

PART I – LICENSE, INSPECTION, INCIDENT/EVENT AND ENFORCEMENT HISTORY

1. AMENDMENTS AND PROGRAM CHANGES SINCE LAST INSPECTION:

| <u>AMENDMENT #</u> | <u>DATE</u> | <u>SUBJECT</u> |
|--------------------|-------------|------------------|
| 0 | 03/08/2017 | Initial Issuance |

2. INSPECTION AND ENFORCEMENT HISTORY:

The NRC conducted a pre-licensing site visit of this facility on February 15, 2017.

3. INCIDENT/EVENT HISTORY:

No open items or events since the license was issued.

PART II – INSPECTION DOCUMENTATION

1. ORGANIZATION AND SCOPE OF PROGRAM:

Premier Cardiovascular Consultants (licensee) was authorized under NRC Materials License No. 21-35394-01, initially issued on March 8, 2017, to use radiopharmaceuticals for diagnostic medical purposes at its facility in Troy, Michigan. At the time of this inspection, the licensee performed cardiac stress tests every on alternating Tuesdays using unit doses of technetium-99m from a local radiopharmacy. The licensee retained the services of a health physics consulting company to oversee the radiation safety program and to perform instrument calibrations and quality control.

2. SCOPE OF INSPECTION:

Inspection Procedure(s) Used: 87130

Focus Areas Evaluated: All

The inspector toured the licensee's clinic in Troy to evaluate the licensee's measures for materials security and hazard communication. The inspector interviewed licensee staff and the licensee's health physics consultant to discuss the conduct of licensed activities and oversight of the radiation safety program.

3. INDEPENDENT AND CONFIRMATORY MEASUREMENTS:

The inspector did not conduct any independent or confirmatory surveys. The licensee used only short-lived radiopharmaceuticals in unsealed form, and at the time of the inspection had not performed any administrations in over a week.

4. VIOLATIONS, NCVs, AND OTHER SAFETY ISSUES:

As a result of this inspection, the inspector identified a Severity Level IV violation of Title 10 of the *Code of Federal Regulations* (CFR) 35.14(b)(1) for the failure notify the

Commission no later than 30 days after a Radiation Safety Officer (RSO) permanently discontinues performance of duties under the license.

In accordance with Inspection Manual Chapter 2800, the inspector attempted to announce this initial inspection to the licensee, but was unable to make contact with the individual listed as RSO in Condition 11 of the initial issuance of NRC License No. 21-35394-01 prior to the inspection. Upon arriving at the clinic, the inspector found that the RSO's contact information on the door of the hot lab had been replaced with that of the owner of the health physics consulting company for which the RSO had worked. The inspector contacted the owner, who stated that the individual listed as RSO for this licensee had left the employment of the consulting company approximately three months prior. The owner assumed the duties of the RSO for this licensee as soon as the listed RSO left, but failed to notify the NRC of this change until the inspector reminded him of this requirement.

Title 10 CFR Part 35.14(b)(1) requires, in part, that a licensee shall notify the Commission no later than 30 days after a Radiation Safety Officer permanently discontinues performance of duties under the license. The licensee's failure to notify the NRC no later than 30 days after this occurred is a violation of 10 CFR 35.14(b)(1).

The inspector determined that the root cause of the violation was an oversight by the licensee's health physics consulting company. As corrective action, the owner of the consulting company prepared the required notification and provided it to the licensee. On January 9, 2018, the licensee provided that notification to the Commission, in the form of an amendment request dated December 27, 2017 to name a new RSO.

The inspector interviewed the clinic's cardiology technician and found that the owner of the consulting company had continued to provide the same level of oversight that the previous RSO had provided, including periodic onsite audits of the nuclear medicine program. During the period of in-office review, the inspector discussed the qualifications of the owner with the license reviewer from NRC Region III who had been assigned this amendment request. The reviewer found that the owner appeared to be qualified to fulfill the duties of an RSO, as he was already currently listed as RSO on several other active NRC materials licenses authorizing diagnostic medical use of radioactive material. Therefore, in accordance with the NRC's Enforcement Policy (example 6.9.D.7), the violation is appropriately characterized as a Severity Level IV.

5. PERSONNEL CONTACTED:

- Mohamad Baydoun – Cardiology Technician
- # Ray Carlson – Owner, Radiation Physics Service, Inc.
- # Attended exit meeting on January 30, 2018.

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