



Region I Office  
Division of Radiological Safety and Security  
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## Telephone Conversation Record

Date: June 16, 2023

License No. 47-01458-01

Docket No.(no hyphens): 03003375

Mail Control/Report No. IR2023-001

Licensee Name: United Hospital Center

Participant(s) Name/Title: Owais (Mohammed) Rafique, Asst. VP Specialty Practices; Kelly Stoneberg, Radiation Safety Officer (RSO); Jim Israel, Authorized Medical Physicist (AMP)

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NRC Representative Name/Title: Anne DeFrancisco, Branch Chief, Jason vonEhr, Senior Health Physicist

Subject: Reactive Inspection – Corrective Action Update and Request for Notice of Program Restart

Discussion: A teleconference was held between radiation safety staff, radiation oncology, United Hospital Center (UHC) management, and NRC Region I staff to discuss the current status of follow-up to the April 19, 2023, reported event (EN56477). The discussion involved four parts: (1) the NRC communicated its request to be notified of the first patient treatment to allow for an onsite inspection for the program's restart; (2) UHC provided its reaction to the HDR manufacturer's (Elekta) conclusion that the third-party applicator (a Mick Radio-Nuclear Instruments, Inc. Split-Ring Applicator) was likely at fault due to internal steps that likely caused the hang-up of the HDR source during retraction; (3) an update on UHC's previously communicated corrective actions; and (4) estimated timeframe for next actions by the NRC and UHC.

Regarding No. 1: UHC consented and agreed to provide notice for the first patient treatment to allow an onsite NRC presence. UHC further elaborated that it anticipated the first patient treatment to be no sooner than 3-4 months, and potentially not in CY2023.

Regarding No. 2: UHC acknowledged Elekta's findings but did not wish to make its own conclusions at the time of the call. UHC intends to coordinate and communicate with the applicator manufacturer, Mick Radio-Nuclear Instruments, Inc., before it makes any commitments regarding the use or replacement of its HDR applicator.

Regarding No. 3: The corrective actions communicated last on May 1, 2023 (Accession No. ML23122A275), remain in process with no material changes. These included:

- New AU authorized for 35.400 and 35.600 receives device specific training from the manufacturer;  
 Status: UHC has notified the NRC of its addition of Dr. Clump as an Authorized User. The NRC acknowledged this amendment is in-house for processing, and no material information appeared to be missing from the request (Accession No. ML23117A314)
- Find root cause of equipment failure from manufacturer;  
 Status: The HDR manufacturer (Elekta) and the source manufacturer (Alpha-Omega) have provided their observations and findings. UHC acknowledged these and intends to engage with the applicator manufacturer for additional review prior to drawing any final conclusions.
- Re-training and equipment testing with the manufacturer;  
 Status: UHC stated that it was in contact with Elekta to organize training for the staff, including the new authorized user, Dr. Clump. UHC stated that this would be a mixture of virtual training and in-person training, where the in-person training would be accomplished at the time of the source installation.
- Re-evaluate policies, procedures, and competencies;  
 Status: UHC reiterated its commitment to fully review, re-evaluate, and, as deemed necessary and appropriate, revise its policies, procedures, and competencies. The NRC reminded UHC that certain procedures (e.g. spot check and emergency response procedures) are tied to its NRC license, and should it deem to necessary and appropriate to revise these policies/procedures, these documents must be submitted for review, approval, and incorporation into the NRC license.

Regarding No. 4: The NRC communicated that the OE panel is intended to be held on June 27, 2023, and that the NRC should be in contact with UHC shortly thereafter (within a week or two) to perform an exit briefing. The NRC further communicated the general enforcement process, should the June 27, 2023, OE panel determine that the inspection findings potentially merit escalated enforcement.

Action Required: No specific actions were required at the conclusion of the call.

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