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Nuclear Regulatory Commission
Region II
61 Forsyth Street, SW. Suite 23T85
Atlanta, Georgia 30303-8931

NOV 10 RECD

November 8, 1999

Attn: Douglas M. Collins
Director Division of Nuclear Materials Safety

Dear Mr. Collins:

In addition to our letter of 9/10/99, I notify you that we completed the actions addressed in your Confirmatory Action letter of September 9, 1999.

1. **Action item #1. We have reviewed the records and identified a total of 15 brachytherapy patients, which include 9 patients already known to you, where both Palladium 103 and Iodine 125 were used together for the treatment implant.**

   a) **In our review we have determined that 9 of the 15 patients were referred to us with clinical stage T1 or T2 disease. After their arrival (after the initial order of seeds) and during the treatment planning process, a biopsy of the seminal vesicles was performed and showed involvement of the seminal vesicles resulting in an increase in the treatment target volume. This required additional seeds in the seminal vesicles. We preferred Iodine 125 strands for the seminal vesicle involvement because of the lower dose rate, higher penetration and geometrical stability. If the seminal vesicle involvement had not been identified, the brachytherapy treatment in these patients would be a failure (100%). We did have documentation of the patient's biopsy and up-stage in the patient's chart. This was not a misadministration but a failure to make the change of order notation properly on the directive.**

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b) **In 6 of the 15 patients we determined after needle placement the target volume had increased because of edema thus additional seeding was required. Five (5) patients were given booster dose of Iodine in the periphery and one (1) patient was given booster dose of Palladium in the center of the prostate. The number of booster seeds was determined to cover the volume increase observed during the implant maintaining our rule of one seed per cubic centimeter. Therefore, there was no misadministration. This conclusion is correct on the assumption that the doses from one Iodine seed and one Palladium seed are equivalent or rather they will produce the same biological effect when they finally decay.**

2. **Action item #4. We have completed an inventory from all the patient records. A cross-reference to the number of seeds implanted and the number of seeds in storage with the number of seeds received was made. All seeds have been accounted for.**

I would also like to confirm that our record keeping has been greatly improved by expanding the log book into a full inventory and initiating a computer program to keep the inventory current and accountable at all times. We believe that our present operations are safe and in complete compliance. I will be glad to answer any further questions you may have.

Sincerely,

P Koutrouvelis MD

Panos Koutrouvelis, M.D.

Cc: Commonwealth of Virginia