

**From:** Penny Lanzisera  
**To:** lanka@umdnj.edu  
**Date:** Fri, Jun 22, 2007 5:15 PM  
**Subject:** Request for Additional Information for UMDNJ Amendment to add Epi-Rad Device

L.N. 29-02957-13  
D.N. 030-09926  
Mail Control No. 140517

Dear Mr. Lanka, please provide the following additional information regarding your recent request to add the Neovista Epi-Rad Ophthalmic System:

1. The FDA documentation submitted indicates that the device use is limited to research. If routine clinical use has been approved, please provide documentation to support.
2. The use of this device may fall under 10 CFR 35.1000 in the future. Please confirm that any future guidance developed by the NRC for use of this device will be reviewed and implemented by UMDNJ, as appropriate.
3. Since the use of this device is sufficiently different from previously used eye applicator devices, confirm that authorized users will meet the training and experience requirements in 10 CFR 35.490.
4. Confirm that the applicator device will be used in conjunction with the Multi-Channel Tester calibrated with the device prior to treatments and that calibrations will be conducted in accordance with the manufacturer's instructions.
5. Confirm that the applicator device will be returned to the storage container when not in use and that the container will be taken to the OR in order to store the source expeditiously.
6. Confirm that the applicator device will be returned to QSA Global no later than 1 year from the initial date of receipt (or no more than 25 uses after initial receipt) for service and maintenance.
7. Confirm that all Authorized Users and the RSO will receive the vendor training described in your application prior to use of the device.

You may fax your response to my attention to 610-337-5269. Please reference mail control number 140517 in your response.

Penny Lanzisera  
US NRC, Region 1

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**Subject:** Request for Additional Information for UMDNJ Amendment to add  
Epi-Rad Device  
**Creation Date** Fri, Jun 22, 2007 5:15 PM  
**From:** Penny Lanzisera  
  
**Created By:** PAN@nrc.gov

**Recipients**

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**Options**

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