

BON SECOURS DEPAUL MEDICAL CENTER  
ONCOLOGY SERVICES

TRANSMITTAL SHEET

TO:	FROM:
US Nuclear Regulatory Commission ATTN: Document Control Desk Washington DC 20555	Kristi Sink Director Oncology Bon Secours Health Ctr at Va Beach
COMPANY:	DATE:
US NRC	3/15/2008
DELIVERY METHOD:	TOTAL NO. OF PAGES INCLUDING COVER:
Delivery via US Postal Service	9
PHONE NUMBER:	SENDER'S PHONE NUMBER:
	757-889-5945
RE:	
Reply to Notice of Violation – Original letter, rev attachments	<b>Resubmission</b>

☒ URGENT    ☐ FOR REVIEW    ☐ PLEASE COMMENT    ☐ PLEASE REPLY    ☐ PLEASE RECYCLE

NOTES/COMMENTS:

To Whom It May Concern:

The enclosed information is a resubmission of our original "Relay to a Notice of Violation" dated March 12, 2008. At the request of the Region 1 office, we are resubmitting this letter with revised attachments so that personal privacy information could be deleted.

Please substitute this submission for our original submission.

Should you have questions or need additional information from us, please contact me at 757-889-5945

Thank You.

Copy to: US Nuclear Regulatory Commission, Region 1 Office; David Setchel, VP Operations DePaul Medical Center; and Robert T. Mariano, M.D., Radiation Safety Officer, DePaul Medical Center

IE07  
RBN-1



BON SECOURS  
DEPAUL MEDICAL CENTER  
Bon Secours Health System

March 12, 2008

U.S. Nuclear Regulatory Commission  
ATTN: Document Control Desk  
Washington, DC 20555

“Reply to a Notice of Violation”

RE: Docket No. 03003302  
NRC License No. 45-00986-01

To Whom It May Concern:

Thank you for your letter dated February 14, 2008, identifying the findings from the NRC safety inspection conducted at Bon Secours DePaul Medical Center on November 7, 2007. Specifically, as of November 7, 2007, a semi-annual inventory of Iodine-125 brachytherapy sources was not performed, resulting in a Severity Level IV violation.

Immediately upon notification of this violation, this was reviewed with the administration and radiation oncology staff. Corrective actions were immediately taken to address and comply with regulatory requirements. Corrective steps have been implemented to insure future compliance and avoidance of future violations.

1. For compliance, the previous physicist's interpretation of the semi-annual physical inventory of sealed sources regulations was based on documentation in the Log Book for “Receipt of Radioactive Materials”. He felt a simpler method for record keeping was needed for the I-125 seed inventory. Upon request by the NRC inspector on Nov. 7, 2007, the physicist produced these records for review, unaware of having to conduct a semi-annual physical inventory of sealed sources or brachytherapy sources.
2. Corrective action has been taken and a physical inventory of all sealed sources or brachytherapy sources was completed on Feb. 5, 2008. A copy of the I-125 seed inventory is provided.
3. We have internally reviewed our procedure for ordering I-125 seeds attempting to reduce excess seeds having to go into inventory after the brachytherapy cases. To avoid future violations, any unused I-125 seeds will be returned to vendor for disposal. Also, the department's policy and procedure for brachytherapy sealed

sources, addressing the semi-annual physical inventory of I-125, was updated with these revisions.

For sealed sources in possession, a semi-annual physical inventory of sealed sources or brachytherapy sources will be performed and submitted to the Radiation Safety Officer and the Radiation Safety Committee for review and compliance. A sample of the inventory record to be completed and submitted is provided.

4. As of Feb. 5, 2008, a physical inventory was completed of sealed sources or brachytherapy sources. Full compliance with this requirement was achieved.

We appreciate the opportunity to learn from this inspection, and welcome your feedback on the actions taken. Bon Secours DePaul Medical Center has a long history of providing excellent care to those in need. As part of this commitment to excellent care, we take seriously our responsibilities related to regulatory compliance and patient safety. We believe the actions outlined above appropriately address the identified deficiencies in our inventory management process, and that they will help future compliance.

Should you have any further questions or desire additional information regarding this matter, please feel free to contact me at (757) 889-5945.

Sincerely,



Kristi Sink  
Director Oncology

Cc: US NRC Regional Administrator, Region 1  
Division of Nuclear Materials Safety  
475 Allendale Road  
King of Prussia, PA 19406-1415

David Setchel, Vice President Operations, Bon Secours DePaul Medical Center

Robert T. Mariano, MD, Radiation Safety Officer, Bon Secours DePaul Medical Center

## Permanent Seed Implants

## 2007 Prostate Seed Inventory Log

Bard: I-125 seeds

Bon Secours DePaul Medical Center; Norfolk, VA 23505

Half-Life (I-125) = 59.6 days

Rec'd Date	2007 Year Patient Name	No# of seeds ordered	Activity per seed (mCi)	Assay Date Total mCi	Implant Date/ Curator	No# seeds Removed/ Activity mCi	No# seeds Implanted/ Activity mCi	No# return to storage/ Total mCi	Inventory Date	Total No# Seeds	Total Activity (mCi)	Survey & Leak Test	Final Check/ Date
		1 Calib				0	0	1					
by: KB	I-125	132			01/08/07	Case	Cancelled	132	02/01/08	133	0.000	LO.005uCi	2/5/08
	Total Activity (mCi)							0.00					2/5/08
		1 Calib	0.425	02/01/07		0	0	1					
by: KB	I-125	116	0.425	02/03/07	02/12/07	116	91	25	02/01/08	26	0.162	LO.005uCi	2/5/08
	Total Activity (mCi)				KB	44.40	34.83	9.94					2/5/08
03/12/07		1 Calib	0.406	03/02/07		0	0	1					
by: KB	I-125	133	0.425	03/03/07	03/13/07	133	81	52	02/01/08	53	0.458	LO.005uCi	2/5/08
	Total Activity (mCi)				KB	50.32	30.65	20.03					2/5/08
03/12/07		1 Calib	0.400	03/05/07		0	0	1					
by: KB	I-125	126	0.393	03/10/07	03/13/07	126	86	40	02/01/08	41	0.355	LO.005uCi	2/5/08
	Total Activity (mCi)				KB	47.82	32.64	15.55					2/5/08
		1 Calib	0.424	03/07/07		0	0	1					
by: KB	I-125	81	0.425	03/10/07	03/16/07	Case	Cancelled	81	02/01/08	82	0.768	~BKgd	2/5/08
	Total Activity (mCi)							32.49					2/5/08
03/30/07		1 Calib	0.465	03/24/07		0	0	1					
by: KB	I-125	128	0.460	03/24/07	04/02/07	Unable to	Implant	128	02/01/08	129	1.539	~BKgd	2/5/08
	Total Activity (mCi)							53.45					2/5/08
04/02/07		1 Calib	0.405	03/22/07		0	0	1					
by: KB	I-125	119	0.393	03/24/07	04/20/07	119	103	16	02/01/08	17	0.173	~BKgd	2/5/08
	Total Activity (mCi)				KB	34.16	29.57	4.88					2/5/08
		1 Calib	0.366	04/11/07		0	0	1					
by: KB	I-125	124	0.360	04/14/07	04/20/07	124	98	26	02/01/08	27	0.322	~BKgd	2/5/08
	Total Activity (mCi)				KB	41.63	32.90	9.06					2/5/08
04/27/07		1 Calib	0.435	04/19/07		0	0	1					
by: KB	I-125	125	0.425	04/21/07	04/30/07	125	93	32	02/01/08	33	0.504	LO.005uCi	2/5/08
	Total Activity (mCi)				KB	47.85	35.60	12.63					2/5/08

Rec'd Date	Patient Name	No# of seeds ordered	Activity per seed (mCi)	Assay Date Total mCi	Implant Date/ Curator	No# seeds Removed/ Activity mCi	No# seeds Implanted/ Activity mCi	No# return to storage/ Total mCi	Inventory Date	Total No# Seeds	Total Activity (mCi)	Survey & Leak Test	Final Check/ Date
05/11/07		1 Calib	0.425	05/03/07		0	0	1					
by: KB	I-125	127	0.425	05/05/07	05/14/07	127	110	17	02/01/08	18	0.323	≤ Bkgd	2/5/08
	Total Activity (mCi)				KB	48.61	42.10	6.88					2/5/08
05/18/07		1 Calib	0.397	05/10/07		0	0	1					
by: KB	I-125	102	0.393	05/12/07	05/21/07	102	88	14	02/01/08	15	0.270	≤ Bkgd	2/5/08
	Total Activity (mCi)				KB	36.10	31.15	5.30					2/5/08
		1 Calib	0.412	05/30/07		0	0	1					
by: KB	I-125	122	0.393	06/02/07	06/08/07	122	95	27	02/01/08	28	0.644	≤ Bkgd	2/5/08
	Total Activity (mCi)				KB	44.71	34.82	10.27					2/5/08
06/22/07		1 Calib	0.399	06/14/07		0	0	1					
by: KB	I-125	117	0.393	06/16/07	06/25/07	117	69	48	02/01/08	49	1.327	≤ Bkgd	2/5/08
	Total Activity (mCi)				KB	41.41	24.42	17.34					2/5/08
06/22/07		1 Calib	0.390	06/14/07		0	0	1					
by: KB	I-125	113	0.393	06/16/07	06/25/07	Case	Cancelled	113	02/01/08	114	3.087	≤ Bkgd	2/5/08
	Total Activity (mCi)							40.34					2/5/08
06/28/07		1 Calib	0.422	06/21/07		0	0	1					
by: KB	I-125	123	0.425	06/23/07	07/02/07	123	90	33	02/01/08	34	1.080	≤ Bkgd	2/5/08
	Total Activity (mCi)				KB	47.08	34.45	13.00					2/5/08
07/03/07		1 Calib	0.448	06/28/07		0	0	1					
by: KB	I-125	116	0.425	06/30/07	07/09/07	116	80	36	02/01/08	37	1.275	≤ Bkgd	2/5/08
	Total Activity (mCi)				KB	44.40	30.62	14.17					2/5/08
07/03/07		1 Calib	0.480	06/28/07		0	0	1					
by: KB	I-125	130	0.460	06/30/07	07/09/07	130	100	30	02/01/08	31	1.156	≤ Bkgd	2/5/08
	Total Activity (mCi)				KB	53.86	41.43	12.85					2/5/08
07/03/07		1 Calib	0.419	06/29/07		0	0	1					
by: KB	I-125	122	0.425	06/30/07	07/10/07	Case	Cancelled	122	02/01/08	123	4.239	≤ Bkgd	2/5/08
	Total Activity (mCi)							46.53					2/5/08
07/09/07		1 Calib	0.370	07/03/07		0	0	1					
by: KB	I-125	120	0.360	07/07/07	07/13/07	120	87	33	02/01/08	34	1.077	≤ Bkgd	2/5/08
	Total Activity (mCi)				KB	40.29	29.21	11.41					2/5/08

Rec'd Date	2007 Patient Name	No# of seeds ordered	Activity per seed (mCi)	Assay Date Total mCi	Implant Date/ Curator	No# seeds Removed/ Activity mCi	No# seeds Implanted/ Activity mCi	No# return to storage/ Total mCi	Inventory Date	Total No# Seeds	Total Activity (mCi)	Survey & Leak Test	Final Check/ Date
07/20/07		0 Calib				0	0	0					
by: KB	I-125	101	0.393	07/21/07	07/30/07	101	86	15	02/01/08	15	0.610	≤ 0.001 µCi	2/5/08
	Total Activity (mCi)				KB	35.75	30.44	5.31					2/5/08
07/20/07		1 Calib	0.450	07/18/07		0	0	1					
by: KB	I-125	116	0.425	07/21/07	07/30/07	116	68	48	02/01/08	49	2.156	≤ 0.001 µCi	2/5/08
	Total Activity (mCi)				KB	44.40	26.03	18.76					2/5/08
08/22/07		0 Calib				0	0	0					
by: KB	I-125	122	0.393	08/18/07	07/30/07	122	91	31	02/01/08	31	1.747	≤ 0.001 µCi	2/5/08
	Total Activity (mCi)				KB	59.80	44.61	15.20					2/5/08
08/22/07		1 Calib	0.429	08/16/07		0	0	1					
by: KB	I-125	125	0.425	08/18/07	08/27/07	125	76	49	02/01/08	50	3.047	≤ 0.001 µCi	2/5/08
	Total Activity (mCi)				KB	47.85	29.09	19.13					2/5/08
08/22/07		1 Calib	0.452	08/16/07		0	0	1					
by: KB	I-125	125	0.425	08/18/07	08/27/07	125	94	31	02/01/08	32	1.950	≤ 0.001 µCi	2/5/08
	Total Activity (mCi)				KB	47.85	35.98	12.26					2/5/08
08/28/07		1 Calib	0.384	08/24/07		0	0	1					
by: KB	I-125	114	0.393	08/25/07	08/31/07	114	112	2	02/01/08	3	0.183	≤ 0.001 µCi	2/5/08
	Total Activity (mCi)				KB	41.78	41.05	1.09					2/5/08
08/28/07		1 Calib	0.454	08/21/07		0	0	1					
by: KB	I-125	112	0.425	08/25/07	08/31/07	112	88	24	02/01/08	25	1.653	≤ 0.001 µCi	2/5/08
	Total Activity (mCi)				KB	44.39	34.88	9.92					2/5/08
08/28/07		1 Calib	0.267	08/22/07		0	0	1					
by: KB	I-125	93	0.260	08/25/07	08/31/07	93	86	7	02/01/08	8	0.324	≤ 0.001 µCi	2/5/08
	Total Activity (mCi)				KB	22.55	20.85	1.94					2/5/08
		1 Calib	0.411	09/06/07		0	0	1					
by: KB	I-125	108	0.393	09/08/07	09/17/07	108	75	33	02/01/08	34	2.446	≤ 0.001 µCi	2/5/08
	Total Activity (mCi)				KB	38.23	26.55	12.04					2/5/08
09/21/07		1 Calib	0.433	09/13/07		0	0	1					
by: KB	I-125	114	0.425	09/15/07	09/24/07	114	103	11	02/01/08	12	1.013	≤ 0.001 µCi	2/5/08
	Total Activity (mCi)				KB	43.64	39.42	4.59					2/5/08

Rec'd Date	Patient Name	No# of seeds ordered	Activity per seed (mCi)	Assay Date Total mCi	Implant Date/ Curator	No# seeds Removed/ Activity mCi	No# seeds Implanted/ Activity mCi	No# return to storage/ Total mCi	Inventory Date	Total No# Seeds	Total Activity (mCi)	Survey & Leak Test	Final Check/ Date
09/21/07		1 Calib	0.392	09/14/07		0	0	1					
by: KB	I-125	114	0.393	09/15/07	09/24/07	114	94	20	02/01/08	21	1.639	L Akgd	X
	Total Activity (mCi)				KB	40.35	33.27	7.43					2/5/08
09/25/07		1 Calib	0.451	09/20/07		0	0	1					
by: KB	I-125	133	0.425	09/22/07	10/01/07	133	110	23	02/01/08	24	2.197	L Akgd	X
	Total Activity (mCi)				KB	50.91	42.10	9.20					2/5/08
		1 Calib	0.434	10/18/07		0	0	1					
by: KB	I-125	125	0.425	10/20/07	10/29/07	125	102	23	02/01/08	24	3.043	L Akgd	X
	Total Activity (mCi)				KB	47.85	39.04	9.19					2/5/08
		1 Calib	0.398	10/23/07		0	0	1					
by: KB	I-125	138	0.393	10/27/07	10/29/07	138	98	40	02/01/08	41	5.215	L Akgd	X
	Total Activity (mCi)				KB	52.99	37.63	15.73					2/5/08
		1 Calib	0.420	10/19/07		0	0	1					
by: KB	I-125	124	0.425	10/20/07	10/30/07	124	78	46	02/01/08	47	5.959	L.O.COSUC	X
	Total Activity (mCi)				KB	46.91	29.51	17.77					2/5/08
11/01/07		1 Calib	0.403	10/23/07		0	0	1					
by: KB	I-125	126	0.393	10/27/07	11/02/07	126	85	41	02/01/08	42	5.342	L Akgd	X
	Total Activity (mCi)				KB	46.18	31.15	15.39					2/5/08
11/01/07		1 Calib	0.376	10/23/07		0	0	1					
by: KB	I-125	128	0.360	10/27/07	11/05/07	128	98	30	02/01/08	31	3.612	L Akgd	X
	Total Activity (mCi)				KB	41.50	31.77	10.05					2/5/08
11/01/07		1 Calib	0.401	10/24/07		0	0	1					
by: KB	I-125	93	0.393	10/27/07	11/05/07	93	53	40	02/01/08	41	5.215	L.O.COSUC	X
	Total Activity (mCi)				KB	32.92	18.76	14.51					2/5/08
by: KB	I-125								02/01/08	0	0.000		
	Total Activity (mCi)					0.00	0.00	0.00					
by: KB	I-125								02/01/08	0	0.000		
	Total Activity (mCi)					0.00	0.00	0.00					

Rec'd Date	2006 Year Patient Name	No# of seeds ordered	Activity per seed (mCi)	Assay Date Total mCi	Implant Date/ Curator	No# seeds Removed/ Activity mCi	No# seeds Implanted/ Activity mCi	No# return to storage/ Total mCi	Inventory Date	Total No# Seeds	Total Activity (mCi)	Survey & Leak Test	Final Check/ Date
		1 Calib	0.430	01/06/06		0	0	1					
by: KB	I-125	123	0.425	01/07/06	01/23/06	123	98	25	02/04/08	26	0.002	≤ Bkgd	<del>2/5/08</del>
	Total Activity (mCi)				KB	43.40	34.58	9.17					2/5/08
		1 Calib	0.366	01/16/06		0	0	1					
by: KB	I-125	100	0.360	01/21/06	01/24/06	100	79	21	02/04/08	22	0.001	≤ Bkgd	<del>2/5/08</del>
	Total Activity (mCi)				KB	34.77	27.46	7.63					2/5/08
		1 Calib	0.518	02/10/06		0	0	1					
by: KB	I-125	130	0.498	02/11/06	02/27/06	Case	Cancelled	130	02/04/08	131	0.015	600000	<del>2/5/08</del>
	Total Activity (mCi)							54.17					2/5/08
		1 Calib	0.276	02/17/06		0	0	1					
by: KB	I-125	96	0.283	02/18/06	10/29/07	96	79	17	02/04/08	18	0.001	LO.00000	<del>2/5/08</del>
	Total Activity (mCi)				KB	0.02	0.02	0.00					2/5/08
		1 Calib	0.486	03/13/06		0	0	1					
by: KB	I-125	128	0.460	03/18/06	03/28/06	128	94	34	02/04/08	35	0.005	≤ Bkgd	<del>2/5/08</del>
	Total Activity (mCi)				KB	52.42	38.49	14.33					2/5/08
		1 Calib	0.379	04/04/06		0	0	1					
by: KB	I-125	139	0.360	04/08/06	04/12/06	139	79	60	02/04/08	61	0.009	≤ Bkgd	<del>2/5/08</del>
	Total Activity (mCi)				KB	47.77	27.15	20.96					2/5/08
		1 Calib	0.386	04/21/06		0	0	1					
by: KB	I-125	96	0.393	04/22/06	05/01/06	Case	Cancelled	96	02/04/08	97	0.019	≤ Bkgd	<del>2/5/08</del>
	Total Activity (mCi)							34.32					2/5/08
		1 Calib	0.404	05/01/06		0	0	1					
by: KB	I-125	119	0.393	05/06/06	05/09/06	119	107	12	02/04/08	13	0.003	≤ Bkgd	<del>2/5/08</del>
	Total Activity (mCi)				KB	45.16	40.61	4.92					2/5/08
		1 Calib	0.400	05/04/06		0	0	1					
by: KB	I-125	126	0.393	05/06/06	05/09/06	126	95	31	02/04/08	32	0.007	≤ Bkgd	<del>2/5/08</del>
	Total Activity (mCi)				KB	47.82	36.05	12.14					2/5/08
		1 Calib	0.471	05/22/06		0	0	1					
by: KB	I-125	132	0.460	05/27/06	06/06/06	132	81	51	02/04/08	52	0.018	LO.00000	<del>2/5/08</del>
	Total Activity (mCi)				KB	54.05	33.17	21.28					2/5/08

**BON SECOURS DEPAUL MEDICAL CENTER**  
**Norfolk, VA 23505**

Department of Radiation Therapy  
Policies and Procedures

Approved \_\_\_\_\_



**Service:**

Radiation Therapy

Radiation Physicist, Dosimetrist and other authorized individuals

**Subject:**

**POLICY:** To adhere to the Federal and State requirements for brachytherapy sealed sources.

**PROCEDURE:**

1. Individual authorized to handle sealed source or brachytherapy source shall follow the radiation safety and handling guidelines provided by the manufacturer.
2. As required in NRC 35.406 and NRC 35.2406, a brachytherapy source accountability record shall be maintained for temporary and permanent implants. (see attached log record)
  - a. For temporary implants (Cs-137, Ir-192, etc.)
    - i) The number and activity of sources removed from storage, the date and time removed, the location of use and the individual who removed them from storage.
    - ii) The number and activity of sources returned to storage, the date and time returned and the name of the individual who returned them to storage.
  - b. For permanent implants (Pd-103, I-125, etc.)
    - i) The number and activity of sources removed from storage, the date removed and the individual who removed them from storage.
    - ii) The number and activity of the sources permanently implanted in the patient.
    - iii) The number and activity of sources not implanted, the date returned to storage and the name of the individual who returned them to storage.
3. On a semi-annual basis, a physical inventory shall be performed of sealed sources or brachytherapy sources in accordance with NRC 35.67.
4. On a semi-annual basis, a test for leakage of sealed sources or brachytherapy sources shall be performed unless a certificate has been provided by the manufacturer indicating that the source was tested within 6 months before transfer. Sealed sources with a half-life of < 30 days and Ir-192 seeds encased in nylon ribbon are exempt from the leak testing requirements. Sealed sources in storage and not being used are also exempt, however each source shall be tested for leakage prior to any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.
5. On a semi-annual basis, a hard copy record of the sealed source or brachytherapy source physical inventory and wipe/leak test shall be provided to the Radiation Safety Committee.

Effective date: March 2008

Reviewed by: Authorized User, Authorized Medical Physicist, Department Manager, Radiation Safety Officer and Director Oncology

\* \* \* Communication Result Report ( Mar. 15. 2008 12:50PM ) \* \* \*

1) Bon Secours Health Ctr Va Beach  
2) Imaging and Laboratory

Date/Time: Mar. 15. 2008 12:43PM

File No.	Mode	Destination	Pg(s)	Result	Page Not Sent
4268	Memory TX	16103375269	P. 10	OK	

## Reason for error

E. 1) Hang up or line fail  
E. 3) No answer  
E. 5) Exceeded max. E-mail size

E. 2) Busy  
E. 4) No facsimile connection

BON SECOURS DEPAUL MEDICAL CENTER  
ONCOLOGY SERVICES

## FACSIMILE TRANSMITTAL SHEET

TO:	FROM:
US NRC Regional Administrator, Region 1	Kristi Sink Director Oncology Bon Secours Health Ctr at Va Beach
COMPANY:	DATE:
US NRC	3/15/2008
FAX NUMBER:	TOTAL NO. OF PAGES INCLUDING COVER:
610-337-5269	10
PHONE NUMBER:	SENDER'S PHONE NUMBER:
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RE: Resubmission of Notice to Violation

☐ URGENT   ☐ FOR REVIEW   ☐ PLEASE COMMENT   ☐ PLEASE REPLY   ☐ PLEASE RECYCLE

## NOTES/COMMENTS:

Please find attached a resubmission of our original "reply to notice of violation" dated March 12, 2008. As requested, we are resubmitting our original letter with revised attachments so that personal privacy information could be deleted.

Please substitute this submission for our original submission.