DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, AR 72114

In Reply Refer To: 598/115HP/NLR

JAN 28 2010

Steven A. Reynolds
Director, Division of Nuclear Materials Safety
Region III, Nuclear Regulatory Commission (NRC)
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA; EA-09-038

Dear Mr. Reynolds:

I am sending this letter in follow-up to the letter from the Acting Under Secretary for Health (AUSH) that was dated January 14, 2010. In that letter, the AUSH indicated that the Veterans Health Administration would submit to you a proposal to retract many of the previously reported medical events at VA Medical Center, Philadelphia.

As stated in the earlier letter, this proposal is based upon a blue ribbon panel of external experts that recommended use of medical event criteria for the treatment site, which are derived from a review of medical images of the actual seed localization as compared to the intended treatment volume. These criteria follow from the NRC Advisory Committee on the Medical Use of Isotopes recommendations in 2005 that the D90 absorbed dose criteria, developed for clinical uses, provide dose data which are both imprecise and too subjective for regulatory reviews.

For your consideration, I am providing four enclosures. The first enclosure has criteria for medical events recommended by the external experts and approved by the National Radiation Safety Committee. The criteria are considered to comply with the current regulations in 10 CFR 35.

The second enclosure has a spreadsheet with a listing of the patient treatments and results with regard to the recommended event criteria. The spreadsheet also lists the patient treatments to be retracted that had previously been reported as medical events.

The third enclosure has details for abbreviations, acronyms, and notes that were used in the spreadsheet. This enclosure has explanation for the columns in the spreadsheet.

Finally, the fourth enclosure has more detailed explanation for use of the criteria.

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In summary, the following patient treatments previously reported as medical events are submitted for retraction based on the criteria recommended by the external experts:

Patients XRT: 002, 003, 004, 007, 008, 009, 012, 015, 016, 017, 021, 022, 023, 024, 026, 028, 030, 032, 035, 036, 038, 040, 041, 044, 045, 048, 049, 050, 051, 052, 053, 054, 056, 057, 058, 059, 061, 062, 063, 064, 065, 067, 068, 069, 070, 071, 072, 073, 074, 077, 079, 081, 082, 083, 085, 087, 088, 089, 091, 092, 093, 094, 095, 097, 100, 103, 105, 108, 109, 110, 112, 114

In addition, the following patient treatments previously reported as medical events are submitted for retraction based on a lack of adequate data (i.e., post-treatment images) to conclude a medical event occurred.

Patients XRT: 020, 025, 031, 033, 076, 084, 104, 111

Please contact me if you have any questions or comments.

Sincerely,

Gary E. Williams
Interim Director, National Health Physics Program

Enclosures

Enclosure 1

VHA Approach to Implementing Current U.S. NRC Medical Event Reporting Rules (as described in 10 CFR 35.2 and 35.3045(a)(1)(i) and (a)(3))

1) **Medical Event (ME) Endpoints (10 CFR 35.2 and 35.3045) for permanent prostate implants.** For implementing the treatment-site accuracy ME pathway definition, the ME endpoint will be ***the total source strength implanted in the treatment site***, not absorbed dose. This decision draws on the definition of "prescribed dose" in 10 CFR 35.2 and the decision by the NRC OGC that "dose," "total dose," and "total source strength" may be used interchangeably in permanent implant written directives (WDs) both prior to implantation and prior to completion of the procedure. For implementing the wrong-site ME definition, absorbed dose DVH metrics for tissues and organs-at-risk outside the treatment site will be used. This implementation is consistent with NRC rule interpretation which permits the licensee to use implanted source strength only for assessing treatment delivery accuracy to the treatment site but requires a dosimetric criterion for identifying wrong-site MEs.

   a) **Treatment-site accuracy ME pathway.** Implanting total source strength in the treatment site which deviates from the post-implant part of the WD by 20% or more will be considered an ME.

      i) The **treatment site** is that volume, as identified by pre-procedure or intraoperative imaging, within which the authorized user (AU) intends to implant all of the sources. This volume includes not only the clinical target volume (CTV) but additional geometric margin within which the AU intends to implant seeds necessary to achieve adequate dosimetric coverage of the CTV.

      ii) The **treatment site** includes CTV tissues expanded 0-10 mm in all directions except toward the rectum, where no expansion is permitted. The margin selected will depend on the dosimetric coverage metric (V_{100} vs. D_{90}) used for the dose prescription and the associated loading pattern (peripheral, uniform, modified uniform), which dictates the maximum distance from the CTV boundary that seeds must be implanted. A typical expansion for a modified uniform loading is 5 mm. The treatment site expansion shall be specified in the individual VAMC's written clinical and planning procedures or in the written directive (if the treatment site varies from patient-to-patient).

      Normally, treatment site accuracy will be assessed by means of CT or MR-imaging performed either at day 0, day 1, or 3 to 5 weeks following the implant procedure.

   b) **Wrong material or patient pathway.** An implant will be classified as an ME when the dose to an organ or tissue exceeds 0.5 Sv (50 rem) or 0.5 Sv (50 rem) shallow dose equivalent to the skin results from any of the following—administration of an incorrect isotope, administration of byproduct material to the wrong individual, or administration of a leaking, sealed source.

c) **Wrong-site ME pathway.**

i) **Absorbed dose criterion.** An implant will be classified as an ME when the implant results in a dose to the skin, or an organ, or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50% or more of the **dose expected** by the authorized user from the administration defined in the WD (excluding seeds that were implanted in the correct site but migrated outside of the treatment site).

ii) **Organ/Tissue specific delineations.** For the purpose of implementing this rule for prostate brachytherapy, the following organs and tissues will be defined: (1) rectum; (2) urinary bladder excluding the bladder tissue extending into the treatment site (CTV plus expansion described above); and (3) all peri-prostatic tissue excluding tissue extending into the bladder, rectum, or treatment site volume (CTV plus expansion described above).

Expected doses shall be defined, relative to the prescription dose to the prostate, as the highest dose anticipated for 1 cc of the rectum, 1 cc of uninvolved bladder, and 2 cc of peri-prostatic soft tissues.

iii) These metrics will be evaluated using ordinary dose-volume histograms. There are no published data indicating that expected doses to other organs and tissues are higher than the prescription dose. Therefore, the expected dose to immediate adjacent non-target volumes is the prescription dose. A refinement of these expected doses will be forth-coming from a review of fully acceptable cases from the RTOG0232 database.

iv) Normally, wrong-site ME determinations will be based upon CT or MR-imaging performed either at day 0, day 1, or 3 to 5 weeks following the implant procedure.

2) **Revisions of the Post-Implant Part of the WD.** The AU is required to complete any revisions to the WD for permanent implants after completion of the procedure and before the patient is released from licensee (permitee) control.

3) **Calculation of the total source strength.** An implant is an ME if the dose calculations used to determine the total source strength documented in the WD are in error by more than 20% in either direction.

1	2	3	4	5	6	7	8	9	10	11	12	13
Patient ID	**Previously Reported to NRC as Medical Event**	**Proposed Final Status**	**Basis for Proposed Final Status (per Blue Ribbon Panel Recommendations)**	**Total Number of Seeds Implanted per WD**	**Total Number of Seeds Implanted (Day 1 CT)**	**Number of Seeds Implanted Outside TS (Day 1 CT)**	**Number of Seeds Implanted Within TS (Day 1 CT)**	**Percentage of Seeds Implanted Within TS (Relative to Column 5)**	**Expected Dose (Gy) to OOT**	**Rectum: Highest Dose (Gy) to 1 cc**	**Bladder Wall: Highest Dose (Gy) to 1 cc**	**Peri-Prostatic Tissue: Highest Dose (Gy) to 2 cc**
XRT 001	Yes	**Declared**	**<80% in TS**	54	54	14	40	**74%**	160	120	32	228
XRT 002	Yes	Retract	Not a Medical Event	42	42	0	42	100%	160	93	107	59
XRT 003	Yes	Retract	Not a Medical Event	78	78	4	74	95%	160	110	73	125
XRT 004	Yes	Retract	Not a Medical Event	75	75	1	74	99%	160	92	140	97
XRT 005	Yes	**Declared**	**<80% in TS & >50% OOT**	81	81	23	58	**72%**	160	156	44	**370**
XRT 006	Yes	**Declared**	**<80% in TS & >50% OOT**	67	67	34	33	**49%**	160	141	29	**367**
XRT 007	Yes	Retract	Not a Medical Event	83	83	8	75	90%	160	227	24	164
XRT 008	Yes	Retract	Not a Medical Event	95	95	9	86	91%	160	131	157	158
XRT 009	Yes	Retract	Not a Medical Event	83	83	6	77	93%	160	128	163	145
XRT 010	Yes	**Declared**	**> 50% OOT**	60	60	11	49	82%	160	132	31	**250**
XRT 011	Yes	**Declared**	**<80% in TS**	45	43	11	32	**71%**	160	70	184	160
XRT 012	Yes	Retract	Not a Medical Event	81	81	1	80	99%	160	113	116	97
XRT 013	Yes	**Declared**	**> 50% OOT**	89	89	16	73	82%	160	107	43	**251**
XRT 014	No	NR	Not a Medical Event	74	74	1	73	99%	160	89	134	92
XRT 015	Yes	Retract	Not a Medical Event	82	82	7	75	91%	160	98	88	123
XRT 016	Yes	Retract	Not a Medical Event	57	57	6	51	89%	160	43	116	165
XRT 017	Yes	Retract	Not a Medical Event	82	82	1	81	99%	160	118	44	128
018:Composite	Yes	**Declared**	**> 50% OOT**	100	100	12	88	88%	160	**354**	196	**247**
XRT 019	Yes	**Declared**	**> 50% OOT**	88	88	13	75	85%	160	143	40	**325**
XRT 020	Yes	Retract	Not a Medical Event	73	NA: Indeterminate (see note 2)				160	NA: Indeterminate (see note 2)		
XRT 021	Yes	Retract	Not a Medical Event	80	77	4	73	91%	160	145	117	113
XRT 022	Yes	Retract	Not a Medical Event	69	68	0	68	99%	160	154	95	64
XRT 023	Yes	Retract	Not a Medical Event	79	79	11	68	86%	160	170	68	164
XRT 024	Yes	Retract	Not a Medical Event	56	56	3	53	95%	160	121	98	100
XRT 025	Yes	Retract	Not a Medical Event	77	NA: Indeterminate (see note 1)				160	NA: Indeterminate (see note 1)		
XRT 026	Yes	Retract	Not a Medical Event	70	70	6	64	91%	145	187	95	120
XRT 027	Yes	**Declared**	**<80% in TS & >50% OOT**	74	74	32	42	**57%**	160	210	42	**448**
XRT 028	Yes	Retract	Not a Medical Event	62	62	3	59	95%	160	49	99	128

1	2	3	4	5	6	7	8	9	10	11	12	13
Patient ID	**Previously Reported to NRC as Medical Event**	**Proposed Final Status**	**Basis for Proposed Final Status (per Blue Ribbon Panel Recommendations)**	**Total Number of Seeds Implanted per WD**	**Total Number of Seeds Implanted (Day 1 CT)**	**Number of Seeds Implanted Outside TS (Day 1 CT)**	**Number of Seeds Implanted Within TS (Day 1 CT)**	**Percentage of Seeds Implanted Within TS (Relative to Column 5)**	**Expected Dose (Gy) to OOT**	**Rectum: Highest Dose (Gy) to 1 cc**	**Bladder Wall: Highest Dose (Gy) to 1 cc**	**Peri-Prostatic Tissue: Highest Dose (Gy) to 2 cc**
XRT 029	No	NR	Not a Medical Event	85	85	0	85	100%	160	122	121	112
XRT 030	Yes	Retract	Not a Medical Event	79	79	10	69	87%	160	140	51	184
XRT 031	Yes	Retract	Not a Medical Event	84	NA: Indeterminate (see note 1)				160	NA: Indeterminate (see note 1)		
XRT 032	Yes	Retract	Not a Medical Event	79	79	0	79	100%	160	107	48	85
XRT 033	Yes	Retract	Not a Medical Event	86	NA: Indeterminate (see note 1)				160	NA: Indeterminate (see note 1)		
XRT 034	No	NR	Not a Medical Event	78	78	0	78	100%	160	100	100	75
XRT 035	Yes	Retract	Not a Medical Event	70	70	4	66	94%	160	206	56	113
XRT 036	Yes	Retract	Not a Medical Event	54	54	2	52	96%	160	91	165	71
XRT 037	Yes	**Declared**	**>50% OOT**	86	86	12	74	86%	160	161	82	**269**
XRT 038	Yes	Retract	Not a Medical Event	75	75	4	71	95%	**145**	104	167	106
XRT 039	No	NR	Not a Medical Event	55	55	0	55	100%	160	82	77	104
XRT 040	Yes	Retract	Not a Medical Event	84	84	0	84	100%	160	158	54	96
XRT 041	Yes	Retract	Not a Medical Event	68	68	6	62	91%	160	134	45	128
XRT 042	Yes	**Declared**	**<80% in TS & >50% OOT**	65	65	30	35	**54%**	160	211	56	**377**
XRT 043	No	NR	Not a Medical Event	73	73	6	67	92%	160	91	82	137
XRT 044	Yes	Retract	Not a Medical Event	61	61	9	52	85%	160	140	58	170
XRT 045	Yes	Retract	Not a Medical Event	77	77	0	77	100%	160	135	55	105
XRT 046	No	NR	Not a Medical Event	63	NA: Indeterminate (see note 3)				160	NA: Indeterminate (see note 3)		
XRT 047	No	NR	Not a Medical Event	67	67	0	67	100%	160	97	88	72
XRT 048	Yes	Retract	Not a Medical Event	79	79	3	76	96%	160	167	127	130
XRT 049	Yes	Retract	Not a Medical Event	54	54	2	52	96%	**145**	127	91	82
XRT 050	Yes	Retract	Not a Medical Event	77	77	1	76	99%	160	179	128	89
XRT 051	Yes	Retract	Not a Medical Event	78	78	9	69	88%	160	182	67	168
XRT 052	Yes	Retract	Not a Medical Event	52	52	0	52	100%	160	56	169	62
XRT 053	Yes	Retract	Not a Medical Event	61	58	5	53	87%	160	99	108	127
XRT 054	Yes	Retract	Not a Medical Event	54	54	2	52	96%	160	157	71	84
XRT 055	No	NR	Not a Medical Event	76	76	1	75	99%	160	94	70	95

1	2	3	4	5	6	7	8	9	10	11	12	13
Patient ID	**Previously Reported to NRC as Medical Event**	**Proposed Final Status**	**Basis for Proposed Final Status (per Blue Ribbon Panel Recommendations)**	**Total Number of Seeds Implanted per WD**	**Total Number of Seeds Implanted (Day 1 CT)**	**Number of Seeds Implanted Outside TS (Day 1 CT)**	**Number of Seeds Implanted Within TS (Day 1 CT)**	**Percentage of Seeds Implanted Within TS (Relative to Column 5)**	**Expected Dose (Gy) to OOT**	**Rectum: Highest Dose (Gy) to 1 cc**	**Bladder Wall: Highest Dose (Gy) to 1 cc**	**Peri-Prostatic Tissue: Highest Dose (Gy) to 2 cc**
XRT 056	Yes	Retract	Not a Medical Event	72 (see note 5)	72	0	72	100%	160	114	58	74
XRT 057	Yes	Retract	Not a Medical Event	76	76	6	70	92%	160	172	56	131
XRT 058	Yes	Retract	Not a Medical Event	77	77	1	76	99%	160	84	74	76
XRT 059	Yes	Retract	Not a Medical Event	66	66	0	66	100%	160	102	89	72
XRT 060	No	NR	Not a Medical Event	48	48	0	48	100%	160	98	81	65
XRT 061	Yes	Retract	Not a Medical Event	74	74	5	69	93%	160	125	73	144
062: Composite	Yes	Retract	Not a Medical Event	90	90	0	90	100%	160	130	61	67
XRT 063	Yes	Retract	Not a Medical Event	88	88	2	86	98%	160	134	48	110
XRT 064	Yes	Retract	Not a Medical Event	73	73	8	65	89%	160	235	110	111
XRT 065	Yes	Retract	Not a Medical Event	66	66	7	59	89%	160	132	49	143
XRT 066	Yes	**Declared**	**<80% in TS & >50% OOT**	61	61	19	42	**69%**	160	203	71	**251**
XRT 067	Yes	Retract	Not a Medical Event	54	54	4	50	93%	160	110	99	90
XRT 068	Yes	Retract	Not a Medical Event	60	60	3	57	95%	160	93	26	123
XRT 069	Yes	Retract	Not a Medical Event	70	70	0	70	100%	160	78	49	62
XRT 070	Yes	Retract	Not a Medical Event	44	44	1	43	98%	160	94	34	63
XRT 071	Yes	Retract	Not a Medical Event	64	64	7	57	89%	160	108	118	124
XRT 072	Yes	Retract	Not a Medical Event	76	76	3	73	96%	160	126	65	115
XRT 073	Yes	Retract	Not a Medical Event	87	86	5	81	93%	160	118	149	124
XRT 074	Yes	Retract	Not a Medical Event	78	78	6	72	92%	160	105	74	199
XRT 075	No	NR	Not a Medical Event	75	75	1	74	99%	160	132	69	107
XRT 076	Yes	Retract	Not a Medical Event	71	NA: Indeterminate (see note 1)				160	NA: Indeterminate (see note 1)		
XRT 077	Yes	Retract	Not a Medical Event	59	59	1	58	98%	160	127	41	113
XRT 078	Yes	**Declared**	**<80% in TS & >50% OOT**	68	68	20	48	**71%**	160	80	23	**353**
XRT 079	Yes	Retract	Not a Medical Event	61	61	6	55	90%	160	65	47	191
XRT 080	Yes	**Declared**	**<80% in TS & >50% OOT**	97	97	27	70	**72%**	160	115	27	**401**
XRT 081	Yes	Retract	Not a Medical Event	93	93	1	92	99%	160	103	70	107
XRT 082	Yes	Retract	Not a Medical Event	67	67	10	57	85%	160	104	49	162

1	2	3	4	5	6	7	8	9	10	11	12	13
Patient ID	**Previously Reported to NRC as Medical Event**	**Proposed Final Status**	**Basis for Proposed Final Status (per Blue Ribbon Panel Recommendations)**	**Total Number of Seeds Implanted per WD**	**Total Number of Seeds Implanted (Day 1 CT)**	**Number of Seeds Implanted Outside TS (Day 1 CT)**	**Number of Seeds Implanted Within TS (Day 1 CT)**	**Percentage of Seeds Implanted Within TS (Relative to Column 5)**	**Expected Dose (Gy) to OOT**	**Rectum: Highest Dose (Gy) to 1 cc**	**Bladder Wall: Highest Dose (Gy) to 1 cc**	**Peri-Prostatic Tissue: Highest Dose (Gy) to 2 cc**
XRT 083	Yes	Retract	Not a Medical Event	73	73	0	73	100%	160	89	21	95
XRT 084	Yes	Retract	Not a Medical Event	64	NA: Indeterminate (see note 1)				160	NA: Indeterminate (see note 1)		
XRT 085	Yes	Retract	Not a Medical Event	79	79	6	73	92%	160	159	50	163
XRT 086	No	NR	Not a Medical Event	70	70	2	68	97%	160	167	51	94
XRT 087	Yes	Retract	Not a Medical Event	50	50	2	48	96%	160	165	51	86
XRT 088	Yes	Retract	Not a Medical Event	83	81	6	75	93%	160	124	60	201
XRT 089	Yes	Retract	Not a Medical Event	85	84	1	83	99%	160	98	88	73
XRT 090	No	NR	Not a Medical Event	59	59	2	57	97%	160	74	93	87
XRT 091	Yes	Retract	Not a Medical Event	62	62	1	61	98%	160	98	53	106
XRT 092	Yes	Retract	Not a Medical Event	75	74	2	72	97%	160	127	52	132
XRT 093	Yes	Retract	Not a Medical Event	55	55	4	51	93%	160	184	55	173
XRT 094	Yes	Retract	Not a Medical Event	83	83	6	77	93%	160	116	75	144
XRT 095	Yes	Retract	Not a Medical Event	55	55	7	48	87%	160	84	53	174
XRT 096	Yes	**Declared**	**<80% in TS & >50% OOT**	71	71	22	49	**69%**	160	141	43	**346**
XRT 097	Yes	Retract	Not a Medical Event	80	80	0	80	100%	160	134	69	115
XRT 098	Yes	**Declared**	**>50% OOT**	77	77	15	62	81%	160	118	57	**304**
XRT 099	No	NR	Not a Medical Event	82	82	2	80	98%	160	118	59	113
XRT 100	Yes	Retract	Not a Medical Event	80	80	0	80	100%	160	145	139	116
XRT 101	No	NR	Not a Medical Event	91	91	0	91	100%	160	134	73	87
XRT 102	Yes	**Declared**	**<80% in TS & >50% OOT**	58	58	15	43	**74%**	160	123	see note 4	**255**
XRT 103	Yes	Retract	Not a Medical Event	81	81	3	78	96%	160	172	88	163
XRT 104	Yes	Retract	Not a Medical Event	70	NA: Indeterminate (see note 1)				160	NA: Indeterminate (see note 1)		
XRT 105	Yes	Retract	Not a Medical Event	58	58	4	54	93%	160	150	59	157
XRT 106	No	NR	Not a Medical Event	63	63	1	62	98%	160	112	100	101
XRT 107	No	NR	Not a Medical Event	80	80	4	76	95%	160	86	54	125
XRT 108	Yes	Retract	Not a Medical Event	86	86	4	82	95%	160	47	47	120
XRT 109	Yes	Retract	Not a Medical Event	56	56	5	51	91%	160	103	58	180
XRT 110	Yes	Retract	Not a Medical Event	66	66	0	66	100%	160	103	70	108

1	2	3	4	5	6	7	8	9	10	11	12	13
Patient ID	**Previously Reported to NRC as Medical Event**	**Proposed Final Status**	**Basis for Proposed Final Status (per Blue Ribbon Panel Recommendations)**	**Total Number of Seeds Implanted per WD**	**Total Number of Seeds Implanted (Day 1 CT)**	**Number of Seeds Implanted Outside TS (Day 1 CT)**	**Number of Seeds Implanted Within TS (Day 1 CT)**	**Percentage of Seeds Implanted Within TS (Relative to Column 5)**	**Expected Dose (Gy) to OOT**	**Rectum: Highest Dose (Gy) to 1 cc**	**Bladder Wall: Highest Dose (Gy) to 1 cc**	**Peri-Prostatic Tissue: Highest Dose (Gy) to 2 cc**
XRT 111	Yes	Retract	Not a Medical Event	80	NA: Indeterminate (see note 1)				160	NA: Indeterminate (see note 1)		
XRT 112	Yes	Retract	Not a Medical Event	56	56	0	56	100%	160	78	60	59
XRT 113	No	NR	Not a Medical Event	70	70	1	69	99%	160	85	90	82
XRT 114	Yes	Retract	Not a Medical Event	69	69	7	62	90%	160	114	38	150

Enclosure 3

1. This enclosure has the details for the following: abbreviations and acronyms; notes explicitly referenced in the spreadsheet; additional notes (not explicitly referenced in the spreadsheet); and, explanation of the data provided in each column of the spreadsheet.

2. The spreadsheet is based on use of new medical event criteria that was developed by a blue ribbon panel of external experts.

Abbreviations and Acronyms	
cc	cubic centimeters (volume)
Gy	Gray (absorbed dose)
OOT	**Other Organs or Tissues:** Refers to organs or tissues other than the treatment site. See description of Treatment Site (TS) below. OOT includes rectum, bladder wall, and peri-prostatic tissues that are outside the treatment site.
NA	**Not Applicable or Available**: Denotes that adequate information was not available to evaluate the item (e.g., not able to retrieve Day-1 CT for evaluations).
NR	**Not Reported**: A medical event was not previously declared and reported for the patient treatment.
TS	**Treatment Site:** The treatment site is that volume, as identified by pre-procedure or intra-operative imaging, within which the authorized user (AU) intends to implant all of the sources. This volume includes not only the clinical target volume (CTV) but additional geometric margin within which the AU intends to implant seeds necessary to achieve adequate dosimetric coverage of the CTV. For purposes of retrospective evaluation of patient treatments, the treatment site is considered to include CTV tissues expanded up to 10 mm in all directions except toward the rectum, where no expansion has been permitted. For purposes of retrospective evaluation of patient treatments, treatment site accuracy has been determined by analyzing CT scans performed the day after the implant procedure ("Day-1 CT"). For patients whose archived CT scans are not available, retrospective evaluations could not be performed; these patients' results are considered to be "indeterminate." The term "Treatment Site" (TS) replaces the previous term of "Designated Treatment Site" (DTS) (referenced in the October 19, 2009, submittal to NRC). The distinction between TS and DTS is important because the DTS concept included posterior expansion into the rectum, which is different from the medical event criteria as defined by the Blue Ribbon Panel.
WD	Written Directive

Notes	
The following notes are explicitly referenced in the spreadsheet:	
1	For items specifically identified as **NA: Indeterminate**, the Day-1 CT was not able to be retrieved for evaluations.
2	**Patient XRT 020:** A hard copy of the summary and a 3-D view of the prostate and rectum are available but the Day-1 CT images are not. A reconstruction of the 3-D image indicated 1 seed external to the Treatment Site and 99% within TS; however, accuracy of the prostate contouring, verification of the number of seeds outside and inside the treatment site, dose to the bladder, rectum and peri-prostatic tissue cannot be verified. As such this patient treatment is being classified as indeterminate.
3	**Patient XRT 046:** This patient's original file data was used to commission new Variseed Version 7.0 software in August 2004. In doing so, the original pre- and post-treatment plans were over-written resulting in loss of original data. Hard copies of original pre- and post-plans are in the patient's clinical chart on file in PVAMC Radiation Oncology; however, the Day-1 CT images were not able to be retrieved for independent evaluation. As such this patient treatment is being classified as indeterminate.
4	**Patient XRT 102:** The bladder wall for this patient could not be completely visualized on Day-1 CT images; therefore, dose to bladder wall could not be evaluated.
5	**Patient XRT 056:** The completed WD is normally maintained in the Radiation Oncology patient file. This patient's clinical Radiation Oncology file could not be located at the time this evaluation was prepared. The Radiation Safety Officer file contains verification that the number of seeds ordered, received, and transferred to the Medical Physicist for this patient match the number implanted and that no seeds were recovered after implantation.
The following notes are not explicitly referenced in the spreadsheet but provide additional information:	
6	**Patients XRT 019, 062 (two treatments), 069, 070, 077, and 109:** The prescribing physician for these six patients was Dr. Whittington. Dr. Kao was the prescribing physician for the other 108 patients.
7	**Patients XRT 026, 038, and 049:** The prescribed dose was 145 Gy for these patient treatments. Other patient treatments had a prescribed dose of 160 Gy.

	Notes
8	**Patients XRT 018 and 062**: These patients had two implants. Only composite values are listed in the spreadsheet.
9	**Patient XRT 011:** This patient's treatment had been reported as a possible medical event in 2005 but was retracted based on results of NHPP's site visit during that year. NHPP's decision to retract was based on the NRC's earlier decision that circumstances for patient XRT 018 were not a medical event. The patient treatment for XRT011 is now considered to be a medical event using the Treatment Site activity metric.
10	**Patient XRT 018:** This patient received two treatments. The initial treatment had been reported as a medical event in 2003 but was later determined not to be a medical event for those reporting circumstances. The composite results for both treatments are presented in this report and are now considered to be medical events due to dose to tissues other than the treatment site.
11	**Patients XRT 001, 005, 007, 008,018, 021,024,026, 027, 035, 041, 042, 050, 051, 054, 057, 064, 066, 071, 093:** Due to application of the new medical event criteria, these patients have a revised number of seeds outside the treatment site as compared to the earlier October 19, 2009, submittal to NRC.
12	**Patients XRT 008, 044, 057:** Peri-prostatic volume contours were re-evaluated and revised by the VHA Director, National Radiation Oncology Program (DRO) for these patient treatments. The revised contours are the basis for doses reported herein for peri-prostatic tissues. In addition, for XRT 057, the number of seeds within and outside TS was revised based on DRO review.
13	**Patient XRT 022:** Dose reported herein for bladder wall was determined based on review by the VHA Director, National Radiation Oncology Program.
14	**Patients XRT 001, 005, 042, 057 and 071:** These patient treatments have been re-contoured and re-planned since October 19, 2009, submittal to NRC using the blue ribbon panel recommendations. The number of sources, percentages, and resultant absorbed doses were updated.
15	**Retained as Declared Medical Events (17):** Patients XRT 001, 005, 006, 010, 011, 013, 018, 019, 027, 037, 042, 066, 078, 080, 096, 098, 102, continue to be considered medical events.

Notes	
16	**Total Proposed Retractions as Medical Events (80):** Patients XRT 002, 003, 004, 007, 008, 009, 012, 015, 016, 017, 020, 021, 022, 023, 024, 025, 026, 028, 030, 031, 032, 033, 035, 036, 038, 040, 041, 044, 045, 048, 049, 050, 051, 052, 053, 054, 056, 057, 058, 059, 061, 062, 063, 064, 065, 067, 068, 069, 070, 071, 072, 073, 074, 076, 077, 079, 081, 082, 083, 084, 085, 087, 088, 089, 091, 092, 093, 094, 095, 097, 100, 103, 104, 105, 108, 109, 110, 111, 112, 114 are proposed for retraction.
17	**Patient Treatments Not Reported as Medical Events (17):** Patient XRT 014, 029, 034, 039, 043, 046, 047, 055, 060, 075, 086, 090, 099, 101, 106, 107, 113, are not considered to be medical events. These patient treatments did not meet previously used or current medical event reporting criteria.

Column	Description
1	**PVAMC Patient ID:** Patient reference number (assigned by VA Medical Center, Philadelphia, consistent with earlier submittals to NRC).
2	**Previously Report as Medical Event:** Indicates whether or not the patient treatment was reported to NRC as a medical event during earlier reviews (during calendar years 2008 or 2009).
3	**Proposed Final Status:** Status of patient treatments as currently proposed by VHA. The basis for this status is use of medical event criteria proposed by a panel of external experts. Additional details are provided in Column 4. "Declared" means that a previously reported medical event continues to be declared under the medical event criteria. Column 4 provides additional details on basis. "Retract" means that a previously reported medical event is not considered a medical event under the new medical event criteria and is proposed for retraction. Patient treatments which are considered to be indeterminate are also proposed for retraction. "**NR**" means the patient treatment was "not reported" previously as a medical event and does not currently meet medical event criteria for reporting.

Column	Description
4	**Basis for Proposed Final Status:** Additional information describing the basis for the proposed status is in Column 3. **<80% in TS** means that medical event criteria for the treatment site were met in that the total source strength (determined by number of seeds) implanted in the treatment site (TS) was less than 80% of the total source strength intended to be implanted, as documented in the written directive For a given patient, a single seed strength (activity per seed) was used so that the number of seeds intended to be implanted (shown in Column 5) is directly proportional to the total source strength. **>50% OOT** means that the dose to "other organs or tissues" (i.e., other than the treatment site, which includes the rectum, bladder wall not included in the treatment site, and peri-prostatic tissue not included in the treatment site) exceeded 50 rem and 150% of the expected dose to these other organs or tissues. For purposes of retrospective evaluations, the expected dose to these other organs or tissues was equated to the prescribed dose to the prostate in gray (i.e., either 160 Gy or 145 Gy, depending on patient). **Not a medical event** means the patient treatment did not result in a medical event per medical event criteria.
5	**Total Number of Seeds Implanted per WD:** Total number of seeds implanted during patient treatment, as documented in the written directive (WD) after implantation but before completion of the procedure. The total source strength implanted per the written directive is considered to be the total number of seeds shown in this column multiplied by the activity per seed for a given patient treatment. Due to use of a single activity per seed for a given patient treatment, the total source strength in a volume is directly proportional to the total number of seeds in that volume. The exposure time used by the Variseed dose planning system is equal to the average life of I-125, or 1.44 times the half-life of I-125 (in hours), and is a constant value for all patient treatments.
6	**Total Number of Seeds Implanted (Day 1 CT):** Number of seeds implanted in patient based on a review of Day 1 CT (unless otherwise) by independent experts. Values have been corrected for redundant and recovered seeds, as described below. For patient treatments with no recoverable Day 1 CT for evaluation (namely, XRT 020, 025, 031, 033, 046, 076, 084, 104, and 111), the value was determined from operating room and radiation safety records of the implant.

Column	Description
	Redundant Seeds: "Redundant Seeds" refers to false or duplicate seeds. VariSeed's redundant seed detecting algorithm attempts to detect redundant (i.e., false or duplicate) seeds in post–operative CT evaluations. VariSeed generates lists of possibly redundant seeds which the user can selectively correct. Redundant seeds are detected by checking each seed with every other seed. Any two seeds are considered redundant when they meet both of the following criteria: The seeds are separated by less than the user defined Three Dimensional distance. They would be separated by less than the user defined In Plane distance if they were projected onto the same XY plane. The Three Dimensional distance (Philadelphia VA value= 5mm) reflects the distance between two seed identifications calculated using all three coordinates. The In-Plane distance (Philadelphia VA value= 0.5mm) refers to the two-dimensional distance (parallel to the imaging planes) between seeds on neighboring images. Reference: VariSeed User Guide (Ver. 7.0), Appendix B-8. **Recovered seeds** are those seeds that were retrieved in the Operating Room during or immediately following the implant procedure as well as those retrieved from the patient's collected urine while admitted as an in-patient.
7	**Number of Seeds Implanted Outside TS (Day 1 CT):** Unless otherwise noted in cell, based on re-contoured Day-1 CT (when performed) or on the original contour (if deemed acceptable) using definition of Treatment Site by independent experts with correction for redundant and recovered seeds.
8	**Number of Seeds Implanted Within TS (Day 1 CT):** Column 6 minus Column 7.

Column	Description
9	**Percentage of Seeds Implanted Within TS (Relative to Column 5):** Column 8 divided by Column 5 and expressed as a percentage. From the perspective of the treatment site, a percentage less than or equal to 80% is deemed to be a medical event based on treatment site medical event criteria. Because the source strength is directly proportional to the number of seeds (see discussion above for Column 5), the percentage value shown in this column is same whether referencing seed number implanted or source strength implanted in TS. For example, a value of 75% in this column means that 75% of the implanted seeds were in the TS; 75% of the implanted source strength was in the TS; and 75% of the dose was delivered to the TS.
10	**Expected Dose (Gy) to OOT:** Absorbed dose in gray (Gy) that is expected to be delivered to the highest exposed regions of the other organs and tissues (OOT) (i.e., other than treatment site). OOT includes rectum, bladder wall, and peri-prostatic tissues as the result of an implant consistent with the treatment plan. The OOT excludes expansions which may be allowed by the authorized user, consistent with the medical event criteria. For purposes of this retrospective evaluation, the expected dose is set equal to the absorbed dose prescribed to the treatment site.
11	**Rectum: Highest Dose (Gy) to 1 cc:** This column provides the highest absorbed dose (Gy) to a 1 cubic centimeter (cc) volume in the rectum based on the re-contoured Day-1 CT image (when performed) or on the original contour (if deemed acceptable). The evaluation method includes corrections for redundant and recovered seeds when applicable.
12	**Bladder Wall: Highest Dose (Gy) to 1 cc:** This column provides the highest absorbed dose (Gy) to 1 cc of the bladder wall outside the treatment site and is based on the re-contoured Day-1 CT image (when performed) or on the original contour (if deemed acceptable). The evaluation method includes corrections for redundant seeds and recovered seeds when applicable.
13	**Peri-Prostatic Tissue: Highest Dose (Gy) to 2cc:** This provides the highest absorbed dose (Gy) to 2 cc of tissue outside the treatment site and is based on the re-contoured Day-1 CT image (when performed) or on the original contour (if deemed acceptable). The evaluation method and includes corrections for redundant and recovered seeds when applicable.

Evaluation of Prostate Brachytherapy Implants

1. Introduction. This narrative supplements the spreadsheet that lists all pertinent data related to the regulatory evaluation of 114 prostate brachytherapy implants, which were performed at the VA Medical Center, Philadelphia from February 2002 to May 2008. Of the patient implants, nine cases do not have CT-imaging data available from the time of the implant and are not evaluable. An evaluation of the remaining 105 patient implants is detailed below.

2. Medical Event Criteria. This final evaluation for regulatory compliance applies to these 105 patient implants using a single set of medical event (ME) criteria, which the VHA has derived from interpretation of the current regulatory definitions listed in 10 CFR 35.2 and 35.3045(a)(1) through (a)(3).

3. Prior Reporting. Prior reports of MEs from the 114 patient implants cohort, which attempted to include all possible MEs, erred intentionally on the side of over-reporting. As a result, some patient implants were previously evaluated and reported on the basis of non-contemporaneous CT-imaging (i.e., images obtained more than six months after the implant); on a judgment about the appearance of a small number of seeds outside of the prostate; or, after computing an absorbed dose metric (i.e., D90), which was both inappropriate for regulatory evaluation and unrelated to the original design of the patient implant. VHA proposes to retract previously reported MEs that were reported solely on the basis of one of the considerations above and that are not within the new ME criteria discussed below.

4. Application of VHA criteria for ME determination. VHA developed ME criteria based on recommendations by a blue ribbon panel of external experts. A copy of the ME criteria that were approved by the National Radiation Safety Committee is provided separately. Use of the new ME criteria identify that from the 105 evaluable patient implants that 17 of the implants should be considered as MEs.

a. Of these 17, 11 are considered to be MEs on the basis of 20% or more seeds having been placed outside of the treatment site. These patient implants are XRT001, XRT005, XRT006, XRT011, XRT027, XRT042, XRT066, XRT078, XRT080, XRT096 and XRT102.

b. An additional six patient implants, XRT010, XRT013, XRT018, XRT019, XRT037, XRT098, are considered to be MEs based upon the delivery of excess dose to the peri-prostatic soft tissues beyond the site intended for seed implantation. With the exception of XRT001 and XRT011, the patient implants reported as MEs due to excess activity beyond the site of treatment, also delivered excess dose to the peri-prostatic soft tissues. Case XRT018, which as indicated above delivered excess dose to the

peri-prostatic soft tissues, also delivered excess dose to the patient's rectum. None of the 105 evaluable patient treatments delivered excess dose to the urinary bladder.

5. Case specific data. The following data detail for each patient treatment the basis of the initial reporting and the associated final evaluation.

a. Based on D90 values determined retrospectively from CT-imaging performed on Day 1 after the implant, patient treatments XRT001 (6/6/2008), XRT005 (7/8/2008), XRT006 (7/8/2008), XRT027 (7/15/2008), XRT066 (7/2/2008), XRT078 (6/25/2008), XRT080 (6/12/2008), XRT096 (8/22/2008), and XRT102 (8/22/2008) were originally reported on the dates shown in parenthesis. Although CT-imaging from Day 1 after the implant was associated with inaccurate absorbed dose values, these image sets could be accurately analyzed for seed placement within the treatment site. **In each of the patient treatments indicated above, 20% or a greater amount of the total activity planned and used per the written directive was placed beyond the treatment site. Therefore, these patient treatments continue to be considered as MEs.**

b. Cases XRT011 and XRT042 were reported on (10/2/2008) on the basis of seeds placed in the bladder wall. Although, final evaluations of these patient treatments noted the dose to the urinary bladder was not excessive, **in both patient treatments, 20% or a greater amount of the total activity planned and used per the written directive was placed beyond the treatment site. These patient treatments continue to be considered as MEs.**

c. Cases XRT002, XRT007, XRT008, XRT016, XRT017, XRT032, XRT035, XRT036, XRT038, XRT044, XRT045, XRT051, XRT052, XRT056, XRT057, XRT058, XRT059, XRT061, XRT062, XRT063, XRT064, XRT065, XRT068, XRT069, XRT070, XRT072, XRT077, XRT079, XRT081, XRT082, XRT083, XRT085, XRT087, XRT091, XRT093, XRT097, XRT100, XRT105, XRT108, XRT109, XRT110, and XRT112 were reported only on the basis of a retrospectively determined D90 value obtained from CT-imaging performed on Day 1 after the implant. Application of the new ME criteria determined these patient treatments to comply with 10 CFR 35.3045. Therefore, these patient treatments are proposed for retraction.

(1) The evaluation previously used for regulatory compliance required D90 values to be greater than 80% of the prescribed dose as determined using CT-imaging performed on Day 1 after the implant. VHA finds this use of an absorbed dose metric to be invalid for the regulatory evaluation of permanent volume implants of the prostate. In requiring the use of the D90 value, reviewers incorrectly assumed the goal of therapy during the period of these patient treatments (from 2002 to 2008) was to produce a predetermined

dosimetric coverage of the CT-volume of the prostate, which was neither the operational nor therapeutic goal of these implant procedures.

(2) No professional society or group recommends the use of D90 for the regulatory evaluation of these volume implant procedures. In fact, in 2005 the NRC Advisory Committee on the Medical Use of Isotopes specifically recommended against the use of an absorbed dose metric. Further, no society or group recommended use of D90 as even a clinical measure of merit prior to 2006.

(3) Additionally, CT-imaging obtained on Day 1 after the implant reflects edema produced as a result of the implant, which can invalidate the use of these images even for estimating the D90 to the prostate. Both the American College of Radiology (ACR) and the American Association of Physicists in Medicine currently recommend the use of D90 for the clinical evaluation of volume implants only after resolution of post-implant edema.

(4) As a result of these considerations VHA assembled an external panel of experts, who advised use of new ME criteria. These are the criteria provided as Enclosure 1 to this letter to NRC.

d. Based upon their associated D90 values, patient treatments XRT010 (7/15/2008), XRT013 (8/13/2008), XRT037 (8/6/2008), and XRT098 (7/18/2008) were originally reported on the dates shown in parenthesis. Though for those reasons stated above VHA does not support the use these D90-based evaluations, **application of the new ME criteria determined each patient treatment to have delivered 50% or more than the expected dose to the peri-prostatic soft tissues. Therefore, these patient treatments are considered to be MEs.**

e. Additionally, patient treatments XRT018 and XRT019, reported on 10/2/2008 for excess dose to the rectum and seeds beyond the treatment site, respectively, are also considered to be MEs based on the finding that **each implant delivered 50% or more than the expected dose to the peri-prostatic soft tissues. Patient treatment XRT018 also delivered 50% or more than the expected dose to the rectum. These patient treatments continue to be considered to be MEs.**

f. Based upon the retrospective evaluation of seed localization indicated on CT-imaging from Day 1 after the implant patient treatments XRT003, XRT012, XRT015, XRT021, XRT024, XRT026, XRT028, XRT030, XRT041, XRT074, XRT088, XRT089, XRT094, and XRT095 were reported on 10/2/2008 based upon five seeds apparently beyond the prostate. Careful evaluation of the patient treatments to include accounting for each seed observed on the post-procedure CT images finds fewer than 20% of the

total seeds beyond the treatment site and no excessive dose delivered to other organs and tissues. Therefore, these patient treatments are proposed for retraction.

g. Also reported on 10/2/2008, patient treatments XRT004, XRT009, XRT071 and XRT073 were noted to have seeds placed within the bladder wall. Final review finds the seed distribution produced necessary coverage for the prostate; did not produce dose to the bladder in excess of expected values; and, did not comprise 20% of the total implanted activity. Therefore, these patient treatments are proposed for retraction.

h. Similarly, patient treatments XRT040, XRT048, XRT049, XRT050, XRT053, XRT054, XRT067, XRT092, XRT103, and XRT114, were reported on 10/2/2008 based on being greater than 150% of the pre-treatment plan dose to 1 cc of the rectum. The pre-treatment plan dose to the rectum is not an accurate indicator of the expected dose to the rectum. This clinical target for quality control is inappropriate for a regulatory evaluation. Delivery of the prescription dose to the anterior rectal wall is an expected result of a prostate volume implant when little separation exists between the prostate and rectum. Review per to the new ME criteria determined that none of these patient treatments delivered 150% or more than the expected rectal dose and was not within other criterion as a ME. Therefore, these patient treatments are proposed for retraction.

i. In addition, the following patient treatments previously reported as medical events are proposed for retraction based on a lack of adequate data (i.e., post-treatment images) to conclude a medical event occurred for patient treatments: XRT020, XRT025, XRT031, XRT033, XRT076, XRT084, XRT104, XRT111.