

June 6, 2025

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, D.C. 20555

Reference: Docket No. 030-39271
NRC Inspection Report No. 030-39271/2025001

Subject: Reply to a Notice of Violation – Violation B 10 CFR35.63(d)

To Whom It May Concern:

This letter is in response to the referenced NRC Inspection Report, dated May 20, 2025, signed by Ms. Farrah C. Gaskins. This report refers to the inspection conducted on February 5, 2025, at the Coto Laurel, PR facility of Cardiovascular Radiology Institute, Inc. with continued in-office review through May 8, 2025.

Enclosed please find the formal response of Cardiovascular Radiology Institute, Inc. to the Notice of Violation B, concerning noncompliance with 10 CFR 35.63(d), issued in NRC Inspection Report No. 030-39271/2025001.

We accepted and addressed the violation and provided here a description of the reason for the violation, corrective actions taken, planned actions to prevent recurrence, and the date when full compliance was achieved as pursuant to 10 CFR 2.201. Supporting documentation is included for reference. We also appreciate the thoroughness and professionalism demonstrated by the NRC inspectors during their visit to our offices.

Please contact me at (787) 370-2960 or via email at gmarquez@atlanticimagingpr.com if further clarification or additional documentation is required.

Sincerely,



Gerardo Marquez-Veglio – President
Cardiovascular Radiology Institute, Inc.

CC: Regional Administrator, Region I

Response to the Notice of Violation

This response addresses Violation B of the Notice of Violation issued to Cardiovascular Radiology Institute, Inc. on May 20, 2025, as identified during NRC Inspection No. 030-39271/2025001.

NRC Statement of Violation: 10 CFR 35.63(d) requires that, unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent.

Contrary to the above, prior to the inspection on February 5, 2025, the licensee administered dosages that did not stay within the prescribed range or exceeded the $\pm 20\%$ limit from the prescribed dosage, without being directed or authorized from the Authorized User (AU). For Fluorodeoxyglucose F-18 (^{18}F -FDG), the dosage was based on patient weight, and for Piflufolostat F-18 (Pylarify), the prescribed range was 8–10 mCi.

Reason for the Violation: Following the inspection, the Radiation Safety Officer (RSO) conducted a review of prior dosage administrations and found that the deviations were due to the absence of a formal procedure to verify and document compliance with prescribed dosage limits or obtain proper authorization. Staff also lacked a clear understanding of how to calculate the $\pm 20\%$ allowable variation. Although certain out-of-range dosages were verbally communicated to the Authorized User (AU), they were not formally documented, leading to multiple administrations outside the prescribed range or dosage without written approval. Cardiovascular Radiology Institute, Inc. acknowledges that this constitutes a violation of NRC requirements.

Corrective Steps Taken and Results Achieved: Following the inspection, several corrective actions were implemented to address the identified issue and re-establish full compliance.

1. A patient dose calculator table was developed and disseminated to nuclear medicine technologists to standardize dose determination for ^{18}F -FDG based on patient weight. Approved by the facility AU, the tool provides the target dose based on patient weight along with the corresponding $\pm 20\%$ limits, allowing technologists to verify compliance at the time of administration.
2. The Patient Daily Log was updated to include required fields for patient weight, indication of dose compliance with the prescribed range or dosage, and documentation of AU approval when applicable.
3. The PET/CT Dose Deviation Approval Form was created to formally document any instance in which the administered dose falls outside the prescribed range or the $\pm 20\%$ prescribed dosage and includes the signature of the AU for approval. A formal communication protocol has also been implemented, requiring technologists to contact the AU before administering any dose expected to exceed the allowable

range or the $\pm 20\%$ prescribed dose limit. The original form is retained in the Patient Daily Log, and a copy is placed in the patient's medical record.

4. The facility's study protocols were revised by AU and a new standard operation procedure (SOP) for radiopharmaceutical administration was created with facility's forms, calculators, define the dose verification process, and clarify dose approval documentation.
5. Training was conducted on April 14, 2025, for the nuclear medicine technologists. The session covered the requirements of 10 CFR 35.63(d), correct use of the dosage calculator, identification of out-of-range doses, and proper communication and documentation procedures with the AU.

All measures were fully implemented as of April 18, 2025, and remain in active use.

Corrective Steps Taken to Avoid Further Violations: To ensure continued compliance and prevent recurrence, the RSO will review dose logs on a monthly basis to confirm that dosing limits are followed and that proper documentation by the AU is in place. Updated SOPs have been fully implemented, and all involved personnel have signed written acknowledgments. This incident will be included in the annual refresher training for technologists, with emphasis on patient-specific dosing and AU authorizations. Additionally, the RSO will conduct regular spot-checks to verify proper use of the dose calculator and ensure compliance with AU communication protocols.

Date Full Compliance Achieved: Full compliance was achieved on April 18, 2025, following the implementation of the dose calculator table, revised dose log form, updated standard SOPs, and comprehensive staff retraining. All radiopharmaceutical doses administered since that date have been reviewed and verified to be within the $\pm 20\%$ acceptable range or were formally authorized by the AU in accordance with the revised protocols.

Attachments:

- (1) FDG Oncology- Patient dose Calculator Table.pdf
- (2) CRI Patient's Daily Log.pdf
- (3) CRI PET-CT Dose Deviation Approval Form.pdf
- (4) CRI Dosage Administration Compliance Training Record.pdf (x2)

FDG F-18 for Oncology Protocols

Dosage by weight using: 0.15 mCi/kg

Pt Weight lbs	Pt Dose mCi	- 20%	+ 20%
75	4.8	3.8	5.7
76	4.8	3.9	5.8
77	4.9	3.9	5.9
78	5.0	4.0	6.0
79	5.0	4.0	6.0
80	5.1	4.1	6.1
81	5.2	4.1	6.2
82	5.2	4.2	6.3
83	5.3	4.2	6.3
84	5.3	4.3	6.4
85	5.4	4.3	6.5
86	5.5	4.4	6.6
87	5.5	4.4	6.6
88	5.6	4.5	6.7
89	5.7	4.5	6.8
90	5.7	4.6	6.9
91	5.8	4.6	6.9
92	5.9	4.7	7.0
93	5.9	4.7	7.1
94	6.0	4.8	7.2
95	6.0	4.8	7.3
96	6.1	4.9	7.3
97	6.2	4.9	7.4
98	6.2	5.0	7.5
99	6.3	5.0	7.6
100	6.4	5.1	7.6
101	6.4	5.1	7.7
102	6.5	5.2	7.8
103	6.6	5.2	7.9
104	6.6	5.3	7.9
105	6.7	5.3	8.0
106	6.7	5.4	8.1
107	6.8	5.4	8.2
108	6.9	5.5	8.2
109	6.9	5.5	8.3
110	7.0	5.6	8.4
111	7.1	5.7	8.5
112	7.1	5.7	8.6
113	7.2	5.8	8.6
114	7.3	5.8	8.7
115	7.3	5.9	8.8
116	7.4	5.9	8.9
117	7.4	6.0	8.9
118	7.5	6.0	9.0
119	7.6	6.1	9.1
120	7.6	6.1	9.2
121	7.7	6.2	9.2
122	7.8	6.2	9.3

Pt Weight lbs	Pt Dose mCi	- 20%	+ 20%
123	7.8	6.3	9.4
124	7.9	6.3	9.5
125	8.0	6.4	9.5
126	8.0	6.4	9.6
127	8.1	6.5	9.7
128	8.1	6.5	9.8
129	8.2	6.6	9.9
130	8.3	6.6	9.9
131	8.3	6.7	10.0
132	8.4	6.7	10.1
133	8.5	6.8	10.2
134	8.5	6.8	10.2
135	8.6	6.9	10.3
136	8.7	6.9	10.4
137	8.7	7.0	10.5
138	8.8	7.0	10.5
139	8.8	7.1	10.6
140	8.9	7.1	10.7
141	9.0	7.2	10.8
142	9.0	7.2	10.8
143	9.1	7.3	10.9
144	9.2	7.3	11.0
145	9.2	7.4	11.1
146	9.3	7.4	11.1
147	9.4	7.5	11.2
148	9.4	7.5	11.3
149	9.5	7.6	11.4
150	9.5	7.6	11.5
151	9.6	7.7	11.5
152	9.7	7.7	11.6
153	9.7	7.8	11.7
154	9.8	7.8	11.8
155	9.9	7.9	11.8
156	9.9	7.9	11.9
157	10.0	8.0	12.0
158	10.1	8.0	12.1
159	10.1	8.1	12.1
160	10.2	8.1	12.2
161	10.2	8.2	12.3
162	10.3	8.2	12.4
163	10.4	8.3	12.4
164	10.4	8.3	12.5
165	10.5	8.4	12.6
166	10.6	8.5	12.7
167	10.6	8.5	12.8
168	10.7	8.6	12.8
169	10.8	8.6	12.9
170	10.8	8.7	13.0

Pt Weight lbs	Pt Dose mCi	- 20%	+ 20%
171	10.9	8.7	13.1
172	10.9	8.8	13.1
173	11.0	8.8	13.2
174	11.1	8.9	13.3
175	11.1	8.9	13.4
176	11.2	9.0	13.4
177	11.3	9.0	13.5
178	11.3	9.1	13.6
179	11.4	9.1	13.7
180	11.5	9.2	13.7
181	11.5	9.2	13.8
182	11.6	9.3	13.9
183	11.6	9.3	14.0
184	11.7	9.4	14.1
185	11.8	9.4	14.1
186	11.8	9.5	14.2
187	11.9	9.5	14.3
188	12.0	9.6	14.4
189	12.0	9.6	14.4
190	12.1	9.7	14.5
191	12.2	9.7	14.6
192	12.2	9.8	14.7
193	12.3	9.8	14.7
194	12.3	9.9	14.8
195	12.4	9.9	14.9
196	12.5	10.0	15.0
197	12.5	10.0	15.0
198	12.6	10.1	15.1
199	12.7	10.1	15.2
200	12.7	10.2	15.3
201	12.8	10.2	15.3
202	12.9	10.3	15.4
203	12.9	10.3	15.5
204	13.0	10.4	15.6
205	13.0	10.4	15.7
206	13.1	10.5	15.7
207	13.2	10.5	15.8
208	13.2	10.6	15.9
209	13.3	10.6	16.0
210	13.4	10.7	16.0
211	13.4	10.7	16.1
212	13.5	10.8	16.2
213	13.6	10.8	16.3
214	13.6	10.9	16.3
215	13.7	10.9	16.4
216	13.7	11.0	16.5
217	13.8	11.0	16.6
218	13.9	11.1	16.6

Pt Weight lbs	Pt Dose mCi	- 20%	+ 20%
219	13.9	11.1	16.7
220	14.0	11.2	16.8
221	14.1	11.3	16.9
222	14.1	11.3	17.0
223	14.2	11.4	17.0
224	14.3	11.4	17.1
225	14.3	11.5	17.2
226	14.4	11.5	17.3
227	14.4	11.6	17.3
228	14.5	11.6	17.4
229	14.6	11.7	17.5
230	14.6	11.7	17.6
231	14.7	11.8	17.6
232	14.8	11.8	17.7
233	14.8	11.9	17.8
234	14.9	11.9	17.9
235	15.0	12.0	17.9
236	15.0	12.0	18.0
237	15.1	12.1	18.1
238	15.1	12.1	18.2
239	15.2	12.2	18.3
240	15.3	12.2	18.3
241	15.3	12.3	18.4
242	15.4	12.3	18.5
243	15.5	12.4	18.6
244	15.5	12.4	18.6
245	15.6	12.5	18.7
246	15.7	12.5	18.8
247	15.7	12.6	18.9
248	15.8	12.6	18.9
249	15.8	12.7	19.0
250	15.9	12.7	19.1
251	16.0	12.8	19.2
252	16.0	12.8	19.2
253	16.1	12.9	19.3
254	16.2	12.9	19.4
255	16.2	13.0	19.5
256	16.3	13.0	19.5
257	16.4	13.1	19.6
258	16.4	13.1	19.7
259	16.5	13.2	19.8
260	16.5	13.2	19.9
261	16.6	13.3	19.9
262	16.7	13.3	20.0
263	16.7	13.4	20.1
264	16.8	13.4	20.2
265	16.9	13.5	20.2
266	16.9	13.5	20.3

Pt Weight lbs	Pt Dose mCi	- 20%	+ 20%
267	17.0	13.6	20.4
268	17.1	13.6	20.5
269	17.1	13.7	20.5
270	17.2	13.7	20.6
271	17.2	13.8	20.7
272	17.3	13.8	20.8
273	17.4	13.9	20.8
274	17.4	13.9	20.9
275	17.5	14.0	21.0
276	17.6	14.1	21.1
277	17.6	14.1	21.2
278	17.7	14.2	21.2
279	17.8	14.2	21.3
280	17.8	14.3	21.4
281	17.9	14.3	21.5
282	17.9	14.4	21.5
283	18.0	14.4	21.6
284	18.1	14.5	21.7
285	18.1	14.5	21.8
286	18.2	14.6	21.8
287	18.3	14.6	21.9
288	18.3	14.7	22.0
289	18.4	14.7	22.1
290	18.5	14.8	22.1
291	18.5	14.8	22.2
292	18.6	14.9	22.3
293	18.6	14.9	22.4
294	18.7	15.0	22.5
295	18.8	15.0	22.5
296	18.8	15.1	22.6
297	18.9	15.1	22.7
298	19.0	15.2	22.8
299	19.0	15.2	22.8
300	19.1	15.3	22.9
301	19.2	15.3	23.0
302	19.2	15.4	23.1
303	19.3	15.4	23.1
304	19.3	15.5	23.2
305	19.4	15.5	23.3
306	19.5	15.6	23.4
307	19.5	15.6	23.4
308	19.6	15.7	23.5
309	19.7	15.7	23.6
310	19.7	15.8	23.7
311	19.8	15.8	23.7
312	19.9	15.9	23.8
313	19.9	15.9	23.9
314	20.0	16.0	24.0

* If patient weight more than 314 lbs, dose is 20.0 mCi (Max dose).

PET/CT Dose Deviation Approval Form

Complete this form for any single dose deviating more than $\pm 20\%$. Remember, if deviation exceeds $\pm 20\%$, AU/MD authorization is required before administration.

Date of Administration: _____

Patient Name: _____ Patient ID: _____

Study Protocol: _____ Radiopharmaceutical: _____

Prescribed Activity: _____ mCi Administered Activity: _____ mCi

% Difference from Prescribed: _____ % Does Activity Exceed $\pm 20\%$?: Yes / No

Deviation Justification?:

AU/MD Contacted Before Administration?: Yes / No

Name of AU/MD Contacted: _____

Date/ Time of Authorization: _____

Technologist Initials: _____

Authorized User (MD) Signature: _____

Date: _____

- This form must be stored in the Patient Daily Log for RSO review.
- A copy must be placed in the patient record.

Radiopharmaceutical Dose Verification Training & Competency Record

Cardiovascular Radiology Institute, Inc.

Training Title: Compliance with $\pm 20\%$ Dose Limit, Use of Dose Calculator, and AU Authorization Documentation- Discussion

Training Date: April 14, 2025

Trainer: Lynes Matos-Rodriguez RSO Consultant

Duration: 30–45 minutes

Training Objectives

- How to calculate patient-specific doses using the approved 18F-FDG Dose Calculator Table.
- How to determine if a dose falls within the prescribed allowable $\pm 20\%$ limit or range.
- When and how to notify the Authorized User if the calculated or drawn dose is outside this limit.
- Documentation requirements: updated Patient Daily Log and AU Authorization Log.
- Overview of revised SOPs and compliance expectations.

Competency Check

- Calculate the $\pm 20\%$ dose limit for a given prescribed dose.
- Use the calculator table to identify correct prescribed dose based on patient weight.
- Accurately document patient weight, calculated dose, and AU contact (if applicable).
- Complete the AU Authorization Log for an out-of-range dose scenario.

Employee Name	Signature	Date	Trainer Initials

Radiopharmaceutical Dose Verification Training & Competency Record

Cardiovascular Radiology Institute, Inc.

Training Title: Compliance with $\pm 20\%$ Dose Limit, Use of Dose Calculator, and AU Authorization Documentation- Discussion

Training Date: April 14, 2025

Trainer: Lynes Matos-Rodriguez RSO Consultant

Duration: 30–45 minutes

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- How to calculate patient-specific doses using the approved 18F-FDG Dose Calculator Table.
- How to determine if a dose falls within the prescribed allowable $\pm 20\%$ limit or range.
- When and how to notify the Authorized User if the calculated or drawn dose is outside this limit.
- Documentation requirements: updated Patient Daily Log and AU Authorization Log.
- Overview of revised SOPs and compliance expectations.

Competency Check

- Calculate the $\pm 20\%$ dose limit for a given prescribed dose.
- Use the calculator table to identify correct prescribed dose based on patient weight.
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Employee Name	Signature	Date	Trainer Initials