



AMERICAN SOCIETY FOR RADIATION ONCOLOGY

Oops, We Did It Again: Learning from Medical Events

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ASTRO

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AMERICAN SOCIETY FOR RADIATION ONCOLOGY

ASTRO is the **leading medical society** dedicated to radiation oncology, biology & physics.

A non-profit professional organization founded in 1958



Our Members

ASTRO's **nearly 10,000 members** include radiation oncologists, biologists, medical physicists, dosimetrists, radiation therapists, nurses, physician assistants, practice administrators & industry representatives.

**Members from 6 continents,
80+ countries & all 50 U.S. states.**



AMERICAN SOCIETY FOR RADIATION ONCOLOGY

RO•ILS

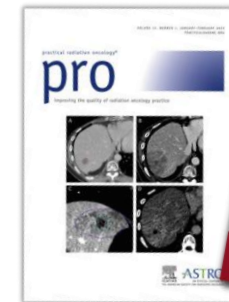
RADIATION ONCOLOGY®
INCIDENT LEARNING SYSTEM

Sponsored by ASTRO and AAPM

Our Mission

Advance the radiation oncology specialty through:

- Promotion of **equitable, high-quality care** for people with cancer
- Cultivating & educating a **diverse workforce**
- Fostering **research & innovation**
- Leading **policy development & advocacy**



RO-ILS: Radiation Oncology Incident Learning System[®]

RO•ILS

RADIATION ONCOLOGY[®]
INCIDENT LEARNING SYSTEM

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.

SPONSORED BY:



SUPPORTED BY:



American Association of Medical Dosimetrists
Sun Nuclear Corporation

Radformation | Radiological Imaging Technology (RIT) | Vision RT

RO-ILS: Statistics

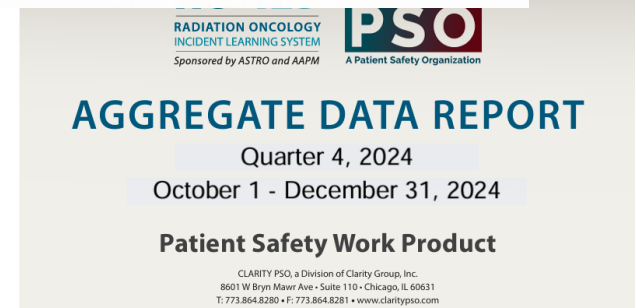
- **780+** (~31%) U.S. facilities enrolled
- Facilities in **48** states and Puerto Rico enrolled
- **45,942+** events have been reported to the PSO
- Education available at www.astro.org/roilsreports

RO-ILS Education

- 16 Quarterly/Bi-Annual Reports
- 22 Case Studies
- 17 Aggregate Data Reports
- 9 Themed Reports
- 10 Good Catch Celebrations
- 1 Safety Notice
- 2 Manuscripts
- 13 User Meetings
- 2 Patient Safety Conversation Hours
- 60+ Presentations



RO-ILS CASE STUDY 21
CONTOURING COMPLEXITY –
Navigating the *Breath* of Multiple CT scans in
Radiation Therapy Planning



RO-ILS Deep Dive #1



Figure 1A: Database Drill Down

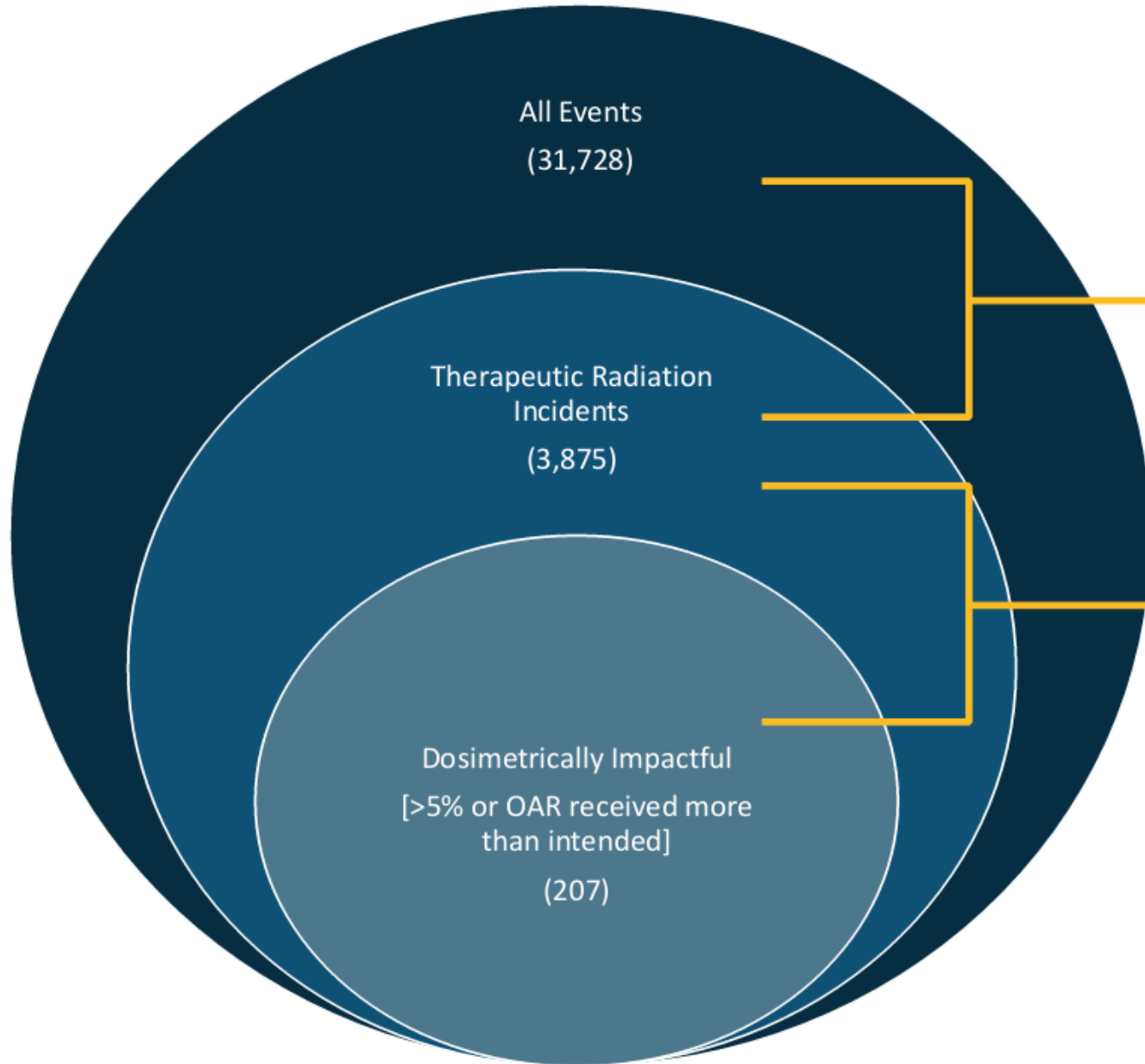


Figure 1B: Event Classification (n=31,728)

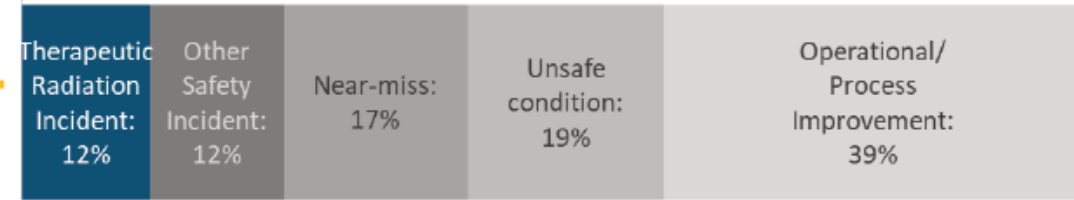


Figure 1C: Dosimetric Impact Distribution of Therapeutic Radiation Incidents that Affected One Patient (n=3,687)

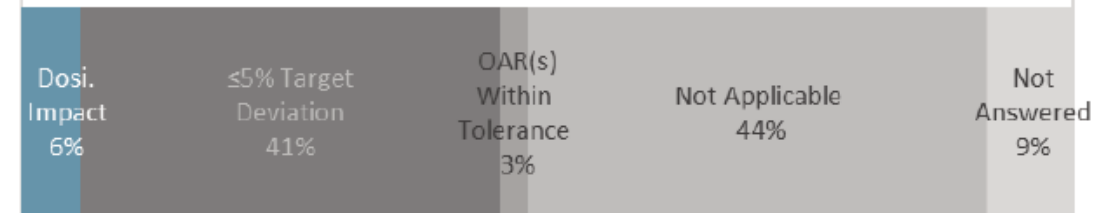


Figure 2: Number of Dosimetrically Impactful Events Increased Over Time but Represent Smaller Percentage of All RO-ILS Events

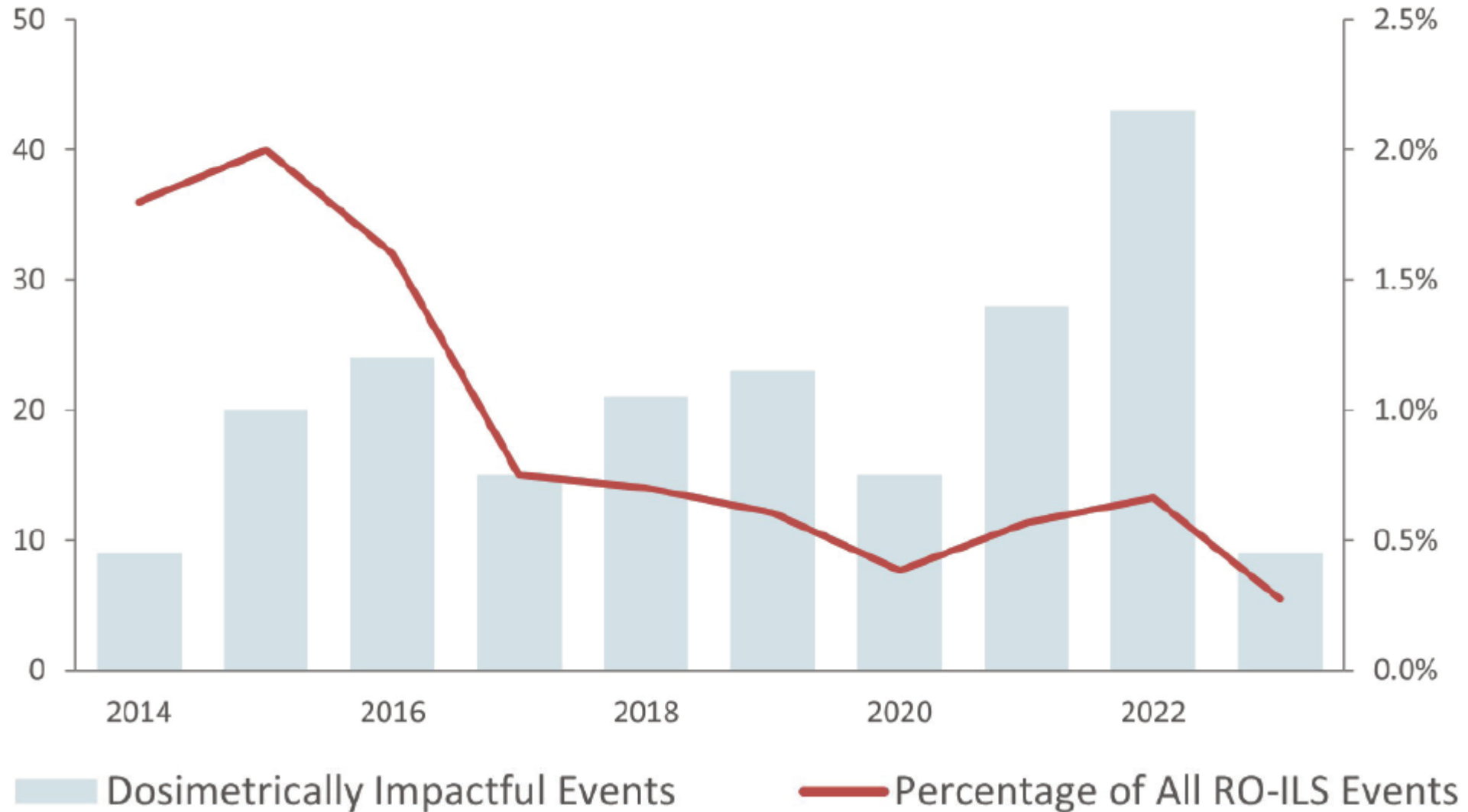


Table 1: Problem Type of Dosimetrically Impactful Events

Problem Type	Count
Wrong patient position, setup point or shift	18
Other	16
Wrong prescription dose fractionation or calculation error	15
Wrong anatomical site (excluding laterality)	12
Wrong, missing, mislabeled or damaged treatment accessories	10
Treatment not delivered: personnel/hardware/software failure	7
Inappropriate or poorly informed decision to treat or plan	5
Wrong target or OAR contours	5
Treatment plan (isodose distribution) unacceptable	3
Anatomical site (excluding laterality) incorrect	2
Radiation therapy scheduling error	2
Treatment accessories: incorrect, missing, mislabeled, misused or damaged	2
Target or OAR contours incorrect or omitted	1
Treatment plan acceptable but not physically deliverable	1
Wrong patient	1
Wrong planning margins	1
Wrong side (laterality)	1
Unknown	105

Figure 3: Most Dosimetrically Impactful Events Not Reported Externally (n=207)

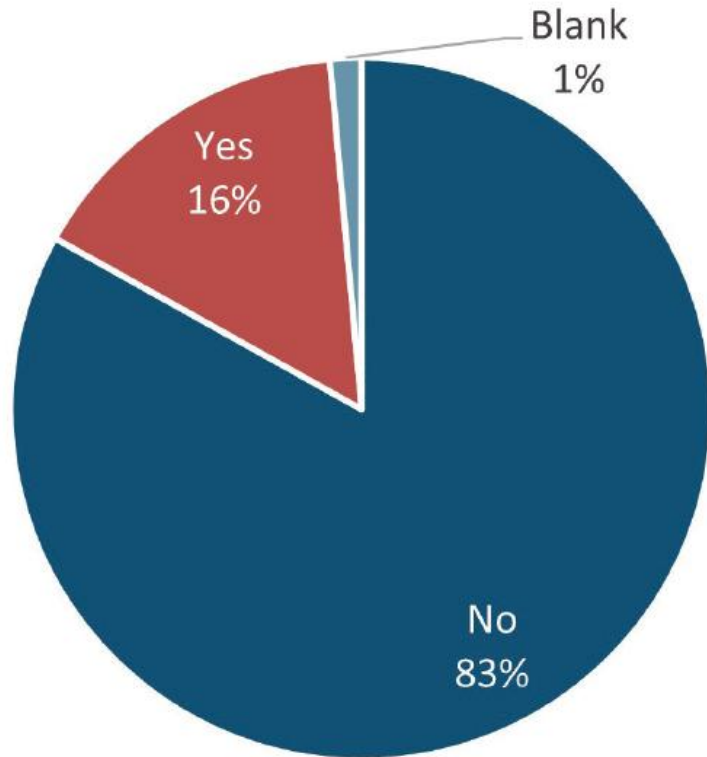
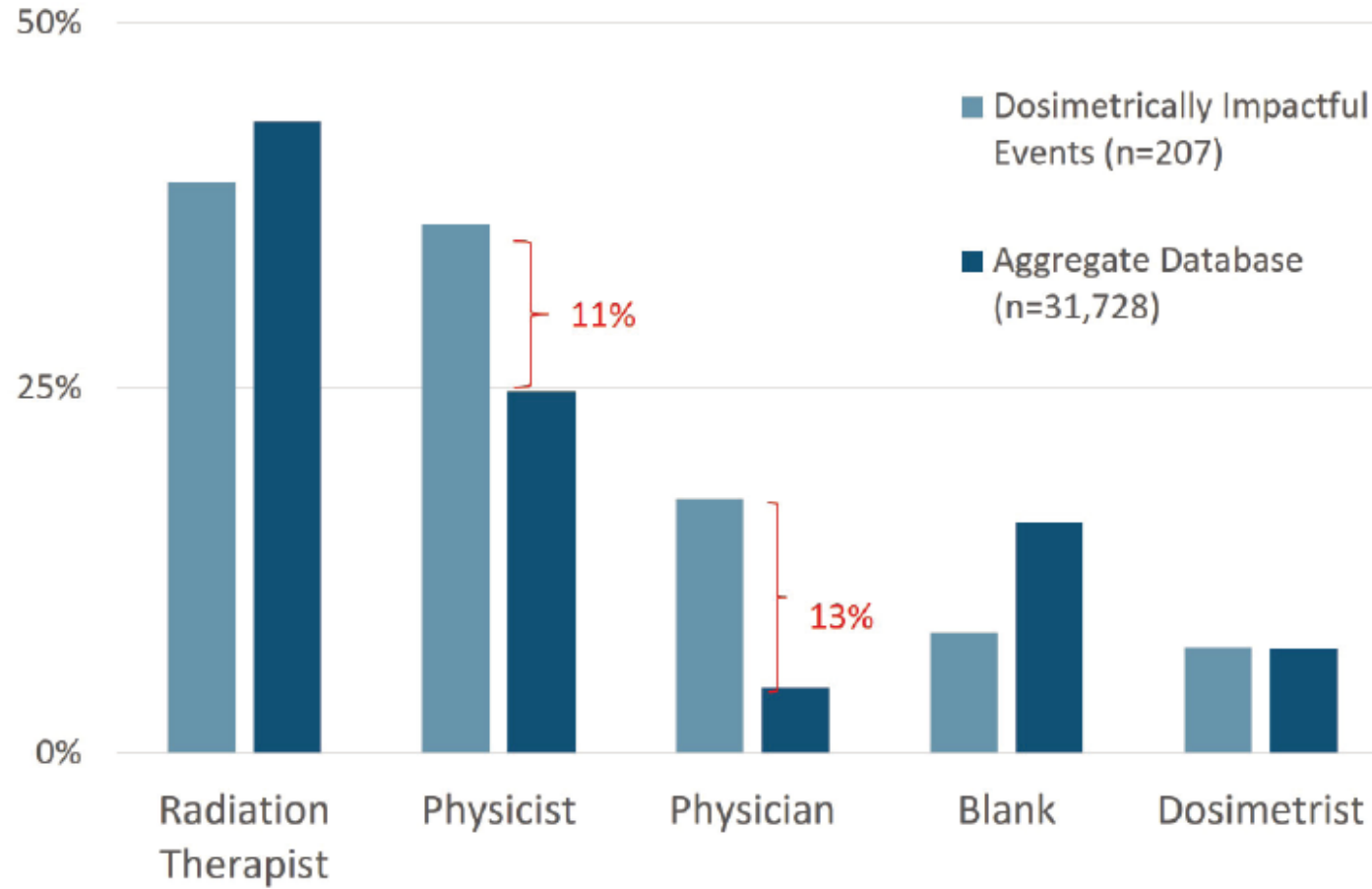


Table 3: Percentage of Events with a Treatment Technique and Difference between Dosimetrically Impactful Events and Aggregate Database

Treatment Technique	Percent of Dosimetrically Impactful Events (n=207)	Percent of Aggregate Database (n=31,728)	Percent Difference	Findings
3D	33%	28%	5%	Techniques Represented MORE in Dosimetrically Impactful Events Than Aggregate
Electrons	13%	5%	8%	
2D	6%	2%	3%	
HDR	4%	2%	2%	
Radiopharmaceuticals	2%	0%	2%	
LDR	2%	0%	2%	
TBI	2%	1%	1%	
Intraoperative	1%	0%	1%	
SRS/SBRT	11%	12%	-1%	Techniques Represented LESS in Dosimetrically Impactful Events Than Aggregate
Particles (Protons)	3%	4%	-1%	
(Blank)	2%	4%	-1%	
Other	2%	5%	-2%	
kV x-rays (i.e., Orthovoltage and superficial)	0%	1%	-1%	
Not Applicable	0%	10%	-9%	
IMRT/VMAT	25%	35%	-10%	

Figure 5: Radiation Oncologists and Medical Physicists were Involved in Identifying a Greater Percentage of Dosimetrically Impactful Events



Case Study: Wrong Anatomic Site Treated with Brachytherapy

- Real-time planning used in procedure room for prostate brachy procedure.
- Ultrasound probe properly inserted during planning (planned using stranded seeds).
- During seed placement, probe was not adequately advanced on sagittal imaging to visualize the prostate gland.
- 63 of 78 stranded seeds implanted immediately inferior to the prostate in the perineum and only 15 loose seeds were implanted in the prostate.
 - A post-implant CT confirmed that actual prostate D90 = 26.26% vs. pre-planned D90 = 104.8%.
 - A significant volume of the perineum received >100 Gy.

Case Study: Recommendations

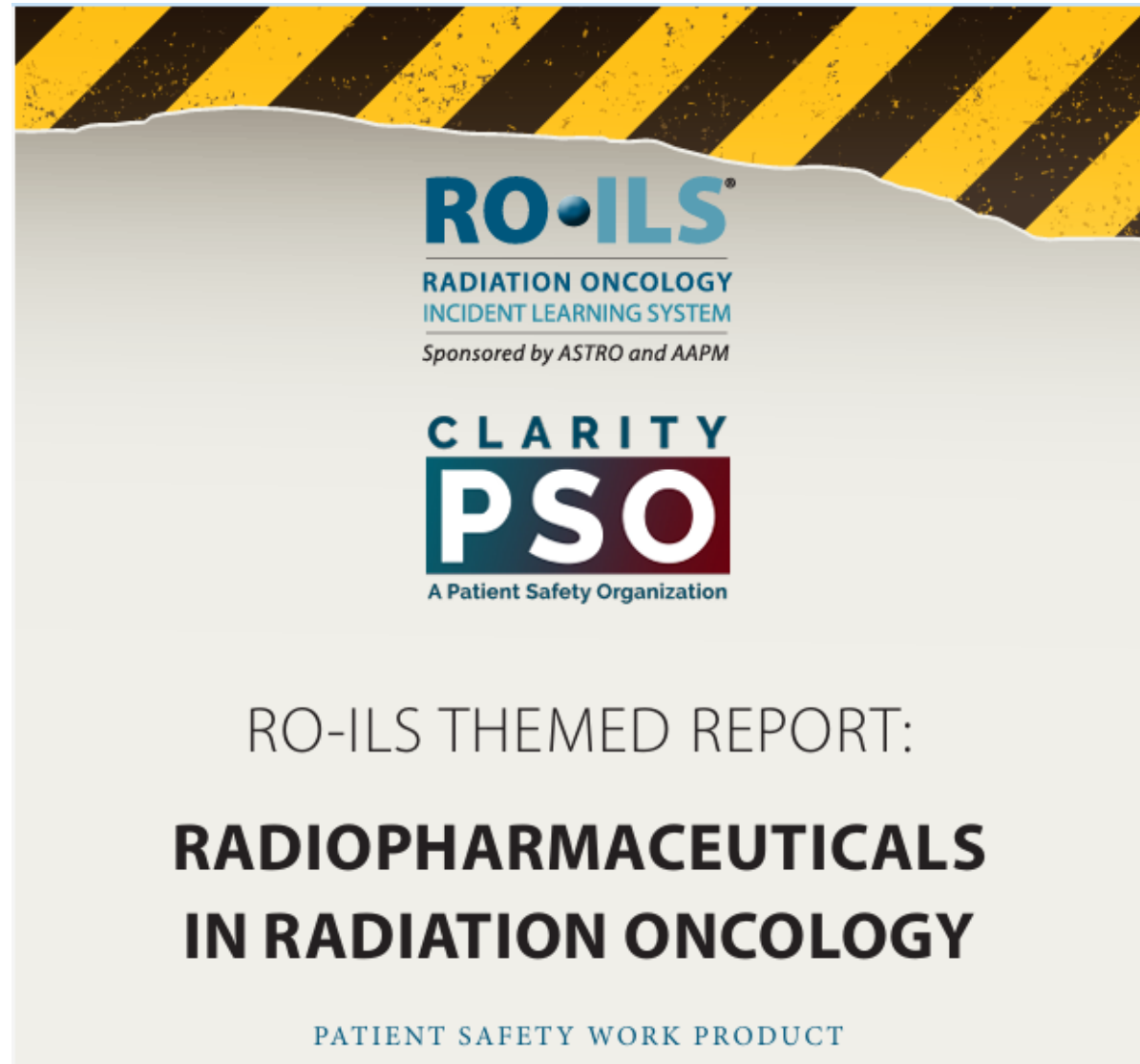
- Treatments with few fractions require additional safety checks prior to, and with each treatment.
 - A misadministration during one treatment has a significant dosimetric impact on the entire treatment course.
- Specialized treatments also require a high level of expertise and rigorous safety processes to prevent gross misadministration.
 - Including proper training and procedural volume.
 - Procedures which are image guided need to adequately use the imaging at hand.
- Additionally, leveraging peer review can be extremely helpful.

Case Study

Theme: Peer Review

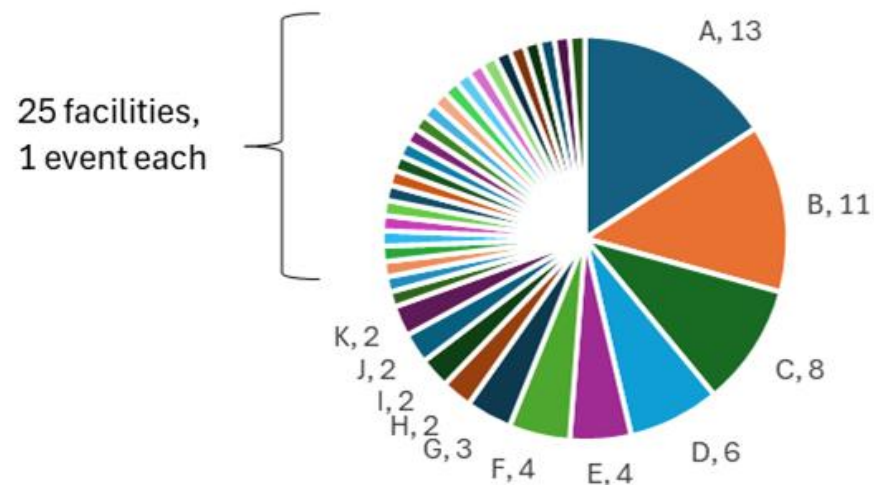
- Conducting a prospective peer review before initiating treatment.
 - Especially vital in the case of high-dose, hypofractionated treatments so the patient doesn't receive most or even all of the prescribed dose before peer review.
- Additionally, leveraging peer review can be extremely helpful.
 - For example, other personnel (e.g., the brachytherapy physicist might be skilled in interpreting ultrasound imaging) can concur on image interpretation and thereby serve as a second check.
 - The addition of an explicit checklist item to the process can also improve safety.

RO-ILS Deep Dive #2



RO-ILS Deep Dive #2: The Data

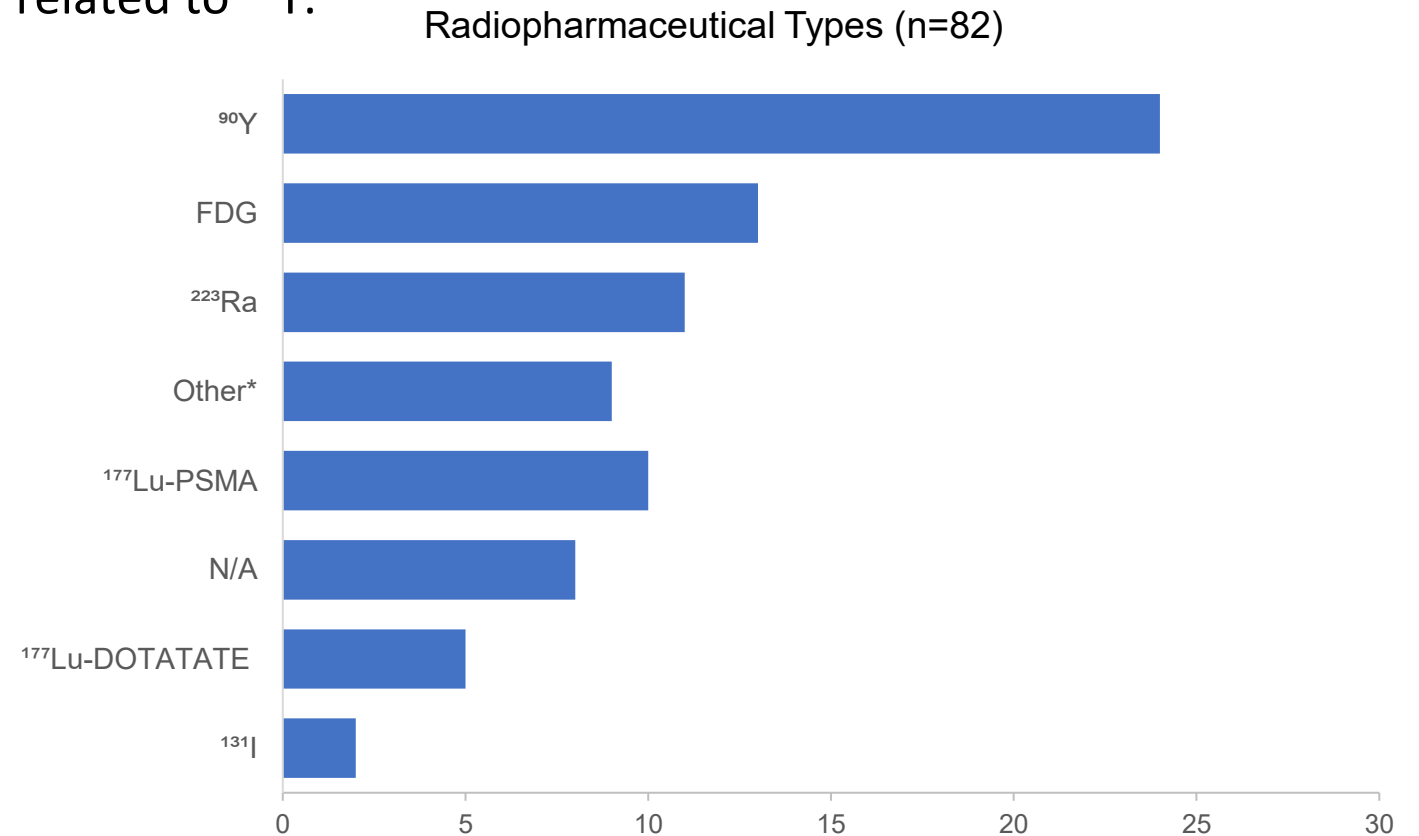
Figure 1: Radiopharmaceutical Event Distribution Across 36 Facilities (n=82 events)



- 82 radiopharmaceutical events from 36 facilities.
- 4 facilities accounted for approximately half of the reported events.
- The remaining events were distributed across a broad range of facilities, with 25 facilities reporting a single event each.
- This reflects the variability of radiopharmaceutical use, RPT patient volumes and diversity of practice-type where the authorized user may be a radiation oncologist, or sometimes a nuclear medicine physician who may not have access or might be less likely to report events to RO-ILS.

RO-ILS Deep Dive #2: The Data

- It is reasonable to speculate that the more relatively established a procedure is, such as ^{131}I , there may be a lower incidence rate as practices improve processes over time based on their experience.
- There is an opportunity to identify mechanisms to mitigate errors across *both* frequently used and emerging agents.
- For comparison: In FY2024, the NRC received 33 medical events related to ^{90}Y .



RO-ILS Deep Dive #2: Case Study #1

Case 1: Unintentional Radiopharmaceutical Exposure

- *A new courier service for a distributor of radiopharmaceuticals mistakenly delivered a 70lb case of radiopharmaceuticals to the radiation therapy area instead of the hot lab, a secure location designated for such deliveries.*
- *The courier did not seek further instructions and left the case on a counter in the radiation therapy area.*
- *The Radiation Safety Officer, Imaging Lead, and distributor pharmacy were notified.*
- *Distributor staff notified the regional operations manager.*
- *A radiation oncology staff member showed the head driver the correct entry and hot lab codes, and the head driver then moved the case to the hot lab.*
- *The exact duration that the case remained in the radiation therapy area is unknown.*

RO-ILS Deep Dive #2: Case Study #1 Recommendations

- Clear delivery protocols for radiopharmaceuticals should be established and communicated to couriers, including detailed instructions and secure access codes.
 - It is essential to handle and store these materials in secure, designated areas to prevent unintentional exposure, with all staff trained in proper procedures.
 - Regular monitoring and auditing of delivery and storage processes help identify and rectify deviations from protocols.
 - Continuous follow-up and feedback with delivery service providers can help promote adherence to protocols and address any operational challenges.
- An emergency response plan for unintentional exposure incidents must be developed.
- Proper documentation and investigation of all incidents should be conducted to improve protocols and prevent future occurrences.

RO-ILS Deep Dive #2: Case Study #2

Case 2: ^{177}Lu -PSMA Doses to Two Patients Swapped

- *Two patients received ^{177}Lu -PSMA doses intended for each other.*
- *While both patients received the correct drug and dose, the vials were incorrectly tagged.*
- *The incident was identified, and no harm was caused as the vials were from the same batch, with identical doses, lot numbers, and expiration dates.*
- *As a result of the event, a quality and safety team mapped the workflow and improved the process for administering ^{177}Lu -PSMA.*

RO-ILS Deep Dive #2: Case Study #2 Recommendations

- It is important to implement robust patient identification protocols, such as barcodes, to promote correct medication administration.
- Staff should also conduct regular team meetings to review schedules, discuss potential issues and confirm process alignment.
 - Staff still need ongoing training on updated procedures and safety protocols to promote compliance.
 - Staff training should emphasize double-checking patient details against vial labels during timeouts to identify errors. Lastly, report and analyze incidents, to identify root causes and inform stakeholders for continuous improvement.
- To address systemic issues (e.g., similar designs), clinicians can provide feedback and collaborate with pharmaceutical vendors for improved labeling and tracking of medication vials.

RO-ILS Deep Dive #2: Conclusions

- Use of radiopharmaceuticals within a radiation oncology practice has its own unique safety challenges.
- Staff must remain up to date on the latest RPT research to support choosing the right type and dose of radiation and selecting the appropriate method of administration.
 - Integrating staff into growing RPT teams and increasing training opportunities.
- Strict safety measures are necessary to protect patients and healthcare workers from radiation exposure.
- External validation programs, such as ASTRO's APEx RPT designation offer another mechanism to comprehensively evaluate and improve safety standards.

APEX: ASTRO's Accreditation Program for Excellence

- APEX was developed by radiation oncology professionals for radiation oncology practices.
- Focuses on the entire radiation oncology team and quality improvement, not just appropriateness criteria.
- Practices are evaluated on APEX Standards and Evidence Indicators.
- Objective reviews with transparent results.

Registration

Self-
Assessment

Facility Visit
Preparations

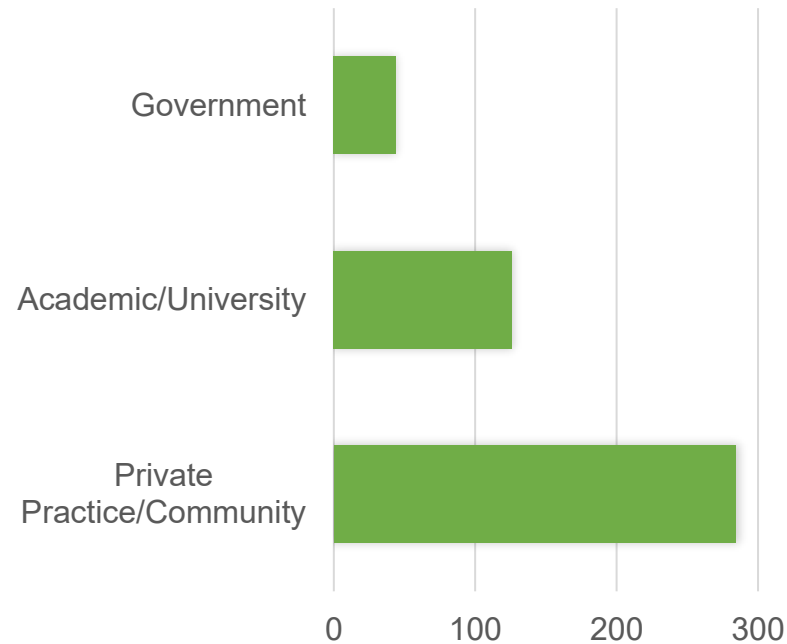
Facility Visit

Determination

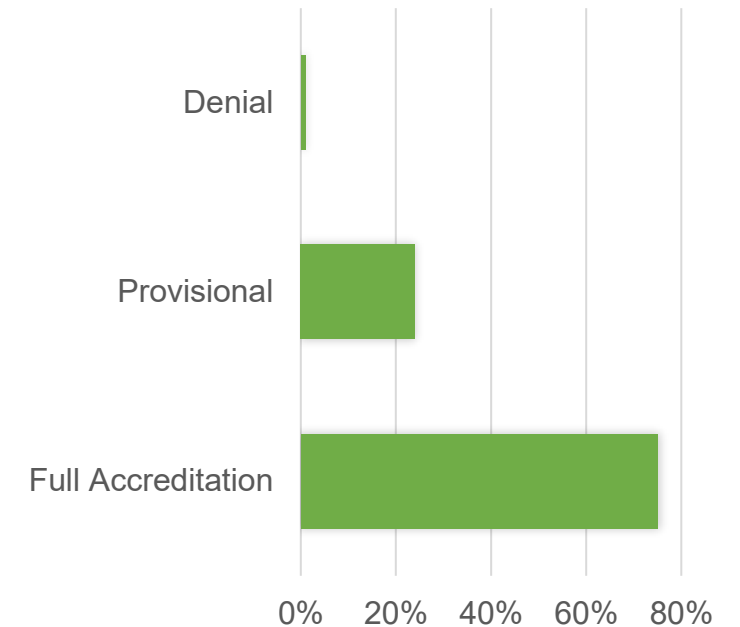
APEX: Statistics

As of April, 2025, there are **500** facilities in APEX, with **454** of these fully accredited.

PRACTICE TYPE



DETERMINATIONS



APEX: RPT Accreditation

Stand-alone or add-on
radiopharmaceutical therapy assessment
focused on:

- Appropriate staffing
- Patient safety
- Care coordination
- Patient education
- Radiation safety
- Peer review
- Compliance with regulatory guidance



Safety White Paper

SPECIAL ARTICLE · Articles in Press, April 04, 2025

Quality and Safety Considerations for Radiopharmaceutical Therapy in the Radiation Oncology Environment: An ASTRO Safety White Paper

Jacqueline E. Zoberi, PhD^a · Youssef Charara, PhD^b · Jessica Clements, MS^c · ... · Ravi B. Patel, MD, PhD^h · Shiv Srivastava, PhDⁱ · John Phillips, MD, MPH^j ... Show more

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Show Outline

Abstract

Purpose

Radiopharmaceutical Therapy (RPT) is the latest topic in a series of white papers published by the American Society for Radiation Oncology addressing quality processes and patient safety. The availability of radiopharmaceutical agents for therapeutic use has broadened patient treatment options; while generally administered systemically, their effects are targeted to cellular receptors or the tumor microenvironment. Radiation oncology is well suited to delivering RPT as clinicians are already experienced in radiation safety, treatment delivery, and on-going patient care. This paper focuses on the logistics of initiating and/or maintaining a RPT program in radiation oncology and includes collaborating with other medical specialties. The white paper addresses the safety processes and workflow considerations for alpha- and beta-emitting radionuclides used for RPT.

Safety White Paper: Recommendations Part 1

1. The radiation medicine physician (who is an AU) should lead the patient care pathway and manage the complexities of on-going patient care.
2. Before starting an RPT program, practices should review their patient volumes and assess whether they expect to treat enough patients to gain sufficient expertise in RPT.
3. Dedicate and train personnel to support RPT programs.
4. **Develop appropriate infrastructure for receiving, storing, preparing, and administering RPTs.**
5. Develop expertise for infusion methods of specific RPTs to be administered.
6. **Develops SOPs for RAM handling and management, including patient release criteria and waste handling to minimize exposure and contamination risks.**

Safety White Paper: Recommendations Part 2

- 7. Program personnel must be certified (or eligible for certification) in their specialty by a national certifying board, and licensed and credentialed as appropriate.**
- 8. A comprehensive QM program must be developed to ensure RPT is performed in a safe and effective manner, and in compliance with the applicable regulations, standards, and recommendations from professional societies/manufacturers.**
9. It is recommended that RPT cases be reviewed in a multidisciplinary setting so that RPTs are being integrated appropriately into the overall oncologic management of the patient.
- 10. Participation in an external audit of a practice's overall QA processes is strongly encouraged.**
- 11. Use an event reporting mechanism for recording variances in the radiation treatment process.**

ASTRO RPT Education

Radiopharmaceutical Therapy Workshop

ASTRO 2025 Annual Meeting: Moscone Center, San Francisco

Saturday, September 27, 2025, 1:00 PM – 5:30 PM PT

This session will focus on clinical indications, difficult cases, medical physics considerations, development of standard operating procedures for clinical implementation, billing and safe theranostic delivery practices.

ASTRO Multidisciplinary Radiopharmaceutical Therapy Symposium

February 17-18, 2026

Palm Desert, CA

Beyond the Beam: A Radiation Oncology Curriculum for Radiopharmaceutical Therapy

Beyond the Beam is a 15-hour in-depth curriculum supplement resource that is designed specifically for radiation oncology residents and practicing radiation oncologists who are planning or participating in a radiopharmaceutical therapy (RPT) clinical program.

More information: www.astro.org

ASTRO Authorized User Education

How to Obtain Authorized User Status

These FAQs are provided as a resource and are intended for educational and informational purposes only. They do not constitute legal advice. You should consult with legal counsel, as well as your radiation safety staff, to determine compliance with all applicable federal, state, local and institutional laws, rules or regulations. ASTRO assumes no responsibility for the accuracy of the below information.

What is an Authorized User (AU) and why would I need to become one?

An AU is a person that meets regulatory training requirements, as determined by the Nuclear Regulatory Commission (NRC) in [10 CFR 35, Medical Use of Byproduct Material](#). This includes uses such as unsealed sources (radiopharmaceuticals), manual brachytherapy, remote afterloader brachytherapy, gamma stereotactic radiosurgery units, Gamma Knife, and Y90 microspheres.

If you plan on using any modality that is regulated by the NRC, you must become an AU under each specific section of the regulations. For instance, you can be an AU for manual brachytherapy and radiopharmaceuticals, but not for remote afterloader brachytherapy. However, if in the future you decide that you will be treating patients with a remote afterloader, you will need to become an AU under that specific section of the regulations.

Authorized User Survey

ASTRO Questions on AUs (OAS)



More information: www.astro.org

**On our
radar**

NRC Rulemakings / Guidance:

- Extravasation*
- Emerging Medical Technologies
- Training and Experience
- Patient Release

Executive Order Implementation

* We are also closely monitoring The Nuclear Medicine Clarification Act (HR 2541)

Questions?

ASTRO Questions on AUs (OAS)



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