ENCLOSURE 2

U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	30-31200
License No.:	53-23297-01
Report No.:	30-31200/96-01
Licensee:	Kapi'olani Health Care System
Facility:	Kapi'olani Medical Center at Pali Momi and the Kapi'olani Medical Center for Women and Children including the Cytogenetics Laboratory
Location:	Honolulu, Hawaii
Dates:	November 18 through December 9, 1996
Inspector:	E. M. Garcia, Sr. Radiation Specialist
Approved By:	L. L. Howell, Chief Nuclear Materials Inspection and Fuel Cycle/Decommissioning Branch Division of Nuclear Materials Safety
Attachment:	Supplemental Inspection Information

EXECUTIVE SUMMARY

Kapi'olani Health Care System
Honolulu, Hawaii
NRC Inspection Report 30-31200/96-01

This routine inspection identified one apparent violation and one violation which is described in the letter transmitting the inspection report and in a Notice of Violation issued concurrently with this report. This inspection report is limited to discussion of an apparent violation identified during the inspection as noted below.

Kapi'olani Health Care System is authorized under NRC License 53-23297-01 to perform diagnostic and therapeutic nuclear medicine procedures at two hospitals. In addition, the license authorizes use of byproduct material at three laboratory facilities. Use of licensed materials in the laboratory facilities includes phosphorus-32 and sulfur-35 as labeled compounds in a deoxyribonucleic acid (DNA) laboratory, a cesium-137 sealed source in a blood irradiator, and iodine-125 in radioimmunoassay (RIA) kits. The licensee had nine authorized medical users and two authorized non medical users.

SECURITY OF STORED MATERIAL

- Security of licensed material in the nuclear medicine departments at both the Kapi'olani Pali Momi and Kapi'olani Women and Children Hospitals appeared adequate to prevent unauthorized access.

- Microcurie quantities of iodine-125 and phosphorus-32 stored at the RIA and DNA laboratories were not secured from unauthorized access or removal. This was identified as an apparent violation of Condition 20.E of NRC License 53-23297-01.

Report Details

1 **Security of Stored Material (83822, 87000, 87101)**

a. Scope of Inspection

During site visits on November 18 through 20, 1996, the inspector toured the licensee's facilities to observe the control of access to license material.

b. Observations and Findings

During tours at Kapi'olani Pali Momi Hospital and Kapi'olani Women and Children Hospital the inspector noted that licensed materials stored in the nuclear medicine departments were secured when the areas were not occupied or under direct surveillance. When not in storage, licensed materials were observed to be under constant surveillance of a nuclear medicine authorized user (AU) or a technologist. However, licensed materials stored in the RIA and DNA laboratories were not provided with the same level of security.

The RIA laboratory is located in the Kapi'olani Women and Children Hospital in a designated room within the main hospital laboratory. The Kapi'olani Women and Children Hospital laboratory includes a number of other rooms and is occupied by members of the public that are either patients, individuals accompanying patients, or hospital personnel not assigned work with licensed material. In order to provide security for licensed materials routinely stored within the RIA laboratory, the door was equipped with a lock and procedural controls were established by the licensee. Specifically, in an attachment to a letter dated August 29, 1996, describing procedures for the RIA laboratory, the licensee stated "the RIA Laboratory will be locked when not occupied." This letter was enclosed with the license application and is incorporated by reference in License Condition 20.E.

On November 18, 1996, when touring the hospital laboratory with a nuclear medicine AU, the inspector observed that the room designated as the RIA laboratory was unoccupied, and the laboratory entrance door was unlocked. The inspector and the AU entered the RIA laboratory and found that licensed materials in the form of RIA kits were stored in an unlocked refrigerator. On November 20, 1996, the inspector again toured the Women and Children Hospital laboratory, this time accompanied by the radiation safety officer (RSO). The inspector again found the RIA laboratory unoccupied, the room door unlocked, and licensed material stored in an unlocked refrigerator. After a few minutes, a technologist returned to the room. During discussions about why the room had been left unsecured, the technologist stated that she had not realized that the room needed to be locked. She also indicated that at that time there were approximately 195 microcuries of iodine-125 stored in the RIA laboratory.

The inspector also toured the cytogenetics laboratory which is located a few blocks from the main building of the Kapi'olani Women and Children Hospital. A number of researchers work in this laboratory, although not all of these individuals are assigned work with licensed material. Only two technicians and the director of the

laboratory work with licensed material. Within the cytogenetics laboratory, licensed material had only been used in the DNA laboratory, which is a separate room within the main cytogenetics laboratory. The licensee had also established physical and procedural controls for the DNA laboratory. The door to the DNA laboratory was equipped with a lock to control access. In addition, Attachment 9.1 to the licensee's August 29, 1996, letter states, in part, that the "DNA Laboratory will be locked when not occupied." Also, Attachment 10.16, in the section titled "DNA Laboratory Operation Procedures," states "the room shall be kept locked when not occupied."

On November 19, 1996, while inspecting licensed activities performed in the DNA laboratory, the inspector observed a custodian emptying waste baskets inside the DNA laboratory. The custodian subsequently informed the inspector that he and his supervisor often performed custodial work in the cytogenetics laboratory, including the DNA laboratory, after normal work hours when the researchers had left for the day. The custodian stated that during the week prior to the inspection, the door to the DNA laboratory was open and that he or his supervisor had mopped the floor and cleaned the sink in the DNA laboratory. The director of the cytogenetics laboratory later indicated that the sink in the DNA laboratory had been used for the disposal of licensed material to the sanitary sewer. The inspector's observations and information provided by the custodian were subsequently discussed with the RSO and laboratory director. The inspector emphasized the need for compliance with procedure requirements intended to ensure that licensed material was adequately secured.

On November 20, 1996, the inspector again visited the cytogenetics laboratory and found that the DNA laboratory was unoccupied, and the door was unlocked and open. A technologist assigned to work with licensed material was in the adjacent laboratory. When questioned about why the door to the DNA laboratory was left unsecured, the technologist stated that she had not realized that she needed to lock the room when she left it. Inventory records of licensed materials in the room, including material in the solid radioactive waste container, indicated that there were approximately 476 microcuries of phosphorus-32 stored in the laboratory.

Condition 20.E of NRC License 53-23297-01 requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in the application and the letter dated August 29, 1996, including any enclosures. Paragraph 2 of Attachment 9.1 of the letter states, in part, that "the DNA laboratory will be locked when not occupied." In addition, Attachment 10.6, at the section titled "DNA Laboratory Operation Procedures," states "the room shall be kept locked when not occupied." Paragraph 2 of the section on the RIA laboratory in the licensee's August 29, 1996, letter states, in part, that "the RIA laboratory will be locked when not occupied." The licensee's failure to lock or otherwise secure the DNA and RIA laboratories when not attended by licensee personnel was identified as an apparent violation of License Condition 20.E (030-31200/9601-01).

Subsequent to the onsite portion of the inspection, the licensee submitted to

Region IV staff a letter dated November 21, 1996, describing the immediate corrective actions taken to ensure security of licensed material. These actions included:

1. Enforcement of the "locked when not occupied" policy for the RIA and DNA laboratories;

2. Providing instruction to all RIA and DNA staff regarding the policy;

3. Requiring written acknowledgment of the instruction by each staff member;

4. Implementing a disciplinary policy for failures to comply with the above noted instructions;

5. Implementing unannounced checks, by the RSO, to verify compliance with the policy within the week, and requiring reports of the RSO's findings to the senior vice president; and

6. Reviewing the internal audit program to identify how it can be strengthened.

1.3 Conclusions

Security of licensed materials in the nuclear medicine departments at both the Kapi'olani Pali Momi and Kapi'olani Women and Children Hospitals was adequate to prevent unauthorized access or removal of licensed material. However, microcurie quantities of iodine-125 and phosphorus-32 stored in the RIA and DNA laboratories were not secured from unauthorized access or removal. This was identified as an apparent violation of License Condition 20.E. At the conclusion of the site visit, licensee management implemented corrective actions, including enforcement of an existing "locked when not occupied" policy for areas where licensed materials are stored and implementation of additional checks of areas where radioactive materials are stored to verify that the areas are secured.

Exit Meeting Summary

On November 20, 1996, at the conclusion of the site visit, the inspector conducted a preliminary exit briefing with licensee representatives. A telephonic exit briefing was subsequently conducted on December 9, 1996, with licensee management. The inspector discussed the inspection findings and the NRC Enforcement Policy. Licensee representatives acknowledged the findings as presented and stated that they had initiated extensive corrective actions to address the problems identified.

The inspector asked licensee representatives present during the telephonic exit briefing whether any material examined during the inspection should be considered proprietary, and licensee representatives acknowledged that no proprietary information was reviewed during the inspection.

ATTACHMENT
SUPPLEMENTAL INSPECTION INFORMATION

PARTIAL LIST OF PERSONS CONTACTED

Kapi'olani Health Care System

John Jeffries, Senior Vice President Administration
Alice Deppe, Director Imaging
Philip Manly, Radiation Safety Officer
Harry Skidmore, Administrator in Charge of Cytogenetics Division
Peter Robbins, M.D., Nuclear Medicine Physician
Herbert Uemura, M.D., Director of Laboratories at Women and Children Hospital (WAC)
Timothy Donlon, Ph.D., Director, Molecular and Cytogenetics Laboratory
John Gross, Laboratory Manager WAC
Sandra Mozingo, Nuclear Medicine Technologist WAC
Fred Ushijima, Lead Nuclear Medicine Technologist at Pali Momi Hospital (PM)
Audrey Leonillo-Marsh, Nuclear Medicine Technologist PM
Lucia Lum, Blood Irradiator Technologist
Ada Terao, Medical Technologist Radioimmunoassay (RIA) Laboratory
Christine Kuslich, Molecular Genetics Technologist
Allison Eberly, Cytogenetics Technologist
Shaun Osato, Custodian

INSPECTION PROCEDURES USED

IP 83822:	Radiation Protection
IP 87100:	Licensed Materials Programs
IP 87101:	Performance Evaluation Factors

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-31200/9601-01	APV	Failure to control access to licensed materials stored in the RIA and DNA laboratories

LIST OF ACRONYMS USED

APV	Apparent Violation
AU	Authorized User
DNA	Deoxyribonucleic Acid
IP	Inspection Procedure
NRC	Nuclear Regulatory Commission
RIA	Radioimmunoassay