



LANCASTER GENERAL HOSPITAL

Member Lancaster Health Alliance

October 8, 1996

Thomas K. Thompson, Sr. Health Physicist
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

RE: Mail Control No. 123628

Dear Mr. Thompson:

This is in reference to your letter dated September 24, 1996, in which you are asking for additional information to support our amendment request dated August 16, 1996. In responding to your questions, I would like to refer to your letter, and answer them in the order in which they were asked:

1. Supplemental information on the credentials of Charles Fuller, Ph.D. is enclosed as Attachment A. This letter was written by a former supervisor of Dr. Fuller's, and should adequately support his having had over one year of full-time experience in therapeutic radiological physics. This letter was originally written to support Dr. Fuller's application to take the American Board of Radiology (ABR) certification examination in therapeutic radiological physics; thus, the statement in the last paragraph regarding Dr. Fuller's "...claim for 17.5 months of clinical experience..." was targeted for the ABR reviewers.
2. The second request for information in your letter is in regard to the use of brachytherapy sources at our facility at 2100 Harrisburg Pike, Lancaster. Since our amendment letter requested authorization for use of two very different types of sources, I would like to address each individually:
 - a) We would like to withdraw our request to use Ir-192 "hairpin" wires at the 2100 Harrisburg Pike facility. We would like to retain our request for their use at our main hospital facility at 555 North Duke Street.
 - b) With regard to our request to use I-125 and Pd-103 seeds for interstitial treatments, we provide the following additional information, as requested:
 - 1) The sources will be stored in a Nuclear Medicine "Hot Lab", which, although designed for this purpose, is not currently in use as a Hot Lab (it is, in fact, not in use at all, currently). This lab has two entrance doors, both of which will be equipped with coded-entry locks, and posted in accordance with 10 CFR 20.1902. This room is located on the

ground floor of the facility, in the Department of Diagnostic Imaging, and is not immediately accessible to public corridors. A drawing is enclosed as Attachment B which shows the room in question. Please disregard the labelling and illustrations of the surrounding rooms - there is no active Nuclear Medicine Department at this time. This is from a drawing made during the planning stages of the facility.

- 2) With regard to the question of where the sources will be "used", and what shielding will be provided, I offer the following. The sources will be stored in the Hot Lab in a shielded container designed specifically for these low-energy sources. Please see Attachment C for an illustration of the type of storage unit which will be used. Even at its thinnest area, the container can easily be shown to provide eight half-value layers of protection from the low-energy radiation. It can equally be shown that, when fully loaded with over 100 needles containing I-125 seeds, the dose rate drops to 2 mR hr^{-1} at less than 30 cm from the container surface. Because of this, we are not planning to supplement the shielding in any room in which these sources are used. They will remain in this container until implanted.

When manipulation of the needles and seeds is required, this shall take place behind a shield which will provide, again, at least eight half-value layers of protection to the worker. An example of what will be provided in this regard is also shown on Attachment C.

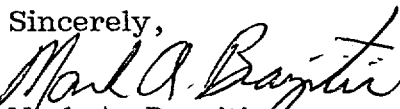

The seeds and needles will be transported, by cart, in the shielded container discussed above, to an operating room in our facility at 2100 Harrisburg Pike. Here, they will be implanted into the patient. Again, it is our contention that, because of the low energy of the radiation involved, and because the sources will be contained in a shielded container of eight half-value layers, no special shielding considerations are required for the operating room. In addition, we feel that this allows us to use any available operating room, and not have to designate one particular room for these procedures.

3. Lastly, we acknowledge your comments regarding the pacemaker issue, and gladly withdraw that portion of the amendment request, as well.

If you have any questions regarding these matters, or need further information, please contact our Radiation Safety Officer, Anthony Montagnese, at 717-290-4901.

Thank you for your assistance.

Sincerely,


Mark A. Brazitis
President 

Attachment C Radiation Therapy Products

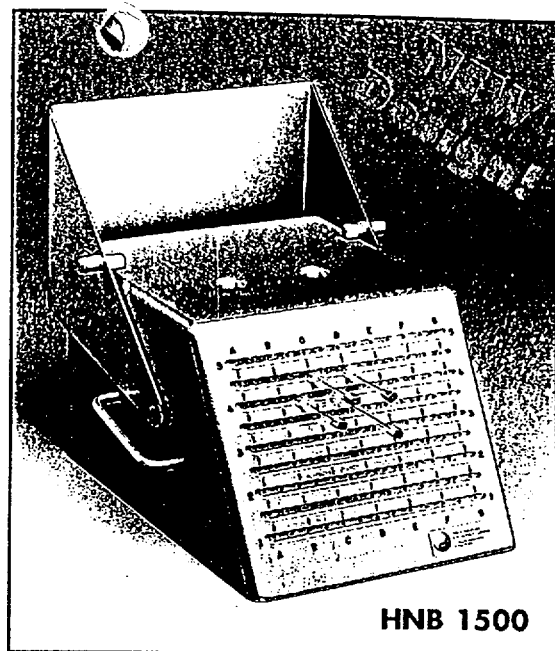
a division of
Real World Design & Development Company

6717 Palatine Avenue N - Seattle, WA 98103 - ph/fax: (206) 789-3380

Custom Shielding ^{125}I / ^{103}Pd Implant Horizontal Needle Box (Autoclavable)

- Custom grid layout to match customer's implant template. Horizontally placed needles prevent dislodging of loose seeds or compression of RAPID Strands™ within the needles.
- Needles are placed in a 60° sloping front face which is configured to make rows and columns clearly identifiable.
- Two wells are provided for holding seeds and spacers for reloading.
- Removable flip-over safety cover guards against bumping of the stylets while carrying or working near the box.
- Materials 5/16" and 5/8" aluminum welded and clear anodized.
- Overall dimensions are 13" x 9.5" x 7.5"

HNB 1500.....\$1250.00

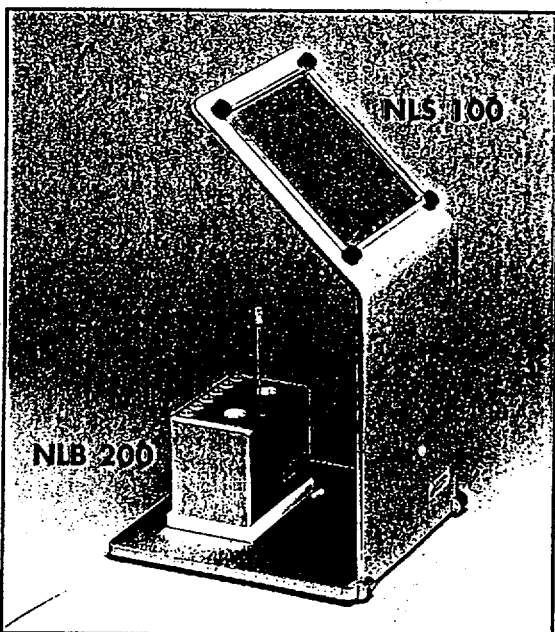


HNB 1500

Needle Loading Shield for ^{125}I or ^{103}Pd

- Specifically designed for loading needles. This shield is 10" wide to permit working around it comfortably with both hands yet still providing protection to the head and torso.
- Upright is 5/16" aluminum with 8"x8" lead glass window. Base is 1/2" aluminum 12"x12".
- Upright is removable for storage.

NLS 100.....\$925.00



NLS 100

Needle Loading Box (Autoclavable)

- Holds needle in place for loading.
- Provided with two wells: one for seeds and one for spacers.
- Segregator tubes allow grouping of needles according to number of seeds.
- HDPE base protects tips of needles.
- Provides shielding for loaded needles.

NLB 200.....\$450.00

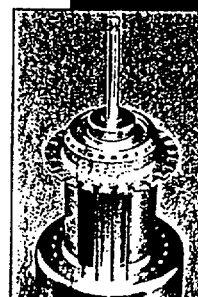


NLB 200

NW Needle Loading Carousel* (Autoclavable)

- This unit was designed to increase the speed of needle loading and reduce exposure to the hands by minimizing handling of loaded needles. Needles are placed in the carousel and loaded according to the prescribed sequence on the standardized loading form. The stylets are then inserted and the stylet to hub distance checked visually with a gauge or centimeter ruler. This gives a double check on the number of seeds in each needle. Then the needles are placed directly into the horizontal needle box.
- Holds 24 needles in numbered stations for loading.
- Seed and spacer wells placed close to needle hubs for fast loading.
- Can be turned on its polyethylene base with one hand to bring each needle into position for easy loading and removal.
- Anodized aluminum with HDPE base.

NLC 240.....\$875.00



NLC 240

NEW!

NLS 100

123628

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* Developed in association with Dr. Peter Grimm & Associates at N.W. Hospital, Seattle, WA.