UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

April 6, 2001

MEMORANDUM TO: Anne Boland, DNMS, Region II
Pat Larkins, OSTP

FROM: Vivian Campbell, RSAO, Region IV

SUBJECT: TEXAS FOLLOW-UP INVESTIGATION REPORT FOR EVENT NOTIFICATION NO. 37542 AND NMED ITEM NO. 000886

Attached is information provided by the State of Texas about the investigation of the incident involving the shipment of Ir-192 brachytherapy seeds from Baylor University Medical Center, Dallas, Texas to Best Industries of Springfield, Virginia.

Texas Department of Health

Charles E. Bell, M.D.
Executive Deputy Commissioner

1100 West 49th Street
Austin, Texas 78756-3189
(512) 458-7111

Radiation Control
(512) 834-6688

March 5, 2001

U.S. Nuclear Regulatory Commission
Region IV
Attn.: Dwight Chamberlain
611 Ryan Plaza Drive, Suite 400
Arlington, Texas 76011-8064

License No.: L-1290
Incident No.: I-7675
Public Health Region: 03

Dear Mr. Chamberlain:

On November 21, 2000, this Agency was notified of a transportation incident by Vivian Campbell of your office concerning Best Industries of Springfield, Virginia and our Licensee, Baylor University medical Center, Dallas, Texas - L01290. This incident was assigned the internal Incident No. 7675.

Direct coordination with Wade Loo of NRC Region indicated that the package was one of three return shipments from Baylor which had been received in Springfield, Virginia, on November 21, 2000, with excessive external radiation levels measured at 2.6 R/hour on contact and 65 millirem at 1-meter (See diagram at Enclosure 1 from Best Industries). The shipment consisted of 10 Iridium-192 Intravascular Brachytherapy seeds encased in nylon ribbon which were secured inside the shielded delivery device (PIG) (See photo at Enclosure 2) contained in the internal packaging (See Photo at Enclosure 3) of a Type A shipping container (See photo at Enclosure 4). This shipment was labeled as a U.S. DOT "Yellow II" with a Transportation Index of 0.4 (See a copy of the Shipper's Declaration For Dangerous Goods, dated 11/17/00 at Enclosure 5 and FEDEX Airbill 8219 4057 6842 at Enclosure 6).

An Agency investigation was conducted on November 28, 2000, with a follow-up investigation conducted on January 30, 2001. During the investigation, the Agency received a copy of Baylor's internal incident report with time line which had been prepared by the facility Radiation Safety Officer (See Enclosure 7). This Agency concurs with the statement on Page 3, III Investigational Findings, paragraph 1, which states: ". . .the source ribbon was improperly packaged prior to shipment and that the package survey failed to detect exposure levels reported by Best Industries." This statement is consistent with exposure levels recorded for personnel who were in contact or close proximity to the delivery device and with the findings of Best Industries during opening of the Type A shipping container and the appearance of the delivery device upon arrival in Springfield, Virginia

(See photos at Enclosures 8, 9, 10, and 11 of the delivery device in a glovebox during unpackaging.) These photos demonstrate that the nylon ribbon is: secure at the knurled knob (Enclosure 8); tightly wrapped around the reeling device (Enclosure 9); apparently not showing any color on the visible ribbon (Enclosure 10); and showing approximately four seeds which "popped" out of the locking mechanism when the lock was released with tension still on the reeling device (Enclosure 11).

The source ribbon was clearly improperly packaged, as the knurled nut was tight upon arrival at Best Industries and the reeling device remained in the tightened position. So an in-transit accidental release of the seeds from the shipping devices can safely be ruled out in this incident. This conclusion points to a problem in the packaging and survey of the shipment before leaving the Baylor University Medical Center's Hotlab (See photos at Enclosures 12, 13, 14 and 15).

Radiation levels recorded on employees personnel monitoring devices demonstrate that the source was exposed prior to the package departing the facility. Exposure to radiation workers were well under the annual limit (See pages 3-5, Enclosure 7). Exposure to the FedEx personnel was addressed in conversations with Roy Parker, Radiation Safety Officer, Federal Express. Mr. Parker told a TDH investigator that the exposure to the drivers would be negligible and not warrant further investigation by his firm due to the uncertainty of approximations in assessing an individual dose. Baylor University Medical Center's attempt to quantify the maximum dose to either driver would have been 171 millirem. Baylor's maximum estimate is a worse case example with the expected exposure agreeing with the philosophy demonstrated by Mr. Parker and estimating an expected exposure of only 15 millirem to each driver. With the package spending the weekend in the FedEx Dangerous Goods warehouse, no exposure to personnel was expected.

Due to the location of the Baylor hotlab minimal exposure to the public is demonstrated by the dose estimates (At Enclosure 16). The Agency concludes that no member of the public came close to either the 2 millirem in any one hour or 100 millirem during the year.

The Agency also concludes that the primary cause of the incident was failure to perform an adequate inspection and survey of the Type A container prior to shipment. Due to the confined space in the facility's hotlab, it is the Agency's opinion that it was possible to miss the activation of the Nuclear Associates, Prime Alert 10, Model 05-433 visual alarm. This is due to two primary factors: 1) the lense of the detector was broken and held in place on the detector with surgical tape which effectively dimmed the flashing light of the alarm; and 2) the placement of the alarm on the rear wall of the hotlab had the alarm behind the operator who was packaging the radioactive materials (See photo at Enclosure 14). Since the detector had no audible alarm, it could have been missed. The alarm was fully functional during inspection of the Hotlab on January 30, 2001. Even if the visual alarm was missed, the radiation survey of each package should have demonstrated the inadequate packaging of the 10 seed package. The visual alarm and all survey instruments used for the surveys were within calibration (See Enclosure 17). Individual responses of the individuals involved in the packaging process do not adequately address the inadequacy of the survey. Survey meters used to perform the package survey were in working order with current calibrations (See Enclosure 17).

The Agency has assessed two violations to the Licensee.

1. Violation of 25 TAC §289.257(h)(9)(A): Failure to properly survey a package of radioactive material offered for transportation which upon receipt revealed radiation levels of 65 millirem @ 1-meter and 2.6 R/hour on the external surface of the package.
2. Violation of 25 TAC §289.257(e)(1)(B): Failure to properly mark and label a shipment of radioactive materials delivered to a carrier for transport by failing to correctly enter the appropriate Transportation Index on the shipment.

A verbal recommendation provided to the Licensee stated that the wall mounted (visual alarm only) detector mounted in the hotlab be repositioned to allow easier visual observation during packaging and unpackaging operations. It was also recommended to check on possible replacement of the alarm with a detector which provides both visual and audible alarms to radiation workers in the hotlab.

This report concludes actions by this Agency concerning our Incident # 7675, Baylor University Medical Center, November 21, 2000.

If you have further questions or would like to comment further on this incident, please contact me at (512) 834-6688, extension 2027 or by E-Mail me at: james.ogden@tdh.state.tx.us

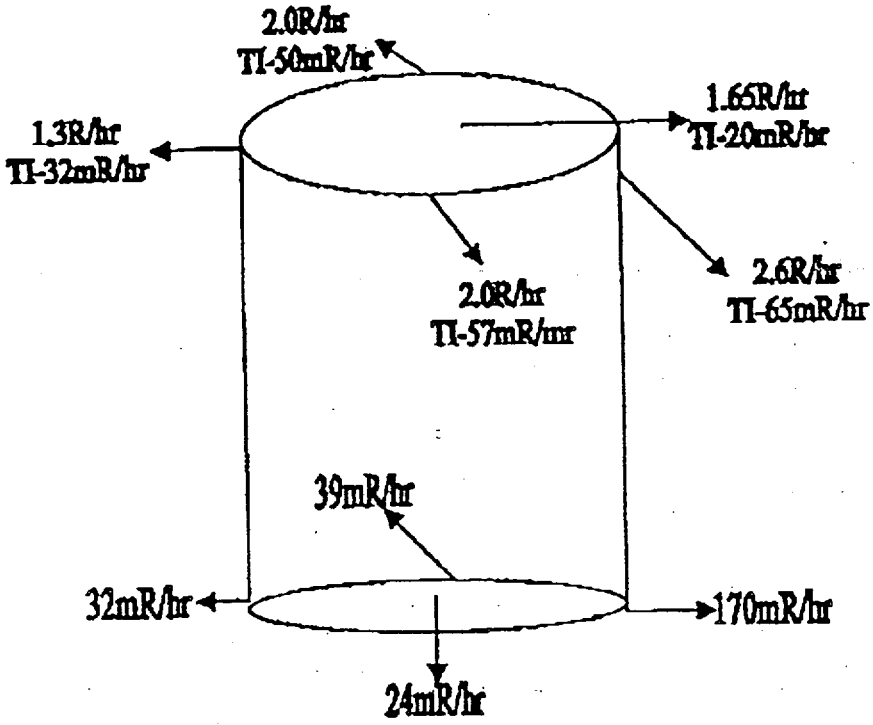
Sincerely,

James H. Ogden, Jr.
Incident Investigation Program
Division of Compliance and Inspection
Bureau of Radiation Control

Enclosures: 17

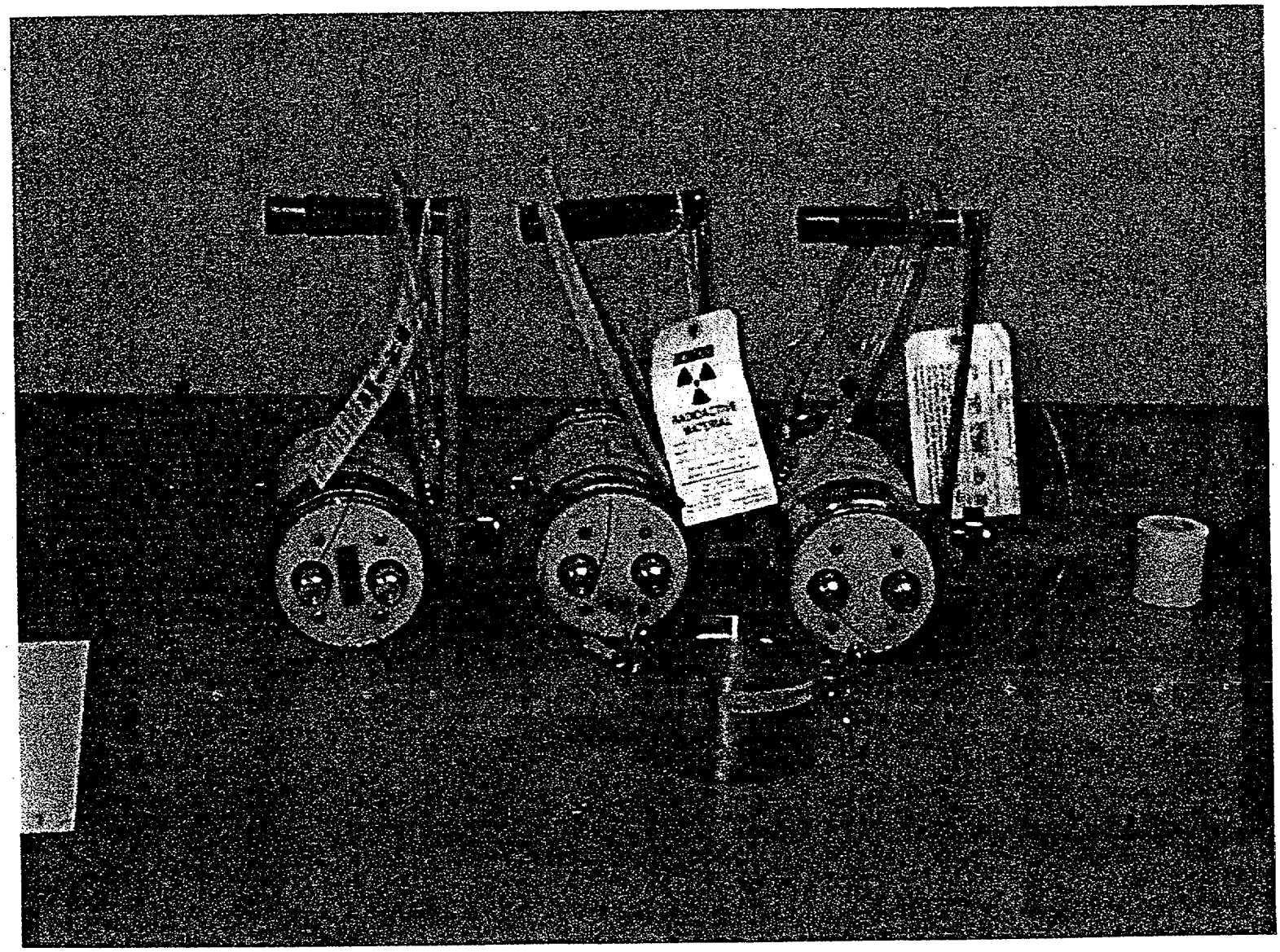
Date: 11/21/00

Drum Survey From Baylor University Medical Ctr.

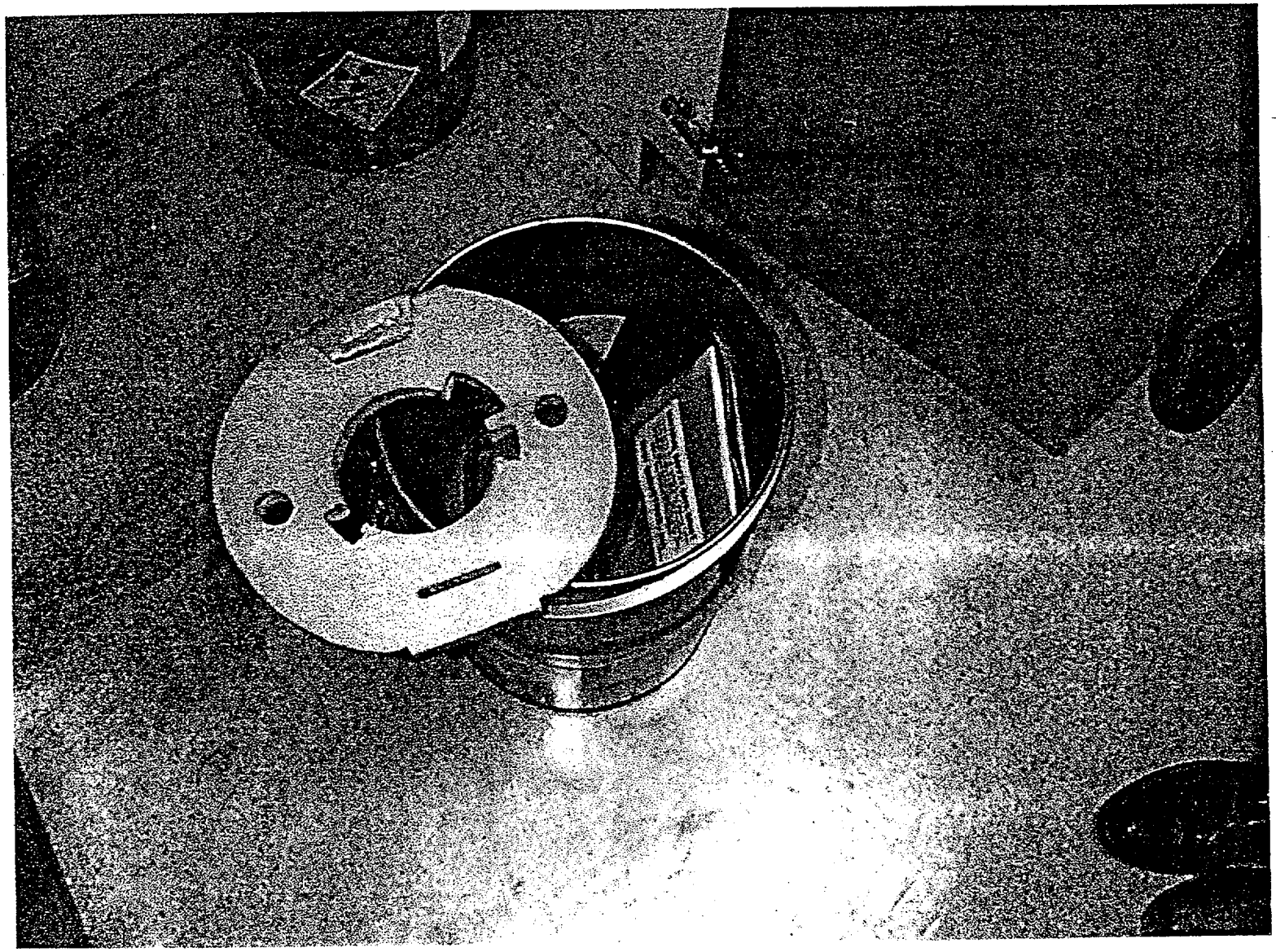


All swipes were relative to background (see Attached)

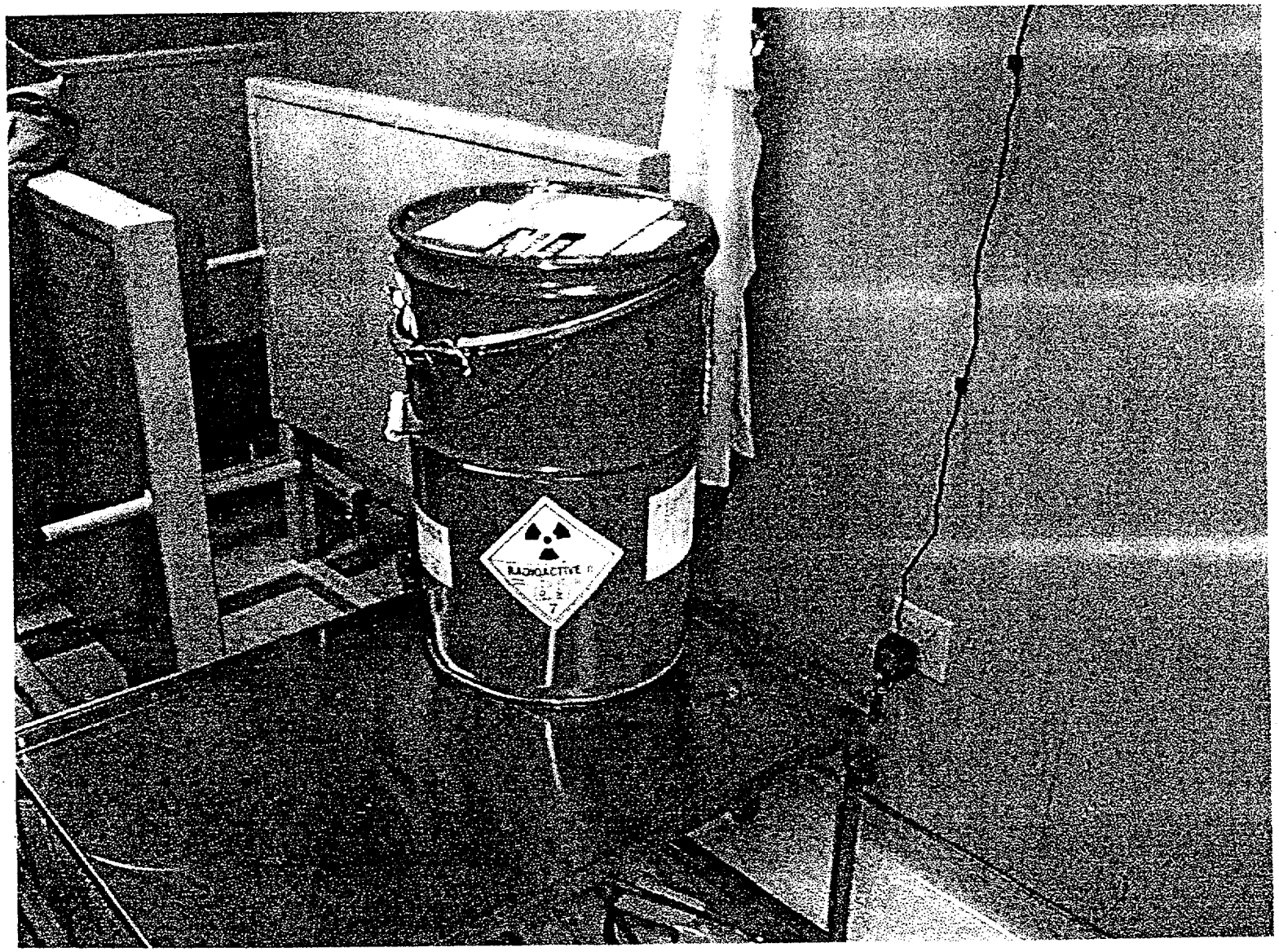
Enclosure 1: Radiation levels on Package, determine by Best Industries, Springfield, Virginia



Enclosure 2: Three Pigs used to ship IR-192 seeds. From left to right, 6-seeds, 10-seeds, and 14-seeds.



Encolusre 3: Interior view of shipping container, with packing material.



Enclosure 4: Type 7A shipping container.

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least two copies to the airline)

Shipper
Baylor University Medical Center
3500 Gaston Avenue
Dallas, TX 75246

Air Waybill No.
Page 1 of 1 Page
Shipper's Reference Number (optional)

Consignee
BEST INDUSTRIES, INC.
7643-B FULLERTON RD.
SPRINGFIELD VA. 22153 USA

BEST
Phone 703-451-2378 • 1-800-336-4970
Fax 703-451-5225 • WWW.BEST-MEDICAL.COM

Two completed and signed copies of this Declaration must be handed to the operator.

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder, or an IATA cargo agent.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: (delete non-applicable)
PASSENGER AND CARGO AIRCRAFT
CARGO AIRCRAFT ONLY

Airport of Departure: Dallas, TX

Airport of Destination: Springfield, VA

Shipment type: (delete non-applicable)
~~NON-RADIOACTIVE~~ RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification: Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and type of packaging	Packing Inst.	Auth.
RADIOACTIVE MATERIAL, N.O.S.	7	UN 2982			Ir 192 Solid Metal 1 Type A Package 9,42~~6~~ GBq Each	Yellow II T.I. 0.4 Dimensions 30 x 25.7 35 / 45 cm	

Additional Handling Information: ALL PREPARED IN ACCORDANCE WITH I.C.A.O. THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN, OR INCIDENT TO, RESEARCH, MEDICAL DIAGNOSIS OR TREATMENT. FOR EMERGENCY ASSISTANCE OUTSIDE THE USA AND CANADA CALL 00-1-703-527-3887.

Emergency Telephone Number: 1-800-424-9300 703-527-3887

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations.

Name/Title of Signatory: Charles Stum Health Physics Assistant

Place and Date: 11/17/00 Dallas, TX 75246

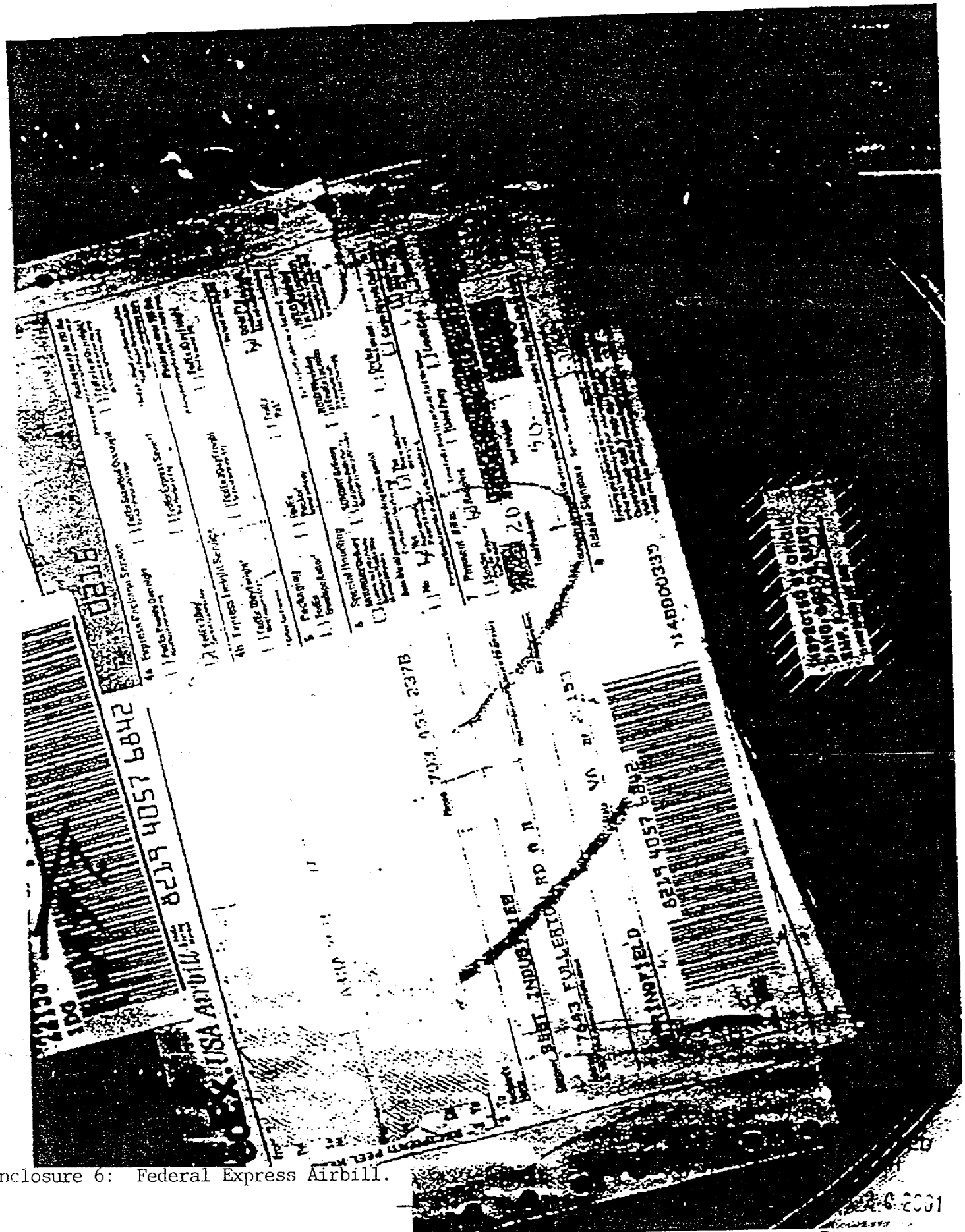
Signature: (see warning above) Charles Stum

IF ACCEPTABLE FOR PASSENGER AIRCRAFT, THIS SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN, OR INCIDENT TO, RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT.

Effective Date: 5/1/00

RECEIVED TCH
JAN 2 C 2001
BUREAU OF RADIATION CONTROL

Enclosure 5: Shipper's Declaration For Dangerous Goods - Baylor to Best Industries.



Enclosure 6: Federal Express Airbill.

Incident Report
Shipment of Ir-192 Sealed Sources
Texas Department of Health Incident Number 7675

I. Introduction

On Friday, November 21, 2000, the Radiation Safety Office at Baylor University Medical Center (BUMC) was notified of a potentially serious incident involving the return shipment of Ir-192 sealed sources from BUMC to Best Industries, Inc. One out of the three containers shipped from Baylor was measured by Best Industries to have much higher exposure levels at 1 meter (Transportation Index) than that indicated by BUMC's Radiation Safety Office. The Transportation Index measured by Best Industries was 63 mR/hour compared to 0.4 mR/hour indicated prior to shipment by the BUMC Office of Radiation Safety. Best also reported readings as high as 2000 mR/hour were measured at the surface of the package. Regulations prohibit shipment of a package designated as "Radioactive – Yellow II – the shipping designation for this container – if the dose rate at any point on the package surface exceeds 200 mR/hour or the Transportation Index exceeds 10 mR/hour. Both federal and state regulations require that the licensee receiving the package notify appropriate regulatory authorities if these levels are exceeded.

Upon notification by Joe Wang, Radiation Safety Officer at Best Industries, the BUMC Radiation Safety Officer responded as follows:

a. Contacted Jim Ogden of the Texas Department of Health (TDH) and Vivian Campbell of the Nuclear Regulatory Commission (NRC) Region II Office to establish direct communications between BUMC and appropriate regulatory agencies.
b. Participated in a conference call with Joe Wang and Bob Wittmer of Best Industries to request that documentation regarding measured exposure levels be faxed to the BUMC Radiation Safety Office (Attachment A).
c. Ordered film badges from three (3) personnel identified as being in close proximity to the sources (Thaddeus Sokolowski, Charles Strain, and Angela Bruner), and one area monitor from a neighboring office returned for emergency processing by Landauer.
d. Requested written statements from Mr. Sokolowski, Mr. Strain, and Mr. Lazarre with narratives of their involvement with the 10 seed Ir-192 sources (Attachment B.1 – B.3).
e. Contacted Stephen Trowbridge, Baylor University Medical Center Vice President, and Dr. Landis Griffeth, Chairman of the Radiation Safety committee, to inform them of the incident and communications with regulatory agencies.
f. Submitted a written notification to Jim Ogden, Texas Department of Health, indicating the nature of the incident, plan of action, and possibility that members of the public may have received exposure in excess of 100 millirem based on exposure measurements reported by Best Industries.

II. Time Line

The source ribbon in question consists of Ir-192 sealed sources encased in nylon ribbon that were received on October 17, 2000. Records on file at the Radiation Safety Office and written correspondence received during investigation indicate the following:

October 17, 2000 — Shipment of three (3) containers was received from Fedex, at the Radiation Safety Office (Hoblitzelle Hospital, Suite 0539). The containers were checked in by Chuck Strain with an RSO number of 9700719 assigned to the 10-seed nylon ribbon. The total activity of the 10 seed ribbon on the day of shipment was 352.85 mCi. A transportation index (TI) of 0.21 mR/hr at 1 meter was measured, and 4.2 mR/hr was measured at the package surface. Measurements were made with a Victoreen 450P (SN 828). Wipes were also obtained and measured using an Atomlab 50 well counter demonstrating no removable contamination.

Enclosure 7: Baylor incident report sent to the Texas Department of Health in answer to Incident 7675.

The containers were transported to the Cardiology Intravascular Brachytherapy (IVB) Hotlab following check-in.

October 18, 2000

At approximately 7:00 AM, each source ribbon device was unpacked and placed on the countertop by Thaddeus Sokolowski. Each ribbon was removed, calibrated, and returned to the shielded delivery device. Two IVB cases were performed, but the 14 seed ribbon was used in each case.

October 25, 2000

At 10:04 am the 10 seed delivery device was transported from the hot-lab to the Cardiac Catheterization Lab, Room 5, for IVB treatment. Chuck Lazarre, the Assistant Radiation Safety Officer, attended the case and completed the Sealed Source Exposure, Transfer, and Room Release Summary (Attachment C). On November 21, 2000, Mr. Lazarre had an immediate recollection of this particular case, and remembered verifying that the sources had been returned to the delivery device during the post-procedure survey. He also indicted that the hot lab wall mounted room area monitor (Victoreen Model 05-0433, Primalert 10, SN 98510) was not displaying a visual alarm as would occur with a source not being completely shielded.

November 17, 2000

At approximately 7 am, Mr. Sokolowski prepared each delivery device for packaging and return shipping by the Radiation Safety Office. It was reported that the three foot nylon ribbon was rewound around the inner track of the cylindrical pig and secured in a "notch" before assuring the locking screw was tight, and placement of the top. The pigs were placed on the floor when finished. Mr. Sokolowski indicated that the total procedure time was 30 minutes total. *Attachment D* pictorially indicates each step in this process.

At approximately 2:15 PM, Mr. Strain loaded the lead pigs into the shipping containers. All three (3) containers were placed on a mobile cart and positioned behind a 1 inch thick mobile lead shield. One at a time, the containers were removed from the cart, placed on the floor near the center of the room, and surveyed with a low-level ionization chamber survey meter (Keithley, Model 36150, SN 84053). A Transportation Index of 0.4 mR/hr is indicated on the Declaration for Dangerous Goods, and is consistent with Mr. Strain's recollection of the measurement.

At approximately 2:30 pm, Mr. Strain transported the containers using the mobile cart from the Cardiology Hot Lab to the Radiation Safety Counting Room. It is noted that the sources were transported through a series of low traffic hallways and involved taking a service elevator from the 3rd to the 5th floor. The elevator was restricted during use, and no delays were incurred during transport.

Mr. Strain completed remaining paper work in the Counting Room and estimated that he spent a total of 45 minutes in close proximity to the sources.

A courier from Fedex picked up the sources at approximately 4:10 pm. Thus, the sources were in the Counting Room no more than 1 hour and 40 minutes.

It is noted that Return Shipping Instructions (Best Industries, Inc., Attachment E) were available and used by Mr. Strain.

November 21, 2000

At approximately 12:30 pm, Joe Wang (Radiation Safety Officer, Best Industries, Inc.), notified the BUMC Radiation Safety Office that a T.I. of 63 mR/hour was measured, in conflict with the T.I. indicated on the Declaration of Dangerous Goods. According to regulatory requirements, a representative from Best Industries, Inc notified the Nuclear Regulatory Commission (NRC) Region II office and the Texas Department of Health prior to notifying BUMC.

III. Investigational Findings

The investigation centered on determining a cause for the error in source positioning and analyzing public and occupational exposure as a result. Evidence seems to indicate that the source ribbon was improperly packaged prior to shipment and that the package survey failed to detect exposure levels as reported by Best Industries. Although there is no evidence of BUMC policies or procedures being violated or regulatory requirements not being adhered to by personnel, occupational exposures reported from Landauer are consistent with exposure levels reported by Best. Several workers and an area monitor received more exposure than expected had the sources been properly shielded. Further, the occupational exposures to Mr. Sokolowski and Mr. Strain are consistent with the amount of time they reported spending in close proximity to the sources (ranging from contact with the pig to a distance of 3 feet) during preparation for shipment. The table below indicates readings provided by Best Industries, and expected ranges for personnel exposure:

		Exposure in millirem after 15, 30 and 60 minutes		
Location	Exposure Rate (mR/hour)	15 minutes	30 minutes	60 minutes
Surface*	1,910	477.5	955	1910
1 foot (estimated)	686	171	343	686
1 meter	63	15.75	31.5	63

* The average surface reading of five measurements near the top of the shipping container is shown.
** Exposure levels at one foot were estimated correcting for inverse-squared effect from the reading reported at 1 meter.

Pictures illustrating the steps in preparing the delivery devices for shipment are enclosed as Attachment D. The procedure used for surveying and shipping the containers is enclosed as Attachment E. Mr. Strain indicated that the written procedure was available and used, that there was a clear understanding of the procedure to be followed, and a definite recollection of conducting the survey. The survey meter used was a Keithley Model 36150 ionization chamber survey meter. It was calibrated on May 22, 2000 and examined following the incident. There was no indication that the instrument was not functioning properly. It seems evident that in some way, an error was made in either recording the measurements, or conducting the survey. (Perhaps the same shipment was measured twice, and the 10-source ribbon container was never measured.)

Personnel dosimeters worn by radiation workers directly represent the occupational exposure received from this incident. The timeline of events and subsequent investigation as presented in this report indicate two individuals that worked closely with the sources. Results indicate the following exposures:

Name	Title	Participation #	DDE	DDE 11/1-11/16*	DDE 11/17 Only
Thaddeus Sokolowski	Rad Therapy Physicist	05541	247	24	223
Chuck Strain	Health Phys. Assistant	05158	168	12	156

* Each badge had been in use for approximately 3 weeks. Occupational exposure expected from routine job responsibilities during this time was calculated based on a three month prior average and corrected for use over only part of a monitoring period.

It is noted that Mr. Sokolowski's dosimeter reading would likely be higher had the sources not been correctly returned to the pig after the case on October 25th. Further, two cases were also performed on October 30th. During preparation for these cases Mr. Sokolowski worked very close to the delivery devices during preparation and in performing dosimetry calculations using the countertop workspace directly in front of the source devices. It is expected that his exposure would be significantly higher had the sources been extruding from the pig on that day. Mr. Lazarre's statement regarding the radiation level survey on October 25th also supports this scenario.

These exposures will result in ALARA Level I (125 millirem/quarter) notification for the fourth quarter of 2000. It is not likely that the exposures will result in ALARA Level II (375 millirem) investigations unless either individual receives more than typical occupational exposure in December. The maximum exposure of 223 millirem is much less than the annual limit of 5,000 millirem for a radiation worker, and does not inherently mandate any further reporting to the Texas Department of Health.

An estimation of public exposure depends primarily on the length of time the Ir-192 source ribbon was incorrectly positioned in the lead pig, and of occupancy of areas in close proximately to the sources. As indicated on the time-line, the sources were handled on three occasions. Each has extensively been considered with respect to the possibility of the sources being positioned incorrectly. This investigation has focused on evidence such as compliance documentation, personal dosimetry readings, functionality of survey meters, and questioning of personnel with regard to radiation safety practices specifically aimed at preventing such an occurrence. Although no conclusion can be made with complete certainty, the most likely scenario indicates that the sources were positioned incorrectly during or just prior to shipment preparations. In this case public exposure could have resulted from the following circumstances:

1. Storage of the sources in the Cardiology Hot lab

   From 7:00 AM to 2:30 PM (approximately 7.5 hours), the sources were in the Cardiology hot lab awaiting final preparations for shipment by the Office of Radiation Safety. The source configuration described by Best Industries was reproduced inside the hotlab during this investigation. The source ribbon was pulled out to the extent that similar readings around the delivery device were measured. A survey was then conducted in all adjacent areas. The maximum exposure was to the adjacent hallway at the entry of the hotlab. At this location, a maximum exposure rate of 3 mR/hour was measured. This results in a total exposure of 22.5 millirem. Applying a reasonable occupancy factor of 1/16th results in an exposure of less than 2 millirem.

2. Transport of the Sources from the Cardiology Hot lab to the Radiation Safety Hot lab

   Mr. Strain noted that there were no delays or instances where members of the public were in close proximity to the sources during transport. Total transport time is typically 7 to 10 minutes. Had an individual walked right next to the sources (at 1 foot), his/her exposure would be about 80 millirem, certainly a worst case approximation. A more realistic approximation would be given by the exposure received by a bystander near the transport cart. This may be calculated by integrating the differential dose delivered at various distances away (Attachment F). This results in less than 1 millrem even with very conservative assumptions.

3. Storage in the Radiation Safety Hot lab

   The sources were placed in the Radiation Safety Hot lab for less than one hour as a temporary storage location while paper work was completed and as the shipment point for FedEx. Exposure to the public can best be represented by personnel dosimeters, one worn by a medical physicist that stood in the doorway for approximately 15 to 30 minutes (nearly 1 meter from the source containers). The other had previously been placed on the opposite side of the wall in an office to monitor public exposure levels. The results of the two dosimeter readings are as follows:

Name	Title	Participation #	DDE	DDE 11/1-11/16*	DDE 11/17 Only
Angela Bruner	Medical Physicist	05627	M	M	M
Area Monitor	Social Workers Office	Acct 046351	17	M	17

   Had a social worker been sitting at the desk next to the wall, they would have received much less than 17 millirem due to the additional distance from the wall. Applying an inverse square law correction would result in an exposure of approximately 7 millirem.

4. Exposure to FedEx employees and others during shipment

   It was not possible to carry out any definitive investigation in this regard. The Radiation Safety Officer of FedEx was contacted to discuss the incident and possibility for exposures to FedEx personnel. It was his opinion that exposures would not warrant further investigation due to the low magnitude and large uncertainty in any approximations. It might be reasonable to assume that a courier could be close to the source container for 15 to 30 minutes. In this case, the estimation of the dose at 1 foot for 15 minutes would be a realistic estimation and represent the maximum expected exposure during shipment. This results in a dose of 171 millirem. However, it is more likely

that couriers would be no closer than 1 meter (on average) to the container and typically spend no more than a few minutes in loading or unloading the container resulting in estimated exposure of 5 to 15 millirem.

Estimated exposures to members of the public are summarized below:

Individual(s)	Location	Expected exposure	Maximum exposure
1. Baylor employees, visitors	Cardiology hallway next to Hot lab	< 2 millirem	23 millirem
2. Baylor employees, visitors	Hallways during internal transport	< 1 millirem	-
3. Social workers	Office next to Radiation Safety	0 - 7 millirem	17 millirem
4. Fedex Courier	Transport	15 millirem	170 millirem

IV. Quality Control Program

Specific regulatory requirements regarding shipment of Radioactive Material have been discussed. The quality control program for the use of Ir-192 in intravascular brachytherapy (IVB) is defined in correspondence to the Texas Department of Health (March 8, 2000), requesting an amendment to BUMC's broad license allowing the use of Ir-192. Naturally, this incident has resulted in an audit of all elements of the quality control program.

During this incident, no deviations from the program could be ascertained. All instrumentation used during IVB (i.e. ionization chamber survey meters, and wall mounted area monitor in the hot lab) had been calibrated within the past 12 months (Attachment G). There is no indication of malfunction in any instrumentation or delivery device. According to Best Industries, there was no evidence of tampering with the container during shipment. All activities had been established through written procedure approved by the TDH through the licensing process and no employee lacked access to written procedures or lacked experience in performing specific responsibilities. Before shipment or and at all times while the sources were at BUMC the sources were under direct surveillance by the RSO or delegate, or locked in a secure designated hot lab.

V. Corrective Action

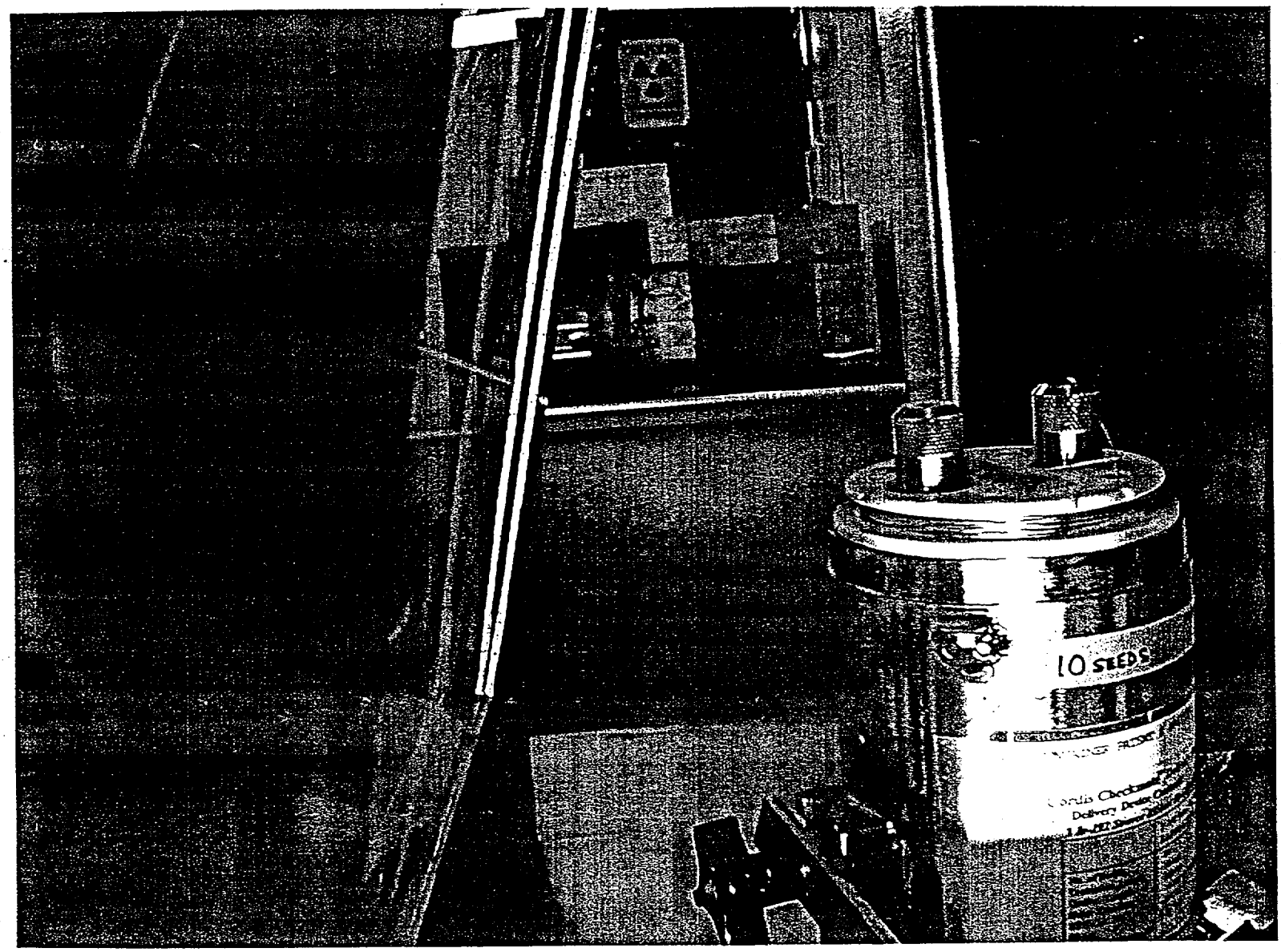
During the investigation, the individuals involved were asked to simulate each step of the shipment process. Additional steps were discussed that would prevent a repeat occurrence of this incident. These are outlined as follows:

1. The health physics assistant will remove the lid and visually verify that approximately 1 to 2 inches of color coded ribbon is extending from each delivery device before loading them into the shipping canisters. He will also verify that the locking screw is tight.
2. A new RAM shipment form (Attachment H) will be used that requires a second package survey to be performed by a medical physicist prior to contacting the carrier for shipment.
3. In addition to visually checking the hot-lab area monitor, an area survey of the lab and adjacent areas will be conducted after each use of the sources (i.e. calibration or treatment).

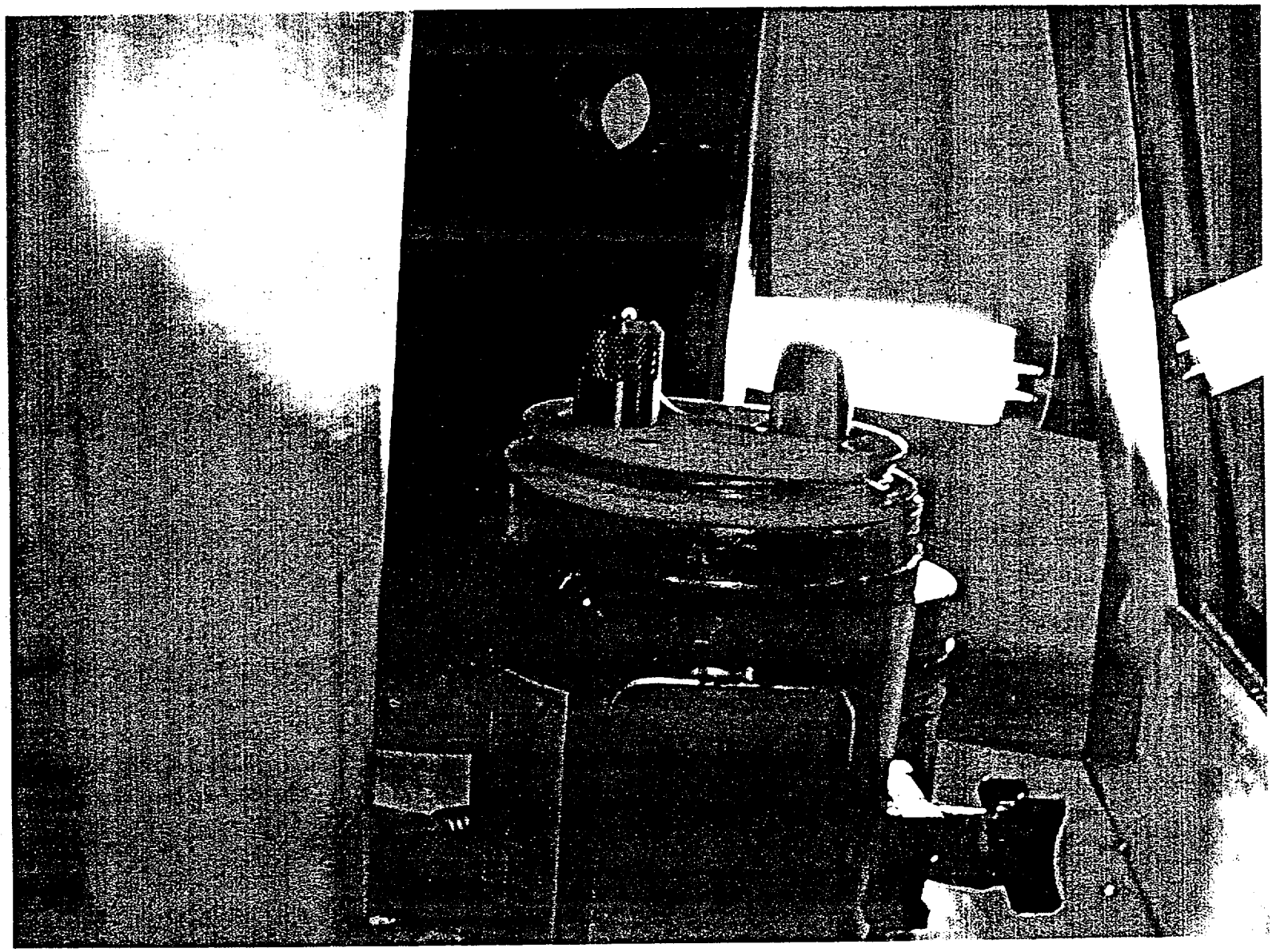
Additional training was given to Mr. Strain to accomplish this. The changes were discussed with the Radiation Safety and Medical Physics staff at a meeting on December 7, 2000.

RSD 12/27/00

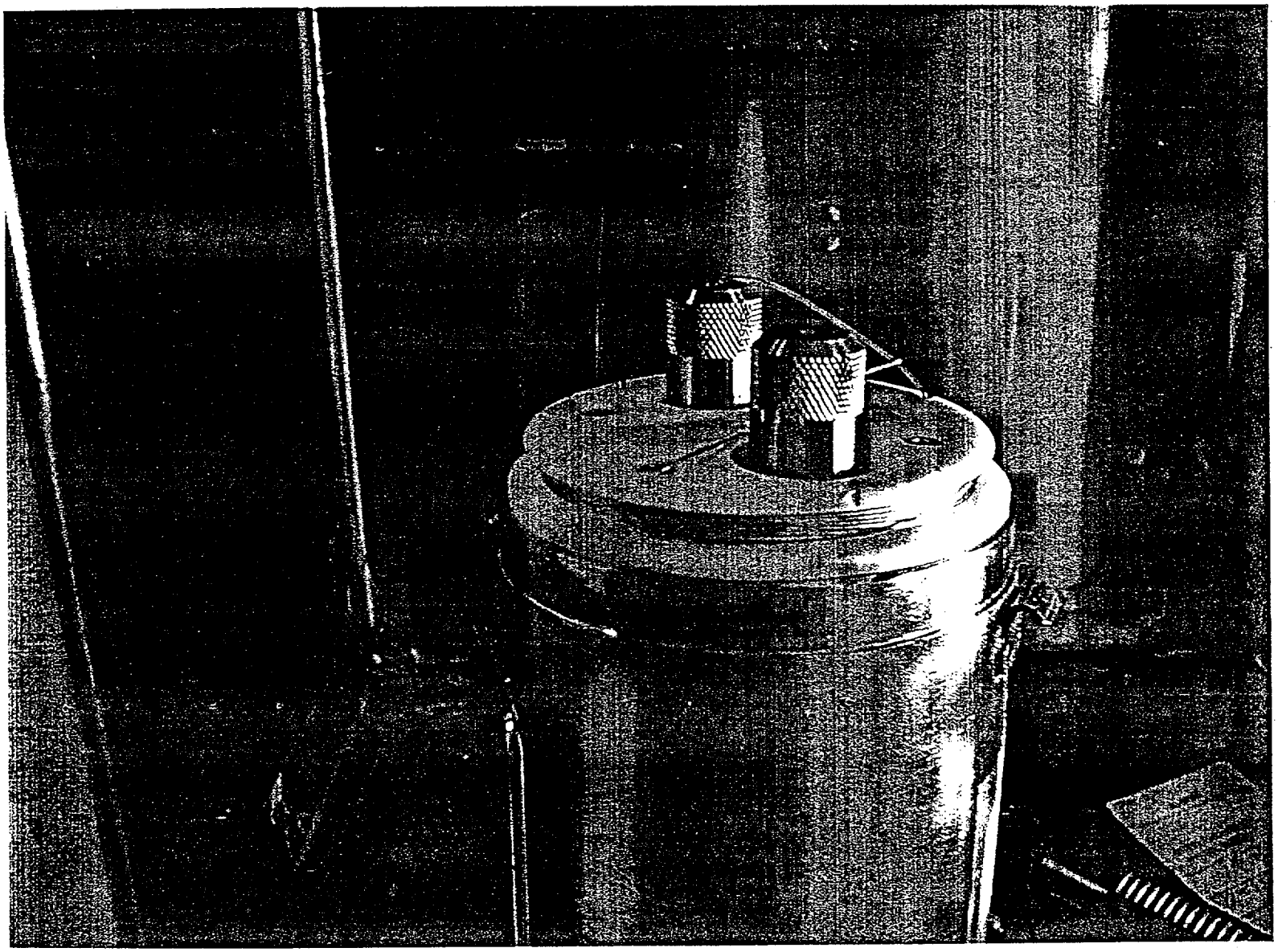
RECEIVED
TDH
JAN 2 C 2001
BUREAU OF
RADIATION CONTROL



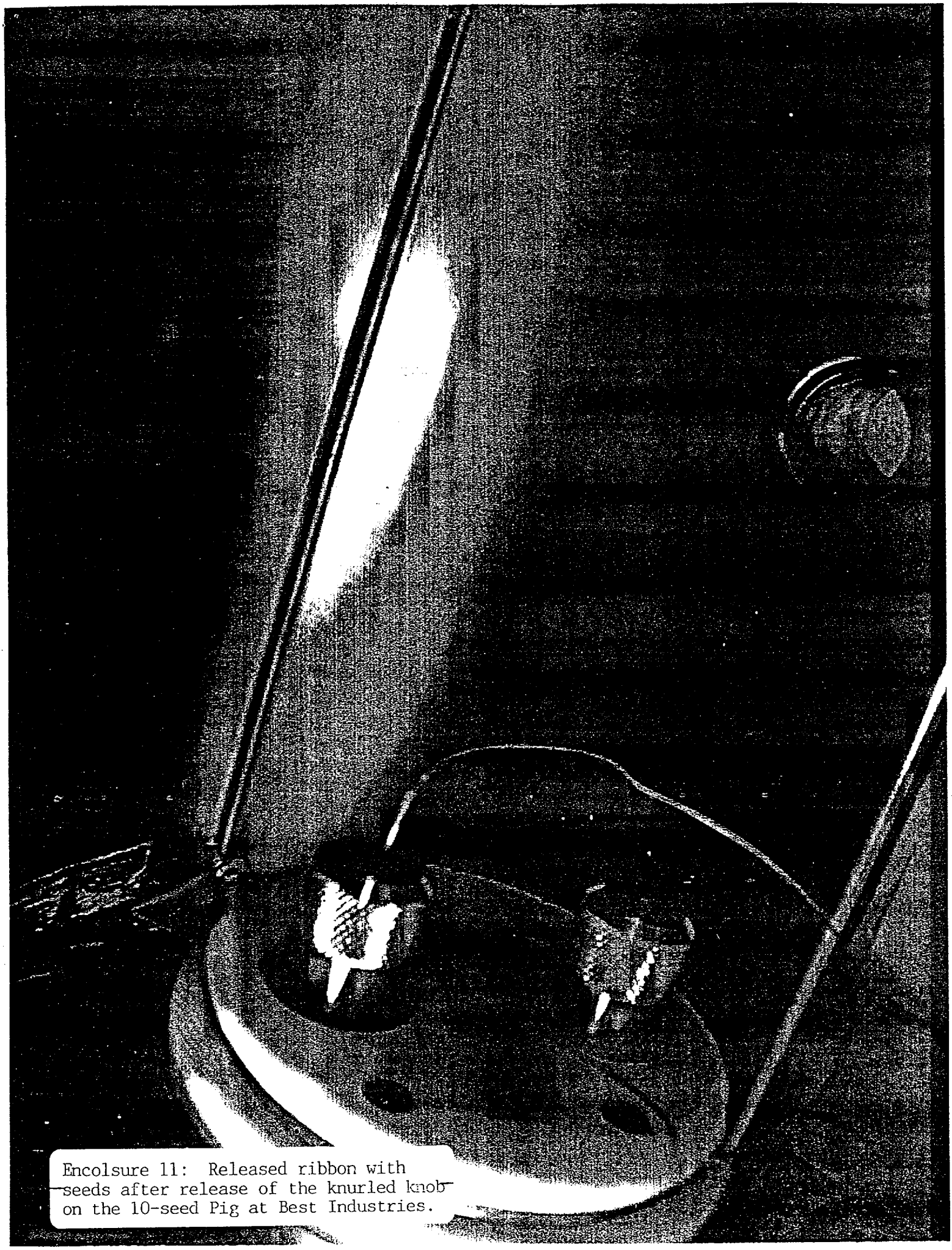
Enclosure 8: 10-seed Pig in glovebox at Best Industries, demonstrating security of ribbon upon arrival.



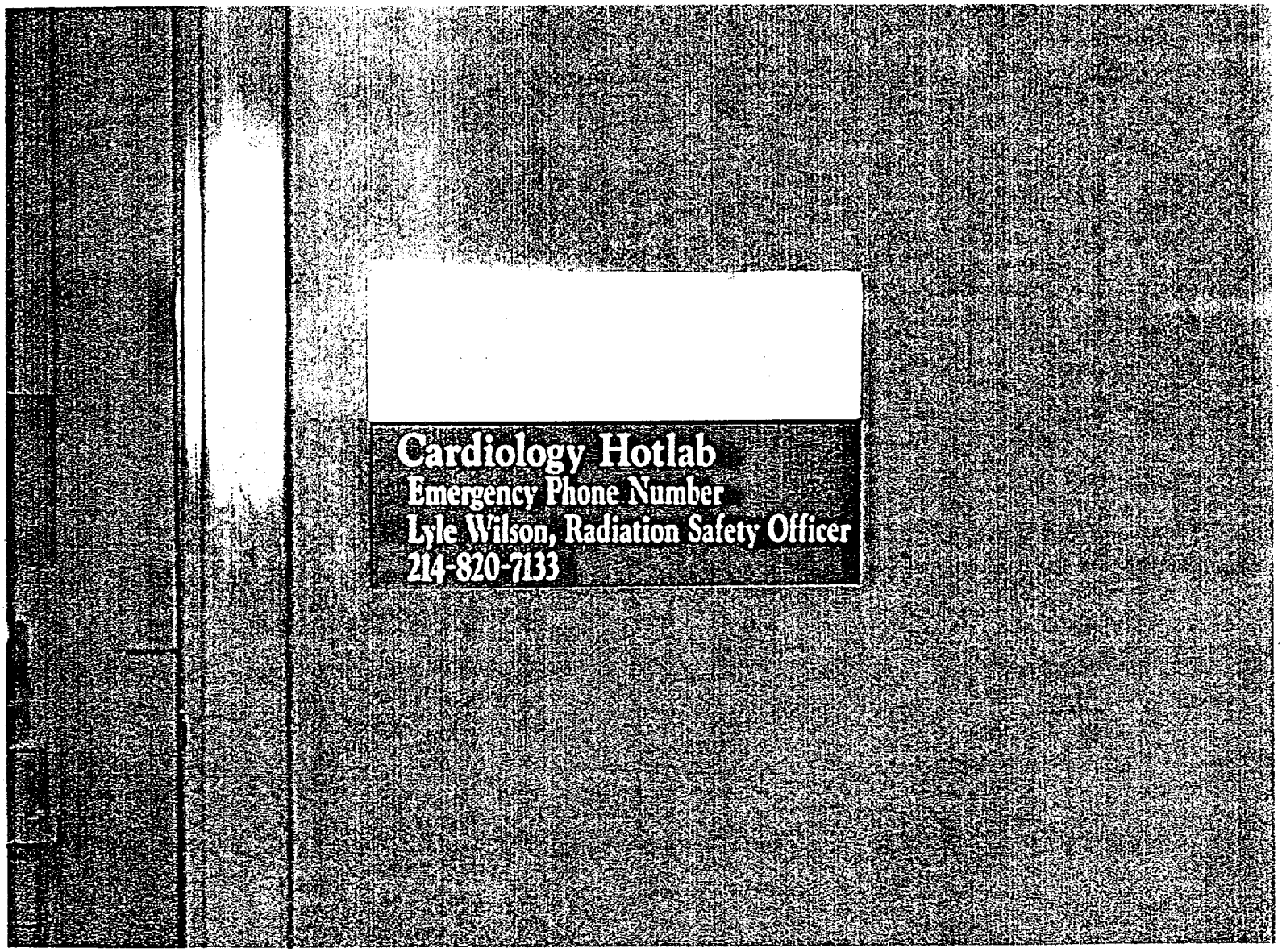
Enclosure 9: 10-seed Pig at Best Industries, demonstrating ribbon secutiry on reeling device.



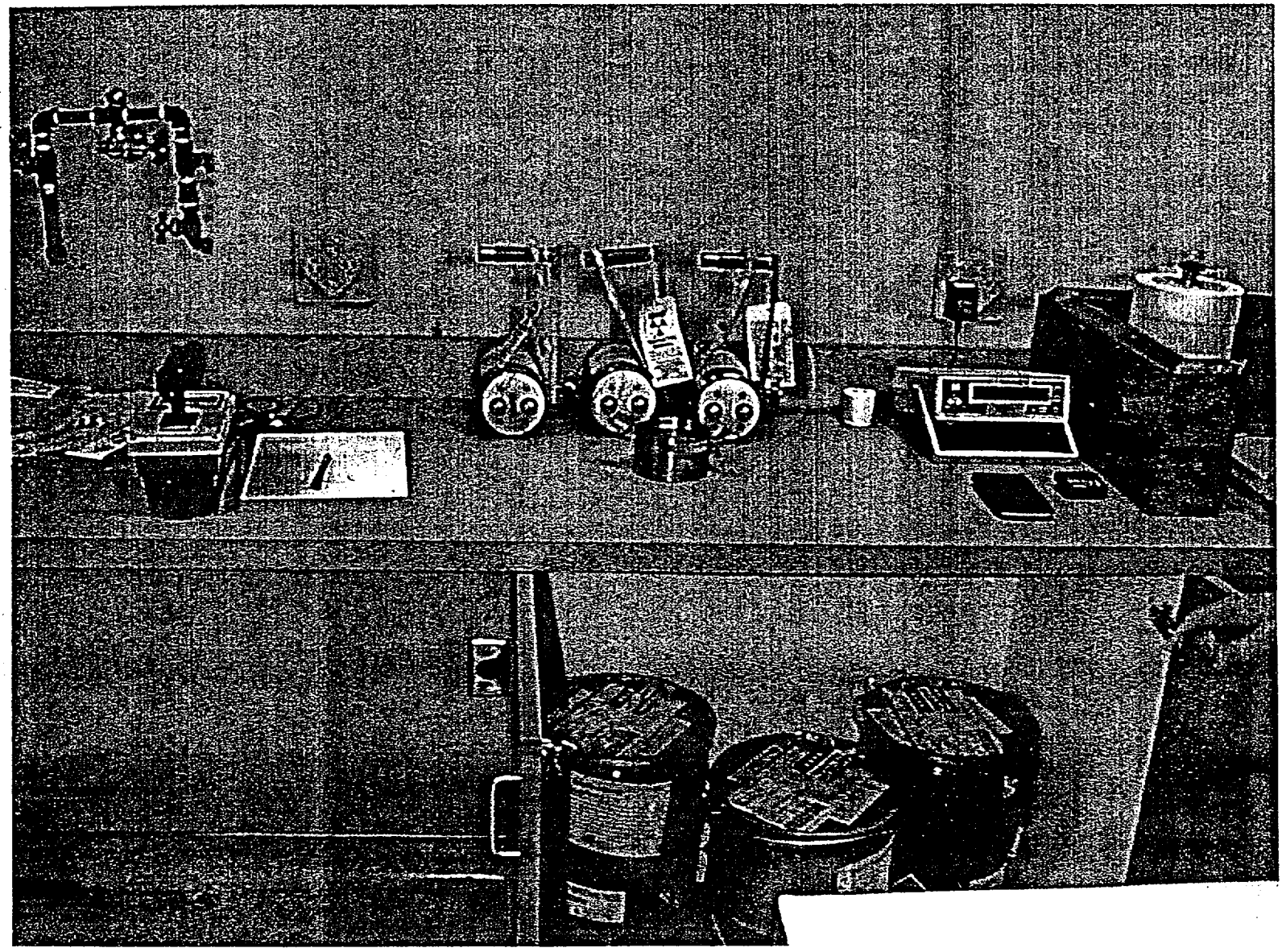
Encolsure 10: 10-seed Pig at Best Industries showing lack of color on secure ribbon.



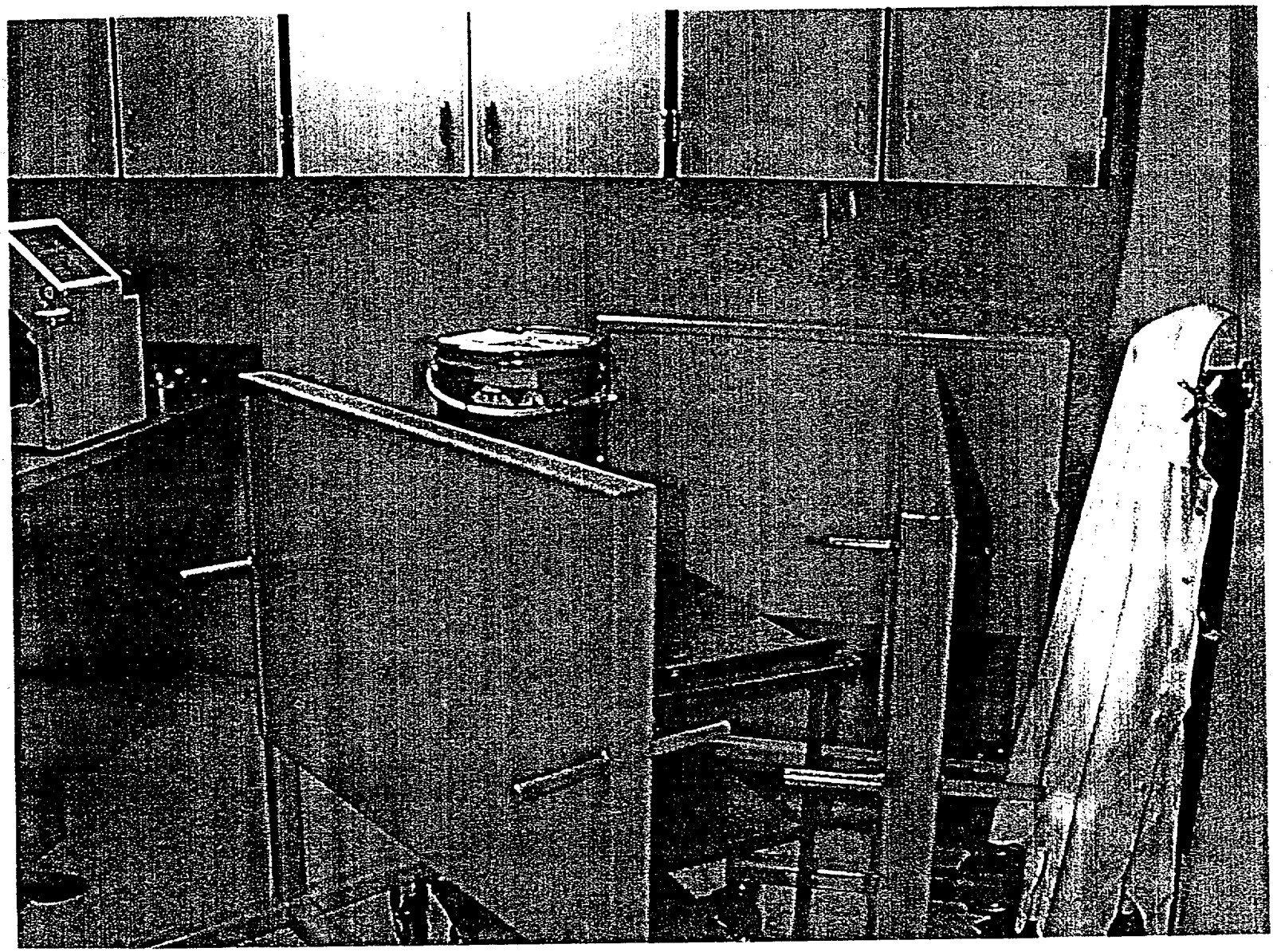
Encolsure 11: Released ribbon with seeds after release of the knurled knob on the 10-seed Pig at Best Industries.



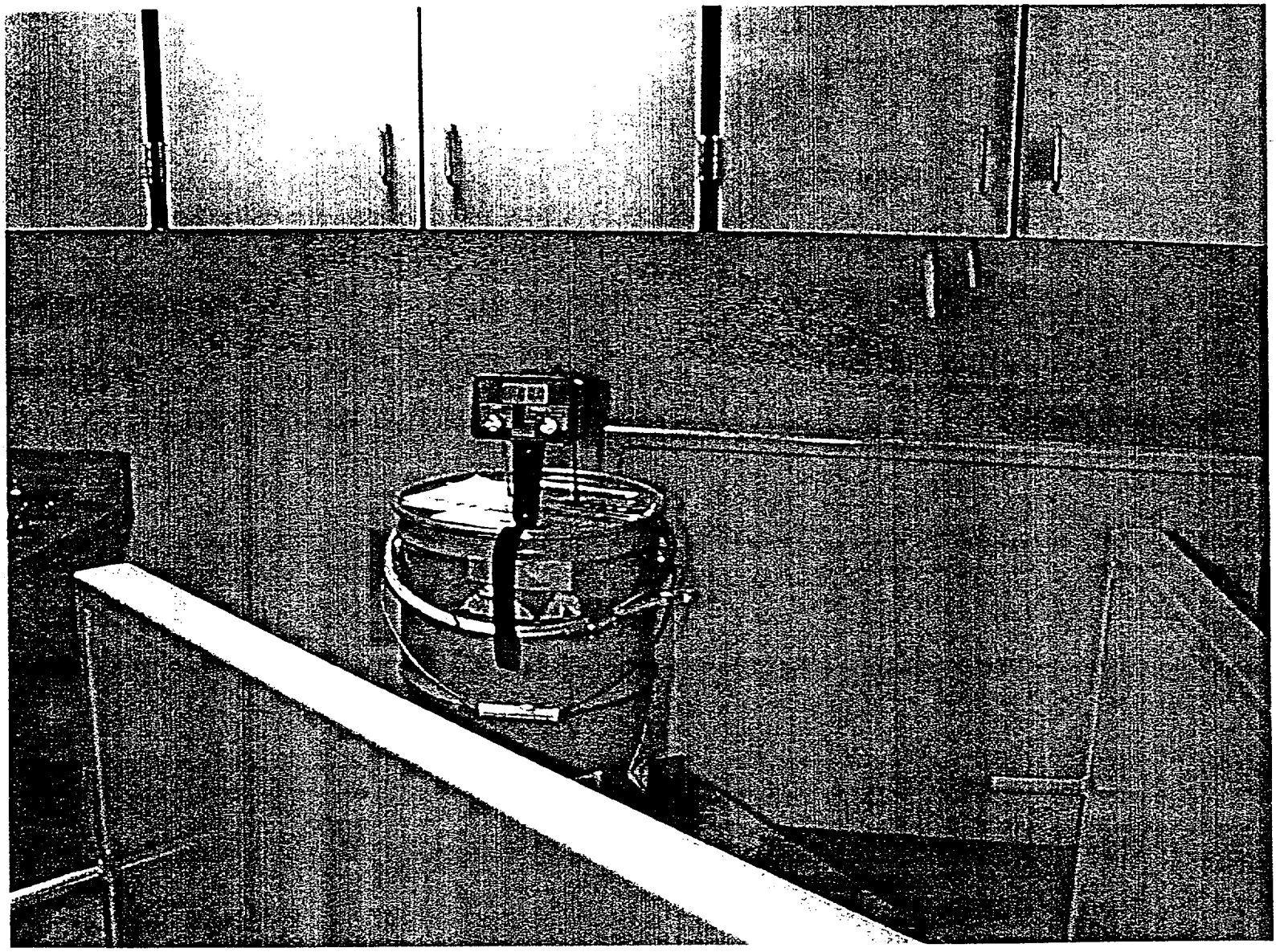
Encolsure 12: Entrance to Baylor University medical Center's Hotlab.



Enclosure 13: Interior of Baylor Hotlab with Pigs on the counter and showing container storage.



Enclosure 14: Shipping container in packaging/unpackaging mode, between 3 lead shields inside the Hotlab.



Enclosure 15: Interior view of Hotlab with shields and packaged Pig on portable table used for transport.

Prepared by Theddeus Sokolowski, RSO Sammons Cancer Center

Charles A. Sammons Cancer Center

Radiation Oncology

R. Pickett Scruggs, M.D.
Director

John S. Bradfield, M.D.
Neil M. Senzer, M.D.

We will restrict the occupancy of the elevator to only radiation workers when the transport of the radioactive material is being made. Further more, transportation of radioactive material will be made during very early hours of the day or during the evening to minimize exposure to individuals in the corridor or elevator since the occupancy of these areas will be at the lowest. One can estimate the dose to individual members of the public resulting from transportation of the lead container along the hospital corridor and elevators. A number of assumptions are made first:

1) Radioactive material is conservatively assumed to consist of 300mCi. Attenuation due to air is neglected.
2) The carrier (Physicist) is assumed to progress down the corridor at a rate of 0.5 miles per hour. This is compared to a brisk walking pace of 4 miles per hour.
3) The implant is treated as a point source and the lateral distance between the implant and the member of the general public is 100cm.
4) A conservative implant frequency of one per week is assumed.

Calculations

The dose delivered to a bystander by a passing radioactive source can be calculated by integrating the differential dose delivered at various distances away.

$$X = \int_{-\infty}^{+\infty} \frac{A\Gamma}{r^2} dt$$

$$dt = \frac{dy}{(dy/dt)}$$

$$r^2 = \frac{1}{x^2 + y^2}$$

$$X = \frac{A\Gamma}{(dy/dt)} \int_{-\infty}^{+\infty} \frac{1}{x^2 + y^2} dy = \frac{A\Gamma\pi}{(dy/dt) * x}$$

A = 300mCi
Γ = 4.69Rcm^2 mCi-hr
dy/dt = 80467.2 cm/hr
x = 100.0 cm

The total exposure to the individual is 0.17mR. A total of 52 procedures per year are assumed and each procedure passes through the hallway twice. Once en route to the Hot Lab in the Cardiology Lab and then a second time from the Cardiology Lab to Sammons Cancer Centre, hot lab. Thus the expected total exposure is 18mR/year. The expected dose to be delivered to

Enclosure 16: Baylor's calculations for dose estimates within the hospital from transport within hospital corridors

Dallas, Texas 75246 214/820-3231 FAX 214/820-7540
Affiliate of Texas Oncology, P.A.

Charles A. Sammons Cancer Center

Radiation Oncology

R. Pickett Scruggs, M.D.
Director

John S. Bradfield, M.D.
Neil M. Senzer, M.D.

members of the public under the described conditions is 18 mrem/year. This is well within the limit of 100mrem/year as established by TRCR 289.202.

Concern 5

Once the sources have been utilized for a particular procedure the sources will be returned for temporary storage at Sammons Cancer Centre and then transferred to the Vendor, ie: Best Medical International. This transfer will be performed within 24 hours after the procedure.

Concern 6

Please find the enclosed letter regarding our Institutions participation in Gamma III- Protocol # P99-5502

I would like to thank you fort taking this time in reviewing this letter and the request for the amendment to our Radioactive Material License, L04878. Since we anticipate an increase in patient cases utilizing this source of radiation especially in gynecological cases and having an interest in pursing the Intravascular Radiation Therapy we are requesting an amendment to our RAML, L04878 for a maximum Ir-192 activity of 5.0Ci. It is hoped that the information forwarded to you in this letter indicates our willingness to pursue the Intravascular Radiation Therapy study as well as other clinical studies that would be safe and beneficial to the patients and to supporting personnel. If I can provide any additional information, please feel free to contact me at (214) 820-2510 and I would be willing to provide further details. Your assistance in this matter is appreciated.

Sincerely

Thaddeus Walter Sokolowski, MSc.
Medical Physicist
Radiation Safety Officer

C:\WINNT\Profiles\twsokol\Personal\Restenosisc.doc

3535 Worth Street Dallas, Texas 75246 214/820-3231 FAX 214/820-7540
An Affiliate of Texas Oncology, P.A.

INOVISION

Radiation Measurements

6045 Cochran Road
Cleveland OH 44139
Phone: 440 248-9300
FAX: 440-349-2307
www.inovision.com
www.surveymeters.com

CERTIFICATE OF COMPLIANCE AND CALIBRATION

Model: 36150 Serial No. 84053 Date: 5/22/00

This notification certifies that the unit described above has been inspected and tested in accordance with specifications published by Inovision Radiation Measurements.

The accuracy and calibration of this instrument are traceable to the National Institute of Standards and Technology (NIST) through equipment that is calibrated at planned intervals by comparison to certified standards.

The reference standards that support this calibration are calibrated on a schedule to maintain the required accuracy level.

Quality Assurance

and Keithley Radiation Measurements

Enclosure 17: Calibration documentation for instruments used at Baylor University Medical Center.

INOVISION

Radiation Measurements

6045 Cochran Road
Cleveland OH 44139
Phone: 440 248-9300
FAX: 440-349-2307
www.inovision.com
www.surveymeters.com

CERTIFICATE OF COMPLIANCE AND CALIBRATION

Model: 36150 Serial No: 84053 Date: 5/17/00

This notification serves to certify that the unit described above has been inspected and tested in accordance with published specifications.

The accuracy and calibration of this instrument are traceable to the National Institute of Standards and Technology through equipment which is calibrated at planned intervals by comparison to certified standards.

The conditions of the actual test are:

The above instument is calibrated with an X-ray beam similar to the NIST L100 beam quality (nominal 100 kVp, 2.8 mm Al 1st HVL). In addition, the instrument has been type tested at other energy points.

RANGE	BEAM	REFERENCE	TEST	% ERROR
20 R/Hr	L100	19.00	18.90	-0.53%
20 R/Hr	M30	8.90	8.98	0.90%
20mR	L100	18.99	18.86	-0.68%
20 mR	M30	18.73	18.92	1.01%

Note: Beam quality ,M30, has a nominal kVp of 30 and 1st HVL of 0.36 mm Al.

Reference Chamber: Model: 96035 Serial No.:47380
NIST Report Number: L100 DG9726/94 M30 DG9718/93

Calibration Laboratory

Technical Review

CLQ-818
Revision C

Model 36150
Page 1 of 1

RECEIVED
TCH
JAN 2 C 2001
BUREAU OF
RADIATION CONTROL

Formerly Victoreen and Keithley Radiation Measurements

INOVISION
Radiation Measurements

6045 Cochran Road
Cleveland OH 44139
Phone: 440 248-9300
FAX: 440-349-2307
www.inovision.com

AREA MONITOR RADIATION RESPONSE CERTIFICATE

Model 05-433 Primalert 10
Serial No. 98510

We hereby certify that this instrument has been operationally checked out in accordance with specifications set forth for this model set forth by INOVISION RADIATION MEASURMENTS. Radiation levels electrical measurements are based on standards whose calibrations are traceable to the N.I.S.T.

Daily checks of the systems response are required by NRC regulations, Title 10 CFR part 35.615(d) . User License requirements, Federal, State or Local regulations may vary.

During calibration the detector was positioned perpendicular to the beam axis.

The source used for testing the systems response was Cs-137.

IMPORTANT

This monitoring unit is designed in conformance with the requirements of Title 10 CFR 35.615(d) but it is the users responsibility to assure that the unit is correctly positioned. for proper operation.

Calibrated by _____ 29-Jun-00

Technical Director Review _____ 6/29/00

Traceable to the N.I.S.T.
Test No. DG10409/99
Dated Feb. 03,1999
Exradin Chamber Model A7
Serial No. 113

INOVISION
Radiation Measurements

6045 Cochran Road
Cleveland OH 44139
Phone: 440 248-9300
FAX: 440-349-2307
www.inovision.com

Survey Meter Calibration Report / Certificate of Calibration

Customer Baylor University Medical Center

Inovision # Repair 62770

Cust PO #

Model 450P-DE
Serial # 828

********** FINAL DATA **********

CALIBRATION NOTES

**** This instrument is in tolerance +/-10% *****

Radiation levels are based on standards whose calibrations are traceable to the N.I.S.T.

The suggested re-calibration date is only a suggestion. The actual frequency of re-calibration may vary depending on Federal, state or local requirements. It is up to the user to determine this.

During calibration the survey meter was positioned with the detector perpendicular to the beam axis.

The source used for this calibration was Cs-137.

The Procedure and Rev used for this calibration was
CAL #450 Rev C

All readings below 10 mR/h were corrected for Background Radiation.

The formula for % Error is:

((Reading - Rate) / Rate) X 100

IMPORTANT

Any corrections made to the instrument reading (e.g. Energy Dependence) are up to the user to apply. Care must be used in applying those factors.

The test response data is on page two (2) of this report.

INOVISION

Radiation Measurements

8045 Cochran Road
Cleveland OH 44139
Phone: 440 248-9300
FAX: 440-349-2307
www.inovision.com

Model 450P-DE Serial No. 828

********** FINAL DATA **********

CALIBRATION DATA

**** This instrument is in tolerance +/-10% *****

RATE

	Range (uR/h)	Rate (uR/h)	Reading (uR/h)	% Error	Comments
Background	0 - 500	N/A	16	N/A	
		407	409	0.49	Cal Point
		211	215	1.90	
	(mR/h)	(mR/h)	(mR/h)		
	0 - 5	3.87	3.87	0.10	Cal Point
		2.02	2.01	-0.30	
	0 - 50	37.1	36.5	-1.62	Cal Point
		19.3	19.4	0.52	
	0 - 500	353	351	-0.57	Cal Point
		184	186	1.09	
	(R/h)	(R/h)	(R/h)		
	0 - 5	3.69	3.73	1.08	Cal Point

INTEGRATE

Range (mR)	Exposure (mR)	Reading (mR)		
0 - 50	9.81	9.79	-0.20	Cal Point

Calibrated by _____ 29-Jan-00

Technical Director Review _____ 29-Jan-00

Suggested re-cal due 29-Jan-01

Traceable to the N.I.S.T.
Test # DG10409/99
Dated Feb. 03,1999
Exradin Chamber Model A7
Serial # 113

Check Source Reading
n / a mR/h

Humidity 30 %

Temperature 19.1 °C

RECEIVED
TDH
JAN 2 6 2001
BUREAU OF
RADIATION CONTROL