From: Tran, Frank
To: Durbin, Christopher M
Subject: Request for additional information for NRC License No. 24-01570-03
Date: Friday, September 03, 2021 5:44:00 PM

Dear Dr. Durbin:

We have reviewed your license renewal application dated July 27, 2021 for NRC License No. 24-01570-03 for St. Luke's Hospital. The licensing guidance for your license is NUREG-1556, Volume 9, Revision 3, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees" which can found on the NRC's website at https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html. Based on the review, we will need the following information.

1. In the letter dated March 17, 2014, the licensee described facility changes in the Nuclear Medicine Department located at St. Luke's Hospital, 232 S Woods Mill Rd., Chesterfield, Missouri. Specifically, the licensee converted an injection room to the hot lab and the old hot lab was converted to an injection room. We could not locate the changes in the renewal application. Please resubmit the facility changes as described in the letter dated March 17, 2014 and any updates if necessary.

2. The licensee has updated the HDR Vault and provided information for the new HDR Vault in the letter dated May 9, 2013. However, the renewal application provided the diagram of the old HDR Vault. Please resubmit the information for the new HDR Vault as described in the letter dated May 9, 2013 including radiation shielding and evaluation; warning systems and restricted area controls (e.g., locks, signs, warning lights and alarms, interlock systems); area radiation monitoring equipment; viewing and intercom systems; methods to ensure that whenever the device is not in use or is unattended, the console keys will be inaccessible to unauthorized persons; and emergency response equipment (tongs, portable lead shielding container, etc.); and any updates as necessary.

3. In the letter dated February 16, 2021, the licensee provided that PET isotopes permitted by 10 CFR 35.200 will be used at 121 St. Luke's Center Drive, Chesterfield, Missouri. Please resubmit the facility and shielding evaluation (for PET/CT room, injection rooms, uptake rooms, hot lab, etc. and the most conservative assumptions used in the calculation) as described in the letter dated February 16, 2017 and any updates as necessary. In addition, please confirm if PET isotopes will be used at 232 S Woods Mill Rd., Chesterfield, Missouri; 5551 Wing Haven Blvd., O'Fallon, Missouri; or 2345 Dougherty Ferry Rd., St. Louis, Missouri. If PET isotopes will be used, please identify the areas where PET isotopes will be used and provide the followings: information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used. The calculations should include the workload and conservative distance assumptions used.

4. Provide information about access control to the restricted areas including if there is a physical door and if it is locked.

5. If there will be in-patient rooms for treatment with 10 CFR 35.300 or 35.400 material, please identify the rooms and provide the followings: information about the type, thickness, and density of any necessary shielding to enable independent verification of shielding calculations, and a description of any portable shields used. The calculations should include the workload and conservative distance assumptions used.

6. Please confirm if there have been no changes to the licensed material authorized for each location of use listed in License Condition 10 in Amendment No. 69 dated June 10, 2021.

7. The licensee is currently authorized for depleted uranium (DU) for use in ADAC Laboratories Transmission Line Source Housing VANTAGE device. However, this device was not described in the renewal application. If the licensee would like to remove this device from the license, please state and provide record of disposal including the transferring receipt and the last leak test if applicable.

8. Provide a confirmation if the model for NeoVista Epi-Rad90 is R2.3.

9. The license is authorized for NeoVista Epi-Rad90 system permitted under 10 CFR 35.1000; however, the renewal application did not provide information as discussed in the Licensing Guidance for the Intraocular Use of NeoVista, Inc.'s Epi-Rad$_{90}$ (Strontium-90) Ophthalmic System dated April 2009. Please provide the followings:
    - The licensee shall follow all the requirements in 10 CFR 35.400, 35.404, 35.406, 35.432, and, if a treatment planning system is used, 35.457. In addition, the licensee commit to the following:

    - The standard protocol will be conducted in the physical presence of an:
        - AMP authorized for the NeoVista Epi-Rad90™ System; or
        - AU authorized for procedures other than the standard protocol; or
        - RSO authorized for the NeoVista Epi-Rad90™ System (except an RSO who is an AU authorized only for the standard protocol).

    - For all procedures other than the standard protocol, the AU will consult with the retinal surgeon and an AMP authorized for the NeoVista Epi-Rad90 System before initiating treatment. The procedures will be conducted in the physical presence of either the AU authorized for procedures other than the standard protocol, or AMP authorized for the NeoVista Epi-Rad90™ System.

    - The activity of each Sr-90 source that is used to determine the treatment times for intraocular ophthalmic treatments will be calculated by either an AMP authorized for the NeoVista Epi-Rad90 System or another individual whose calculation will be reviewed by the AMP authorized for the NeoVista Epi-Rad90 System. If an individual other than an AMP authorized for the NeoVista Epi-

Rad90 System calculates the activity of the Sr-90 source, the AMP will review the calculated activity within 30 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 §35.432. As an alternative to the decay calculations and treatment time determinations being performed or reviewed by an AMP, for the standard protocol, the standard calibration certificate (provided by the manufacturer) will be used to determine the treatment times (calculated by the manufacturer) needed to deliver 24 gray. The standard calibration certificate will indicate the prescribed treatment times for various date periods.

- 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 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.

If the licensee would like to make changes to the program to adopt the new revision of the Licensing Guidance for the Intraocular Use of NeoVista, Inc.'s Epi-Rad$_{90}$ (Strontium-90) Ophthalmic System, provide the following.

- The licensee requests to incorporate into its license a change process similar to 10 CFR 35.26 for the use of NeoVista, Inc.'s Epi-Rad$_{90}$ (Strontium-90)

Ophthalmic System. Such a change process can allow some future changes to radiation safety programs provided that the change process requires the following conditions to be met for revisions to the radiation safety program:

- the revision is in compliance with the regulations; and
- the revision is based upon NRC's current licensing guidance for the NeoVista Epi-Rad$_{90}$ System, pursuant to 10 CFR 35.1000 use, as posted on the NRC web site; and
- the revision has been reviewed and approved by the licensee's radiation safety officer and licensee's management; and
- the affected individuals are instructed on the revised program before the change is implemented; and
- the licensee will retain a record of each change for five years; and
- the record will include a copy of the appropriate Web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

10. Provide the medical license number for each authorized user, the issuing entity (e.g., Missouri), and status (e.g., active).

11. Provide the statement "We have developed and will implement and maintain written procedures for a program for training required under 10 CFR 19.12 for each group of workers, including (i) topics covered, (ii) qualifications of the instructors, (iii) method of training, (iv) method for assessing the success of the training, (v) initial training, and (vi) annual refresher training."

12. In the renewal application, the licensee did not specific commit to have radiation monitor instruments be calibrated by persons who are licensed by the NRC or an Agreement State. Provide the following statement "Radiation monitoring instruments will be calibrated by a vendor who is licensed by the NRC or an Agreement State to perform instrument calibrations."

13. Provide a description of the equipment used to measure the dosages for the use of 10 CFR 35.100, 35.200 and 35.300 material.

14. The licensing guidance asks for procedures required by 10 CFR 35.643, "Periodic spot-checks for remote afterloader units". The licensee provided the "MICRO SELECTRON HIGH-DOSE RATE TREATMENT PROCEDURES"; however, this procedure did not specifically discuss the periodic spot-checks for the HDR. Please submit the High Dose Rate Brachytherapy QA Protocol which discussed the spot-check requirement as seen in the application dated March 7, 2011 listed in License Condition 14.A. in Amendment No. 69 dated June 10, 2021 or an alternate.

15. In the "Occupational Dose" of the renewal application, the licensee made a commitment to NUREG-1556, Vol. 9, Rev. 1 which is out dated. Please provide the

statement “We will maintain, for inspection by the NRC, documentation demonstrating that unmonitored individuals are not likely to receive a radiation dose in excess of the limits in 10 CFR 20.1502; or we will monitor individuals in accordance with the criteria in the section titled, ‘Radiation Safety Program–Occupational Dose’ in NUREG–1556, Vol. 9, Rev. 3, ‘Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licensees.’”

16. Confirm that non-routine maintenance activities associated with the HDR will only be performed by the vendor, manufacturer, or persons licensed by the NRC or an Agreement State.

17. Provide the following statement “We will develop, implement, and maintain written procedures for licensed material accountability and control to ensure that:

    - license possession limits are not exceeded,
    - licensed material in storage is secured from unauthorized access or removal,
    - licensed material not in storage is maintained under constant surveillance and control records of,
    - receipt (either from the licensee’s own production operations or from, and
    - another licensee), transfer, and disposal of licensed material, are maintained.”

18. If the leak test for sealed sources used pursuant to 10 CFR Part 35 will be conducted by the licensee, provide the statement “We have developed and will implement and maintain written procedures for sealed-source leak testing that meet the requirements of 10 CFR 35.67.” If not, provide an alternate. If the leak test of other sealed source such as calibration sources, if applicable, will be conducted by the licensee, provide the statement “We will implement the model leak test program published in Appendix Q of NUREG–1556, Volume 9, Rev. 3, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses” or an alternate. For your information, Section 8.10.11, “Leak Tests” in NUREG-1556, Vol.9, Rev. 3 provides useful information about the sealed source leak test.

19. Section “Safe Use of Unsealed Licensed Material” of the renewal application cited an incorrect section of NRC regulation, provide the following statement “We have developed and will implement and maintain written procedures for safe use of unsealed byproduct material that meet the requirements of 10 CFR 20.1101 and 10 CFR 20.1201.”

To continue the review of your application, we request that you submit your response under a dated and signed cover letter within 30 days. In the cover letter, please refer the license number, docket number and Mail Control No. 628104.

If you have questions, require additional time to respond, or require clarification on any of the information stated above, please contact me at 630-829-9623 or reply to this email.

In accordance with Title 10 of the *Code of Federal Regulations* (10 CFR) 2.390 of the NRC’s “Rules of Practice,” a copy of this correspondence will be made available

electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Best regards,

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