From: James L. Montgomery
To: INTERNET: rodwimmer@lycos.com
Date: 11/3/04 6:18PM
Subject: I-125 Iotrex amendment request for St. James Healthcare

Rod: Please provide the following additional information re. the subject amendment request. You can e-mail back to me or regular mail at 5803 Pine Hollow Road, Clayton, CA 94517.
1. Confirm that the written directive will also include the patient's name and treatment site.
2. Confirm you will retain records of your assessment of the catheter integrity. Confirm the record will include the model and serial number of the balloon treatment catheter, date and results of the assessment, and the name of the individual who performed the assessment.
3. Confirm that if the catheter fails the above assessment (i.e. prone to leakage), you will remove it from use and file a report of the failure to the NRC within 5 days of the assessment.
4. Because the iodine-125 Iotrex liquid brachytherapy source is a manual brachytherapy source, please confirm you will apply the manual brachytherapy requirements in 10 CFR 35.404, 35.406(a) and (b); 35.410; 35.415(a) and (c); 35.457; 35.490; 35.940 and the exceptions listed below to complete your radiation safety precautions and instructions:

A. Confirm you will make and retain a record of I-125 Iotrex brachytherapy source accountability for 3 years.

B. Confirm that your brachytherapy source storage record will include the activity of the I-125 Iotrex sources removed from storage; the time and date they were removed from storage; the name of the individual who removed them from storage; the location of use; and, if at the end of the I-125 Iotrex source implantation, the remaining I-125 Iotrex is not treated as waste.

C. Confirm the activity of the I-125 Iotrex sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage.

5. Confirm that you will use a dose calibrator setting, syringe size and type described in the Proxima's instructions and will follow Proxima's instructions on the measurement of Iotrex.

6. Confirm you will maintain records of the Iotrex calibrations for 3 years and that the records will include the date of calibration; the manufacturer's lot number for the source and and the instruments used to calibrate the source; the Iotrex activity; and the name of the individual performing the calibration if performed by the licensee.

If you have any questions concerning the above request, pls. e-mail or call at 925-673-9646.
THANKS, JIM MONTGOMERY, NRC REGION IV

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