

# Centro de Radioterapia Medical Event

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Region I**

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# Background Information

- Centro de Radioterapia at Hospital Auxilio Mutuo, located in Hato Rey, Puerto Rico, is authorized for the use of iridium-192 in a Varian Medical Systems GammaMed Plus iX high dose rate remote afterloader unit (HDR) permitted by 10 CFR 35.600
- Active HDR program which treats 8-10 patients per week. Almost all of the patients are gynecological cases using vaginal cylinders, interstitial applicators, or tandem and ovoids

# NRC Inspection Timeline

- On 2/8/18, the licensee identified that a medical event had occurred involving a patient overexposure to iridium-192 during an HDR treatment (reported to NRC on same date)
- NRC conducted an onsite inspection on 2/13/18 (within 5 working days as required by NRC Management Directive 8.10)
- NRC continued an in office review of the event over the next few months including hiring a medical consultant on 3/15/18
- NRC conducted an onsite follow up inspection on 6/21/18 to review the licensee's corrective actions that were implemented in response to the event
- NRC issued a Notice of Violation on 7/20/18 upon conclusion of the inspection

## Event Description

- Patient (being treated for Stage 1 endometrial cancer) was scheduled to receive 3 treatment fractions of 400 cGy (400 rad) per fraction to the vaginal cuff approximately one week apart
- Prior to the third treatment fraction on 1/24/18, a nurse noted bilateral redness (erythema) on the patient's inner thighs 10-12 cm posterior to the vaginal cuff
- It was unclear to the medical staff if the redness was radiation related.
- After some discussion, the third fraction was administered as planned

## Event Description (cont'd)

- During a follow up visit on 2/6/18, the licensee identified that the erythema had progressed to a moist desquamation phase indicating possible radiation exposure to the affected area
- On 2/8/18, the radiation safety committee reviewed the event and determined that a medical event had occurred (most likely during the first or second treatment fraction) and estimated a dose of 51 – 85 Gy (5,100 – 8,500 rad) to the inner thighs

**WARNING**  
**Graphic Images On Following Slide**



# Consideration of Possible Cause of Overexposure

- The authorized medical physicist (AMP) and authorized user (AU) noted that given the injury appeared to be limited to a well-defined 5 cm by 0.2 cm area, the thighs only received significant dose from a single treatment
- Multiple treatments to the thighs would likely have resulted in either multiple skin reactions or overlapping skin reactions that would be larger than the treatment length (not the exact treatment length as observed)
- AMP and AU also believed that only the internal catheter was dislodged and touched the patient's bilateral thighs and that the cylinder remained in the vaginal cuff during the treatment (neither nurse nor patient noted that the cylinder had moved from intended position)



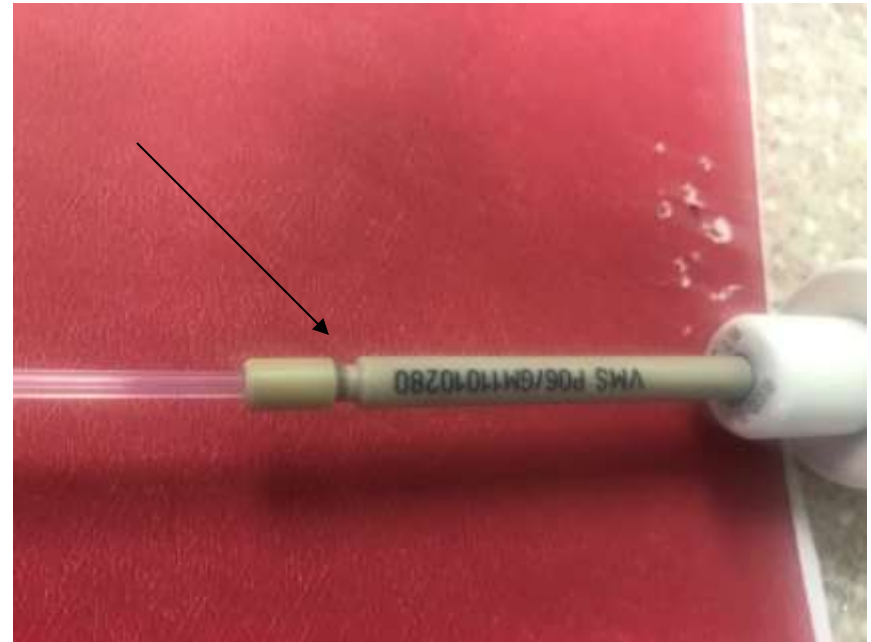
# Additional Considerations

- Internal catheter is supposed to be fixed in place via a type of pressure coupling once the cylinder is assembled and the locking nut is then tightened
- The position of the cylinder and internal catheter was visually but not physically verified
- Locking nut was likely too loose and either patient movement or weight of sheet (used for patient warmth) may have put weight on transfer tube which then pulled on the internal catheter and caused it to slide out
- Licensee was using a donut ring to secure the patient's legs during treatment (more comfortable) instead of source securing tabletop clamping device (less comfortable)

# Cylinder Set Used in Treatment



# Internal Catheter



# New Cylinder Set



# Tabletop Clamping Device



# Medical Consultant Conclusions & NRC Inspection Results

- On 5/28/18, the NRC received the medical consultant's final report which confirmed the licensee's event scenario and dose to the unintended area
- On 7/20/18, the NRC issued a Notice of Violation to Centro de Radioterapia for failure to develop or implement an adequate written procedure to provide high confidence that each administration was in accordance with the written directive (SL IV)



## Licensee Actions Taken to Prevent Recurrence

- Trained staff on revised HDR protocols and new segmented cylinder set (which does not contain a removable internal catheter)
- Physician to assemble and insert cylinder and double check all connections and device placement immediately prior to treatment
- Utilize source securing tabletop clamping device
- No longer using donut ring to secure legs when lowered to table

***Thank you!***

