From: Penny Lanzisera
To: achowdhu@gw-hospital.com
Date: Wed, Nov 22, 2006 3:24 PM
Subject: Request for Additional Information regarding Amendment Request, MCN 139420

License No. 08-30607-01
Docket No. 030-35424
Mail Control No. 139420

Dr. Chowdhury,

The web guidance regarding the seedSelectron use has temporarily been removed. Please confirm that your RSC will use the Licensing Guidance for 10 CFR 35.1000 sealed sources and devices, including the guidelines for the Nucletron seedSelectron System, when published, for approvals of facilities, equipment, authorized users, and procedures. For instance, the authorized users should be 10 CFR 35.400 users with vendor training for the seedSelectron system. Additionally, device checks should include: source positional accuracy, length of source transfer tubes and applicators, the compatibility and function of source transfer tubes, applicators, and transfer tube-applicator interfaces, source exposure indicator lights, radiation detectors used to indicate the source train position, clock (date and time) in the unit computer/treatment planning computer, proper operation of the unit by performing a dummy run, decayed source activity in the unit's computer/treatment planning computer for each cassette installed, and autoradiograph of source cassette to confirm source inventory. The RSC should also review procedures for written directives, that should include procedures to: (i) confirm the accuracy of the base plane setting and the needle loading sequence input into the system; (ii) check that the internal radiation detectors confirm the correct loading sequence; and (iii) assure that the imaging system used to visualize the treatment area is compatible with the Nucletron seedSelectron system (or Nucletron First System, as appropriate), the resolution is sufficient to visualize needle and initial seed position, and the treatment area and the implanted seeds is being properly imaged so that the licensee can confirm that treatment site for each administration is in accordance with the treatment site in each written directive. Finally, the RSC should consider the applicability of the following requirements for this use: 10 CFR 35.41 including(b)(4), 35.404(a) and (c), 35.406 (a) and (c), 35.410, 35.415 except (b)(2), 35.432, 35.2310, 35.2404, 25.2406 (a) and (c), 35.3045, 35.600, 35.605, 35.610, 35.630(a) and (c), 35.657 except (b), 35.2605, 35.2630, and physical presence requirements for authorized users.

Please fax your response to my attention at 610-337-5269 and reference Mail Control No. 139420.

Penny Lanzisera
US NRC, Region 1

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From: Penny Lanzisera

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