

RO-ILS SAFETY NOTICE: SRS HETEROGENEITY CORRECTION

During the review of events reported to RO-ILS, the Radiation Oncology Healthcare Advisory Council (RO-HAC) may identify an event worthy of escalated status and determine that a Safety Notice is warranted. A RO-ILS Safety Notice communicates RO-ILS findings that may be novel to the community, of higher clinical significance, and/or deserve more prompt review. RO-HAC determined that the following event warranted a Safety Notice because the systematic errors affected multiple patients and was difficult to detect.

DESCRIPTION

A radiation oncology practice purchased a new linac and upgraded their existing intracranial stereotactic radiosurgery (SRS) program. A qualified medical physicist commissioned the replacement SRS program that included new hardware and software. The immobilization system for this new SRS program included a substantial base plate and accessories, which the physicist(s) decided to contour in order to account for this new density device in the beam path. Given the amount of air within the mask, the result was a long physical pathlength but relatively short effective pathlength used in the dose calculations. Physics staff assumed that heterogeneity corrections were accounted for in the new planning software, but they were not. This incorrect utilization of the software resulted in a ~10% deviation in dose for patients treated before the miscalculation was discovered and corrected. A more detailed description and analysis of these events can be reviewed in the corresponding <u>"RO-ILS Case Study: SRS Heterogeneity Correction and Commissioning."</u>

CONTRIBUTING FACTORS

The following factors contributed to the dose calculation error and/or the delay in identifying it:

- The vendor manual for the new software specifically stated that heterogeneity corrections are <u>not</u> used and <u>not</u> to include the baseplate and accessories in the contours. However, the information was missed by staff and they were unaware of formal training sessions for commissioning this software.
- Plan information was displayed in a different system which indicated that doses are calculated according to the standard algorithm. Multiple staff members assumed this meant heterogeneity corrections were included since the standard algorithm for this system is to include heterogeneity corrections.
- Independent end-to-end testing was performed using a phantom (i.e., without the baseplate and accessories) and so it did not identify the dose calculation error.
- As designed, the independent monitor unit check software, by default, assigned water density along the pathlength, mimicking the error. This was not understood by staff.
- Staff was under time pressure when conducting commissioning and therefore lacked necessary resources and leadership support.

LESSONS LEARNED FOR THE RADIATION ONCOLOGY COMMUNITY AT LARGE

Commissioning of treatment planning software is standard work for all radiation oncology programs. Errors during the commissioning process can result in systematic errors that affect many patients, with clinical consequences that range from problematic to severe.

- Acceptance and Commissioning
 - o Manuals provided with equipment should be carefully reviewed.
 - All practices should review existing guidance on commissioning and acceptance testing, including 2019 Safety is No Accident, AAPM Task Group (TG) 106 on Accelerator Beam Data Commissioning and AAPM-RSS Medical Physics Practice Guideline (MPPG) 9.a. for SRS-SBRT.
 - o Adequate resources (time and staff) should be provided when commissioning.
 - o New equipment and/or processes should prompt extra caution amongst staff.
- Independent Verification Procedures:
 - o Practices should employ comprehensive second check processes (e.g., peer review, independent end-toend testing).
- Training:
 - o Practices should be aware of, and avail themselves of, all relevant training.
 - o Administrators should support attendance of relevant staff at vendor-supplied training, both on new equipment and for new staff using existing equipment.
 - o Staff competencies should be assessed regularly and include knowledge of the use, functionalities and potential weaknesses of equipment.
- Learning and Safety Culture
 - o Practices should cultivate a strong safety culture.

CONSIDERATIONS FOR EQUIPMENT AND SOFTWARE VENDORS

While this event was a result of multiple factors, vendors have the unique opportunity to support practitioners with equipment and software designed to act as a complementary safeguard. Vendors should consider the following:

- Heterogeneity corrections are now included in dose calculations in many clinical systems. If a vendor software does **not** include heterogeneity corrections, this information should be clearly and prominently disclosed to the user (e.g., an explicit alert, setting display, manual announcement, detailed trainings).
- The software should state explicitly what setting is being utilized (e.g., heterogeneity off OR heterogeneity on).
- All pertinent training should be specifically suggested to practices.

CONCLUSIONS

The mission of RO-ILS is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure and non-punitive environment. Prior to the implementation of RO-ILS, the radiation oncology community was only privy to public records of very severe events. Yet much can be learned from all variety of events, including near misses and events that do not meet the threshold for external reporting. RO-ILS allows for wide-spread dissemination of non-identified information so that all practices can learn from one another. This event did not meet mandatory reporting requirements, further exemplifying the value of the program. This safety notice reveals opportunities for improvement by various members of the radiation oncology community. RO-HAC and Clarity PSO are grateful to all RO-ILS participants, ASTRO, AAPM, vendor partners and all supporters of the program for making the community safer. RO-ILS is extremely grateful for the participants who submitted this event and for their collaboration in writing this Safety Notice.