**From:** Gabriel, Sandra
**Sent:** Monday, September 27, 2010 11:09 PM
**To:** 'willswilmington@aol.com'
**Subject:** Additional information for NRC license application, mail control 573238

Licensee: Wills Surgery Center
License Number: 07-31415-01
Docket Number: 03038327
Mail Control: 573238

To: Michelle Serfass

Please provide the following additional information regarding your request for a new NRC license:

1) Attachment C to your application described equipment and facilities.

   a) You stated that your survey instrumentation will be a GM meter such as Ludlum Model 3 with GM probe. You did not propose instrumentation suitable to detect and assess small quantities of removable contamination, for example, if a seed should rupture. We request that you give strong consideration to obtaining an instrument with a thin crystal sodium iodide probe. This will aid in detection of small quantities of removable contamination and also of dislodged sources that may be shielded by interposed materials.

   b) You stated that you have developed and will implement and maintain written survey meter calibration procedures, however you have not requested authorization for a survey meter calibration source. NRC licensing guidance allows you to substitute the following commitment: "Radiation monitoring instruments will be calibrated by a person qualified to perform survey meter calibrations."

   c) You stated that seeds will be kept in a locked cabinet in the seed preparation room, and that a "Caution – Radioactive Materials" sign will be placed on the room door whenever seeds are present and not locked in the storage cabinet. Please confirm that you will also place a "Caution – Radioactive Materials" sign on the storage cabinet, and describe how the keys will be secured from unauthorized access.

   d) Please clarify which room is considered the seed preparation room; is this the room labeled "B" on the facility diagram? Also provide a magnified diagram of the seed preparation room, showing the location of the storage cabinet and other equipment related to the seed implant program.

   e) You stated "licensed material will be prepared and stored in a shielded area." Please describe this shielding, including any shielding available to protect personnel, such as a mobile or fixed L-block shield.

   f) You stated that personnel monitoring will be conducted using whole body film dosimeters. NRC licensing guidance allows you to substitute the following commitment, if you wish: "Either we will perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in 1 year, a

radiation dose in excess of 10% of the allowable limits in 10 CFR Part 20 or we will provide dosimetry that meets the requirements listed under 'Criteria' in NUREG-1556, Vol. 9, Rev. 2, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." Your assessment of the need for personnel monitoring should consider the potential for both whole body and extremity exposures. Please note that item 6 of your "General Radiation Safety Rules" on page 12 states "wear a finger exposure monitor when handling brachytherapy sealed sources or applicators that contain brachytherapy sealed sources."

2) Page 8 of Attachment D described your procedure for package receipt, and stated that packages will be opened only by a medical physicist or other person specifically trained to perform this function. Is it planned that a medical physicist will come to your facility on days that package deliveries are expected? In the absence of a medical physicist, which other staff members will be trained to perform this function?

3) Please confirm that you will perform brachytherapy procedures only on patients who can be released under the provisions of 10 CFR 35.75.

4) Several of your submitted procedures were not required to be submitted and will not be considered part of your license. We did note, however, that certain portions of your procedures are not consistent with current NRC regulations:

   a) Pages 18-20 of Attachment D described your Brachytherapy Quality Management Program, in accordance with the requirements of 10 CFR 35.32. Please note that 10 CFR Part 35 underwent a major revision in October 2002 and the regulations no longer include 35.32. The regulations are now less prescriptive, however, 10 CFR 35.41 requires you to develop, implement, and maintain written procedures to provide high confidence that treatments are delivered in accordance with the written directive. Please confirm that you will update your procedures to be consistent with the current regulatory requirements.

   b) The description of written directives on page 18 of Attachment D is not consistent with the current regulatory requirements of 10 CFR 35.40(b)(6). Please note that the current regulation requires the written directive to include two sections, one before implantation and one after implantation but before completion of the procedure, with contents somewhat different than those described in your procedures. Please confirm that you will update your procedures to be consistent with the current regulatory requirements.

5) Please describe the way in which you will comply with 10 CFR 35.432 for calibration measurements of brachytherapy sources. Do you plan to use measurements provided by the source manufacturer or an accredited calibration laboratory that are made in accordance with 10 CFR 35.432(a) or do you plan to obtain calibration instrumentation and perform your own calibration measurements?

6) The NRC maintains a database of contact information for each licensee's Radiation Safety Officer. Please provide contact information for Dr. Raben, including a daytime telephone number, fax number, and e-mail address.

Please provide a signed written response to these items by October 20. You may provide this to my attention by letter or fax (610-337-5269), referencing mail control 573238. If we do not receive a reply by this date, we will assume that you do not wish to pursue your application.

Thank you for your cooperation, and I look forward to meeting you later this week. Please contact me by telephone or e-mail with any questions. I am frequently away from the office, but am usually able to check and respond to voicemail and e-mail messages daily.

Sandy Gabriel, Ph.D.
Senior Health Physicist
Medical Branch
NRC Region I
610-337-5182 (voice)
610-337-5269 (fax)

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## E-mail Properties

Mail Envelope Properties (F858CAD8A3CD394A8F6D77BC7ED91612150C204574)

Subject: Additional information for NRC license application, mail control 573238
Sent Date: 9/27/2010 11:08:48 PM
Received Date: 9/27/2010 11:08:00 PM
From: Gabriel, Sandra

Created By: Sandra.Gabriel@nrc.gov

Recipients:
willswilmington@aol.com ('willswilmington@aol.com')
Tracking Status: None

Post Office:
R1CLSTR01.nrc.gov

| Files | Size | Date & Time |
|---|---|---|
| MESSAGE | 20328 | 9/27/2010 |

Options
Expiration Date:
Priority: olImportanceNormal
ReplyRequested: False
Return Notification: False

Sensitivity: olNormal
Recipients received: