DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AIR FORCE MEDICAL OPERATIONS AGENCY
BROOKS AIR FORCE BASE, TEXAS

22 DEC 1992

FROM: HQ AFMOA/SGPR
8901 18th St
Brooks AFB TX 78235-5217

SUBJ: Use of Omnitron Model 2000 High Dose Rate Afterloading Brachytherapy Unit; USAF Permit 23-01002-2AFP, Docket 030-02260; NRC License 42-23539-01 AF, Docket 030-28641

TO: U.S Nuclear Regulatory Commission
Washington, DC 20555
ATTN: Document Control Desk

1. Reference NRC Bulletin 92-03, Release of Patients after Brachytherapy.

2. Attachment 1 suspended use of the Keesler Technical Training Center Medical Center's Omnitron unit for patient treatment and requested the Medical Center to conduct a risk management review of continued use of the unit with the additional safeguards given in Bulletin 92-03.

3. Attachment 2 is the Medical Center's recommendation they be allowed to continue with use of the unit for patient care and certifying that they have the additional safeguards of Bulletin 92-03 in place to support such use.

4. This will confirm that the Air Force intends to continue use of the Omnitron unit at Keesler Medical Center at this time in accordance with the NRC's regulations affecting such units and the added requirements of Bulletin 92-03.

5. Please do not hesitate to contact me at (210) 536-3331 should you have any questions concerning this response.

DAVID G. WOOD, COLONEL, USAF, BSC
Chief, USAF Radioisotope Committee Secretariat
Office of the Surgeon General

2 Atch
1. HQ AFMOA/SGPR Ltr, 10 Dec 92
2. KTTC/SGHRP Med Cen Ltr, 21 Dec 92 w/o Atch

cc: HQ ATC/SGP/SGPB
KTTC Med Cen/SG/SGHR/SGHRT
HQ AFMOA/SGP
USNRC, Region IV (Ms. McLean)

STATE OF TEXAS)
)
COUNTY OF BEXAR)

This instrument was acknowledged before me on the 22nd day of December 1992, at Brooks Air Force Base Texas, by DAVID G. WOOD, Colonel, USAF.

CARMEN G PEREZ
Notary for and in the State of Texas
My commission expires: 7-26-93

29-100

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS AIR FORCE MEDICAL OPERATIONS AGENCY
BROOKS AIR FORCE BASE, TEXAS

10 DEC 1992

FROM: HQ AFMOA/SGPR
8901 18th St
Brooks AFB TX 78235-5217

SUBJ: Nuclear Regulatory Commission (NRC) Bulletin 92-03:
Release of Patients After Brachytherapy

TO: HQ ATC/SGP
Keesler TTC Medical Center/SG
IN TURN

1. Subject bulletin (Atch) identifies two serious incidents involving the Omnitron Model 2000 High Dose Rate (HDR) Afterloading Brachytherapy Unit. Because of these incidents, we are suspending your authorization to use the Omnitron for patient treatment under USAF Radioactive Material Permit 23-01002-2AFP until you have evaluated your situation and have decided to either discontinue use or have implemented the NRC Actions required for continued use.

2. Please conduct a risk management assessment and recommend whether your Omnitron should be used for patient treatment subject to the NRC requirements. Ensure input from your physician user staff, medical physicist, and legal counsel. You may conduct non-patient testing of your unit if essential to the assessment provided you take special measures for operator protection and source recovery in event of the failures noted. If you determine not to recommend use, be sure procedures are established to preclude patient referral for HDR treatment by the Omnitron device. If you determine to recommend use, certify you have in place the procedures to comply with the NRC Action requirements. Please provide the results of your assessment and recommendations to HQ AFMOA/SGP for review and approval by 21 Dec 92.

3. I can be reached at DSN 240-3331 (FAX: DSN 240-4382, Com (210) 536-4382). HQ AFMOA/SGP FAX is DSN 354-8089, Com (202) 404-8089.

DAVID G. WOOD, COLONEL, USAF, BSC
Chief, USAF Radioisotope Committee Secretariat
Office of the Surgeon General

1 Atch
NRC Bulletin 92-03

cc: HQ ATC/SGPB
KTTC Med Cen/SGHR/SGHRT
HQ AFMOA/SGP
USNRC, Region IV (Ms. McLean)

ATCH 1

DEPARTMENT OF THE AIR FORCE
KEESLER MEDICAL CENTER (ATC)
KEESLER AIR FORCE BASE MS 39534-5300

REPLY TO ATTN OF: SGHRP (Maj Erb, DSN: 597-6291) 21 Dec 1992

SUBJECT: Nuclear Regulatory Commission (NRC) Bulletin 92-03: Release of Patients After Brachytherapy

TO: HQ ATC/SGP/SGPB
HQ AFOMA/SGP/SGPR
IN TURN

1. References.

a. U.S. Nuclear Regulatory Commission Bulletin 92-03, "Release of Patients After Brachytherapy," dated 08 Dec 1992.

b. HQ AFOMA/SGPR letter to HQ ATC/SGP and Keesler Medical Center/SG, "Nuclear Regulatory Commission (NRC) Bulletin 92-03: Release of Patients After Brachytherapy," dated 10 Dec 1992.

c. HQ ATC/SGP letter to Keesler Medical Center/SG, "Nuclear Regulatory Commission (NRC) Bulletin 92-03: Release of Patients After Brachytherapy (Suspense: 18 Dec 1992)," dated 10 Dec 1992.

2. On 17 Dec 1992, SGH, SGJ, SGHR, SGHRT, and SGHRP met to decide on a response to HQ AFOMA/SGP and the NRC. Our response to the NRC's request to either discontinue use of the Omnitron High Dose Rate (HDR) Brachytherapy System, or continue use by implementing certain procedures, is that we wish to continue to use the system. Therefore, we have developed local operating instructions to implement the following procedures to be observed in conjunction with any use of the Omnitron HDR System.

a. We commit to performing a radiation survey of the patient and the treatment room immediately after the completion of therapy, and prior to removal of the patient from the treatment room.

b. Pending further guidance from the NRC, we will use only closed-end catheters and needles for treatment. We will not use the "Pulmocath" nor the "Omnicath," both of these catheters are designed to remain in the patient between fractionated treatments. Use of closed-end catheters should enable a detached source to be removed simply by removing the catheter or needle.

c. As for surgical intervention, neither incident reported by the NRC would have required surgery to retrieve the source. When coupled with our commitment to use only closed-end, easily-removed catheters and needles, we do not believe the need for surgical intervention is demonstrable. However, in consideration of the diminutive possibility than the source cannot be removed from the patient by removing the catheter or needle, the radiation oncologist shall determine if the source can be removed by "minor surgery" in the treatment room, or the situation requires significant intervention.

Atch 2

(1) To accommodate minor surgery, an HDR Brachytherapy "Crash Cart" will be in the treatment room whenever an HDR treatment is being performed. The HDR Crash Cart contents and procedure for use is described our "Omnitron HDR 'Crash Cart' and Minor Surgery" OI (see Attachment 1).

(2) Should the radiation oncologist determine that the source cannot be removed from the patient by "minor surgery," the "Omnitron HDR Major Surgery" OI shall be implemented (see Attachment 2). For major surgery, the radiation oncologist shall immediately consult with the Chairman of Surgery to determine if the surgery should be performed in the treatment room, or the patient transported to the operating room.

e. All personnel involved in the use of the HDR Brachytherapy System shall be trained in both the routine use of the device and emergency procedures to return the source to a safe position (see Attachment 6).

3. We have reviewed the continued use of the Omnitron from the perspective of risk management and cost benefit analysis. We firmly believe that HDR brachytherapy treatments are an integral part of radiation therapy treatments for cancer patients. There are many cases where HDR brachytherapy is the only viable treatment (e.g., tumor occlusion of a main bronchus) to effect immediate relief for the patient. Additionally, we can demonstrate a savings of $680,000 per year (based on 150 patients per year), by performing HDR brachytherapy treatments in-house versus sending the patients to a civilian medical facility (Attachment 3).

4. We believe that by following the procedures we have described, we can safely perform HDR brachytherapy treatments for our patients. Additionally, the projected annual savings of $680,000 by performing the treatments in-house represents a significant and efficacious savings of tax dollars. Therefore, we request permission to use our Omnitron HDR Brachytherapy System to treat patients.

JOHN C. ERB, Major, USAF, BSC
Consultant for Medical Physics to
the USAF Surgeon General

DAVID G. YOUNG, Lt Col, USAF, MC
Director, Hospital Services

8 Atch
1. SGHRP OI 160-504, 16 Dec 92
2. SGHRP OI 160-505, 21 Dec 92
3. SGHRP Memo, 18 Dec 92
4. SGHRP Policy Ltr, 07 Dec 92
5. SGHRP OI 160-502, 25 Nov 92
6. SGHRP OI 160-501, 25 Nov 92
7. SGHRP OI 160-111, 25 Nov 92
8. SGHRP OI 168-503, 25 Nov 92