



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION I  
2100 RENAISSANCE BLVD.  
KING OF PRUSSIA, PA 19406-2713

May 25, 2021

EA-21-023

Margaret Colarossi, Administrator  
Jefferson University Radiology Associates, LLC  
dba Jefferson Outpatient Imaging  
850 Walnut Street, Walnut Towers  
Philadelphia, PA 19107

**SUBJECT: JEFFERSON UNIVERSITY RADIOLOGY ASSOCIATES, LLC, DBA  
JEFFERSON OUTPATIENT IMAGING (JURA) - NRC INSPECTION  
REPORT 15000037/2021001 AND APPARENT VIOLATION**

Dear Ms. Colarossi:

On January 15, 2021, with continued in-office review through May 21, 2021, Shawn Seeley of this office conducted a routine remote inspection of your activities performed under your Commonwealth of Pennsylvania license No. PA-1416. The inspector discussed the inspection findings with Jay Yoder, Radiation Safety Officer, and you, telephonically, on May 21, 2021.

Based on the results of this inspection, the NRC determined that one apparent violation of NRC requirements occurred related to the failure to provide accurate information to the NRC when filing for reciprocity. This apparent violation is being considered for escalated enforcement in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. Please be advised that the number and characterization of the apparent violations described in the enclosed inspection report may change as a result of further review. You will be advised by separate correspondence of the results of our deliberations on this matter. The circumstances surrounding the apparent violation, the significance of the issue, and the need for lasting and effective corrective actions were discussed with you during the May 21, 2021, telephone call.

Before the NRC makes its enforcement decision regarding the apparent violation, we request that you provide additional information regarding JURA's corrective actions for this event. Although we noted that your immediate corrective actions to change the reciprocity request form appeared to be effective, it is not clear if adequate actions to prevent recurrence have been developed and/or implemented. You should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violation. The guidance in the enclosed excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful.

The written response should be sent to the NRC within 30 days of the date of this letter. The NRC recognizes that many licensees have been impacted by the public health emergency caused by the Coronavirus Disease 2019 (COVID-19). Consequently, you may request an

extension of time to submit the response by contacting Donna Janda, Chief, Medical and Licensing Assistance Branch, via electronic mail at [donna.janda@nrc.gov](mailto:donna.janda@nrc.gov). Such an extension request should explain the basis for the request and should specify the amount of additional time being requested. This extension request must be submitted to the NRC no later than 20 days from the date of this letter (i.e., at least 10 days before the initial 30-day deadline to submit the written response).

Your response 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. You should clearly mark the response as a "Response to Apparent Violation in NRC Inspection Report No. 15000037/2021001; EA-21-023," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, NRC Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406. 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 pre-decisional enforcement conference (PEC).

In lieu of providing this written response, you may choose to provide your perspective on this matter, including the significance, cause, and corrective actions, as well as any other information that you believe the NRC should take into consideration by: (1) requesting a PEC to meet with the NRC and provide your views in person; or (2) requesting Alternative Dispute Resolution (ADR).

If you choose to request a PEC, the meeting should be held within 30 days of the date of this letter, although this timeframe may be extended due to impacts from COVID-19. The conference will include an opportunity for you 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 topics discussed during the PEC 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. Please note that if a PEC is held, the NRC would issue a press release to announce the conference time and date.

In lieu of a PEC or written response, you may request ADR with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation; 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 ADR program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC program as a neutral third party. Please contact

ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. The ADR mediation session should be held within 45 days of the date of this letter, although this timeframe may be extended due to impacts from COVID-19. The mediation session would be closed to public observation, but the time and date would be publicly announced.

Please contact Ms. Janda at [donna.janda@nrc.gov](mailto:donna.janda@nrc.gov) within **10 days** of the date of this letter to notify the NRC which of the above options you choose. If you do not contact the NRC within the time specified, and an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision.

In accordance with 10 CFR 2.390 of the NRC's Rules of Practice," a copy of this letter, 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 from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

If you have any questions concerning this matter, please contact Shawn Seeley of my staff at [shawn.seeley@nrc.gov](mailto:shawn.seeley@nrc.gov).

Sincerely,

Blake Welling, Director  
Division of Radiological Safety and Security  
Region I

Docket No. 15000037  
License No. PA-1416

Enclosures:

1. Inspection Report 15000037/2021001
2. NRC Information Notice 96-28

cc w/Encls: Jay Yoder, RSO  
Commonwealth of Pennsylvania

JEFFERSON UNIVERSITY RADIOLOGY ASSOCIATES, LLC DBA JEFFERSON OUTPATIENT IMAGING (JURA) - NRC INSPECTION REPORT 15000037/2021001, PHILADELPHIA, PENNSYLVANIA DATED May 25, 2021

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U.S. NUCLEAR REGULATORY COMMISSION  
REGION I

INSPECTION REPORT

Inspection No. 15000037/2021001  
Docket No. 15000037  
License No. PA-1416  
EA No. EA-21-023  
Licensee: Jefferson University Radiology Associates, LLC  
dba Jefferson Outpatient Imaging  
Address: 850 Walnut Street, Walnut Towers  
Philadelphia, PA 19107  
Inspection Dates: January 15, 2021, through May 21, 2021  
Exit Meeting: May 21, 2021  
Inspector: *Shawn W. Seeley* \_\_\_\_\_ 5-21-2021 \_\_\_\_\_  
Shawn Seeley date  
Health Physicist  
Medical and Licensing Assistance Branch  
Division of Radiological Safety and Security  
Approved By: \_\_\_\_\_  
Donna M. Janda, Chief date  
Medical and Licensing Assistance Branch  
Division of Radiological Safety and Security

Enclosure

## EXECUTIVE SUMMARY

Jefferson University Radiology Associates, LLC dba Jefferson Outpatient Imaging  
NRC Inspection Report No. 15000037/2021001

On January 15, 2021, the NRC initiated a routine announced inspection to review the organization and scope of activities performed under Jefferson University Radiology Associates, LLC dba Jefferson Outpatient Imaging (JURA) Commonwealth of Pennsylvania License No. PA-1416. JURA is a small University Healthcare provider located in Philadelphia, Pennsylvania and licensed by the Commonwealth to provide mobile Positron Emission Tomography (PET) imaging to clients. The licensee has been conducting patient studies under reciprocity for numerous years at St. Francis Healthcare, located in Wilmington, Delaware.

One apparent violation of NRC requirements was identified and is being considered for escalated enforcement. 10 CFR 30.9(a) states that information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects. 10 CFR 150.20(b) requires that an Agreement State licensee shall, at least 3 days before engaging in licensed activity in non-agreement states for the first time in a calendar year, file a submittal containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States." The regulation further requires that the Agreement State licensee shall file an amended NRC Form 241 or letter with the Regional Administrator to request approval for changes in work locations, radioactive material, or work activities different from the information contained on the initial NRC Form 241. The NRC Form 241 requires the signature approval of a Radiation Safety Officer (RSO) or management representative who certifies, in part, that the information on the form is true and complete. Contrary to the above, on 10 occasions between April 24, 2020 and December 30, 2020, the Agreement State licensee provided information to the NRC that was not complete and accurate in all material respects. Specifically, the general licensee submitted ten Form 241s with photocopied signatures of a former RSO. This information is material to the NRC because the NRC relies on the RSO or management representative to maintain awareness of the licensee's activities in NRC jurisdiction and ensure that they are performed in accordance with the specifications and limitations described on the Form 241.

Immediate corrective action included submitting a corrected form signed by an authorized individual on January 21, 2021, for work to be conducted on January 22, 2021.

## **REPORT DETAILS**

### **1. Organization and Scope of the Program**

#### a. Inspection Scope

The inspector reviewed the organization and scope of activities performed under Jefferson University Radiology Associates, LLC dba Jefferson Outpatient Imaging's (JURA) Commonwealth of Pennsylvania License No. PA-1416. Information was gathered through interviews with licensee staff, including the new Radiation Safety Officer, and through reviews of selected records.

#### b. Observations and Findings

JURA is a small University Healthcare provider located in Philadelphia, PA. They are licensed by the Commonwealth of Pennsylvania (under timely renewal) to provide mobile Positron Emission Tomography (PET) imaging to clients. The licensee has been conducting patient studies under reciprocity for numerous years at St. Francis Healthcare, located in Wilmington, Delaware.

The Radiation Safety Officer (RSO) for JURA's license is a health physics consultant who is available by telephone daily and onsite as necessary. The license was amended via letter dated April 17, 2020, to change the RSO from Mr. Adam Henry to Mr. Jay Yoder. The amended license was signed on April 24, 2020.

#### c. Conclusions:

No violations of NRC requirements were identified.

### **2. Review of Licensed Activities**

#### a. Inspection Scope

The inspector performed a remote announced routine inspection utilizing NRC Inspection Procedure 87130, "Nuclear Medicine Programs, Written Directive Not Required," to conduct the inspection. Information was gathered through interviews with cognizant personnel and a review of records.

b. Observations and Apparent violations

The inspector determined the licensee submitted their initial NRC Form 241 for calendar year 2021, via facsimile to the Region I office on December 30, 2020, to conduct licensed activities at St. Francis Healthcare in Wilmington, DE on January 7<sup>th</sup> and 21<sup>st</sup> of 2021. The form was co-signed by Adam Henry, Radiation Safety Officer (RSO) and Lauren Odell, Certified Nuclear Medicine Technologist (CNMT). Whereas the fee was not included, NRC staff attempted to contact the licensee to inquire about the fee payment.

Multiple attempts by telephone and email were made to Mr. Adam Henry, RSO, and Ms. Margaret Colarossi, Office Manager for Jefferson to obtain the payment information. Neither party responded until after January 7, 2021. On January 12, 2021, NRC staff contacted the client to alert them that Jefferson had not been approved for work on January 21, 2021. During this call, staff learned that Jefferson had conducted licensed activity on one patient on January 7, 2021. The client then contacted Jefferson about the upcoming patient schedule for January 21.

On January 15, 2021, Ms. Margaret Colarossi was contacted and a payment was submitted over the phone. Subsequently, an inspection was opened by the Medical Branch.

The inspection was conducted remotely due to the ongoing COVID PHE. During the inspection, the inspector determined that Jefferson had submitted forms on a monthly basis for prior years as patient cases dictated. The inspector attempted to contact the RSO, Mr. Adam Henry, to discuss the Form 241 filings. The inspector reached Mr. Jay Yoder, president of Keystone Health Physics, the consulting company supplying the RSO services to Jefferson, who informed the inspector that Mr. Henry had not worked there since the end of March 2020. The inspector determined that the licensee had used a pre-signed form by the RSO for the CNMT to submit whenever the patient schedule had been established each month. This pre-signed form was submitted on April 24, 2020, June 1, 2020, June 29, 2020, July 17, 2020, August 28, 2020, September 28, 2020, November 2, 2020, December 1, 2020, and December 16, 2020. The forms signed from June 29, 2020, until the end of the year had been co-signed by the CNMT.

The inspector determined that on 10 occasions, JURA's submittal of an NRC Form 241 that had been pre-signed by an RSO who was no longer affiliated with the company, constituted an apparent violation of 10 CFR Part 30.9, Completeness and Accuracy of Information.

Apparent Violation

10 CFR 30.9(a) states that information provided to the Commission by a licensee or to the Commission by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the licensee shall be complete and accurate in all material respects.

10 CFR 150.20(a)(1) states that any person who holds a specific license from an Agreement State, where the licensee maintains an office for directing the licensed activity and retaining radiation safety records, is granted a general license to conduct the same activity in non-agreement states.

10 CFR 150.20(b) states, in part, that an Agreement State licensee shall, at least 3 days before engaging in each activity for the first time in a calendar year, file a submittal

containing an NRC Form 241, "Report of Proposed Activities in Non-Agreement States." The Agreement State licensee shall file an amended NRC Form 241 or letter with the Regional Administrator to request approval for changes in work locations, radioactive material, or work activities different from the information contained on the initial NRC Form 241. The NRC Form 241 requires the signature approval of an RSO or management representative who certifies, in part, that the information on the form is true and complete.

Contrary to the above, on 10 occasions between April 24, 2020 and December 30, 2020, Jefferson University Radiology, which holds a specific license from an Agreement State and, therefore, holds a general license from the NRC to conduct the same activity in non-agreement states, provided information to the NRC that was not complete and accurate in all material respects. Specifically, the general licensee submitted ten Form 241s with photocopied signatures of a former RSO. This information is material to the NRC because the NRC relies on the RSO or management representative to maintain awareness of the licensee's activities in NRC jurisdiction and ensure that they are performed in accordance with the specifications and limitations described on the Form 241.

#### Summary of Corrective Actions

Immediate corrective action included submitting a corrected form signed by an authorized individual on January 21, 2021, for work to be conducted on January 22, 2021.

c. Conclusions

One apparent violation of NRC requirements was identified and is being considered for escalated enforcement as noted above.

**3. Exit Meeting**

On May 21, 2021, the inspector presented the results of the inspection by telephone. The licensee acknowledged the apparent violation.

**ATTACHMENT: SUPPLEMENTAL INFORMATION**

**PARTIAL LIST OF PERSONS CONTACTED**

Licensee

\*Jay Yoder, Radiation Safety Officer

\*Margaret Colarossi, Administrator

\*Present at telephone exit meeting on May 21, 2021

**INSPECTION PROCEDURES USED**

- 1) Manual Chapter 2800, "Materials Inspection Program"
- 2) Inspection Procedure 87130, "Inspection of Nuclear Medicine Programs, Written Directive Not Required"

**LIST OF NRC SURVEY INSTRUMENTS USED**

None used – remote inspection only

**LIST OF ACRONYMS USED**

CFR	Code of Federal Regulations
CNMT	Certified Nuclear Medicine Technologist
NRC	Nuclear Regulatory Commission
RSO	Radiation Safety Officer