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RI - DNMS Licensee Event Report Disposition

Licensee:	BEST MEDICAL INTERNATIONAL, INC.		
Event Description:	LOST SEEDS REPORTED FROM PALMETTO BAPTIST MEDICAL CENTER, SC		
License No:	SEE ABOVE	Docket No:	
Event Date:	12-6-05	Report Date:	12/05
		MLER-RI:	2005-070
		HQ Ops Event #:	

1. REPORTING REQUIREMENT

<input type="checkbox"/>	10 CFR 20.1906 Package Contamination	<input type="checkbox"/>	10 CFR 30.50 Report
<input type="checkbox"/>	10 CFR 20.2201 Theft or Loss	<input type="checkbox"/>	10 CFR 35.3045 Medical Event
<input type="checkbox"/>	10 CFR 20.2203 30 Day Report	<input type="checkbox"/>	License Condition
<input type="checkbox"/>	Other _____		

2. REGION I RESPONSE

<input type="checkbox"/>	Immediate Site Inspection	Inspector/Date	
<input type="checkbox"/>	Special Inspection	Inspector/Date	
<input type="checkbox"/>	Telephone Inquiry	Inspector/Date	
<input type="checkbox"/>	Preliminary Notification/Report	<input type="checkbox"/>	Daily Report
<input checked="" type="checkbox"/>	Information Entered in RI Log	<input type="checkbox"/>	Review at Next Inspection
<input type="checkbox"/>	Report Referred To: _____		

3. REPORT EVALUATION

<input checked="" type="checkbox"/>	Description of Event	<input checked="" type="checkbox"/>	Corrective Actions
<input checked="" type="checkbox"/>	Levels of RAM Involved	<input type="checkbox"/>	Calculations Adequate
<input checked="" type="checkbox"/>	Cause of Event	<input type="checkbox"/>	Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

<input type="checkbox"/>	Release w/Exposure > Limits	<input type="checkbox"/>	Deliberate Misuse w/Exposure > Limits
<input type="checkbox"/>	Repeated Inadequate Control	<input type="checkbox"/>	Pkging Failure > 10 rads/hr or Contamination > 1000x Limits
<input type="checkbox"/>	Exposure 5x Limits	<input type="checkbox"/>	Large# Indivs w/Exp > Limits or Medical Deterministic Effects
<input type="checkbox"/>	Potential Fatality	<input type="checkbox"/>	Unique Circumstances or Safeguards Concerns
If any of the above are involved:			
<input type="checkbox"/>	Considered Need for IIT	<input type="checkbox"/>	Considered Need for AIT
Decision/Made By/Date: _____			

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

<input type="checkbox"/>	Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
<input type="checkbox"/>	Medical Consultant Used-Name of Consultant/Date of Report: _____
<input type="checkbox"/>	Medical Consultant Determined Event Directly Contributed to Fatality
<input type="checkbox"/>	Device Failure with Possible Adverse Generic Implications
<input type="checkbox"/>	HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

Review July next routine inspection

<input type="checkbox"/> Non-Public	Inspector Signature: _____	Date: _____
<input checked="" type="checkbox"/> Public-SISP REVIEW COMPLETE	Branch Chief Initials: <u>[Signature]</u>	Date: 1/3/2006

BEST MEDICAL INTERNATIONAL, INC.

December 9, 2005

Mr. David Collins
U.S.N.R.C. Region II
Sam Nunn Atlanta Federal Center, 23 T85
61 Forsyth Street, S.W.
Atlanta, GA 30303-8931

RE: Incident Report From Hospital

Dear Mr. Collins:

On December 6, 2005, we were notified by Dr. Hassan Alkatib of Palmetto Baptist Medical Center, Columbia, SC of an incident regarding a shipment sent by us on December 1, 2005, and received by the hospital on December 2, 2005. The order contained 100 Iodine-125 seeds in 10 Mick Cartridges (10 seeds per cartridge) and 10 loose Iodine-125 seeds in a screw cap vial inside a stainless steel container.

Dr. Hassan Alkatib called us in the afternoon of December 6 and informed us that some loose seeds came out of the container. He informed us that he did not perform a survey of the package prior to opening. However, he performed a wipe test, and everything was normal. The package did not exhibit any tampering or damage, and it was intact upon receipt. We told him that it was highly improbable that seeds came out, due to the fact that loose seeds are packaged in a stainless steel container which has a top cap screwed tightly. Also, there is a plastic security seal to indicate tampering. We requested that he check the seal on the container and call us back. He agreed.

Dr. Hassan Alkatib called the next day, along with RSO (Radiation Safety Officer) Lee, and spoke with our RSO Billy Bass and our Project Engineer, Rohit Mehta. This time RSO Lee said the loose seeds did not come out of the container; they said that one of the Mick Cartridges containing Iodine seeds had opened. The RSO further indicated that the outside package was intact, and when they received the package they did not do a survey of the package. The package was opened 4 days after receipt of shipment.

Best Medical shipping records were checked thoroughly, and we did not discover any discrepancy in packaging. The shipment was packaged according to our internal shipping procedures. Digital pictures show the correct number of seeds in the cartridges, and the cartridges were properly secure. These pictures, along with an e-mail received earlier today from RSO Lee, are included in this report. The Mick Cartridges are manufactured by Mick Radio Nuclear, Inc., New York. They were inspected by Mick Radio Nuclear when sent to us. We also inspected the cartridges prior to loading the seeds in them.

REC'D IN LAT 12/14/2005

7643 Fullerton Road • Springfield, VA 22153 • USA • Phone: 703-451-2378 • 800-336-4970 • Fax: 703-451-5228 • Web: www.bestmedical.com



Best® Iodine 125 Seed

THINK BEST®

Best® Palladium 103 Seed

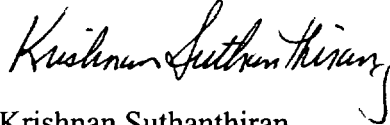


Mr. David Collins, U.S.N.R.C. Region II
December 9, 2005
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Best Medical procedures for shipping seeds in cartridges are as follows: The package consists of seeds loaded in cartridges. These cartridges are photographed and the seeds counted in them before packaging to make sure we have a record of everything we send out. These cartridges are then put inside a zip-lock bag. This bag then goes inside a lead pouch that has a two-inch flap to make sure that the contents are secured. This pouch is secured tightly between two foam inserts and the box is closed and secured with packing tape. The package is then wipe tested and surveyed for loose contamination or radiation. Pictures of the assembly and components are also enclosed. FedEx picked up the package on 12/01/05, and no trouble or damage to the package was reported to us by Fed Ex.


Our internal investigation indicates that all procedures were followed, and the package left intact. The report from the hospital concluded that the package was intact when received. We find the description of the incident given by the hospital staff contradictory and puzzling. We continue to investigate this incident. Please feel free to contact me if you need any additional information.

With kind regards,

A handwritten signature in cursive script, reading "Krishnan Suthanthiran".

Krishnan Suthanthiran
President


 Inbox (350/25)


From: "Rohit Mehta" <rohit@bestmedical.com> 
 To: "Krishnan Suthanthiran" <krish@bestmedical.com>
 Cc: "Carol Grogan" <carol@bestmedical.com>
 Date: 12/09/05 14:25:13
 Subject: Fwd: I-125 Seed Missing

FYI

-----Original Message-----

From: "Kevin Lee" <Kevin.Lee@PalmettoHealth.org>
 To: bbass@bestmedical.com, rohit@bestmedical.com
 Date: Fri, 09 Dec 2005 14:18:52 -0500
 Subject: I-125 Seed Missing

Per our conversation on 12/7/05, I am letting you know that I notified my regulator South Carolina Department of health and Environmental Control) of the one (1) 300 uCi I-125 sealed source missing from the shipment we received at our facility. The missing seed was discovered upon opening the package on 12/6/05. Please see the specific information I faxed you on 12/7/05. My regulator is satisfied with the surveys we did at our facility. By regulation, I will providing them with a written report of the incident within 30 days.

I could not find the cartridge in question. I have one other individual I need to ask to see if they stored it somewhere. I will keep you posted.

Did you notify Fed Ex and the NRC?

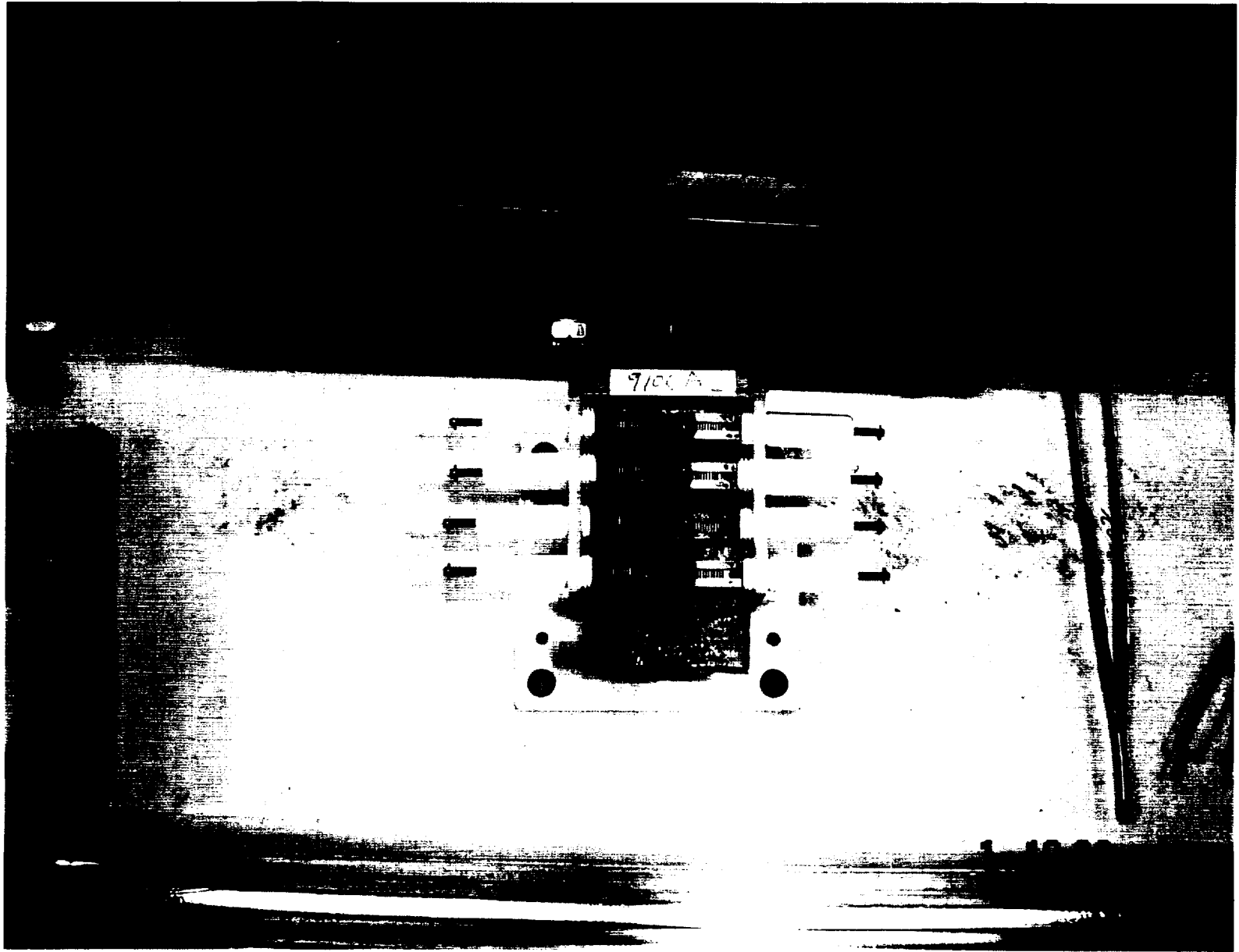
Kevin Lee
 Radiation Safety Officer
 Palmetto Health
 Pager: (803) 352-0729

 PALMETTO HEALTH CONFIDENTIALITY NOTICE

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 Inbox (350/25)

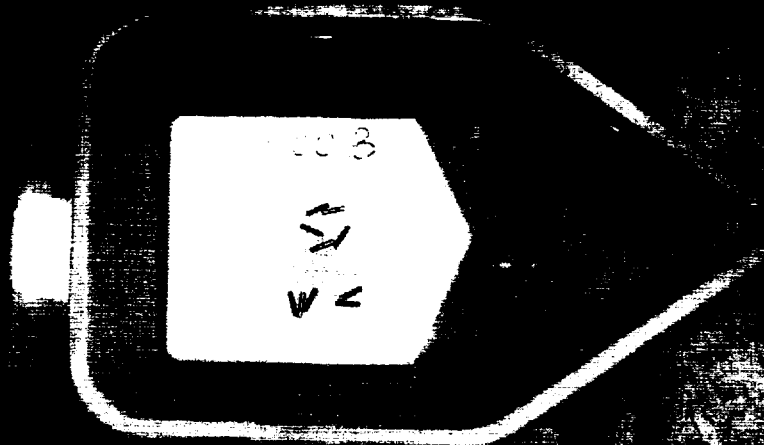



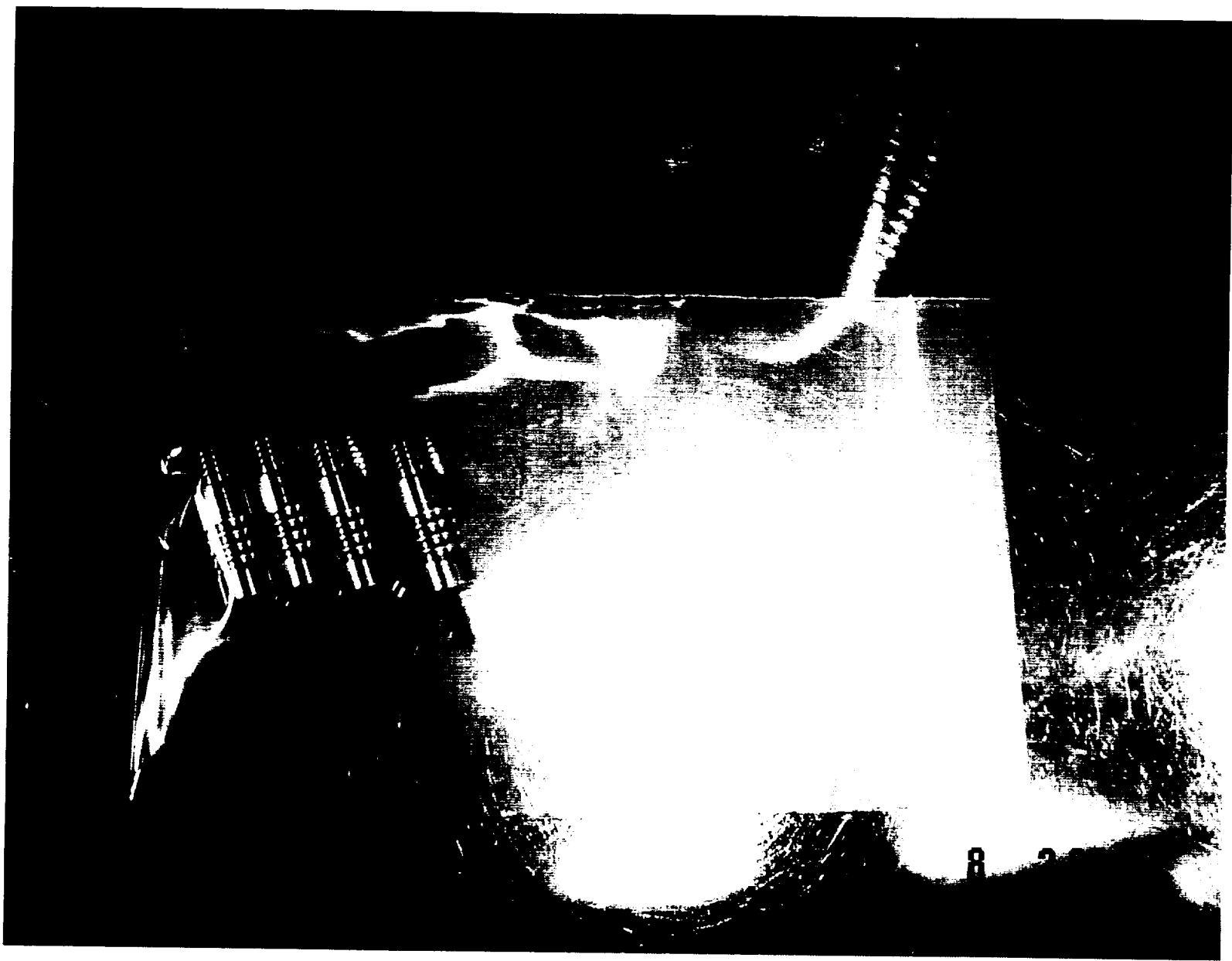
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