



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION IV  
1600 EAST LAMAR BOULEVARD  
ARLINGTON, TEXAS 76011-4511

September 21, 2022

EA-22-053

Stephanie Whalen  
Executive Director  
Hawaii Agriculture Research Center  
P.O. Box 100  
Kunia, HI 96759

SUBJECT: HAWAII AGRICULTURE RESEARCH CENTER NRC INSPECTION  
REPORT 030-06839/2022-001

Dear Stephanie Whalen:

This letter refers to the announced routine inspection that was performed on April 8, 2022, at your facility in Waipahu, Hawaii. The inspection continued with in-office review through July 28, 2022. The inspection was conducted to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission (NRC) rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observation of licensed activities and facilities, independent radiation measurements, and interviews with personnel. The enclosed report presents the results of this inspection. The inspector discussed the preliminary inspection findings with Dr. Blake Vance, Assistant Director, Dr. Ming-Li Wang, Biologist, and Ronald Frick, Radiation Safety Officer, on April 8, 2022, at the conclusion of the onsite portion of the inspection. A final exit briefing was conducted via videoconference with Dr. Vance and Ronald Frick on August 22, 2022.

Based on the results of this inspection, seven apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy.

The current Enforcement Policy is included on the NRC website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violations involve your:

(1) ownership and possession of byproduct material not authorized in a specific license, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 30.3(a); (2) failure to inventory all radioactive materials in storage every 6 months, as required by license condition 15 of License No. 53-00515-01, Amendment No. 75; (3) failure to perform a test for leakage and/or contamination of stored sealed sources, as required by license condition 13.B of License No. 53-00515-01, Amendment Nos. 73, 74, 75; (4) failure to conduct monthly radiation and wipe surveys in an area where radioactive materials were stored, as required by license condition 15 of License No. 53-00515-01, Amendment No. 75; (5) failure to periodically (at least annually) review the radiation protection program content and implementation, as required by 10 CFR 20.1101(c); (6) failure to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures of its license application, as required by license condition 15 of License No. 53-00515-01,

Amendment No. 75; and (7) failure to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance, as required by 10 CFR 20.1101(a). The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with Dr. Vance and Ronald Frick during the videoconference exit meeting on August 22, 2022.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in the inspection report within 30 days of the date of this letter; (2) request a predecisional enforcement conference (PEC); or (3) request alternative dispute resolution (ADR). If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference. Please contact Dr. Lizette Roldán-Otero, Chief, Materials Inspection Branch, at 817-200-1455 or [Lizette.Roldan-Otero@nrc.gov](mailto:Lizette.Roldan-Otero@nrc.gov) within 10 days of the date of this letter to notify the NRC of your intended response to either provide a written response, participate in a PEC, or pursue ADR. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report 030-06839/2022-001; EA-22-053" 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; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. Your written response, should you choose to provide one, should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with identical copies mailed to Mary Muessle, Director, Division of Radiological Safety & Security, Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011, and emailed to [R4Enforcement@nrc.gov](mailto:R4Enforcement@nrc.gov) within 30 days of the date of this letter. 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 PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. In presenting your corrective actions, 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 NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response (Agencywide Documents Access and Management System (ADAMS) Accession No. ML061240509).

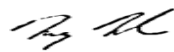
In lieu of a PEC or written response, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC employs is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC's ADR program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact the Institute on Conflict Resolution 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.

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 on our deliberations in this matter.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, and its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Dr. Lizette Roldán-Otero of my staff at 817-200-1455.

Sincerely,



Signed by Muessle, Mary  
on 09/21/22

Mary C. Muessle, Director  
Division of Radiological Safety & Security

License No.: 53-00515-01  
Docket No.: 030-06839

Enclosure:  
NRC Inspection Report 030-06839/2022-001

cc w/Enclosure:  
Thomas Lileikis, Chief  
Indoor and Radiological Health Branch  
State Department of Health  
99-945 Halawa Valley Street  
Aiea, HI 96701

# HAWAII AGRICULTURE RESEARCH CENTER NRC INSPECTION REPORT 03006839/2022-001 - DATED SEPTEMBER 21, 2022

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**U.S. NUCLEAR REGULATORY COMMISSION  
REGION IV**

Docket No.:	030-06839
License No.:	53-00515-01
Inspection Report No.:	030-06839/2022-001
EA No.:	EA-22-053
Licensee:	Hawaii Agriculture Research Center (HARC)
Location Inspected:	HARC Kunia Substation 94-340 Kunia Road Waipahu, Hawaii 96797
Inspection Dates:	April 8, 2022; continued in-office review through July 28, 2022
Exit Meeting Date:	August 22, 2022
Inspector:	Janine F. Katanic, PhD, CHP Senior Health Physicist Materials Inspection Branch Division of Radiological Safety & Security, Region IV
Approved by:	Lizette Roldán-Otero, PhD Chief, Materials Inspection Branch Division of Radiological Safety & Security, Region IV
Attachment:	Supplemental Inspection Information

Enclosure

## **EXECUTIVE SUMMARY**

### **Hawaii Agriculture Research Center (HARC) NRC Inspection Report 030-06839/2022-001**

On April 8, 2022, the U.S. Nuclear Regulatory Commission (NRC) performed an announced, routine inspection of the Hawaii Agriculture Research Center (HARC or licensee). NRC Materials License No. 53-00515-01 authorized HARC to possess and store certain byproduct materials, with the intent to dispose of those materials. Inspection activities were performed at the licensee's Kunia Substation in Waipahu, Hawaii. The inspector continued in-office review through July 28, 2022. The inspection examined activities conducted under the HARC license to confirm compliance with the NRC's rules and regulations and with the conditions of the license. The inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel.

For over three decades, HARC used unsealed byproduct material for tracer studies in plants and soils and used sealed sources for sample analysis. In 2009, HARC completed decommissioning activities at its former facility in Aiea, Hawaii, and placed its licensed radioactive materials, as waste, into six 55-gallon drums. The drums and a radioactively contaminated trash compactor were moved into storage at the HARC Kunia Substation in Waipahu, Hawaii. In 2015, at HARC's request, the license was renewed for "possession and storage only with intent to dispose" of the licensed material.

Based on the results of the inspection, seven apparent violations were identified regarding HARC's: (1) ownership and possession of byproduct material not authorized in a specific license, as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 30.3(a); (2) failure to inventory all radioactive materials in storage every 6 months, as required by license condition 15 of License No. 53-00515-01, Amendment No. 75; (3) failure to perform a test for leakage and/or contamination of stored sealed sources, as required by license condition 13.B of License No. 53-00515-01, Amendment Nos. 73, 74, 75; (4) failure to conduct monthly radiation and wipe surveys in an area where radioactive materials were stored, as required by license condition 15 of License No. 53-00515-01, Amendment No. 75; (5) failure to periodically (at least annually) review the radiation protection program content and implementation, as required by 10 CFR 20.1101(c); (6) failure to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures of its license application, as required by license condition 15 of License No. 53-00515-01, Amendment No. 75; and (7) failure to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance, as required by 10 CFR 20.1101(a).

## REPORT DETAILS

### 1 Program Overview (Inspection Procedure (IP) 87126 and IP 84900)

#### 1.1 Program Scope

The Hawaii Agriculture Research Center (HARC or licensee) NRC Materials License No. 53-00515-01 authorized the possession and storage of certain byproduct materials, with the intent to dispose. The licensed materials were authorized to be possessed and stored at the licensee's facility in Waipahu, Hawaii.

#### 1.2 Observations and Findings

On April 8, 2022, the NRC performed an announced, routine inspection of HARC. Inspection activities were performed at the licensee's Kunia Substation in Waipahu, Hawaii. The inspector continued in-office review through July 28, 2022. The scope of the inspection was to examine the activities conducted under the HARC license and to confirm compliance with the NRC's rules and regulations and with the conditions of the license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel.

The HARC is a research institution that was first established in 1895, and specializes in crop research, plant nutrition, genetic engineering, pest and disease control, and pesticide usage. As part of HARC's mission, it demonstrates agricultural technologies and performs research related to agriculture. The main research areas are sugarcane, coffee, cacao, tropical fruits, tropical flowers, forestry, and bioenergy. They also support agricultural development, provide education to the public, and train agricultural workers.

The HARC Kunia Substation, located in Waipahu on the island of Oahu, Hawaii, consists of a research farm and physical facilities with laboratories and administrative offices. The main 22,000 ft<sup>2</sup> laboratory has a dedicated 202 ft<sup>2</sup> room, designated as the "Radioisotope Room," for the storage of NRC licensed materials.

### 2 Background (IP 87126 and IP 84900)

#### 2.1 History of the HARC NRC license

The HARC has been an NRC licensee for over three decades, originally as the Hawaiian Sugar Planters' Association. Licensed activities included the use of unsealed hydrogen-3 (tritium), carbon-14, phosphorus-32, and other radionuclides for tracer studies in plants and soils. Licensed activities also included the use of nickel-63 sealed sources in electron capture detectors for use in gas chromatographs for sample analysis. In 1996, the license name was changed from the Hawaiian Sugar Planters' Association to HARC.

The licensee previously used licensed material at a building with laboratory facilities in Aiea, Hawaii. The licensee also had access to a 108-acre parcel of land and some physical facilities at its Kunia Substation in Waipahu, Hawaii. In October 2006, the ownership of the laboratory facilities building in Aiea changed, and HARC entered into an agreement with the new building owners to decommission the Aiea facility and to vacate as tenants within approximately two years. Concurrently, HARC purchased the

land and physical facilities at its Kunia Substation in Waipahu, Hawaii, which it had previously leased. The licensee subsequently began modification of the existing physical facilities at its Kunia Substation, including the construction of modern laboratory facilities for research.

In 2009, the licensee completed decommissioning activities at its former facility in Aiea, Hawaii, and requested that the location be removed from the license (ML092610751 and ML101340799). The NRC reviewed this information and concluded that the HARC facility in Aiea met the NRC criteria in 10 CFR 20.1402 to be released for unrestricted use, and the location was removed from the license with Amendment No. 70 on June 10, 2010 (ML101610417, ML101610635, and ML101610043). The expiration date of the NRC license was set to be June 30, 2015. Radioactive materials that had been used and stored at the Aiea facility were transported by HARC personnel to the HARC Kunia Substation in Waipahu, Hawaii, facility in August 2009.

In a letter dated March 21, 2013, which is not publicly available because it contains security related information, the licensee requested its license be amended to remove nickel-63 sealed sources from the license, stating that the nickel-63 had been returned to the manufacturer for disposal. Amendment No. 71 was issued on June 12, 2013, removing nickel-63 from the license (ML13165A389 and ML13165A390).

On June 29, 2015, HARC submitted its license renewal application, which is not publicly available. In its renewal application, HARC indicated that it no longer intended to use licensed material and notified the NRC of its intent to terminate the license. The licensee stated, in part, "We have had absolutely no activity using radioisotopes in the last few years but have maintained our (sic) NRC license and have a restricted area where we store very small quantities of radioisotopes. We have now come to the conclusion that we no longer intend to use radioisotopes and so within the next 6 months make preparations for decommissioning our radioisotope lab."

Because the licensee did not dispose of its licensed material or decommission its radioisotope lab in Waipahu, Hawaii, prior to the June 30, 2015, license expiration date, HARC requested that the license be renewed. The HARC had been previously categorized by the NRC as license program code 3620, "Research & Development-Other." The licensee's June 29, 2015, renewal application requested that the license be renewed for "possession and storage only with intent to dispose of the licensed material." The licensee noted that the licensed material was stored in steel drums and that it was expected that the material would be removed from the premises by September 30, 2015. Amendment No. 72 of the HARC license was issued on November 20, 2015, with the NRC license program code 3810 for "Possession and storage only with intent to dispose." The license expiration date was set to October 31, 2017 (ML15288A384 and ML15288A385).

As the licensee approached the October 31, 2017, license expiration date, it still had not disposed of the licensed materials or decommissioned the facility. Accordingly, on October 31, 2017, the licensee submitted a letter to the NRC requesting renewal of the HARC license (ML18029A926). In the letter, the licensee noted that the former Radiation Safety Officer (RSO) had not disposed of the licensed materials as expected and that the licensed material was still located in storage in the steel drums at the HARC Kunia Substation in Waipahu, Hawaii. The licensee also requested that a new RSO be named in the license. The proposed RSO was a consultant, not a HARC employee. The



licensee stated that the new RSO would “assist HARC in the disposal of the licensed material.” This individual had previously been a third-party consultant to HARC for many years, providing such services as radiation safety program reviews, and was very familiar with the HARC licensed activities. Amendment No. 73 was issued on February 3, 2018, authorizing the change of RSO (ML18044A974 and ML18044A973).

In support of the license renewal request, the licensee submitted letters dated February 14, and February 27, 2018 (ML18052A096 and ML18064A299). The licensee committed to continue to take all actions within its ability to dispose of its licensed material. The licensee provided information to the NRC to support that it had been in contact with a radioactive materials waste broker in 2015. Amendment No. 74 was issued on February 28, 2018, again renewing the HARC license. In the renewal, the license was again authorized for possession and storage only with intent to dispose. The license expiration date was set to expire on February 29, 2028 (ML18064A293 and ML18064A292). A subsequent NRC internal audit identified that the license expiration date was incorrect for a possession and storage only license. A corrected copy of Amendment No. 74 was issued on April 16, 2018, correcting the license expiration date to February 29, 2020 (ML18113A993 and ML18113A992).

As the licensee approached the February 29, 2020, license expiration date, it still had not disposed of the licensed materials or decommissioned its facility. On January 29, 2020, the licensee submitted a license renewal application, which is not publicly available. The licensee provided additional information to the NRC in a letter dated June 30, 2020, which is not publicly available. In the letter, the licensee described that coordination with the radioactive materials waste broker to dispose of the licensed materials had “restarted in earnest in January 2020.” The HARC Associate Director noted that the contents of the steel drums had been resorted more than once. Amendment No. 75 was issued on July 14, 2020, again renewing the HARC license, again for possession and storage only with intent to dispose. The license expiration date was set to expire on July 31, 2022 (ML20239A964 and ML20239A967).

As the licensee approached the July 31, 2022, license expiration date, it still had not disposed of the licensed materials or decommissioned its facility. On June 23, 2022, the licensee submitted a license renewal application, which is not publicly available. As of July 28, 2022, the license renewal application was still under NRC review.

## 2.2 Recent NRC Inspection History of HARC

On September 18, 2008, the NRC performed a routine inspection of HARC at its former facilities in Aiea. The inspector noted that the licensee was in the process of moving to the new laboratory space in Waipahu, which was expected to be completed in 2009. The inspector noted that the licensee was still actively using licensed materials at the Aiea location. No violations were identified (ML083020701).

On July 18, 2013, the NRC performed a routine inspection of HARC at its new laboratory facilities at the Kunia Substation in Waipahu. The inspector noted that there was no active use of licensed materials, that the licensee had six drums of radioactive waste and a trash compactor that was contaminated, and that the licensee was pursuing the disposal of the waste through brokers. The inspector further noted that they held a discussion with the HARC Assistant Director regarding the actions that would be necessary to terminate the NRC license. No violations were identified (ML13344B182).

On September 20, 2016, the NRC performed a routine inspection of HARC at the laboratory facilities at the Kunia Substation in Waipahu. The inspector noted that the licensee had not used licensed materials since 2009. The inspector noted that HARC stated that it had discussions with a radioactive materials waste broker for disposal of the licensed materials. It was noted that to facilitate disposal, HARC would have to repackage the drums according to the radioactive materials waste broker instructions. No violations were identified (ML16348A231).

On January 15, 2020, the NRC performed a routine inspection of HARC at the laboratory facilities at the licensee's Kunia Substation in Waipahu. The inspector reviewed documents maintained by the licensee regarding the contents of the six radioactive materials drums that were in storage. The inspector identified that among the contents of the drums, the licensee possessed: three electron capture detector cells, each containing a 15 millicurie nickel-63 source, and one electron capture detector cell that contained a 250 millicurie hydrogen-3 source. All four of the items were required to be possessed under a specific NRC license. However, the HARC license did not authorize the possession of these sources. In an NRC Inspection Report issued on April 21, 2020, this was identified as a Severity Level IV violation of 10 CFR 30.3(a) (ML20113E777).

### **3 Possession and Storage Activities (IP 87126 and IP 84900)**

#### **3.1 Inspection Scope**

On April 8, 2022, the NRC performed an announced, routine inspection of HARC. Inspection activities were performed at the laboratory facilities at the licensee's Kunia Substation in Waipahu, Hawaii. The inspector continued in-office review through July 28, 2022. The scope of the inspection was to examine the activities conducted under the HARC license and to confirm compliance with the NRC's rules and regulations and with the conditions of the license. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel.

#### **3.2 Observations and Findings**

The inspector observed the licensee's Radioisotope Room. The room had a single door entry point, which was secured. Within the room, the inspector observed six 55-gallon steel drums. The drums had labels indicating that they were "Radioactive Material, Excepted Package, UN2910." The inspector also observed an item that was covered with black poly garbage bags and taped closed. The licensee informed the inspector that under the poly bags was the contaminated trash compactor that did not fit into a 55-gallon drum. The area in the Radioisotope Room with the drums and trash compactor can be seen in the photograph in Figure 1.



Figure 1. HARC Radioisotope Room drums and trash compactor

The Radioisotope Room had two laboratory-type benchtops along the length of the room. The benchtops had storage drawers and cabinets. On the floor and on the benchtops, the inspector observed assorted disused laboratory equipment and cardboard boxes with unknown contents. The inspector also observed a refrigerator/freezer at the back of the Radioisotope Room that had a posting and labels on it indicating the presence of radioactive materials. Figure 2 is a photograph of the Radioisotope Room refrigerator/freezer with some of the disused laboratory items around it.

One of the disused pieces of laboratory equipment in the Radioisotope Room was a Beckman LS 6500 liquid scintillation spectrometer/counter as observed in Figure 3. The liquid scintillation counter had a label on it indicating that it contained a 30 microcurie cesium-137 source with a calibration date of October 1, 2004. The label indicated that the possession, use, and transfer of the device was subject to an NRC general license. The label further indicated that the device shall not be transferred, abandoned, or disposed of except through transfer to a person holding a specific radioactive material license to receive the device. The licensee representatives were unable to articulate a plan for the proper transfer or disposal of the device to a specific licensee.

Until approximately 2015, the licensee had been performing routine wipe surveys of the Radioisotope Room to check for removable radioactive contamination. The HARC Radiation Safety Manual, section "Laboratory Operation Procedures," Item 10, requires, in part, that monthly radiation and wipe surveys be conducted in areas where radioactive materials are used or stored. The HARC Radioisotope Room logbook noted that on January 22, 2015, the licensee "collected" wipes for radioactive contamination but could not analyze them because the liquid scintillation counter was not working. As of the date of the inspection, the liquid scintillation counter had not been repaired. Although the licensee stated that it had made arrangements with another NRC licensee to use the other licensee's equipment to analyze wipe surveys for removable contamination, HARC had not acted on these informal arrangements to utilize the other licensee's equipment.



Figure 2. Refrigerator/freezer and boxes in the HARC Radioisotope Room



Figure 3. Beckman LS 6500 liquid scintillation counter

The inspector observed that the refrigerator/freezer was posted and labeled as containing radioactive materials. The items in front of the refrigerator/freezer were moved in order to gain access to the area. When the freezer compartment was opened, the inspector observed that it contained various items that were labeled as being radioactively contaminated or as containing radioactive material. Similarly, the refrigerator compartment was also observed by the inspector to contain various items that were labeled as being radioactively contaminated or as containing radioactive material. The inspector observed that, for some of the containers and items with visible labels, it was indicated that the licensed material was carbon-14, with dates from 2007.

The RSO and Assistant Director were unaware that any radioactive materials were stored in the refrigerator/freezer. The HARC Radiation Safety Manual, section "Laboratory Operation Procedures," Item 13, and section "Radioactive Materials Inventory," Item 2, states, in part, that an inventory of all radioactive materials in storage shall be performed every six months. However, HARC failed to inventory its radioactive materials in storage, including unsealed byproduct material contained in a refrigerator/freezer in the HARC Radioisotope Room.

The inspector inquired about the origin of the radioactive materials that were located in the refrigerator/freezer. The radioactive materials that had been used at the former HARC facility in Aiea were transported by the licensee to the Kunia Substation in Waipahu in August 2009. Some of the materials in the refrigerator/freezer had labels that predated 2009. Therefore, it was not clear why the materials were located in the refrigerator/freezer at the Kunia Substation and not stored as waste within the 55-gallon drums that were intended for disposal. The presence of the radioactive materials in the refrigerator also calls into question whether these radioactive materials had been "used" at the Kunia Substation. The licensee stated that radioactive materials were never "used" at the laboratory facility at the Kunia Substation and were only stored there in the drums. Therefore, licensee representatives could not offer any explanation regarding the presence of the radioactive materials in the refrigerator/freezer, their origin, their use, and why they were not stored as waste in the drums.

Correspondence from HARC, including the HARC license application dated January 29, 2020, Item 11, "Waste Management," states, in part, that waste is being held in six 55-gallon steel drums plus one trash compactor that does not fit into a 55-gallon drum. However, as observed by the inspector, the licensee also stored unsealed carbon-14 waste and other radioactively contaminated items in a refrigerator/freezer in the Radioisotope Room.

The inspector reviewed the list of items that were contained in each of the six 55-gallon drums. The HARC Radioisotope Room logbook indicated that in June 2016, the licensee removed items from the six 55-gallon drums in order to separate out mixed waste and catalog the items. The logbook indicated that, after this activity, the licensee collected wipes to determine any removable radioactive contamination as a result of removing the potentially contaminated materials from the drums. However, the wipes were not analyzed by the licensee because their liquid scintillation counter was not functional. HARC also did not implement its stated arrangements with another NRC licensee for the use of a liquid scintillation counter to analyze the wipes.

The inspector reviewed the licensee's corrective actions regarding the Severity Level IV violation (030-06839/2020-001-01) from the previous NRC inspection on January 15,

2020. The violation was regarding the licensee's possession of three electron capture detector cells, each containing a 15 millicurie nickel-63 source, and one electron capture detector cell that contained a 250 millicurie hydrogen-3 source. All four of the sources were required to be possessed under a specific NRC license. However, the HARC license did not authorize the possession of these sources. As corrective actions, the licensee submitted a license renewal application on January 29, 2020, which is not publicly available. In the license renewal application, the licensee requested that nickel-63 and hydrogen-3 sources be added to the license as part of the renewal. In its May 5, 2020, response to the NRC Notice of Violation, the licensee also noted that it intended to dispose of the materials and terminate its NRC license within the following year (ML20148M179).

The inspector observed that Amendment No. 75, dated July 14, 2020, that renewed the HARC license, did not fully correct the issues that were identified during the previous NRC inspection. The inspector determined that in its license renewal request, the licensee did not specify the number of nickel-63 sources possessed. Amendment No. 75 successfully authorized the one hydrogen-3 source, but only authorized one of the three nickel-63 sources. As a result, the licensee continued to own and possess two nickel-63 sources that were not authorized in a specific license issued by the NRC.

The HARC license requires that no sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination. The licensee placed the nickel-63 sources into storage in 2009. The licensee provided records to the inspector to indicate that the nickel-63 sources were last tested for leakage and/or contamination on July 13, 2007. As a result, the nickel-63 sources had been in storage for a period in excess of 10 years without being tested for leakage and/or contamination.

The inspector inquired how the licensee planned on decommissioning the Radioisotope Room after the licensed materials were eventually disposed. The licensee representatives stated that believed that they were not required to perform any final radiation surveys or wipes for removable radioactive contamination. This was based on their understanding that since the time that the materials had been placed in storage, they had not been "used" within the Kunia Substation facility. The inspector noted to the licensee representatives that the drums had been opened several times since they were placed into the Radioisotope Room, and the contents of the drums, which were potentially radioactively contaminated, were placed on the floor and benchtops for sorting and examination. Therefore, the surfaces of the Radioisotope Room had potential radioactive contamination.

Furthermore, there were unsealed radioactive materials and contaminated items in the refrigerator/freezer that were not in storage in the drums. As noted above, licensee representatives could not explain how the materials came to be in the refrigerator/freezer, why the materials were not within the drums, or if the materials were ever used at the Kunia Substation. Based on the potential for equipment, items, and surfaces in the Radioisotope Room being potentially radiologically contaminated, the licensee would need to demonstrate that the equipment, items, and facility met the NRC criteria for unrestricted release. To demonstrate that the criteria are met and to support an eventual license termination request, the licensee would need to perform appropriate surveys and tests for removable radioactive contamination.

The licensee is required to periodically (at least annually) review the radiation protection program content and implementation. The RSO stated that radiation protection reviews had not been performed. The RSO believed that it was unnecessary to perform radiation protection program reviews because the licensee was not “using” the licensed material but instead only had it “in storage.”

Licensees are required to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. The HARC license authorized the possession and storage only of licensed materials with the intent to dispose. Based on the observations during the NRC inspection, HARC failed to develop, document, and implement a radiation protection program that was commensurate with the possession of licensed material in storage with the intent to dispose.

Since 2009, the licensee has not made progress in disposing of the licensed materials and has not taken all reasonable actions within its ability to dispose of the licensed materials. The licensee’s efforts for over a decade have consisted of a few inquiry emails to a radioactive materials waste broker. The radioactive materials waste broker would repeatedly send instructions for preparing the drums for disposal and for completing the required documentation. However, the licensee would not take sufficient actions to initiate the disposal process.

Since the previous NRC inspection in January 2020, the licensee took no tangible actions to address the disposal of the licensed materials until the current inspector announced and scheduled the April 2022 inspection. After the current inspection was scheduled, licensee representatives sent another inquiry email to a radioactive materials waste broker but made no measurable progress to dispose of the licensed materials. The inspector also observed that in 2021, the licensee failed to renew its State of Washington Department of Health Site Use Permit for Commercial Low Level Waste Disposal, which is necessary to dispose of the licensed materials.

Seven apparent violations were identified regarding the licensee’s: (1) ownership and possession of byproduct material not authorized in a specific license; (2) failure to inventory all radioactive materials in storage every 6 months; (3) failure to perform a test for leakage and/or contamination of stored sealed sources; (4) failure to conduct monthly radiation and wipe surveys in an area where radioactive materials were stored; (5) failure to periodically (at least annually) review the radiation protection program content and implementation; (6) failure to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures of its license application; and (7) failure to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance.

#### **Apparent violation of 10 CFR 30.3(a)**

Title 10 CFR 30.3(a) requires, in part, that no person shall own or possess byproduct material except as authorized in a specific license issued in accordance with the regulations in 10 CFR Chapter I.

License Condition 6.D, of NRC Materials License No. 53-00515-01, Amendment No. 75 authorized a maximum of 15 millicuries total of nickel-63 foils for possession and storage only with intent to dispose.

Contrary to the above, on April 8, 2022, the licensee possessed byproduct material that was not authorized in a specific license issued in accordance with the regulations in 10 CFR Chapter I. Specifically, the licensee possessed approximately 35 millicuries of nickel-63 foils and was only authorized to possess 15 millicuries of nickel-63 foils per License Condition 6.D of NRC Materials License No. 53-00515-01.

The licensee's ownership and possession of byproduct material not authorized in a specific license was identified as an apparent violation of 10 CFR 30.3(a). (030-06839/2022-001-01)

### **Apparent violation of License Condition 15**

License Condition 15 of NRC Materials License No. 53-00515-01, Amendment No. 75 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures to the application for license renewal dated January 29, 2020.

In the application dated January 29, 2020, Item 10, "Radiation Safety Program," states, in part, that the radiation safety program is documented in the Radiation Safety Manual. The Radiation Safety Manual, section "Laboratory Operation Procedures," Item 13, and section "Radioactive Materials Inventory," Item 2, states, in part, that an inventory of all radioactive materials in storage shall be performed every six months.

Contrary to the above, from July 14, 2020, to April 8, 2022, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures to the application for license renewal dated January 29, 2020. Specifically, the licensee failed to perform an inventory of all radioactive materials in storage every 6 months. The licensee failed to inventory its radioactive materials in storage, including carbon-14 unsealed byproduct material contained in a refrigerator/freezer in the HARC Radioisotope Room.

The licensee's failure to perform an inventory of all radioactive materials in storage every 6 months was identified as an apparent violation of License Condition 15 of NRC Materials License No. 53-00515-01, Amendment No. 75. (030-06839/2022-001-02)

### **Apparent violation of License Condition 13.B.**

License Condition 13.B. of NRC Materials License No. 53-00515-01, Amendment Nos. 73, 74, and 75 requires, in part, that no sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

Contrary to the above, from 2019 to April 8, 2022, the licensee stored sealed sources for a period of more than 10 years and failed to perform a test for leakage and/or contamination. Specifically, on April 8, 2022, the licensee had three electron capture detectors containing nickel-63 sealed sources that were placed into storage in 2009 and the sources were last tested for leakage/contamination on July 13, 2007. Thus, the



licensee stored sealed sources for more than 10 years without performing a required test for leakage and/or contamination.

The licensee's failure to perform a test for leakage and/or contamination of stored sealed sources was identified as an apparent violation of License Condition 13.B. of NRC Materials License No. 53-00515-01, Amendment Nos. 73, 74, and 75. (030-06839/2022-001-03)

### **Apparent violation of License Condition 15**

License Condition 15 of NRC Materials License No. 53-00515-01, Amendment No. 75 requires, in part, that the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures to the application for license renewal dated January 29, 2020.

In the application dated January 29, 2020, Item 10, "Radiation Safety Program," states, in part, that the radiation safety program is documented in the Radiation Safety Manual. The Radiation Safety Manual, section "Laboratory Operation Procedures," Item 10, requires, in part, that monthly radiation and wipe surveys be conducted in areas where radioactive materials are used or stored.

Contrary to the above, from July 14, 2020, to April 8, 2022, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures to the application for license renewal dated January 29, 2020. Specifically, the licensee failed to conduct monthly radiation and wipe surveys in the radioisotope room, an area where radioactive materials were stored.

The licensee's failure to conduct monthly radiation and wipe surveys in an area where radioactive materials were stored was identified as an apparent violation of License Condition 15 of NRC Materials License No. 53-00515-01, Amendment No. 75. (030-06839/2022-001-04)

### **Apparent violation of 10 CFR 20.1101(c)**

Title 10 CFR 20.1101(c) requires that licensees shall periodically (at least annually) review the radiation protection program content and implementation.

Contrary to the above, from January 15, 2020, to April 8, 2022, the licensee failed to periodically (at least annually) review the radiation protection program content and implementation.

The licensee's failure to periodically (at least annually) review the radiation protection program content and implementation was identified as an apparent violation of 10 CFR 20.1101(c). (030-06839/2022-001-05)

### **Apparent violation of License Condition 15**

License Condition 15 of NRC Materials License No. 53-00515-01, Amendment No. 75 requires, in part, that the licensee shall conduct its program in accordance with the

statements, representations, and procedures contained in the documents, including any enclosures to the application for license renewal dated January 29, 2020.

In the application dated January 29, 2020, Item 11, "Waste Management," states, in part, that waste is being held in six 55-gallon steel drums plus one trash compactor that does not fit into a 55-gallon drum.

Contrary to the above, from July 14, 2020, to April 8, 2022, the licensee failed to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures to the application for license renewal dated January 29, 2020. Specifically, the licensee failed to hold or store all its waste in six 55-gallon steel drums and one trash compactor. The licensee stored unsealed carbon-14 waste and other radioactively contaminated waste items in a refrigerator/freezer.

The licensee's failure to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures of the application dated January 29, 2020, was identified as an apparent violation of License Condition 15 of NRC Materials License No. 53-00515-01, Amendment No. 75. (030-06839/2022-001-06)

#### **Apparent violation of 10 CFR 20.1101(a)**

Title 10 CFR 20.1101(a) requires, in part, that each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20.

License Condition 9.A.-D. of NRC license No. 53-00515-01, Amendment No. 75, authorized licensed material for possession and storage only with intent to dispose.

Contrary to the above, from July 14, 2020, to April 8, 2022, the licensee failed to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with the provisions of 10 CFR Part 20. Specifically, the licensee failed to develop, document, and implement a radiation protection program that was commensurate with the possession of licensed material in storage with the intent to dispose.

The licensee's failure to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance was identified as an apparent violation of 10 CFR 20.1101(a). (030-06839/2022-001-07)

### **3.3 Causal Evaluation**

The inspector did not perform a formal causal factors analysis as it was beyond the scope of the inspection. Based on interviews conducted during the inspection, it was determined that the current HARC management and staff had not previously been users of the licensed materials in the drums. They lacked familiarity with the previous research activities at HARC or types of radioactive materials that were stored in the drums. They also did not understand the complexities of disposing of the licensed materials or what

was necessary to perform the subsequent decommissioning of the Radioisotope Room. The RSO, who was familiar with the history of radioactive materials use at HARC and had extensive experience with radiation safety and regulatory compliance, had not taken on the task of spearheading and coordinating the disposal of the licensed materials. Although the HARC personnel lacked the expertise, and the RSO was not engaged in the disposal planning, the licensee did not seek out other resources or expertise to assist in the disposal planning and execution.

The licensee expressed to the inspector its position that there is minimal risk associated with the stored materials. As a result, the licensee did not have a sense of urgency to dispose of the licensed materials. The inspector observed that it appeared that the licensee would only contact a potential radioactive materials waste broker either after the NRC scheduled an inspection, or when NRC's license reviewers followed up as part of a license renewal application. Then after contacting the radioactive materials waste broker, the licensee would fail to follow up or obtain the assistance of the RSO or other appropriate subject matter experts to assist in preparing the materials for shipment and disposal.

### 3.4 Corrective Actions

At the conclusion of the onsite inspection on April 8, 2022, the inspector discussed the preliminary inspection findings with licensee personnel and the RSO. Licensee personnel and the RSO committed to search the Radioisotope Room and identify any byproduct material that was stored outside of the drums, which would include any byproduct materials in boxes, cabinets, drawers, and inside of the refrigerator/freezer. The inspector requested that for any byproduct material identified, the licensee provide a description that included the isotope, quantity, model number and serial number, if applicable, and any associated calibration, measurement, or use date, along with photographs. The licensee committed to provide this information by April 21, 2022. As of August 22, 2022, this information has not been provided to the NRC.

Following the onsite inspection, on April 29, 2022, the licensee submitted an amendment request (ML22157A168). The licensee requested to amend the license possession limit for nickel-63 to account for all the known nickel-63 electron capture detectors possessed under the license. Amendment No. 76 of the HARC license, authorizing the increased possession limit for nickel-63 was issued on June 15, 2022, (ML22166A448 and ML22166A456). Amendment No. 76 included the addition of License Condition 15, following the NRC licensing guidance established in Checklist A.8 of NUREG-1556, Volume 20, Revision 1. License Condition 15 states: "The licensee will continue to take all actions within its ability to dispose of its material and notify NRC within 30 days if disposal is achieved."

On June 23, 2022, the licensee submitted its application to renew the HARC license. The renewal application is not publicly available. The renewal application notes that waste is being held in six 55-gallon steel drums and one trash compactor. Therefore, it fails to mention the additional byproduct material that was identified by the inspector and located in the refrigerator/freezer. The application did not provide an update regarding any disposal efforts.

### 3.5 Conclusions

Seven apparent violations were identified regarding the licensee's: (1) ownership and possession of byproduct material not authorized in a specific license; (2) failure to perform an inventory all radioactive materials in storage every 6 months; (3) failure to perform a test for leakage and/or contamination of stored sealed sources; (4) failure to conduct monthly radiation and wipe surveys in an area where radioactive materials were stored; (5) failure to periodically (at least annually) review the radiation protection program content and implementation; (6) failure to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures of its license application; and (7) failure to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance.

## **4 Exit Meeting Summary**

On August 22, 2022, a final telephonic exit meeting was conducted with Dr. Blake Vance, Assistant Director, and Ronald Frick, Radiation Safety Officer, to discuss the inspection findings. The NRC representatives discussed the content of the inspection report, described the NRC's enforcement process, and described the options for the licensee to: (1) respond in writing to the apparent violations described in the inspection report; (2) request a predecisional enforcement conference, or (3) request alternative dispute resolution. The licensee did not identify any proprietary information.

## **Supplemental Inspection Information**

### **PARTIAL LIST OF PERSONS CONTACTED**

Blake Vance, PhD, Assistant Director  
Ming-Li Wang, PhD, Biologist  
Ronald Frick, CHP, RSO

### **INSPECTION PROCEDURES USED**

87126 Industrial/Academic/Research Programs  
84900 Low-Level Radioactive Waste Storage

### **ITEMS OPENED, CLOSED, AND DISCUSSED**

#### **Opened**

030-06839/2022-001-01	AV	Ownership and possession of byproduct material not authorized in a specific license. (10 CFR 30.3(a))
030-06839/2022-001-02	AV	Failure to perform an inventory all radioactive materials in storage every 6 months. (License Condition 15 of NRC Materials License No. 53-00515-01, Amendment No. 75)
030-06839/2022-001-03	AV	Failure to perform a test for leakage and/or contamination of stored sealed sources. (License Condition 13.B. of NRC Materials License No. 53-00515-01, Amendment Nos. 73, 74, and 75)
030-06839/2022-001-04	AV	Failure to conduct monthly radiation and wipe surveys in an area where radioactive materials were stored. (License Condition 15 of NRC Materials License No. 53-00515-01, Amendment No. 75)
030-06839/2022-001-05	AV	Failure to periodically (at least annually) review the radiation protection program content and implementation. (10 CFR 20.1101(c))
030-06839/2022-001-06	AV	Failure to conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures of application dated January 29, 2020. (License Condition 15 of NRC Materials License No. 53-00515-01, Amendment No. 75)
030-06839/2022-001-07	AV	Failure to develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure compliance. (10 CFR 20.1101(a))

Closed

None

Discussed

030-06839/2020-001-01      VIO      Possession of byproduct material types and quantities that were not authorized in the NRC specific license.  
(10 CFR 30.3(a))

LIST OF ACRONYMS AND ABBREVIATIONS USED

10 CFR	Title 10 of the <i>Code of Federal Regulations</i>
ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
AV	Apparent Violation
HARC	Hawaii Agriculture Research Center
IP	Inspection Procedure
NRC	U.S. Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSO	Radiation Safety Officer
VIO	Violation