October 12, 2020

PNRI REGULATORY BULLETIN No. 20-01

MEDICAL EVENT: MISADMINISTRATION OF UNSEALED RADIOACTIVE MATERIAL

ADDRESSEES

All PNRI license holders for the medical use of unsealed radioactive material in Nuclear Medicine.

PURPOSE

This Bulletin is issued to provide guidance to the above-mentioned licensees to emphasize the potential radiation dose implications as a result of misadministration of unsealed radioactive materials for radiotherapy or diagnostic imaging of humans. This issuance is aimed to reiterate the proper implementation of quality assurance program to prevent recurrence of the medical event.

DESCRIPTION OF CIRCUMSTANCES

Incident A:

The authorized user ordered 15mCi Radioactive Iodine (RAI) Therapy to be administered to a patient. A Nuclear Medicine personnel called the supplier to reserve 15mCi RAI capsule. It was correctly written in the ordering and receiving logbook, but another staff made a typographical error of encoding 150mCi on the worksheet schedule in their database.

On the ordering day, the technologist on-duty ordered 150mCi RAI capsule, as reflected in the worksheet schedule. A representative from the supplier called back to verify the dose of the RAI capsule since the reserved dose was 15mCi while the ordered dose was 150mCi. The technologist checked the worksheet schedule and confirmed that the dose is 150mCi.

The following day, the technologist received the 150 mCi RAI capsule with the patient's details and specific dose on the lead container. The RAI capsule was

verified using a dose calibrator and measured 148.3 mCi. The patient was ready for the procedure while the authorized user is not available on the day of administration. On the assumption that the documents were complete and correct, the technologist asked for the approval of another physician on-duty if he could proceed with the procedure as approved by the authorized user. The physician on-duty approved to go through prompting the technologist to proceed with the procedure. The patient was administered 150mCi RAI capsule instead of the intended dose of 15mCi.

Incident B:

A patient with disability, accompanied by her mother and sister, was scheduled for bone imaging at the Nuclear Medicine Department. The radiologic technologist trainee discussed the procedure with the patient and relatives. The informed consent was then signed by the patient's sister. The radiologic technologist trainee aspirated the radiopharmaceutical and endorsed the administration to senior radiologic technologist. Unfortunately, the radiologic technologist trainee failed to verify the identity of the radiopharmaceutical contained in the leaded vial. The patient was then injected with 740 MBq of supposedly Tc99m-MDP.

During the imaging, it was discovered that the required skeletal muscles for imaging were not visible. At this stage, senior radiologic technologist verified that the patient was injected with Tc99m-DTPA instead of Tc99m-MDP. The manager was immediately notified on the incident. The manager then explained it to the relatives of the patient and assured them of the safety of the patient and the necessity of the second injection of the correct radiopharmaceutical to complete the procedure.

DISCUSSIONS

All PNRI license holders for the medical use of unsealed radioactive material in Nuclear Medicine are reminded of the necessity of ensuring the safe performance of licensed activities, in accordance with the PNRI Regulations, specifically the Code of PNRI Regulations (CPR) Part 13, Licenses for Medical Use of Unsealed Radioactive Material. The aforementioned medical event showed the inadequacy of supervision by the authorized user in the administration procedure performed by nuclear medicine staff. The medical event also demonstrated a lack of familiarity with appropriate procedure for dose administration and the necessity of consistently following quality control procedures. In incident A, a radiation dose of 150mCi administered to the thyroid which is ten times higher than the prescribed dose of 15mCi could lead to changes in the biological kinetics of the patient specifically the thyroid.

Following these circumstances, the licensees that have experienced the misadministration of unsealed radioactive material are required to report within twenty-four (24) hours such occurrence to PNRI. The licensee should adopt preventive and corrective measures, and provide sufficient evidence and tangible course of action to PNRI to ensure that similar medical event will not recur. Some of the recommendations that a licensee needs to undertake are:

- Conduct periodic refresher training course for all nuclear medicine personnel involved in the performance of radiotherapy and diagnostics imaging. The training must emphasize the effects of misadministration to patients. The licensee must maintain and secure records of the periodic refresher training courses along with other training requirements.

- Familiarize the authorized user or any physician under the supervision of the authorized user and the technologists involved on the proper procedure of administration of unsealed radioactive material.

- Comply with Section 17 of CPR Part 13 which states that “for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to ensure the following: the patient's identity is verified before each administration; and each administration is in accordance with the written directive”.

- Comply with CPR Part 13 on the measurement of unsealed radioactive material dose, syringe shields and labels, and vial shields and labels prior to administration, and maintain records of dose disposition.

- Develop procedures to be done when a medical event on improper dose administration occur and make it available at all times to assist the patient for medical interventions, which include internal bioassay, measurement of the dose rate before and after administration, and before release of patient, and other monitoring procedures that aids in intervention.

REQUIRED ACTION BY THE LICENSEES

All PNRI licensees in medical use of unsealed radioactive material in Nuclear Medicine must ensure that the provisions of the applicable Parts and Sections of the Code of PNRI Regulations and the conditions of the license are satisfactorily addressed to prevent unnecessary disruption of authorized activities.

Please acknowledge receipt of this bulletin through mail or fax to the contact person. Furthermore, licensees are reminded to report and notify PNRI of any medical event as stated in Section 51 of CPR Part 13 and take appropriate actions to prevent recurrence.

CONTACT PERSON

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Date: 23 November 2020