U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

Inspection No.	03031642/2020001
EA No.	EA-20-025
Docket No.	03031642
License No.	06-28502-01
Licensee:	Connecticut Imaging Partners, LLC 111 Founders Plaza, Suite 400 East Hartford, CT 06108
Location:	704 Hebron Avenue, Suite 101 Glastonbury, Connecticut, 06033
Inspection Dates:	February 13, 2020 with in office review through March 10, 2020

Inspector(s):

Robin Elliott _____ March 26, 2020
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Health Physicist
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Division of Nuclear Materials Safety

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Approved By:

Donna M. Janda Digitally signed by Donna M. Janda Date: 2020.03.26 10:15:45 -04'00' _____ March 26, 2020
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EXECUTIVE SUMMARY

Connecticut Imaging Partners, LLC
NRC Inspection Report No. 03031642/2020001

A routine unannounced inspection was performed of Connecticut Imaging Partners, LLC, on February 13, 2020. In office review concluded on March 10, 2020. The inspection was conducted on Connecticut Imaging Partners' radioactive materials license (NRC license number 06-28502-01). Inspection procedure 87131 was utilized. The inspection focused on the performance of the licensee's program as well as the records maintained by the licensee.

Based on the results of this inspection, four SLIV violations of NRC requirements were identified.

REPORT DETAILS

1. Organization and Scope of the Program

a. Inspection Scope

The inspectors reviewed the organization and scope of the licensee's nuclear medicine program through direct observations, reviews of records, and interviews with licensee staff.

b. Observations and Findings

At the time of the inspection Connecticut Imagine Partners, LLC (CIP) was an imaging center authorized for 10 CFR 35.100, 10 CFR 35.200, and 10 CFR 35.300. The hours of operation were 0700 - 1600, Monday through Friday. They had no routine on-call or weekend staffing. There were three full time Nuclear Medicine Technologists (NMTs) and one part time NMT. The Radiation Safety Officer (RSO) was an authorized user available by phone. A health physics consultant was on-site quarterly to perform audits, sealed source leak testing, sealed source inventory, sealed source return, training, instrument quality control, records review, and annual program review. There was no Radiation Safety Committee.

2. Material Receipt, Use, Transfer, and Control

a. Inspection Scope

The inspectors reviewed the material receipt, use, transfer, and control of the licensee's nuclear medicine program through direct observations, reviews of records, and interviews with licensee staff.

b. Observations and Findings

Overall Program

The nuclear medicine (NM) department included one hot lab with one dose calibrator, three imaging cameras, and one spare dose calibrator located in one of the camera rooms. The NM department averaged 20-25 patients per day. Radiopharmaceuticals were received daily from Cardinal Health's East Hartford location with the exception of DaT scan (Ioflupan I-123 injection) material which was received from GE's Chicago location via FedEx. Only unit doses were utilized. Dose calibrators were used to assay doses prior to administration.

The licensee primarily used Tc-99m to perform a full range of general studies; no cardiac studies were performed. Other radionuclides used included I-123, Xe-133, and Ga-67. The licensee did not perform any PET scans or research studies. The licensee performed I-131 therapies on an outpatient basis. All dosages were less than 150 mCi

and supplied in capsule form. Approximately 70 studies were performed per year.

The licensee underwent a change of control which resulted in a license name change from Jefferson Radiology to Connecticut Imaging Partners in 2019. The inspectors noted that the sign outside the facility as well as all the paperwork used at the facility referenced the name Jefferson Radiology. The licensee indicated that they did not want to use the new name because of the association with Hartford Healthcare. The inspectors shared this information with Regional Counsel who agreed that the license needed to add a "dba Jefferson Radiology" to their current license to reflect the actual status of their operation. The licensee agreed via email dated February 25, 2020, to submit the amendment request.

Sealed sources in nuclear medicine included one Cs-137 source, two Ba-133 sources, and four Co-57 flood sources, two of which were in storage.

The inspectors observed a NMT perform a package receipt survey, provide an explanation of a procedure to a patient, prepare a patient dose, administer a patient dose, maintain material security, perform waste management activities, and survey the hot lab for contamination. The following is a summary of the findings from the operational observations:

- During the package receipt process the NMT was questioned about their process for returning packages to the pharmacy. The NMT stated that there is no procedure and that no surveys were performed prior to the return of the limited quantity packages.

- During the patient dose administration, the NMT dropped the patient dose on the floor of the camera room. When the dose fell, the needle broke off the syringe. The break caused a spill to occur. The NMT picked the dose and needle up from the floor with an ungloved hand. The NMT surveyed his feet but did not perform a survey of his hands or the area. The inspectors requested that the NMT survey the area and his hands. Contamination was found on his hands and the floor. The NMT sent the patient dose to the hot lab with the lead NMT for further assessment. It was determined that a new dose was needed. The lead NMT ordered a new dose. Meanwhile, the original NMT moved the patient to the adjacent camera room, closed the camera room where the spill occurred, placed a "do not enter" sign on the contaminated room, and began decontaminating his hand. He lowered the contamination from over 50,000 counts per minute (cpm) to approximately 300 cpm and wore a glove on his hand for the remainder of the day. The inspectors noted that the root cause of the spill was the licensee's method of shielding and transporting the dose. It was stored in an open transport pig rather than in a shielded dose carrier. The transport pig was not stable and was knocked over by the NMT's arm when he moved something else. This would not have occurred had the dose been in a shielded dose carrier. The inspectors recommended that the licensee discontinue the practice of transporting doses in this way until they could use a proper dose carrier.

- During the area contamination survey the NMT failed to utilize the wipe counter

as calibrated. Specifically, the NMT loaded the wipe in the test tube which was placed in the wipe counter but not in the correct geometry to produce accurate results. The results for the area wipe were approximately -50 dpm. The inspector requested that the wipe be recounted in the correct geometry; the results were approximately 75 dpm. The procedure for performing area contamination surveys did not include how to utilize the counting equipment.

Review of Records

Records reviewed included: written directives, written procedures for spills, safe use of licensed material and package receipt, patient release instructions, patient release surveys, daily area surveys, weekly area wipes, sealed source inventory and leak test, dosimetry, waste disposal, instrument calibration, annual audits, radiation safety training, DOT/HAZMAT training, and others were reviewed since the last inspection in 2017. The following is a summary of the findings from the records review:

- A sample of 10% of the written directives for 10 CFR 35.300 administrations were reviewed and found to be complete. All therapy treatments were performed on an outpatient basis. Calculations were performed to ensure that patients were released in accordance with 10 CFR 35.75. Instructions for minimizing exposure were reviewed with the patient prior to the treatment and each patient received a paper copy of the instructions.

- The area contamination survey records showed a trend of counts significantly below background being reported. Specifically, 48 out of 52 weekly area surveys were below 0 in 2019.

- The package receipt contamination survey records showed a trend of counts significantly below background being reported. Specifically, 448 out of 761 package surveys were below 0 in 2019.

- Sealed source disposal records indicated that on April 26, 2018, CIP disposed of two Colbalt-57 flood sealed sources in the general trash waste stream. However, after this occurrence, on June 5, 2019, having recognized that the previous disposal was not in accordance with 10 CFR 35.92 ,the licensee disposed of two other Co-57 sources through return to manufacturer.

Independent Radiation Measurements

Independent radiation surveys were conducted in the hot labs, outside the quiet room and in injection areas; the survey results were consistent with the licensee's postings, the licensee's results, and applicable regulatory limits.

Instrument type: Model # 2401-EC
NRC S/N: 214309 calibration expiration date: July 11, 2020

Instrument type: Model # 2401-P
NRC S/N: 281353 calibration expiration date: January 30, 2021

c. Conclusions

During this inspection, four SLIV violations of NRC requirements were identified. The following are the violations:

A. Condition 14 of License No. 06-28502-01 requires, in part, that the licensee shall conduct its program in accordance with statements, representations, and procedures contained in the application dated June 17, 2015.

The application dated June 17, 2015, states, in part, that the licensee developed and will implement and maintain a written procedure for safe response to spills of licensed material in accordance with 10 CFR 20.1101. The licensee created the procedure, "Policy and Procedure for Radioactive Spills," dated May 2018, which states, in part: "3. Wear gloves and personal protective equipment such as lab coat and booties to clean the spill up using absorbent materials;" additionally, "5. Check areas around spill and also survey hands, clothing and shoes for contamination."

Contrary to the above, on February 13, 2020, CIP did not conduct its program in accordance with statements, representations, and procedures contained in the application dated June 17, 2015. Specifically, the licensee did not implement the written procedure for safe response to spills of licensed material, in that, one of the NMTs dropped a syringe containing a dose of Tc-99m, picked it up with an ungloved hand and did not survey his hand for contamination.

This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3)

B. 10 CFR 35.92 requires, in part, a licensee may hold byproduct material with a physical half life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity.

Contrary to the above, on April 25, 2018, CIP did not comply with the requirement to only hold byproduct material with a physical half life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity. Specifically, CIP held two sealed cobalt-57 flood sources, which had a half-life of 270 days (i.e., greater than 120 days), for decay-in-storage before disposal without regard to their radioactivity.

This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3)

C. 10 CFR Part 71. 5(a) requires, in part, that each licensee who transports licensed material outside the site of usage, as specified in the NRC license, shall comply with the applicable requirements of the Department of Transportation regulations in 49 CFR Parts 171 through 180, appropriate to the mode of transport.

49 CFR 173.421(a) provides that radioactive material of limited quantities are excepted from shipping and packaging requirements of the subchapter, in part, if the nonfixed contamination on the external surface of the package does not exceed the limits specified in Section 173.443(a).

49 CFR 173.443(a) states, in part, the level of non-fixed contamination must be kept as low as reasonably achievable on the external surfaces of each package offered for transport. The level of non-fixed radioactive contamination may not exceed the limits set forth in Table 9 (220 dpm/cm2) and must be determined by either: (i) wiping an area of 300 cm2 of the surface concerned with an absorbent material, using moderate pressure, and measuring the activity on the wiping material….; or (ii) Alternatively, the level of non-fixed radioactive contamination may be determined by using other methods of equal or greater efficiency.

Contrary to the above, from March 30, 2016, to February 13, 2020, CIP offered for transport packages of limited quantities of radioactive material as excepted from shipping and packaging requirements of the subchapter without confirming that the nonfixed (removable) radioactive surface contamination on the external package did not exceed 220 dpm/cm2. Specifically, the licensee returned limited quantity packages to the radiopharmacy without conducting the required contamination check.

This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3)

D. 10 CFR 20.1101(a) states, 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 provision of this part. 10 CFR 20.1501 states, in part, each licensee shall make surveys of areas including the subsurface that are reasonable under the circumstances to evaluate the concentrations or quantities of residual radioactivity and the potential radiological hazards of the residual radioactivity detected.

Contrary to the above, as of February 13, 2020, CIP did not develop or implement a radiation protection program commensurate with the scope and extent of licensed activities and sufficient to ensure surveys are made that are reasonable under the circumstances to evaluate the concentrations or quantities of residual radioactivity and the potential radiological hazards of the residual radioactivity detected. Specifically, CIP's procedure for area surveys did not provide adequate instruction to ensure proper performance of wipe tests, in that the procedure did not include instruction on how to analyze wipe tests to obtain accurate results. On February 13, 2020, one NMT analyzed an area wipe test using a geometry for which the instrument was not calibrated. The improper geometry led to erroneous counts below zero. Further, a review of the 2018 records for wipe tests revealed 48 of the 52

weeks with wipe tests results below zero, indicating an improper use of the counting equipment and possible false negative results.

This is a Severity Level IV violation (NRC Enforcement Policy, Section 6.3)

3. Exit Meeting

On March 10, 2020, the inspectors conducted an exit meeting by telephone with Connecticut Imaging Partners. The inspection finding and violations were discussed. The licensee acknowledged the inspection findings, discussed corrective and preventative actions, and emphasized that Connecticut Imaging Partners is committed to compliance with NRC requirements.

ATTACHMENT

PARTIAL LIST OF PERSONS CONTACTED

Individual(s) present at entrance meeting
* Individual(s) present at on-site inspection debrief
+Individual(s) present for telephonic exit meeting

+* Luce Buhl, Senior Director of Outpatient Services
+* Amy Bullen, Chief Quality and Safety Officer
#* Ron Christenson, Lead NMT
* Kim Crockwell, Office Manager
+Peter Mas, consulting physicist
John Natkiel, NMT

INSPECTION PROCEDURES USED

IP 87131, Nuclear Medicine Programs, Written Directive Required

LIST OF ACRONYMS USED

CIP: Connecticut Imaging Partners
CFR: Code of Federal Regulations
NMT: Nuclear Medicine Technologist
RSO: Radiation Safety Officer