



November 3, 1982

D. G. Wiedeman, Chief
Materials Radiation Protection
Section 1
U. S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, Illinois 60137

Re: License No. 12-02530-03

Dear Mr. Wiedeman,

This letter shall serve as our response to the Notice of Violation dated October 13, 1982 resulting from Mr. Reichhold's routine inspection. This response is enumerated to correspond with the similarly numbered violations in the Notice.

1. During both mentioned instances, April and October of 1981, the persons involved believed that an occupancy factor of 0.25 existed in the hallway, given that it is never occupied by the same person continuously. Should this factor have been used, the levels in the hallway would have been far below the maximum permissible limits.

In addition, during the April therapy, the patient was positioned in the room to achieve the lowest exposure rates possible. However, given the nature of the implant and the lack of a rolling radiation shield, the exposure rates in the hall still exceeded 2 mR/hr.

Corrective action has been taken to see that the above mentioned instances are not repeated. Last fall we acquired a rolling radiation shield which has been very effective in reducing exposure levels to unrestricted areas. A number of months ago, our physics consultant, based on our correspondence with the NRC, had concluded that the use of an occupancy factor had not been approved. He warned that we should keep our exposure levels below 2 mR/hr. in the hall. This we have done. Further, a recent I. E. Notice has brought to our attention the need to keep the integral exposure to points in unrestricted areas below 100 mR/week. We now closely monitor exposure levels with this in mind. Full compliance has been achieved and will be maintained.

2.

2. The Amendment request, dated December 4, 1980, was drafted by a physics consultant, who either apparently misunderstood the meaning of "maximum activity assayed" to mean "maximum dose assayed" or simply failed to communicate this to the technologists performing the linearity checks on the dose calibrator.

In either case, using the first elution of our generator for a linearity check would be totally unfeasible. Our 1.0 curie generators are generally delivered on Sunday and first milked Monday morning. Committing the first elution to a linearity check would leave insufficient activity to meet our clinical workload for possibly several days. An amendment request is being drafted to bring our license into accordance with our procedures as currently practiced. We hope that this amendment will be approved expeditiously such that this state of technical violation will not exist beyond December 31, 1982.

We believe that Capintec, the company which repaired our dose calibrator, performed a geometrical variation check after the repair was effected, though we had no record of this at the time of inspection. We will attempt to acquire this record and forward a copy to your office. However, in the future we will see that such checks are performed as required and that a permanent record of such is maintained.

3. The hospital returns spent Mo-99/Tc-99m generators to a representative of Squibb, the supplying company, via a NRC approved procedure developed by Squibb. The company representative removes the generators with the assistance of one of the nuclear medicine technologists. To date, no mention has been made to us by the company representative that wipe tests of spent generators are necessary for his legal transportation of them.

Furthermore, the age of the generators returned all exceed ten half-lives beyond the assayed date of the Mo-99 parent nuclide. Our license typically allows us to dispose of radioactive materials in the normal waste when ten half-lives of the longest lived nuclide has been exceeded.

The above reasons lead us to believe that wipe tests were not required. We apologize for the misunderstanding. We shall immediately comply by wipe testing all exiting generators and recording results.

3.

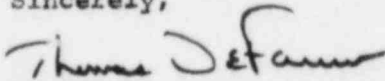
Again, we return Ir-192 shipments to the supplier according to an NRC approved procedure, which makes no mention of wipe testing the package. A copy of this procedure has been enclosed for your inspection.

Further, we believed that because of the "special" solid form of this material, it was exempted from DOT requirements for wipe testing, as it is exempted when such packages are received.

The above reasons lead us to believe that wipe testing the external surfaces of packages containing Ir-192 seeds was not required. We apologize for this misunderstanding. We have already complied by wipe testing all exiting packages of Ir-192 since the inspection and will continue to do so unless otherwise instructed by representatives of the NRC. The results of the wipe tests will be maintained as required.

We wish to thank you for your time and consideration on this matter. We also wish to thank Mr. Reichhold for his participation, and in particular, for his detailed explanation of his findings and suggestions. We feel that the inspection resulted in an improved radiation safety program at Rockford Memorial Hospital.

Sincerely,



Thomas D. DeFauw
Vice President of Operations
TDD/bjm

CC. R. E. Goodman, M.S.

Specific instructions will have to be given to the carrier regarding the exact location of pick-up. The carrier will ask the following type of questions:

- a. The total number of packages to be picked-up:
- b. The contents of the package(s):
- c. Destination of the package(s): Arlington, Va. 22206
- d. Type of service for package(s):
- e. When the package(s) will be ready for pick-up and where the driver can make the pick-up:
- f. What is the latest time the driver can pick-up from your facility:
- g. In case of a problem, who should be contacted. Be prepared to give your name and phone number.

10. Instructions for completing Shippers Certification.

- a. Columns 1, 2, 3, 4 and 9 have been completed by Best Industries. Do not add any information on these columns.
- b. The total activity of all shipments should be specified in Curies or milliCuries as of the date of shipment on column 5.
- c. The total number of packages should be indicated in column 6.
- d. The category of radioactive labels affixed to the outside of the package should be indicated in column 7. See the table below for selecting the proper label:

RADIOACTIVE MATERIAL PACKAGE LABEL CRITERIA

(173.399)

DOSE RATE LIMITS

<u>LABEL</u>	<u>AT ANY POINT ON ACCESSIBLE SURFACE OF PACKAGE</u>	<u>AT THREE FEET FROM EXTERNAL SURFACE OF PACKAGE (TRANSPORT INDEX)</u>
"RADIOACTIVE - WHITE I"	0.5 mR/hr	0
"RADIOACTIVE - YELLOW II"	50 mR/hr	1.0 mR/hr
"RADIOACTIVE - YELLOW III"*	200 mR/hr	10 mR/hr

* Require Vehicle Placarding
(This label mandatory for any fissile Class III (173.389 A) or large quantity package (173.389B), regardless of dose rate levels.)

- e. Transportation index should be indicated in column 8.
- f. At the bottom of the page fill out name and full address of your hospital or company and date on the bottom left hand side.
- g. On the bottom right hand side, enter your name and title and sign.

BEST Industries, Inc.

RETURN SHIPPING INSTRUCTIONS

1. Do not leave Iridium 192 ribbons in individual holes of the shipping container. Use the large central cavity for return of used or unused (altered, but not used) Iridium 192 for waste disposal. If the shipping container does not have a large central cavity, use separate lead container with at least one (1) inch thick lead shielding.
2. Attach "Caution - Radioactive Material" label with information including: # of seeds and total activity (mCi/Curie), date and time.
3. Fill out the Iridium 192 waste return form, sign and enclose one copy with the shipment and retain one copy for your records.
4. Measure the radiation exposure levels at the surface of the box and at one (1) meter.
5. If the readings are more than 200 mR/hr at the surface or 10 mR/hr at one (1) meter, recheck the packaging. Do not ship any packages which exceed these radiation exposure levels.
6. Place appropriate radioactive labels outside the box, (please cover the inbound shipping labels, except D.O.T. certification labels) and complete the shipper's certification form (red and white striped form), enclose two (2) copies and retain one (1) copy for your records.
7. Package the shipping container properly and secure the package with a security seal (Enclosed). For detailed information refer to: "A Review of the Department of Transportation Regulations for Transportation of Radioactive Materials". Dated October 1977
8. Place address label on can.
9. Telephone carrier for pick-up of the container.

Carrier to be Used: _____

Phone Number: _____

Address: _____

LABORATORY
2244 S. Shirlington Road
Arlington, Va. 22206

ACCOUNTING
P.O. Box 681
Washington, D.C. 20044

Customer Service & information: (703) 521-7336
For ordering call Toll Free: 1-800-336-4970