RO•ILS

RADIATION ONCOLOGY ®
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

IN REVIEW

FIRST FIVE YEARS OF EXPERIENCE

2014 - 2019

ˈro•ils

noun \ˈrȯi(-ə)ls\

Radiation Oncology Incident Learning System; a system to facilitate safer and higher quality care in radiation oncology at no cost to providers or facilities; the only medical specialty society-sponsored radiation oncology incident learning system.

EXECUTIVE SUMMARY

- Over the first five years of the program, RO-ILS has successfully grown to include more than 500 U.S.-based facilities, which represents roughly a quarter of U.S.-based facilities.
- RO-ILS facilities include a variety of practice settings representing the diversity of radiation oncology providers.
- In total, the national PSO database has accrued more than 12,000 safety events. The specialty-specific data gathered via the RO-ILS portal and analyzed by the RO-HAC has provided valuable data to inform the safe delivery of radiation therapy.
- Two new data elements were added to the RO-ILS portal: "Problem Type" to assist in categorizing events and "Dosimetric Change" (e.g., replanning) to aid in assessing event severity.
- A new triage mechanism was implemented to identify events worthy of RO-HAC review.
- Nine out of 10 RO-ILS users find the program moderately to very valuable. The program continues to facilitate the sharing of critical information with the broader radiation oncology community via detailed aggregate reports and case studies.
- RO-ILS will continue leveraging lessons learned from the program to ensure ongoing quality improvement and patient safety in radiation oncology.

BACKGROUND

The American Society for Radiation Oncology (ASTRO) and the American Association of Physicists in Medicine (AAPM) launched RO-ILS: Radiation Oncology Incident Learning System®, a national patient safety initiative, on June 19, 2014.

RO-ILS is a key milestone in the ASTRO Target Safely campaign, a comprehensive plan to improve safety and quality for radiation oncology. 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.

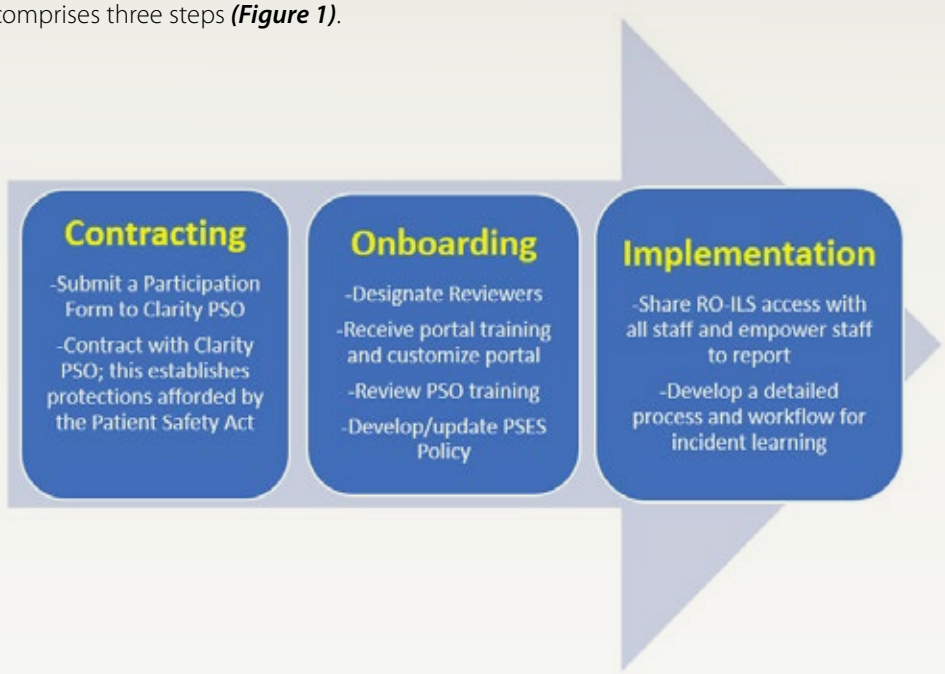
The Patient Safety and Quality Improvement Act of 2005 (PSQIA) authorizes the creation of Patient Safety Organizations (PSOs) to address the needs identified in the 1999 Institute of Medicine (IOM) report "To Err is Human: Building a Safer Health System," particularly the need to capture data on medical errors and provide confidentiality and privilege protections.

ASTRO contracted with Clarity PSO to build the online interface and provide the affiliated patient safety services outlined in the PSQIA to practices enrolled in RO-ILS. Clarity PSO was one of the initial organizations to be federally listed as a PSO by the Agency for Healthcare Research and Quality (AHRQ).

ENROLLMENT

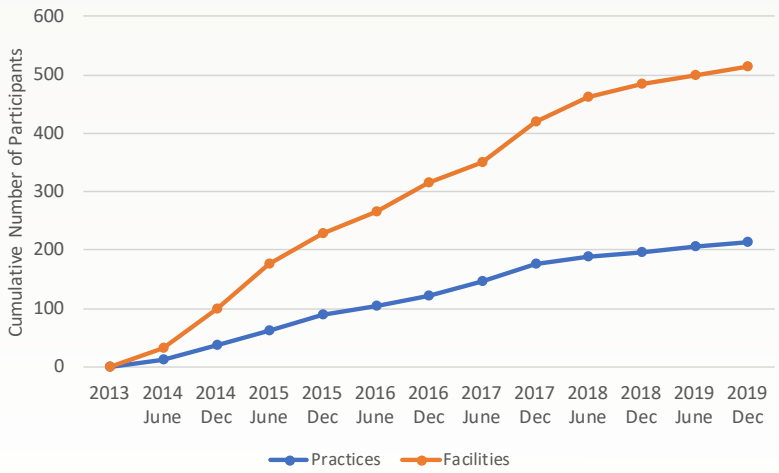
The enrollment process for RO-ILS comprises three steps ***(Figure 1)***.

Figure 1: RO-ILS Enrollment Process



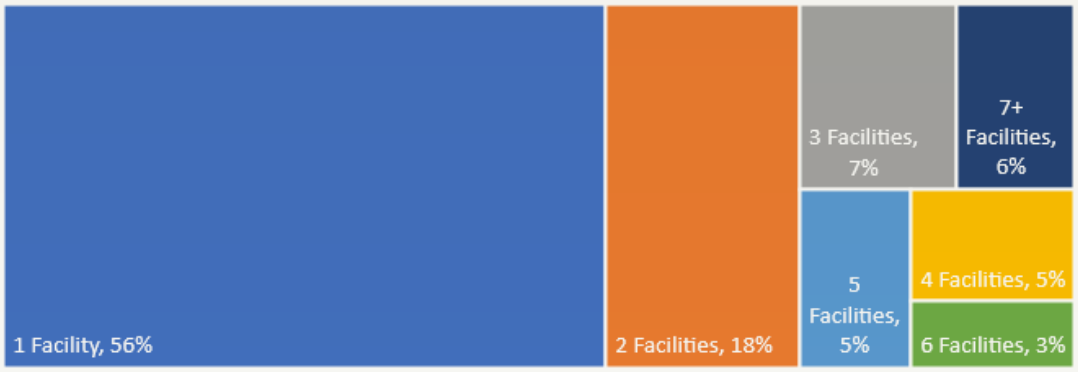
Throughout the first five years, there has been no charge to enroll in the program. However, interested practices must first sign a contract with Clarity PSO to receive the protections outlined in the PSQIA. While RO-ILS does not require submission of protected health information, all practices participating in RO-ILS also enter into a business associate agreement with Clarity PSO prior to reporting any safety information. Depending on the practice structure, these contracts can cover multiple facilities. Over the first five years of the program, 214 practices have executed contracts covering 514 facilities ***(Figure 2)***.

Figure 2: Cumulative Number of Contracted Practices and Facilities Over Time



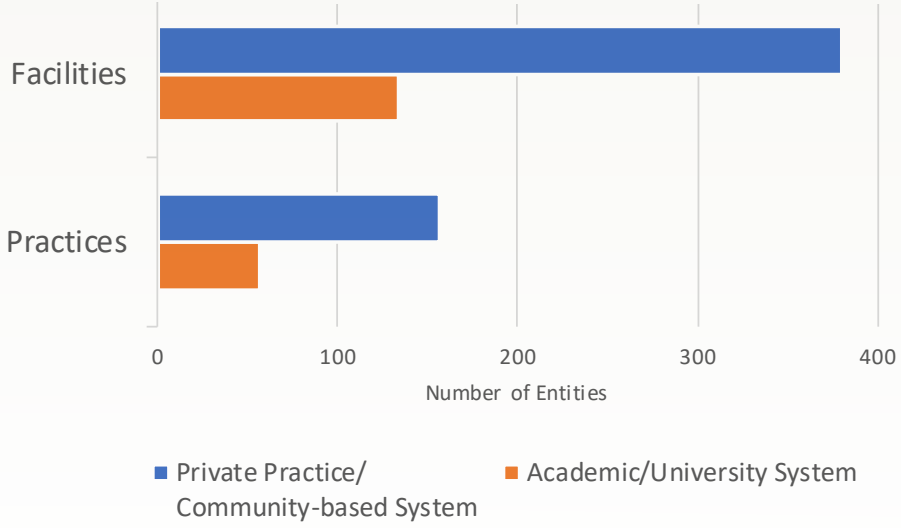
Seventy-four percent of enrolled practices comprises either one or two facilities ***(Figure 3)***. In just a couple of years, there has been a 300% increase in the number of RO-ILS practices composed of seven or more facilities. Five of these practices were contracted before 2017 but added more facilities since their original contracting, indicating that practices are satisfied with RO-ILS and therefore expand to include more locations after initially implementing at a few of their facilities. This complements results from the 2018 ASTRO Membership Survey in which nine out of 10 RO-ILS participants expressed that they found the program moderately to very valuable. Since the RO-ILS portal is web-based, it is easy to deploy one shared system across an entire health network and eliminate data silos. Practices can benefit from data aggregation and improved analytic capabilities by identifying unique and shared data trends across different facilities. Once contracted, practices need only to complete a simple form to add more facilities to an existing practice.

Figure 3: Contracted Practice Size



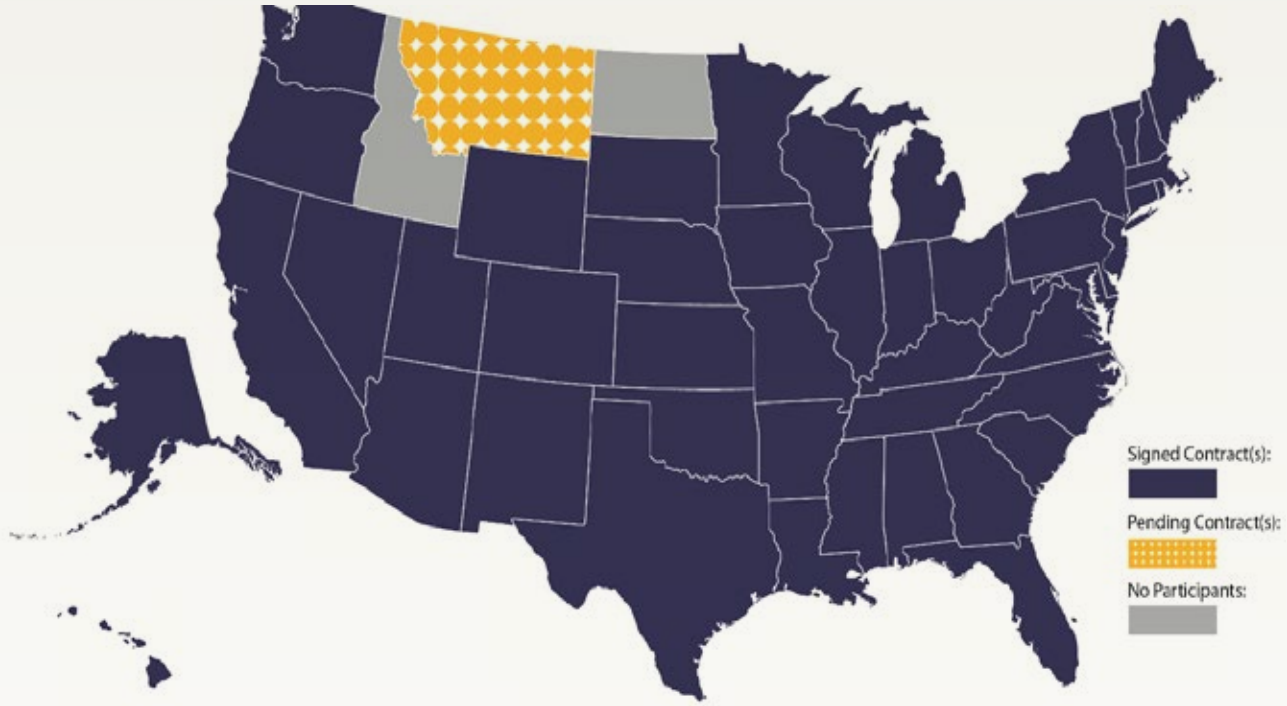
Each practice and its associated facilities have a single "practice type." Whether calculated per practice or per facility, the distribution of practice type is roughly three private practice/community-based entities for every one academic/university entity ***(Figure 4)***.

Figure 4: Practice Setting Distribution by Entity Type



During the first five years, RO-ILS has achieved national expansion with contracted RO-ILS practices widespread across almost the entire country ***(Figure 5)***. The dark blue color represents states which have one or more facility currently contracted with RO-ILS. The yellow dotted state, Montana, contains only facilities with pending contracts. The only states without a contracted practice are Idaho and North Dakota.

Figure 5: Distribution of RO-ILS Participants



The median time to complete contracting for private/community-based practices was roughly two months, compared to four-and-a-half months for academic/university practices. This suggests that the contracting process is less streamlined in academic/university settings, leading to a slower rate of adoption in these settings. When users were asked about delays in contracting, most indicated that the postponement was internal. An additional 26 practices consisting of 53 facilities are currently in the process of executing contracts.

Once the agreements have been executed, Clarity creates the practice's RO-ILS portal. For added security, each practice has its own unique URL to the RO-ILS portal. In addition to on-boarding trainings on the portal and PSOs, the practice designates which staff members will act as internal "Reviewers." The median time for on-boarding for both academic and private practices, a process step that is more managed by Clarity PSO, is less than two months. The last step in the enrollment process is implementation, which is when the practice deploys the program locally with their staff. This includes sharing access to the RO-ILS portal and empowering staff to submit events. The RO-ILS program has several resources to help staff implement RO-ILS locally, including an implementation PowerPoint, tips on how to incentivize/reward reporting and increase overall engagement, and a RO-ILS desktop icon to increase visibility and access to the portal.

PARTICIPATION

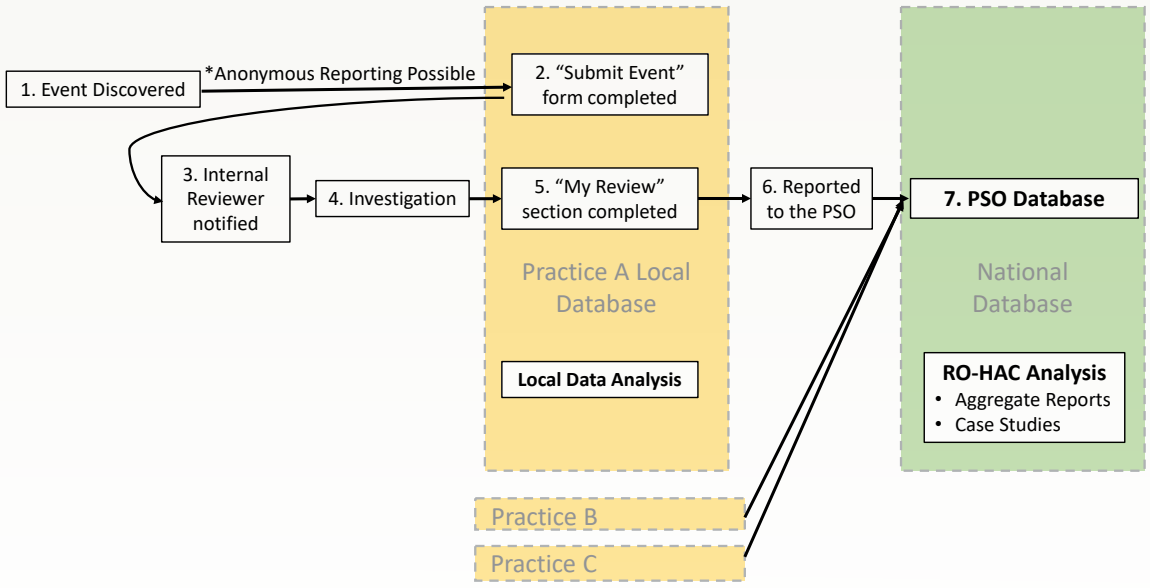
The RO-ILS portal is divided into two sections with associated user accounts.

> ***Submitter:*** The "Submitter" account is a general login that should be shared with all staff. Utilizing the "Submitter" account, any staff member can access the RO-ILS portal and complete the initial, front-line reporting form (i.e., the "Submit Event" form). This page includes fewer than 10 questions and typically takes only a few minutes to complete. There is an optional data element for the reporter's name which allows reporters to remain anonymous.
>
> ***Reviewer:*** "Reviewer" accounts are specific to one individual within the practice. Reviewers have access to the "My Review" section of the portal where users enter follow-up analysis and eventually report the event to the PSO. This section includes more detailed questions, some of which may require investigation into the event, such as causal factors. Each practice only has access to its own local database.

The typical RO-ILS process of event reporting ***(Figure 6)*** is:

1. An event is discovered.
2. Any staff member logs into the shared "Submitter" account and complete the "Submit Event" form.
3. Reviewer(s) receives an automatic notification of submission.
4. Reviewer(s) completes the practice's internal protocol for investigating the event, which can vary depending on the severity of the event.
5. Reviewer(s) completes the "My Review" section of the portal.
6. Reviewer(s) reports the event to the PSO.
7. A copy of the event is sent to the national PSO database. If there are any changes to the event in the practice-specific database, it is automatically updated in the national database.

Figure 6: RO-ILS Submission and Reporting Workflow



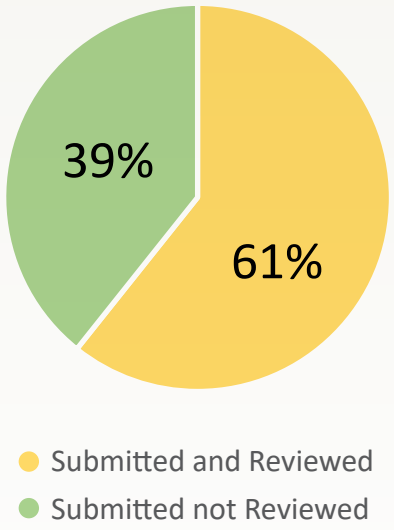
Currently, 61% of the events that are submitted locally (i.e., Step 2) are reviewed (i.e., Step 5) ***(Figure 7)***. Only those events that are reviewed can be added to the national database. A practice limits its own ability to identify local trends and areas for improvement if the "My Review" section is not completed, further highlighting the importance of review.

Given this unexpected gap in the data in the first five years of the program, RO-ILS initiated process improvement efforts in 2019 to begin to address this disparity:

- ***More Reviewers:*** The number of permitted Reviewers has increased from two per practice to 10 per facility. With more Reviewers, practices can task more individuals to help investigate and enter information into the follow-up section of the portal. RO-ILS also released a new form to more easily add and remove Reviewers.
- ***New Education:*** RO-ILS created new documentation for Reviewers regarding notifications and "My Review," hosted a targeted webinar for Reviewers and updated resource documents so practices can better track their Reviewers.
- ***Reduced Burden:*** Two data elements related to patient demographics, the patient's age as a range and patient's gender, are no longer required. These data elements were originally included based on guidance from AHRQ, which developed "common formats" as a means to facilitate standardized data collection and aggregation across all PSOs. Even though these data elements include options for "unknown" and "report not patient related", users voiced frustration that these data points are burdensome and not particularly helpful for local analysis.

RO-ILS is committed to further investigating what other challenges exist to reviewing events and developing an improvement plan to alleviate other barriers.

Figure 7: Review of Submitted Events

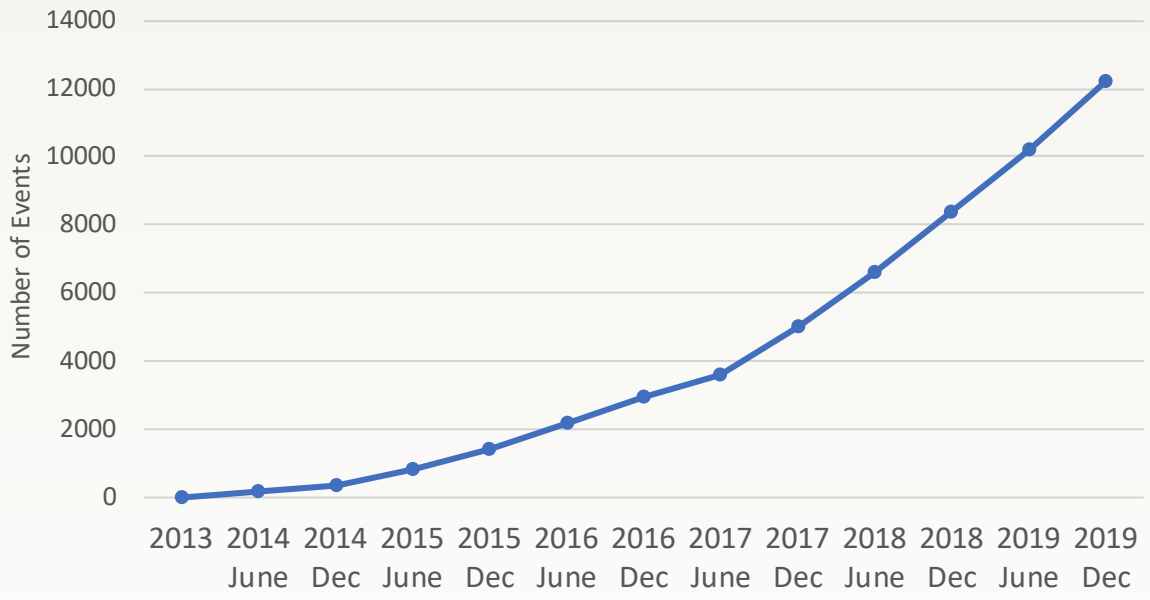


DATA

Data analysis of events in the PSO database is completed by Clarity PSO and the Radiation Oncology Healthcare Advisory Council (RO-HAC). RO-HAC is an interdisciplinary group of 12 radiation oncology professionals, including radiation oncologists, physicists, dosimetrists, therapists and an administrator, who provide subject-matter expertise on data interpretation and reporting and suggest possible interventions. The RO-HAC operates as part of Clarity PSO's patient safety evaluation system and is not subject to either ASTRO or AAPM review or oversight.

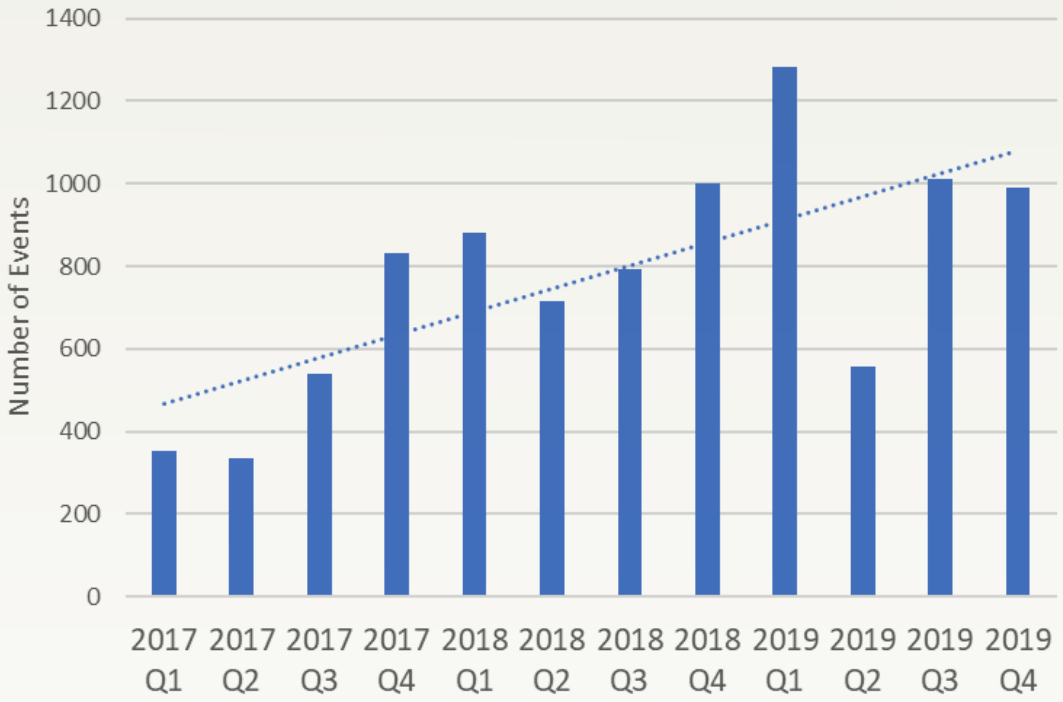
Adoption and the number of events reported to the PSO have grown steadily over the initial five years. In June 2019, the program hit a milestone of accruing 10,000 safety events in the national database, which rose to over 12,000 events by the end of the year ***(Figure 8)***. In the past couple of years, some larger practices have abandoned their own homegrown systems and now utilize RO-ILS exclusively, which contributed to an increase in utilization.

Figure 8: Cumulative Number of Events Reported to Clarity PSO Over Time



The average quarterly number of events reported to the PSO rose by 90%, from 513 to 961, in the past two years ***(Figure 9)***. Figure 9 also shows that there is an increase in reporting around the end and beginning of each year. While it is unknown why reporting dropped in the second quarter of 2019, it has recovered.

Figure 9: Number of Events Reported to Clarity PSO Per Quarter Over Time



Triage Mechanism

As the number of events rose, the need for a more sustainable process for RO-HAC review became more evident. RO-HAC developed an objective, automatic triage mechanism based on user-entered RO-ILS data elements to identify the events worthy of individual human review. Over the course of many iterations, RO-HAC determined that a new data element capturing whether the error resulted in a dosimetric change to the plan (e.g., replanning) would benefit the triage mechanism. After beta testing with RO-ILS practices, this new, required data element was added to the RO-ILS portal in July 2019.

All events classified by the practice as therapeutic radiation incidents, totaling approximately 10% of all events, are reviewed by RO-HAC ***(Figure 10)***. These events are subdivided into a high priority bin if one of following criteria is met (as specified by the practice):

- "Severe" on the significance scale ***(Figure 11)***;
- Affected multiple patients;
- Dose deviation greater than 5%;
- Organs at risk received more than intended and exceeded tolerance levels;
- More than one fraction was delivered incorrectly;
- Involved an SRS/SBRT or brachytherapy treatment.

All other therapeutic radiation incidents fall into a lower priority bin. The remaining group of event classifications (i.e., near misses, unsafe conditions, operational/process improvements and other safety incidents) utilize a similar mechanism to identify high priority events. RO-HAC reviews these non-therapeutic events if any one of the following criteria is met (as specified by the practice):

- "Severe" or "Moderate" on the significance scale;
- Event was discovered late in the process of care but occurred early in the process;
- Event was equipment-related;
- Error resulted in replanning.

High priority non-therapeutic events represent 35% of the total database. All remaining events fall into a lower priority bin and are not individually reviewed by RO-HAC, thereby reducing the workload in half. The triage mechanism has officially been implemented as of the end of 2019.

Figure 10: RO-HAC Triage Groupings

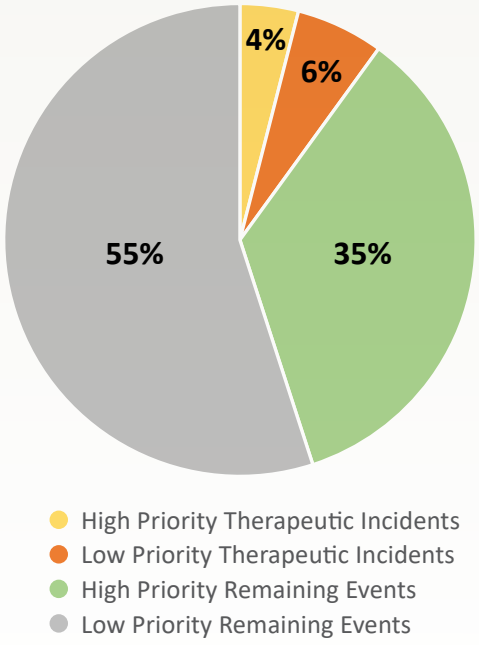
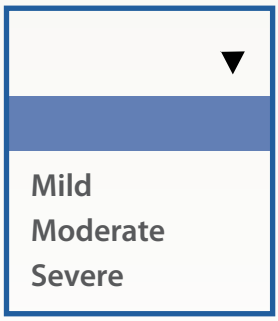


Figure 11: Significance Scale

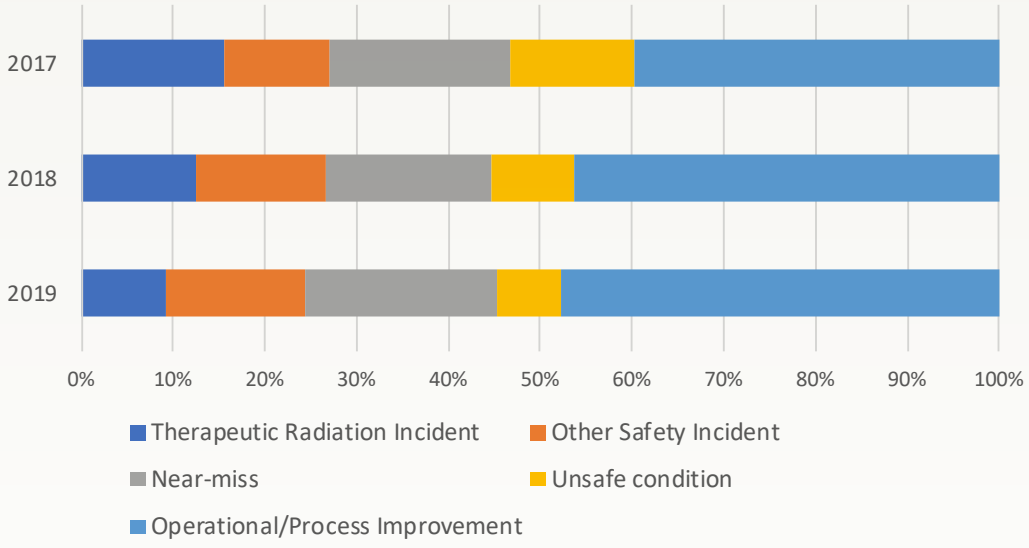


While the low priority non-therapeutic events will not undergo individual RO-HAC review, practices should continue to report all events to the PSO. All data in the national database benefit the overall mission of the program as it is utilized when analyzing patterns and identifying case examples for aggregate reports. Multiple RO-ILS users previously noted a fear of burdening the RO-HAC with minor issues such as scheduling or missing documentation. Practices should no longer be concerned and should regularly report such issues to the PSO. While there are many nuances to the legal protections afforded by the PSQIA, it is recommended that a practice establish an active reporting relationship with the PSO and regularly report events to the PSO.

Event Classification

Event classification is a key data element in tracking and analyzing events. The annual rate of therapeutic radiation incidents, defined as radiation dose not delivered as intended, with or without harm, has been slowly decreasing from 16% to 9% over the course of three years ***(Figure 12)***. This corresponds to an increase in operational/process improvement events. The operational/process improvement option was added in late 2016 to allow for comprehensive tracking within an institution and was envisioned for events related to incomplete or late documentation/orders, patient delays, patient dissatisfaction or scheduling events that don't impact safety. ***These trends suggest practices are utilizing the system for more inclusive quality improvement and that changes to clinical practice may have improved safety since fewer events are reaching the patient.***

Figure 12: Event Classification Percentage Over Time



"RO-ILS empowers our staff and provides them a way to make their voice heard and change their working environment. It's improved staff morale and patient safety."

— Samantha Hedrick, PhD, DABR, Provision Center for Proton Therapy in Knoxville, TN

Problem Type

In October 2019, RO-ILS added a new required data element to categorize all events according to the "Problem Type." This data element and the associated examples were adapted with permission from the National System for Incident Reporting – Radiation Treatment (NSIR-RT) Minimum Data Set (Ottawa, Ont.: CIHI, 2019). Users should select the option that best categorizes the event from the perspective of how it directly affected the patient (if it was an incident) or how it would have affected the patient had it not been identified prior to reaching the patient (for non-incidents). The NSIR-RT Spring Bulletin discussed the extensive testing, revision and improvements made to the "Problem Type" data element. While there is still limited RO-ILS data for analysis, ***Table 1*** shows the top five problem types in RO-ILS for the first three months of utilization compared to the NSIR-RT, as reported in the NSIR-RT Spring Bulletin. The second most common RO-ILS problem type is scheduling errors, confirming the finding that operational/process improvement events are most common in the RO-ILS database.

Table 1: NSIR-RT vs. RO-ILS Problem Type Ranking

Most Common	NSIR-RT Problem Type (July 2017 to March 2019)	RO-ILS Problem Type (October to December 2019)
1	Other	Other
2	Wrong patient position, setup point, or shift	Radiation therapy scheduling error
3	Wrong, missing, mislabeled, or damaged treatment accessories	Wrong, missing, mislabeled or damaged treatment accessories
4	Excess imaging dose	Wrong patient position, setup point or shift
5	Radiation therapy scheduling error	Failure to perform on-treatment imaging per instructions

ANALYSIS AND EDUCATION

RO-ILS participants continue to receive bi-annual practice-specific reports that include a report card comparing the practice and the aggregate historical sums as well as practice-specific graphs. RO-ILS practices also receive an accompanying PowerPoint for each aggregate report in an effort to promote discussion and dissemination internally with staff. As a benefit to users, the RO-ILS portal has a built-in AnalysisWizard for trending and analyzing local data. In 2019, Clarity hosted two live webinars to showcase the various features of the AnalysisWizard and a recording was posted in the portal for on-demand viewing. Users are also invited to attend user meetings at the AAPM and ASTRO Annual Meetings.

Promoting Shared Learning

In total, RO-HAC has issued sixteen aggregate reports, which are posted on the RO-ILS website to facilitate shared learning across the field of radiation oncology. Currently, aggregate reports are released twice a year. All aggregate reports include multiple case reviews focused on one or more themes, potential mitigation strategies and additional resources. Focus and attention was placed to including more case examples and actionable mitigation strategies in recent reports. For example,

one recent Aggregate Report contains seven case reviews focused on three themes: vertebral body alignment; HDR treatment length and dwell times; and patient identification and communication. ASTRO continues to offer continuing medical education on aggregate reports.

Beginning in late 2018, RO-HAC began developing stand-alone case studies summarizing a RO-ILS event and providing feedback and suggestions. 2019 RO-ILS Case Study 02 illustrates the importance of reviewing standard processes surrounding automation of treatment planning and quality assurance checks to improve the effectiveness and efficiency of adaptive planning. RO-ILS Case Study 03 discusses a typographical error that resulted in the planning target volume being assigned a density of zero that wasn't caught until after the first fraction was delivered. The case study provides suggestions on how to diminish the effects of a busy clinic and leverage forcing functions to require certain checks before treatment is delivered.

In 2019, RO-HAC increased engagement with practices that reported safety events. With the PSO acting as a conduit, practices who agree to an open dialogue are given the option to remain anonymous to the RO-HAC members on a conference call. RO-HAC had one-on-one conversations with multiple practices to discuss events that would be included in RO-ILS education. While this cannot be done for every event, these efforts have gathered more important information, promoted a positive safety culture and improved the content of RO-ILS education.

With the new RO-HAC triage process in place, RO-HAC is looking forward to refocusing its attention and producing more high quality and beneficial education for the community.

ACCREDITATION PROGRAMS

Since its inception, ROILS has worked to be meet patient safety critical components of accreditation programs.

APEx

The ASTRO Accreditation Program for Excellence (APEx®) was created to support quality improvement in radiation therapy practices. Through a review of documented policies and procedures and a site visit by a radiation oncologist and a physicist, APEx evaluates practices focusing on quality and safety of radiation oncology processes. APEx Standard 7 seeks to assess that the practice fosters a culture of safety in which all team members participate in assuring safety, the practice capitalizes on opportunities to improve safety and no reprisals are taken for staff that report safety concerns.

RO-ILS can be utilized to satisfy most evidence indicators within this standard. RO-ILS enables the collection of all types of safety events (with the option of anonymity), analysis and identification of local trends, creation of reports to facilitate discussion at internal safety meetings and reporting events to a national PSO. To learn more about APEx and join the list of accredited facilities, visit the APEx website.

NAPBC

The National Accreditation Program for Breast Cancers (NAPBC) is a coalition of professional organizations seeking to improve the quality and outcome of patients with breast cancer through standard-setting, scientific validation, patient and professional education and accreditation. NAPBC Standard 6.1 on quality and outcome specifies that breast centers must conduct or participate in a minimum of one in-house project and either another local project or a specialty-specific quality improvement program each year. RO-ILS is now an approved quality improvement program. RO-ILS practices will need to collect breast-specific events to show compliance. To learn more about this accreditation program, visit the NAPBC website.

MEDICARE REIMBURSEMENT

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) established the Quality Payment Program (QPP), which transitions Medicare from fee-for-service to pay-for-performance, emphasizing quality care. Participation in the QPP is either through the Merit-based Incentive Payment System (MIPS) or through Alternative Payment Models (APM). Participation in RO-ILS can meet requirements in these programs and positively impact Medicare reimbursement.

MIPS

For the first three years of the QPP program, the majority of radiation oncologists have participated in the MIPS program. There are numerous nuances to the program, particularly around participation and requirements in the performance categories. One of the four performance categories is Improvement Activities (IA). Participation in RO-ILS can meet two of the Improvement Activities:

- *Participation in an AHRQ listed PSO* (Activity ID = IA_PSPA_1): To meet this requirement, CMS only requires a provider to attest to participating in a PSO but recommends keeping "documentation from an AHRQ-listed patient safety organization (PSO) confirming the eligible clinician or group's participation with the PSO." Therefore, upon request, Clarity PSO will send a Letter of Participation stating that an eligible practice participated in RO-ILS during the reporting period. Please email radoncsupport@claritygrp.com to request a RO-ILS Letter of Participation.

- *Participation in MOC Part IV* (Activity ID = IA_PSPA_2): Completing the RO-ILS PQI template, along with documentation of monthly activities assessing performance (e.g., reviewing outcomes), addressing areas of improvement and evaluating the results, meets the requirements for this activity.

Find more details about the MIPS program on the ASTRO website and send any MIPS questions to mips@astro.org.

APM

To date, radiation oncologist participation in APMs has been limited but a specific model for the specialty is forthcoming. APMs require physicians to take on financial risk and responsibility for their own cost and quality performance. ASTRO worked many years to craft a viable payment model that would stabilize payments and improve patient care. Aspects of ASTRO's concept paper were utilized in the proposed radiation oncology APM (RO Model) developed by Center for Medicare and Medicaid Innovation. The proposed RO Model includes a requirement to participate in a radiation oncology-specific PSO that would be satisfied by RO-ILS. A final rule has not yet been published, and therefore the start date is still unknown. For the latest information visit the ASTRO website.

SUPPORT

Since the inception of the program, RO-ILS has been sponsored by:

ASTRO
AMERICAN SOCIETY FOR RADIATION ONCOLOGY

AAPM

Additionally, the following companies and associations generously provided financial support in 2019:

varian

American Association of Medical Dosimetrists (AAMD)
Sun Nuclear Corporation

We continue to seek support from the vendor community and related associations for 2020 and the coming years. Please contact ASTRO's Corporate Relations department (corporaterelations@astro.org) to discuss industry support opportunities. Associations can contact RO-ILS (roils@astro.org) to learn more about how to get involved.

For more information on RO-ILS visit www.astro.org/roils.