



NATIONAL NAVAL MEDICAL CENTER

BETHESDA, MARYLAND - 20014

IN REPLY REFER TO

NNMC-COO-mbj
17 August 1972

From: Commanding Officer, National Naval Medical Center, Bethesda, Maryland 20014

To: Division of Material Licensing, Atomic Energy Commission, Bethesda, Maryland 20014

Subj: Emergency Amendment to NNMC Broad Byproduct Material License No. 19-02891-05; request for

Encl: (1) Case of Darlene Ritter, permission to use whole body radiation in
(2) Report of Medical Isotope and Radiation Safety Committees Meeting of 17 August 1972

Callahan

AFRR

Amendment?

License?

for about

1. For humanitarian purposes a 13 year old female dependent patient of the Naval Hospital, NNMC, Bethesda, Maryland, has been accepted for treatment of acute lymphoblastic leukemia. The treatment that has been recommended is whole body irradiation followed by bone marrow transplant. Of the facilities available for providing whole body radiation, the Cobalt Irradiator of the Armed Forces Radiobiology Research Institute is the only source suited to this particular purpose. Since the AFRRRI and NNMC have separate licenses, permission is requested for the use of the AFRRRI source to provide irradiation in the amount of 1200 rads mid-line tissue dose at the rate of 5 rads per minute to patient Darlene Ritter of the Naval Hospital, NNMC.

2. Medical care of the patient will be provided by the Naval Hospital, NNMC, physicians LCDR R. Cahill, pediatric hematologist, and LT S. Larson, pediatrician. Environmental control of the patient will be provided by LCDR J. Curry, a physician of the Tissue Bank of the Naval Medical Research Institute, NNMC.

The radiation therapy will be performed by the Radiology Service of the Naval Hospital, NNMC, under the direct supervision of Captain J. E. Turner, a radiotherapist certified by the American Board of Radiology. LCDR D. Karp, a Board eligible radiotherapist who completed his therapy residency in June, will be present throughout the procedure.

Captain Kenneth Sell, Chief, Transplant Service of the Naval Medical Research Institute, NNMC, will coordinate the patient care. Dosimetry services at AFRRRI will be provided by Major D. Verelli of the Radiation Physics Section at AFRRRI. He will be assisted by CDR R. E. George, radiation physicist of the Naval Hospital's Radiation Therapy Branch.

3. The patient will be transported from the hospital ward to AFRRRI by ambulance on a gurney. She will be positioned in the exposure room on a small bed within a pre-sterilized laminar airflow unit equipped with a HEPA filter. Continuous monitoring will be provided by two television

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cameras, EKG monitor with respiratory lead and a two-way microphone speaker system for verbal communication with the patient. Emergency equipment under the charge of the senior pediatric resident and a nurse will be provided. The patient will receive nothing by mouth for twelve hours prior to start of therapy, and will receive nothing by mouth until she is able to tolerate food after therapy. She will be well hydrated with IV fluids and will be maintained with a slow running IV drip. She will be administered allopurinol for two days prior to therapy to prevent kidney damage from uric acid accumulation. Sedation (Demerol-Phenergan-Thorazine "cocktail") will be administered prior to therapy. Following therapy, the patient will be immediately returned to the hospital and placed in the sterile patient isolator laminar flow facility for intensive nursing care. Matched granulocytes and platelets for post-irradiation support will be provided as needed by the Blood Component Laboratory of the Transplant Service.

4. Dosimetry will be calculated prior to irradiation by using a tissue equivalent phantom of the size and anatomical configuration of the patient.

5. By separate letter the AFRRRI is requesting permission to change their AEC license to permit this emergency use in a human. The AFRRRI license number is 19-08330-03.

6. Enclosure (2) contains the NMMC committee action recommending approval of this procedure for this patient only.

F. P. BALLENGER



NAVAL HOSPITAL
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BETHESDA, MARYLAND - 20014

IN REPLY REFER TO
20-JET:sez
6470
17 August 1972

From: Chairman, Medical Isotope Committee, National Naval Medical Center, Bethesda, Maryland 20014
To: Commanding Officer, National Naval Medical Center, Bethesda, Maryland 20014
Subj: Report of Medical Isotope Committee and Radiation Safety Committee joint meeting of 17 August 1972

1. A combined meeting of the National Naval Medical Center's Radiation Safety and Medical Isotope Committees met at 1000 this date. Present were:

Captain J. E. Turner
Captain M. J. Valaski
CDR R. E. George
CDR J. A. Spahn
LCDR L. Heck
LCDR J. Duley
Dr. G. B. Thurman
LCDR David Karp (Interested observer)

2. The purpose of the meeting was to consider humanitarian request to render total body irradiation of 1200 RADS to a bone marrow transplant patient. The patient is refractory to chemotherapeutic agents. Doctor Turner reviewed the case history of the case in question and Doctor Karp reviewed the proposed treatment, including the experience of 52 cases treated elsewhere. On the basis of this experience, he arrived at the proposed total dose and dose rate to be administered.

3. The Committees were informed that the only local facility available to deliver this dose and rate is the AFRRRI cobalt radiation facility. Since this involves two separate licensed facilities, the Committees were asked to consider the feasibility of providing the treatment. The responsibility of the treatment will be the Radiology Service of the Hospital. The clinical care before, during, and after the treatment will be by the Hematology and Pediatric Services of the Hospital. Parental informed consent was discussed and considered necessary.

20-JET:sez
6470
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4. A motion was made and seconded to administer total body radiation to the patient previously approved by the Surgeon General and Secretary of the Navy at the AFRRRI under the direct supervision of the qualified staff of the Naval Hospital. The motion carried with one dissenting vote. Basis for the dissenting vote was insufficient time to consider all aspects of the case.

5. The Committee agreed that an emergency amendment to the NNMC Broad Byproduct Material License #19-02891-05 be requested of the AEC. At the same time, a request will be submitted to amend AFRRRI Cobalt facility license #19-08330-03 to allow for human use.



J. E. TURNER

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AEC
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