

From: Donna Janda
To: jmerkin@bbmc.org
Date: Thu, Jun 1, 2006 9:11 AM
Subject: additional information for Southern Delaware Surgery Center application

Applicant: Southern Delaware Surgery Center
Docket No. 03037185
Mail Control No. 138651

Subject: Additional information needed for Southern Delaware Surgery Center license application

Mr. Merkin,

In order to complete our review of Southern Delaware's application for an NRC materials license, we need the following additional information:

1. Please provide a total maximum possession limit for all iodine-125 sealed sources to be possessed under 35.400 authorization at any one time, including waste.
2. The active Sealed Source and Device Registration (SSDR) certificate for the Imagyn Medical Technologies Model 12501 sealed source is now named IS-125 Series manufactured by IsoStar Texas, Inc. dba Imagyn Medical Technologies and the Medi-Physics, Inc. Model 6702 sealed source is manufactured/distributed by Amersham/Medi-Physics with the same model number. Please confirm that these sealed sources are the model numbers which you want authorization
3. You requested to list Mr. Jack Merkin as Radiation Safety Officer (RSO) on your license. The license that references Mr. Merkin as RSO is not a medical license; however, Mr. Merkin may have current or previous experience as an RSO on a medical license that authorizes 35.400. If this is the case, provide the license number, if an NRC license, or copy of the license, if an Agreement State license, listing Mr. Merkin as RSO, and documentation of continuing training and experience if he was listed as RSO on a medical license more than 7 years ago. If Mr. Merkin has not previously been listed as an RSO on an NRC or Agreement State license with 35.400 authorization, you may provide the appropriate information required by 10 CFR 35.50, which describes the qualifications for an individual to be named RSO on a medical license. As an alternative, you may propose an individual who is already an RSO on a license with 35.400 authorization to be RSO on your license.
4. Your application states that the sealed sources will be stored in a locked cabinet. Please describe who will have access to the locked cabinet. In addition, please describe the location where the I-125 sealed sources will be delivered, who will receive the sources, and the training the individual(s) will receive. Also, Your application provides information on a dose calibrator. Please state whether you will have a "hot lab" facility where instrumentation and any reference sources will be stored. If this is the case, please provide a diagram of this location.
5. Item 9 of your application states that you will possess a Ludlum Model 14C GM meter with an end window probe. Please note that this portable survey instrument may not be sufficiently sensitive to detect dislodged sources that are shielded by other objects in the procedure room or the recovery room. Consider the need for a sodium iodide probe to detect dislodged I-125 seeds.
6. Please confirm that you will maintain on-site patient records sufficient to show compliance with NRC regulations, including 10 CFR 35.40 regarding written directives and 10 CFR 35.41 (i.e., documentation of the evaluation performed for each patient to confirm that the administration was in accordance with the written directive.)
7. Please describe your emergency response equipment (i.e., shielded container, forceps)

to retrieve stray I-125 sources.

8. Please note that your license will restrict manual brachytherapy authorization to patients who can be released under the provisions of 10 CFR 35.75.

Because your response will contain license commitments, please have your response signed and dated by an individual authorized to make binding commitments and sign official documents on behalf of the licensee. Please be sure to include Mail Control No. 138651 in your response. Please note that you may not reply to this letter by return email. Your reply must be in writing by letter or facsimile (610-337-5269). If we do not receive a reply from you within 20 calendar days from the date of this email, we will assume that you do not wish to pursue your application.

If you have any questions regarding these items, please call me at 610-337-5371.

Thank you for your attention to this matter.

Sincerely,

Donna Janda
Health Physicist, Medical Branch
Division of Nuclear Materials Safety
U.S. NRC Region I

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