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# RO-ILS THEMED REPORT: **SPECIALIZED TREATMENT TECHNIQUES**

PATIENT SAFETY WORK PRODUCT

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## INTRODUCTION

This report examines RO-ILS: Radiation Oncology Incident Learning System® trends and events related to specialized treatment techniques reported to the program from 2014 through March of 2024. RO-ILS users are required to identify the relevant treatment technique(s) pertinent to the event or operational issue for each event. In almost ten years of operations, the RO-ILS database has accrued more than 36,000 events of various treatment techniques **(Figure 1**). The Radiation Oncology Healthcare Advisory Council deemed selection of any of the following answer options to fall into the category of "specialized" techniques: intraoperative radiation therapy (IORT), kV x-rays, lowdose rate brachytherapy (LDR), high-dose rate brachytherapy (HDR), radiopharmaceutical therapy, or total body irradiation (TBI). This categorization resulted in the identification of 1507 events.



**Figure 1:** Specialized treatment techniques least common in RO-ILS database (n=36,583)

*Abbreviations: HDR= high-dose rate; IMRT= intensity-modulated radiation therapy; IORT= intraoperative radiation therapy; LDR= lowdose rate; RPT= radiopharmaceutical therapy; SRS = stereotactic radiosurgery; SBRT= stereotactic body radiation therapy; TBI = total body irradiation; and VMAT =volumetric modulated arc therapy*

While not commonplace at every facility, proton therapy, stereotactic radiosurgery and stereotactic body radiation therapy events were not integrated into this analysis given their increasing prevalence and workflows that are similar to standard 3D and intensity-modulated photon treatment. Analysis of these techniques warrants its own separate report given their unique considerations.

A key word search of free text fields was used to identify additional relevant events for analysis. Expanding to include newer and more infrequent technologies, the search identified 262 additional events that included one of these key word(s):

- o **Total Skin Electron Therapy:** "TSE," "TSBE," "total skin"
- o **Total Lymphatic Irradiation:** "TLI," "total lymphoid," "total lymph node"
- o **Clinical Set up:** "clinical setup," "clinical set-up," "clinical set up," "hand calc," "hand calculation"
- o **Adaptive and MR-guided adaptive radiation therapy (MRgRT):** "Adaptive," "ART," "MR guided," "MRgRT"
- o **Extended SSD:** "Extended SSD"

In total, 1,769 unique events were identified to comprise the "specialized" technique cohort for this report (**Figure 2**). While this only represents 6% of the entire RO-ILS aggregate database, the events come from more than 250 different facilities.



**Figure 2:** Distribution of specialized technique (n=1,769) **Figure 2:** Distribution of specialized technique (n=1,769)

*Abbreviations: HDR= high-dose rate; IORT= intraoperative radiation therapy; LDR= low-dose rate; MRgRT= MR-guided radiation therapy; TBI = total body irradiation; TLI= total lymphatic irradiation; TSE = total skin electron therapy.*

This report is divided up into three major sections. The first section explores structured data element trends and compares specialized with routine techniques. The second section provides a few case examples and commentary on some of the specialized techniques followed by section three on possible mitigation strategies.

## SPECIALIZED VS. ROUTINE TECHNIQUE TRENDS

## **A. Event Classification and Significance**

All RO-ILS events are divided into classifications, including whether the event reached the patient (i.e., incident), did not (e.g., near miss), or there was some other underlying issue (i.e., unsafe condition, operational/process improvement). **Figure 3** compares the relative percentages of each classification for specialized and routine technique events. Incidents and near-misses were overrepresented in specialized techniques which may suggest that these often low-volume techniques require extra safety precautions.



**Figure 3:** Incidents and near misses are overrepresented in specialized techniques **Figure 3:** Incidents and near misses are overrepresented in specialized techniques

Not only were the number of specialized technique events overrepresented but they were also more severe when compared to routine events. **Figure 4** shows how the users rated severity for specialized and routine events. A higher percentage of specialized events were rated with higher severity compared to routine events, with 20% vs. 14% for moderate ratings and 5% vs. 2% for severe ratings, respectively.



#### **Figure 4:** Users rate specialized technique events as more significant

This trend confirms findings from a recent RO-ILS [Themed Report on Dosimetrically Impactful. Th](https://www.astro.org/ASTRO/media/ASTRO/Patient%20Care%20and%20Research/PDFs/ROILS_TR_Dosi.pdf#page=7)at analysis found there was a higher proportion of specialized techniques (e.g., HDR, radiopharmaceutical therapy, LDR) in the high impact events (i.e., therapeutic radiation events with ≥5% dosimetric deviation from planned dose) than in total RO-ILS submissions. This is likely a result of fewer fractions prescribed for many specialized techniques. When there is only one fraction or treatment, it is impossible to rectify dose delivery in future fractions.

## **B. Problem Type**

In addition to providing a detailed summary of the event, users must enter discrete data to bring focus to the specific problem. Use of the "Problem Type" field enables the reporter to decompartmentalize the event and pinpoint the primary concern so suitable actions can be identified. Of the 1,769 specialized technique events, 64% (1,125) are indistinct while the remaining 46% are spread across 21 variables, with just the top 10 categories displayed in **Table 1**.



**Table 1:** Top 10 problem types for specialized techniques

The narrow spread of results means no overarching issue with specialized techniques can be identified. This required data element was implemented into RO-ILS in late 2019 and the answer options were adjusted in mid-2023 with the hope that the revisions and [associated education](https://events.healthcaresafetyzone.com/EventsModuleWeb/Attachments/812dd06e-b573-4ae6-9d46-74aca7e4ac6f.pdf) would reduce user selection of "Other." It would be of great value to future analysis to see an increase in the selection of actionable variables. Bias in data element development – which focuses on the most common issues in the most frequent techniques – may also be contributing to increased selection of "other" for specialized techniques.

When the relative frequency of problem types for specialized and routine treatment techniques was compared, issues with treatment accessories was almost double for specialized techniques (5.8% in specialized vs 3.1% in routine techniques). This is an interesting observation to investigate; however, additional information is needed (e.g., type of device; documentation process and method) to identify reoccurring themes to proactively implement appropriate corrective measures.

## **C. Workflow Steps**

Examination of the workflow steps where the specialized technique events were discovered shows that these events were typically caught later in the workflow than routine treatment events (**Figure 5**). This suggests that because of the relatively low frequency of these types of treatments, as part of a facility's overall treatment mix, staff unfamiliarity with these specialized treatments may play some role in the genesis of these errors. The relatively higher proportion of catches during the pre-treatment quality assurance (QA) and treatment delivery is encouraging. It may indicate that the staff responsible for the final review of these infrequent events show a high degree of diligence in reviewing these uncommon treatment plans.



## Figure 5: Specialized technique events more likely to occur during treatment delivery compared to routine techniques

## **D. Discoverer**

Since more errors involving specialized treatment types are caught during QA, it is not surprising that medical physicists are the leading discoverers of these events (**Figure 6**). Presumably, the physicists performing the pretreatment QA reviews are on "high alert" because of the infrequency of these treatment techniques. Although most of the events were caught at the treatment delivery phase, radiation therapists discover fewer of these events relative to the number of events they discover for routine treatment types. This may be because of unfamiliarity with these treatment types and an overreliance on the pre-treatment QA to confirm no errors are present.



**Figure 6:** Identifiers of specialized technique events by role **Figure 6:** Identifiers of specialized technique events by role

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## **E. Contributing Factors**

To support the investigative process and explore possible root causes, RO-ILS users can select causal factors relevant to an event. Since this multi-select data element is optional, it was only answered for 36% of the specialized technique events. For the 634 specialized technique events with known contributing factors, the top factors were policy not followed (28%) and compressed time scale/rushing (21%).

To dive further into one of these top contributing factors, consider findings from a separate analysis released earlier in the year. For the 2024 RO-ILS Rushing/Scheduling Themed Report analysis, 90% of the "rushing/scheduling" events were identified by keyword search and only 10% from structured fields. Therefore, the rushing themed report is a more comprehensive dataset than just studying a single structured data element like "contributing factors." The [Rushing/Scheduling Themed Report](https://www.astro.org/getmedia/4a587cca-804b-4d5f-b2c8-2e624c495d9b/ROILS_TR_Rushing.pdf#page=9) explores the relationship between different treatment techniques. With the exception of kV x-rays, all the specialized techniques had significantly more rushing and scheduling issues than non-rushing. For example, 73% of the 182 TBI events had some rushing or scheduling component as defined for the report. The report states, "Transplants requiring TBI necessitate extensive planning and typically have the treatment schedule and prescription doses determined well in advance. Given the decreasing use of TBI and its status as an uncommon procedure, one possible explanation for the increase in rushing could be the *lack of well-established and practiced processes* compared to procedures like IMRT/VMAT." Additionally external forces may be occurring more frequently or having a significant impact on care for patients requiring specialized techniques. For example, a medical change in a patient receiving a bone marrow transplant will result in last minute scheduling changes for TBI.

**Table 2** focuses on answers to the structured contributing factor question that most differed in the specialized technique cohort relative to routine techniques. For example, equipment/hardware failure was selected in 9% of specialized techniques with known contributing factors compared to only 3% of routine techniques. Specialized equipment may be more difficult to service, and facilities often have limited alternatives. Even when using more standard equipment, a linac experiencing downtime will more drastically impact TBI treatments than other techniques, due to their finite deadlines. The increased prevalence of equipment failures in specialized techniques also impacts rushing and scheduling.

**Table 2:** Differences in user contributing factors between specialized and routine technique events (\*Top 10 contributing factors for specialized technique cohort)



Failure to follow through, acting outside of one's scope, and inadequate staff competency assessment were also all more prevalent in events from specialized techniques. Each of these attributes has an implied link to lack of familiarity with the procedure. This highlights the particular importance of detailed process documentation, ongoing and timely training, appropriate staffing and review of staff expectations and competencies for specialized techniques.

Some of the techniques classified as specialized were previously used more frequently, but with advancements in medicine they have become uncommon. While most routine techniques have benefited for technological advancement, some of the advancements either have not been extended to or are not applicable to these specialized procedures. For example, imaging and automation made possible by technological advancements cannot be easily applied to some "specialized" setups making what was once a fairly simple treatment technique complicated because of infrequent utilization. Developing a well delineated workflow for specialized treatment procedures may be more difficult to accomplish because it may not be technology-driven nor necessarily well-practiced. Additionally, there is a generational impact on the workforce that may contribute to the lack of well-established processes and experience. The historical knowledge of carrying out SSD, TBI and clinical setup procedures is transitioning out of the profession with the retiring workforce and the decreasing volume of these procedures being performed.

## TECHNQIUE-SPECIFIC CONSIDERATIONS

## **A. TBI**

TBI procedures prepare patients for bone marrow transplants. Treatment delivery requires a field that is larger than the capability of the linac jaw setting at standard distances. For this reason, this type of treatment is considered specialized because beam parameters and machine plan angles fall outside of a standard setup. Some facilities have adopted VMAT treatment while others use an extended distance technique.

The technique discussed in this segment of the report involves reversing the patient's orientation to feet-first toward the machine as opposed to head-first. For planning the gantry was set at 5-degrees off true lateral; 275 and 85. However, treatment was delivered with the gantry at the 275-degree angle. Field delineation included upper and lower ports; full field and segmented ports to encompass the full targeted area. The patient was rotated anterior and posterior for an AP/PA treatment.

#### **Case #1: Opposing Field Misalignment**

*The patient was scheduled for six fractions using an AP/PA TBI technique. During the last treatment session, the therapist realized the field opening for the PA port in the field-in-field setup was incorrectly positioned superiorly in the thoracic area instead of inferiorly in the pelvic area. Further investigation determined that this displacement had occurred in all previous treatment fractions as well. Treatment was paused, and a new plan was developed for the final treatment delivery to correct the error. Physics review of the incident determined that the patient's orientation to the beam was rotated 180 degrees, with the gantry set in the lateral position. The gantry remained stationary throughout the treatment, while the patient was rotated between fields. This change*  in patient orientation was not accounted for during the planning process, resulting in the superior displacement *of the PA field opening. Lung and other organs received roughly 5% higher dose than originally planned. No significant difference in side effects noted during follow-up visit.*

The plan check process failed to detect the error in this event, demonstrating the importance of multitiered, redundant plan check processes that are not rushed. During the therapist's plan review, verification of gantry, field arrangements, patient orientation and field positioning should be thoroughly checked. Employing automation and other tools can be beneficial for quality assurance. For example, scripts can compare the planned gantry angles in relation to patient orientations against standard orientation and flag issues for review to avoid a non-standard gantry and misalignment.

On the first day of treatment, therapists should image all treatment fields including subfields (i.e., field-in-field technique). Additionally, a verification simulation appointment may be beneficial as a real-life check. This helps mitigate rushing on the actual day of treatment and allows staff new to the process an opportunity to learn and become familiar with the protocol/process. For each treatment fraction, therapists should visually inspect the clinical setup fields; this is especially important for cases in which the patient is not treated on the treatment couch and indexed to specified locations. Even though the non-standard orientation was not accounted for in planning, looking at the treatment fields would have prevented the error. Prior to IMRT and imaging advancements visualizing treatment fields/images was a key part of daily treatment delivery, but this is a skill that is not regularly exercised. It should be reiterated to staff that these imaging advancements help workflow, but do not apply to all treatment techniques.

While adding treatment field verification tasks to checklists and the facility's process documentation is helpful, workflow tools and dashboards can help monitor compliance and staff completion of tasks. Lastly, this case demonstrates a hybrid technique (planned/clinical), and therefore facilities should implement formal training, document competency, and schedule appropriately trained staff to be involved for every treatment session. Regardless of experience, staff should receive routine retraining and competency assessment.

## **B. Brachytherapy**

Brachytherapy procedures involve the use of radioactive material placed inside of the patient to deliver the radiation. The sources can be implanted directly into the patient using needles (e.g., LDR prostate implant) or placed into an applicator that is placed inside of the patient (e.g. HDR ring and tandem). The sources can be classified as low dose rate (dose rate less than or equal to 2 Gy/hr), medium dose rate (dose rate greater than 2 Gy/hr but less than or equal to 12 Gy/hr) or high dose rate (dose rate greater than 12 Gy/hr).

## **HDR**

## **Case #2: Incorrect Source Position**

*Patient was implanted with 60 mm Smit sleeve which became dislodged over the weekend. The practice did not have a replacement 60 mm sleeve available but did have a 40 mm sleeve. The treatment planner generated a plan on the 60 mm tandem to mimic a 40 mm tandem that would be used for the treatment. This was achieved by not using the distal 4 dwell positions. The patient was imaged, and the treatment delivered. Upon review during posttreatment dose reconstruction, it was discovered that the dwell positions had not been moved to the end of the 40 mm sleeve thus resulting in the dose being delivered 20 mm proximal to the intended treatment position.* 

While important to any procedure, developing and adhering to thorough policies and procedures is especially important for specialized procedures. In this case, a work around was devised because the proper equipment was not available for this case, resulting in the treatment being delivered to the incorrect location. This further highlights the overrepresented equipment contributing factor (See Table 2). Policies and procedures should require that a treatment plan only be developed on the geometry that will be used for treatment. Reviewing the dose distribution and treatment geometry on scans with the geometry used for treatment *prior* to the administration of the treatment should be done.

## LDR

## **Case #3: Incorrect Seed Placement**

*During an LDR prostate implant a patient was set up in the operating room. The prostate was visualized and seeds were implanted. Prior to seed placement the ultrasound probe was not advanced to the correct position. This resulted in seeds being placed inferiorly to the planned position.* 

Identifying and documenting the location of the base and apex of the prostate prior to implementation is essential when performing a prostate implant. The stepper holding the ultrasound probe should be adjusted to indicate the location of the base of the prostate. It is essential that staff be properly trained on the equipment being used in any procedure. In this case, staff should have been appropriately trained on the equipment so that the location of the base slice of the prostate was clearly indicated. Additionally, radiopaque markers are often implanted in the base and apex of the prostate as a secondary check of their location. This secondary check allows the user to verify the base and apex locations using a second independent imaging method. Alternatively, a marker cable in the fixation needle and C-arm fluoroscopy can be used to verify the location of implanted seeds.

## **C. MR-guided Adaptive Radiation Therapy**

MRgRT is an advanced cancer treatment that uses real-time magnetic resonance imaging to increase the precision of radiation delivery. Unlike traditional methods that rely on static pre-treatment imaging, MRgRT enables clinicians to continuously monitor the tumor and surrounding tissues during treatment. This approach allows for real-time adjustments to the radiation dose based on changes in the tumor's position, shape or size, which can vary between treatment sessions. By adapting radiation delivery to these changes, MRgRT enhances the accuracy of tumor targeting while minimizing radiation exposure to surrounding healthy tissues. This is especially beneficial for tumors located in areas prone to movement and near radiosensitive structures, such as those in the abdomen. However, MRgRT adds additional complexity and pressures which can stress processes.

### **Case #4: Adaptive Contouring Error**

*A patient undergoing MR-guided stereotactic body radiotherapy for pancreatic cancer experienced an unintended dose deposition to the duodenum because of a contouring error. During the adaptive treatment process, the covering physician failed to correctly contour the duodenum, which was adjacent to the target area. This error led to the duodenum receiving an unintended radiation dose. The issue was only discovered after the treatment had been completed, during an audit of the adapted plan.*

This incident demonstrates the critical importance of thorough training for MRgRT, particularly in target and normal tissue delineation, to prevent serious errors. It also emphasizes the need for clinicians to resist the pressure to rush. Facilities need to foster a culture of open communication where concerns can be raised by any team member. Regular peer review and the use of video sign-out processes are additional strategies that could significantly improve treatment safety and efficacy.

## **D. Infrequent Techniques**

## Clinical Set-ups

Clinical setups are treatments where simulation is done with the patient present but no imaging is performed. Instead, the treatment location is based on some easily definable anatomic feature such as a scar or palpable lesion. In most cases, a simple manual calculation is used to determine treatment time or monitor units (MU).

#### **Case #5: Incorrect Beam Energy Used for AP PA Treatment**

*The patient was prescribed a single fraction to be delivered AP/PA using a clinical setup. The method uses no multileaf collimators and an independent dose calculation software is used to determine the treatment MU. The software-determined MUs must be verified by a physicist (hand calculation) prior to initiating treatment. This verification was performed by the physicist, and the therapists verified treatment parameters correctly. However, after the PA field was delivered correctly with 10MV, the AP field was started with the incorrect beam energy of 6 MV. The error was discovered by the treating therapists after 48 MU had been delivered. The remaining MU to be*  *delivered with the prescribed energy of 10MV was calculated by the therapists and the radiation oncologist using an independent dose calculation software. The physicist determined with hand calculation that the remaining 180 MUs were within 3% agreement.*

To minimize the likelihood of this error, second checks for manual calculations should include double check of all field parameters including beam energy. Therapists should also verify that the beam energy matches the prescription prior to initiating beam on. Clinical setups are frequently done in a compressed time frame and/or outside of normal clinical hours and therefore extra precaution is needed. Many staff are becoming less familiar with manual calculations as dependence on treatment planning software increases and thus increased education is necessary.

## Extended SSD

Extended SSD techniques are used when the length of desired treatment area or target exceeds the mechanical limits of the treatment unit. Most treatment units are only capable of a maximum field size of approximately 40cm. This field size is defined at the treatment isocenter. Therefore, because of beam divergence, increased field sizes are achievable by increasing the SSD beyond the source-axis distance of the treatment unit. Increased field sizes of around 1.2-1.3 times the isocentric maximum are achievable.

#### **Case #6: Incorrect SSD Used for Treatment**

*Patient was simulated for urgent next day treatment. Treatment plan was developed using extended SSD well after regular working hours. Plan was approved and physics check was performed in compressed timeline the following morning. Even with the rushing, the patient's treatment was delayed. Therapists manually set 100cm SSD rather than using shifts from treatment plan. Patient treatment was delivered at incorrect SSD of 100cm instead of intended SSD of 120cm.*

In this event, the dosimetrist identified the compressed timeframe as leading to lack of communication with the therapists about the unusual 120cm SSD setup. While the plan was done correctly for extended SSDs and all checks verified this, therapists were presented with the complete plan well after patient's scheduled start. The atypical setup was not specifically noted in plan documentation.

Extended SSD treatments are infrequent and often used in emergent or urgent situations. If extending time frames is not feasible, consideration should be given to improving communication between staff, especially regarding unusual treatment techniques. Facilities need to have well established policies documented for extended SSD treatments, including the use of imaging the superior and inferior field borders to confirm treatment parameters.

## Superficial / kV X-Rays

Superficial or orthovoltage treatments are treatments using a specially designed x-ray unit capable of delivering treatment beams with energies in the range of 40-150 kV. These beams deposit maximum dose at or near the skin surface with a rapid drop-off beyond this depth. These treatments are typically used to treat superficial skin cancers, but can be used in other settings, such as post-surgical irradiation of incisions in patients with a propensity for keloid development.

#### **Case #7: Patient Treated with Incorrect Energy after Plan Change**

*Patient was prescribed treatment to two sites using 100 kV treatment energy. Calculations were performed for 100 kV and initial physics checks were performed. The radiation oncologist changed the treatment energy to 70 kV in the prescription documented in the oncology information system (OIS), but no other communication of change to the treatment intent occurred. Therapists treated the patient with initial calculated time for the treatment fields.*

In this event, the treating therapists did not have access to the OIS at the orthovoltage treatment unit control station, so they used initial calculation printouts to set time and energy. As a result of this event, this practice will implement a prescription check in their OIS prior to orthovoltage treatments.

Orthovoltage treatments may be calculated infrequently, so staff diligence in using calculation software and entering treatment parameters is vital. Inoperability between orthovoltage treatment units and OISs requires pretreatment checks to be more involved for superficial treatments than with other routine techniques. Communication of plan changes is important for all techniques but especially when staff may be relying on printed materials that may be outdated.

## Intraoperative Radiation Therapy

IORT is the use of brachytherapy, orthovoltage or electron sources to treat areas of the body accessible only by invasive procedures that generally occur in an operating room setting. Examples are treatment of surgically exposed tumors or tumor beds and intraluminal treatment of the bronchi.

## **Case #8: IORT Shielding Not Used**

*IORT treatment was delivered without intended intraoperative shielding being placed. Incident was discovered by physicist monitoring dose outside of treatment area.* 

The reporting facility indicated that they initiated a treatment device checklist for IORT cases as a result of this case. IORT frequently involves the use of specialized treatment devices and care must be taken for correct usage of these devices. IORT requires extensive communication between radiation and surgical personnel who may not be familiar with each other's area of expertise, so clear communication between teams must be a priority.

## MITIGATION STRATEGIES

## **1. Clear, concisely written policies and procedures**

Seldom performed procedures are inherently prone to error because staff are not very familiar with them and therefore, well detailed standard operating procedures and job aides are useful. Procedural documents provide more in-depth explanations and instructions, and should be easily accessible to staff. Job aides allow for quick reference for assurance that staff actions are aligned with the process steps. These documents should be written for the novice and not the expert. Organizations should engage with staff that are considered subject matter experts to draft the document from a training perspective and include other staff in review.

## **2. Ongoing and just-in-time training**

Specialized techniques with a small but relatively constant volume of patients, such as HDR brachytherapy, warrant regular training for staff. For other specialized techniques that occur seldomly, training immediately prior to the patient case can be helpful. This refresher of processes and potential pitfalls or concerns can minimize errors. Both just-in-time training and dry runs can improve the team's confidence and help the team to perform optimally.

## **3. Staff "credentialing" and expertise**

Specialized procedures, by definition, fall outside the conventional scope of practice in radiation oncology. These procedures often use specialized equipment on which staff are not normally trained. Because of this, it is advisable to have an internal "credentialing" program for staff involved in these procedures. This program should include, but is not limited to, training for the specialized procedures and the equipment used, and should be renewed periodically, either annually or semi-annually. While there may be staff with expertise for specialized procedures, there must be planning for backup when staff are unavailable to ensure others receive the necessary training and experience.

#### **4. Allocating appropriate time and staff**

When possible, staff with experience and prior experience should use their skills for specialized procedures. However, practices must plan for appropriate staffing coverage so other staff are properly prepared to serve as backup for primary staff that perform specialized techniques. In all instances, providing staff adequate time for training and associated treatment tasks, including performing QA, is necessary. Staff should be afforded sufficient time to review, ask questions and possibly perform a dry run on these cases. Creating a safe space should be priority, where staff do not feel rushed and are comfortable speaking up. Asking for help is critical for an effective safety culture and optimal patient care.