RO-ILS® Participation Guide

The RO-ILS Participation Guide provides an overview of the program and step-by-step instructions to help interested participants enroll in RO-ILS.

RO-ILS®
RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

V3.0 / Updated January 2021

AMERICAN SOCIETY FOR RADIATION ONCOLOGY
703-502-1550 • FAX: 703-502-7852
ROILS@astro.org

TABLE OF CONTENTS

RO•ILS®

RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

OVERVIEW

INTRODUCTION

Since its launch in June 2014, more than 600 facilities across the country have joined RO-ILS: Radiation Oncology Incident Learning System® to contribute patient safety data to the only medical specialty society-sponsored radiation oncology incident learning system. RO-ILS is a secure, online safety tool tied to a patient safety organization (PSO), with accompanying confidentiality and privilege protections outlined in the federal Patient Safety and Quality Improvement Act of 2005, also known as the Patient Safety Act or PSQIA. **This program is open only to U.S.-based practices**. 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.

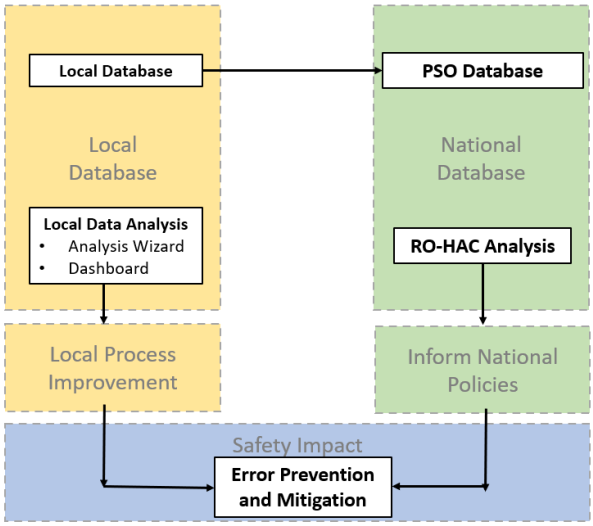
Enrollment and participation in RO-ILS is free thanks to the generous financial support of co-sponsors ASTRO and American Association of Physicists in Medicine (AAPM) and supporters comprising of vendors and sister societies.

PSOs are federally recognized entities that collect information about medical errors and safety risks in a confidential and protected environment. The RO-ILS program is associated with Clarity PSO, one of the first PSOs federally-listed by the Agency for Healthcare Research and Quality (AHRQ). A practice can participate in more than one PSO. Therefore, a practice may utilize a hospital- or institution-wide PSO that focuses on medication errors, falls, etc., and RO-ILS, which collects radiation oncology-specific information.

The enrollment process is initiated by submission of the Enrollment Form to Clarity indicating interest. Practices are required to sign an agreement with Clarity as stipulated in the Patient Safety Act. The practice is then on-boarded and receives tools and support to implement the program locally. Enrolled practices receive access to a unique instance of the RO-ILS Portal where they enter a wide-range of safety events, analyze their trends and send data to a national database. The specific steps of enrollment and participation are detailed later in the guide.

The Portal was designed to support a variety of practice settings and is the gateway between the local and national database (***Figure 1***). The local level is the radiation oncology practice or for multi-facility practices, could be defined at the facility level. This is managed by each practice. Comparatively, the national level is the aggregate program and is managed by Clarity. Enrolled practices have their own local practice-specific database. Through a multi-step process in which an event is entered into the Portal and reviewed locally, the event can then be shared with the national database. Specific staff within the practice have access to their practice's own local database; they cannot view another practice's data nor the national database. These staff members also have access to data analysis tools and reports to help analyze local data and initiate quality and process improvement initiatives.

Figure 1: Local and National Structure



The national database is analyzed by Clarity and the Radiation Oncology Healthcare Advisory Council (RO-HAC). RO-HAC is an interdisciplinary group of 12 radiation oncology professionals who provide subject matter expertise to RO-ILS by conducting data analysis on the national dataset and developing education for the community.

Currently, RO-ILS education typically comes in the form of:

- **Safety Notices:** A safety notice communicates findings that may be novel to the community, of higher clinical significance and/or deserve more prompt review.
- **Case Studies:** These stand-alone case studies summarize one RO-ILS event and provide learning, feedback and suggestions from RO-HAC.
- **Themed Reports:** Focused on various topic areas, themed reports transcend the entire RO-ILS database and include multiple case examples.
- **Aggregate Data Reports:** These reports provide a high-level look at the trends in the national database and include a "report card" and graphs.

This education, presentations and other RO-ILS activities seek to inform national safety learning and impact initiatives (such as accreditation and training). Together, through this collaboration, RO-ILS seeks to improve patient safety and to mitigate the potential for error in radiation therapy processes.

BENEFITS OF PARTICIPATION

RO-ILS helps practices improve the quality of care for their patients and makes processes safer. It also helps improve safety culture, better communication and builds a collaborative team dedicated to assessing ways to increase effectiveness and efficiencies. Participation in RO-ILS contributes to national safety data and collectively improves the field of radiation oncology.

Enrollment and participation in RO-ILS provides a host of additional benefits. Radiation oncology practices and staff:

- Improve your practice's safety culture by tracking and reviewing internal incidents, near misses and unsafe conditions.
- Receive regular education based on events reported throughout the country, including suggestions on how to prevent errors.
- Gain access to analysis tools within the RO-ILS Portal, practice-specific reports and program education.
- Meet Medicare requirements: get credit for up to two Improvement Activities in Medicare's Merit-based Incentive Payment System (MIPS) or meet the requirement to participate in a PSO within the radiation oncology alternative payment model (i.e., the "RO Model").
- Meet components of accreditation programs, including ASTRO's APEx® program.

One of the unique benefits of the RO-ILS program is the legal protection from discovery for information that meets necessary requirements. Information that qualifies as patient safety work product (PSWP) is given privilege and confidentiality protections against disclosure and discoverability by the Patient Safety Act, except in limited circumstances. PSWP can be any data, reports, records, memoranda, analyses (such as root cause analyses) or written or oral statements (or copies of any of this material) that could improve patient safety, health care quality or health care outcomes. PSWP is, essentially, the information that is developed through the deliberative process created by the provider to collect and submit information for review by a PSO. In response to questions raised about the protection of materials prepared to fulfill external obligations (e.g., state and federal reporting or recording keeping requirements), HHS issued additional guidance in 2016. Practices should review and understand the reporting and recordkeeping requirements in their state, as this will impact what information can be PSWP.

STAKEHOLDERS

A national incident learning system represents a key commitment of ASTRO's ***Target Safely*** initiative dedicated to improving the safety and quality of radiation oncology. ASTRO partnered with AAPM to develop RO-ILS and, together, sponsor the program. ASTRO contracted with Clarity (Clarity Group, Inc., and Clarity PSO) to develop and administer RO-ILS. Clarity is not affiliated with ASTRO; they are independent entities providing PSO services to radiation oncology professionals.

Clarity Group, Inc.: This health care professional liability risk management organization developed and manages the Healthcare *SafetyZone*® Portal, which is a flexible, web-based system used by a wide range of health care providers to manage the collection and analysis of safety events across their unique delivery networks. The RO-ILS Portal is built on the Healthcare *SafetyZone*® Portal architecture and platform. Clarity Group, Inc., provides the IT support for the program.

Clarity PSO: Clarity PSO, a component PSO, is a division of Clarity Group Inc. Clarity PSO was one of the first PSOs to be listed with AHRQ (P0015).

Clarity works with RO-HAC to oversee the national database and with ASTRO to oversee the program.

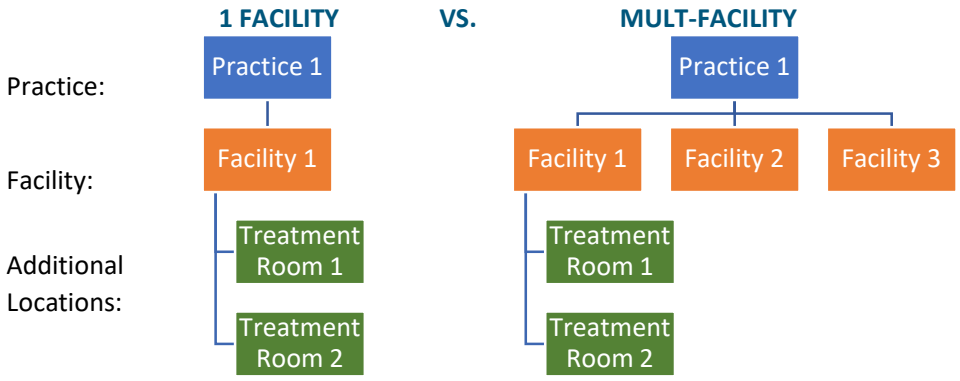
RO-HAC: These safety experts provide subject-matter expertise to the program by reviewing events reported to the PSO, analyzing and interpreting trends and developing national education. RO-HAC is interdisciplinary and includes radiation oncologists, physicists, dosimetrists, therapists and administrators. These patient safety experts receive an honorarium and must sign a Business Associates Agreement (BAA)[i] and an Independent Contractor Agreement with Clarity PSO before accessing any data. 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. Members must comply with ASTRO's Conflict of Interest Policy for RO-HAC. More information about the RO-HAC qualifications, responsibilities and the selection process can be found on the RO-HAC webpage.

PARTICIPATION

PRACTICE STRUCTURE

The program structure allows for collaboration at the "local" level. A practice is one or more sites (i.e., facilities) where radiation therapy services are provided under the direction of common set of standard operating procedures. By establishing a shared system between satellite sites, it enables larger practices the ability to review trends and work across multiple facilities within their network. Regardless of whether it is a one-facility or multi-facility practice, the practice can customize and specify additional locations within a specific facility, if desired ***(Figure 2)***.

Figure 2: Practice and Facility Structure



Users have the ability to query and analyze data within their local structure (i.e., practice-level or facility-level) but do not have access to the national database. In order to protect the confidentiality of enrolled practices and events, the national database managed by Clarity cannot be queried at this time.

USER TYPES

Practices enrolled in the program are granted access to a secure RO-ILS Portal to submit information, report to the PSO and perform analysis. Users view the Portal in a web browser; no application needs to be installed on local computer systems or mobile devices.

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

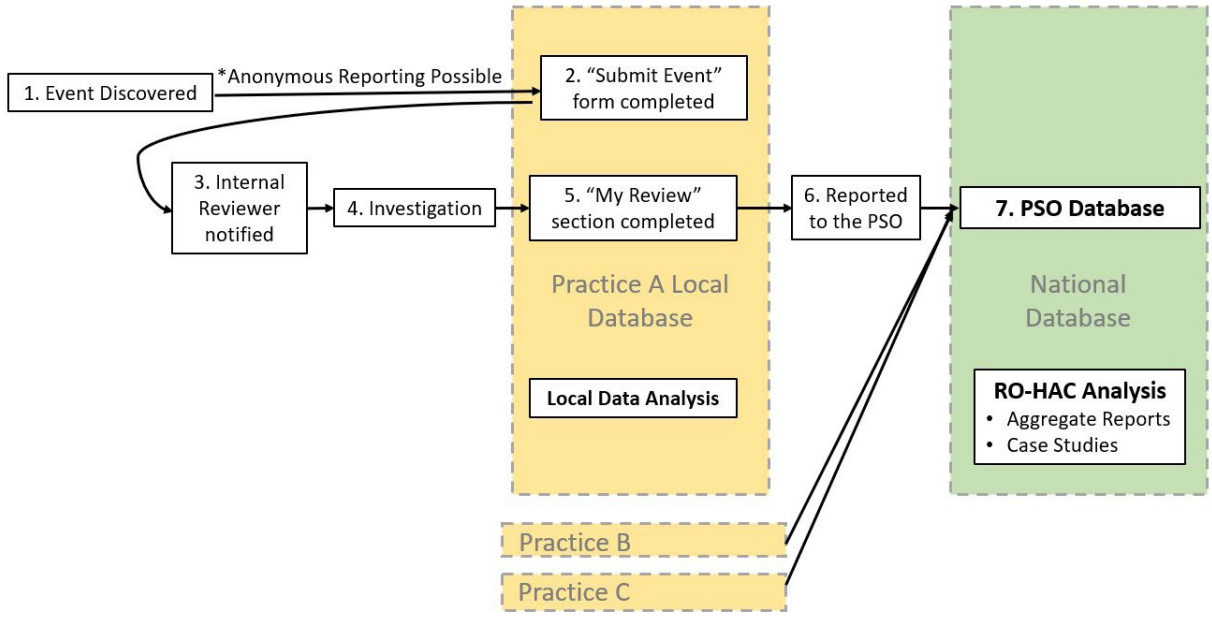
> ***Submitter:*** The "Submitter" account is a general login that should be shared with all staff across the practice. RO-ILS is structured to allow anyone who is part of the radiation oncology treatment team to submit data. This includes radiation oncologists, medical physicists, dosimetrists, nurses, trainees, radiation therapists and practice administrators. 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 less 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. By utilizing a shared login account, staff anonymity is guaranteed.
>
> ***Reviewer:*** "Reviewer" accounts are specific to an individual within the practice, with a limit of 10 Reviewers per facility. Reviewers enter follow-up analysis in the "My Review" section of the Portal and 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. They also have access to the Analysis Wizard and Dashboard within the Portal to support the practice's work in identifying trends. Therefore, Reviewer accounts are intended for staff who will play an active role in directing the practice's patient safety activities. The practice initially chooses who will be Reviewers during on-boarding, but this can be changed at any time. As a baseline, Reviewers are given access to all the events reported within the practice. However, if Reviewers need to be designated access to only events reported within a particular facility, this can be done.

PROCESS FOR SUBMITTING AND REPORTING EVENTS

The typical RO-ILS process of event reporting (***Figure 3***) is:

1. An event is discovered.
2. Any staff member logs in to the shared "Submitter" account and completes 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 3: RO-ILS Submission and Reporting Workflow



Reporting to RO-ILS does not replace other reporting requirements placed on a practice, and therefore, practices must still comply with their other reporting requirements. Practices are subject to reporting requirements imposed by the federal government (e.g., the Nuclear Regulatory Commission), state and local agencies (e.g., departments of health) and often by their own institutions.

Currently, there is no mechanism to map and transfer data from existing incident learning systems to RO-ILS. However, ASTRO is exploring the feasibility of an application programming interface (API) to support electronic data transfer to RO-ILS. There already exists a mechanism in the RO-ILS Portal for RO-ILS Reviewers to download and export their data to a PDF or spreadsheet.

In compliance with Health Insurance Portability and Accountability Act (HIPAA) and the Patient Safety Act, Clarity and the individual RO-HAC members are bound by confidentiality provisions that protect the confidentiality of identifiable data that is shared. In general, data shared with RO-HAC is stripped of identifying, structured data elements (e.g., location information); however, the free text fields as provided by the practice are reviewed by RO-HAC. Information shared outside of RO-HAC is always "non-identified." As defined in the Patient Safety Act, this means that it is stripped of identifying elements, including information that could identify the practice, patient and/or healthcare providers.

DATA ELEMENTS

ASTRO has published online the complete list of RO-ILS data elements associated with events. RO-ILS can be utilized to collect any kind of event; from events that reach the patient (i.e., incidents) to near misses, unsafe conditions and operational/process improvement events. Extensive branching logic reduces the total number of questions that may appear for a given event. For example, dose deviation will only appear for events classified as "Therapeutic Radiation Incidents."

The original RO-ILS data elements were based on consensus recommendations[ii] that underwent beta testing before the public launch of the program in 2014. With increased experience additional revisions have been made to reduce reporting burden while improving data quality. Data elements are reviewed on a regular basis as part of ongoing quality improvement and incorporated into a user friendly, optimized interface.

The only patient-specific data elements in RO-ILS are the patient's age (as a range) and gender. Both data elements are optional and include an answer option of "unknown" or "report not patient related." These data elements were selected based on guidance from AHRQ, which developed "common formats" to facilitate standardization of data collection and aggregation across all PSOs.

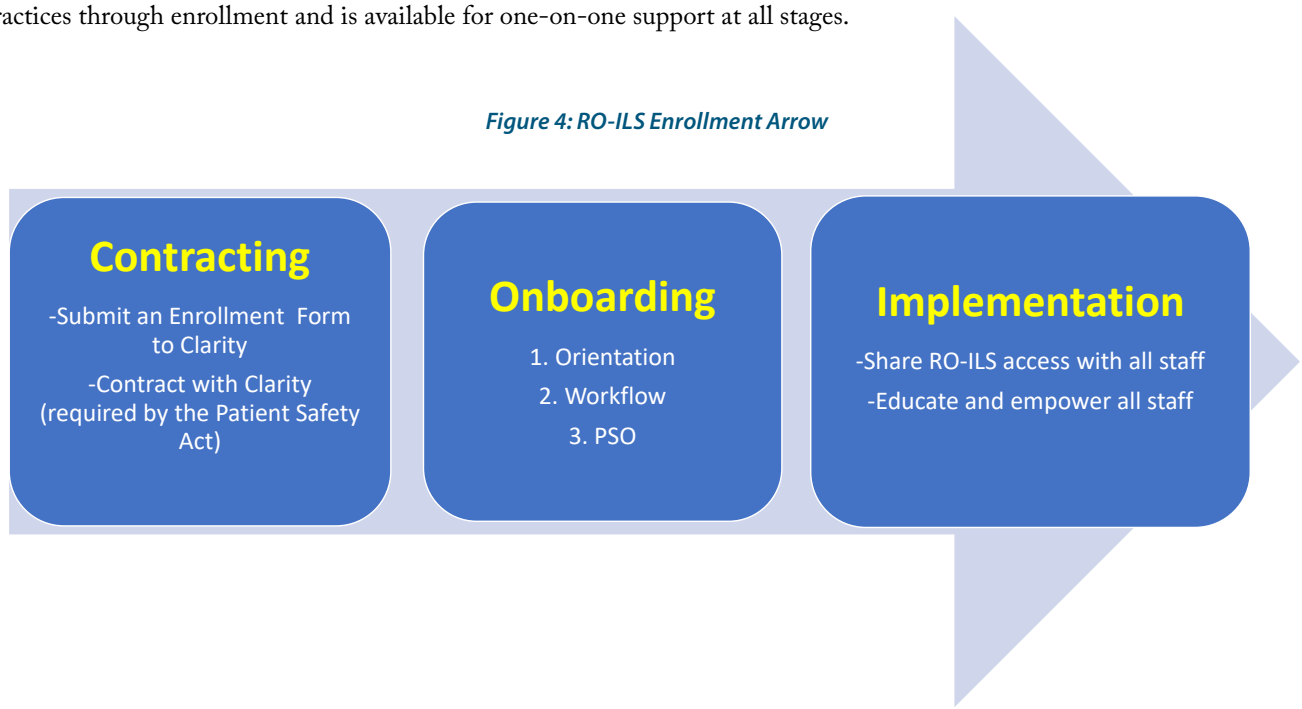
RO-ILS does not require submission of protected health information (PHI). Nevertheless, all practices participating in RO-ILS enter into a BAA as defined by the HIPAA with Clarity prior to reporting any safety information. In the event PHI is submitted to RO-ILS or reported to the PSO, the HIPAA requirements for sharing PHI are met. Users are still encouraged to not include identifiable information (e.g., patient or clinician name) in free-text data fields to safeguard anonymity.

ENROLLMENT

To indicate interest in the program and begin the enrollment process, send a completed Enrollment Form to Clarity. **There is no cost to enroll or participate in RO-ILS.**

Enrollment is accomplished in three stages: contracting, onboarding and implementation (***Figure 4***). Clarity staff will guide practices through enrollment and is available for one-on-one support at all stages.

Figure 4: RO-ILS Enrollment Arrow



ENROLLMENT FORM/KEY CONTACTS

The Enrollment Form (Appendix A) initiates the enrollment process. The form must be completed and sent to Clarity, preferably by email at radoncsupport@claritygrp.com or via mail at RO-ILS Program PSO Staff, 8601 West Bryn Mawr Ave., Suite 110, Chicago, IL 60631.

The provided practice information is helpful in drafting the contract agreement. To enroll a multi-facility practice, the parent organization that owns, manages or oversees the facilities will need to contract with Clarity. Clarity will work with the practice staff to determine the approach that best meets the needs of the institution.

Staff will need to specify key contacts on the Enrollment form. Changes can be made throughout the enrollment process and once participating, as needed.

The Authorized Representative

The Authorized Representative is the designated person with authority to sign contracts with Clarity (discussed below). The Authorized Representative is chosen based on the individual practice's processes for contract signing.

The Pso Liaison

The PSO Liaison is the one primary contact for RO-ILS and is responsible for overall participation in RO-ILS by all facilities covered under the practice. This individual needs to be actively engaged in the program, respond to Clarity's targeted emails, and relay important information to the practice. The Authorized Representative and the PSO Liaison may be the same individual for some practices.

Facility Contacts

Identify two contacts, preferably a physician and physicist, from each facility covered under the practice. This will ensure that each facility is receiving communications about the RO-ILS program.

Refer to the sample memo (Appendix B) to support conversations on RO-ILS enrollment with institution's leadership. If additional information or guidance on gathering support is needed, email roils@astro.org.

CONTRACTING

A practice must contract with Clarity to establish the protections afforded by the Patient Safety Act; therefore, all RO-ILS practices enters into a PSO Provider Service Agreement with Clarity. Additionally, to meet HIPAA needs, the practice also enters into a BAA with Clarity.

Upon receiving the completed Enrollment Form, Clarity will send the key contacts an editable Provider Services Agreement for review. At this time, the practice may request changes and discuss the contract with Clarity. In preparation, you may review a contract. It is within the contract that the practices authorize Clarity and ASTRO to publicly list their name as an enrolled practice. The practice also will be requested to provide their BAA for Clarity's review and inclusion in the final contracts or utilize Clarity's template BAA. ASTRO encourages practices to confer with qualified legal counsel. While this guide provides information to help familiarize you with the RO-ILS program, it is not intended to be legal advice.

ONBOARDING

After contracting is complete, the practice enters the onboarding stage which is comprised of three consecutive steps:

- **Orientation:** Key staff within the practice will get oriented with the overall program, especially in understanding the mechanism of submitting and reviewing an event.
- **Workflow:** As staff determine their internal workflow, they will also specify the Reviewers and additional locations. The practice will receive their practice-specific URL and Submitter account information.
- **PSO:** With the provided guidance, the practice will develop their internal patient safety evaluation system (PSES) policy to document the processes associated with data protection.

Throughout the onboarding process, the practice receives access to on-demand training videos, numerous written program information and sample documents to allow the practice to move at their desired pace. Clarity staff will check-in throughout and is available for extra support at each step.

IMPLEMENTATION

The last stage of enrollment is implementation. This is when the practice deploys the program to all staff and initiates the internal processes developed during onboarding. Resources such as sample implementation plans, PowerPoint presentations and Clarity staff support are available. This process is critical to staff engagement so practices should proactively plan to

promote reporting and good catches to help increase participation. Throughout deployment, it is important to emphasize safety culture and actively work to promote a supportive, nonhierarchical and psychologically safe work environment.

ADDITIONAL INFORMATION

For more information, please contact RO-ILS staff at roils@astro.org. Additional information can be found on the RO-ILS webpage and RO-ILS FAQs.

To reach Clarity for specific PSO information, email your questions to radoncsupport@claritygrp.com.

APPENDICES

APPENDIX A – ENROLLMENT FORM

RO-ILS Enrollment Form

INSTRUCTIONS:
Please complete and email this form to radoncsupport@claritygrp.com or mail to RO-ILS Program PSO Staff at 8601 West Bryn Mawr Ave, Suite 110, Chicago, IL 60631.

Sections I, II, **and** III are **required** in all instances.

Within five to seven business days upon receipt, you will receive communication from Clarity PSO regarding the process for RO-ILS enrollment (contracting, onboarding and implementation). Please contact Clarity PSO (radoncsupport@claritygrp.com; 708-667-7730) for any questions.

I. *PRACTICE SETTING

Provide the name and address of the main entity that will be enrolling in RO-ILS and contracting with Clarity.

Practice Name: _____

Address: _____

_____

City: _____ State: _____ Postal Code: _____

Indicate the practice type:

- ◯ Academic/University System
- ◯ Private Practice/Community-based system
- ◯ Government

Total number of facilities joining RO-ILS: _____

How did you first hear about the RO-ILS? (Select all that apply)

- ☐ Association Newsletter/Emails
- ☐ Association Website
- ☐ Association Annual Meetings
- ☐ Association Specialty Meeting
- ☐ Mailed Marketing
- ☐ Association Social Media
- ☐ Advertisement in Journals
- ☐ Referral, specify who and their institution: _____
- ☐ Other: _____

Does the practice collect/submit safety data to any of the following systems? (Select all that apply)

- ☐ Hospital patient safety organization (PSO)
- ☐ RO-specific local incident learning system
- ☐ Hospital incident learning system/database
- ☐ None, we will only be reporting to RO-ILS

*Required Section

II. *PRACTICE REPRESENTATIVES

Authorized Representative

The Authorized Representative is the designated person with authority to sign contracts with Clarity.

First Name: _____ *Last Name:* _____

Title: _____

Email: _____

Phone (Including Ext.): _____ *Degree(s):* _____ *(e.g., MD, PhD, BS)*

PSO Liaison

The PSO Liaison is the primary contact for RO-ILS from the practice and is responsible for overall participation in RO-ILS by all facilities covered under the contract.

First Name: _____ *Last Name:* _____

Title: _____

Email: _____

Phone (Including Ext.): _____ *Degree(s):* _____ *(e.g., MD, PhD, BS)*

III. *FACILITY SETTING AND CONTACTS

Please list all sites or locations that will participate in the RO-ILS program under this practice. If the location listed in Part I will be contributing data to RO-ILS, please re-enter the facility name and address here. The total number of facilities listed here should match the number provided in Part I. If you have more than 2 additional facilities participating, please complete the additional pages found at the end of the form.

1	Facility Name: _____ Address: _____ _____ City: _____ State: _____ Postal Code: _____ Contact Person #1 Name: _____ Email: _____ Contact Person #2 Name: _____ Email: _____ Indicate the practice location for this facility: ◯ Free standing/Satellite Clinic ◯ Hospital Facility size based on annual total number of unique patients: ◯ Small (0 – 499) ◯ Medium (500 – 999) ◯ Large (1000 – 1499) ◯ Jumbo (1500+) Number of full-time radiation oncologists: _____ FTE (e.g., 5 FTE or 2.5 FTE)

*Required Section

2	Facility Name: _____ Address: _____ _____ City: _____ State: _____ Postal Code: _____ Contact Person #1 Name: _____ Email: _____ Contact Person #2 Name: _____ Email: _____ Indicate the practice location for this facility: ◯ Free standing/Satellite Clinic ◯ Hospital Facility size based on annual total number of unique patients: ◯ Small (0 – 499) ◯ Medium (500 – 999) ◯ Large (1000 – 1499) ◯ Jumbo (1500+) Number of full-time radiation oncologists: _____ FTE (e.g., 5 FTE or 2.5 FTE)

IV. QUESTIONS

Please list any questions you may have regarding the program. Clarity PSO will answer these when they contact you regarding enrollment.

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

IIIB. FACILITY SETTING AND CONTACTS, CONTINUED

If you have additional facilities enrolling under this practice, please complete this section. If your practice has more than 6 facilities, please contact radoncsupport@claritygrp.com.

3	Facility Name: _____ Address: _____ _____ City: _____ State: _____ Postal Code: _____ Contact Person #1 Name: _____ Email: _____ Contact Person #2 Name: _____ Email: _____ Indicate the practice location for this facility: ◯ Free standing/Satellite Clinic ◯ Hospital Facility size based on annual total number of unique patients: ◯ Small (0 – 499) ◯ Medium (500 – 999) ◯ Large (1000 – 1499) ◯ Jumbo (1500+) Number of full-time radiation oncologists: _____ FTE (e.g., 5 FTE or 2.5 FTE)
4	Facility Name: _____ Address: _____ _____ City: _____ State: _____ Postal Code: _____ Contact Person #1 Name: _____ Email: _____ Contact Person #2 Name: _____ Email: _____ Indicate the practice location for this facility: ◯ Free standing/Satellite Clinic ◯ Hospital Facility size based on annual total number of unique patients: ◯ Small (0 – 499) ◯ Medium (500 – 999) ◯ Large (1000 – 1499) ◯ Jumbo (1500+) Number of full-time radiation oncologists: _____ FTE (e.g., 5 FTE or 2.5 FTE)

5	Facility Name: _____ Address: _____ _____ City: _____ State: _____ Postal Code: _____ Contact Person #1 Name: _____ Email: _____ Contact Person #2 Name: _____ Email: _____ Indicate the practice location for this facility: ◯ Free standing/Satellite Clinic ◯ Hospital Facility size based on annual total number of unique patients: ◯ Small (0 – 499) ◯ Medium (500 – 999) ◯ Large (1000 – 1499) ◯ Jumbo (1500+) Number of full-time radiation oncologists: _____ FTE (e.g., 5 FTE or 2.5 FTE)
6	Facility Name: _____ Address: _____ _____ City: _____ State: _____ Postal Code: _____ Contact Person #1 Name: _____ Email: _____ Contact Person #2 Name: _____ Email: _____ Indicate the practice location for this facility: ◯ Free standing/Satellite Clinic ◯ Hospital Facility size based on annual total number of unique patients: ◯ Small (0 – 499) ◯ Medium (500 – 999) ◯ Large (1000 – 1499) ◯ Jumbo (1500+) Number of full-time radiation oncologists: _____ FTE (e.g., 5 FTE or 2.5 FTE)

APPENDIX B – SAMPLE MEMO

Sample memo to organization from radiation oncology professional to request organization's participation in RO-ILS.

TO:

FROM:

RE: PARTICIPATION IN RO-ILS: RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM®

The American Society for Radiation Oncology (ASTRO) collaborates with Clarity Group, Inc., and Clarity PSO to facilitate a safety and quality initiative with the goal of enhancing safety culture and the best outcomes in the delivery of radiation therapy. RO-ILS: Radiation Oncology Incident Learning System® is a patient safety program specifically developed to address issues associated with radiation oncology safety, and will be carried out through Clarity PSO, a federally listed patient safety organization (PSO), RO-ILS consists of event reporting coupled with analysis to recognize gaps, or potential gaps, in clinical practices that can be explored and analyzed to identify improvements in patient safety. RO-ILS is the only medical specialty society-sponsored incident learning system for radiation oncology. With funding and professional and technical assistance contributed by both ASTRO and AAPM as well as additional financial support from vendors and sister societies, there is no fee to participate in RO-ILS.

The landmark document from the Institute of Medicine, "To Err is Human: Building a Safer Health System" (1999), illustrated the magnitude of human factors in medical incidents. As a result, Congress passed the Patient Safety and Quality Improvement Act of 2005 (PSQIA). The PSQIA authorizes PSOs, which confer certain privilege and confidentiality protections. Clinicians and health care organizations can voluntarily report, aggregate and analyze data within a PSO with the goal of reducing the risks and hazards associated with patient care. These PSOs are qualified by the Agency for Healthcare Research and Quality (AHRQ) and are listed on the AHRQ website.

PSOs must comply with the Health Insurance Portability and Accountability Act (HIPAA) and its implementing privacy, security, breach notification and enforcement regulations. Clarity Group, Inc., which administers the technology aspects of the program, has taken additional security measures, including SSA SOC 2 Type II certification and compliance. The PSQIA includes confidentiality and privilege protections for voluntary patient safety information that providers develop above and beyond their existing reporting or record keeping requirements. This gives radiation oncology providers the opportunity to conduct quality and safety work in both a legally protected and electronically secure environment.

To participate in RO-ILS, it is necessary for a practice to formally contract with Clarity PSO. To take full advantage of RO-ILS, it is preferable that the employing practice sign a contract with Clarity PSO on behalf of the radiation oncology department. This type of arrangement can allow all staff within the radiation oncology department, including residents, students, full- or part-time staff and contracted staff, to participate in RO-ILS.

There is no limit to the number of PSOs in which a practice can participate. Practices already participating in a PSO are still able to participate in RO-ILS. Participating in RO-ILS allows the radiation oncology department to be a part of a PSO focused on their specialty. We are requesting that in consultation with qualified legal counsel, <INSERT PRACTICE NAME> enter into an agreement with Clarity PSO on behalf of the radiation oncology department to allow for participation in RO-ILS.

Sincerely,

<NAME>

APPENDIX C –GLOSSARY

Commonly Used Acronyms in the RO-ILS Program

AHRQ = Agency for Healthcare Research and Quality
BAA = Business Associate Agreement
PSES = Patient Safety Evaluation System
PSO = Patient Safety Organization
PSQIA = Patient Safety and Quality Improvement Act of 2005
PSWP = Patient Safety Work Product
RO-HAC = Radiation Oncology Healthcare Advisory Council

Agency for Healthcare Research and Quality (AHRQ): The federal agency within the U.S. Department of Health and Human Services responsible for the creation and oversight of the Patient Safety Act regulations.

Aggregate Data Reports: RO-ILS education that provides a high-level look at the trends in the national database and include a "report card" and graphs.

Analysis Wizard: An analysis tool within the RO-ILS Portal that allows Reviewers to pull, track, graph practice data, save template report and set automated scheduled reports.

Authorized Representative: The designated person with authority to sign contracts with Clarity.

Business Associate Agreement (BAA): An agreement between covered entities and business associates to ensure that the business associates will appropriately safeguard PHI as required by the HIPAA Rules.

Case Studies: RO-ILS education that summarizes one RO-ILS event and provide learning, feedback and suggestions from RO-HAC.

Clarity PSO: Provides the PSO services to RO-ILS practices and a safe learning environment for contracted practices to closely examine and learn from patient safety data. Clarity PSO is a division of Clarity Group, Inc., a health care professional liability risk management organization.

Facility: A distinct site that provides radiation therapy services. Facilities are separate sites situated in different locations (e.g., satellite clinics).

Dashboard: Pre-set, up-to-date charts within the RO-ILS Portal that display a snapshot of the practice's data trends.

Health Insurance Portability and Accountability Act of 1996 (HIPAA): A federal law that created national standard to protect PHI from being disclosed without the patient's consent or knowledge.

Patient Safety and Quality Improvement Act of 2005 (also known as the Patient Safety Act or PSQIA): A federal law that allows providers to examine and to learn from patient safety events or incidents. The law authorizes patient safety organizations (PSOs) which confer certain privilege and confidentiality protections. Clinicians and health care organizations can voluntarily report, aggregate and analyze data, within a PSO with the goal of reducing the risks and hazards associated with patient care.

Patient Safety Organization (PSO): Federally recognized entities that collect information about medical errors and safety risks in a confidential and protected environment.

PSO Liaison: The primary contact for RO-ILS from the practice and is responsible for overall participation in RO-ILS by all facilities covered under the practice.

Practice: One or more sites where radiation therapy services are provided under the direction of common set of standard operating procedures. The entity that owns, manages or oversees a facility(s) that will contract with Clarity to participate in RO-ILS.

Patient Safety Work Product (PSWP): Information that is developed through the deliberative process created by the provider to collect and submit information for review by a PSO, thus receiving legal protections afforded by the Patient Safety Act. PSWP can be any data, reports, records, memoranda, analysis (such as root cause analysis) or written or oral statements (or copies of any of this material) that could improve patient safety, health care quality or health care outcomes. PSWP is defined in the federal regulations at 42 C.F.R. § 3.20.

Patient Safety Evaluation System (PSES): Mechanism for collecting, managing and analyzing information and data for reporting to or by a PSO.

Protected Health Information (PHI): Identifying, patient-specific information that is protected by HIPAA Privacy Rule.

Reviewer: An account type and staff person within the practice responsible for entering follow-up analysis in the "My Review" section of the Portal and reporting event to the PSO. There is a limit of 10 Reviewers per facility.

Radiation Oncology Healthcare Advisory Council (RO-HAC): An interdisciplinary group of 12 radiation oncology professionals who provide subject matter expertise to RO-ILS by conducting data analysis on the national dataset and developing RO-ILS education for the community.

RO-ILS Portal: A web-based interface that RO-ILS enrolled practices utilize to enter, review, and report events to the PSO. The RO-ILS Portal is divided into two sections: "Submit Event" and "My Review" and contains analysis tools.

Safety Culture: An environment in which all team members can participate in assuring and improving safety, with no reprisals taken for staff reporting safety concerns.

Safety Notices: RO-ILS education that communicates findings that may be novel to the community, of higher clinical significance and/or deserve more prompt review.

Submitter: An account type that is a general login shared with all staff across the practice and allows staff to anonymously submit an event locally in the RO-ILS Portal.

Target Safely: An ASTRO initiative dedicated to improving the safety and quality of radiation oncology.

Themed Reports: RO-ILS education focused on various topic areas that transcend the entire RO-ILS national database and include multiple case examples.

---

i U.S. Department of Health & Human Services. Business Associate Contracts: Sample Business Associate Agreement Provisions. 2013. https://www.hhs.gov/hipaa/for-professionals/covered-entities/sample-business-associate-agreement-provisions/index.html

ii Ford EC, Fong de Los Santos L, Pawlicki T, et al. Consensus recommendations for incident learning database structures in radiation oncology. *Med Phys*. 2012. 39(12):7272-90.

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.

RO•ILS®

RADIATION ONCOLOGY
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

ASTRO
TARGETING CANCER CARE

ABOUT ASTRO

The The American Society for Radiation Oncology (ASTRO) is the world's largest radiation oncology society, with more than 10,000 members who are physicians, nurses, biologists, physicists, radiation therapists, dosimetrists and other health care professionals who specialize in treating patients with radiation therapies. The Society is dedicated to improving patient care through professional education and training, support for clinical practice and health policy standards, advancement of science and research, and advocacy. ASTRO publishes three medical journals, International Journal of Radiation Oncology • Biology • Physics, Practical Radiation Oncology and Advances in Radiation Oncology; developed and maintains an extensive patient website, RT Answers; and created the nonprofit foundation Radiation Oncology Institute. To learn more about ASTRO, visit our website, sign up to receive our news and follow us on our blog, Facebook, Twitter and LinkedIn.

AAPM

ABOUT AAPM

AAPM, the premier organization in medical physics, both in the U.S. and abroad, represents over 9,000 medical physicists. The mission of AAPM is to advance medicine through excellence in the science, education and professional practice of medical physics--a scientific and professional discipline that uses physics principles to address a wide range of biological and medical needs. Clinically, medical physicists work side by side with radiation oncologists to design treatment plans and monitor equipment and procedures to ensure that cancer patients receive the prescribed dose of radiation at the correct location. Medical physicists also contribute to the effectiveness of medical imaging by ensuring the safe and effective use of radiant energy (e.g., optical, ionizing, ultrasonic, or radiofrequency) to obtain detailed information about the form and function of the human body.