Guam Medical Imaging Center

Nuclear Medicine
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April 24, 2017

To: US Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington D.C. 20555-0001

Mr. Mark R. Shaffer
Director Division of Nuclear Materials Safety
US Nuclear Regulatory Commission Region IV
1600 East Lamar Blvd
Arlington, TX 76011-4511

Subj: Response to an Apparent Violation in NRC Inspection Report
030-35716/2017-001; EA-17-026
License No. 56-27702-01

Dear Sir/Madam:

Thank you for your thorough evaluation of our nuclear medicine facility. We appreciate your expertise, professionalism and valuable input you provided during our recent inspection. In response to the Executive Summary we received, we have been working diligently to evaluate the sources of the problems and to develop and implement appropriate solutions. In this regard, the actions described below have already been taken.

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Response to an Apparent Violation in NRC Inspection Report
030-35716/2017-001; EA-17-026
License No. 56-27702-01

Apparent violation of 10 CFR 35.40 (a)

Regarding our Non-Compliance with regulations governing Written Directives:

1. All orders for radioactive therapy, both 131-Iodine and 223-Radium, are now and will always be reviewed by both an authorized user and a certified nuclear medicine technologist. If a case is approved, a written directive will be prepared that conforms to 10CFR 35.40. It will contain the patient's name and another identifier to include the patient's date of birth and a permanent medical record number. It will also include the planned radioactive pharmaceutical, the dosage, and the route of administration. Once prepared, it will be reviewed for accuracy by the authorized user. When found to be properly prepared, the written directive will be physically signed and dated by an authorized user prior to the administration of any therapeutic dose.

Apparent violation of 10 CFR 35.41 (a)(2)

2. All written directives have been reviewed for compliance from the date of inspection until the date of this letter, following written instructions outlined in letter dated January 16, 2017 (attached):

    a. Six 223-Radium Dichloride injections were administered, all with written directives.

    b. Five 131-Iodine therapies took place, all had written directives. This was following a consultation where we reviewed radiation safety and looked at the family living arrangements. Two were below 7 mCi (3 mCi and 5 mCi) and both patients were released per table U-1. One 10 mCi therapy patient was measured at 1.1 mrem/hr and was released. Two 30 mCi therapy patients had doses administered, were measured and were placed in isolation at home. One patient returned at two days post treatment and the other at three days post treatment. Both had readings below 7 mrem/hr and were released to the general population.

        i. All Iodine therapy patients were provided written instructions, along with general reminders, trash bags, and radiation warning cards.

        ii. We found 100% compliance during the three months since the inspection.

We take to heart your having identified serious flaws in our program. Moving forward, we will continue to more carefully monitor our program for deficiencies and will act diligently to correct all those identified thoroughly and quickly.

Thank you,

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January 15, 2017

To: Janine F. Katanic, PhD, CHP
Senior Health Physicist
US Nuclear Regulatory Commission
Region IV/DNMS/NMSB-A
1600 E Lamar Blvd, Arlington, TX 76011

Subj: Response to NRC Inspection Findings

Dr. Katanic:

Thank you for your thorough evaluation of our nuclear medicine facility. We appreciate your expertise, professionalism and valuable input during our recent inspection. In response to your observations, we are working together to evaluate the sources of the problems and to develop appropriate solutions. We are dedicated to our patients and will do what is needed to ensure compliance and the continued delivery of quality care. In this regard, the actions described below have already been taken.

Regarding our Non-Compliance with regulations governing Written Directives:

a. History – findings you identified:

Following a discussion of all case between the technologist and the authorized user, cases were planned and a verbal order was provided to the technologist. We have always used electronic signatures which were then applied to the order. These were co-signed by the certified nuclear medicine technologist. This process was only used for standard doses. All cases were discussed between an authorized user and the certified nuclear medicine technologist before applying the electronic signature and always prior to the administration of doses.

b. Response:

i. All authorized users and the technologist have read NUREG 1556 Vol.9 Rev. 2 section 8.35 and appendix S. We have set in place the following permanent changes to our operating procedures:

1. All orders for radioactive therapies, both 131-Iodine and 223-Radium, will be reviewed by both an authorized user and a certified nuclear medicine technologist. If a case is approved, a written directive will be produced that conforms to 10CFR 35.40. It will contain the patient's name and another identifier to include the patient's date of birth and permanent medical record number. It will also include the planned radioactive drug, dosage, and route of administration. Once prepared, it will be reviewed for accuracy by the authorized user. When found to be properly prepared, the written directive will be physically signed and dated by an authorized user prior to the administration of any therapeutic dose.

2. All written directives will be reviewed for compliance at each quarterly Radiation Safety Committee meeting.

2. Release of 131-Iodine Radiotherapy patients

a. History – findings you identified:

i. We met with all potential radioiodine therapy patients to go over their low iodine diet, and to review medications. At that time we also reviewed home life and living conditions to ensure that they were aware of the radiation precautions and restrictions. We specifically addressed issues relating to the age of occupants of the household. We always had a detailed discussion regarding the necessary restrictions including isolation or segregation. We used lay language when talking about the use of time, distance and shielding to ensure that the general public dose limits would not be exceeded.

b. Response:

i. All authorized users and the technologist have read NUREG 1556 Vol.9 Rev. 2 section 8.36 and appendix U. We have set in place the following permanent changes to our operating procedures:

1. All patients receiving 131-Iodine will be counselled prior to administration, as done previously and described above. In addition of the following will be completed at the time of dose administration:

a. Patients will be given specific bags for waste disposal. The specified trash bags will be leak proof. The patient will be instructed that the bags should be tightly closed and stored in a secure place at least 6 feet away from people and

animals at the end of the isolation period. If they do not indicate that they have a garbage can that has a lid that can close, they will be instructed to purchase one. The patient will be told that the bags can be taken to the usual household trash disposal sites after 80 days (10 half lives of 131-Iodine). Note: this will ensure the safety of the general public and radiation detectors at the waste handling facilities should not produce alarms. Each provided bag will be clearly labeled as to what date constitutes 80 days after the dosage administration.

b. Patients receiving therapeutic doses of 131-iodine for hyperthyroidism will be measured after dose administration at 1 meter. They will be discharged if the measurement level is below7 mrem/hr. They will be held if above the 7 mrem/hr and measured at 30 min intervals until the level is below 7mrem/hr – the unrestricted release mark.

c. If the patient was treated for thyroid cancer with a therapeutic dose of 131-Iodine, they will have been instructed regarding their isolation procedures as above. They will also have been instructed to return in 3-5 days at which time another measurement will made to determine if they can be released. They will be released if measured at 1 meter, the level is below 7mrem/hr. If they are measured at a level above 7mrem, they will stay in isolation and will return daily for measurement and will not be released until measured below 7mrem/hr at 1 meter distance.

d. All patients receiving more than 7 mCi of 131-Iodine will be given written instructions on precautions and the waste disposal bag.
Please see the attached written instructions.

We take to heart you having identified serious flaws in our program. Moving forward, we will more carefully monitor our program for deficiencies and will act diligently to correct all those identified thoroughly and quickly.

Thank you,

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