U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 30-01379/86-002(DRSS)

Docket No. 030-01379 License No. 12-01257-04

Licensee: Mercy Hospital and Medical Center
Stevenson Expressway at King Drive
Chicago, IL 60616

Inspection Conducted: May 7 and 8, 1986

Inspector: T. L. Simmons T. L. Simmons June 10, 1986
Radiation Specialist Date

Approved By: D. J. Sreniawski, Chief D J Sreniawski June 11, 1986
Nuclear Materials Safety Date
Section 2

Inspection Summary

Inspection on May 7, 1986 through May 8, 1986 (Report No. 30-01379/86002(DRSS))
Areas Inspected: This was an unannounced special safety inspection initiated by an allegation. The subsequent special inspection included a review of procedures, records and interviews of personnel.
Results: Of the areas inspected, one violation was identified: License Item No. 7.G in vitro material used in a form other than prepackaged kits.

DETAILS

1. Persons Contacted

Kate De Mille, Administrative Director of Pathology and Nuclear Medicine
Robert Surbaugh, Pathology Supervisor
Lucita De Rong, Laboratory Technologist
Frances Wasowicz, Laboratory Technologist
James Kissane, M.S., Senior Scientist, Research Department
Henry Huang, PhD, Senior Research Scientist
J. M. Liu, M.S., Assistant Research Scientist
D. Abrams, Researcher

2. Purpose of Inspection

This was an unannounced special inspection concerning allegations of unauthorized use of iodine -125 for in vitro purposes.

3. Specific Allegations and NRC Findings

a. Allegation: The research department has been utilizing iodine -125 in their radioimmunoassay (RIA) procedure in violation of the NRC license conditions.

Findings: Items No. 6.G. and 9.G. of the Mercy Hospital and Medical Center specific NRC license authorize the possession and use for in vitro purposes of any byproduct material listed in Section 31.11(a) of 10 CFR 31. Iodine -125 is one of several nuclides listed in Section 31.11(a). The licensee routinely used iodine-125 in diagnostic tests which is authorized by their license.

This allegation was not substantiated. No violation was identified.

b. Allegation: Mercy Hospital has used iodine -125 kits for their radioimmunoassay (RIA) procedure for only the last four months. Prior to that time Mercy Hospital obtained byproduct material in bulk form.

Findings: There are two areas at Mercy Hospital and Medical Center where RIA procedures are performed. Both departments use iodine -125.

RIA Diagnostic Laboratory: According to Mr. R. Surbaugh, Pathology Supervisor and Ms. L. De Rong, RIA technologist, prepackaged kits containing iodine -125 have been used in diagnostic testing since 1977. A review of receipt and use records from 1977 through the present indicated that iodine -125 had been purchased from various vendors in forms and quantities well within licensed constraints. A physical inventory was performed during this inspection. The licensee had in storage and in use a total of 300 microcuries of iodine -125 all of which was in prepackaged in vitro kits.

Research Department: Dr. H. Huang, Senior Research Scientist and Mr. J. Liu, Assistant Research Scientist have performed RIA procedures using iodine labeled compounds obtained from Northwestern University since February 1984. The compounds, which are protein hormones, are

labeled at Northwestern University by Mr. Liu. The iodinated protein is brought to Mercy Hospital and Medical Center Research Department for in vitro assay. The typical yield from the labeling procedure is 100 microcuries. This procedure has been performed nine times since February 1984. According to Dr. Huang and Mr. J. Kissane, Senior Research Scientist, the Research Department occasionally performs assays for the University in exchange for the use of its facilities. The use and quantities of iodine -125 handled by the Research Department are within licensed limits, however, the form of the byproduct material used is in violation of License Item No. 7.G. which requires that byproduct material used for in vitro purposes to be in the form of prepackaged kits.

In December 1985, several prepackaged kits containing a total of 120 microcuries of iodine where purchased by the Research Department from a vender. This purchase was within license constraints.

Bulk or free iodine has not been used by either department since at least 1978.

This allegation was substantiated in that the Research Department has only recently began to use prepackaged kits and that iodine -125 has been used in a form other than the one specified by the license.

One violation was identified.

4. Exit Interview

On May 20, 1986, separate telephone exit interviews were conducted with Dr. Hawrylewicz, Director of Research and Sister Dorothy Burns, Vice-President to discuss the allegations, NRC findings, and the licensees corrective actions. Corrective action includes using only that material authorized by the license or amending the license to reflex the form of iodine-125 used by the Research Department.