JUN 28 1985

Docket No. 030-04639 License No. 20-04490-01

Center for Blood Research
ATTN: Fabian J. Lionetti, Ph.D.
Radiation Safety Officer
800 Huntington Avenue
Boston, Massachusetts 02115

Dear Sir:

This is in response to your letter dated May 15, 1985 and to a subsequent telephone conversation between Dr. J. Piccone of this office and yourself on May 29, 1985.

Section 31.11 of 10 CFR 31 (enclosed) establishes a general license authorizing clinical laboratories to possess certain small quantities of byproduct material for in-vitro clinical or laboratory tests. The provisions of this paragraph exempt most byproduct materials used pursuant to this general license from the requirements of 10 CFR 19, 20 and 21. Because of the exemption from the provisions of 10 CFR 20, most radioactive wastes generated in the use of these in-vitro tests may be disposed of as ordinary waste. One of the limitations of the general license is a limit on the quantity a licensee may possess at any one time at any one location of storage or use (31.11 (c)(1)). A general licensee shall not possess a total amount of iodine-125, iodine-131, selenium-75 and/or iron-59 in excess of 200 microcuries.

A general licensee is required to file NRC Form 483 (3 copies enclosed), "Registration Certificate - In Vitro-Testing with Byproduct Material Under General License" with the Director of Nuclear Material Safety and Safeguards, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555 and receiving from the Commission a validated copy of NRC Form 483 with registration number assigned.

Should you have any questions concerning this matter, we will be pleased to discuss them with you.

Sincerely,

Original Signed By:
John D. Kinneman

John D. Kinneman, Chief
Nuclear Materials Safety Section A,
Division of Radiation Safety
and Safeguards

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Enclosure: 1. 10 CFR 31
2. NRC Form 483 (3)
3. "Disposal of Byproduct Material Used For Certain In-Vitro Clinical or Laboratory Testing."

cc w/encl:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Massachusetts

bcc w/encl:
Region I Docket Room (w/concurrences)

RI:DRSS	RI:DRSS
Piccone/mmb	Kinneman
6/24/85	6/25/85

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