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DEC 0 8 1989

The University of Michigan
Medical Center
ATTN: B. Shapiro, M.D., Chairman
Subcommittee on the Human Use
of Radioisotopes
Department of Internal Medicine
Division of Nuclear Medicine
B1G412 University Hospital
Ann Arbor, MI 48109-0028

License No. 21-00215-04

03001988

Gentlemen:

This refers to your letter received in the Region III office on November 6, 1989. This letter was in response to our telephone request of October 19, 1989, concerning allegations pertaining to the University's use of iodine-131 (MIBG).

In our telephone request, we asked that you provide this office with information pertaining to your use of iodine-131 (MIBG) with regard to a pediatric patient treated on three occasions in 1985 and 1986. The specific information requested included a copy of your protocol which was submitted to the Food and Drug Administration, a copy of the University's subcommittee approval for the use on iodine-131 (MIBG) and a copy of the actual prescription, and dispensation records for the patient in question.

A review by this office of the submitted documents has determined that your use of iodine-131 (MIBG) on the patient in question was in accordance with both your NRC byproduct material license and your submitted protocol to the Food and Drug Administration. We, therefore, have no further questions regarding your use of iodine-131 (MIBG) in this particular case.

Subsequent, however, to our initial request of October 19, 1989, our office received additional allegations regarding the radiation safety aspects of your use of iodine-131 (MIBG) on the same patient. The allegations are summarized in the enclosure to this letter. We are requesting that you review the allegations, initiate an appropriate investigation, and take any actions you deem necessary and report your findings to the NRC within 30 days of the date of this letter. Your response should contain no personal privacy or proprietary information so that it can be placed in the NRC Public Document Room. If necessary, such information should be contained in a separate attachment which will be withheld from public disclosure and the affidavit required by 10 CFR 2.790(b) must accompany your response.

ENCLOSURE CONTAINS
10CFR2.790 INFORMATION
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The enclosure to this letter is considered Exempt from Public Disclosure in accordance with Title 10, Code of Federal Regulations, Part 2.790(a). However, a copy of this letter, excluding the enclosure, will be placed in the Public Document Room.

The response requested by this letter and the accompanying enclosure are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, PL 96-511.

If you have any questions related to our request, please contact Mr. Roy Caniano of my staff at (708) 790-5721.

Your cooperation is appreciated.

Sincerely,

Charles E. Norelius, Director
Division of Radiation Safety
and Safeguards

Enclosure: Summary of
Allegations
(10 CFR PART 2.790 INFORMATION)

cc w/o enclosure, w/ltr dtd
10/13/89:
DCD/DCB (RIDS)

RIII	RIII	RIII	RIII
Caniano/jl	Funk	Mallett	Norelius
11/28/89	11/28/89	11/28/89	11-28

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10CFR2.790 INFORMATION
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LETTER