VA | U.S. Department of Veterans Affairs

Veterans Health Administration
National Health Physics Program
2200 Fort Roots Drive
North Little Rock, Arkansas 72114-1706

May 21, 2021

Bryan Parker
Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission (NRC), Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License No. 03-23853-01VA

Dear Mr. Parker,

We are providing a written report regarding an incident that occurred at the VA Pittsburgh Healthcare System, Pittsburgh, Pennsylvania. The facility holds VHA Permit Number 37-01230-03.

The incident occurred on May 7, 2021, and was discovered on May 10, 2021. It involved treatment of a patient with iodine-131 sodium iodide (I-131 NaI). An activity of 60 millicuries was prescribed in a written directive. A dosage of I-131 NaI for this treatment was ordered from a commercial radiopharmacy. The dosage consisted of two capsules. However, only one of the two capsules was administered to the patient.

We notified NRC Operations Center by telephone on May 10, 2021, of a medical event, because initial information from the facility indicated that the activity administered to the patient was substantially less than eighty percent of the prescribed activity. The reported event was assigned Event Number 55245.

Since that time, the capsule that was not administered was assayed. It is now estimated that about eighty two percent of the prescribed activity was administered. We contacted NRC Operations Center by telephone on May 20, 2021, and requested retraction of the medical event notification.

The enclosure to this letter contains the information specified in 10 CFR 35.3045, including a brief description of the event, cause(s) of the event, and actions taken to prevent recurrence.

We are conducting an inspection to evaluate the circumstances to the incident, the

causes, actions to prevent recurrence, and regulatory compliance. Please contact me, at 501-257-1571, if you have any questions about this matter.

Sincerely,

Edwin M. Leidholdt 398105

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Edwin M. Leidholdt Jr., Ph.D., FACR
Director, VHA National Health Physics Program

Enclosure

Department of Veterans Affairs

Memorandum

Date: May 21, 2021

From: Director, VA Pittsburgh Healthcare System (VAPHS), VISN 4, Station 646

Subj: VAPHS Medical Event 15-Day Report (#55245)

To: Director, VHA National Health Physics Program (11SPEC12)

1. Thank you for your onsite inspection of the reported medical event that occurred at VAPHS in our Nuclear Medicine clinic.

2. Per your request, please accept the enclosed VAPHS Medical Event 15-Day Report for case reference number: 55245. Based on our investigation VAPHS is requesting to retract our declaration of a medical event to the NHPP and NRC.

3. If you have any questions, please contact VAPHS Radiation Safety Officer, Mitchell Belanger at 412-360-3221.

Donald E. Koenig 1786488

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Date: 2021.05.21 13:03:26 -04'00'

Donald E. Koenig
Medical Center Director

Enclosure

VA Pittsburgh Healthcare System Medical Event 15-day Report – Ref: Event #55245

(i). Licensee's name:

VA Pittsburgh Healthcare System (VAPHS)

(ii). Name of prescribing physician:

Rashmikant B. Shah, MD.

(iii). Description of the event:

1. Pre-dose administration-

The VAPHS nuclear medicine clinic administered an I-131 therapy dose to an out-patient on 5/7/21. The patient was prescribed with a dosage of 60 mCi of I-131 (sodium iodide). The clinical team consisted of an AU (authorized user) and two Nuclear Medicine Technologists.

2. Dose administration-

A nuclear medicine technologist handed the patient the therapy dose vial and told the patient that there were two capsules in the vial that he would have to swallow.

After the therapy dose was administered the patient handed the dose vial back to the technologist. The technologist did not visually inspect or assay the post-therapy dose vial on the dose calibrator to check that it was completely empty. The technologist immediately disposed of the vial into the long half-life radioactive waste container located in a radioactive waste decay storage room.

The second nuclear medicine technologist assumed that the technologist administering the dosage had properly checked that the dose vial was empty, so recorded "0.0" for the "Measured activity in syringe/vial", on an administration form. The second nuclear medicine technologist also did not visually inspect or assay the post-therapy dose vial on the dose calibrator to check that it was completely empty.

3. Discovery of I-131 capsule-

On 5/10/21, the facility's Radiation Safety Officer (RSO) entered a radioactive waste decay storage room to perform a weekly inspection. Upon entering the room, the ionization chamber he was carrying indicated unexpectedly high radiation exposure levels. The reason for the unusually high exposure rate was investigated. A nuclear medicine technologist and the RSO retrieved the therapy patient's dose vial to see if it still contained a dose capsule and discovered that the vial contained one of the two dose capsules that the patient should have ingested. The facility concluded that a medical event had occurred and notified the VHA's National Health Physics Program (NHPP).

4. Re-assay of remaining dose capsule-

During the NHPP's reactive inspection visit, it was suggested that we assay the remaining dose capsule. VAPHS' assay of the patient's total dose (i.e. both capsules) at the time of the dose administration was 62.4 mCi. On 5/18/21 VAPHS re-assayed the remaining dose capsule and, after correcting for radioactive decay, we calculated the activity of this capsule at the time of the patient's dose administration to be 12.49 mCi. Subtracting 12.49 mCi from the total dose assay of 62.4 mCi equals 49.9 mCi. Dividing 49.9 mCi by the prescribed dose of 60 mCi calculates to a percent value of 83%. Given that the 49.9 mCi activity is within 20% of the prescribed dose, VAPHS now concludes that a medical event did not occur.

(iv). Why the event occurred:

This event occurred because the post-therapy dose vial was not checked, either visually or by placing it inside of the dose calibrator, to ensure that all of the prescribed dose had been given to the patient, as required by written procedures. A contributing factor was insufficient oversight of the dose administration by the clinical team leadership.

Additional likely contributing factors included more staff than usual performing the dosage administration, lack of coordination among team members, and perceived time pressure due to other patients waiting for diagnostic procedures.

(v). The effect, if any, on the individual who received the administration:

No adverse effect is expected on the patient given the patient received 49.9 mCi of the prescribed 60 mCi I-131 dosage. The patient's actual dosage was within 20% of the prescribed dose.

(vi). What actions, if any, have been taken or are planned to prevent recurrence:

VAPHS will revise our procedures for administrations requiring written directives and will retrain all Nuclear Medicine technologist staff and all physicians who are designated as authorize users for 10 CFR 35.300 procedures.

(vii). Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

The referring physician initially spoke to the patient and notified him about the incident on 5/10/21. On 5/19/21 the referring physician contacted the patient and updated him about the corrected dose calculations and the determination that a medical event had not occurred and that the patient's dose was in fact within the 20% regulatory limit.

DEPARTMENT OF VETERANS AFFAIRS
Veterans Health Administration (VHA)
National Health Physics Program (NHPP)
2200 Fort Roots Drive
North Little Rock, AR 72114

May 20, 2021

Bryan Parker
Materials Licensing Branch
Division of Nuclear Material Safety
U.S. Nuclear Regulatory Commission (NRC),
Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352

Re: NRC License 03-23853-01VA
Letter dated March 23, 2021, from Edwin M. Leidholdt, Jr., Ph.D.

Dear Mr. Parker:

In follow up to the letter referenced above, this letter is to notify you that we completed our review of radiological survey information related to former radioactive material use and storage areas at Nebraska / Western Iowa Health Care System CBOC, 600 South 70th Street, Lincoln, Nebraska. The location was previously issued VHA Permit No. 26-16293-01 for medical purposes under 10 CFR 35 and 31.11. In addition, prior to our master materials license, the location was also issued NRC License No. 26-16293-01 for medical uses. Uses under both the former VHA permit and NRC license occurred in a single building at that street address.

Radiological release information provided to NHPP by the permittee supported characterization of the location as a "Group 2" facility under NRC NUREG-1757, Vol. 1, Rev. 2, and a decommissioning plan was not required under 10 CFR 30.36 to release the location. In accordance with Paragraph 36.b. of the VHA-NRC Letter of Understanding (referenced in Condition 19.ZE. of our master materials license), NHPP reviewed the release information and determined the former locations of use meet conditions in 10 CFR 20.1402 and are suitable for release for unrestricted use. NHPP has subsequently terminated Permit No. 26-16293-01 and ended authorization to use permitted radioactive material at the entire site at the 600 South 70th Street address. The entire facility will be closed. The property has been sold to a developer, who will take possession on June 1, 2021.

If NRC requires further information related to this matter or the associated permitting action, please contact me, or Kim C. Wiebeck, BSRT (R)(T), at 501-257-1571.

Sincerely,

Edwin M. Leidholdt 398105

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Edwin M. Leidholdt, Jr., Ph.D., FACR
Director, VHA National Health Physics Program

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