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Affiliated with the
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MS 16

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September 7, 2000

U.S. Nuclear Regulatory Commission
Region I, 475 Allendale Road
King of Prussia, Pennsylvania 19406

29-02641-03
030-02452

Reference : Control Number 127938

Dear Mrs. Beardsley,

I have enclosed the additional information you requested regarding performing insertions of episcleral eye plaques for the treatment of intraocular malignancies as an out-patient procedure.

The patient shall consult with a Radiation Oncologist prior to treatment. The Radiation Oncologist shall evaluate the ability of the patient to follow the radiation safety precautions sheet. If the Radiation Oncologist feels that the patient will not be able to follow instruction sheet the patient will then be treated as an in-patient.

If the patient is able to be treated as an out-patient the patient is given verbal and written instructions on specific radiation safety precautions that will be used while the patient has the applicator in at home. A signed copy is maintained on record in the Radiation Oncology Department. A copy of the radiation safety instructions is enclosed.

The plaque is surgically sutured to the eye, hence creating a fixed source of radiation and virtually eliminating the chance of the source becoming dislodged.

On the day of administration the Medical Physicist transports the seeds to the OR for the procedure. When the procedure is complete but before the patient leaves the OR, a Medical Physicist surveys the area for any possible dislodged sources and attaches a radioactive materials wrist band to the patient. The wrist band shall indicate the isotope, number of seeds, activity per seed, and an emergency contact number. In addition, an ion chamber survey shall be used to measure the exposure rate at 1 meter from the patient after the insertion takes place as required by Regulatory Guide 8.9. For iodine 125, if the exposure level exceeds 1 mr/hr @ 1 meter or the total administered activity is greater than 9mCi the patient shall be given wrap around leaded eye glasses with sufficient lead to reduce the exposure levels below the release

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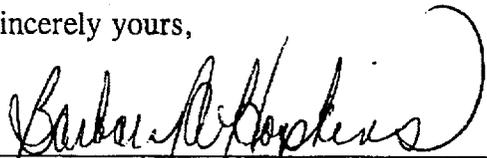
criteria requirements. Otherwise the patient can be released without the leaded eye glasses. For Palladium 103, if the exposure level exceeds 3 mr/hr @ 1 meter or the total administered activity is greater than 40mCi the patient shall be given wrap around leaded eye glasses with sufficient lead to reduce the exposure levels below the release criteria requirements. Otherwise the patient can be released without the leaded eye glasses. Records of the surgical suite and patient survey shall be maintained on record in Radiation Oncology. The Radiation Oncologist will specify how long the eye plaque shall remain in place before source removal.

The Ophthalmologist will schedule time in the OR and remove the plaque at the time specified in the treatment plan. A member of the Medical Physics staff shall take the source and plaque back to Radiation Oncology in a lead container. The sources shall be removed and placed in storage in the Hot lab.

If you have any questions regarding this, please contact Mr. Eric Weiss, at (201) 996-2548.

Thank you for your consideration in this matter.

Sincerely yours,



Barbara A. Hopkins, M.P.A., CHE
Vice President, Operations

**Hackensack University Medical Center
Department of Radiation Oncology**

**INSTRUCTIONS FOR THE FAMILY AND THE RELEASED PATIENT IMPLANTED
WITH PALLADIUM-103 / IODINE 125 EYE PLAQUE**

DATE : _____
 NAME OF PATIENT : _____
 ISOTOPE : _____

PATIENT

1. REPORT TO YOUR SURGEON ON _____ AT _____ FOR PLAQUE REMOVAL Failure to return on time will result in radiation overdose to your eye.
2. Leaded wrap around eye glasses have been provided and must be worn at all times.
3. Your ophthalmic plaque is sutured securely in place, however, in the extremely unlikely event of plaque being dislodged please call our office immediately and follow the instructions. As an emergency precaution we provided you with a lead container to be used for storing the plaque if it has to be removed in medical emergency outside our facility.
4. You must stay in your home at all times until you return to have the eye plaque removed. You may not leave your home for any reason even to do shopping or visit another physician.
6. There is a risk of small radiation exposure to persons who get very close to your implanted eye. Avoid such contacts. We ask you to limit your close (one foot away or closer) contacts particularly with children to less than 20 minutes per day, however , unlimited contacts are permitted if you keep a distance of 3 feet or more.
7. Your body fluids ARE NOT radioactive and your clothing and other utensils can be handled by others safely. We ask that you sleep in a separate bed which should not be in a children's bedroom.

FAMILY

If patient becomes hospitalized or other emergency should occur while implant is in place, please notify us immediately.

Please sign the copy of these instructions after you read them, and all your questions have been answered.

 Patients Signature

EMERGENCY CONTACT NUMBERS

OPHTHALMOLOGIST : _____

RADIATION ONCOLOGIST : _____