



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-4005

January 25, 2005

EA-04-194

James Gaines, Ph.D., Vice President of Research
University of Hawaii at Manoa
Office of the President
Bachman 204
2444 Dole Street
Honolulu, Hawaii 96882

SUBJECT: NRC INSPECTION REPORT 030-07113/04-001 AND OI INVESTIGATION
REPORT 4-2004-008

Dear Dr. Gaines:

This refers to the inspection conducted on March 15-18, 2004, at your facility in Honolulu, Hawaii. This inspection was an examination of activities conducted under your license as they relate to safety and compliance with the Commission's rules and regulations and with the conditions of the license. Within these areas, the inspection consisted of selective examination of procedures and representative records and interviews with personnel. The enclosed report presents the results of the inspection. (Enclosure 1) The preliminary inspection findings were discussed with Messrs. Takekawa, Sakimoto, Kramer, and Moy of your staff on March 18, 2004. Additionally, an investigation by the NRC Office of Investigations was initiated on April 5, 2004. A final telephonic exit meeting was conducted with you and other members of your staff on January 24, 2005.

Based on the results of this inspection, one apparent violation was identified and is being considered for escalated enforcement action in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600. The apparent violation involves the failure to secure from unauthorized access, licensed material that was stored in controlled areas. The apparent violation is of particular concern because it may have involved willful action on the part of licensee personnel. OI Report 4-2004-008 concluded that a member of the University of Hawaii at Manoa staff willfully failed to secure from unauthorized access, licensed material that was stored in controlled areas. A Factual Summary of the investigation is included as Enclosure 2.

The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **What We Do, Enforcement**, then **Enforcement Policy**. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective action were discussed with you and members of your staff during the final exit meeting on January 24, 2005. As a result, it may not be necessary to conduct a predecisional enforcement conference in order to enable the NRC to make an enforcement decision.

Before the NRC makes its enforcement decision, we are providing you an opportunity to either: (1) respond to the apparent violation addressed in this inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference. If a conference is held, it will be closed to public observation. The NRC will also issue a Meeting Notice to announce the conference. Please contact Mr. Jeffrey Cruz at (817) 860-8287 within 7 days of the date of this letter to notify the NRC of your intended response.

If you choose to provide a written response, it should be clearly marked as a "Response to An Apparent Violation in Inspection Report 030-07113/04-01; EA-04-194" and should include for each apparent violation: (1) the reason for the apparent violation, or, if contested, the basis for disputing the apparent violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. In presenting your corrective action, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the enclosed excerpt from NRC Information Notice 96-28 (Enclosure 3), "SUGGESTED GUIDANCE RELATING TO DEVELOPMENT AND IMPLEMENTATION OF CORRECTIVE ACTION," may be helpful. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a predecisional enforcement conference.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results of our deliberations on this matter.

Instead of a predecisional enforcement conference, you also may request alternative dispute resolution (ADR) with the NRC (Enclosure 4). Alternative dispute resolution is a general term encompassing various techniques for resolving conflict outside of court using a neutral third party. The technique that the NRC has decided to employ during a pilot program which is now in effect is mediation. In mediation, a neutral mediator with no decision-making authority helps parties clarify issues, explore settlement options, and evaluate how best to advance their respective interests. The mediator's responsibility is to assist the parties in reaching an agreement. However, the mediator has no authority to impose a resolution upon the parties. Mediation is a confidential and voluntary process. If the parties to the ADR process (the NRC and the licensee/individual) agree to use ADR, they select a mutually agreeable neutral mediator and share equally the cost of the mediator's services. Generally, the NRC is willing to discuss the resolution of three potential issues: 1) whether a violation occurred; 2) the appropriate enforcement action; and 3) the appropriate corrective actions for the violation(s).

Additional information concerning the NRC's pilot program can be obtained at <http://www.nrc.gov/what-we-do/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC's program as an intake neutral. Intake neutrals perform several functions, including: assisting parties in determining ADR potential for their case, advising parties regarding the ADR process, aiding the parties in selecting an appropriate mediator, explaining the extent of confidentiality, and providing other logistic assistance as necessary. Please contact ICR at 877-733-9415 within 10 days of the

date of this letter if you are interested in pursuing resolution of this issue through ADR. You may also contact Nick Hilton, Office of Enforcement, at 301-415-3055 for additional information.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, Enclosures 1 & 2, and your response (if any) will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/Adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction.

Please note that on October 25, 2004, the NRC suspended public access to ADAMS, and initiated an additional security review of publicly available documents to ensure that potentially sensitive information is removed from the ADAMS database accessible through the NRC's web site. Interested members of the public may obtain copies of the referenced documents for review and/or copying by contacting the Public Document Room pending resumption of public access to ADAMS. The NRC Public Document Room is located at NRC Headquarters in Rockville, MD, and can be contacted at 800-397-4209 or 301-415-4737 or pdr@nrc.gov.

Sincerely,

/RA/

Charles L. Cain, Acting Director
Division of Nuclear Materials Safety

Docket No.: 030-07113
License No.: 53-00017-09

Enclosures:

1. NRC Inspection Report 030-07113/04-001
2. Factual Summary of Office of Investigations Report 4-2004-008
3. NRC Information Notice 96-28
4. Post-Investigation ADR Program

cc w/Enclosures 1 & 2:
Hawaii Radiation Control Program Director

Irene Sakimoto, Radiation Safety Officer
University of Hawaii at Manoa
Environmental Health and Safety Office
Radiation Safety Program
2040 East-West Road
Honolulu, Hawaii 96822

University of Hawaii at Manoa

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Kenton Kramer, Ph.D.
Chair - Radiation Safety Committee
University of Hawaii at Manoa
Bachman 204
2444 Dole Street
Honolulu, Hawaii 96882

bcc w/Enclosures 1 & 2 via ADAMS:

JCruz
 FJCongel, OE
 CLMiller, NMSS
 GFSanborn
 HAFreeman
 KSFuller
 CLCain
 JEWhitten
 RRErickson
 MLBurgess, NMSS
 GKMorell, OE
 NMIB File
 OEMail
 SLMerchant, OE
 RIV File (5th Floor)

SISP Review Completed: rre

ADAMS: X Yes No Initials: RRE

Publicly Available Non-Publicly Available Sensitive Non-Sensitive

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GFSanborn*	CLCain	
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01/06/05	01/25/05	

*Previously concurred OFFICIAL RECORD T=Telephone E=E-mail F=Fax

ENCLOSURE 1

U.S. Nuclear Regulatory Commission
Region IV

Docket No.: 030-07113
License No.: 53-00017-09
Report No.: 030-07113/04-01
EA No.: 04-194
Licensee: University of Hawaii at Manoa
Facility: Hawaii Research Irradiator
Food Technology Building
Location: Honolulu, Hawaii
Dates: March 15, 2004 through January 24, 2005
Inspector: Randy R. Erickson, Health Physicist
Nuclear Materials Inspection Branch
Approved By: Jeffrey Cruz, Chief
Nuclear Materials Inspection Branch
Attachment: Supplemental Inspection Information

EXECUTIVE SUMMARY

University of Hawaii at Manoa (UHM)
Hawaii Research Irradiator
NRC Inspection Report 030-07113/04-001

This was a routine, unannounced inspection of licensed activities involving the use of byproduct material for teaching and research activities at the UHM Hawaii Research Irradiator. The scope of the inspection was limited to direct observation of the irradiator facility and interviews with licensee personnel.

Program Overview

- On the date of the inspection, the University of Hawaii at Manoa (UHM) was authorized under NRC License 53-00017-09 to use byproduct material for irradiation of materials in a modified Brookhaven National Laboratories designed Mark IV research food irradiator located in the Food Technology Building on the UHM main campus. Access to and use of the irradiator, in addition to all teaching and research activities involving the irradiator, were under the exclusive control of the principal investigator (PI) until March 18, 2004, when the irradiator was formally placed into possession and storage only status at the request of UHM administration.

Security of Licensed Material

- On March 15, 2004, during a routine inspection of the UHM broad scope license, a university staff member approached an NRC inspector and stated that on March 17, 2003, in order to have light bulbs replaced in the irradiator room in his absence, he disabled the combination lock on the door to the irradiator room and disengaged the alarm system on the irradiator door so that a UHM maintenance worker could enter and replace the bulbs. He then left the facility to attend to another appointment. The PI stated that over his 37 years with the university, when light bulbs needed to be replaced, he would disable the lock on the door and disengage the alarm system so that light bulbs could be replaced when he was not present. This was identified as an apparent violation of 10 CFR 20.1801 (Section 2).

Licensee Corrective Actions

- After the licensee discovered the unlocked irradiator door, the university ordered a 24-hour guard posted to the irradiator facility until the electronic security system could be redirected from the phone system to the fire alarm system. Immediately following the discovery, the PI was called to administration to explain his activities, provide written documentation of the event, and was then verbally reprimanded by the university. On January 7, 2004, the university requested a license amendment to remove the PI from his position as radiation safety officer (RSO) and installed the broad scope license RSO as the new irradiator RSO. The university also asked to formally place the irradiator into storage only status. This was granted by the NRC on March 18, 2004. The sources contained in the irradiator are scheduled to be removed in March 2005, after which the facility is scheduled to be formally decommissioned and closed. (Section 3).

Report Details

1 Program Overview (87122)

1.1 Inspection Scope

The inspector reviewed the license application, supporting documents, and other records maintained by the licensee. Collectively, these documents describe the licensee's radiation safety program. Interviews with licensee personnel were also conducted.

1.2 Observations and Findings

On the date of the inspection, the University of Hawaii at Manoa (UHM) was authorized under NRC License 53-00017-09 to use byproduct material for irradiation of materials in a modified Brookhaven National Laboratories designed Mark IV research food irradiator located in the Food Technology Building on the UHM main campus. Access to and use of the irradiator, in addition to all teaching and research activities involving the irradiator, were under the exclusive control of the principal investigator until March 18, 2004, when the irradiator was formally placed into possession and storage only status at the request of UHM administration.

2 Security of Licensed Material

2.1 Inspection Scope

The inspector's review of this program area included interviews with licensee personnel, direct observation of licensed activities, and the review of procedures and records associated with the receipt and handling of licensed material.

2.2 Observations and Findings

10 CFR 20.1801 requires, in part, that the licensee secure from unauthorized access, licensed materials that are stored in controlled or unrestricted areas. As defined in 10 CFR 20.1003, *controlled area* means an area, outside of a restricted area but inside the site boundary, access to which can be limited by the licensee for any reason. 10 CFR 30.34(a) requires, in part, that the licensee comply with the terms and conditions of the license. License Condition 15A requires, in part, that the licensee will comply with the provisions described in the licensee's application and standard operating procedures dated February 1, 2001. Specifically on Page 3 in the section entitled "Facility Operation", licensee personnel are required to lock the irradiator room with a combination lock at all times when not in use, and requires operators to secure and lock access to the room whenever they were not actually in the area.

On March 15, 2004, during a routine inspection of the UHM broad scope license, the radiation safety officer (RSO) informed the inspector that the university had recently requested an amendment to place the irradiator which was licensed under a separate NRC license, into "storage only" status. The RSO stated that the university was working

with U.S. Department of Energy (DOE) to assist with the disposal of the remaining 1100 curies of cobalt-60 still contained within the irradiator. The inspector then reviewed the physical layout of the irradiator to determine the status of ongoing activities.

During a walk-through of the irradiator facility, the principal investigator (PI) and formerly the irradiator license RSO, told the inspector that he was opposed to the shut down of the irradiator facility, and felt that its closure was to punish him for an incident that happened approximately 1 year earlier. The inspector asked the former RSO to describe the incident.

The PI stated that in early March 2003, he had asked to have two light bulbs in the irradiator room replaced. He added that on March 17, 2003, a UHM maintenance worker came to the irradiator facility, and after confirming the work to be done, placed his ladder in the irradiator room, then left the facility to get the proper bulbs so he could complete the task. The maintenance worker didn't immediately return, so the PI, needing to leave the campus for an appointment, made the decision to disable the combination lock on the door to the irradiator room, leaving it unlocked, then disengaged the alarm system on the irradiator door allowing the maintenance worker to gain access to the facility. The PI locked the door to the office area of the irradiator facility because he was aware the maintenance worker had a pass key that would allow him access to that portion of the facility, and that he could then re-enter through the unlocked irradiator door to complete the job. The PI did not lock the outer doors to the irradiator facility when he left.

During the absence of the PI, officers from the Honolulu Police Department were on campus conducting unescorted security inspections for the Department of Homeland Security. NRC's Office of Investigations (OI) determined through interviews with campus and police department officials, that police officers found an unlocked door in another building on campus. This door was required to be locked so the police notified the university president of their findings. At some point, a mis-communication appears to have taken place, because in response to the police department findings, the Chief of Staff was dispatched by the university president to the irradiator building to investigate. The Chief of Staff found the outside entrance to the irradiator building unlocked and stated that when he entered the building, he found a door that he described as the irradiator door, to be locked. It is unclear if the door he found locked was the irradiator room door or the locked office door. However, believing the door found open by the police department was the irradiator room door, university administration summoned the PI the next day and questioned him about the event. The PI admitted to disabling the lock on the door and disengaging the security alarm so the maintenance worker could replace the bulbs. The PI documented the event at the request of administration having been told that the police department had found the irradiator door open, when in fact it was determined that leaving the door to the irradiator open was discovered by chance events.

The PI also told OI that when he left the building at approximately 12:30 p.m., he had left the irradiator door open and disengaged the combination lock and security system to allow maintenance in, and added that he had locked the door to the office area because he was aware that maintenance had a passkey to that area and could change the light while he was gone. The PI initially told the inspector on March 15, 2004, that when he

returned to the irradiator, he found the building as he had left it. He added that upon his return, he locked the doors and reset the alarm system.

The day the unlocked irradiator door was discovered, the university immediately posted a 24-hour guard to the building until the electronic security system could be re-wired. Originally, the security system had been wired into the phone system. The phone in the radiation safety office would ring if a breach were detected, however, if nobody was in the radiation safety office, no one would get the call and any breach would go undetected. After this event, the security system was re-routed through the fire alarm system so it could be monitored 24 hours per day by the security department. Re-routing the security system took 3 days, after which the security guard was taken off the building. The day after the event, the PI was called to administration to explain his activities and provide written documentation of the event. The PI was verbally counseled by the university. No further specific actions were taken against the irradiator facility PI at that time, nor was the issue discussed at any radiation safety committee meeting. Sometime later, a decision was ultimately made to decommission the irradiator.

During the investigation, the PI informed the OI investigator that in over 37 years working with the irradiator, he had on several occasions over that time-span, left the irradiator unlocked when light bulbs needed to be replaced just as he had on this occasion.

The failure of the licensee to secure from unauthorized access, licensed material that were stored in controlled areas was identified as a violation of 10 CFR 20.1801, and the licensee's Standard Operating Procedures. (030-07113/0004-01).

2.3 Conclusions

One violation was identified regarding the failure of the licensee to secure from unauthorized access, licensed materials that are stored in controlled or unrestricted areas.

3 **Licensee Corrective Actions (87122)**

3.1 Inspection Scope

The inspector's review of the licensee's corrective actions included interviews with the UHM radiation safety officer, the PI, the director of the environmental health and safety office, the radiation safety committee chair, UHM security department staff, as well as other members of the licensee's technical staff.

3.2 Observations and Findings

After discovering the unlocked irradiator door, the university ordered a 24-hour guard posted to the irradiator facility until the electronic security system could be re-directed from the phone system to the fire alarm system. Originally, the security system had been connected to the phone system. This would cause the phone to ring in the radiation safety office if a security breach were detected. However, if nobody was in the

radiation safety office when that call came in, the call would go unanswered. After this event, the security system was permanently re-directed through the fire alarm system so it could be monitored 24 hours per day by the security department. Re-routing the security system took 3 days, after which the security guard was taken off the building. The day after the event, the PI was called to administration to explain his activities, provide written documentation of the event, and was then verbally reprimanded by the university. No further specific actions were taken against the irradiator facility PI. In a letter dated January 7, 2004, the university requested a license amendment to remove the PI from his position as RSO and install the broad scope license RSO as the new irradiator RSO. The university also asked to formally place the irradiator into storage only status. The combination lock to the irradiator room door was changed and distribution of the combination was limited to the radiation safety program, the College of Tropical Agriculture, and Human Resources administrators. After coordinating with DOE for removal of the sources, the irradiator facility will formally be decommissioned and closed. A subsequent telephonic conversation with university representatives determined that the sources are scheduled for removal by the end of December 2004. Following removal, the building will be decommissioned and closed and the license will be terminated.

3.3 Conclusions

The licensee's corrective actions included: 1) posting a guard to the building while the alarm system was redirected from the phone system to the fire alarm system so it could be more closely monitored, 2) verbally reprimanding the PI, 3) removing the PI as the license RSO, and; 4) placing the irradiator into storage only status with decommissioning and closure of the irradiator by the end of March 2005.

4 **Exit Meeting Summary**

A preliminary site exit briefing was conducted on March 18, 2004. A final telephonic exit meeting was conducted with the Interim President and other members of the licensee's staff on January 24, 2005. Licensee representatives acknowledged the inspector's findings. No proprietary information was identified.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Licensee

James Gaines, Ph.D., Vice President of Research
James H. Moy, Ph.D., Principal Investigator and Former Radiation Safety Officer
Irene Sakimoto, Radiation Safety Officer
Nancy Miyake, Radiation Safety Specialist
Bradley Smith, Radiation Lab Technician
Roy Takekawa, Director, Environmental Health And Safety Office
Donald F. Dawson, Captain, Campus Security
Bob Shinagawa, Maintenance Department
Wayne Fujishige, Chief of Staff
Irineo Gappe, Jr., Safety Specialist

INSPECTION PROCEDURES USED

83822 Radiation Protection
87122 Irradiator Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-07113/0004-01 APV A failure to secure from unauthorized access, licensed material that was stored in controlled areas was identified as an apparent violation of 10 CFR 20.1801.

Closed

None

Discussed

None

LIST OF ACRONYMS USED

CFR Code of Federal Regulations
DOE Department of Energy
NRC Nuclear Regulatory Commission
OI Office of Investigations
PI Principal Investigator
RSO Radiation Safety Officer
UHM University of Hawaii at Manoa
APV Apparent Violation

ENCLOSURE 2

Factual Summary Office of Investigations Report 4-2004-008 University of Hawaii at Manoa

This investigation was initiated by the NRC's Office of Investigations (OI) in April 2004 and involved an apparent violation of NRC requirements regarding the security of NRC-licensed radioactive material. The purpose of the investigation was to determine whether the apparent violation, which involved a failure to secure access to the university's irradiator facility, was committed willfully. The irradiator was a small pool irradiator which contained approximately 1,100 curies of cobalt-60. The apparent violation, which occurred in March 2003, was brought to the NRC's attention during a March 2004 routine inspection at the university.

The investigation found that on March 17, 2003, a professor responsible for the irradiator facility placed a request to have two burned-out fluorescent lights replaced in the irradiator room. A maintenance employee came to replace the lights but left to obtain supplies. The professor had business elsewhere, so he left the door to the facility and door to the irradiator room unlocked to allow the maintenance employee to return to replace the lights.

Leaving the irradiator facility unlocked and unattended violated NRC requirements in 10 CFR 20.1801 and 20.1802 regarding the security and control of licensed radioactive material, and violated licensee procedures that required the irradiator room to be locked with a combination lock at all times when not in use, and required operators to secure and lock access to the room whenever they were not actually in the area. A review of the professor's educational credentials, training history, and work history indicated that he was very experienced in radiation safety matters. In fact, at the time of the apparent violation, he was the university's radiation safety officer for the irradiator facility. The investigation found that the professor willfully violated NRC requirements when he left the facility unlocked and unattended.