U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	99990001/2010-001
Docket No.	99990001 (during inspection)/030-38337
License No.	99-99999-99 (during inspection)/06-31417-01
Licensee:	Health Center Imaging
Location:	999 Silver Lane Trumbull, Connecticut 06611
Inspection Dates:	January 13, 2010 and February 22, 2010 (on site); January 14, 15 and 27, 2010; April 1, 2010 and May 31, 2011

Inspectors: ____**/RA/**_____ _____5/31/11_____
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EXECUTIVE SUMMARY

NRC Inspection Report No. 99990001/2010-001

A reactive inspection of Heath Center Imaging was conducted in response to a possible improper disposal of radioactive material as reported to the NRC by the State of Connecticut's Department of Environmental Protection (CTDEP) after a bag of radioactive waste was detected by a radiation monitor at a normal waste facility in Connecticut. Health Center Imaging is a private practice cardiology facility which uses only accelerator-produced radioactive materials that were formerly regulated by the State of Connecticut. Health Center Imaging was registered as a radioactive materials user with the State of Connecticut during the time of this inspection. At the time of the incident and the inspection, due to changes required by the Energy Policy Act of 2005, the licensee was under the jurisdiction of the NRC but was not yet required to apply for an NRC license. Health Center Imaging was issued an NRC license on November 3, 2010. The NRC conducted an inspection at the licensee's facility located in Trumbull, Connecticut. The focus of the inspection was to determine how the radioactive material got into the normal trash disposal system. In addition, inspectors reviewed other areas of the licensee's radiation safety program.

Within the scope of this inspection, one apparent violation was identified for failure to perform a survey in accordance with 10 CFR 20.1501. Because of this apparent violation, the licensee nearly disposed of radioactive waste containing an estimated 300 microcuries of strontium-82 (Sr-82)/rubidium-82 (Rb-82), and/or strontium-85 (Sr-85) by releasing this material to the normal trash disposal system, a method not authorized by §20.2001.

REPORT DETAILS

I. Organization and Scope of the Program

a. Inspection Scope

The inspectors reviewed, through interviews with the technical director and a tour of the facility, the organization and scope of activities with radioactive materials. The inspectors also reviewed the radiological characteristics of the rubidium-82 (Rb-82) generator.

b. Observations and Findings

The facility is a private practice cardiology center, licensed by the State of Connecticut to use strontium-82/rubidium-82 (Sr-82/Rb-82), an accelerator-produced radioactive material, for imaging. Health Center Imaging was registered as a radioactive materials user with the State of Connecticut. Due to changes mandated by the Energy Policy Act of 2005, at the time of the incident and during most of the inspection, the licensee was under the jurisdiction of the NRC but was not yet required to apply for an NRC license and had not yet submitted an application for use of byproduct material to the NRC. Health Center Imaging was issued an NRC license on November 3, 2010.

At the time of the event, Johann Bragg was the President of Health Center Imaging. Crystal McCarthy was the Technical Director and the only Nuclear Medicine Technologist. Ms. McCarthy worked with a full-time nurse at this facility, and under the supervision of Adam Schussheim, M.D., a cardiologist at another facility and the Medical Director for Health Center Imaging. Cleaning staff was contracted by Health Center Imaging and was present at the facility on Mondays, Wednesdays, and Fridays.

The facility had one camera. Cardiology imaging was performed on patients using Rb-82 eluted from a generator and administered to the patient intravenously. Patients were treated several days each week. The licensee received a new generator every two weeks.

Health Center Imaging also had a cobalt-57 source for their camera and a germanium-68 source, used for transmission tests, during imaging.

The radionuclide used for imaging, Rb-82, has a half-life of 75 seconds. It decays by positron emission and emits two 511 kiloelectron volt (keV) photons which are detected during imaging. It is produced by the decay of strontium-82 (Sr-82), a radionuclide that is produced in an accelerator. Sr-82 has a half-life of 25 days, and decays by electron capture, emitting only low-energy x-rays which are not easily detected. During production of the Sr-82, strontium-85 (Sr-85) also is produced and is present as a contaminant in the Rb-82 generator. Sr-85 has a half-life of 65 days and decays by electron capture, emitting a 514 keV photon. When the Rb-82 generator is used, a quality control (QC) test is required to be performed to confirm that the eluate contains less than 0.02 microcuries of Sr-82 per millicurie of Rb-82, and less than 0.2 microcuries of Sr-85 per millicurie of Rb-82. This is sometimes referred to as the ‘breakthrough’ test. The typical

adult dose used is 40 millicuries of Rb-82 per injection, and a patient will be injected twice (once for the resting image and once for the stress image.) Unlike other radiopharmaceuticals, the Rb-82 eluate is eluted directly into the patient intravenously, because its short half-life does not allow drawing up doses and injection by syringe.

c. Conclusions

No violations or safety concerns were identified.

II. Review of the Improper Waste Disposal Event

a. Inspection Scope

Inspectors performed a special inspection in response to a notification by the State of Connecticut that Health Care Imaging disposed of a bag of radioactive waste to the normal trash system, which set off a radiation alarm at a normal trash incinerator facility. The inspectors interviewed licensee staff to determine how the radioactive waste was disposed of as normal trash, performed surveys at the facility, and reviewed records. The inspectors were accompanied by representatives of the State of Connecticut Department of Environmental Protection (CTDEP).

b. Observations and Findings

Based on the interviews with the Nuclear Medicine Technologist (NMT)/Technical Director, representatives of the State of Connecticut, and the cleaning staff, the inspectors developed the following timeline of events:

Tuesday, December 15, 2009, The NMT stated that she had only one patient and used the generator one time that day. The QC check performed on the generator that day showed that there was no breakthrough exceeding regulatory limits of Sr-82, the parent nuclide to Rb-82. That was also the last day that the old generator (Serial number: 823161195) was used.

Friday, December 18, 2009, A new generator (Serial number: 82330619) was received. The new generator sat in its original packaging until December 21 when the old generator was switched with the new one.

Monday December 21, 2009, No patients were seen on this day. The NMT switched from the old generator to the new one at approximately 6:30 am. When switching the generators, the NMT stated that she placed blue absorbent pads on the floor between the generator cart and the old empty generator shipping package, and the new generator shipping package with the new generator still in the package. The NMT said she removed the tubing from the old generator, snipping the tubing connection that contained the needle and disposed of the needle into a container specifically for sharps. She stated that her normal practice is to dispose the tubing into the “red bag” waste (biohazardous waste) which is separate from regular trash. She stated that she lifted the old generator from the cart, set it down on the blue absorbent pads, and then she lifted the old generator from the pads and placed it into the old shipping container. She stated

that she next lifted the new generator from its container onto the absorbent pads and then lifted it to the cart. The NMT stated that both generators rested on the absorbent pads briefly and that. when she was done, she placed the absorbent pads and used tubing into the “red bag” waste. After the process of switching the generator, a QC check was done of the Rb-82 eluate and the results indicated that the material met the standards for patient use.

Cleaning staff were on site on that day and stated that they performed their normal cleaning duties. They stated that they do not touch any “red bag” waste, or any radioactive waste, but that they did empty the normal trash containers in the treatment room.

Note: At the time of the inspection, the container that the sharps were placed into was still onsite, as was the box containing the ‘red bag” waste. The NMT stated that she does not normally survey the “red bag” waste before it is disposed of. She stated that the only items normally disposed of as radioactive waste are the vials from the QC tests.

Tuesday, December 22, 2009, The QC test done that day was normal and patients were treated. The NMT left for the day at approximately 2:30 pm and subsequently went on vacation.

Wednesday, December 23, 2009, CTDEP received a call at approximately 4:30 am that a radiation alarm was set off at the normal trash incinerator facility. Michael Firsick, Supervisor, received the call. The alarm was triggered when a trash truck was driven past the plastic scintillator radiation detectors. It is normal practice for the incinerator facility to notify the CTDEP when this happens and the truck was held until a CTDEP representative arrived. Mr. Firsick stated that if CTDEP can confirm that the alarm was caused by short-lived medical waste, then it is allowed to be sent to the incinerator. Gary Cahill, CTDEP, responded to the incinerator facility at 9:00 am, and performed a radiation survey and spectrum analysis of the truck. The spectrum analysis did not clearly identify the radionuclide so the load from the truck was dumped onto the tipping floor. Mr. Cahill stated that he sorted through the pile and surveyed items until he identified the bag which caused the alarm and isolated it. Mr. Cahill stated that the bag he found was plastic but he was certain that it was not in a red bag because he knows red bags are used for biohazardous waste and he would not have opened a red bag. Mr. Cahill opened the bag and found a “lightweight small rectangular tub”, which the NMT confirmed to be the packaging for the new generator tubing. Other items found in the bag included a shipping label for a Rb-82 generator with Health Center Imaging’s address on it, gloves, miscellaneous items, and blue absorbent pads with measurable radiation levels. Mr. Cahill kept the radioactive items and the labels with information, and placed them in another bag. CTDEP staff contacted Health Center Imaging and required them to retrieve the bag containing the radioactive material.

On this same day, while on vacation out of state, the NMT received a call from the practice president informing her of the radioactive waste found at the incinerator facility. Because she was not available to retrieve the material, the practice president agreed to pick up the bag of waste. Mr. Cahill stated that he remained at the incinerator facility with the bag of contaminated items until the practice president picked up the bag.

Radiation surveys were conducted by Mr. Cahill at the incinerator facility using a Ludlum Model 3 with a 44-2 sodium iodide detector probe. He measured 10 millirem per hour (mrem/h) near contact with the bag, 1.5 mrem/h at 1 foot from the bag, and 0.5 mrem/h at 1 meter from the bag.

During the inspection, the NMT maintained that the blue absorbent pads were items that she would normally throw away in "red bag" waste and believes that she did put them in the "red bag" waste on the day that she changed out the generators. The blue pads were also items that might have been used during patient treatment and she would normally dispose of them in "red bag" waste.

Wednesday, December 30, 2009, Mike Firsick and Gary Cahill returned to Health Center Imaging to conduct surveys for removable contamination, by taking wipes of the floor and surfaces of the treatment room. Another spectrum analysis was done of the wipes, which confirmed the presence off 511 keV photons, which was evidence that Rb-82 was present. Inspectors were concerned because Rb-82 has a half-life of only 75 seconds, and could only be present at this time if the parent radionuclide, Sr-82, was still present in the contaminated materials.

Monday, January 4, 2010, The NMT returned to the facility. As requested by the NRC, the NMT performed surveys of the bag of waste retrieved from the incinerator facility. Using a Ludlum 14C with a pancake probe, the NMT measured approximately 0.7 mrem/h at 3 feet from the bag, with the open window facing the bag. She measured approximately 0.1 mrem/h at 3 feet from the bag with the window facing away from the bag. The NMT checked the bag daily until the date of the inspection and stated that the measurements did not change much.

c. Conclusions

One apparent violation was identified for failure to perform a survey in accordance with 10 CFR 20.1501. Because of this, radioactive waste was transferred to the incinerator facility as normal trash and was nearly disposed of, a method which is contrary to regulations set forth in 10 CFR 20.2001.

III. Radiation Level and Contamination Surveys

a. Inspection Scope

NRC and CTDEP inspectors conducted surveys at the licensee's facility to establish the scope of any contamination at the facility, and to assess radiation levels at the licensee's facility. Survey results were used to estimate the amount of radioactive material disposed of as normal trash.

b. Observations and Findings

In a telephone conversation on December 28, 2009, the NRC inspectors requested that the NMT hold the waste until the inspectors arrived so that independent surveys could be performed. On December 30, the CTDEP visited the licensee's facility and performed

another spectrum analysis of the bag of waste retrieved from the incinerator, and confirmed the presence of 511 keV photons, indicating that Rb-82 was present. Given that Rb-82 has only a 75-second half-life, the inspectors concluded that if Rb-82 was present, then Sr-82 parent must also have been present and still producing the daughter nuclide. The inspectors also considered that, given the difficulty in distinguishing between 511 keV and 514 keV photons, it was possible that the Sr-85 contaminant from the Sr-82/Rb-82 generator was present in the waste. The CTDEP inspectors also performed wipe surveys for removable contamination in the hot lab. Analysis of the wipes determined that there was no removable contamination.

Upon returning to work on January 4, 2010, the NMT performed a survey of the bag of waste retrieved from the incinerator facility. The NMT used a Ludlum 14C with a pancake probe and measured radiation levels of 0.7 mrem/h at 3 feet from the bag, with the open window facing the bag and 0.1 mrem/h with the open window facing away from the bag. Between the day that she returned to work and the day of the NRC inspection, the NMT conducted surveys daily of the bag of waste and stated that radiation levels did not change much.

During the January 13 inspection, NRC inspectors performed confirmatory surveys of the bag of waste retrieved from the incinerator. Using a Ludlum 14C survey meter with a pancake detector, the inspectors measured 1 mrem/h at approximately 3 feet away with the window facing the bag and 0.2 mrem/h with the window facing away from the bag. These surveys were directly compared to the NMT's measurements, using the licensee's Ludlum 14C survey meter with a pancake detector, who measured 0.9 mrem/h and 0.1 mrem/h, respectively, side-by-side with the NRC detector. The inspectors also measured 100 µrem/h at approximately 3 feet away using a Bicron microrem meter.

Also during the January 13 inspection, a box of 'red bag' waste that was packaged and ready to be shipped was identified with measurable radiation levels. It was tested for removable contamination by the CTDEP inspectors. The wipe was counted by the NMT, and 100 counts per minute (cpm) was detected on the wipe. At the request of the inspectors, the NMT also removed the old generator, still being held at the facility, from its shipping container and the CTDEP inspectors obtained a wipe sample from the outside of the generator. The NMT counted the wipe, which had 899 counts per minute (cpm) detected on it, confirming that removable contamination was on the outside of the old generator, which could have caused the contamination of the blue absorbent pads found in the bag of waste retrieved from the incinerator. The wipe was counted periodically during the inspection and even at an hour later, the count remained in the range of 900 cpm, indicating that either Sr-82/Rb-82 or Sr-85 was present. The CTDEP inspectors took the generator wipe to their laboratory for further analysis, and confirmed the presence of photons in the 511/514 keV range, but could not be more specific.

During the January 13 inspection, inspectors requested that the cleaning staff return to the facility in order to survey their equipment for removable contamination. The inspector used a Ludlum 14C with a pancake probe to survey the cleaning supplies including a vacuum cleaner, mop and bucket, and rags (which had already been washed) for the presence of contamination. Results of the surveys were indistinguishable from background. The cleaning staff stated that they use their personal vehicles when transporting trash from the facility to the dumpster. Inspectors surveyed the two vehicles

that had been last used when the cleaning staff was at the facility and confirmed there was no contamination in either of the vehicles.

An NRC inspector returned to the licensee facility on February 22, 2010, to perform additional surveys using a Ludlum 14C survey meter with a pancake probe. The radiation level measured at approximately 3 feet from the bag was 0.4 mrem/h. Radiation levels measured at about 1 centimeter from the bag were 0.7 mrem/h, with the pancake probe window facing the bag, and 0.1 mrem/h with the window facing away from the bag. A survey of the biological hazardous waste box in storage in the closet was 0.5 mrem/h on contact with one side of the box. The NMT performed a contamination wipe survey and confirmed that there was no removable contamination on the box.

The NRC inspectors performed calculations to determine the approximate activity of Sr-82/Rb-82 and/or Sr-85 inside of the bag of trash retrieved from the incinerator. Because of the 75-second half-life of Rb-82, Rb-82 could only be present if the same amount of the parent Sr-82 was present. The radiation levels from the bag were readily detectable even on February 22, more than 60 days after the blue absorbent pads were found at the incinerator facility. In addition, the radiation is either 511 keV photons such as emitted from Rb-82, or 514 keV photons such as emitted by Sr-85. Therefore, the contamination in the waste could be from Sr-82/Rb-82, or from Sr-85, or some combination thereof. Although many surveys were performed, only surveys performed at approximately 1 meter were useful in the calculated estimate of activity, because the bag was not a point source of radiation for measurements at closer distances. The Bicron microrem meter, which has a flat energy response to radiation, measured 100 microrem per hour from the bag at 3 feet on January 13. From this measurement, the NRC estimated that 0.16 millicuries Sr-82/Rb-82 only, or 0.30 millicuries of Sr-85 only, or some combination of the two radionuclides was contained in the bag of trash on that date. If the bag contained only Sr-82/Rb-82, the activity in the bag on December 23 would have been 0.29 millicuries; if only Sr-85, it would have been 0.38 millicuries.

c. Conclusions

Wipe samples confirmed that contamination was present on the old generator, which could have transferred to the blue absorbent pads that were in the bag of waste retrieved from the incinerator facility. Surveys confirmed that the contaminated items in the bag still had measurable radiation levels 21 days and 62 days after the bag was retrieved from the incinerator facility. Most likely the contamination is due to the presence of residual Sr-82 producing Rb-82, and/or residual Sr-85, but the analyses performed are not sufficiently sensitive to distinguish between these radionuclides.

IV. Radioactive Waste Management

a. Inspection Scope

The inspectors interviewed Health Center Imaging personnel and ancillary personnel to determine radioactive waste disposal practices.

b. Observations and Findings

The NMT stated that some of the items retrieved from the incinerator facility were usually considered 'red bag' waste and she did not know how the items ended up with the normal trash. According to the cleaning staff, they followed their usual routine on Monday, December 21, 2009, at the licensee's facility, before the bag was discovered at the incinerator facility early on Wednesday morning.

Inspectors identified measurable radiation levels on one box of biohazardous waste in storage (the "red bag" waste in storage for disposal). The inspectors reminded the NMT that this material could not be disposed of until the radiation levels were indistinguishable from background, in accordance with the license condition requirements for disposal of radioactive material by decay-in-storage. The licensee did maintain decay-in-storage records for radioactive wastes and had procedures in place for waste that was radioactive, but had not considered the "red bag' waste to also be radioactive waste.

One individual who normally cleans the facility demonstrated how she would clean the treatment room in which radioactive materials were used. The individual showed the inspectors the normal waste container which the cleaning staff routinely emptied as part of their duties. This individual stated that cleaning staff never touched the 'red bag' waste. During the inspection, this individual contacted the two staff members who cleaned the licensee facility on December 21, and they also stated that they did not touch the 'red bag' waste but did dispose of waste from the normal trash can.

The NMT stated that since the incident, she places the normal trash can in the hallway outside the treatment room for the cleaning staff to empty, after surveying the normal trash. Cleaning staff no longer enter the room where radioactive materials are used and stored. In addition, the NMT stated she would perform decay-in-storage surveys of red bag waste prior to disposal in the future.

c. Conclusions

The licensee had appropriate procedures in place for disposal of radioactive waste, but did not routinely survey non-radioactive wastes to verify if materials were placed in the wrong containers.

V. Evaluation of the Rb-82 Generator

a. Inspection Scope

NRC requested that GE Healthcare, the radiopharmacy that manufactures and distributes the Rb-82 generator, evaluate the generator used by the licensee to determine if there were any defects in the operation of the generator that could have resulted in the unusual radiation and contamination levels identified during this event. In particular, the manufacturer was asked to confirm if the eluate from the generator contained amounts of Sr-85/Sr-82 in excess of the product specifications, which could have affected the patient dosages.

b. Observations and Findings.

The licensee received its Rb-82 generator from the GE Healthcare radiopharmacy in South Plainfield, New Jersey. Wayne London, the Senior Nuclear Safety Program Leader for GE Healthcare in Arlington Heights, Illinois, agreed that GE Healthcare would conduct an analysis on the Rb-82 generator they supplied to the licensee in order to determine if there was a manufacturing defect or other issue with the generator that resulted in the contamination of the generator and blue absorbent pads.

The generator was returned to GE Healthcare on February 9, 2010. Results of the evaluation were provided to the NRC in a letter dated March 30, 2010. The manufacturer stated that the generator was eluted the same way as it would be by the customer, and that the generator performed as expected with no evidence of any damage. GE Healthcare stated that the Sr-85/Sr-82 breakthrough test results were within product specifications. The manufacturer also wipe-tested the outside of the generator, and identified removable contamination on the order of 800 disintegrations per minute (dpm). A gamma spectrum analysis of this wipe identified only a 514 keV peak, indicating that Sr-85 was the contaminant present. GE Healthcare did not identify Sr-82/Rb-82 in the external contamination on the generator approximately 4 months after the incident.

c. Conclusions

Based on analysis of the generator as well as interviews with the NMT and a review of the quality control tests performed by the licensee on the generator, inspectors concluded that Sr-85/Sr-82 breakthrough did not exceed limits and patient dosages were acceptable. In addition, the manufacturer stated that the contamination identified on the generator in March 2010 was limited to Sr-85.

VI. Exit Meeting

Inspectors met with licensee representatives prior to leaving the site on January 13 and February 22, 2010. Additional information was requested from the licensee on January 14, 15 and 27, 2010. The results of the evaluation of the generator were received on April 1, 2010. On April 1, 2010, a preliminary exit meeting was conducted by telephone with Chrystal McCarthy, the Nuclear Medicine Technologist and facility Technical Director. Inspectors summarized the areas reviewed during the inspection, and discussed the results of the generator evaluation. Inspectors reviewed an apparent violation for the improper disposal of radioactive waste. On May 31, 2011, a final Exit Meeting was conducted and an apparent violation for failure to survey in accordance with 10 CFR 20.1501 was discussed with those in attendance.

PARTIAL LIST OF PERSONS CONTACTED

Licensee
Crystal McCarthy, Health Center Imaging, Nuclear Medicine Technologist/ Technical Director
Paula Zuber, Health Center Imaging, Office Manager

GE Healthcare
Wayne London, Senior Nuclear Safety Program Leader, Arlington Heights, Illinois
Charlie Pelliccia, Radiation Safety Officer, South Plainfield, New Jersey

Connecticut Department of Environmental Protection
Michael Firsick, Connecticut Department of Environmental Protection
Gary Cahill, Connecticut Department of Environmental Protection