JAN 28 1997

Robert G. Zamenhof, Ph.D.
Administrative Principal Investigator
BIDMC
185 Pilgrim Road
Boston, MA 02215

Dear Dr. Zamenhof:

This refers to your letter dated January 17, 1997 concerning Amendment No. 38.

You requested clarification of your authorizations with regard to boron neutron capture therapy. Your understanding is correct. The facility license references an August 30, 1996 letter which we understood to be a request for relief from specific patient criteria. Your license as written is intended to permit your use for any patient if the criteria in Condition 10 of your license is followed and any other applicable State and Federal requirements.

If there are any questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:
THOMAS K. THOMPSON

Thomas K. Thompson, Sr. Health Physicist
Division of Nuclear Materials Safety

License No. 20-00289-07
Docket No. 030-01808
Control No. 123724

cc: Phil Cobb, RSO
Beth Israel Deaconess Medical Center, Inc.
West Campus
185 Pilgrim Road
Boston, Massachusetts 02215

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Mr. Thomas Thompson
United State Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

January 17, 1997

Re: Clarification of Regulations Pertaining to the Boron Neutron Capture Therapy Component of our License

LICENSE NO. 20-00289-07, Beth Israel-Deaconess Medical Center, West Campus

Dear Mr Thompson:

Following a recent telephone conversation between you and our RSO, Mr. Phil Cobb, and a similar telephone conversation between myself and one of your staff during your absence last week, I would like to submit in writing my understanding of the issue discussed in these two conversations.

Back in 1992, the New England Medical Center submitted an amendment request to its license (No. 20-03857-06) to allow the MIT Research Reactor to be employed as a remote treatment site in an experimental boron neutron capture therapy protocol. Dr. Keith Brown was the NRC individual handling the request at that time. As part of that amendment request, a fair degree of detail was included not only with regard to the radiation issues involved but also with regard to the *inclusion criteria* of the phase-I study. Currently, the clinical studies are being carried out under FDA IND #46,175, for which a number of amendments have been requested since the original submission of the license amendment request to the NRC. These amendments have *not* involved any change in the methodology originally approved by NRC for dosimetry, neutron delivery, and monitoring, but have related to changes in the *inclusion criteria* for the subjects in the study. For example, the current FDA criteria now permit intracranial metastatic melanoma as well as glioblastoma subjects to be included, and do not restrict the upper age limit *pe se*.

Mr. Cobb's and my questions sought to establish whether there was a necessity to amend our NRC license in parallel with every amendment of our FDA IND, assuming that the amendments were unconnected with the dosimetry, radiation delivery, or monitoring of the MITR-II irradiation facility.

In 10 C.F.R. Section 35.6, under "Provision for Research Involving Human Subjects," it is stated:

"...A licensee may conduct research involving human subjects using byproduct material provided that the research is conducted, funded, supported, or regulated by ***another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects...*** [my bold text].

The interpretation that you and one of your staff placed on this statement, if my own understanding is correct, is that as long as our protocol for human studies is overseen by the FDA under a currently approved IND, and as long as we have current approval for the study from our institution's IRB, we do not need to maintain a parallel flow of amendment requests to NRC in issues *not* relating to dosimetry, radiation delivery, or monitoring.

I would be grateful if you would either confirm or challenge in writing my understanding of Section 10 C.F.R. 35.6 in this context, and I thank you in advance for your time.

Sincerely,

Robert Zamenhof

Robert G. Zamenhof, Ph.D.
FDA IND Sponsor
Administrative Principal Investigator
Harvard-MIT Program in Boron Neutron Capture Therapy

Cc: Mr. Phil Cobb, RSO Beth Israel-Deaconess Medical Center West Campus
Ms. Rosemary Kennedy, RSO for Beth Israel-Deaconess Medical Center East Campus
Dr. David Kiszkiss, Research Administration, Beth Israel-Deaconess Medical Center, West Campus