

**From:** Sandra Gabriel  
**To:** snick@wgh.org  
**Date:** Mon, Jan 31, 2005 6:19 PM  
**Subject:** NRC Amendment Request for Warren General Hospital, mail control 136247

Reference: Warren General Hospital, NRC license 37-17863-01, docket 03013549, mail control 136247

Nick Smarra:

Please provide the following information regarding the amendment request to restore 35.400 to your license for prostate brachytherapy. Please respond within 30 days. You may fax your response to 610-337-5269, referencing mail control 136247. Please contact me by e-mail with any questions.

1) The current commercially available Pd-103 sources are produced in a cyclotron and are not subject to licensing by NRC. Please contact Pennsylvania for information about licensing for Pd-103 brachytherapy procedures. These sources will not be listed on your NRC license.

2) Brachytherapy sources will be listed on your license based on the manufacturer and model number currently listed in the Sealed Source and Device Registry. Many vendors market their sources under names different from those in the registry. We have attempted to translate your list of requested sources into those I-125 and Cs-131 sources currently listed in the Registry. Please confirm that these are the sources you are requesting or provide corrections:

- a. Bard source will be listed as Bard Brachytherapy, Inc. Model STM-1251.
- b. We believe that the source currently marketed by Mentor is Mills Biopharmaceuticals, Inc. Models I-125 SL and I-125 SH.
- c. Oncura-Amersham source will be listed as MediPhysics, Inc. Model 6711 [manufactured by Medi-Physics Inc. or Amersham Health].
- d. PSA/Theragenics source will be listed as Theragenics I-Seed Model I25.S06.
- e. Isoray source will be listed as Isoray Model Cs-1.

3) Yours is the first request we have received to authorize use of the Isoray Cs-131 source. Please confirm with Isoray that their sources are reactor-produced.

4) Provide a maximum possession limit for 35.400 sources to cover the maximum activity you will have on hand at any one time, including waste.

5) Where will 35.400 sources be delivered and stored? If you have not previously provided a drawing of the storage area to NRC, please provide a drawing and room number.

6) Specify the survey instrument you will use to locate sources that may become dislodged during implantation or after surgery. This instrument should be equipped with a thin sodium iodide crystal detector probe to maximize detection efficiency for these low energy sources.

7) What release surveys and release criteria do you plan to use for patients undergoing Cs-131 implants to assure compliance with 10 CFR 35.75 (i.e., to assure that no individual member of the public is likely to receive more than 500 millirem total effective dose equivalent)? Appendix U to NUREG-1556, Vol. 9 provides model guidance, however it does not address Cs-131.

8) If applicable, please provide a room description and room numbers where patients will be housed if they cannot be released from the hospital under the provisions of 10 CFR 35.75.

9) Please confirm that your Radiation Safety Officer, Lawrence Lareau, M.D. has received (or will receive) training in the radiation safety aspects of prostate implants.

Thanks for your help.

Sandy Gabriel  
Senior Health Physicist  
Medical Branch  
NRC Region I

**Mail Envelope Properties**

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**From:** Sandra Gabriel

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