

## NRC Reportable Event 30.5(c)(2) Written Report

Location of Event: United Hospital Center, Radiation Oncology Department, 327 Medical Park Drive, Bridgeport, WV 26330

(NRC/Agreement State) License Number: NRC - 47-01458-01

Date and Time of Event: April 19, 2023, 10:30 AM

Event Number: 56477

Description of Event:

HDR Unit – Nucletron B.V. Model 136149A02 Flexitron HDR remote afterloader.

At the end of the HDR treatment, the HDR unit generated an error message, and the radiation monitors in the room and above the door indicated that the source did not return to the safe position as expected. As a result, we terminated the treatment and instituted emergency procedures.

The primary probable cause of the event is believed to be a failure of primary motor in the HDR unit that retracts the source back into the shielded base unit and also a failure of the secondary motor which is present in the event of a primary motor failure. The causes of both motor failures are being investigated by the manufacturer. The A drive containing both motor systems was extracted from the unit on 5/11/23 and shipped to the manufacturer for evaluation. Results of the evaluation are pending.

The HDR Ir-192 source was also extracted from the unit on 5/11/23 and shipped to the source manufacturer for evaluation. The source is to be evaluated by the manufacturer for structural issues that could have contributed to the issue. Results of the evaluation are pending.

Other factors being investigated are applicator placement, applicator model, and patient motion during procedure.

Radioactive Source: Iridium-192 Sealed Source (Alpha-Omega Services, Inc., Model 136147)

Activity of Ir-192 Source: 7.23 Ci at time of event (Calibration of 10.514 Ci on 3/10/23)

Corrective actions:

Along with the physical evaluation of the equipment, a complete internal review of the following policies and procedures is in progress. Corrective actions to be instituted based on review findings. Below is a current summary of the evaluation.

1. **Review Assessment - Personnel dosimetry program as regards the HDR program:** The authorized user was not wearing dosimeter at the time of the emergency source retraction.

**Corrective Action:** A “timeout” policy will be instituted to require a staff dosimeter inventory and reconciliation prior to initiating an HDR procedures. See attached draft policy.

Also, a policy has been developed to require “instant read” dosimeters or pocket dosimeters be available for use during emergency procedure operations. See attached draft policy.

2. **Review Assessment – HDR emergency procedures and HDR operator training:** Training process was reviewed. Annual training was not completed by all individuals participating in HDR procedures.

**Corrective action:** Training policy, including frequency reviewed and revised. See attached policy. The HDR operator training policy has also been revised. All authorized users and authorized medical physicists will be required to complete manufacturer’s hands-on training prior to participating in any HDR procedures.

3. **Review Assessment - Response processes for unintended deviations (error codes) occurring during HDR procedures:** Currently working with manufacturer on reviewing and clarifying error code system and expected process and response time by the manufacturer. This process is ongoing.

**Corrective action:** Upon completion of the above review, general HDR procedure policy instituted and updated to provide guidance for unintended deviations in HDR procedures. See attached draft policy.

Extent of Exposure of Individuals:

The following hospital personnel received noted exposures in excess of normal occupation dose.

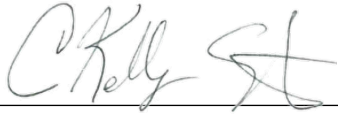
Authorized User, Whole Body – 66 mrem (estimate)  
Authorized Medical Physicist, Whole Body – 47 mrem  
Nurse Anesthetist, Whole Body – 33 mrem (estimate)  
Radiation Therapist 1, Whole Body – 87 mrem  
Radiation Therapist 2, Whole Body – 2 mrem

The patient received the following exposures in excess of the HDR treatment dose.

Whole Body – 1410 mrem  
Extremity – 7125 mrem

Note: Dose estimates initially were immediately completed for the authorized user, the authorized medical physicist, nurse anesthetist and the radiation therapists. These estimates were conservative in nature and also contained a decimal point calculation error. This caused the estimates to exceed the maximum permissible limits for some personnel. These dose estimates were proved to be incorrect after receiving the results of the processed dosimeters physically worn by personnel during the emergency procedure. Those results are listed above.

**\*\*\*Note: Since the HDR event occurred on 4/19/23, HDR procedures have not been resumed at the facility. United Hospital Center commits to suspending the HDR program until all corrective actions are in place and approved by NRC.**

A handwritten signature in black ink, appearing to read "C. Kelly Stoneberg". The signature is written in a cursive style with a large initial "C" and "K".

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C. Kelly Stoneberg, Radiation Safety Officer

## Instant Dose Dosimeter Inventory and Reconciliation Prior to Treatment Initiation

**Purpose:** To ensure all individuals are wearing the required dosimeters for exposure evaluation when performing an HDR procedure.

**Process:** Prior to the beginning of an HDR procedure, a “timeout” will be initiated to inventory the dosimeter availability and placement for the following individuals:

Authorized User – Whole Body

Authorized Medical Physicist – Whole Body and Ring

Radiation Therapist(s) – Whole Body

Support Staff (nurses, anesthesiology etc.) – Whole Body

**Action(s)** – The procedure will not be initiated unless all involved personnel are properly wearing their assigned dosimeters.

## Instant Read Dosimeters Use During HDR Emergency Procedures

**Purpose:** To provide all HDR personnel instant read dosimeters to be used in the event of the activation of the emergency procedure process during HDR treatment.

**Process:** Mirion Instadose monitors will be available in the HDR are of the radiation oncology department. (number) of instadose monitors will be located \_\_\_\_\_.  
Staff will be made aware of the location of the dosimeters as part of the emergency procedure training.

**Action(s)** – Staff will retrieve and wear the instadose dosimeters in the event of the activation of the HDR emergency procedure process. The dosimeters will be worn at body location

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## HDR Personnel Emergency Training

**Purpose:** To ensure all individuals involved in HDR treatments are adequately trained in the manufacturer emergency procedure processes in the event of the HDR Ir-192 source cannot be retracted into the required lead shielding in the HDR unit.

**Process:** The HDR manufacturer provides emergency procedures training for the scenario where the source is unable to be retracted into the shielded HDR unit. The training review can be completed by the manufacturer when they are present on-site.

**Action(s):** The hands-on training will take place at an interval of three times per year. This hands-on training will occur when the manufacturer is on-site for the scheduled Ir-192 source exchange.

It will be required that the AU or AMP be physically present for the training session with the manufacturer. It is highly recommended that the support staff be physically present for the hands-on training. If certain staff cannot be present for the manufacturer training, the AMP or AU will complete the hands-on training with them as soon as practical. Individuals who do not complete the most recent training session will not be permitted to participate in the HDR treatment procedures until the training is completed.

## HDR Operator Procedure Training

**Purpose:** To ensure all authorized users and authorized medical physicists involved in HDR treatments are adequately trained in the operating procedure processes upon initiation of participation in HDR treatments

**Process:** The HDR manufacturer provides HDR operator “hands-on” training both physically on site and remotely.

**Action(s):** All HDR authorized users and authorized medical physicists will be required to complete the manufacturer’s HDR operator training upon hire and prior to participating in HDR treatments. Refresher training will be provided as deemed necessary.

## HDR Treatment Procedure

**I. Policy Reference:** Administration of Radioactive Material for Therapeutic Use

**II. Guideline Reference:** HDR Guideline for Administration of Radioactive Material for Therapeutic Use

**III. Procedure:**

Daily quality control procedures must be performed prior to patient treatment each day of treatment. Refer to daily quality control procedure.

The Authorized User (AU) and Authorized Medical Physicist (AMP) must be present during HDR Procedures. Physicians or physicists in training may perform the tasks outlined below under the DIRECT supervision of the AU and AMP.

1. The patient is set up according to the plan using the applicator as prescribed. The oncologist places applicator or examines surgically implanted catheters.
2. Imaging is performed as prescribed by the physician and appropriate procedures are followed to evaluate proper positioning. The physician, in consultation with the medical physicist, determines if the applicator is in the same position as the plan. If the position has changed significantly, re-planning is necessary, and the oncologist will determine if the planned delivery will proceed.
3. The remote afterloader and emergency equipment is positioned by the medical physicist.
4. The physician or medical physicist connects the transfer guide tube to the applicator, careful to note the correctly numbered applicator lumens are connected to the corresponding transfer guide tubes.
5. A distance check is performed if warranted using the appropriate manufacturer distance tool.
6. The medical physicist performs a survey of background, the patient, and the top of the afterloader for baseline readings and records on the daily fraction treatment form.
7. The medical physicist is the last person to leave the room and confirms no one else is present in the room upon closing the door.
8. The patient plan is loaded into the control console and the decay corrected dwell times are verified by the medical physicist. Note that this may be performed prior to steps 1-7 above; however ONLY if the treatment begins within 10 minutes of performing the decay correction (authorize treatment on the treatment console).
9. A pre-treatment plan is reviewed by the AU and AMP.
10. The medical physicist is responsible for ensuring that one of the therapists has a stopwatch, that the physician and physics personnel are wearing their personnel monitoring devices and that the patient can be visualized and heard appropriately.
11. A "time-out" is performed in accordance with "time-out" procedures.
12. The AU initiates the treatment.
13. During treatment, visual and audible contact with the patient will be conducted by staff. The area monitor should be observed to function once the treatment is initiated.
14. If at any time during the HDR procedure an unintended deviation occurs (ex. unit warning/error code, patient distress), the procedure will be halted. The deviation will be evaluated. Based on the evaluation, the authorized user will determine whether the procedure will resume or be terminated.
15. Upon completion of the treatment, the medical physicist is the first to open the door and enter the room with survey meter in hand to ensure source retraction.

16. The medical physicist observes the area monitor and the survey meter to ensure that the source has retracted and notifies other personnel of the status of retraction.
17. The medical physicist uses the survey meter to measure the patient reading and afterloader top reading and records on the daily fraction treatment record.
18. A completion summary is printed, and the AU and AMP will sign the completion summary document.

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