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

In Reply Refer To: 598/115HP/NLR

May 18, 2017

Patricia J. Pelke
Division of Nuclear Material Safety
Nuclear Regulatory Commission (NRC), Region III
2443 Warrenville Road, Suite 210
Lisle, Illinois 60532-4352
(forwarded via Email)

Re: NRC License No. 03-23853-01VA (Event No. 52728)

Dear Ms. Pelke:

On May 2, 2017, while conducting a routine unannounced inspection at the VA New Jersey Health Care System, East Orange, New Jersey, we discovered 9 incorrect written directives among a group of 48 under review. VHA Permit Number 29-04481-01 is assigned to that medical center. On May 3, 2017, we made an initial report to the NRC Operations Center and Event No. 52728 was assigned.

Pursuant to 10 CFR 35, we are providing a written report with additional details about the incorrect written directives. There were six reportable medical events per the definition of 10 CFR 35.3045(a)(1)(i).

A contributing factor of four reportable medical events was failure to replace millicurie, pre-printed on the written directive form, with microcurie (as intended).

- Prescribed dosage on October 28, 2015, of 155 millicuries of radium-223 (Ra-223) dichloride with an administered activity of 154.18 microcuries on December 3, 2015.
- Prescribed dosage on March 7, 2016, of 128 millicuries of Ra-223 dichloride with an administered activity of 127.68 microcuries on March 11, 2016.
- Prescribed dosage on June 3, 2016, of 131 millicuries of Ra-223 dichloride with an administered dosage of 130.97 microcuries on July 18, 2016.
- Prescribed dosage on August 14, 2016, of 155 millicuries of Ra-223 dichloride with an administered dosage 155.5 microcuries on August 18, 2015.

A contributing factor of one reportable medical event was the authorized user physician erroneously annotating the wrong radiopharmaceutical on the written directive form.

- Prescribed dosage on March 28, 2017, of 25 millicuries of Ra-223 dichloride with an administered dosage of 25.9 millicuries of sodium iodide I-131 on March 31, 2017. The intended radiopharmaceutical (sodium iodide I-131) was administered; however, the written directive was incorrectly annotated.

Patricia Pelke

A contributing factor of one reportable medical event was transposition of numbers on the written directive form.

- Prescribed dosage on February 20, 2016, of 211 microcuries of Ra-223 dichloride with an administered dosage of 121.28 microcuries on February 23, 2016. The intended dosage was 121 microcuries of Ra-223 dichloride; however, the written directive was incorrectly annotated.

We also discovered three incorrect written directives that did not align with the reporting requirements of 10 CFR 35.3045(a)(1)(i). A contributing factor in each was no prescribed dosage was annotated on the written directive form. Our inspection report will reflect non-compliance with 10 CFR 35.41 which contributed to non-compliance with 10 CFR 35.40.

A contributing factor of three incorrect written directives was failure of the authorized user to annotate the prescribed activity on the pre-printed written directive form.

- The prescribed activity on August 21, 2015, was blank of Ra-223 dichloride with an administered dosage of 130.3 microcuries on September 24, 2015. The intended dosage was 130 microcuries of Ra-223 dichloride.
- The prescribed activity on November 4, 2015, was blank of Ra-223 dichloride with an administered dosage of 142.15 microcuries on December 9, 2015. The intended dosage was 142 microcuries of Ra-223 dichloride.
- The prescribed activity on December 9, 2015, was blank of Ra-223 dichloride with an administered dosage of 132.85 microcuries on January 14, 2016. The intended dosage was 132 microcuries of Ra-223 dichloride.

As provided by the medical center, a brief description of the reportable medical events, cause of the reportable medical events, corrective actions taken, and other required information are contained in the enclosure. As of this date, our inspection remains open. Please contact Mr. David Burkett, at (615) 218-9131, if you desire additional information.

Sincerely,

Craig L Adams 490757

Digitally signed by Craig L Adams 490757
DN: dc=gov, dc=va, o=internal, ou=people, 0.9.2342.19200300.100.1.1=craig.adams@va.gov, cn=Craig L Adams 490757
Date: 2017.05.18 15:43:07 -05'00'

Craig L. Adams, MPH
Director

Enclosure

cc: Director (561/00), VA New Jersey Health Care System
Network Director, VISN 2 (10N2)
Chair, National Radiation Safety Committee (10P11H)

This is a notification, pursuant to 10 CFR 35.3045, of a medical event that occurred on December 3, 2015, at the VA New Jersey Health Care System, East Orange, New Jersey.

Licensee's Name.
VA New Jersey Health Care System, East Orange, New Jersey; Permit Number 29-04481-01, under Department of Veterans Affairs Master Materials License Number 03-23853-01VA.

The name of the prescribing physician.
Michael A. Cook, D.O.

A brief description of the event.
On December 3, 2015, a dosage of 154.18 microcuries of radium-223 (Ra-223) dichloride was administered to a patient for treatment of osseous metastases from prostate cancer. The prescribed dosage on the written directive was incorrectly annotated by the authorized user physician as 155 millicuries. The basis for identifying this as a medical event is that the administered dosage differed from the prescribed dosage, as annotated on the written directive, by more than 20 percent. The authorized user physician was interviewed and stated the intended prescription for injection was 155 microcuries of Ra-223 dichloride. No harm to the patient is expected since the treatment was successfully performed with the administration of a dosage nearly identical to the intended dosage. The medical event was discovered May 2, 2017, during an unannounced inspection of our facility conducted by the National Health Physics Program (NHPP).

Why the event occurred.
The prescribed dosage was incorrectly annotated on the written directive, in part, because the form was preprinted with a unit of measure in millicuries. The NHPP inspection is ongoing to determine overall compliance with 10 CFR 35.40, 10 CFR 35.41 and 10 CFR 35.3045. The medical center does not order millicurie amounts of this material.

The effect, if any, on the individual(s) who received the administration.
No adverse biological effect to the patient is expected since the treatment was successfully performed with administration of a dosage nearly identical to the intended dosage.

What actions, if any, have been taken or are planned to prevent recurrence.
To prevent recurrence, we have updated our written directive procedures and the written directive form. The changes are outlined below:

1) Updated the written directive procedure
2) Updated the written directive
3) A section was added to the written directive for the Radiation Safety Officer (RSO) signature post RSO review
4) Train all authorized users on the location of the written directive procedures
5) Train all authorized users on the written directive procedures
6) Ensure all authorized users adhere to the written procedures
7) The Radiation Safety Office will increase the frequency of the review of the Nuclear Medicine Program
8) All authorized users will submit documentation of completing the training on the new written directive procedures.

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

Notification of the patient was not necessary. Based on the supporting documents present in the medical record and interviews with staff, we have concluded no harm to the patient was done since the treatment was successfully performed with the intentions of the authorized user physician in the presence of the RSO.

This is a notification, pursuant to 10 CFR 35.3045, of a medical event that occurred on March 11, 2016, at the VA New Jersey Health Care System, East Orange, New Jersey.

Licensee's Name.
VA New Jersey Health Care System, East Orange, New Jersey; Permit Number 29-04481-01, under Department of Veterans Affairs Master Materials License Number 03-23853-01VA.

The name of the prescribing physician.
Michael A. Cook, D.O.

A brief description of the event.
On March 11, 2016, a dosage of 127.68 microcuries of Ra-223 dichloride was administered to a patient for treatment of osseous metastases from prostate cancer. The prescribed dosage on the written directive was incorrectly annotated by the authorized user physician as 128 millicuries. The basis for identifying this as a medical event is the administered dosage differed from the prescribed dosage, as annotated on the written directive, by more than 20 percent. The authorized user physician was interviewed and stated the intended prescription for injection was 128 microcuries of Ra-223 dichloride. No harm to the patient is expected since the treatment was successfully performed with the administration of a dosage nearly identical to the intended dosage. The medical event was discovered May 2, 2017, during an unannounced inspection of our facility conducted by the NHPP.

Why the event occurred.
The prescribed dosage was incorrectly annotated on the written directive, in part, because the form was preprinted with a unit of measure in millicuries. The NHPP inspection is ongoing to determine overall compliance with 10 CFR 35.40, 10 CFR 35.41, and 10 CFR 35.3045. The medical center does not order millicurie amounts of this material.

The effect, if any, on the individual(s) who received the administration.
No adverse biological effect to the patient is expected since the treatment was successfully performed with administration of a dosage nearly identical to the intended dosage.

What actions, if any, have been taken or are planned to prevent recurrence.
To prevent recurrence, we have updated our written directive procedures and the written directive form. The changes are outlined below:

1) Updated the written directive procedure
2) Updated the written directive
3) A section was added to the written directive for the RSO signature post RSO review
4) Train all authorized users on the location of the written directive procedures
5) Train all authorized users on the written directive procedures
6) Ensure all authorized users adhere to the written procedures
7) The Radiation Safety Office will increase the frequency of the review of the Nuclear Medicine Program
8) All authorized users will submit documentation of completing the training on the new written directive procedures.

Certification the licensee notified the individual (or the individual's responsible relative or guardian), or if not, why not.
Notification of the patient was not necessary. Based on the supporting documents present in the medical record and interviews with staff, we have concluded no harm to the patient was done since the treatment was successfully performed with the intentions of the authorized user physician in the presence of the RSO.

This is a notification, pursuant to 10 CFR 35.3045, of a medical event that occurred on July 18, 2016, at the VA New Jersey Health Care System, East Orange, New Jersey.

Licensee's Name.
VA New Jersey Health Care System, East Orange, New Jersey; Permit Number 29-04481-01, under Department of Veterans Affairs Master Materials License Number 03-23853-01VA.

The name of the prescribing physician.
Michael A. Cook, D.O.

A brief description of the event.
On July 18, 2016, a dosage of 130.97 microcuries of Ra-223 dichloride was administered to a patient for treatment of osseous metastases from prostate cancer. The prescribed dosage on the written directive was incorrectly annotated by the authorized user physician as 131 millicuries. The basis for identifying this as a medical event is the administered dosage differed from the prescribed dosage, as annotated on the written directive, by more than 20 percent. The authorized user physician was interviewed and stated the intended prescription for injection was 131 microcuries of Ra-223 dichloride. No harm to the patient is expected since the treatment was successfully performed with the administration of a dosage nearly identical to the intended dosage. The medical event was discovered May 2, 2017, during an unannounced NHPP inspection of our facility.

Why the event occurred.
The prescribed dosage was incorrectly annotated on the written directive, in part, because the form was preprinted with a unit of measure in millicuries. The NHPP inspection is ongoing to determine overall compliance with 10 CFR 35.40, 10 CFR 35.41, and 10 CFR 35.3045. The medical center does not order millicurie amounts of this material.

The effect, if any, on the individual(s) who received the administration.
No adverse biological effect to the patient is expected since the treatment was successfully performed with administration of a dosage nearly identical to the intended dosage.

What actions, if any, have been taken or are planned to prevent recurrence.
To prevent recurrence, we have updated our written directive procedures and the written directive form. The changes are outlined below:

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5) Train all authorized users on the written directive procedures
6) Ensure all authorized users adhere to the written procedures
7) The Radiation Safety Office will increase the frequency of the review of the Nuclear Medicine Program

8) All authorized users will submit documentation of completing the training on the new written directive procedures.

Certification the licensee notified the individual (or the individual's responsible relative or guardian), or if not, why not.
Notification of the patient was not necessary. Based on the supporting documents present in the medical record and interviews with staff, we have concluded no harm to the patient was done since the treatment was successfully performed with the intentions of the authorized user physician in the presence of the RSO.

This is a notification, pursuant to 10 CFR 35.3045, of a medical event that occurred on August 18, 2015, at the VA New Jersey Health Care System, East Orange, New Jersey.

Licensee's Name.
VA New Jersey Health Care System, East Orange, New Jersey; Permit Number 29-04481-01, under Department of Veterans Affairs Master Materials License Number 03-23853-01VA.

The name of the prescribing physician.
Michael A. Cook, D.O.

A brief description of the event.
On August 18, 2015, a dosage of 155.5 microcuries of Ra-223 dichloride was administered to a patient for treatment of osseous metastases from prostate cancer. The prescribed dosage on the written directive was incorrectly annotated by the authorized user physician as 155 millicuries. The basis for identifying this as a medical event is the administered dosage differed from the prescribed dosage, as annotated on the written directive, by more than 20 percent. The authorized user physician was interviewed and stated the intended prescription for injection was 155 microcuries of Ra-223 dichloride. No harm to the patient is expected since the treatment was successfully performed with the administration of a dosage nearly identical to the intended dosage. The medical event was discovered May 2, 2017, during an unannounced NHPP inspection of our facility.

Why the event occurred.
The prescribed dosage was incorrectly annotated on the written directive, in part, because the form was preprinted with a unit of measure in millicuries. The NHPP inspection is ongoing to determine overall compliance with 10 CFR 35.40, 10 CFR 35.41, and 10 CFR 35.3045. The medical center does not order millicurie amounts of this material.

The effect, if any, on the individual(s) who received the administration.
No adverse biological effect to the patient is expected since the treatment was successfully performed with administration of a dosage nearly identical to the intended dosage.

What actions, if any, have been taken or are planned to prevent recurrence.
To prevent recurrence, we have updated our written directive procedures and the written directive form. The changes are outlined below:

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4) Train all authorized users on the location of the written directive procedures
5) Train all authorized users on the written directive procedures
6) Ensure all authorized users adhere to the written procedures

7) The Radiation Safety Office will increase the frequency of the review of the Nuclear Medicine Program
8) All authorized users will submit documentation of completing the training on the new written directive procedures.

Certification the licensee notified the individual (or the individual's responsible relative or guardian), or if not, why not.
Notification of the patient was not necessary. Based on the supporting documents present in the medical record and interviews with staff, we have concluded no harm to the patient was done since the treatment was successfully performed with the intentions of the authorized user physician in the presence of the RSO.

This is a notification, pursuant to 10 CFR 35.3045, of a medical event that occurred on February 23, 2016, at the VA New Jersey Health Care System, East Orange, New Jersey.

Licensee's Name.
VA New Jersey Health Care System, East Orange, New Jersey; Permit Number 29-04481-01, under Department of Veterans Affairs Master Materials License Number 03-23853-01VA.

The name of the prescribing physician.
Michael A. Cook, D.O.

A brief description of the event.
On February 23, 2016, a dosage of 121.28 microcuries of Ra-223 dichloride was administered to a patient for treatment of osseous metastases from prostate cancer. The prescribed dosage on the written directive was incorrectly annotated by the authorized user physician as 211 microcuries. The basis for identifying this as a medical event is the administered dosage differed from the prescribed dosage, as annotated on the written directive, by more than 20 percent. The authorized user physician was interviewed and stated the intended prescription for injection was 121 microcuries of Ra-223 dichloride. No harm to the patient is expected since the treatment was successfully performed with the administration of a dosage nearly identical to the intended dosage. The medical event was discovered May 2, 2017, during an unannounced inspection of our facility conducted by the NHPP.

Why the event occurred.
The prescribed dosage was incorrectly annotated on the written directive, in part, because the form was preprinted with a unit of measure in millicuries. The NHPP inspection is ongoing to determine overall compliance with 10 CFR 35.40, 10 CFR 35.41, and 10 CFR 35.3045. The medical center does not order millicurie amounts of this material.

The effect, if any, on the individual(s) who received the administration.
No adverse biological effect to the patient is expected since the treatment was successfully performed with administration of a dosage nearly identical to the intended dosage.

What actions, if any, have been taken or are planned to prevent recurrence.
To prevent recurrence, we have updated our written directive procedures and the written directive form. The changes are outlined below:
1) Updated the written directive procedure
2) Updated the written directive
3) A section was added to the written directive for the RSO signature post RSO review

4) Train all authorized users on the location of the written directive procedures
5) Train all authorized users on the written directive procedures
6) Ensure all authorized users adhere to the written procedures
7) The Radiation Safety Office will increase the frequency of the review of the Nuclear Medicine Program
8) All authorized users will submit documentation of completing the training on the new written directive procedures.

Certification the licensee notified the individual (or the individual's responsible relative or guardian), or if not, why not.
Notification of the patient was not necessary. Based on the supporting documents present in the medical record and interviews with staff, we have concluded that no harm to the patient was done since the treatment was successfully performed with the intentions of the authorized user physician in the presence of the RSO.

This is a notification, pursuant to 10 CFR 35.3045, of a medical event that occurred on March 31, 2017, at the VA New Jersey Health Care System, East Orange, New Jersey.

Licensee's Name.
VA New Jersey Health Care System, East Orange, New Jersey; Permit Number 29-04481-01, under Department of Veterans Affairs Master Materials License Number 03-23853-01VA.

The name of the prescribing physician.
Michael A. Cook, D.O.

A brief description of the event.
On March 31, 2017, a dosage of 25.9 millicuries of sodium iodide I-131 was administered to a patient. The radiopharmaceutical on the written directive was incorrectly annotated by the authorized user physician as Ra-223 dichloride. The basis for identifying this as a medical event is the wrong radiopharmaceutical was annotated on the written directive. The authorized user physician was interviewed and stated the treatment administered was as intended. No harm to the patient is expected since the treatment was successfully performed with the administration of the intended radiopharmaceutical. The medical event was discovered May 2, 2017, during an unannounced inspection of our facility conducted by the NHPP.

Why the event occurred.
The authorized user physician erroneously wrote Ra-223 dichloride instead of sodium iodide I-131. The NHPP inspection is ongoing to determine overall compliance with 10 CFR 35.40, 10 CFR 35.41, and 10 CFR 35.3045.

The effect, if any, on the individual(s) who received the administration.
No adverse biological effect to the patient is expected since the treatment was successfully performed with the intended radiopharmaceutical.

What actions, if any, have been taken or are planned to prevent recurrence.
To prevent recurrence, we have updated our written directive procedures and the written directive form. The changes are outlined below:
1) Updated the written directive procedure
2) Updated the written directive
3) A section was added to the written directive for the RSO signature post RSO review

4) Train all authorized users on the location of the written directive procedures
5) Train all authorized users on the written directive procedures
6) Ensure all authorized users adhere to the written procedures
7) The Radiation Safety Office will increase the frequency of the review of the Nuclear Medicine Program
8) All authorized users will submit documentation of completing the training on the new written directive procedures.

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

Notification of the patient was not necessary. Based on the supporting documents present in the medical record and interviews with staff, we have concluded no harm to the patient was done since the treatment was successfully performed with the intentions of the authorized user physician in the presence of the RSO.

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