NUCLEAR REACTOR LABORATORY
AN INTERDEPARTMENTAL CENTER OF
MASSACHUSETTS INSTITUTE OF TECHNOLOGY

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J. A. BERNARD, JR.
Director of Reactor Operations

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U.S. Nuclear Regulatory Commission
Washington, D.C. 20555
Attn: Document Control Desk

Gentlemen:

I am writing to inform you that the Massachusetts Institute of Technology initiated a Phase I trial of boron neutron capture therapy on 6 September 1994. Enclosed is a copy of the news release. I also wish to take this opportunity to compliment the Commission on the professional attitude and competency of the NRC Staff (Non-Power Directorate, NMSS, and Region I) during the development and implementation of the technical specification that governs the use of the MIT Research Reactor's medical therapy beam for human therapy.

Sincerely,

John A. Bernard, Ph.D.
Director of Reactor Operations
MIT Research Reactor

JAB/CRM

cc: USNRC - Project Manager,
NRR/ONDD

USNRC - Region I - Chief,
Effluents Radiation Protection Section (ERPS)
FRSSB/DRSS

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- For Immediate Release -

Press Release

The Massachusetts Institute of Technology (MIT), the New England Medical Center (NEMC), and Boston University Medical Center (BUMC) jointly initiated a Phase One trial of Boron Neutron Capture Therapy (BNCT) on 6 September 1994 at the MIT Research Reactor which is located on the MIT campus in Cambridge, Massachusetts. BNCT is a novel form of experimental cancer therapy that is being developed for certain types of highly malignant brain tumors such as glioblastoma. Glioblastoma kills about 8,000 people in the United States each year. If BNCT is successfully developed it might also be applicable for the treatment of other forms of cancer such as melanoma.

Unlike most cancer treatments, such as chemotherapy or conventional radiation therapy, which involve only one agent for destroying the tumor, BNCT involves two. A boron-containing compound is given to the patient and is taken up by tumor cells. The tumor site is then irradiated with a neutron beam. The neutrons cause the boron to fission, i.e., to split into two highly energetic particles which destroy the tumor cells while largely sparing adjacent healthy cells.

BNCT was first attempted in the United States in the 1950s at the Brookhaven National Laboratory and in the 1960s at MIT. Those trials were unsuccessful although a great deal was learned which has assisted subsequent efforts. The present MIT/NEMC/BUMC effort benefits from an improved boron-containing drug, improved neutron beams, accurate and rapid boron analysis technology, and other important advances. For example, in the 1950s and 1960s, thermal (low energy) neutron beams were used. These required that the patient undergo surgery to allow the neutron beam to reach the tumor site. The current MIT beam is an epithermal (intermediate energy) one that can penetrate more deeply. No surgery is therefore needed.

The current Phase One trial is part of a study mandated by the U.S. Food and Drug Administration to demonstrate that the therapy will not cause harm. The process calls for the experimental treatment to be given to a limited number of patients who have melanoma lesions on the extremities starting at a low radiation dose followed by a step-wise increase to a therapeutic dose. The entire process may take 15-30 months.

The treatment performed at the MIT Research Reactor (MITR-II) on 6 September 1994 is the first use of BNCT on a human patient in the United States in more than thirty years and the first ever use of an epithermal beam for neutron capture therapy. The preparations for these trials have involved a major interdisciplinary and inter-institutional effort on several fronts. The NEMC contribution to this research effort was led by Dr. Robert Zamenhof who is a Senior Medical Physicist. At MIT the research was led by Dr. Otto K. Harling who is a Professor of Nuclear Engineering and Director of the MIT Nuclear Reactor Laboratory. The clinical aspects of the joint program are under the direction of Dr. Hywel Madoc-Jones who is Radiotherapist in Chief and Head of the Department of Radiation Oncology at NEMC. Dr. Gary Rogers, a dermatologist at BUMC, is also participating in the clinical aspects of these trials. A number of faculty and students from MIT's Nuclear Engineering Department and Nuclear Reactor Laboratory, and doctors and staff from the NEMC have worked for more than six years to develop the technology needed to initiate these patient trials. Funding for the research has been provided by the U.S. Department of Energy's Office of Energy Research and the Herbert M. Karol Cancer Foundation which is located in Brookline, Massachusetts. In addition, NEMC and MIT contributed substantially to support this research which developed all of the necessary technology needed to start clinical studies. The process required the approvals of the U.S. Food and Drug Administration, the U.S. Nuclear Regulatory Commission, and the U.S. Department of Energy, as well as those of nine separate MIT and NEMC committees.

Individuals interested in the program are asked to contact NEMC or BUMC via their primary care physician.