

United States Nuclear Regulatory Commission Attn: Document Control Desk Washington, DC 20555

21 April 1994

Re:

Response to Notice of Violation

Routine Inspection No. 030-30125/94-001

License No. 20-28072-02

Dear Sir or Madam:

Pursuant to 10 CFR §2.201 and a letter from the United States Nuclear Regulatory Commission (USNRC) dated 21 March 1994, BioSurface Technology, Inc. (BTI) is submitting this response to a Notice of Violation. If you have any questions regarding this submission, please call me at (617) 494-8484.

Sincerely,

Christine Regan, M.Eng., RAC

Manager, Regulatory Affairs

Olaniyi Kehinde

Vice President, Technical Operations

Radiation Safety Officer

Copy: Regional Administrator, USNRC, Region I

Mark Citron

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Table of Contents

Section	<u>P</u> :	age
NRC Violations		1
Violation 1		1
Violation 2		2
Attachments		3

NRC Violations

10 CFR 71.5(a) requires, in part, that no licensee shall transport any licensed material outside the confines of his plant or other place of use, or deliver any licensed material to a carrier for transport, unless the licensee complies with applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170-189.

Violation 1

49 CFR 172.200(a) requires that each person who offers a hazardous material for transportation describe the hazardous material on the shipping paper.

Contrary to the above, on August 28, 1991, an AECL Model Gammacell 220 irradiator, serial number 208, containing approximately 4600 curies of cobalt-60, was transported from One Kendall Square in Cambridge, Massachusetts to 64 Sidney Street in Cambridge, Massachusetts, and shipping papers were not available for inspection.

Response 1

BTI agrees with the observation that the shipping papers used during the transportation of the AECL Gammacell 220 irradiator from One Kendall Square in Cambridge, Massachusetts to 64 Sidney Street in Cambridge, Massachusetts were not available for inspection during the inspection conducted by NRC on 9 February 1994. However, we know that the properly completed shipping papers were available at the time of transportation of the irradiator in compliance with 49 CFR §172.200(a). Due to changes in personnel at BTI, the file containing the shipping papers used during the move could not be located during the 9 February 1994 inspection. BTI has obtained a copy of these shipping papers (please refer to Attachment 1) for our files and has, therefore, corrected this record keeping violation as of 5 April 1994.

Violation 2

49 CFR 173.416 specifies, in part, the packages authorized for shipment of radioactive material in quantities exceeding the activity of special form radioactive material as listed in 49 CFR 173.435, and includes the requirement that the package or container be approved by the NRC,

49 CFR 173.435 establishes this value to be 7 curies for cobalt-60 in special form (the maximum A sub one quantity).

Contrary to the above, on August 28, 1991, approximately 4600 curies of cobalt-60 contained in an AECL Model Gammacell 220 irradiator, serial number 208, was transported from One Kendall Square in Cambridge, Massachusetts to 64 Sidney Street in Cambridge, Massachusetts and that package (container) was not approved by the NRC. Specifically, the Gammacell 220 had a foreign competent authority certificate, revalidated by the DOT, which allowed shipments made to or from locations outside the United States, but did not allow shipments to and from locations within the United States.

Response 2

In accordance with USNRC's "Notice of Violation" which requests we state our "...basis for disputing the violation", BTI submits that we believe that we transported the AECL Model Gammacell 220 irradiator on August 28, 1991, in compliance with all applicable NRC and DOT regulations, and made said shipment in an approved container. BTI, in preparing for the move of the irradiator, tried to locate a container approved by NRC for transport within the United States and learned that no such container existed. At that time, our only viable option was to obtain a one time exemption for shipment of the irradiator within the United States in a Type (B) container approved for transport of the irradiator into or out of the United States.

On 13 December 1990, J. D. Bernardy, then Director, Regulatory Affairs for BTI, wrote to Mr. John White, then Supervisor, Licensing Materials Section, Nuclear Materials Safety & Safeguards Branch, USNRC Region I, requesting that License No. 20-28072-02 be amended to reflect a change in address and facilities to 64 Sidney Street in Cambridge, Massachusetts (refer to Attachment 2). On 22 February 1991, Mr. Bernard: abmitted to Mr. White a request for one-time shipment authorization, using Type (B) packaging approved for import/export, for transport of the irradiator within Cambridge, Massachusetts (refer to Attachment 3). On 22 March 1991, BTI received an amended NRC Material License No. 20-28072-02 reflecting approval of the use of the irradiator at the new facility and incorporating, by reference in Section 3, Mr Bernardy's letters to USNRC of 13 December 1990 and 22 February 1991 (refer to attachment 4). As indicated in a letter from Mr. Bernardy to Mr. Terry Kehoe of Nordion International (refer to attachment 5), permission to transport the irradiator in the type B(U) packaging, granted Canadian Atomic Energy Control Board Approval Certificate No. CDN/2013/B(V), Rev 7 and US Department of Transportation Certificate USA/6125/B(U), Rev 7, is incorporated by reference to BTI's letter to the USNRC, Region I dated 22 February 1991 (refer to attachment 3) in the approval of the amendment to Material License No. 20-28072-02. Therefore, appropriate approval of the shipping container was obtained from NRC prior to shipment of the irradiator from One Kendall Square in Cambridge, Massachusetts to 64 Sidney Street in Cambridge, Massachusetts in type B(U) packaging approved by DOT for import/export.

Therefore, BTI believes that we were, and still are, in compliance with NRC and DOT regulations regarding the transport of radioactive materials in quantities exceeding the activity of special form radioactive material as listed in 49 CFR 173.435. No corrective steps are warranted at this time.

Attachments

Attachments 1 through 5 may be found on the following pages.



10 July, 1991

Mr. Terry Kehoe Nordion International, Inc. 447 March Road/Chemin P.O. Box/C.P. 13500 Kanata, Ontario Canada K2K-1X8

Dear Mr. Kehoe:

Pursuant to our discussions today, please find enclosed a copy of our NRC license permitting use of the Gammacell 220 at One Kendall Square and 64 Sidney Street. (Note Item number 10.) Permission to transport the unit in the type B(U) packaging, granted Canadian Atomic Energy Control Board Approval Certificate No. CDN/2013/B(V), Rev. 7 and US Department of Transportation Certificate USA/6125/B(U), Rev. 7, is incorporated by reference to BioSurface Technology, Inc.'s letter to the U.S. Nuclear Regulatory Commission, Region One dated 22 February 1991 in the amendment's approval. (Note Item 3 of the license. Letters of 22 February 1991 and 13 December 1990 are also enclosed.)

As we discussed, our move date is subject to completion of the 64 Sidney Street production facility's construction and certification. Move of the irradiator will be the final step of the process. Assuming construction completion by 12 July, the earliest possible irradiator move date would be about 31 July - 2 August. I will keep you informed as things develop and fix the exact move date more precisely. Please remember that moving the unit is likely to be a 2-3 day process, the most difficult part being rigging the unit out of One Kendall Square's basement location.

Sincerely.

Director, Regulatory Affairs

Encs.: US NRC Materials License No 20-28072-02 Amendment No 2

BioSurface Technology, Inc. letter dated 22 February 1991

BioSurface Technology, Inc. letter dated 13 December 1990

O. Kehinde, VP Tech Ops & RSU

W. Kuri-Harcuch, VP, Ops & Proc Dev

T. Surgenor, VP, Finance & Admin

N. Weil, Dir, Engineering

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Navi: Please remember will need

riggers, a qualified driver & dedicat 5 ton truck. Thank DB

ATTACHMENT

This form may be printed by private parties provided it conforms to the official form. For sale by the Superintendent of LNI NOICEON and local Customs District Directors. The "Correct LNI NOICEON LCG, 2002". 4069 269 619.CZ

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RADIOACTT PS59346 UN2982, N PS	CRMAL FORM, COBALT 60 4,712 CURLES (175 TBq) FORM: ELFMENT FORM: SOLID INDEX: VE YELLOW AUTBORITY CERT.NO. B(U), REV. 7 NO. CDN/2013/B(U), REV YEATION: RADICACTIVE RS N.O.I. OTHER THAN ING RADICACTIVE MATERIA D BY THE TARIFF. SHIPPER MUST COM TAL CUBAGE DIMENSIONAL WT. ER OR CONSIGNEE) TO APPLY IN PREPAYMENT OF THE CHARGE ON THE PROPERTY DESCRIBED HEREIN AGENT OR CASHIER CARRIER	AL APLATE THE FOLLO TOTAL WT. 9,700 LBS ATTONAL INC. DEGLARED VALUE \$ VALUATION CONSIGNEE	This is to certify materials are propackaged, marked proper condition to the applicable DEPARTMENT OF	perly classified, described, and labelled and cre in for transportation according regulations of THE TRANSPORTATION. Signature SHIPPER SHOW AMOUNT OF C.O.D. C. AMOUNT \$ D. PEE \$ INBOUND \$

AND

PORT

Plant Notation: * RADICACTIVE

BICSURFACE TECHNOLOGY 64 SIDNEY STREET CAMBRIDGE, MASSACHUSETTS U.S.A.	SHIPPER: BIOSURFACE TECHNOLOGY INC. 1 KENDALL SQUARE BUILDING ZOO CAMBRIDGE, MASSACHUSETTS 02139 U.S.A.
DATE: 91 AUGUST 27	ORDER NO: PS 59346
CLASSIFICATION: (7) RADIOACTIVE MATERIAL Normal Form Soecial Form	CAR NO:
AADIONUCLIDE: COBALT-60	ROUTING:
CURIE CONTENT: 4,712 CURIES (775 TBq)	
LABEL: RADIOACTIVE I (White) RADIOACTIVE II (Yellow) RADIOACTIVE III (Yellow)	
TRANSPORT INDEX:	ORIGIN: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
MODEL: GC-220 SERIAL NO: 208R	WEIGHT OR VOLUME: 9,700 LES.
B Certificate: CDN/ 2013/BCUY REV 7	USA Cordificate: USA/ 6125/8(U), REV.7
RADIOACTIVE PLACARD IN CANADA: Placard road vehicles/rell cars when transporting Radioactive I (white) OR Radioactive II (yellow) OR Radioactive III (yellow) labelled packages. IN USA: Placard road vehicles/rail cars when transporting Radioactive III (yellow) labelled packages only.	SHIPPER'S CERTIFICATION This is to certify that the above named materials are properly classified, described, peckaged, marked and labelled, and are in proper condition for transportation according to the applicable regulations of Transport Canada and the United States Department of Transportation.
	SHIPPER'S SIGNATURE:
POTENTIAL	HAZAROS

HEALTH

Radiction hazard may be internal due to breathing vapour or dust or contemination of skin, open cuts, etc. Radiation hazard may be external (like x-rays) from contamination on skin or exposure to unshielded material. Prolonged exposure may be a threat to health or life. Effects of radiation may be delayed.

EMERGENCY ACTION

Keep unnecessary people swey. Keep upwind, isolate hazard area (at least 50 m sters - 164 fd. Wear self-contained breathing apparatus and full protective clothing. Delay cleanup until arrival of qualified radiation monitoring assistance.

FIRE

Small fires: Dry Chemical or CO2

Large fires: Foam or water

Fight fire from maximum distance. More undamaged packages from fire area if without risk, Do NOT move damaged

peckages.

Do not touch spilled material or leaking or damaged packages.

Small Soills: Take up with sand, earth or other noncombustible absorbent material.

Large Spills: Dike for letter decontemination and disposal. Do not enter the spill area unless absolutely necessary to

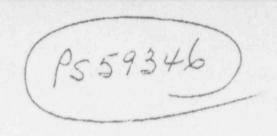
seve life. Limit entries to shortest possible time. Alterness persons for entry if possible.

FIRST AID OTOD

Call physician. Use standard first aid procedures. Remove conteminated clothing and shower with soap and water.

NORDION INT Page 3 of 6

	CODALT CO	
RADIONUC	LIDE: COBALT-60	ROUTING:
CURIE CON	TENT: 4,712 CURIES (175 TBq)	
LABEL:	AADIOACTIVE (White)	
wite.	RADIOACTIVE II (Yellow)	
	RADIOACTIVE III (Yellow)	
TRANSPORT		ORIGIN: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Type 'A	Type 8'	AMAZZONE CHUDKIDGE, MASS.
MODEL:_G	C-220 SERIAL NO: 208R	WEIGHT OR VOLUME: 9,700 LBS.
AECE Certific	am: CDN/ 2013/8 (U) REV 7	USA Certificate: USA/ 6125/B(U), REV.7
RADIOACTIV	/E PLACARD	
	Placard road vehicles/rail cars when transporting	SHIPPER'S CERTIFICATION
Radioactive I	(white) OR Redioactive II (vellow) OR Redinactive III	This is to cartify that the above named materials are properly
(yellow) labell	ed packages.	classified, described, Dackaged, marked and labelled, and are in proper condition for transportation according to the applicable
IN USA: PIAC	and road vehicles/rail cars when transporting	regulations of Transport Canada and the United States Department
Madidactive III	(yellow) labelled packages only.	of Transportation.
		SHIPPER'S SIGNATURE:
	POTENTIAL	HAZARDS
HEALTH		
HEALTH	Radiation hazard may be internal due to breathin	ng vapour or dust or contemination of thin, open cuts, etc. Radiation
HEALTH	Radiation hazard may be internal due to breathin hazard may be external (like x-rays) from cont	ng vapour or dust or contamination of thin, open cuts, ext. Radiation termination on skin or exposure to unshielded material. Prolonged of radiation may be delayed.
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Keep unnecessary full protects	Radiation hazard may be internel due to breathin hazard may be external (like x-rays) from contexposure may be a threat to health or life. Effects EMERGENC Try people away. Keep upwind, isolate hazard area (a live clothing. Delay cleanup until arrival of qualified rad Small fires: Dry Chemical or CO ₂ Large fires: Foam or weter Fight fire from maximum distance. Move undamaged packages. Do not touch spilled material or leaking or damaged Small Spills: Take up with sand, earth or other nome.	ng vapour or dust or contamination of thin, come cure, exc. Radiation termination on skin or exposure to unahielded material. Prolonged of radiation may be delayed. EY ACTION It least 50 meters - 164 ft), Wear self-contained breathing apparatus lietion monitoring assistance.
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Keep unnecessary full protects FIRE SPILL OR LEAK	Radiation hazard may be internal due to breethin hazard may be external (like x-rays) from contexposure may be a threat to health or life. Effects EMERGENC The clothing being cleamap until arrival of qualified rad Small fires: Dry Chemical or CO2 Large fires: Foam or water Fight fire from maximum distance. Move undamaged small Spills: Take up with sand, earth or other non- Large Spills: Dike for later decontamination and save life. Limit entries to shortest poss	of vapour or dust or contemination of thin, come dust, est. Radiation temination on skin or exposure to unshielded material. Prolonged of radiation may be delayed. EY ACTION It least 50 meters - 164 ft). Wear self-contained breathing apparatus lietion monitoring assistance. ged packages from fire area if without risk. Do NOT move damaged packages. Combustible absorbent material. disposal. Do not enter the spill area unless absolutely necessary to sible time. Alternate persons for entry if possible. Remove contaminated clothing and shower with soap and water.
Keep unnecessary full protects FIRE SPILL OR LEAK	Radiation haterd may be internal due to breethin hazard may be external (like x-rays) from contexposure may be a threat to health or life. Effects EMERGENC EMERGENC Investigation of the start of the start area (a live clothing. Delay cleamap until arrival of qualified rad Small fires: Dry Chemical or CO2 Large fires: Foam or water Fight fire from maximum distance. Move undamaged small Spills: Take up with sand, earth or other non Large Spills: Dike for later decontamination and save life. Limit entries to shortest possible. Call physician. Use standard first aid procedures.	of vapour or dust or contamination of thin, open dust, est. Radiation termination on skin or exposure to unshielded material. Prolonged of radiation may be delayed. EY ACTION It least 50 meters - 164 ft), Wear self-contained breathing apparatus liet on monitoring assistance. ged packages from fire area if without risk. Do NOT move damaged packages. Combustible absorbent maperial. disposal. Do not enter the spill area unless absolutely necessary to sible time. Alternate persons for entry if possible. Remove contaminated clothing and shower with soap and water, or equipment may be radioactively contaminated.
Keep unnecessary full protects FIRE SPILL OR LEAK	Radiation hazard may be internal due to breathin hazard may be external (like x-rays) from contexposure may be a threat to health or life. Effects EMERGENC Try people away. Keep upwind, isolate hazard area (a live clothing. Delay cleanup until arrival of qualified radiosed fires: Ony Chemical or CO2 Large fires: Foam or weter Fight fire from maximum distance. Move undamaged small Spills: Take up with sand, earth or other non Large Spills: Dike for later decontamination and save life. Limit entries to shortest possible rescue personnel and physicians that person of EMERGENCY - T	of vapour or dust or contemination of thin, open dust, est. Radiation temination on skin or exposure to unshielded material. Prolonged of radiation may be delayed. EY ACTION It least 50 meters - 164 ft). Wear self-contained breathing apparatus lietion monitoring assistance. ged packages from fire area if without risk. Do NOT move damaged packages. Combustible absorbent maperial. disposal. Do not enter the spill area unless absolutely necessary to sible time. Alternate persons for entry if possible. Remove conteminated clothing and shower with some and water, or equipment may be radioactively conteminated. FELEPMONE
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FIRE PILL OR EAK	Radiation hazard may be internel due to breathin hazard may be external (like x-rays) from contexposure may be a threat to health or life. Effects EMERGENC Try people away. Keep upwind, isolate hazard area (a live clothing. Delay cleanup until arrival of qualified radiosed fires: Ony Chemical or CO2 Large fires: Foam or weter Fight fire from maximum distance. Move undamaged small Spills: Take up with sand, earth or other non Large Spills: Dike for later decontamination and save life. Limit entries to shortest possible rescue personnel and physicians that person of EMERGENCY - T. 1. Local Police AND NORDION INTERNAT	ng vapour or dust or contamination of skin, open duts, etc. Radiation termination on skin or exposure to unshielded material. Prolonged of radiation may be delayed. EY ACTION It least 50 meters - 164 ft), Wear self-contained breathing apparatus diction monitoring assistance. ged packages from fire area if without risk. Do NOT move damaged packages. Combustible absorbent material. disposal. Do not enter the spill area unless absolutely necessary to sible time. Alternate persons for entry if possible. Remove contaminated clothing and shower with soat and water, or equipment may be radioactively contaminated. FELEPHONE IONAL INC. 1-613-592-2790



DATE: 91 august 23	
TO: F. DOWD	
FROM: B. ENGLEHART	
RE: PS 59346 DOCUMENTATION COVERING SEIPMENT OF GC 220 # 208R	
TO Singular Sectoring mess To Singular Sectoring Mass. + Attached please find the following documentation:	Hazatu
Shipping Labels (Red) Stowage Labels (Green) Empty Labels Category Labels (II & III) Truck Placards Highway Route Controlled Not Highway Route Controlled Seafreight Container Placards Yellow Danger Tags Red Danger Tags-Do Not Open Wire Seals Truck Bill of Lading Emergency Response Form Package Certificates CDN/20/3/3/(4) Kell.7 USA/4/35/18(4) Call SPECIAL FORM CERT. CDN/0010/S U.S. Shipper's Export Declaration Canada Customs Invoice	
Shipping Instructions for the Return of Cobalt 60 Cammacells Empty Cobalt Containers	0

ETO E

KORDKOR	V INTERNATIONAL	INC.					INPUT
SIOSURFACE TECHN NE POALL SQUE SUILL G 200 DAMBRIDGE, MASSA	CLOGY INC. ARE CHUSETTS 02139	SHIP VIA YELLOW FRET	GHT SYSTEM	INC P	REPAID		91 Apr. 12 SEPT 03 INVOICE NO.
J.D. BERNA BIOSURFACE TE		NET 30 DAYS					ORDER NO.
ONE KENDALL S BUILDING 200		EX WORKS KAN			SUBTOMER N	Q.	59346
CAMERIDGE, MA ATTN: ACCOUNT	SSACHUSETTS 02139, S PAYABLE	P.O. 4298-35	gry. ORD.	OTY SHP.	84662 UNIT P	CONSTRUCTION - JUST	AMOUNT
M DESCRIPTION - CAT. NO		THE RESERVE OF THE PERSON OF T	ZIT. SAU.	- AND REAL PROPERTY OF	and the speed of	1000	
1 RELOCATION OF FROM BIOSURFACE TE 1 KENDALL SQU BUILDING 200 CAMBRIDGE, MA	ARE 6	TO TO LOSURFACE TEXHNOLOGY SIDNEY STREET AMBRIDGE, MASS.	LOT	IO	Ţ		10035.00
2 SHIPPING MATE PACKAGING FRO MASSACHUSEITS		UCK TRANSPORT FOR CANADA TO CAMBRITISE,					453.05
DO. SER NO.	ISOTOFE	CONTAINER TYPE	NO. OF PROYAGI	6.5	Punos U.S.	T-0-1-0	10,488.05
			NO. OF PROYAGE			I	10,488.05
SICAL FORM	ISOTOPE MEAS, DATE	CONTAINER TYPE RETURNALE TYPE RADIATION			U.S.	I	10,488.05
SCAL FORM M. FORM		SELL/SERVICE SCHOOLS	WEIGHT		U.S.	2	10,488.05
DO SER NO. SK. AL FORM IM. FORM HOENTRATION	MEAS, DATE	RETURNABLE TOWNSHIP.	WEIGHT		U.S.	2	10,488.05