC or an Agreement State to perform such services. Service and maintenance will be conducted at intervals specified in the SS&D registration certificate.

Prior to each treatment, the LV Y-90 Disc source will be sterilized and installed into the ophthalmic applicator system by the licensee following the manufacturer instructions.

6.6. Surveys

In addition to the surveys after source implant and removal, and surveys of the patient or human research subject, required by 10 CFR 35.404, as well as the area surveys required by 10 CFR Part 20 and 10 CFR 35.70, "Surveys of ambient radiation exposure rate," the licensee shall commit to survey in accordance with the manufacturer's recommended procedures, pre-treatment and post-treatment visual inspections will be conducted, and a survey of the patient or human research subject and ophthalmic applicator system should be conducted with a portable radiation detection survey instrument to confirm that the source has been removed from the patient or human research subject and returned to the safe shielded position. In addition, pretreatment and post-treatment surveys of the storage container, ophthalmic applicator system, and procedure room will be conducted to ensure that the source has been stored in its storage location.

6.7. Emergency Procedures

Written emergency procedures will be developed, implemented, and maintained. As a minimum, these procedures will address appropriate preparation and handling procedures when emergency source manipulation is needed, when emergency operations must be performed, and steps needed when the source or source assembly is damaged. The procedures will include a description of appropriate emergency response equipment, any appropriate surgical interventions, and responsible individuals.

7. NOTES TO LICENSEES

7.1. Alterations to the LV Y-90 Disc and iWand® Ophthalmic System

This licensing guidance is based on the SS&D safety evaluation in Registration Certificate NH-1501-S-101-S. Modification of the source (including source model or size), will require a new or amended SS&D safety evaluation that addresses the conditions of use and safety of the modified LV Y-90 Disc. Additionally, modification of the Liberty Vision iWand® or use of other manual brachytherapy systems or the source-device combination may require a new or amended SS&D safety evaluation that addresses the conditions of use and safety of the modified LV Y-90 Disc and iWand® Ophthalmic System.

7.2. Changes in Physical Conditions of Use

If the physical conditions of use exceed those reported in the SS&D registration certificate, a limited specific medical use licensee shall request an amendment for the new conditions, and a broad scope licensee shall perform its own engineering and radiation safety evaluations addressing those differences.

7.3. Notification for AUs and AMPs

The NRC recognizes that if an AU or AMP satisfies the T&E listed in the NRC's licensing guidance for the LV Y-90 Disc source and is currently listed on a Commission or Agreement State medical use license or permit for episcleral brachytherapy use of the LV Y-90 Disc, the AU or AMP should be allowed to work under a different license for the same medical use. A limited specific medical use applicant initially applying for authorization for the medical use of the LV Y-90 Disc or an existing licensee applying for an amendment for the medical use of the LV Y-90 Disc may request authorization to notify the NRC in the future that it has permitted an AU or AMP to work at its facility without the need to request an additional license amendment, provided the following conditions are met:

- The AU or AMP meets the training and experience criteria listed in NRC's current licensing guidance for the LV Y-90 Disc and iWand® Ophthalmic System; and

- The AU or AMP is currently listed for the LV Y-90 Disc use on a Commission or Agreement State license, a permit issued by a Commission Master Material License, a permit issued by a Commission or Agreement State licensee of a broad scope, or a permit issued by a Commission Master Material License broad scope permittee; and

- The licensee provides NRC a copy of the license or permit on which the AU or AMP was originally listed for the LV Y-90 Disc; and

- The licensee provides documentation to NRC for each AU or AMP of the above listed conditions no later than 30 days after the date that the licensee allows the AU or AMP to work as an AU or AMP for the LV Y-90 Disc.

If this authorization is approved, these notification conditions will be incorporated as license conditions in the licensee's license.

7.4. Brachytherapy Source Accountability

Licensees shall maintain accountability at all times for all brachytherapy sources in storage or use in accordance with 10 CFR 35.406, “Brachytherapy sources accountability.” When not in use, the LV Y-90 Disc and ophthalmic applicator system should be stored in its storage container and the storage container will be locked in an authorized secure location. In addition, licensees shall maintain records of brachytherapy sources accountability in accordance with 10 CFR 35.2406, “Records of brachytherapy source accountability.”

8. NOTES TO REGULATORS

8.1. Alterations to the LV Y-90 Disc and iWand® Ophthalmic System

License reviewers should confirm that the model and size of the source match those listed in the current SS&D registration certificate.

8.2 Inspection Frequency

Licenses authorizing the LV Y-90 Disc should be inspected every two years. Per Enclosure 1 to Inspection Manual Chapter 2800, “Materials Inspection Program,” licenses authorizing emerging technology under 10 CFR 35.1000 are assigned a Priority 2 inspection code.

8.3 Program Code

The NRC Regions should use program code 02240.

9. PAPERWORK REDUCTION ACT STATEMENT

This licensing guidance provides voluntary guidance for implementing the mandatory information collections in 10 CFR Parts 30 and 35 that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et. seq.). These information collections were approved by the Office of Management and Budget (OMB), approval numbers 3150-0017 and 3150-0010. Send comments regarding this information collection to the Information Services Branch (T6-A10M), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by e-mail to Infocollects.Resource@nrc.gov, and to the OMB reviewer at: OMB Office of Information and Regulatory Affairs (3150-0017 and 3150-0010), Attn: Desk Officer for the Nuclear Regulatory Commission, 725 17th Street, NW Washington, DC 20503; e- mail: oira_submission@omb.eop.gov.

10. PUBLIC PROTECTION NOTIFICATION

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.