

LEHIGH VALLEY HOSPITAL
DEPARTMENT OF RADIOLOGY
ADMINISTRATION
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FACSIMILE TRANSMITTAL SHEET

TO: Pamela Henderson FROM: Cynthia Goodman Mumma /RSD
COMPANY: Region I NRC DATE: July 3 2002
FAX NUMBER: 610 337 5269 TOTAL NO. OF PAGES INCLUDING COVER: 4
PHONE NUMBER: SENDER'S REFERENCE NUMBER:
RE: YOUR REFERENCE NUMBER:

URGENT FOR REVIEW PLEASE COMMENT PLEASE REPLY PLEASE RE CYCLE

NOTES/COMMENTS:

Placemat:
Uro Med is now "Alliant" Corporation.
Contact #: 1-800-433-5474
1-781-762-2080
(Norwood MA, corporate headquarters)

LEHIGH VALLEY HOSPITAL
DEPARTMENT OF RADIOLOGY
CEDAR CREST & I-78, P. O. BOX 689
ALLENTOWN, PA 18105-1556

LEHIGH VALLEY
HOSPITAL AND
HEALTH NETWORK

March 27, 2002

Hubert J. Miller
Administrator
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: Report No. 38803

Pursuant to the reporting requirements of 10 CFR 20.2201, we submit the following summary of events associated with the failure to account for one UroMed Symmetra I-125 sealed source (nominal activity 0.305-0.330 mCi as of 3/1/02). Please note that telephone notification concerning this issue was made to Mr. Mike Norris at the NRC Operations Center on 3/27/02 (Report No. 38803):

On Friday March 1, 2002, in the course of verifying the inventory associated with the sealed source shipment in question, Radiation Oncology Physicist Carmine Pierno, M.S. discovered that of the 96 I-125 sources ordered, only 95 were present. A radiation survey of the environs of the assay room was performed with a NaI detector, and was negative for the presence of a stray source. A second source count was performed, and again 95 sources were found to be present. It should be noted that the external shipping container as well as the source containment vial were found to be completely intact as received from the air courier (Federal Express), such that the possibility of a source being lost in transit was deemed untenable. Further, the source shipment had remained sealed until being brought to the assay station for counting.

Mr. Pierno then contacted UroMed Corporation concerning the inventory discrepancy. The summary of the findings issued by Mr. John Ring, QA Engineer for that company, indicates that although there was found to be no discrepancy in the source count as a result of the investigation by the shipment's originator (Isotope Product Laboratories (Valencia, CA), manufacturer and distributor of the Symmetra product for UroMed), the source batches utilized for this particular order had been depleted. Therefore, no definitive substantiation of IPL's findings could be provided. Mr. Ring's report is attached for your reference.

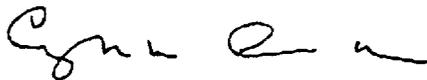
*Celebration of
Community*

It appears most probable, then, that given the negative result of the radiation survey conducted at this site as well as the integrities of both the shipping container and source vial, that the source was never shipped by UroMed/IPL.

We recognize, of course, that the exposure rate of a single I-125 source of the nominal activity stated would be non-trivial (approximately 450 mR/hour on contact).^{*} It is in recognition of this level of hazard that this facility maintains a strict program of brachytherapy source accounting, including shipment inventory verification as well as post-implantation source counts.

Please contact me at 610.402.8386 if you have any additional questions.

Sincerely,



Cynthia H. Goodman Mumma, MS, MSE
Radiation Safety Officer, Medical Radiological Physicist

^{*} Exposure rate calculated assumes a midrange nominal activity of 0.318 mCi, an exposure rate constant of 1.42 R cm/mCi hr (NUREG 1556 Appendix U) and a "contact" distance of 1 cm.

cc: Mark Holtz, Vice President



Isotope Products Laboratories

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Valencia, California 91355

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20 Mar 02

John Ring, Jr., QA Engineer
UroMed Corporation
1400 Providence Highway, Building 2
Norwood, MA 02062

Reference: Customer Complaint (LaHigh Valley Hospital WOW 16262)

John Ring, Jr.:

This is a response to the above Customer Complaint. The description of the Discrepancy is:

Order quantity 96 seeds, package labeled 96 seeds, customer claims only 95 seeds in the package.

IPL's laboratory personnel conducted an investigation to determine the root cause of the discrepancy. IPL's investigation and records indicate that there was no discrepancy in the seed count.

The batches of seeds (two batches were used to fill this order) used for this order are depleted; therefore, we could not further substantiate IPL's accuracy in counting the seeds.

IPL's laboratory personnel continue to reduce possibilities of inaccurate counting. IPL has ordered and is anticipating an automatic Seed Counter to be on line in Apr 02. This will significantly increase the accuracy in counting seeds.

Please contact me if you have further questions.

Sincerely,

Lloyd L. Flowers
Director, Therapy Department