

CARILION

Health System

November 29, 2004

US Nuclear Regulatory Commission
Division of Nuclear Materials Safety
Region I
475 Allendale Road
King of Prussia, PA 19406

MS 16

P-6

ATTN: Ms. Penny Lanzisera
Senior Health Physicist
NRC Region 1

RE: Mail Control No. 135674 - E-mail Request for Additional Information (dated 11/26/04) regarding Carilion Health System's (CHS) two Amendment Requests (dated 09/01/04 & 10/25/04) to USNRC Radioactive Materials License No. 45-25395-01 (Docket No. 030-34470)

The following information is provided in response to your request as referenced above:

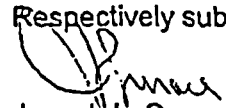
- 1) For disposal documentation of Cordis and Guidant Intravascular Brachytherapy (IVB) sealed sources with confirmation of receipt by the source supplier or manufacturer, i.e. Best Industries in the case of the two Cordis' sources and Guidant for their single source, refer to ATT.A.1. and A.2., respectively.

The following is a revision to our original Amendment Request dated 09/01/04:

- 1) The section, identified as Item 2., regarding the request to add the use of the Novoste Intravascular Radiotherapy Treatment "Beta-Cath 3.5F" Transfer Delivery Device System should be deleted entirely.

Mr. Jeffrey G. Messinger, RSO for CHS and I remain available for any additional or clarifying information you require for completing your review of these amendment requests.

Respectively submitted:


Joseph L. Surace, M.S.
Director Department of Physics
Administrative Representative for CHS

rsc/hrcamendment18.req

135674
NMSS/RGNI MATERIALS-002

Jeff Messinger - RE: Chekcmate cases for November

Page 1

A77.A.1.
Pg. 1 of 5
11/29/04

From: "Grant, Jacqueline [CRDUS]" <JGrant5@CRDUS.JNJ.com>
To: Jeff Messinger <Jmessinger@carilion.com>
Date: 12/2/03 7:55PM
Subject: RE: Chekcmate cases for November

Jeff,

I double checked and the December Gamma shipment was indeed canceled.
Please feel free to contact me if you have any questions.

Jackie

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

From: Jeff Messinger [mailto:Jmessinger@carilion.com]
Sent: Monday, December 01, 2003 3:46 PM
To: JGrant5@CRDUS.JNJ.com
Subject: Re: Chekcmate cases for November

Jacqueline,

There were a single case in Nov.

Scott had e-mailed me that he had forwarded to Best Industries our request to cancel the Dec. shipment and all future ones, since the only cardiologist still using the Cordis system is departing the hospital in mid-Dec. and the sources received in the Nov. shipment don't expire until after that time.

Jeff

>>> "Grant, Jacqueline [CRDUS]" <JGrant5@CRDUS.JNJ.com> 12/01/03 03:16PM >>>
Jeff,

I am covering for Scott Smith for the next few months for the Checkmate system. When it is convenient can you send me the number of procedures performed in November? I would appreciate any assistance and please feel free to give me a call if you have any questions.

Kind Regards,

Jacqueline E. Grant
Cordis Corporation, a Johnson & Johnson Company
Emerging Technology Specialist/NOGA Field Sales Trainer
(713)828-2085 - Cellular
(800)327-2490 xt. 7676
(877)308-2933 - Pager

Best Ind. - Boba Witmore 12/03/02 0910 Vice-mat'l Confirming To
Rtn. Shipment of Nov. sources
as last shipment. No Dec.
shipment from Best. *[Signature]*

9-1 (800) 327-4970

8217

A77.A.1.-13.2.F5

ENGLISH

1083-0212R3 154-4151-4

IRIDIUM 192 RETURN FORM

BEST MEDICAL INTERNATIONAL, INC. is authorized by the United States (U.S.) Nuclear Regulatory Commission license number 45-19757-01 to receive Iridium 192 seeds. BEST MEDICAL INTERNATIONAL, INC. packaging meets U.S. Department of Transportation specification for 7A, Type A.

SHIPPERS CERTIFICATION

Please complete the following for your return shipment:

Radioactive Material: Iridium 192 seeds in nylon ribbons

Total Source Output S_k : _____ U or Apparent Activity 7446 (MBq) or _____ (mCi)
on 12/30/03 (yyyy/mm/dd)

Air kerma strength conversion factor: 4.030 U mCi⁻¹ (per AAPM TG-43)

Air kerma strength (S_k), unit of $S_k = U = \mu\text{Gy m}^2 \text{h}^{-1}$

Number of Seeds: 10 seed train

Container Serial Number: 934AB02

RECEIVED ON

JAN 02 2004

BY PM

Shipper's Name: Department of Physics, Carilion Health System

Phone Number: 540-981-7379

Address: 2013 South Jefferson Street

Roanoke, VA 24014

Purchase Order Number: #389164

Date: 12/30/03

By: Joseph L. Surace, Physicist

all this portion will be removed from recipient's records.

12/30/03

FedEx Tracking Number

838466016650

Print Name and Title

Sender's Name: Joseph L. Surace

Phone: 540-981-7379

Signature

Company: Carilion Roanoke Memorial Hospital

Address: 2013 S. Jefferson Street

540-981-7379

City: Roanoke

State: VA

Zip: 24014

Our Internal Billing Reference

Best Medical International, Inc.

7643 Fullerton Road
Springfield, VA 22153 USA

Phone: (703) 451-2378

Fax: (703) 451-5228

ART.A.I. - P. 3.05

ENGLISH

1083-0210R4 154-4153-4

Best Medical International, Inc.
7643 Fullerton Road
Springfield, VA 22153
USA
Phone: (703) 451-2378
Fax: (703) 451-5228

Certificate No.: 934AB02

CALIBRATION CERTIFICATE For RADIOACTIVE Ir-192 SEEDS IN NYLON RIBBON

Catalog No.: 508-010P
Serial No.: 934AB02
ISO Classification No.: C23211

Radionuclide: Iridium-192

Mass Number: 192
Chemical Symbol: Ir

Source: Dimensions of ribbon source: See Product Label

Material of seed construction: Pt/Ir wire surrounded by Stainless Steel tubing

Air kerma strength conversion factor: 4.030 U mCi^{-1} (per AAPM TG-43)Air kerma strength (S_K), unit of $S_K = U = \mu\text{Gy m}^2 \text{ h}^{-1}$

Total Source Output S_K : 1223.662 U or Apparent Activity 11235 (MBq) or 303.64 (mCi) determined on
2003/11/13 (yyyy/mm/dd)

The total air kerma strength (S_K) is the number of seeds multiplied by the mean S_K of a sample of individually calibrated seeds from the same batch of irradiated seeds. The accuracy of measurement is better than $\pm 5\%$.

Calibration is done using a Capintec Isotope Calibrator Model CRC-15R. The calibrator is standardized against an Iridium 192 seed, the calibration of which is traceable to the National Institute of Standards and Technology (NIST), Gaithersburg, MD.

It is further certified that all the Ir-192 ribbons are measured individually and only those ribbons, the total S_K of which agrees within $\pm 5\%$ of the average S_K , are sent herewith.

Freedom from leakage and surface contamination:

Method of test: Dry wipe test

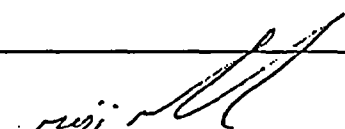
Result of test: Less than 185 Bq per test sample

Date of test: 2003/11/13 (yyyy/mm/dd)

We certify these Ir-192 seeds in nylon ribbon comply with all applicable requirements of ISO 1677-1977(E) and that the above information is correct.

We declare that we hold source approval certificate No. NR-187-S-101-S with respect to these Ir-192 seeds in nylon ribbon, issued on January 12, 1998 by the United States Nuclear Regulatory Commission

Date: 2003/11/13 (yyyy/mm/dd)

Signature: 
Radiation Physicist

8053

A77.A.1. 7.4.F5

ENGLISH

1083-0212R3 154-4151-4

IRIDIUM 192 RETURN FORM

BEST MEDICAL INTERNATIONAL, INC. is authorized by the United States (U.S.) Nuclear Regulatory Commission license number 45-19757-01 to receive Iridium 192 seeds. BEST MEDICAL INTERNATIONAL, INC. packaging meets U.S. Department of Transportation specification for 7A, Type A.

SHIPPERS CERTIFICATION

Please complete the following for your return shipment:

Radioactive Material: Iridium 192 seeds in nylon ribbons

Total Source Output S_k : _____ U or Apparent Activity 10145 (MBq) or _____ (mCi)
on 12/30 /03 (yyyy/mm/dd)

Air kerma strength conversion factor: 4.030 U mCi^{-1} (per AAPM TG-43)

Air kerma strength (S_k), unit of $S_k = \text{U} = \mu\text{Gy m}^2 \text{h}^{-1}$

Number of Seeds: 14 seed train

Container Serial Number: 934AC02

RECEIVED ON

JAN 02 2004

BY PM

Shipper's Name: Carilion Health System, Department of Physics

Phone Number: 540-981-7379

Address: 2013 S. Jefferson Street

Roanoke, VA 24014

Purchase Order Number: #389164

Date: 12/30/03

By: Joseph L. Surace, Physicist

ALL THIS PORTION CAN BE REMOVED FOR RECIPIENT'S RECORDS.

Print Name and Title

te 12/30/03 FedEx Tracking Number

838456016503

nder's
me Joseph L. Surace

Phone 540 981-7379

Signature

Company Carilion Roanoke Memorial Hospital

Address 2013 S. Jefferson Street

1-981-7379

y Roanoke

State VA Zip 24014

our Internal Billing Reference

al, Inc.

7643 Fullerton Road
Springfield, VA 22153 USA

Phone: (703) 451-2378

Fax: (703) 451-5228

A.T.A.I. - P.5.F5

ENGLISH

1083-0210R4 154-4153-4

Best Medical International, Inc.
7643 Fullerton Road
Springfield, VA 22153
USA
Phone: (703) 451-2378
Fax: (703) 451-5228

Certificate No.: 934AC02

CALIBRATION CERTIFICATE For RADIOACTIVE Ir-192 SEEDS IN NYLON RIBBON

Catalog No.: 508-014P
Serial No: 934AC02
ISO Classification No.: C23211

Radionuclide : Iridium-192

Mass Number: 192
Chemical Symbol : Ir

Source : Dimensions of ribbon source: See Product Label

Material of seed construction: Pt/Ir wire surrounded by Stainless Steel tubing

Air kerma strength conversion factor: 4.030 U mCi⁻¹ (per AAPM TG-43)Air kerma strength (S_K), unit of S_K = U = μGy m² h⁻¹

Total Source Output S_K: 1713.153 U or Apparent Activity 15729 (MBq) or 425.10 (mCi) determined on
2003 / 11 / 13 (yyyy/mm/dd)

The total air kerma strength (S_K) is the number of seeds multiplied by the mean S_K of a sample of individually calibrated seeds from the same batch of irradiated seeds. The accuracy of measurement is better than ± 5%.

Calibration is done using a Capintec Isotope Calibrator Model CRC-15R. The calibrator is standardized against an Iridium 192 seed, the calibration of which is traceable to the National Institute of Standards and Technology (NIST), Gaithersburg, MD.

It is further certified that all the Ir-192 ribbons are measured individually and only those ribbons, the total S_K of which agrees within ± 5% of the average S_K, are sent herewith.

Freedom from leakage and surface contamination:


Method of test: Dry wipe test

Result of test: Less than 185 Bq per test sample

Date of test: 2003/11/13 (yyyy/mm/dd)

We certify these Ir-192 seeds in nylon ribbon comply with all applicable requirements of ISO 1677-1977(E) and that the above information is correct.

We declare that we hold source approval certificate No. NR-187-S-101-S with respect to these Ir-192 seeds in nylon ribbon, issued on January 12, 1998 by the United States Nuclear Regulatory Commission

Date: 2003 / 11 / 13 (yyyy/mm/dd)Signature: 

Radiation Physicist

GUIDANT

October 20, 2004

Roanoke Memorial Hospital
Bellview at Jefferson
Roanoke VA 24033-3367
Attn: Mr. Jeffrey G. Messinger, ME
Radiation Safety Officer

A77.A.2.
11/29/04

Dear Sir


Subject: Deinstallation of Guidant Galileo® III Radiotherapy System

Guidant hereby confirms that the Guidant Galileo® III Radiotherapy System was de-installed from the Roanoke Memorial Hospital on October 11, 2004. This de-installation was performed by Mr. Randy Bacon of Nucletron a subcontractor trained and qualified to perform this function. The de-installation activities included the disassembly of the Source Delivery Unit (head and base) and the packaging of these items for return to Guidant Corporation.

Guidant further confirms that all Guidant P-32 sources and source cartridges have been returned by Roanoke Memorial Hospital to Guidant Corporation at our Pearland facility for disposal of the sources and refurbishment of the source cartridges.

If you have any additional questions or need any additional information, please contact me. I can be reached at 713 218 9353. Thank you.

Sincerely,



Martha Poston-Brown
Manager, Radiation Licensing and Logistics
Guidant Corporation - VI
Radiation Therapy Business Unit