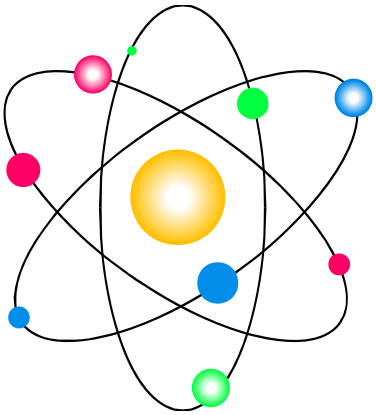
RADIOACTIVE MATERIALS REGULATORY GUIDE



INTRAOCULAR USE OF NEOVISTA EPI-RAD90™ OPHTHALMIC

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February 13, 2009

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GUIDANCE FOR THE INTRAOCULAR USE OF NEOVISTA EPI-RAD90™ OPHTHALMIC SYSTEM

The NeoVista Epi-Rad90™ Epiretinal Ophthalmic System is an ophthalmic device used for intraocular treatment by means of high dose rate focal delivery of radiation (i.e., Strontium-90) to target tissues. The design and operation is significantly different from that of Strontium-90 (Sr-90) superficial eye applicators that are currently regulated in accordance with 4731.4450, "Use of brachytherapy sources." As such, the intraocular use of the NeoVista Epi-Rad90™ System is regulated in accordance with the provisions of 4731.4404, "Other medical uses."

Consistent with the direction in 4731.4404, licensees must use these devices in accordance with the following requirements which will be incorporated into the license either through license condition or through incorporation by reference to licensee submittals that include commitments consistent with these requirements.

This guidance represents an acceptable means of complying with regulations that apply to the NeoVista Epi-Rad90™ System and is not intended to be the only means of satisfying requirements for a license. Therefore, the applicant may, unless the information is specifically required by regulation, submit alternative commitments for review by the MDH staff to determine whether the regulatory requirements are met. In addition, the commitments pertaining to the Epi-Rad90™ System that are incorporated into the applicant's license, either through license condition or through incorporation by reference to licensee submittals, will be reviewed during routine inspections.

Radionuclides, Form, Possession Limits, and Purpose of Use

The applicant must identify the radionuclide(s), chemical/physical form, maximum possession limit, and purpose of use. For example, the following provides the format for an acceptable request:

Requested Material:	*Strontium-90/Yttrium-90*
Chemical or Physical Form:	*Sealed sources (manufacturer and model number; e.g., QSA Global GmbH Model SICW.3)*
Possession Limit:	*15 mCi (0.56 GBq) per source; 30 mCi (11.1 GBq) total*
Authorized Use:	*For medical use in the NeoVista Epi-Rad90™ Model R2.3 Applicator Device permitted by 4731.4404*

Facility Address and Description

The applicant must provide an address of use, facility diagram and a description of the location(s) where the Epi-Rad90™ System will be used and stored.

Training and Experience (T&E) for Authorized Individuals
MDH has determined that the individuals meeting the guidance below will be considered qualified and authorized for intraocular use of the NeoVista Epi-Rad90™ System. Applicants may also submit alternative Training and Experience commitments to be reviewed on a case-by-case basis by MDH staff. The alternative information should include an explanation as to why the applicant believes the alternative information demonstrates that the individual is qualified to be an authorized individual.

If the MDH staff revises the Training and Experience criteria, individuals who were authorized for the NeoVista Epi-Rad90™ System in accordance with these criteria or previous criteria, do not have to meet the revised criteria.

Authorized User (AU)
An authorized user (Authorized User) for the medical use of the NeoVista Epi-Rad90™ System should meet the Training and Experience requirements in 4731.4458, "Manual brachytherapy training" or 4731.4479, "Remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units; Training." The Authorized User and retinal surgeon should additionally receive training in the operation, safety procedures, and clinical use of the NeoVista Epi-Rad90™ System that includes hands-on device operation. This training requirement may be satisfied by satisfactory completion of a training program provided by the NeoVista Epi-Rad90™ System vendor; or by receiving training supervised by an Authorized User or Authorized Medical Physicist, as appropriate, who is authorized for the NeoVista Epi-Rad90™ System.

The applicant must submit documentation for all of the above Training and Experience for each Authorized User of the NeoVista Epi-Rad90™ System. MDH Form 313T, "Authorized User Training and Experience and Preceptor Attestation" for uses defined in accordance with 4731.4450 and 4731.4463 should be used.

Authorized Medical Physicist (AMP)
An Authorized Medical Physicist for the medical use of the NeoVista Epi-Rad90™ System should meet the Training and Experience requirements in 4731.4412, "Authorized medical physicist training;" or the definition of authorized medical physicist in 4731.0100, "Definitions."

The Authorized Medical Physicist must receive training in the operation, safety procedures, and clinical use of the NeoVista Epi-Rad90™ System that includes hands-on device operation. This training requirement may be satisfied by satisfactory completion of a training program provided by the NeoVista Epi-Rad90™ System vendor and/or by receiving training supervised by an Authorized Medical Physicist authorized for the NeoVista Epi-Rad90™ System.

The applicant must submit documentation for all of the above Training and Experience for each Authorized Medical Physicist of the NeoVista Epi-Rad90™ System. MDH Form 313B, "Authorized Medical Physicist Training and Experience and Preceptor Attestation," should be used to document Training and Experience.

Note: MDH will not require medical physicists seeking authorization for the NeoVista Epi-Rad90™ System to obtain a preceptor statement for the use of this device.

Written Directives
For the NeoVista Epi-Rad90™ System, the written directive shall, before treatment, contain the patient or human research subject's name; the radionuclide; treatment site; and total source activity and exposure time (or total dose).

Specific Information on Radiation Safety Precautions and Instructions
The applicant shall commit to following all the requirements in 4731.4450, 4731.4451, 4731.4452, 4731.4731.4455, and, if a treatment planning system is used, 4731.4457. In addition, the applicant should commit to the following:

- Procedures will be conducted under the supervision of an Authorized User authorized for the NeoVista Epi-Rad90™ System. Before initiating treatment, the Authorized User will consult with the retinal surgeon and an Authorized Medical Physicist authorized for the NeoVista Epi-Rad90™ System. The procedures will be conducted in the physical presence of the Authorized User or Authorized Medical Physicist.
- The activity of each Sr-90 source that is used to determine the treatment times for intraocular ophthalmic treatments will be performed by either an Authorized Medical Physicist authorized for the NeoVista Epi-Rad90™ System or another individual whose calculation will be reviewed by the Authorized Medical Physicist authorized for the NeoVista Epi-Rad90™ System. If an individual other than an Authorized Medical Physicist authorized for the NeoVista Epi-Rad90 ™ System calculates the activity of the Sr-90 source, the records will include the name of the individual who performed the activity calculation and the signature of the Authorized Medical Physicist who reviewed the calculation. The decay will be based on the activity determined in accordance with 4731.4455.
- Service and maintenance will be performed only by the manufacturer or persons specifically licensed by the NRC or an Agreement State to perform such services. Service and maintenance will be conducted at intervals specified in the Sealed Source and Device certificate (e.g., every two years or no more than 25 uses after initial receipt).
- Prior to each treatment, the applicator device will be tested with the NeoVista Multi-Channel Tester, calibrated by the manufacturer with the applicator device in accordance with the manufacturer's instructions.
- In accordance with the manufacturer's recommended procedures, pre-treatment and post-treatment visual inspections will be conducted to ensure that the slider mechanism of the delivery device is in the locked position. In addition, pre-treatment and post-treatment surveys of the storage container, delivery device, and procedure room will be conducted to ensure that the source has been fully retracted to its storage position.
- The delivery device will be returned to the storage container when not in use and the storage container will be locked in an authorized secure location.
- In accordance with the manufacturer's instructions, the applicator device will be transported to the treatment room in the device holder and returned to the device holder immediately after treatment to shield the device.
- Written emergency procedures will be developed, implemented, and maintained. As a minimum, these procedures will address source recovery when it cannot be confirmed that the source reached the treatment site, or when the source will not return to the shielded storage position in the delivery device. The procedures will include a description of appropriate emergency response equipment and any appropriate surgical interventions.

Change in Physical Conditions of Use
If the physical conditions of use exceed those reported in the Sealed Source and Device (SSD) certificate, the limited specific medical use licensee should request an amendment for the new conditions. A broad scope licensee should perform its own engineering and radiation safety evaluation addressing those differences.

Investigational Device Exemption (IDE) Restrictions
The NeoVista Epi-Rad90^{TM} System is accepted by the U.S. Food and Drug Administration (FDA) under the provisions of an Investigational Device Exemption (IDE) which allows the investigational device to be used in order to collect safety and effectiveness data required to support a premarket approval application or a 510(k) submission to the FDA. This is a research use and therefore, the licensee must meet the requirements in 4731.4401, "Provisions for the protection of human research subjects." Nothing in the MDH license relieves the licensee from complying with additional FDA requirements under the IDE.

SUMMARY OF REVISIONS

REVISION	SECTION	DESCRIPTION