

Docket File Information

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/LOCATION INSPECTED: Medi-Physics, Inc. d/b/a GE Healthcare 4380 Brockton SE, Suite 3 Kentwood, MI 49512 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) 030-34090	4. LICENSE NUMBER(S) 21-26707-01MD	5. DATE(S) OF INSPECTION April 3, 2019
--------------------------------------	---	---

6. INSPECTION PROCEDURES USED 87127	7. INSPECTION FOCUS AREAS 03.01-03.08
--	--

SUPPLEMENTAL INSPECTION INFORMATION

1. PROGRAM CODE(S) 02500	2. PRIORITY 2	3. LICENSEE CONTACT Stephen M. Williams, R.Ph. - RSO	4. TELEPHONE NUMBER (616) 554-5717
-----------------------------	------------------	---	---------------------------------------

Main Office Inspection Next Inspection Date: April 3, 2022
 Field Office Inspection _____
 Temporary Job Site Inspection _____

PROGRAM SCOPE

This was an unannounced, routine inspection of a radiopharmacy located in Kentwood, Michigan. This radiopharmacy employed one pharmacist, four pharmacy technicians, and eleven drivers. The licensee distributed approximately 220 doses daily. The pharmacy was open weekdays from 1:30 am through 4:30 pm, with limited hours on weekends. The weekday runs were done at 4:00am, 8:30am, and 11:00 am, with deliveries made as needed throughout the day. The licensee received several technetium-99m generators each week for preparation and distribution of unit doses and bulk technetium to clients. In addition, the licensee distributed occasional thallium-201, gallium-67, and indium-111 unit doses prepared from bulk materials. The licensee also prepared and distributed iodine-123 and iodine-131 diagnostic capsules to customers.

PERFORMANCE OBSERVATIONS

The inspector observed licensee personnel perform generator elution, molybdenum assay, kit preparation and QC, drawing doses and bulk technetium, packaging and surveying of doses, pig and package surveys and wipes, verification of package contents, preparation of labels and shipping papers, shipment assembly, blocking/bracing of packages, placement of shipping papers, waste disposal, and use of syringe shields and long-handled tools. Licensee personnel demonstrated and described daily area surveys and wipes, package receipt surveys, spill procedures, indium blood labeling, waste disposal, and other procedures. The inspector determined, through interviews, that licensee personnel were knowledgeable of radiation safety concepts and procedures. The inspector performed independent and confirmatory radiation measurements, which indicated results consistent with licensee survey records and postings.

The inspector reviewed a selection of records, including internal audits, dose calibrator constancy, dose calibrator linearity, dose calibrator accuracy, survey meter calibration certificates, hazmat training records, well counter constancy, area surveys, and dosimetry reports.

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