MARQUETTE GENERAL HEALTH SYSTEM
580 W. College Avenue • Marquette, Michigan 49855 • 906-228-9440 • Toll free 1-800-562-9753 • Website: www.mgh.org

May 25, 2005

Nuclear Materials Licensing Branch
Nuclear Regulatory Commission Region III
2443 Warrenville Road Suite 210
Lisle, IL 60532-4352

Re: Materials License No. 21-05432-04, control #314402

Please remove the authorization for the Sr-90 Novoste devices from our license. Enclosed are the source calibration certificates for the last four sources returned to Novoste. The leak test results are included.

Regarding the request for Y-90 SIRSpheres, please change the specified inventory frequency from semi-annual to quarterly. If a decision is made by NRC management that semi-annual frequency is acceptable, we may request this change. Also, in accordance with the Microsphere Brachytherapy Sources and Devices Licensing Guidance, we request authorization to allow future changes to our radiation safety program provided the conditions given below are met.

(1) the revision is in compliance with the regulations;
(2) the revision is based upon NRC's current guidance for TheraSphere and SIRSpheres yttrium-90 microspheres 35.1000 use posted on the NRC Web site;
(3) the revision has been reviewed and approved by the licensee's radiation safety officer and licensee's management;
(4) the affected individuals are instructed on the revised program before the change is implemented;
(5) the licensee will retain a record of each change for five years; and
(6) the record will include a copy of the appropriate Web site guidance, the old procedure, the new procedure, the effective date of the change, and the signature of the licensee management that reviewed and approved the change.

We commit to these conditions.

If you have further questions, please contact Shan Marlette, R.S.O. at (906) 225-3102 or fax number (906) 225-3772.

Sincerely,

Shan Marlette

Shan Marlette, RSO

MARQUETTE GENERAL HEALTH SYSTEM

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☐ **Urgent**
☐ **Return Phone Call**
☐ **Fax Back Reply**
☐ **Informational**

Radiation Oncology
580 West College Avenue
Marquette, MI 49855
P – 906 . 225 . 3102
F – 906 . 225 . 3772

Recipient Information

Name: Colleen Carey
Organization: NRC Reg III
Phone number:
Fax number: 630-515-1259
# of pages: 2 (including cover sheet)

Sender Information

Name: Shawn Mauldin
Phone number: 906 225 6967
Fax number:

Message: **Date:** 5-25-5

I just placed cut & paste 4 pp from NRC website!

Thanks!

Fax Back Reply:

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Radiation Oncology
580 West College Avenue
Marquette, MI 49855
P – 906 . 225 . 3102
F – 906 . 225 . 3772

Recipient Information

Name: Colleen Casey
Organization: NRC Region III
Phone number: 630 829 9841
Fax number: 630 515 1259
# of pages: 6 (including cover sheet)

Sender Information

Name: Shan Marbette
Phone number: 906 225 6967
Fax number: 906 225 3772

Message: **Date:** 5-25-05

Control # 314402

(Thanks!)

Fax Back Reply:

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If you have further questions, please contact Shan Marlette, R.S.O. at (906) 225-3102 or fax number (906) 225-3772.

Sincerely,

Shan Marlette

Shan Marlette, RSO

This page replaced with subsequent fax of same date. C. Casey 5/25/05

Novoste Active Transfer Device within White Lead Lined Storage Container

ORDER # (REF) : TDA-1060

Jacketed Radiation Source Train (JRST) **Active Length:** 60 mm

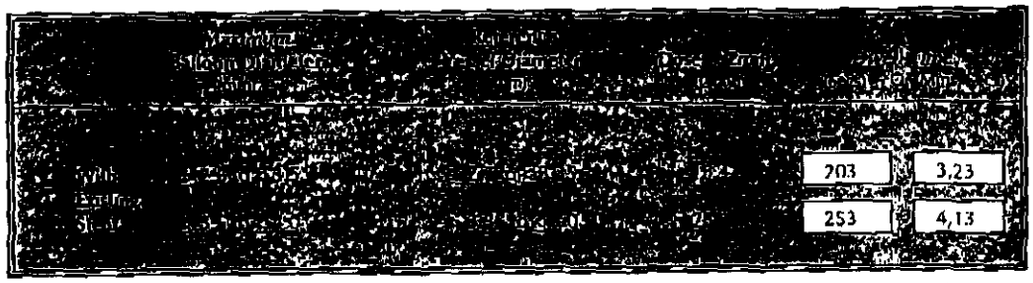
Description: SICW.2.H : 60 series of : 24 Model SICW.2 sealed sources jacketed in a stainless steel coil (0.47 mm OD) with non-radioactive radiopaque marker welded to each end.

Radionuclide: Sr-90 **Total Activity:** 2.64 GBq **Assay Date:** 13Aug03

Recommended Radiation Treatment

Transfer Device Serial #: 90658 **Effective Date From: 28Jul04**

Radiation Source Train Serial #: ZB876 **To: 26Jan05**



NOTE: If the ratio of the maximum balloon diameter to reference vessel diameter is between 1/1 and 1/1.2, dose can be prescribed according to balloon diameter. Dose can also be administered by visual assessment of reference vessel diameter.

Radiation Output: 0.0935 $Gy\text{-}s^{-1}$ ±20% in H_2O at 2mm from the center line of the Radiation Source Train. Date: **13Aug03**

Result traceable to the National Institute of Standards and Technology.
Uniformity verified +/-10% along the middle portion of the Radiation Source Train.

Sealed Radioactive Source:

AEA Technology, QSA GmbH, Model SICW.2
Radionuclide: Sr-90 Activity: **0.118** GBq/Source

The contained activity per source is the product of the measured source train absorbed dose rate in Gy/sec, at 2 mm from the source center line in water and the conversion factor 34.2 mCi/seed (1.27 GBq/seed) per Gy/sec. The contained activity in the source train is equal to the contained activity per source times the number of sources in the train.

Description: Sr-90 wire in sealed single stainless steel capsule.
Length: 2.5 mm Diameter: 0.38 mm ISO 2919 classification: $C53X_{1,3,3}1$ [1]

[1] Where X_1, X_2, and X_3 represent respective special "impact," "step" and "crush" tests simulated for circumstances that could reasonably be expected to exist outside the Beta-Cath™ 3.5F System during off-normal accident situations.

ISO Leak Test: ISO 9978, Notes, immersion into ultrasonic cleaning water with detergent solution at 70°C for at least 30 mins.
Result: <185 Bq Date: **24Jun03**

Novoste Leak Test:
H_2O passed over the Radiation Source Train and then analyzed for radioactive content
Result: <185 Bq Date: **28Jul04**

Manufactured by:	Sales and Service:	Certified by Novoste Corporation:
Novoste Corporation 3890 Steve Reynolds Blvd. Norcross, Georgia USA 30093 Tel: +1 770 717 0904	Novoste Corporation 3890 Steve Reynolds Blvd. Norcross, Georgia USA 30093 Tel: +1 800 NOVOSTE	Patricia A Bluto 7/28/04 Manufacturing Date Wood 7/28/04 Quality Assurance Date

D02211A

Novoste™ Active Transfer Device with Beta-Lined Storage Container

ORDER # (REF):TDA-1040

Jacketed Radiation Source Train (JRST) Active Length: 40mm
Description: *SICW.2.R 40 : series of 16 Model SICW.2 sealed sources jacketed in a stainless steel coil (0.47 mm OD) with non-radioactive radiopaque marker welded to each end.*
Radionuclide: Sr-90 **Total Activity:** 2.09 GBq **Assay Date:** 26Jun02

Recommended Radiation Treatment

Transfer Device Serial #: 89651 **Radiation Source Train Serial #:** ZA17Z
Effective Date From: 11Oct04 **To:** 11Apr05

	Maximum Balloon Diameter (mm)	Reference Vessel Diameter (mm)	*Dose @ 2mm* (Gray)	Dwell Time (Secs) or (Mins, Secs)	
With Existing Stent	≥ 2.5 to < 3.5	≥ 2.7 to ≤ 3.35	18.4	190	3, 10
	≥ 3.5 to ≤ 4.0	> 3.35 to ≤ 4.0	23.0	238	3, 58

NOTE: If the ratio of the maximum balloon diameter to reference vessel diameter is between 1/1 and 1/1.2, dose can be prescribed according to balloon diameter. Dose can also be administered by visual assessment of reference vessel diameter.

Radiation Output: 0.1029 Gy-s⁻¹ ± 20% in H_2O at 2 mm from the center line of the *Radiation Source Train*. Date: 26Jun02

NON-STERILE

Result traceable to the National Institute of Standards and Technology.
Uniformity verified +/- 10% along the middle portion of the Radiation Source Train.

Sealed Radioactive Source:

AEA Technology, QSA GmbH, Model SICW.2
Radionuclide: Sr-90 Activity: 0.131 GBq/Source

The contained activity per source is the product of the measured source train absorbed dose rate in Gy/sec, at 2mm from the source center line in water and the conversion factor 34.2 mCi/seed (1.27GBq/seed) per Gy/sec. The contained activity in the source train is equal to the contained activity per source times the number of sources in the train.

IPX1

Description: Sr-90 wire in sealed single stainless steel capsule.
Length: 2.5mm Diameter: 0.38mm ISO 2919 classification[1]: C53$X_{1,2,3}$ 11

[1] Where X_1, X_2 and X_3 represent respective special "impact", "step" and "crush" tests simulated for circumstances that could reasonably be expected to exist outside the Beta-Cath™ 3.5F System during off-normal accident situations.

ISO Leak Test: ISO 9978, Notes, immersion into ultrasonic cleaning water with detergent solution at 70°C for at least 30 mins.
Result: <185 Bq Date: 07Mar01

Novoste Leak Test:
H_2O passed over the Radiation Source Train and then analyzed for radioactive content using liquid scintillation counting.
Result: <185 Bq Date: 11Oct04

Sales and Service:
Novoste Corporation
4350 International Boulevard
Norcross, Georgia
USA 30093
Tel: +1 800 Novoste

Certified by Novoste Corporation:

Elaine Bowse 10-11-04
Manufacturing Date

10/11/04
Quality Assurance Date

Rec'd 10-18-04 JM

Active Transfer Device within White Lead-Lined Storage Container

ORDER # (REF) : TDA-1030

Jacketed Radiation Source Train (JRST) **Active Length:** 30 mm

Description: StCW.2.H : 30 series of : 12 Model StCW.2 sealed sources jacketed in a stainless steel coil (0.47 mm OD) with non-radioactive radiopaque marker welded to each end.

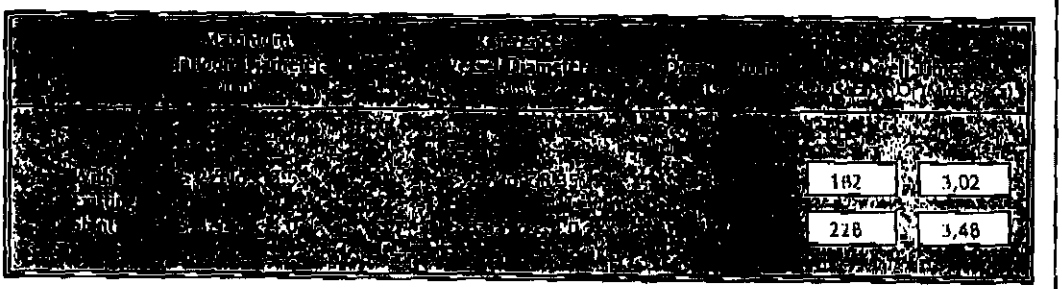
Radionuclide: Sr-90 **Total Activity:** 1.62 GBq **Assay Date:** 30Apr02

IPX1

Recommended Radiation Treatment

Transfer Device Serial #: 89643 **Effective Date From:** 15Jun04

Radiation Source Train Serial #: ZA588 **To:** 14Dec04



NOTE: If the ratio of the maximum balloon diameter to reference vessel diameter is between 1/1 and 1/1.2, dose can be prescribed according to balloon diameter. Dose can also be administered by visual assessment of reference vessel diameter.

Radiation Output: 0.1069 $Gy\text{-}s^{-1}$ ±20% in H_2O at 2mm from the center line of the Radiation Source Train. Date: **30Apr02**

Result traceable to the National Institute of Standards and Technology.
Uniformity verified +/-10% along the middle portion of the Radiation Source Train.

Sealed Radioactive Source:

AEA Technology, QSA GmbH, Model SICW.2
Radionuclide: Sr-90 Activity: 0.135 GBq/Source

The contained activity per source is the product of the measured source train absorbed dose rate in Gy/sec, at 2 mm from the source center line in water and the conversion factor 34.2 mCi/seed (1.27 GBq/seed) per Gy/sec. The contained activity in the source train is equal to the contained activity per source times the number of sources in the train.

Description: Sr-90 wire in sealed single stainless steel capsule.
Length: 2.5 mm Diameter: 0.38 mm ISO 2919 classification: $C53X_{1,2,3}11$

[1] Where X_1,X_2, and X_3 represent respective special "impact," "step" and "crush" tests simulated for circumstances that would reasonably be expected to exist outside the Beta-Cath™ 3.5F System during off-normal accident situations.

ISO Leak Test: ISO 9978, Notes, immersion into ultrasonic cleaning water with detergent solution at 70°C for at least 30 mins.
Result: <185 Bq Date: **12Mar02**

Novoste Leak Test:
H_2O passed over the Radiation Source Train and then analyzed for radioactive content using liquid scintillation counting.
Result: <185 Bq Date: **15Jun04**

Manufactured by:	**Sales and Service:**	**Certified by Novoste Corporation:**
Novoste Corporation 3890 Steve Reynolds Blvd. Norcross, Georgia USA 30093 Tel: +1 770 717 0904	Novoste Corporation 3890 Steve Reynolds Blvd. Norcross, Georgia USA 30093 Tel: +1 800 NOVOSTE	Ebonie Dawson 6-15-04 Manufacturing Date 6/15/04 Quality Assurance Date

D02211A

ctive Transfer Device within White Lead Lined Storage Container

ORDER # (REF) : TDA-1040

adiation Source Train (JRST) Active Length: 40 mm

ion: SICW.2.H : 40 series of : 16 Model SICW.2 sealed sources jacketed in a stainless steel coil (0.47 mm with non-radioactive radiopaque marker welded to each end.

adionuclide: Sr-90 Total Activity: 2.18 GBq Assay Date: 12Dec02

Recommended Radiation Treatment

Transfer Device Serial #: 89088 **Effective Date From: 21Apr04**

Radiation Source Train Serial #: ZB219 **To: 20Oct04**

NOTE: If the ratio of the maximum balloon diameter to reference vessel diameter is between 1/1 and 1/1.2, dose can be prescribed according to balloon diameter. Dose can also be administered by visual assessment of reference vessel diameter.

Radiation Output: 0.1074 $Gy\text{-}s^{-1}$ ±20% in H_2O at 2mm from the center line of the Radiation Source Train. Date: **12Dec02**

Result traceable to the National Institute of Standards and Technology.
Uniformity verified +/-10% along the middle portion of the Radiation Source Train.

Sealed Radioactive Source:

AEA Technology, QSA GmbH, Model SICW.2
Radionuclide: Sr-90 Activity: **0.136** GBq/Source

The contained activity per source is the product of the measured source train absorbed dose rate in Gy/sec, at 2 mm from the source er line in water and the conversion factor 34.2 mCi/seed (1.27 GBq/seed) per Gy/sec. The contained activity in the source train is qual to the contained activity per source times the number of sources in the train.

Description: Sr-90 wire in sealed single stainless steel capsule.
Length: 2.5 mm Diameter: 0.38 mm ISO 2919 classification: $C53X_{1,2,3}11$

* Where X_1X_2 and X_3 represent respective special "impact," "jaw" and "crush" tests simulated for circumstances that could reasonably be expected to exist outside the Beta-Cath™ 3.5F System during off-normal accident situations.

ISO Leak Test: ISO 9978, Notes, immersion into ultrasonic cleaning water with detergent solution at 70°C for at least 30 mins.
Result: <185 Bq Date: **17Sep02**

Novoste Leak Test:
H_2O passed over the Radiation Source Train and then analyzed for radioactive content using liquid scintillation counting.
Result: <185 Bq Date: **21Apr04**

Manufactured by:	Sales and Service:	Certified by Novoste Corporation:
Novoste Corporation 3890 Steve Reynolds Blvd. Norcross, Georgia USA 30093 Tel: +1 770 717 0904	Novoste Corporation 3890 Steve Reynolds Blvd. Norcross, Georgia USA 30093 Tel: +1 800 NOVOSTE	Elaine Bowser 4-21-04 Manufacturing Date 4/21/04 Quality Assurance Date

D02211A