CONVERSATION RECORD | TIME | DATE 6/18/18

O VISIT O CONFERENCE X TELEPHONE

0 INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT	ORGANIZATION (OFFICE, DEPT.ETC.)	TELEPHONE NO.
Mark Driscoll, RSO	University of Michigan	734-647-2251
Dennis Palmieri, Sr. H.P		
Joe Miklos, Byron Bryant, H.P.		
Brandon Eggleston, HP Technician		
Karl Fischer, H.P.		

SUBJECT

Periodic Contact (License No. 21-00215-04, Docket No.: 03001988)

SUMMARY

Radiation Safety Organization/Staffing Changes: Danielle Sheen is the Executive Director of EH&S. Joe Miklos works part time. Byron Bryant is a new H.P. for the hospital and Brandon Eggleston is a new H.P. Technician.

New Processes/Activities: The licensee has a pending license amendment request regarding an off-campus radiopharmacy involving Tc-99m unit dosages and actinium-225 for therapy. The licensee has a pending license amendment request for an exemption for family members of MIBG patients for a 2 rem limit. The licensee conducted its first Lu-177 treatment last week.

Events: None

Self-Identified Violations: None

Medical Administrations Deviated From Prescribed: On June 13th, there was an F-18 (FDG) under-dosage incident in Nuclear Medicine involving the MEDRAD Intego PET infusion system (injector). The patient was scheduled to receive 8 mCi of F-18 (FDG); but, the patient was administered 5.82 mCi and it was 27% less than the prescribed dose. The licensee investigated the event. The prescribed 8 mCi of F-18 (FDG) results in an effective dose of 560 mrem. The administered 5.82 mCi of F-18 (FDG) results in an effective dose of 407 mrem. As such, the licensee determined that the underdose event was not a medical event. The licensee determined that the cause of the event was flow resistance during the patient's administration of the prescribed 8 mCi of F-18 (FDG). The licensee provided its information that it used to determine that the incident was not a medical event. The inspector reviewed the information and determined that the incident was not a medical event because the administered dose (407 mrem) differed from the prescribed dose (560 mrem) such that the administered dose differed from the prescribed dose, resulting in a 27% underdose. As such, the patient did not get the additional 153 mrem that was prescribed, which is less than 5 rem (reference 10 CFR 35.3045(a)(1)).

In addition, the licensee is investigating a nuclear medicine incident involving another diagnostic study. The inspector asked the licensee to provide the bases and results to determine whether or not the incident was a medical event. On 6/15/18, the licensee provided the requested information. The inspector reviewed the information and noted that the patient was prescribed to have oral administration of 1 mCi of Tc-99m sulfur colloid in eggs and 0.075 mCi of In-111 DTPA liquid. The patient was orally administered 1 mCi of Tc-99m sulfur colloid in eggs and orally administered 1 mCi of Tc-99m sulfur colloid in liquid. The inspector

determined that the incident was not a medical event because dose the difference was less than 20% and the dose difference was well below 5 rem.

Major Spills: None

Fires: None

Loss: None

Theft: None

Floods: None

ACTION REQUIRED

NAME OF PERSON DOCUMENTING CONVERSATION | SIGNATURE | DATE

Bob Gattone | Robert B. Gattone, Jr. | 6/18/18

ACTION TAKEN

SIGNATURE | TITLE | DATE