U. S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 99990003/90009(DRSS)

Docket No. 99990003

License No. General License Registration No. 1305

Licensee: Joel I. Hamburger, M.D.
29877 Telegraph Road
Southfield, MI 40034

Inspection Conducted: August 3, 1990

Inspectors: Gary L. Shear for
Bryan A. Parker
Radiation Specialist
Date: 8/20/90

James L. Cameron
James L. Cameron
Radiation Specialist
Date: 8/17/90

Approved By: Gary L. Shear for
Roy J. Caniano, Chief
Nuclear Materials Safety
Section 2
Date: 8/20/90

Inspection Summary

Inspection Conducted on August 3, 1990 (Report No. 99990003/90009(DRSS))
Areas Inspected: This was an unannounced, special inspection conducted in response to information received by NRC Region III regarding the possession and use of byproduct material under the general license. The areas examined included a summary of events and interviews.
Results: One apparent violation was identified pertaining to the reception, possession, and use of byproduct material which is not labeled in accordance with the provisions of a specific license issued pursuant to 10 CFR 32.71.

## DETAILS

1. Persons Contacted

*Micheal Kaplan, M.D.
*Elaine Levine, Medical Technologist
*Sandy Richter, Nuclear Medicine Technologist
Mila Bednarz, Laboratory Manager

*Present at exit meeting held August 3, 1990

2. Summary of Events

From discussions with Mr. Thomas Kralian and Ms. Mila Bednarz, it was revealed that Dr. Hamburger is conducting a research project involving various, similar iodine-125 radioimmunoassay (I-125 RIA) kits. The purpose of the research is to compare the kits and conclude if one gives superior results over the others. The research involves using the kits for clinical diagnosis.

The discussions also revealed that Mr. Kralian has been providing one brand of I-125 RIA kit to Dr. Hamburger for use in the research for approximately four years at a rate of about 10 kits per month. This particular kit is manufactured in Yugoslavia by a company known as Kardon Nuclear. Kardon Nuclear does not have an authorized distributor in the United States.

Dr. Hamburger possesses a general license issued pursuant to 10 CFR 31.11 which allows him to possess and use I-125 RIA kits. The kits must contain less than 10 microcuries (uCi) of I-125 each, with a maximum total possession limit of 200 uCi. However, in order for the kits to be used under 31.11 (i.e. for clinical diagnosis), the kits must be manufactured or distributed by a licensee holding a specific license issued under the provisions of 10 CFR 32.71. The Yugoslavian kit provided by Mr. Kralian is used for clinical diagnosis, but is not manufactured or distributed under a specific license pursuant to 10 CFR 32.71. This constitutes an apparent violation of 10 CFR 31.11(d). The root cause for the violation appears to be a lack of knowledge on the part of the licensee that the material does not meet the specifications outlined in 10 CFR 31.11.

The licensee indicated that use of the unauthorized kit would cease immediately. Also, the remaining kits in their possession would be disposed of as soon as possible without being used.

With regard to the other requirements of the general license, no violations were identified. All of the kits are stored in their original containers and, except for the Yugoslavian kits, are labeled in accordance with 10 CFR 32.71. Dr. Hamburger's total possession of I-125 is less than 200 uCi and each individual kit contains less than 10 uCi.

All of the material is disposed in the sanitary sewer in accordance with Part 20. Also, the inspectors confirmed that the other RIA kits used in the research project are all distributed by a 10 CFR 32.71 licensee.

One violation of NRC requirements was identified.

3. Exit Meeting

Following the inspection, an exit meeting was held with those individuals indicated in Section 1. The scenario was explained to the licensee as were the findings of the inspection. NRC Enforcement Policy was also discussed. No information within this report was considered proprietary by the licensee.