St. Vincent
INDIANAPOLIS

2001 W. 86th Street
Indianapolis, IN 46260
stvincent.org

Licensee Name:
St. Vincent Hospital and Health Care Center
2001 West 86th Street, Indianapolis, Indiana 46280

Licensee Number:
13-00133-03 Amendment Number 143

Location, Time and Date:
St Vincent Hospital's HDR Suite, Monday, April 13th 2015 at 8:42am
2001 West 86th Street, Indianapolis, Indiana 46280

Prescribing Physician:
Dr. Frank W. Peyton Jr., M.D.
Attending Physician:
Dr. Thomas C. Dugan, M.D.
Referring Physician
Dr. Thomas Schmidt, M.D.

Devices:
Elekta Nucletron Afterloader, Model V3, SN 31149
SAVI Partial Breast Applicator, 11 channel

Failing Device:
Elekta Nucletron Check Cable, 21mm into travel within catheter 3, failed to retract.

Patient Notification of Event:
The patient was immediately notified by Dr. Dugan following the event on Monday April 13th 2015 at approximately 9:00am. The information was presented by Dr. Dugan verbally to the patient and that she was/is entitled to a paper copy of the event, which she refused at the time.

Referring Physician Notification:
Dr. Dugan notified the referring physician, Dr. Schmidt on Monday April 13th 2015 at 1430.

Patient Outcome:
Per the radiation oncology physicians, (Dr. Dugan and Dr. Peyton) the interrupted treatment (first fraction) was fully resumed on April 20th 2015 at 15:07.

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Physician Notation via Electronic Medical Record (ARIA):

Per Dr. Thomas Dugan: "HDR machine had failure this AM and she only received a partial treatment which technically is a misadministration.
I notified the patient herself at the time of the treatment this morning. Since it was a lower dose than planned, there will be no consequence to the patient other than the inconvenience of re-scheduling.
I notified the referring MD (Schmidt) at 2:30PM today."

Prior to the Event:

On April 13, 2015, at or around 8:00am prior to use of the Elekta Nucletron HDR unit, the daily HDR quality assurance (QA) program was conducted. The daily quality assurance program tests the validity of the system and integrity of the safety mechanisms employed by the Elekta Nucletron afterloader.

As has been the method within the clinic for several years without issue, the daily quality assurance program is performed by the following steps: 1) the source position indicator is connected to channel 1, 2) a timer test is performed in channel 2, and 3) an obstruction/friction test is performed in channel 3. In regard to the event in question, the ability of the system to fully retract the source and the check cable is tested multiple times throughout the daily QA program.

The source retraction worked appropriately the morning of the event. After completion of the daily quality assurance program to ensure the device was working safely the patient was shown to the treatment room to begin treatment using a SAVI applicator for partial breast irradiation.

Description of Event:

This patient was receiving treatment for a carcinoma of the right breast with a SAVI partial breast 11 channel applicator. The Elekta Nucletron console indicated a friction event in catheter 3 while sending out the check cable. The treatment computer initiated appropriate responses to this event; however, while trying to retract the check cable, the afterloader was not able to fully and correctly retract the check cable. The console indicated the failure to retract on-screen, though the console also showed the problem was with the source cable and not the aforementioned check cable. Emergency procedures were initiated immediately according to vendor recommendations. The emergency stop was pressed at the console unit engaging further mechanicals to try and bring the "source" cable into the correct and safe position. The pressing of the emergency stop failed to fully retract the "source" cable and this was indicated onscreen at the operator's console.

Since the console indicated the "source" cable had failed to retract, emergency procedures with regard to ALARA principles were initiated. The physicist present during the event evaluated the in-room monitors and the console's radiation monitor which indicated no radiation levels were present within the room. The console also indicated the source was "in safe", contrary to the warning indications given on-screen. Next, the physicist proceeded into the treatment room to check for radiation with the GM survey meter. Upon entering the room, the physicist manually manipulated the gold crank on the afterloader, noting no change in position or resistance. While conducting a radiation inspection of the HDR suite, the physicist noted a background measurement on the patient, on the transfer tubes and on the unit itself, showing the source was indeed housed within the safe and in a safe condition. The patient was disconnected from the afterloader via the transfer tube patient connectors, and was escorted out of the room by the nursing staff.

The on-screen indicators showed the source failed to retract at 21mm outside of the afterloader within catheter 3. The physicist disconnected catheter 3 from the afterloader and visually verified a cable was protruding from the afterloader approximately 2cm from the head of the afterloader. The physicist verified with the GM survey meter that the cable sticking out from the head was indeed the check cable. Not being fully satisfied, the physicist redundantly verified the cable with an ion chamber survey meter, again noting no radiation present.

After confirmation of the status of the cable both physically and with separate survey meters, the physicist manually manipulated the check cable crank on the afterloader and fully retracted the check cable. The physicist performed a dry run with a SAVI applicator, and the unit performed without fail. The physicist performed another daily QA check of the unit, and initiated a check cable run, the unit again detected a friction and failed to fully retract the check cable. At that point the vender, Elekta Nucletron, was notified via the field service engineer. The day's treatments were discontinued after the failure during the quality assurance testing, the vault was labeled with a no entrance sign and the current patient went home after speaking with Dr. Dugan.

The field service engineer replaced the check cable on Tuesday morning the following day and the patients under treatment restarted their treatments as prescribed Tuesday afternoon. The routine morning daily QA was performed by the physicist while the field service was present on-site, and both noted full functionality of the system to perform as intended.

After the field service engineer replaced the check cable, the faulty cable was fully inspected. The staff noted a fray in the cable approximately 15cm from the cable tip. The fraying of the check cable produced a strand which became

disconnected from the main body of the cable, which was physically pulled out of the QA transfer tube during the check cable exchange.

Why the Event Occurred:

Failure of the HDR unit to retract the check cable was an unforeseeable event which after an in depth review with peer facilities, Elekta Nucletron, and in-house trouble shooting which included but was not limited to interviews and reenactments could be attributed to multiple variables or a combination there of. Further, it is highly likely we may never know for certain which variable caused the failure.

Some of the variables occurring concurrently include the following: a recent extensive upgrade to the afterloader's head unit, the condition of the patient transfer tubes, the daily QA programs wear on the check cable, the SAVI applicator itself, and the manufacturing of the check cable.

While no single item can be directly linked to the failure of the check cable to fully retract, the hospital continues to adhere to a strict and rigorous QA program, scrutinizing the performance of each item throughout the lifetime of the check cable and continuously monitoring the system closely until the true failing circumstance is revealed.

Future Actions to Prevent Reoccurrence:

1. On April 24, 2015, the hospital introduced a new method of testing the functionality of the friction/obstruction daily test.

   This method will replace the previous obstruction test performed daily by a friction test. The previous test required sending the check cable out into an impinged transfer tube, letting the check cable strike the impingement, and verifying the system will fully retract the check cable back into the unit. The new method uses a coiled transfer tube, slowing the check cable as it traverses the coil, and ultimately causing the check cable to see a friction error, causing the check cable to retract back into the unit and notify the user.

2. The transfer tubes were replaced less than two years prior to the event, which is consistent with the manufacturer's recommendations. The hospital has purchased new tubes to rule out any flaw that could be present internally within a transfer tube.

4. Elekta Nucletron verified that the upgrade performed on the afterloader was done in a manner that did not produce any mechanical flaws within the check cable drive system.

5. The hospital has sent the failed device to Elekta Nucletron for metallurgical testing.

Erica Wehrmeister, COO
St. Vincent Hospital, Indianapolis