Medical Consultant Report
(To be completed by medical consultant)

Medical Consultant Name: Ronald E. Goans, PhD, MD, MPH
Report Date: Initial analysis 12/11/2008; additional analysis 10/12/2009
Signature Ronald E Goans 11/9/2009

Licensee Name	Department of Veterans Affairs Medical Center, Philadelphia, PA 3900 Woodland Avenue Philadelphia, PA 19104
License No.	03-23853-01VA
Event #	44219
Docket No.	030-34315
Facility Name:	Radiation Oncology Department Department of Veterans Affairs Philadelphia, PA

Incident Dates: 2/25/2002 through 5/6/2008
Date of Notification: Initial notification 5/15/2008

Executive Summary

A total of 39 cases from the Philadelphia VA brachytherapy program have been evaluated in this consultant report and in the prior report of 12/11/2008. In addition, a site visit was made August 27-28, 2009. The staff in the Radiation Oncology Department have continued to be quite helpful and a number of cases are being recontoured. This report examines two aspects: (a) selected cases referred by NRC Region III for review, and (b) a brief review of an Excel spreadsheet (current August 6, 2009) of all cases identified to date.

A review of past performance in the brachytherapy program is quite puzzling and shows considerable inconsistency in seed placement. In some cases, e.g. XRT 002, 100% of seeds were placed within the designated treatment site (DTS), while in others, e.g. XRT 006, only 49.3% of seeds were within the DTS. This inconsistency is also noted in other cases. It would be interesting to know if all of these were teaching cases for radiation oncology residents, and which residents did what percentage of seed implants.

A brief analysis is also presented of the summary statistics and statistical distribution for the initial contours of (a) prostate dose, (b) rectal dose D 1.33 cc, (c) bladder dose 1 cc, and (d) peri-prostatic dose.

In the cases reviewed in this report, most patients appear to be doing well clinically. Most have symptoms of dysuria and urinary frequency to be expected for this type of procedure. One case showed radiation proctitis and another case showed fairly benign vascular signs of radiation dose on colonoscopy.

Case XRT 053 had a prostate dose of 118 Gy for a prescribed dose of 160 Gy. At the initial evaluation he had a Gleason 5 (2+3) adenocarcinoma in the left apex of the prostate and noted in 1/6 cores. In addition the patient had a cutaneous T-cell lymphoma, for which he received PUVA therapy. The patient is currently considered for hyperbaric oxygen therapy (HBO) for radiation proctitis and cystitis. Some initial seeds were noted in the rectum. Of a more significant note, the PSA has been rising since 2006, suggesting relapse of the prostate adenocarcinoma. Current biopsy results show significant disease with Gleason 6 at the right apex, Gleason 7 in the right mid-gland, Gleason 8 in the right base, Gleason 8 in the left apex, Gleason 7 in the left mid-gland, and Gleason 7 disease in the left base. The patient is receiving care at another institution and is undergoing evaluation for extraprostate disease.

Individual's / Patient Physician Name and Address:

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Records Reviewed: (General Description)

1. NRC Enclosure - Description of the Medical Event
2. NRC Preliminary Notification of Event (Event # 44219)
3. NRC Medical Event Reporting and supporting literature
4. NRC Notes on the event
5. Department of Veterans Affairs Medical Center correspondence to the NRC

6. Detailed review of 39 patient records (underdoses and overdoses)
7. Memorandum, Director VA national Health Physics Program
8. Excel spreadsheet summary of 98 VA Philadelphia VA brachytherapy cases to date
9. VA Consent form for Radiation Therapy – Prostate Implant.
10. Statement of Gary Kao, MD, PhD submitted to the Hearing for the Senate Committee of Veterans Affairs, June 29, 2009.

Additional Review:

Site visit to the Philadelphia VA Medical Center with NRC personnel on August 27, 2009; personal review of contouring data and dosimetry results to date; interviews with Dr. Maity, Ms. Moore, and Ms. Salanitro.

Estimated Dose to Individual or Target Organ:

See list of cases below. This varies by case.

Probable Error Associated with Estimation: 10 %.

Prescribed Dose (Medical Misadministration Only): 160 Gy to the prostate.

Method Used to Calculate Dose: Clinical dose profile and physical dosimetry.

Description of Incident:

The index case refers to a permanent implant brachytherapy procedure performed on May 5, 2008 at the Department of Veterans Affairs Philadelphia Medical Center using I-125 seeds. The prescribed dose was 160 Gy to the prostate. In that case the D90 dose was only 47% of the prescribed dose. The root cause of the index case involved not only improper physician seed placement, but also incorrect seed activity.

The licensee subsequently conducted a review of all cases of brachytherapy in the time period 2002-2008. Subsequently, 98 cases have been identified with either underdosing or overdosing the prostate and/or adjacent organs such as rectum, bladder or the perineum. The VA Medical Center suspended its prostate program on June 11, 2008, pending extensive internal and external review.

The initial analysis conducted in December, 2008 involved 15 cases; subsequently another 15 cases have been identified which could result in patient complications. These will be reviewed below with analysis currently based on data of August 6, 2009. It is possible that cases will be dropped from the list of reportable events as recontouring is performed by the medical physicist.

Clinical Details (August 6, 2009 VA analysis; day 1 CT scan)

Case XRT 001

Procedure date 8/13/2007
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 54
Seeds external to designated treatment site (DTS) – 10
Prostate dose – 89 Gy
Rectum dose (1.33 cc) – 113 Gy
Bladder dose (D1 cc) – 28 Gy
Peri-prostatic dose external to DTS (D1cc) – 299 Gy to 468 cc volume.
% seeds within DTS = 81.48%

Clinical note:

Suspicious for failure under the Phoenix criteria (PSA nadir + 2 ng/ml); numerous seeds outside of DTS. Gleason (3+3) adenocarcinoma of the prostate; stage T1c; 40 additional seeds implanted 10/14/2008. Complaints of urinary obstructive symptoms, +dysuria and ED.

Case XRT 004

Procedure 2/14/2005
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 75
Seeds external to DTS – 2
Prostate dose – 143 Gy (recontour)
Rectum dose (1.33 cc) – 88 Gy (recontour)
Bladder dose (D1 cc) – 140 Gy (recontour)
Peri-prostatic dose external to DTS (D1cc) – 124 Gy to 348 cc volume
% seeds within DTS = 97.3%

Clinical Note: Gleason 6 (3+3_ adenocarcinoma of the prostate. No apparent clinical problems post-implant.

Case XRT 009

Procedure date 12/6/2004
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 83
Seeds external to DTS – 7
Prostate dose – 118 Gy (recontour)
Rectum dose (1.33 cc) – 68 (recontour)
Bladder dose (D1 cc) – 163 Gy (recontour)

Peri-prostatic dose external to DTS (D1cc) – 281 Gy to 451 cc volume.
% seeds within DTS = 91.6%

Clinical note:

Gleason 6 (3+3); stage T1cN0 adenocarcinoma. No apparent urinary problems; s/p subtotal colectomy for diverticuli; decreasing PSA to 1.0. Colonoscopy: patches of inflammation, possibly radiation proctitis, clinically mild.

Case XRT 015

Procedure date 11/1/2004
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 82
Seeds external to DTS – 8
Prostate dose – 143 Gy (recontour)
Rectum dose (1.33 cc) – 93 Gy (recontour)
Bladder dose (D1 cc) – 88 Gy (recontour)
Peri-prostatic dose external to DTS (D1cc) – 173 Gy to 659 cc volume.
% seeds within DTS = 90.2%

Clinical note:

Gleason 6 (3+3); stage T1cN0 adenocarcinoma. No apparent urinary problems; and decreasing PSA. Colonoscopy: patches of telangectasia, possibly radiation-related. Some rectal bleeding. These are relatively benign dilated blood vessels often seen as a result of high dose local irradiation.

Case XRT 027

Procedure date 1/14/2008
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 74
Seeds external to DTS – 30.5
Prostate dose – 67 Gy initial contour
Rectum dose (1.33 cc) – 196 Gy (initial contour)
Bladder dose (D1 cc) – 42 Gy (initial contour)
Peri-prostatic dose external to DTS (D1cc) – 588 Gy to595 cc volume.
% seeds within DTS = 58.8%

Clinical note:

Gleason 6 (3+3); stage T1cN0; areas of high grade PIN; reimplantation in Seattle VA 11/3/08; PSA 0.02 5/21/09 and remaining low.

Case XRT 031

Procedure date 10/2/2006
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 84
Seeds external to DTS – 8.5

No day 1 CT in database

Prostate dose – 106.6 Gy initial contour
Rectum dose (1.33 cc) – NA
Bladder dose (D1 cc) – NA
Peri-prostatic dose external to DTS (D1cc)–NA
% seeds within DTS = 89.9%

Clinical note:

Gleason 6 (3+3) in 1/6 sextants; stage T2a; increasing PSA. Hx of endorectal advancement flap and s/p radiation therapy to the anal canal for rectal cancer. Possibly one seed in the bowel.

Case XRT 032

Procedure date 5/9/2005
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 79
Seeds external to DTS – 3
Prostate dose – 107 Gy initial contour
Rectum dose (1.33 cc) – 106 Gy initial contour
Bladder dose (D1 cc) – 43 Gy initial contour
Peri-prostatic dose external to DTS (D1cc)–126 Gy to 242 cc volume.
% seeds within DTS = 96.2+%

Clinical note:

Gleason 7 (3+4) in 2/6 sextants; stage T1cN0; areas of lower grade adenocarcinoma; PSA 0.3; most seeds are clustered in peripheral zone around the apex.

Case XRT 035

Procedure date 2/11/2008
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 70
Seeds external to DTS – 3
Prostate dose – 105 Gy (recontour)

Rectum dose (1.33 cc) – 205 Gy (recontour)
Bladder dose (D1 cc) – 55 Gy (recontour)
Peri-prostatic dose external to DTS (D1cc) – 162 Gy to481 cc volume.
% seeds within DTS = 95.71%

Clinical note:

Gleason 6 (3+3) in 4/6 sextants; +several seeds in pelvic floor musculature. Reimplant 11/4/2008. Clinical history of severe dysuria, urgency, frequency.

Case XRT 040

Procedure date 6/20/2005
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 84
Seeds external to DTS – 0
Prostate dose – 122.3 Gy (recontour)
Rectum dose (1.33 cc) – 150 Gy (initial contour)
Bladder dose (D1 cc) – 54 Gy (initial contour)
Peri-prostatic dose external to DTS (D1cc) – 109 Gy to 462 cc volume.
% seeds within DTS = 100%

Clinical note:

Gleason 6 (3+3) in 2/6 sextants; PSA 6/19/2009 0.16; stage T1c adenocarcinoma; Clinical picture of radiation proctitis.

Case XRT 042

Procedure date 9/8/2003
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 65
Seeds external to DTS – 5
Prostate dose – 91 Gy (initial contour)
Rectum dose (1.33 cc) – 77 Gy (initial contour)
Bladder dose (D1 cc) – 65 Gy (initial contour)
Peri-prostatic dose external to DTS (D1cc) – 215 Gy to265 cc volume.
% seeds within DTS = 92.3%

Clinical note:

Adenocarcinoma in 1/6 sextants; PSA 6/19/2009 0.16; case evaluated by AFIP; well differentiated adenocarcinoma, nuclear grade I in one biopsy; seeds noted in the bladder.

Case XRT 053

Procedure date 1/10/2005
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 63
Seeds external to DTS – 7
Prostate dose – 118 Gy (initial contour)
Rectum dose (1.33 cc) – 110 Gy (initial contour)
Bladder dose (D1 cc) – 72 Gy (initial contour)
Peri-prostatic dose external to DTS (D1cc) – 165 Gy to384 cc volume.
% seeds within DTS = 88.9%

Clinical note:
Gleason 5 (2+3) adenocarcinoma in the left apex of the prostate and noted in 1/6 cores. Initial symptoms included frequency and nocturia, but no dysuria. In addition the patient has a cutaneous T-cell lymphoma, for which he is receiving PUVA therapy. PSA 6.2 stage T1c. Clinically with relapse and being evaluated currently at FCCC. Current symptoms include frequency, dysuria, urgency incontinence and dysuria with bladder spasm. The patient is currently considered for HBO therapy for radiation proctitis and cystitis. Some initial seeds were noted in the rectum.

PSA has been rising since 2006. Current biopsy showed Gleason 6 at the right apex, Gleason 7 in the right mid-gland, Gleason 8 in the right base, Gleason 8 in the left apex, Gleason 7 in the left mid-gland, and Gleason 7 disease in the left base. CT to evaluate for extraprostate disease.

Case XRT 062

Procedure date 10/25/2004
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 90
Seeds external to DTS – 1
Prostate dose – 49 Gy (initial contour)
Rectum dose (1.33 cc) – 24 Gy (initial contour)
Bladder dose (D1 cc) – 70 Gy (initial contour)
Peri-prostatic dose external to DTS (D1cc) – 36 Gy to712 cc volume.
% seeds within DTS = 98.89%

Clinical note:

Gleason 6 (3+3) in 1/6 sextants; T1c; PSA 6.5; by Dr. Whittington: 10/25/2004, 56 seeds; 10/25/2004 52 seeds

Case XRT 085

Procedure date 4/14/2008
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 79
Seeds external to DTS – 6
Prostate dose – 103 Gy (recontour)
Rectum dose (1.33 cc) – 146 Gy (initial contour)
Bladder dose (D1 cc) – 54 Gy (initial contour)
Peri-prostatic dose external to DTS (D1cc) – 209 Gy to483 cc volume.
% seeds within DTS = 92.4%

Clinical note:

Atypical glands suspicious for adenocarcinoma; increasing PSA velocity; consult VAMC Pittsburgh; moderately differentiated adenocarcinoma, Gleason 6 (3+3); 2/6 sextants involved; stage T2a; AFIP review .

Case XRT 104

Procedure date 11/13/2006
Prescribed dose 160 Gy
Procedure: I-125 seeds 0.38 mCi per seed
Total seeds implanted– 70
Seeds external to DTS – 24
Prostate dose – 84 Gy (initial contour)
Rectum dose (1.33 cc) – no 1 day CT contour
Bladder dose (D1 cc) – no 1 day CT contour
Peri-prostatic dose external to DTS (D1cc) – 556 Gy to562 cc volume.
% seeds within DTS = 65.7%

Clinical note:

Gleason 6 (3+3) in 3/6 sextants; hospitalized 10/2007 for rectal bleeding; colonoscopy showed proctitis; prior CT showed at least two seeds close to the rectum.

Statistical Analysis

Average percent of seeds within DTS 91.3% ±0.96 (standard error of the mean, SEM)
Prostate dose statistics:

Summary statistics (MedCalc 11.0.1, 2009)

Prostate Dose Statistics

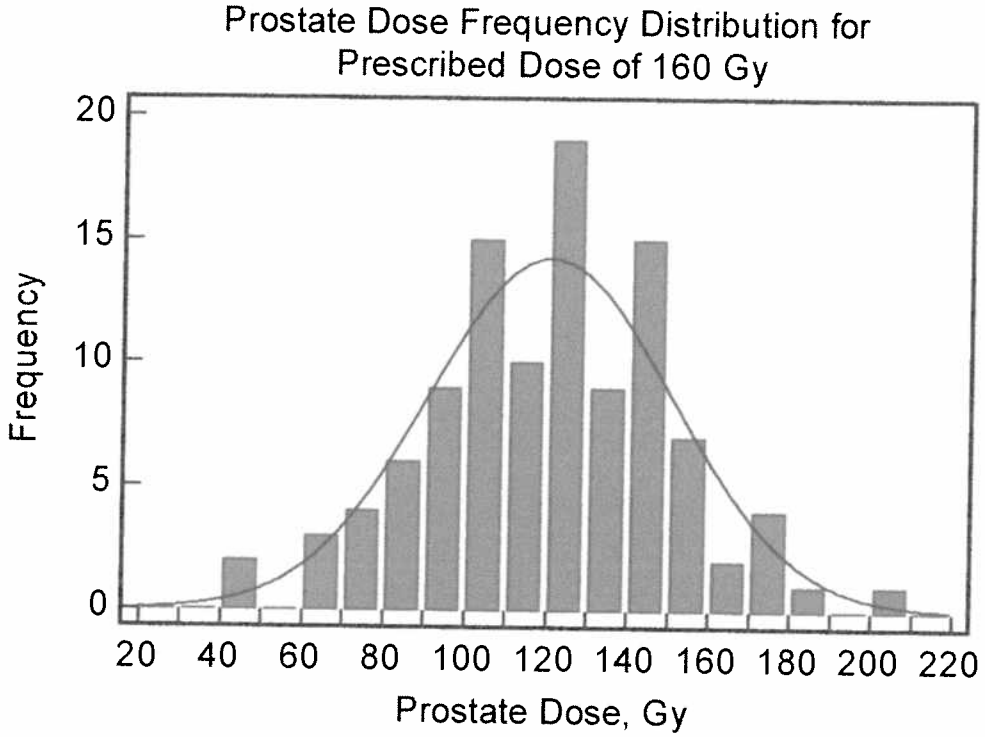
Variable
Prostate Dose, Gy

Sample size	107
Lowest value	47.0000
Highest value	208.0000
Arithmetic mean	120.6593
95% CI for the mean	114.9235 to 126.3952
Median	123.0000
95% CI for the median	113.0000 to 127.1146
Variance	895.5933
Standard deviation	29.9265
Relative standard deviation	0.2480 (24.80%)
Standard error of the mean	2.8931
Coefficient of Skewness	-0.001530 (P=0.9946)
Coefficient of Kurtosis	0.1430 (P=0.6239)
D'Agostino-Pearson test for Normal distribution	accept Normality (P=0.8867)
10% Trimmed mean (n=97)	120.6861
95% CI of Trimmed mean	114.3052 to 127.0670

Percentiles		95% Confidence Interval
2.5	60.5250	
5	69.5500	48.8765 to 82.2765
10	83.2000	68.6484 to 91.0000
25	101.2500	91.0000 to 107.4783
75	143.0000	131.5217 to 146.5237
90	156.6000	148.3800 to 173.9010
95	173.3000	157.0000 to 182.6668
97.5	177.0000	

The prostate doses (N=107 cases) fit a normal distribution with mean 120.6 Gy and summary statistics as above, compared to a prescribed dose of 160 Gy. Source: VA summary statistics current August 6, 2009. These data are the original data since many had not been recontoured

at the time of analysis. The complete recontoured series would be expected to be closer to the prescribed dose of 160 Gy.



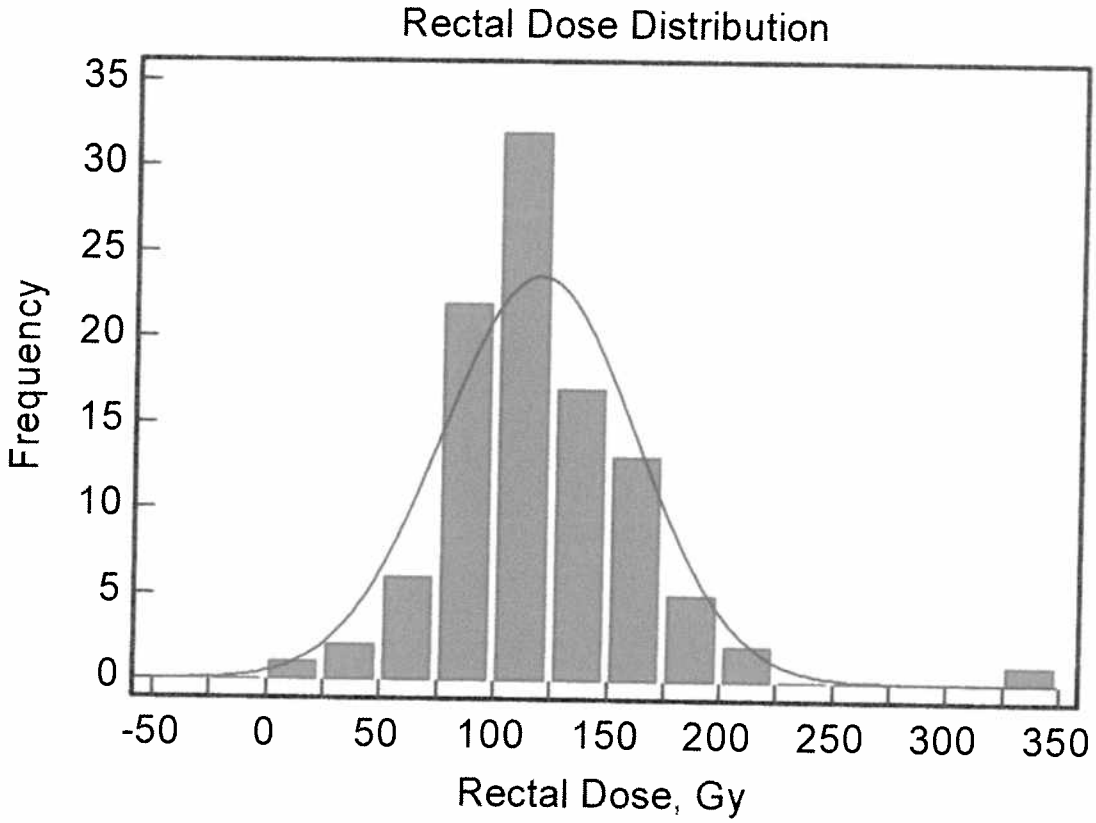
Rectal Dose 1.33 cc Statistics

Summary statistics

Variable	Rectal Dose, Gy
Sample size	101
Lowest value	24.0000
Highest value	328.0000
Arithmetic mean	118.6832
95% CI for the mean	110.2588 to 127.1075
Median	112.0000
95% CI for the median	106.3489 to 122.8256
Variance	1821.0586
Standard deviation	42.6739
Relative standard deviation	0.3596 (35.96%)
Standard error of the mean	4.2462
Coefficient of Skewness	1.2862 (P<0.0001)
Coefficient of Kurtosis	4.9254 (P<0.0001)
D'Agostino-Pearson test for Normal distribution	reject Normality (P<0.0001)

10% Trimmed mean (n=91)		116.8352
95% CI of Trimmed mean		107.4567 to 126.2137

Percentiles		95% Confidence Interval
2.5	44.1500	
5	53.3000	39.3327 to 75.4223
10	76.2000	50.7454 to 82.0000
25	93.5000	82.9776 to 103.4887
75	142.0000	128.5339 to 155.5336
90	169.0000	157.1540 to 193.8820
95	190.0500	169.0000 to 245.2034
97.5	203.8000	

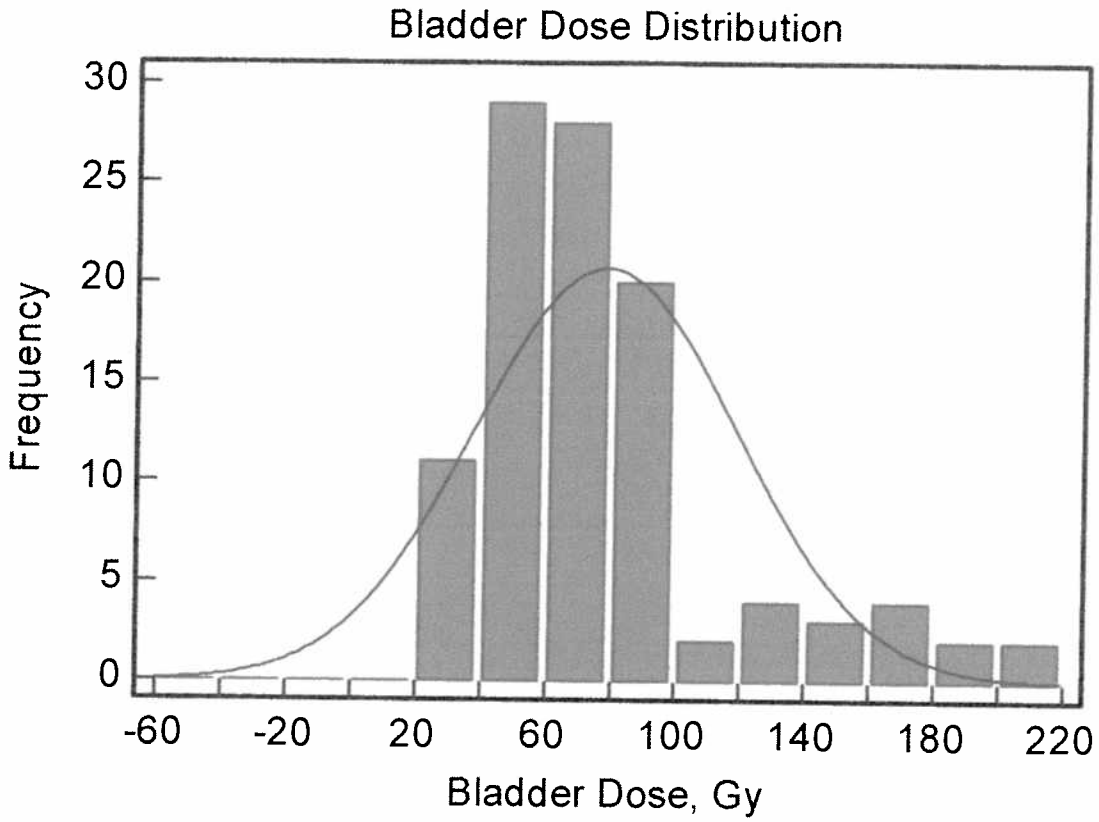


Bladder Dose Statistics D1 cc

Summary statistics

Variable	Bladder Dose, Gy
Sample size	105
Lowest value	21.0000
Highest value	209.0000
Arithmetic mean	78.0476
95% CI for the mean	70.2154 to 85.8798
Median	68.0000
95% CI for the median	60.9808 to 74.0575
Variance	1637.9304
Standard deviation	40.4714
Relative standard deviation	0.5185 (51.85%)
Standard error of the mean	3.9496
Coefficient of Skewness	1.4054 (P<0.0001)
Coefficient of Kurtosis	1.8080 (P=0.0091)
D'Agostino-Pearson test for Normal distribution	reject Normality (P<0.0001)
10% Trimmed mean (n=95)	74.8526
95% CI of Trimmed mean	66.1364 to 83.5689

Percentiles		95% Confidence Interval
2.5	23.6250	
5	29.7500	22.7613 to 38.4963
10	39.0000	29.4072 to 45.3626
25	53.2500	46.0000 to 55.6565
75	92.2500	82.3435 to 98.3582
90	144.0000	108.5613 to 167.3714
95	166.0000	146.5185 to 208.1194
97.5	192.2500	



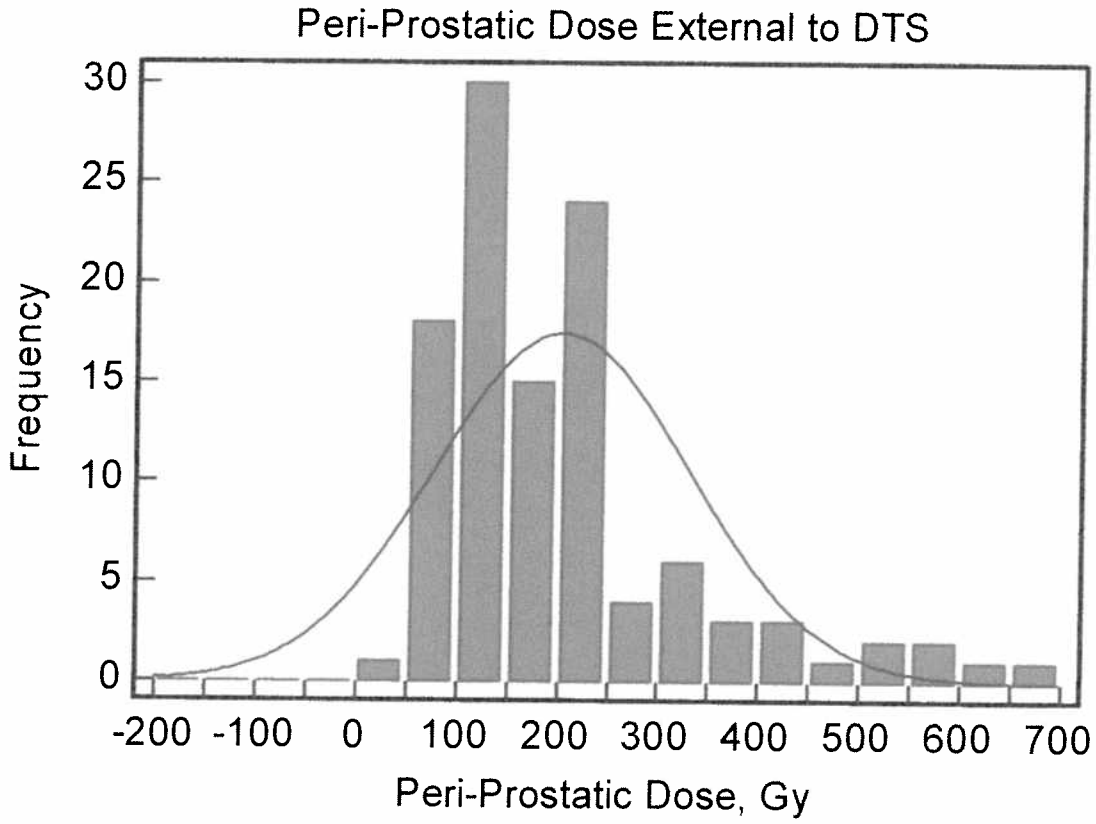
Summary Statistics for Peri-Prostatic Dose

Variable	Peri-prostatic Dose, Gy

Sample size	111
Lowest value	36.0000
Highest value	667.0000
Arithmetic mean	202.8559
95% CI for the mean	178.9761 to 226.7356
Median	172.0000
95% CI for the median	140.5784 to 201.0000
Variance	16116.7427
Standard deviation	126.9517
Relative standard deviation	0.6258 (62.58%)
Standard error of the mean	12.0497
Coefficient of Skewness	1.6201 (P<0.0001)
Coefficient of Kurtosis	2.6291 (P=0.0011)
D'Agostino-Pearson test for Normal distribution	reject Normality (P<0.0001)

10% Trimmed mean (n=101)	190.8218
95% CI of Trimmed mean	164.2505 to 217.3930

Percentiles		95% Confidence Interval
2.5	64.2750	
5	75.1000	61.1643 to 78.9210
10	79.6000	74.3430 to 99.0000
25	122.5000	103.5999 to 130.4022
75	234.5000	211.1957 to 299.4250
90	370.8000	301.7333 to 504.2994
95	500.4500	384.7942 to 608.7953
97.5	581.9500	



Deterministic Effects of the Radiation Exposure on the Individuals:

The Excel spreadsheet provided by the Philadelphia VA Staff was used as a basis for analysis in the cases presented above. Certain deterministic effects (dysuria, obstructive urinary symptoms. radiation-induced proctitis, telangectasia, and rectal bleeding) are noted. However, these are

also found in well-performed brachytherapy to the prostate. The seed placement in most cases in noted to be erratic as described in the prior analysis, December, 2008.

Briefly describe the current medical condition of the exposed individual:

Patient records for approximately 30 cases have been extensively analyzed. In both underdosing and overdosing, a number of patients experienced post-procedure nocturia, dysuria, and in some cases hematuria and rectal bleeding. However, Most of the cases appear to be doing well clinically, with stable PSA values, and seem not have had significant adverse reactions. Several cases have appropriately gone to retreatment. One case, XRT 053, is in clinical relapse.

References

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Stock, RG, Stone, NN. Importance of Post-Implant Dosimetry in Permanent Prostate Brachytherapy. European Urology 41: 434-439, 2002.

Was individual or individual's physician informed of DOE Long-term Medical Study Program?

No patient contact resulted from this consult.

If yes, would the individual like to be included in the program?

COMPLETE FOR MEDICAL MISADMINISTRATION
(To be completed by Medical Consultant)

1. Based on your review of the incident, do you agree with the licensee's written report that was submitted to the NRC pursuant to 10 CFR 35.33 in the following areas:

a. Why the event occurred – Yes. Circumstances of this event were largely documented in the Department of Veteran Affairs National Health Physics Program memorandum.

b. Effect on the patient – Patient records were examined and my independent dose estimates generally agree with those provided by the hospital.

c. Licensee's immediate actions upon discovery – There was immediate reporting of the event to the NRC, once the index case was noted. Many cases go back to 2002 and it is clear that there was poor review of treatment results during that period. No corrective actions appear to have been in place during the period 2002-2008.

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d. Improvements needed to prevent recurrence - Yes. This is a multiple human factors issue, correctable by education and improved procedures.

2. In areas where you do not agree with the licensee's evaluation (report submitted under 10 CFR 35.33, provide the basis for your opinion: N/A

3.

Did the licensee notify the referring physician of the misadministration? Yes

Did the licensee notify the patient's or the patient's responsible relative or guardian? Yes

If the patient or responsible relative or guardian was not notified of the incident, did the licensee provide a reason for not providing notification consistent with 10 CFR 35.33? N/A

Explain rationale for response.

4. Provide an opinion of the licensee's plan for patient follow-up. If available.

The patients in question are followed clinically by the Philadelphia VA Medical Center and at other institutions. After discussion with all of the principal participants, I feel that the VA system will institute an effective program to prevent a recurrence of these events. A number of deficiencies have been noted:

a. Lack of proper quality control and management of the brachytherapy program
b. Lack of policies to address post-implant management of patients and patient dose.
c. Lack of program oversight and with inadequate review surrounding past trigger events.

My professional medical opinion is that the prior brachytherapy program did not remotely meet current medical standards. However, I continue to be impressed with the efforts of the current VA oncology department staff and would not foresee a recurrence of the situation seen in the time frame 2002-2008.