

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED:

Moon Pak, M. D.
811 Oakwood Dr.
Ste. 201
Rochester, MI 48307-1361

REPORT NUMBER(S) 2019001

2. NRC/REGIONAL OFFICE

Region III
U. S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

3. DOCKET NUMBER(S)

030-37786

4. LICENSE NUMBER(S)

21-32680-01

5. DATE(S) OF INSPECTION

5/1/19

LICENSEE:

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

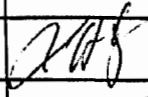
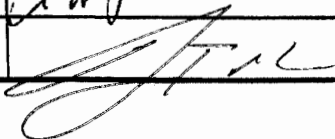
- ☒ 1. Based on the inspection findings, no violations were identified.
- ☐ 2. Previous violation(s) closed.
- ☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

Non-cited violation(s) were discussed involving the following requirement(s):

- ☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
- (Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE'S REPRESENTATIVE			
NRC INSPECTOR	Luis Nieves Folch		8/1/19
BRANCH CHIEF	Aaron McCraw		8/6/19

Docket File Information**SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION**

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3. DOCKET NUMBER(S) 030-37786	4. LICENSE NUMBER(S) 21-32680-01	5. DATE(S) OF INSPECTION August 1, 2019
6. INSPECTION PROCEDURES USED 87130	7. INSPECTION FOCUS AREAS All	

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02201	2. PRIORITY 5	3. LICENSEE CONTACT Alton Garfield Smith- RSO	4. TELEPHONE NUMBER (248) 656-0177
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☒ Main Office Inspection Next Inspection Date: August 1, 2024

☐ Field Office Inspection _____

☐ Temporary Job Site Inspection _____

PROGRAM SCOPE

This was a routine, unannounced inspection of a small cardiac clinic authorized to use unsealed byproduct material for diagnostic administrations of radiopharmaceuticals at its facility in Rochester, Michigan. The licensee employed one part-time nuclear medicine technologist who performed approximately four to six studies per day, only on Thursdays. The licensee only used unit doses provided by a local radiopharmacy. The licensee retained the services of a medical physics consultant to perform instrument calibrations, leak tests, and quarterly audits of the radiation safety program.

PERFORMANCE OBSERVATIONS

The inspector toured the hot lab and evaluated the licensee's measures for material security, radiological shielding, and hazard communication. The technologist demonstrated adequate knowledge of radiation protection principles and licensee procedures through interviews and demonstrations of package receipt, area surveys, spill response and waste handling. The inspector observed one diagnostic administration of radiopharmaceuticals while on site, noting adequate use of time and shielding to maintain exposures ALARA. Independent and confirmatory surveys of the hot lab and other areas found no residual contamination or exposures to members of the public distinguishable from background.

The inspector reviewed a selection of licensee records for instrument quality control, package receipt, dose preparation, sealed source inventory and leak testing, training, quarterly audits, and dosimetry, which indicated that exposures from licensed activities were below regulatory limits.

No violations of NRC requirements were identified as a result of this inspection.