10/26/99 EVENT RIDS DIS
(DCD SP04)
cc: PLarkins, OSP
LBolling, ASPO

ARIZONA
RADIATION REGULATORY AGENCY

TO: Lloyd Bolling

FAX NUMBER: 1-301-415-3502

RE: Misadministration ?

DATE: 10/25/99

NUMBER OF PAGES: 3

COVER SHEET

FAX

From the desk of...

William A. Wright
Program Manager/RAM/ME
Arizona Radiation Regulatory Agency
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Phoenix, Az 85040
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Fax: (602) 437-0705

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PDR STPRG

SP-E-9

L. Bolling: Technically, it is a misadministration -- dose differs greater than 20%, See §35.2

SAMARITAN HEALTH SYSTEM

October 12, 1999

Dan Kuhl
Arizona Radiation Regulatory Agency
4814 South 48th Street
Phoenix, AZ 85040

RE: Possible Misadministration, ARRA License 7-56

Dear Mr. Kuhl,

Good Samaritan Regional Medical Center is participating in the FDA-approved "INHIBIT" trial to prevent restenosis for patients with prior cardiac-stent implant. This trial, sponsored by the Guidant Cooperation, is a double-blind, sham-controlled study, in which the patients are randomly assigned to one of the two groups. One group will receive 20 Gy to 1 mm into the coronary artery wall and the other group will only receive "sham" wire treatment (0 Gy). Within GSRMC, only physicists and the radiation oncologists know whether a patient has actually received the radiation treatment. Cardiologists and patients do not know whether the wire introduced into the patient is the "active wire" or the "dummy wire". All patients have been informed about this study and signed a consent form. Patients are to be followed-up, including angiogram at 9 months after the procedure.

Our intravascular brachytherapy (IVBT) unit, made by Nucletron, was delivered at the end of the August. Brad Bisson, the clinical research coordinator from Guidant, was here for about a week to provide training and oversee the first 5 studies on September 1, 1999.

On September 22, 1999, during case 138-1406, we felt there was some discrepancy between our observation and the treatment record from the IVBT unit. This patient was randomized to receive radiation treatment and the machine was programmed correctly to deliver radiation treatment. However the radiation oncologist noticed that, during study-wire extension, the wheel associated with "sham wire" or the dummy source was turning. Since our IVBT unit employed a P-32 source, the survey meter was not useful to detect the beta source inside the patient. During the source retraction, several people witnessed the turning of the black "dummy" wheel and the survey meter did not register any radiation during the retracting process. We did notice that there was an interruption with error code 1514 at one minute into the treatment.

After case 138-1406, we had another case 138-1407 scheduled. Between cases, we were trying to contact the Guidant Corporation and test the IVBT unit. The unit tested out OK and the second case was completed successfully.

The next day, we sent computer back-up tape and all relevant documents to Guidant for evaluation. On 10/5/99, I received an e-mail back from Nucletron, via Guidant, that confirmed our observation that only the check source was used for treatment from the "first analysis on the data". I immediately provided all information to ARRA via e-mail regarding this unusual event.

I would like to point out a few things regarding this case:

1. This is an experimental procedure approved by the FDA. Since this is a randomized study, some patient may not receive radiation treatment.
2. There was no harm at all to the patient in this case 138-1406. There was a 50% chance that the patient may receive no radiation by randomization.
3. All records from the IVBT unit showed that the patient was treated correctly with radiation with no misadministration.
4. All information I received from the Guidant/Nucletron was preliminary information. With further analysis and testing, it is possible that the final result may be different and I'll keep you informed.
5. Since this is a randomized study, the patient and the cardiologist are not supposed to know whether this patient received radiation treatment or sham treatment. Since there was no harm to the patient and informing patient and the cardiologist may jeopardize the randomized study, the patient and the cardiologist are not informed about this possible misadministration. (R12-1-708 A.1)

If you need additional information, please call me at (602) 239-2226. Thank you for your assistance.

Sincerely,

David Liu, Ph.D.

David Liu, Ph.D., RSO

Copy: Brad Bisson, Guidant Co.
Susan Dimpfel
Dr. Lucas