RO-ILS®

RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

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CLARITY PSO
A Patient Safety Organization

RO-ILS THEMED REPORT:

EQUIPMENT QUALITY ASSURANCE

PATIENT SAFETY WORK PRODUCT

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INTRODUCTION

The field of radiation oncology is known for the advanced technology employed to treat cancer. Thus, the correct functioning of hardware and software is imperative to deliver safe and high-quality care. The ongoing quality assurance (QA) of equipment, particularly linear accelerators (linacs), may appear to fall solely under the scope of medical physicist duties. While they are ultimately responsible for this critical activity, it is helpful for the entire team to have a good understanding of equipment QA and communicate necessary information regarding equipment function to the physics team.

Existing guidance describes specific actions, tests, frequencies and other critical components for evaluating and maintaining proper linac performance. American Association of Physicists in Medicine (AAPM) Task Group (TG) report 142 specifies linac QA and TG 198 offers guidance on how to implement the recommendations in TG 142.[1,2] AAPM Medical Physics Practice Guidelines (MPPGs) complement the TG reports and describe the recommended minimum level of medical physics support. As an example, MPPG 8a describes linac performance tests and is currently being updated.[3] Other relevant reports include TG 135 for robotic radiosurgery and TG 224 for proton equipment.[4,5] Even with detailed guidance available, implementation of these recommendations varies.

Some of this variation is not surprising. After all, many of the recommended tests can be performed in more than one way. Additionally, as the complexity of treatment delivery and patient setup verification increased, so did the number of tests. TG 198 recommends that practices perform the QA tests at the provided frequency but acknowledges that this may change as the practice learns from their risk analysis work described in TG 100.[2,6] While practices will take into consideration their institutional needs, available testing equipment, time and other factors, this critical work must be prioritized and meet baseline standards as set out by AAPM. In support of the AAPM guidelines, ASTRO's Accreditation Program for Excellence (APEx) standard 12 focuses on the quality management of treatment procedures and modalities.[7] In the 2019 5-year report, APEx described areas of improvement as they related to equipment QA.[8] Performance during the self-assessment and from the facility visit indicated that some practices were not sufficiently reviewing trends related to machine calibrations, QA results, machine downtime and service reports, or were not maintaining necessary QA documentation. Additionally, machine QA accounted for 37% of corrective actions for the practices that received provisional accreditation. Often, there was no evidence a qualified medical physicist had reviewed the QA data or other documentation was missing. More recently, APEx shared anecdotal evidence in which surveyors observed deviations from established QA practices, such as not performing comprehensive annual QA but rather repeating monthly QA activities in its place.[9]

Subpar equipment performance can bring significant risk to patient care, especially as this has the potential for a systemic error that could affect multiple patients. All members of the radiation oncology team interact with equipment, and everyone knows all too well the clinical and operational impact when a machine is not operational. Previous RO-ILS themed reports have tackled broader topics such as peer review. This report explores a more specific topic from the lens of RO-ILS: the importance of proper equipment QA.

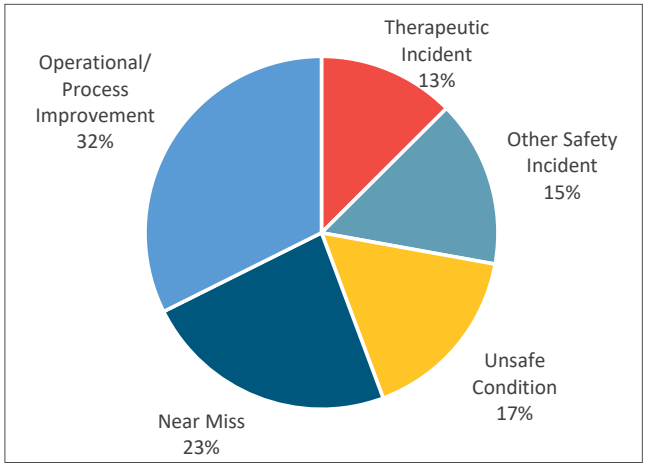
ANALYSIS & TRENDS

To identify relevant events, all the RO-ILS events reported to the patient safety organization from the inception of the program through the end of January 2022 were searched for events in which the RO-ILS user self-reported that the error occurred during "equipment and software QA" or that a contributing factor was either "inadequate QA or quality control" or "inadequate policies and procedures for QA or quality control." This resulted in a total of 686 (3%) events out of approximately 21,500 total events. Approximately half of the events were identified based on where in

the workflow the event occurred and the other half from the optional contributing factors field. While this subset of events may include some QA-related data not specific to equipment, this approach was used to be as inclusive as possible.

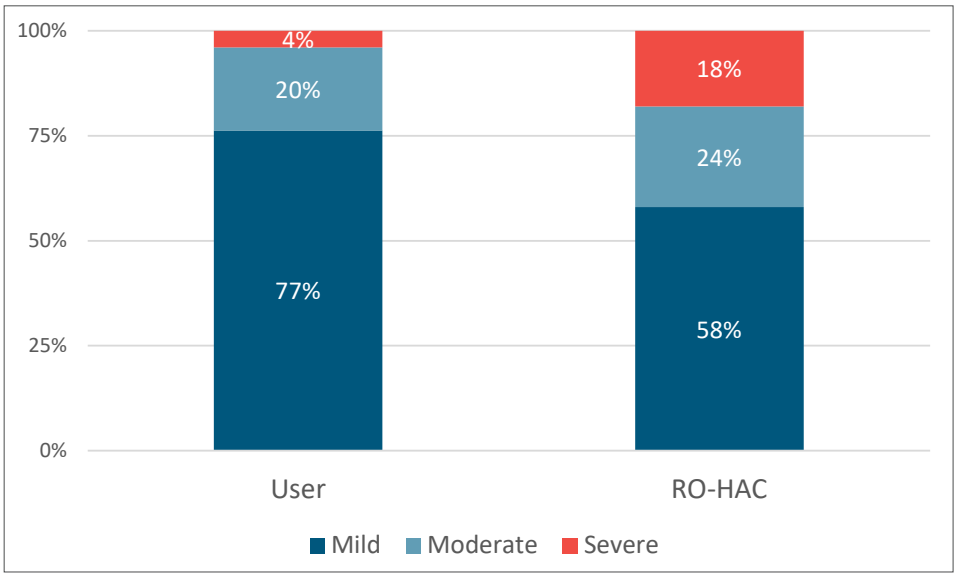
Figure 1 displays the event classification distribution for this subset of equipment QA events, in which operational/process improvement events are most common, followed by near misses and then unsafe conditions, similar to the full RO-ILS database.

Figure 1: Event Classification of Equipment QA Events (n= 686)



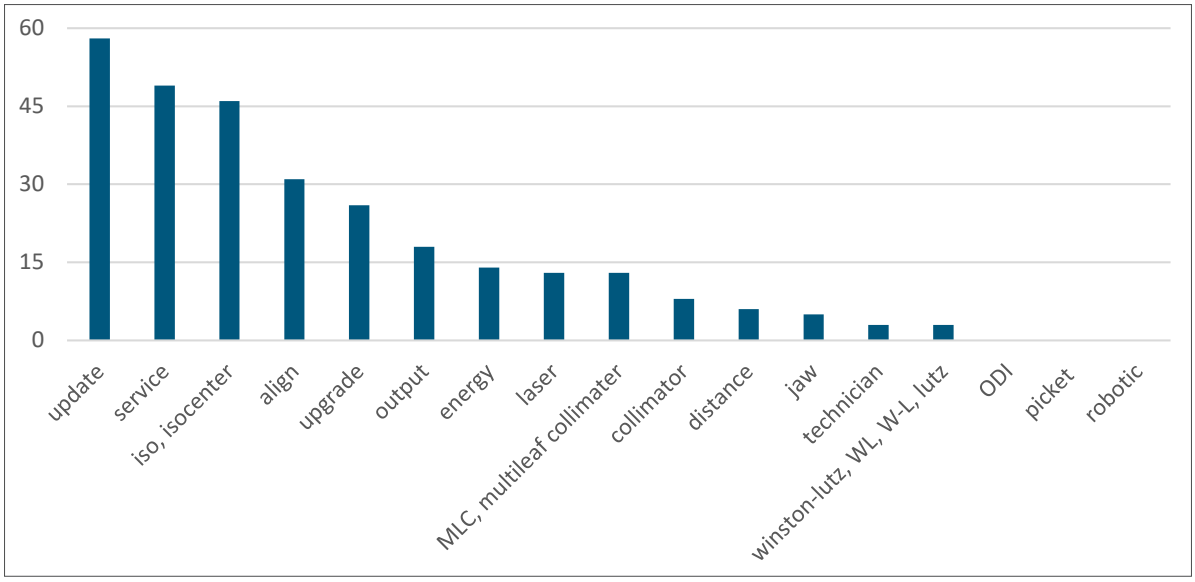
RO-ILS users and RO-HAC reviewers utilize slightly different scales to assess the event's significance or severity; however their rating can still be compared. Figure 2 displays the distribution of mild, moderate and severe events based on user and RO-HAC perspective, respectively, for the subset of equipment QA events. Users only designated 4% of events as severe as compared to 18% by a RO-HAC member. The user or practice may be apprehensive to classify an event as "severe" given that likely no actual harm was caused to the patient. Additionally, users could be confused on how to account for *potential* severity. Therefore, a knowledgeable but objective third party, like the RO-HAC, may have a unique and more consistent perspective on the *potential* severity or the importance of the lessons that can be learned from the error.

Figure 2: User and RO-HAC Event Severity of Equipment QA Events



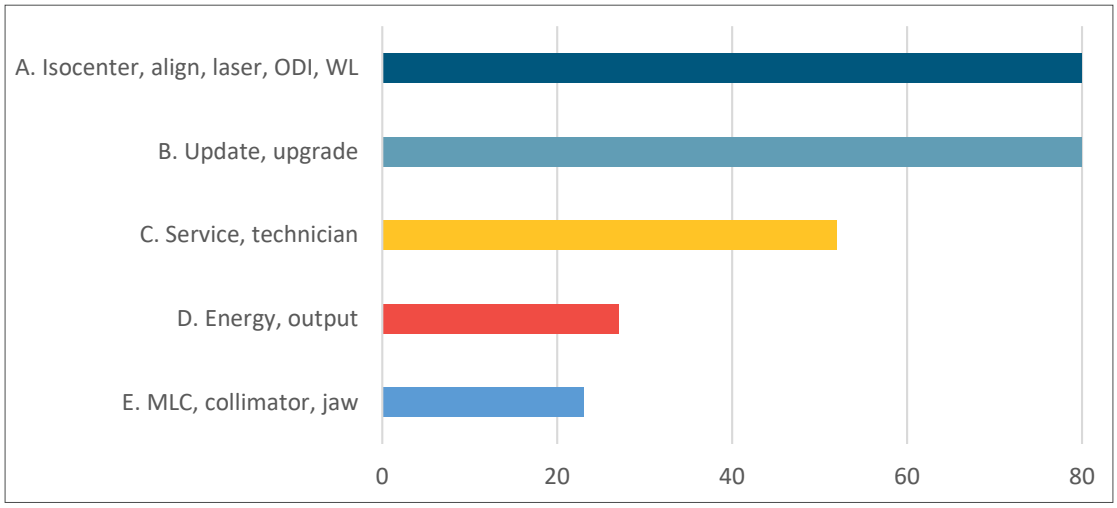
The subset was searched for key words based on published risk analysis results, including "output," "laser," "distance," "ODI," "collimator," "jaw."[3, 10] RO-HAC physicists identified additional terms based on personal experience and knowledge gained from reviewing RO-ILS events, including the concepts of isocenter, Winston-Lutz, energy, align, picket, multileaf collimator, robotic, service, technician, update and upgrade. Figure 3 displays the number of events that included one of these keywords in a free-text data element. In total, 239 (35%) of the events contained at least one of the key words.

Figure 3: Keyword Search Results



The key words can be grouped into 5 categories which would comprise nearly all the events that contained a key word (235 events out of 239, 98%) (see Figure 4).

Figure 4: Key Word Groupings



To provide a more nuanced review of this subset of events, two RO-HAC physicists reviewed the details of over 100 events, focused on the highest priority events (defined as user 'severe' significance or RO-HAC score of 4 or 5). Some case examples are described below to explore the categories in more depth.

SUBTOPICS AND CASES

A. ISOCENTER, ALIGN, LASER, ODI, WL

Event #1: Routine Alignment Error

The therapists were performing morning QA on the linac and noted that the imaging and radiation isocenters were off by 3mm. They communicated this to the physics staff and the issue was resolved prior to treatment.

This event underscores the value of daily QA and a communication/response protocol that protects patient safety. Treatment planning and image guidance almost always require the imaging and radiation congruence to be tighter than 3mm and if this had not been caught and addressed, patients could have had misdirected radiation treatments. Also important to note is that issues like this typically happen over time and do not self-correct, so it is plausible that this was a 1 and 2mm issue before it became a 3mm issue. Setting appropriate tolerance limits, ensuring proper notification and communication expectations, and responding to QA test results appropriately are as important as running the QA tests themselves. In the event there was a sudden jump in 3mm, this drastic change requires more investigation as it would not be typical.

SAFETY CHECK

How often are daily QA results proactively monitored by the physics team? Is there a standard policy in place regarding communication and review of alignment errors of a certain magnitude?

Event #2: Laser Alignment Caught by QA

A trainee performed a patient-specific QA in the evening. During the process of performing the patient-specific QA there was a collision between the table and a cart used to transport a water phantom. The trainee was not aware that a collision like this could cause the table to lose its known position and therefore it was not communicated to physics staff. The incorrect table position was caught by routine QA prior to any treatments.

This event illustrates the importance of proper training and supervision of trainees, including students, residents and new staff. Often trainees are not aware of the effects that even a "minor" collision could have on equipment used to treat patients. Additionally, safety culture, either at the current practice or negative previous experience, may also have contributed to the individual's hesitancy to report the collision. This event also highlights the importance of having a robust routine QA program that is performed prior to patient treatments.

SAFETY CHECK

How likely is it that a seemingly benign collision in your practice would be reported to someone who would follow up and assess alignment accuracy?

B. UPDATE, UPGRADE

The life cycle of equipment involves planned updates and upgrades. While there may be a significant difference in scale regarding how much change is anticipated between an update and upgrade, both must be carefully implemented and tested. While an update may target one area of equipment, staff must confirm that ripple effects have not occurred

in other functions or processes. The error described in the only RO-ILS safety notice to date started after an upgrade to a stereotactic radiosurgery program that included new hardware and software.[11] As described in the safety notice and case study, an oversight during commissioning can result in a systematic error that can affect multiple patients, which is why these changes cannot be undervalued. Acceptance testing and commissioning requires adequate staff resources that must be appreciated by the whole radiation oncology team. Underestimating the effect of an update or upgrade is not uncommon.

C. SERVICE, TECHNICIAN (UNPLANNED)

Compared to typically anticipated updates or upgrades, servicing of equipment that is down may result in additional unexpected downtime. While a practice cannot always plan for when a machine may be unavailable, tracking the frequency and occurrence of downtime is important for overall quality management. Given the unplanned nature, caution and vigilance is all the more important.

Event #3 Communication with Service Technician
The linac was down in the morning, which required a vendor service engineer to be on site for an emergency repair. After the repair was completed, the linac was released to the clinic without notifying physics staff. The vendor later informed physics that after repairing this equipment, its calibration needs to be verified before treatments are resumed. That did not happen in this case.

In event #3, communication was insufficient from the vendor staff to physics staff. However, communication among the radiation oncology team members was also poor, as the therapists did not automatically confer with physics before initiating treatment. This further exemplifies the importance of team members being aware of their colleague's role and sharing information with the physics team.

SAFETY CHECK

Is there a formalized process for handoff from service engineers to physics, then from physics to the radiation therapist team after machine repairs? Is there a process for documenting the clinical use status for each piece of equipment?

D. ENERGY, OUTPUT

Equipment calibrations for energy and output are among the most critical of QA duties as they would not only affect all patients but could also have very serious clinical significance. Energy and output tests are routinely performed by both the therapy and physics staff; while therapists typically verify daily constancy, qualified medical physicists perform monthly and annual calibrations. As this is such a critical component of treatment safety, daily trends and atypical or unexpected results must be communicated and followed up on in a timely manner. Proactive communication regarding QA results and planned actions to address findings supports a key component of radiation therapy safety.

Event #4: Daily QA Performed But Not Recorded
Daily QA was performed but not recorded in the institution's QA software. It is unclear whether it was user error or a software error that resulted in the daily QA results not being recorded. The results from the previous day were reviewed and the therapists did not recall anything out of the ordinary. This issue was identified during physics review of the morning QA records.

While finding an egregious error during daily QA checks that would stop treatment is rare, the checks are a necessary and critical safety net to prevent systematic errors from affecting patients. Unfortunately, rare, unexpected and catastrophic safety events do occur. When the necessity of these tests is undervalued, serious safety events are given a pathway through which to propagate.

SAFETY CHECK

How does your practice confirm that QA records are documented? Are missing QA records a recurrent issue and how likely are they to be discovered? Is there a formalized process for a qualified medical physicist to review daily, monthly and annual QA results?

E. MLC, COLLIMATOR, JAW

Of the five groupings of key words, the one with the least number of events included the terms MLC, collimator and jaw. This may be because the radiation oncology community has made improvements and paid special addition to this area of linac QA as errors made the news and research was published. Errors related to MLC, collimator and jaw, are typically identified during patient-specific QA. Historically patient-specific QA was generally completed by the third fraction or before 10% of the dose was delivered but it is now standard practice prior to treatment start.[12] APEx standard 3.4.3a requires that patient-specific plan QA be completed before treatment initiation or when changes are made to the treatment plan. Additionally, other tests do identify these errors, including a weekly qualitative MLC test (e.g., picket fence), as recommended in AAPM TG 142.[1]

F. OTHER (EXTERNAL FACTORS)

Event #5: Room Temperature Affected Machine Function

The air conditioning (AC) system was not working and therefore the room ultimately became too hot for the linac to function. The machine shut down due to temperature in the room.

Air quality is important to proper equipment functionality and room temperature is one aspect which can be challenging. This case brings up the importance of awareness by the broader radiation oncology team, communication and sense of urgency. If this is a known possibility and is addressed proactively with an appropriate sense of urgency, downtime may be avoided. For example, fans can sometimes be used to help circulate cold air from an area that does have functioning air conditioning. Additionally, this event raises an issue that may be more of a concern in certain parts of the country and world with warmer weather and limited power supply/availability.

SAFETY CHECK

Are all practice staff that provide administrative support (e.g., custodial staff) aware of the potential negative impact that temperature or other environmental issues could have on radiation oncology equipment?

DISCUSSION/MITIGATION STRATEGIES AND SOLUTIONS

1. **Educate and Engage All Staff.**
   The radiation oncology team cannot work in silos. The delivery of safe radiation therapy depends on the intricate coordination of countless tasks by all members of the clinical team. Therefore, all staffs' understanding of general equipment QA is important so they can better appreciate potential issues and communicate with necessary staff. This is particularly important for trainees (students and residents) as well as new staff who may be unfamiliar with the nuances of specific equipment. When equipment is updated and/or upgraded, all staff must be informed of changes as it may pertain to their responsibilities.

2. **Communicate Appropriately with the Physics Team.**
   A common thread seen through many of the RO-ILS case examples is poor or missing communication. All team members can help be the eyes for their group and share relevant information to ensure the necessary QA steps are completed. This includes informing appropriate individuals when something occurs (e.g., collision in event #4) but also sharing preemptive information. For example, it is important for a practice's information technology team to inform the radiation therapy physics team of relevant work (e.g., changes to security requirements) as it may impact radiation equipment and require additional QA tests; as noted in RO-ILS Case Study 08.[13] Similarly, it is important that the physics team educate the information technology team about the nature of computer use to avoid untimely backups or other interventions that could slow down or compromise equipment function. Whenever radiation equipment is serviced, whether planned or unplanned, there should be communication with the physics staff before it is released for clinical use (as was not the case in event #3).

3. **Ensure Physics Oversight.**
   While a number of different individuals may engage in performing equipment QA, a qualified medical physicist should oversee the overall effort. This includes oversight and monitoring of trainees, reviewing QA data, setting policy and documenting acceptance. They should also be involved in both unscheduled maintenance and planned upgrades/updates. Ultimately, it is up to the qualified medical physicist, communicating with the vendor who performed the service, to determine what QA needs to be done, if the QA process was done correctly and if a machine should be released for clinical use.

4. **Perform Appropriate QA Measures in Place.**
   Radiation oncology practices should work towards implementing the recommendations of AAPM reports for routine QA (e.g., TG 142, TG 224) and follow manufacturer recommendations for what checks need to be done for maintenance. Additionally, practices should aim to meet accreditation standards to demonstrate how they are performing at a high level. Lastly, practices should perform risk analysis work to determine if additional, non-routine QA is necessary.

CONCLUSION

Even in more niche topics like equipment QA, a lot can be learned from the RO-ILS database. Documenting errors in an incident learning system supports quality improvement and can be used to teach colleagues the intersection of everyone's responsibilities.

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