

5364

Abdul

Lodhi

1953

KARLA:

I HAVE ATTACHED ALL THE BACKUS HOSPITAL MATERIAL. SATAR IS SUPPOSED TO BE WRITING THE LETTER TO BACKUS FOR YOUR SIGNATURE INDICATING THAT EVERYTHING IS AGREED UPON WHICH WILL BE WITHHELD.

SUSAN NEILSON SAID THE LETTER IS TO ^{BU}SENT TO:

THE WILLIAM W. BACKUS HOSPITAL
ATTN: MR. BRIAN SMITHWICH
VICE PRESIDENT
326 WASHINGTON STREET
NORWICH, CONNECTICUT 06260

(WITH A CC TO SUSAN NIELSON AT:

WIGGIN & DANA
ONE CENTURY TOWER
NEW HAVEN, CONNECTICUT 06508

203-448-4563

FAX 203-787-2839

SUSAN ALSO WANTED TO KNOW IF THE CLIENT WILL HAVE TO SIGN ANYTHING SAYING HE AGREES TO EVERYTHING BEING WITHHELD. ALSO, SUSAN WOULD LIKE A CALL WHEN THE LETTER IS BEING MAILED TO BACKUS HOSPITAL AT (203) 498-4563.

MARY JO
8/26/94

F/3

~~AD~~

KARLA:

I SPOKE WITH SUSAN NEILSON, ATTORNEY FOR BACKUS HOSPITAL, AND SHE WENT OVER THE INFORMATION AGAIN THAT WILL BE WITHHELD AND SHE WAS GOING TO GET BACK TO HER CLIENT AND LET THEM KNOW AND GET BACK TO ME AND LET ME KNOW THAT EVERYTHING WAS OK OR IF THERE WAS A PROBLEM ABOUT NOT WITHHOLDING MORE INFORMATION.

I WILL GET THE MATERIAL BACK TO YOU AFTER I HEAR FROM HER AND HAVE SATTAR DRAFT UP A LETTER.

MARY JO
8/5/94

Susan Neilson
called 8/10 to say Client said
OK -

Kigger, Dana
One Century Tower
New Haven Ct 06508

Does Client have to sign something
Rey still draft up letter

Spoke to Sattar week to 10 days
Gk of 8/22 to get letter to Karla but will
do 8/10 - Mary J



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

FACSIMILE TRANSMISSION

DATE: 10/6/94

MESSAGE TO: Susan Nielson

TELECOPY NUMBER: _____

**FROM: MARY JO CAMPION
ORA SECRETARY**

Tel. (610) 337-5095
Fax. (610) 337-5241

SUBJECT: Backus Hospital

No. PAGES ENCLOSED: 7

- | | | |
|---|---|--------------------------------------|
| <input type="checkbox"/> As Requested | <input type="checkbox"/> For your information | <input type="checkbox"/> Action |
| <input type="checkbox"/> Per our conversation | <input type="checkbox"/> For comment | <input type="checkbox"/> Concurrence |

Remarks:

SUSAN:

Attached is the attachment to Backus Hospital's 7/6/94 letter. All the blanks is what will be withheld from PDR, plus the charts that were attached, they all will be withheld. If this is not correct, please contact me at (610) 337-5095. The letter will be going out next week to Backus Hospital. Our attorney would like you to prepare a letter for the patient's agreement that he understands what will be withheld and what will not be withheld and have the patient sign the letter.

Any questions, contact me at (610) 337-5095.

Mary Jo Campion



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Mary Jo Campion

ATTACHMENT

Misadministration of 6/21/94 at Backus Hospital: Interim Analysis of Patient Radiation Doses and Remedial Therapy

Regarding the misadministration of 6/21/94 occurring at The William W. Backus Hospital in Norwich, Connecticut, the following is a summary of radiation doses which the patient received, as well as the therapeutic interventions to remedy the misadministration.

As radiation oncologists, physicists, and radiobiologists readily appreciate, the description and reporting of brachytherapy dose distributions is rather difficult given the inherent dose inhomogeneities. Correlating the risk for future radiation injury from brachytherapy, furthermore, is also inherently difficult as a general rule. For this patient, reasonable steps have been taken and will be taken in the future to remedy the misadministration as detailed below. It should also be noted that many late occurring radiation complications are potentially temporary should they occur. Moreover, the risk of radiation toxicity is a very complex function of radiation dose, dose rate, volume of tissues receiving a particular dose, proliferative or mitotic status/capacity of irradiated tissues, vascular integrity and blood/oxygen perfusion of irradiated tissue, as well as intracellular mechanisms capable of repairing sublethal radiation damage. Other factors that contribute to risk of radiation injury are other diseases affecting tissues receiving radiation dose, trauma, and infection,

1) On the morning of 6/21/94, the patient underwent an uncomplicated placement of 112 I-125 seeds into his prostate and surrounding periprostatic soft tissues for treatment of his localized early stage prostate cancer. This procedure was accomplished in the operating room using an ultrasound and fluoroscopic guided trans-perineal template system. The quality of the implant with appropriate distribution of I-125 seeds was judged to be good. The intended implant dose was $0.444 \text{ mCi/seed} \times 112 \text{ seeds} = 49.73 \text{ mCi}$. By preplanning dosimetry this was intended to deliver a peripheral target dose of 16,000 cGy (total decayed dose).

2) Soon after the implant was performed, the misadministration was discovered. The patient had in fact received I-125 seeds with an activity 10 fold higher than prescribed at 4.44 mCi/seed. Total activity implanted was thus 497.3 mCi.

4) During the prostatectomy/Hartmann's procedure, one I-125 seed was inadvertently ruptured and suctioned into a bottle in the operating room. Contamination of the patient at this time is felt to be minimal. Detailed thyroid measurements and dosimetry are not yet available. The patient has been treated with oral potassium iodide to minimize thyroid uptake of I-125.

Further details of thyroid and urine I-125 dosimetry can be provided in the near future if requested.

5) On 6/23/94, the patient was transferred to the Yale-New Haven Hospital for further management.

Date

7/6/94

Kenneth B. Roberts, MD

Kenneth B. Roberts, MD