

## UNITED STATES NUCLEAR REGULATORY COMMISSION

REGION I 2100 RENAISSANCE BLVD. KING OF PRUSSIA, PA 19406-2713

March 26, 2020

EA-20-025

Ethan Foxman, M.D. Conneticut Imaging Partners, LLC 111 Founders Plaze, Suite 400 East Hartford, CT 06108

SUBJECT: CONNECTICUT IMAGING PARTNERS, LLC - NRC INSPECTION NO.

(03031642/2020001) AND NOTICE OF VIOLATION

Dear Dr. Foxman:

This letter refers to the inspection conducted on February 13, 2020, at your Glastonbury, Conneticut facility. This inspection examined activities conducted under your license as they relate to public health and safety, and to confirm compliance with the Commission's rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel. The inspection included in office review through March 10, 2020. As a result of this review it was noted that an amendment request was needed to add "dba Jefferson Radiology" to your license name to reflect your current operations. You agreed on February 25, 2020, to submit that amendment request.

Based on the results of this inspection, the NRC has determined that four Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <a href="https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html">https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html</a>. The violations are cited in the enclosed Notice of Violation (Notice) because the violations were identified by the NRC.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

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

If you have any questions regarding this matter, please contact Robin Elliott of my staff at (610) 337-5076 or via electronic mail at <a href="mailto:robin.elliott@nrc.gov">robin.elliott@nrc.gov</a>.

Thank you for your cooperation.

Sincerely,

Donna Janda, Chief Medical and Licensing Assistance Branch Division of Nuclear Materials Safety Region I

Docket No. 03031642 License No. 06-28502-01

Enclosure: Notice of Violation

cc w/ enclosure Ronald Rosenberg, Radiation Safety Officer State of Connecticut CONNECTICUT IMAGING PARTNERS, LLC - NRC INSPECTION NO. (03031642/2020001) AND NOTICE OF VIOLATION DATED March 26, 2020

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## NOTICE OF VIOLATION

Conneticut Imaging Partners, LLC East Hartford, Conneticut

Docket No. 03031642 License No. 06-28502-01

During an NRC inspection conducted on Feburary, 13, 2020, four violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

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, Connecticut Imaging Partners, LLC, (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 Nuclear Medicine Technologists 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, CIP held byproduct material with a physical half life greater than 120 days for decay-in-storage before disposal without regard to its radioactivity. Specifically, on April 26, 2018, CIP disposed of two Colbalt-57 flood sealed sources, which have a half-life of 270 days, 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 Nuclear Medicine Technologist 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)

Pursuant to the provisions of 10 CFR 2.201, Conneticut Imaging Partners, LLC, is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated This 26th day of March 2020