Telecopier Transmittal
Safety and Risk Evaluation

July 5, 1994

From:
P.O. Box 1625
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Idaho Falls, ID 83415-3850

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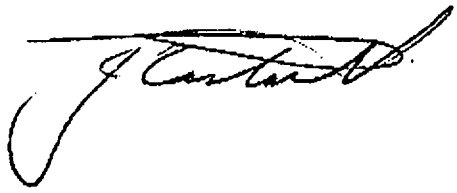
To: **Dr. R. R. Bellamy**

At: **NRC RI**

Fax: **215-337-5269**

Pages: **12**

Enclosed are reports from my medical subcontractors. I will confirm with Dr. Johnson tomorrow that no changes have resulted from the completion of Dr. Thomadsen's confirmation of the Y-NH dosimetry calculations.



B/9

Return-Path: <thomad@madrad.radiology.wisc.edu>
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(4.1/INEL-MH-10.0) id AA00969; Mon, 4 Jul 94 11:47:56 MDT
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Date: Mon, 4 Jul 94 12:47:29 -0500
Message-Id: <9407041747.AA23329@madrad.radiology.wisc.edu>
To: jpt@inel.gov
From: thomad@madrad.radiology.wisc.edu (Dr Bruce Thomadsen)
Subject: misadministration report

Jim,

Following is a first report. Please let me know what else you would like in the final copy. I'm afraid that it lost some of the formating coming into the mail program.

Bruce

Medical Physicist's Report

>From the Checklist:
a. QM plan - Did not cover brachytherapy.
b. Computerized planning system - No problem.
c. Patient's chart - The only anomaly noted is a discrepancy in the loading diagram for the implant. The first needle shows five seeds in the "load pattern", but under "# of seeds" has the "5" crossed out and "4" written. The 4 seeds matches the totals listed. KS or KB (I can't tell which) who filled out the form, probably corrected the number of seeds for that needle but missed changing the pattern. This is the only place that I find a physician signing for the activity of the sources. I cannot make out who the physician is, and the signature doesn't match either Dr. Roberts's or Friedman's.
d. Written directive - present and clear.
e. Dose calculations/preparation - The dose calculation was correct. Obviously, the dose preparation was the problem, discussed below.
f. Documentation of dose calculation - adequate.
g. Procedures for source control - While the procedures for source control were adequate (the weak area comes under the next item), a modification in the receiving protocol could have prevented the accident. Their rationale for not having the nuclear medicine technologist perform more checks on the sources on receipt actually makes sense. The physicist

was concerned that the nuclear medicine technologist might loss sources while verifying the count of the seeds, being unused to working with small, discrete sources (a real hazard). There would be no reason not to have the technologist check the activity against that ordered without opening the vial to count the number of the seeds, but the alternative of having the dosimetrist perform the check is as reasonable. A double check, of course would be much better. As Robert Lovinger, retired from NBS use to say, "Redundancy is not just duplication."

h. Procedures - Here they have a problem.

(i). Treatment. The question is, did they have a procedure for checking the seed strength, and if they did, was it followed. They obviously did not have a written procedure for such a check - neither they nor we could find one. But they all felt that they did have such a procedure, and all of the principals independently described the procedure identically, that the dosimetrist checked the activity against that used in planning at the time of loading the needles. Even the person making the error thought that that was the procedure. Under tort law, I believe that such agreement means that they did have a procedure, and the contract obligated the physics group to follow that procedure. The physics group agrees that they were bound to follow that procedure. I suspect that it did not make it into the written procedures because it seemed so obvious that nobody worried about that step being missed. Often, written procedures concentrate on the areas perceived to be at risk. If they had such a procedure, was it omitted? Apparently not. The dosimetrist did check the activities. He didn't notice the erroneous decimal place, a serious omission for which he will pay for the rest of his life. But he followed the procedure! There certainly could have been better procedures; the same could be said for most procedures at most facilities.

(v). QM program. As close as I can tell, they had not QM program for brachytherapy. This is a question for the regulators and inspectors (How could they have authorization for the seeds without satisfying the license requirements?). Could a QM program have averted this catastrophe? I would guess not. The QM program would not have likely had included any different procedures from those already in place.

i. Treatment plan and dose schedule - No problems.

j. Patient instructions - No problems.

k. Patient preparation - No problem.

l. Dose administration - Problem as discussed above.

m. Post treatment procedures - discussed below.

Summarize the findings, and report to the team leader:

1. Reconstruct the misadministration - Jim, I wouldn't take the time to copy the time course of events. Mostly I would be copying it from what you sent me. If you want, I can do this later.

2. Medical effect on the patient - Doug Johnson is awaiting my dose calculations to answer this.

3. Mitigative actions - Again, the time course you can copy from the notes. The real question is of the appropriateness of the actions. The initial dose rate of the implant would have been 18.5 Gy/day. For comparison, a conventional low dose-rate implant runs at about 13.2 to 18 Gy/day. For a curative case with no external beam therapy, such an implant might last about 3.5 days. Surgery could follow immediately without much complication due to the radiation. From this, mitigative surgery probably could have waited a day or two, possibly allowing more planning and preparation, which might have allowed for the removal of more tissue around the prostate at the initial surgery.

Between the removal procedures the "dose rate" by the mass of seeds low in the pelvis ran about 0.5 to 0.6 Gy/hr (14 Gy/day), typical for a conventional low dose-rate implant, and not much changed from the original dose rate, but this dose rate encompasses a volume of only 23 cm3 (2.8 cm average dimension, approximately). The upper mass of seeds ran with a maximum significant dose of about 0.3 Gy/hr (7.2 Gy/day) on the patient's right side, and about 0.1 Gy/hr (2.4 Gy/day) on the left. The right side enclosed a volume of approximately 10 cm3, and on the left about 1 cm3. The doses and volumes contain a larger uncertainly than usual for brachytherapy calculations (normally about 2%) because the films used were not taken under controlled conditions and lack the normal alignment information.

The dosimetry performed by Yale on the final result appears to be correct. From my results the dose through full decay of the seeds would deliver a maximum significant dose in the lower seed mass of about 1100 Gy, in the upper group of maybe 1000 Gy, and for the few seeds by themselves 200 Gy. The maximum significant dose may not be a meaningful indicator. A normal prostate implant also gives astronomical doses. Looking at the "peripheral dose", where this implant intended to deliver 160 Gy at the periphery of a 5 cm diameter volume, for the same size volume this actual implant will end up giving about 550 Gy to the lower seed mass. The upper mass is more diffuse, and a value of 160 Gy (i.e., normal for a prostate implant) may be a reasonable estimate at 5 cm diameter. These values pretty much include the dose received between procedures.

4. Actions to prevent recurrence- Backus Hospital has taken effective actions for now, terminating the program. If they resume the program, this question become relevant and needs assessment.

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The dosimetry performed to be correct. From my results the do would deliver a maximum significant 1100 Gy, in the upper group of maybe themselves 200 Gy. The maximum sig indicator. A normal prostate implant at the "peripheral dose", where this i the periphery of a 5 cm diameter volu actual implant will end up giving abou upper mass is more diffuse, and a val prostate implant) may be a reasonabl values pretty much include the dose

4. Actions to prevent recurrence actions for now, terminating the prog question become relevant and needs assessment.

Using CT scan after last surgery.

May sig dose 40,000 rad
5 cm iso 25,000 rad
only 2.5 on this

Bruce Thomadsen will 7/6/94 at 11:00 A.M.

Additional report: Dose to the surgeon's fingers during the removal of the prostate.

Using the Anderson nomogram, a 4.5 cm average diameter organ with 69 seed would need seeds of 0.65 mCi each to deliver 1.84 Gy / day to the periphery. Thus, the peripheral dose rate here would be
(1.84Gy/day)(day/24 hr)(4.4 mCi/seed)(100rem/Gy)/(0.65mCi/seed)
= 7.7 rem/hr.

From my measurements, the gloves transmit 0.038 of I-125 radiation. Assuming the surgeon had the organ in his hand for 0.5 hour, the dose to his hand would be
(7.7 rem/hr)(0.038)(0.5 hr)(1000 mrem/rem)
=150 mrem.

Please direct any questions about this report to Bruce Thomadsen, (608) 263 - 8500.

Dr Bruce Thoma..., 6:48 AM 7/5/94 ...,Correction for report 1

Return-Path: <thomad@madrad.radiology.wisc.edu>
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Date: Tue, 5 Jul 94 06:48:51 -0500
Message-Id: <9407051148.AA25042@madrad.radiology.wisc.edu>
To: jpt@inel.gov
From: thomad@madrad.radiology.wisc.edu (Dr Bruce Thomadsen)
Subject: Correction for report

Jim,

There is a correction in the last paragraph of the report I sent you yesterday. The final paragraph should read:

Additional report: Dose to the surgeon's fingers during the removal of the prostate.

Using the Anderson nomogram, a 4.5 cm average diameter organ with 69 seed would need seeds of 0.65 mCi each to deliver 1.84 Gy / day to the periphery. Thus, the peripheral dose rate here would be
(1.84Gy/day)(day/24 hr)(4.4 mCi/seed)(100rem/Gy)/(0.65mCi/seed)
= 7.7 rem/hr.

From my measurements, the gloves transmit 0.195 of I-125 radiation. Assuming the surgeon had the organ in his hand for 0.5 hour, the dose to his hand would be
(7.7 rem/hr)(0.195)(0.5 hr)(1000 mrem/rem)
=750 mrem.

This agrees fairly well with the estimate of James Picone of 30 June 1994 of 1001 mrem. My value of 750 does not acount for exposure after removal of the prostate, while the surgeon explored the pelvis.

The other doses in Mr. Picone's letter seem reasonable, and those that can be verified by radiation monitor will serve as tests for those that cannot.

Douglas W. Johnson, M.D., P.A.
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8265 Riding Club Road
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(904) 642-6016

4 July 1994

Mr. Jim Tortorelli
INEL
P.O. Box 1625
Lindsay Blvd.
Idaho Falls, ID 83415-3850

Dear Jim:

Attached is my medical impact assessment of the recent Backus Hospital misadministration event.

The original is coming via Federal Express on 5 July 1994. I thought it might be helpful to you in preparing the final report to provide some background about this disease, relative risks of other treatment approaches, etc., and these are incorporated into the report as well. I still have not received independent dosimetry assessment from Bruce Thomadsen in Wisconsin, but was able to get the latest Yale dosimetry on 1 July FAX'd to me. It is upon this information that I have based my assessment, and in the interest of time have decided to forward my report now. If any radical changes come to light following Bruce's analysis, I will amend the document accordingly.

Hope this is helpful to you. Please let me know if you have any further questions. I'll be at (707) 423-7691 for the next two weeks if you need to reach me.

Sincerely,

Douglas W. Johnson, M.D., F.A.C.R.

dwj

MEDICAL IMPLICATIONS REPORT IN SUPPORT OF EG&G/NRC MISADMINISTRATION INVESTIGATION--BACKUS HOSPITAL NORWALK, CT

4 July 1994

I. BACKGROUND

Prostate cancer is a common malignancy, with 165,000 new cases diagnosed and 35,000 deaths estimated in 1993 in the Unites States.(1) Most newly diagnosed cases have tumor confined to the region of the prostate gland. Although selected patients may be simply observed following diagnosis, most patients with such locally-confined cancers are offered aggressive curative treatment such as radical prostatectomy, external-beam radiation therapy, or radioactive implant (permanent: I-125 or Pd-103, or temporary: Ir-192).

Treatment options are discussed with the patient in detail, including the risks and benefits of each procedure. For example, radical prostatectomy entails a 72% risk of subsequent impotence and a 42% risk of at least occasional urinary incontinence (2), with a 0-2% risk of perioperative mortality.(3) External-beam radiation treatments carry a 3% risk of chronic intestinal complications (diarrhea, proctitis, anal stricture, rectal bleeding), and a 7% risk of urinary complications (hematuria, cystitis, urethral stricture), and a very low risk of procedure-related mortality (0.2%).(4) I-125 seed implantation performed from a suprapubic laparotomy approach entails a 1-8% risk of perioperative complications (bleeding, infection), an 8% risk of chronic bowel complications (bleeding, proctitis), a 6% risk of bladder complications (hematuria, dysuria, urgency, or incontinence), and a 10% risk of impotence.(5) There has been a recent trend to avoid invasive surgery by implanting the seeds directly into the gland and surrounding tissues using a transperineal template to direct needles into the prostate under transrectal ultrasound guidance. This approach has allowed source placement with accuracy at least as good as the open laparotomy approach, and can be done as an outpatient "day-stay" procedure with regional anesthesia. The latter approach was used in this misadministration event.

II. TYPICAL I-125 TRANSPERINEAL IMPLANT PROCEDURE

A. PREPLAN: After suitable candidate has consented to the implant procedure, he is placed in the proper implant position, and a transrectal ultrasound apparatus is positioned in the patient's rectum. Detailed outlines of the location of the gland including contours at several gland levels are obtained. Next, computerized treatment planning using these contours to reconstruct the gland dimensions allows the dosimetrist to calculate the proper seed quantity, strength, and spacing to achieve the target dose specified by the authorized user (Radiation Oncologist).

B. SEED ACQUISITION: After plan is reviewed/approved by the Radiation Oncologist, the dosimetrist or physics staff arrange for ordering the seed quantity and strength based upon a physician's written directive. In general, seeds are ordered in a strength of 0.4-0.6 mCi/seed in sufficient quantity to deliver a total dose of 16,000cGy to the periphery of the gland over 1 year. Once the seeds are shipped to the facility, the physics or dosimetry staff log in the sources to the facility. Implicit in this procedure is not only making sure the number of seeds received actually matches the number on the shipping label, but also matches the requested number and strength ordered.

C. PREPARATION FOR IMPLANT: Based upon the preplanned dosimetry, sterilized seeds and spacers are positioned in implant needles or in cartridges which are later attached to the implant needles.

These loaded needles or cartridges are then transported to the operating room for the implant itself. Seeds are logged out of the "hot lab".

D. IMPLANT: Patient is anesthetized and placed in the implant position (known as the lithotomy position) identical to that used for preplanning. The transrectal ultrasound equipment is properly positioned along with the transperineal guide template. The grid coordinates of the template are matched to the preplan, and the urologist then places implant needles into the perineum percutaneously to a proper depth determined by ultrasound guidance. A steel trocar is used to leave the seeds behind, in the tissues, as the needles are withdrawn. After the procedure the only external evidence of the procedure is the small puncture sites of the needles, which heal rapidly. Personnel involved in the procedure should wear appropriate body and ring badges to allow for accurate measurement of exposure.

E. POST-PROCEDURE: Unused seeds are returned to the "hot lab" and logged back in, stored for decay, etc. Needles, dressings, and the operating room are cleared by Geiger counter, and these surveys are documented. Days to weeks following the implant, the patient is brought back for final dosimetry based upon the actual positioning of the implanted seeds seen on orthogonal radiographs. Badges are read and reviewed by medical physics (exposure is usually minimal to staff and operators due to the weak nature of I-125, 27Kev, the shielding provided by the needles and cartridges, and the shielding afforded by the patient's own tissues. Patient is instructed to screen his urine for the rare seed which is excreted, along with appropriate handling and notification procedures in that event.

III. RECORDS REVIEWED: Backus Hospital inpatient hospital chart, implant preplan, post-implant and post-mitigative surgery dosimetry, Backus Hospital contracts with consulting Yale/New Haven Medical Center, Backus Hospital Radiation Safety Committee minutes, Backus inservice program agenda and various attendant training forms, notes from preliminary NRC investigation team.

IV. STATEMENT OF MEDICAL PROBLEM: 73 year old white male was scheduled to receive a transperineal prostate I-125 implant. Although the Urologist and Radiation Oncologist involved thought they were implanting 0.449mCi/seed, they in actuality were implanting 4.49mCi/seed. A total of 112 seeds were implanted with a total activity of 502.88mCi. The implant procedure went smoothly and good positioning of the seeds was documented. The activity problem was noted by the dosimetrist following the procedure. The initial planned peripheral tumor dose (PTD) was 16,000cGy. By inference of the factor of ten error in seed strength, the PTD achieved if the seeds were left in place was 160,000cGy over 1 year.

Although details of the sequence of events leading to this event are outlined by other team members, the critical deficit lay in the failure of anyone (nuclear medicine staff, dosimetrist, physicist, physician) to ever compare the strength of seeds received to the strength of seeds ordered by the Radiation Oncologist.

V. UNMITIGATED POTENTIAL MEDICAL IMPACT (PATIENT):

The quantity of irradiation implanted was life-threatening to the patient. Undetected and without mitigative actions, the doses to the rectal, perineal, prostatic, and bladder tissues would have far exceeded tolerance. I am unaware of any recorded similar cases to compare with, but with doses exceeding standard tissue tolerance limits for at least a few centimeters from the implanted gland, general radiobiologic and physiological inferences can be made:

A. Prostate: expected effects over the first several weeks might include progressive intense dysuria, and urethral edema with subsequent difficulty initiating a urinary stream. Later effects

might include hematuria and liquefactive necrosis of the gland, surrounded by areas of dense fibrosis in the periprostatic tissues and urogenital diaphragm. Loss of urinary sphincter control and impotence could be anticipated. Total urinary obstruction or fistula formation to surrounding viscera (rectum) would be likely. Pain from nerve entrapment or secondary severe genital edema might occur.

B. Bladder: the bladder would suffer early on from radiation mucositis causing dysuria, frequency, and hematuria. Disruption of the mucosal lining might later precipitate life-threatening hemorrhage. Outlet obstruction of the bladder neck would later lead to secondary hydronephrosis, renal failure, and death, barring medical intervention.

C. Rectum: initial rectal urgency and perianal irritation would develop within several weeks, and might well progress rapidly to frank rectal wall ulceration, hemorrhage, sepsis, and death. If patient were to survive long enough, impairment of anal sphincter tone would be likely secondary to fibrosis and potential nerve damage.

D. Sacral Plexus Nerves: It appears that 3 seeds have migrated into the neural foramina of the sacrum, at separate sites around the left S2-3 nerve roots, perhaps via Batson's venous plexus. These nerve roots innervate the posterior femoral cutaneous nerve and based upon point dose calculations of greater than 10,000cGy at 1cm from a point-dose seed, these nerve roots may be functionally impaired over the next 6-12 months. This impairment might cause permanent dysesthesias in the left leg.

VI. MITIGATING ACTIONS: To the credit of the Urologist, dosimetrist, and Yale personnel, action was undertaken shortly after the error was discovered. Within 4 hours, the patient was back in surgery--this time for a radical prostatectomy in an attempt to remove the majority of the seeds. Sixty-nine seeds were recovered in this fashion. One seed was transected in the operative field, and subsequent activity was detectable in the thyroid. SSKI was later given in an attempt to suppress further thyroid uptake of circulating I-125. As intraoperative x-rays revealed, a significant number of seeds remained in the region of the urogenital diaphragm and rectum, and an appropriate decision to perform a protective colostomy was made. The patient was transferred to Yale/New Haven where more formal dosimetry on the remaining 43 seeds could be performed. The concentration of seeds remaining in the urogenital diaphragm area still represented the most serious area of concern for life-threatening complication, and a perineal exploration was undertaken 6 days following the initial implant. Fifteen additional seeds were recovered in this fashion, leaving a total of 28 in place (125.7mCi): 12 in the perineum, 5 in the left upper perirectal area, 8 in the right upper perirectal area, and 3 in the left sacrum. Other remedies were considered, including insertion of a "radioprotective agent" on a tampon into the rectum, but this was felt to be impractical due to the chronic low dose rate of the I-125, uncertain uptake of the agent into the rectal wall, and lack of convincing evidence that it would work.

VII. MITIGATED EXPECTED MEDICAL IMPACT (PATIENT): Because of the mitigating effects of early discovery of the error and prompt removal of the bulk of the seeds, updated Yale dosimetry predicts the total dose delivered to the rectum and bladder to range from 5000-10,000cGy, with a very small portion of the right rectal wall receiving up to 20,000cGy. Radiation effects to those structures might include rectal edema, possible proctitis for several weeks, a late risk of rectal stenosis or rectal bleeding, painful cystitis, urethral stenosis, intermittent urethral or bladder ulceration or bleeding. The scattered locations of the remaining seeds will help reduce the overall tissue toxicity and dose. As noted previously, the left S2-3 sacral nerves will receive a dose likely to cause permanent impairment of function.

Although the additional surgeries were clearly indicated to save the patient's life, complications related to these surgeries might include those noted in the initial background section related to radical prostatectomy, as well as poor wound healing, poor urethral and anal sphincter tone/control, pelvic adhesions, and pelvic floor scarring/fibrosis. In addition, there is a risk of ensuing hypothyroidism over the next 2 years. I have discussed the concerns regarding sacral nerve injury with Dr. Ken Roberts on 1 July 1994, and suggested that he get neurosurgical opinion regarding impact of loss of nerve function, as well as feasibility or reasonability of attempted neurosurgical resection/removal of the seeds. Further surgeries to attempt additional seed resection from the pelvic soft tissues might entail more risk to the patient than benefit, at this point.

VIII. EXPECTED MEDICAL IMPACT (STAFF/OPERATORS): Readings from collar badges are pending. Finger rings were not worn by the Urologist or Radiation Oncologist. Nevertheless, with the low energy of the I-125 seeds and the fact that they were inside steel trocars when in the operating room, as well as the limited time of the implant procedure, it is doubtful that these personnel exceeded their allowable doses during the initial implant procedure(another way to think of this is that they did "10-12 procedures", which is not an uncommon number for experienced implanters). Of more concern is the additional dose the urologist was subjected to during the subsequent retropubic prostatectomy, in which considerable time was spent dissecting the tissues within the pelvis. The urologist tried to limit his hand dose by the use of invasive radiologist-style lead-lined gloves during the prostatectomy. It is doubtful there was any significant exposure to the other operating room or ward personnel, based upon survey measurements of 4mr/hr at 1 meter from the patient measured shortly after the implant. Indeed, exposure calculations performed at Yale (Dr. Michael Bohan) for all personnel involved at Yale and at Backus Hospitals indicate whole body and extremity doses were well within Federal Guidelines, with the dosimetrist receiving the highest calculated dose of 278mR whole body, and 2416mR to the extremities (5000 mR whole body and 50,000mR extremity allowed per year). These doses are estimates, and have yet to be confirmed by badge dosimetry.

IX. BACKUS HOSPITAL PLANS TO PREVENT REPEAT OF MISADMINISTRATION: Shortly after the misadministration, Backus Hospital administrators decided to halt the entire implant program, pending detailed review. A meeting of administration and the Radiation Safety Officer is scheduled on day 10 to discuss long-term solutions. Program agenda items include altering procedures for logging in sources with required comparison to the physicians written directive, as well as a need to "delineate more clearly" responsibilities of the various personnel from the two institutions involved with the implant, and discussion on whether or not to cancel the implant program permanently.

X. UNIQUE CIRCUMSTANCES/RECOMMENDATIONS: Several items contributed to the misadministration:

A. The I-125 implant program was new to Backus Hospital, and this was only the eighth case performed. Personnel were not yet proficient enough with the whole process to realize who was responsible for what (specifically between the Backus Nuclear Medicine department and Yale dosimetry), and to recognize an "abnormal" quantity of isotope for the indicated procedure. Nuclear Medicine personnel admitted that they did not feel adequately trained in their understanding of the proper use of the material.

B. Procedures for ordering and receiving the I-125 were inadequate, and in fact were in a state of flux prior to this implant. Procedures for comparing the received material activity to that ordered by the Radiation Oncologist did not exist.

C. Lack of communication precipitated lack of understanding and lack of procedures formalizing responsibilities between the Hospital and Yale/New Haven Medical Center.

D. There was confusion over the strength of seeds ordered over the telephone, as evidenced by the findings of the initial investigators. This might be obviated by the requirement for a FAX confirmation of the order (physician's

written directive) to the manufacturer, prior to shipment of seeds.
E. Backus Hospital has an active Radiation Safety Committee, of which a Yale Radiation Oncologist is a member. Committee attendance records, however, fail to show any attendance by a the Radiation Oncologist, or direct input from him. If the brachytherapy program is to continue at Backus, more direct interaction of the Radiation Oncology staff in Committee proceedings is imperative.
F. Although Backus Hospital staff were provided a comprehensive initial inservice, no records exist to document indoctrination of new staff subsequently, or recurrency training as an on-going policy. This should be addressed.
G. Backus Hospital had no formal Quality Management Program/Policies for brachytherapy services that I saw. If this is indeed the case, the situation should be corrected prior to resumption of implant services.
H. Our dose estimates to the operator involved would have been much more accurate and useful had he worn finger rings. This needs to be emphasized as part of the QM Program.
I. Lack of ability to easily discern "standard" strength I-125 seeds from "high-activity" seeds, which were inadvertently used in this case (of note, these "high activity" seeds only came into being in the early 1980s in response to a need for a removable source with good radiation protection properties--these seeds were and are used almost entirely for temporary implants only, especially in areas like the brain and breast). I would recommend that any seed greater than 1.0mCi be identifiable by color as different from the standard seeds. This will require manufacturer input and assistance, but would go a long way in helping prevent accidental use of these special seeds.

VIII. MEDICAL SUMMARY:

Mitigative actions by numerous professionals involved have dramatically decreased the patient's risk of mortality, assuming he develops no perioperative complications. Some morbidity, however, is likely due to the extensive intervention required. Careful follow-up and attention to the rectum, bladder, perineum, anal and urinary sphincters, sacral nerves, and thyroid gland is imperative, as dysfunction of any of these structures may occur over the next few months to years, and may require further medical or surgical intervention.

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Respectfully submitted,

DOUGLAS W. JOHNSON, M.D., F.A.C.R.