



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

March 25, 1994

The Honorable John Joseph Moakley
United States House of
Representatives
Washington, DC 20515-2109

Dear Congressman Moakley:

I am responding to your February 10, 1994 letter in which you forwarded a letter dated February 8, 1994 from several of your constituents concerning the status of their license application to utilize a measuring device that contains radium-109, a sealed radioactive source, to determine bone lead concentrations in high school students by measuring the fluorescence generated by the external radiation. This application involves a project that we have been told is the graduate thesis of one of the authors of the letter, Jane Hoppin, the community Lead Study Coordinator. While your constituents' letter refers to the Brigham and Women's Hospital NRC license and is written on Harvard School of Public Health letterhead, and the Brigham and Women's Hospital Institutional Review Board has approved the study for human use, the actual applicant for a license is Howard Hu, M.D., M.P.H., Sc.D., as an individual rather than Harvard University or Brigham and Women's Hospital.

Dr. Hu's application is dated December 3, 1993 and was received by the NRC Region I office on December 6, 1993. The NRC staff completed the fees review process for the application on December 20, 1993. It was assigned to an NRC staff license reviewer on December 30, 1993. After completing her technical review, the reviewer contacted the applicant on February 15, 1994 and requested additional information needed to continue the review of the application. The NRC staff believes that institutional oversight of a study involving human research on minors may be warranted. We are working with the applicant to ensure that the oversight required for the use of radioactive materials on humans is provided. We also asked for more details regarding the secure storage of the radioactive materials at Randolph High School. On March 7, 1994, we received a letter from Randolph High School satisfactorily addressing the access and security question.

A member of the NRC staff from our Office of Nuclear Material Safety and Safeguards has been in contact with Dr. Hu by telephone and has offered to meet with him if this would expedite resolution of the licensing issues. As a result of these telephone discussions, Dr. Hu has initiated efforts to have the Brigham and Women's Hospital take responsibility for oversight of this project under that license. Assurance that the research is carried out in accordance with the Uniform Federal Policy on the Use of Human Subjects would be the responsibility of the Brigham and Women's Hospital's Institutional Review Board. This evaluation would include a determination that the required consent forms adequately express any risk from the radiation exposure to the students.

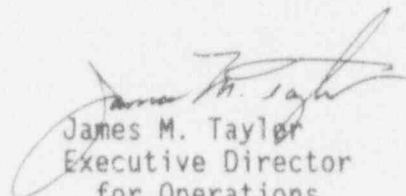
9404190311 940325
PDR DRG NE ED
PDR

057

The Honorable John Joseph Moakley -2-

I believe that we have been responsive to your constituent's application. Please be assured that we will continue to address this application as expeditiously as possible.

Sincerely,


James M. Taylor
Executive Director
for Operations