ASTRO
TARGETING CANCER CARE

RO-ILS® and APEx®: Instruments for Quality Improvement

RO•ILS®

APEx
ASTRO Accreditation Program for Excellence
Safety and quality for radiation oncology practice

Samantha Dawes, CMD
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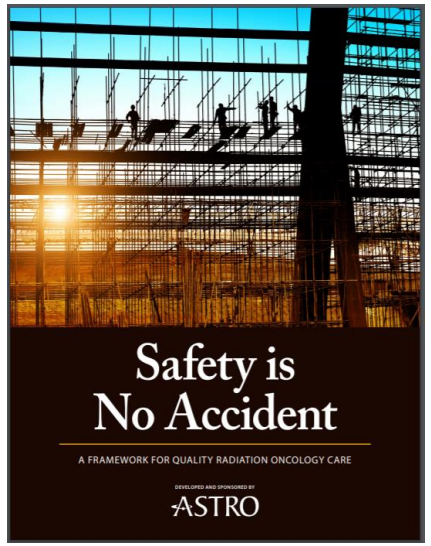
ASTRO
TARGETING CANCER CARE

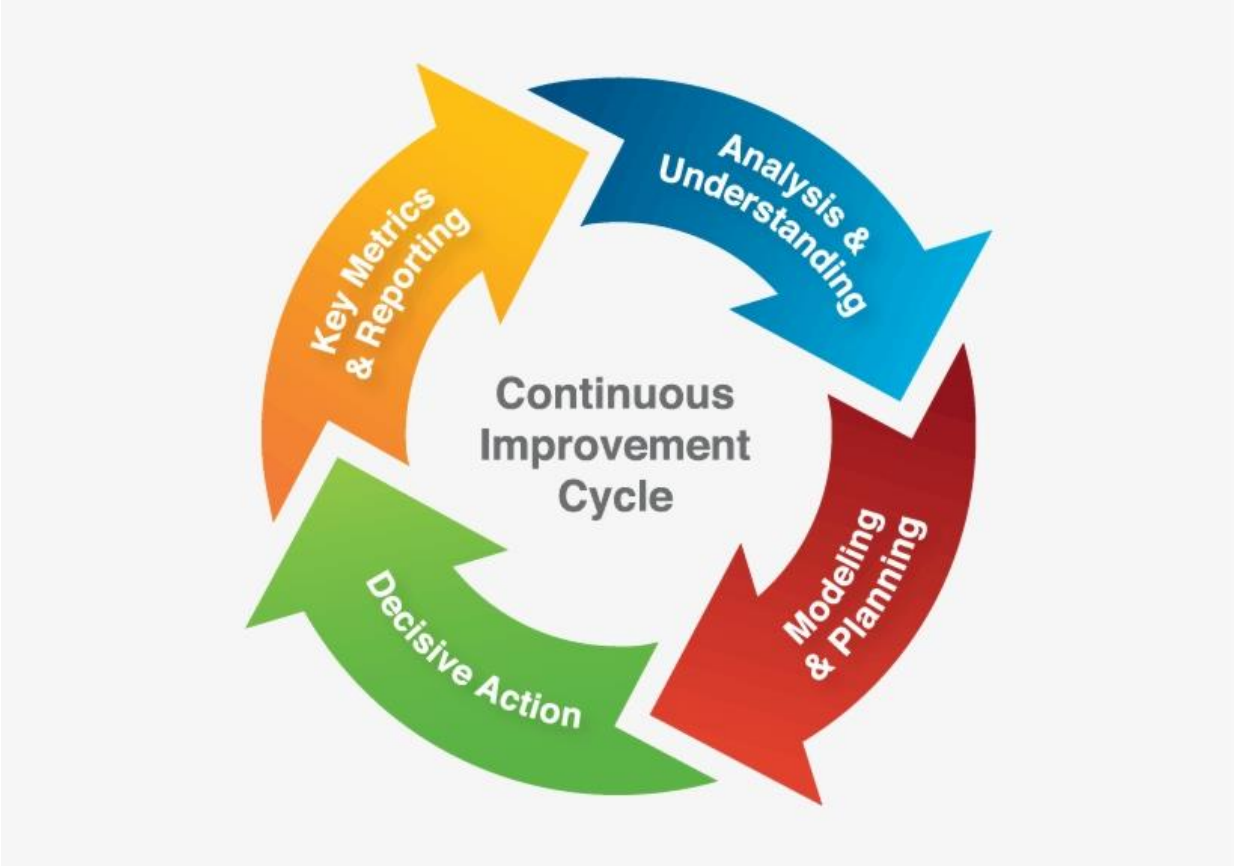
Disclosures:

- Employees of ASTRO

Quality Improvement

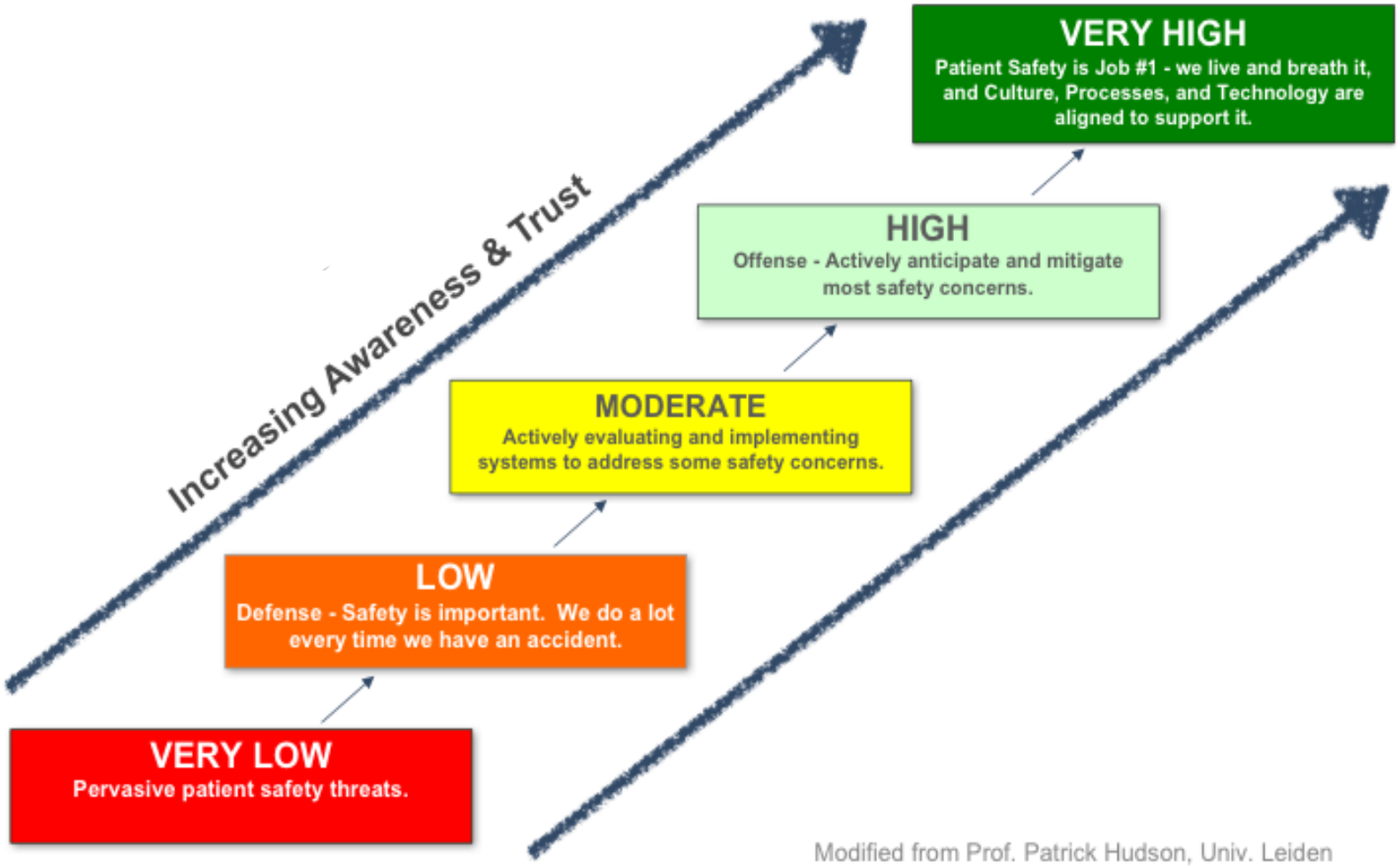
- Target Safely campaign
- Part of ASTRO's strategic plan
- Safety is No Accident





Culture of Safety

Varies widely, evolves, is measurable and can be improved



Modified from Prof. Patrick Hudson, Univ. Leiden

Key Features:

- Acknowledgment of high-risk nature of work.
- Encouragement of collaboration and learning
- Organizational commitment.
- No fear of reprimand for reporting.

https://www.healthcatalyst.com/insights/safety-culture-healthcare-7-step-framework

Safety Culture and Adverse Events

- Favorable patient safety culture is associated with fewer adverse events in hospitals.
  - 7 of the 15 safety culture variables were related to increased in-patient adverse events (statically significant).
  - Moderate effect size (-0.15 to -0.41) for all variables.

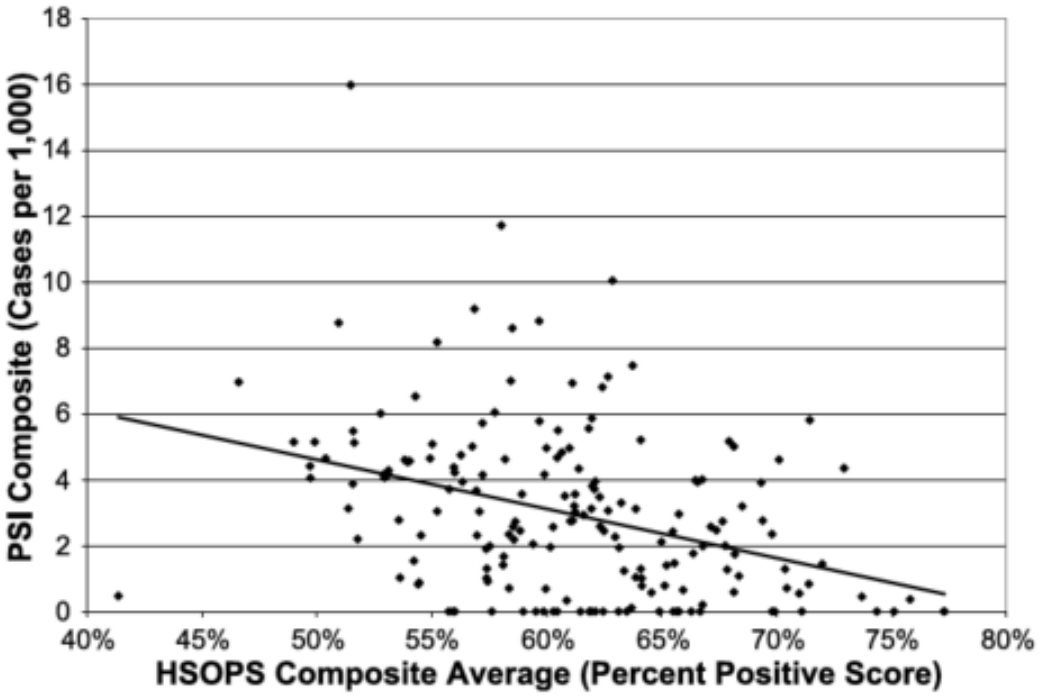


FIGURE 1. Scatter plot of PSI composite versus HSOPS composite average (N = 179).

R Mardon, et al, Exploring Relationships Between Hospital Patient Safety Culture and Adverse Events. *Journal of Patient Safety,* 20106:4, p 226-232

Interplay of ILS and Safety Culture

- **REPORT** → **ANALYZE** → **MAKE IMPROVEMENTS**

- More reporting → Improve Safety/Quality

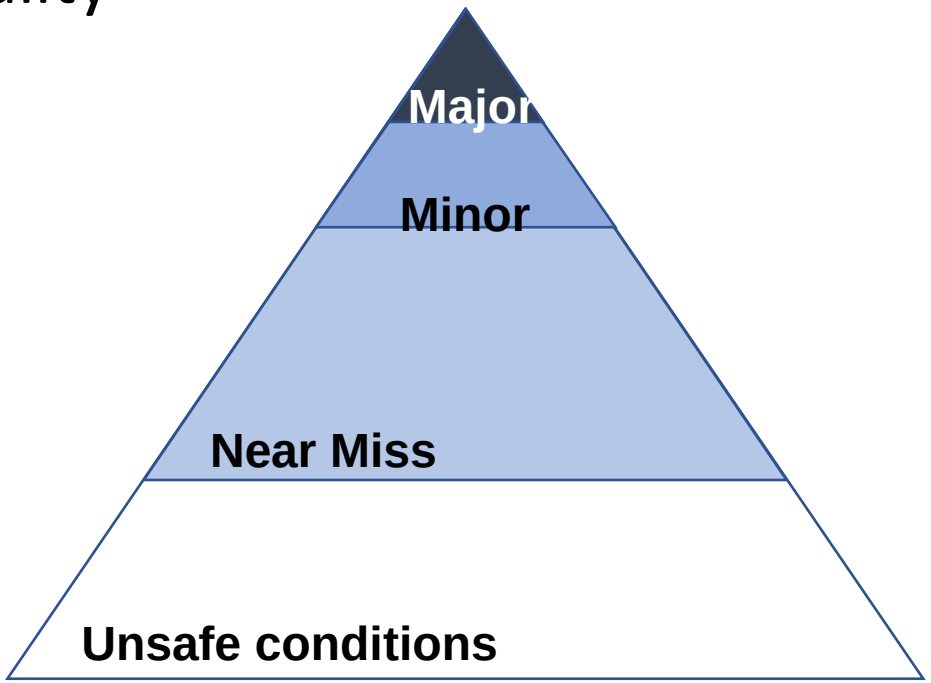
- **Focus on process,** not people

  To err is human.

  We must learn from it

"The single greatest impediment to error prevention is . . . that we punish people for making mistakes."

-Lucian Leape



Heinrich's Triangle

Heinrich, HW. Industrial accident prevention: a scientific approach, 1st Ed., 1931

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****.*

RO•ILS®

Background and Enrollment

- Patient Safety and Quality Improvement Act of 2005.
  - Collect patient safety data in a protected space.
  - Formation of Patient Safety Organizations (PSOs).
  - Data reported to a PSO is privileged and confidential.

CLARITY PSO
A Patient Safety Organization

Contracting

-Submit a Participation Form to Clarity PSO.

-Contract with Clarity PSO; this establishes protections afforded by the Patient Safety Act.

Onboarding

-Designate reviewers.

-Receive portal training and customize portal.

-Review PSO training.

-Develop/update PSES Policy.

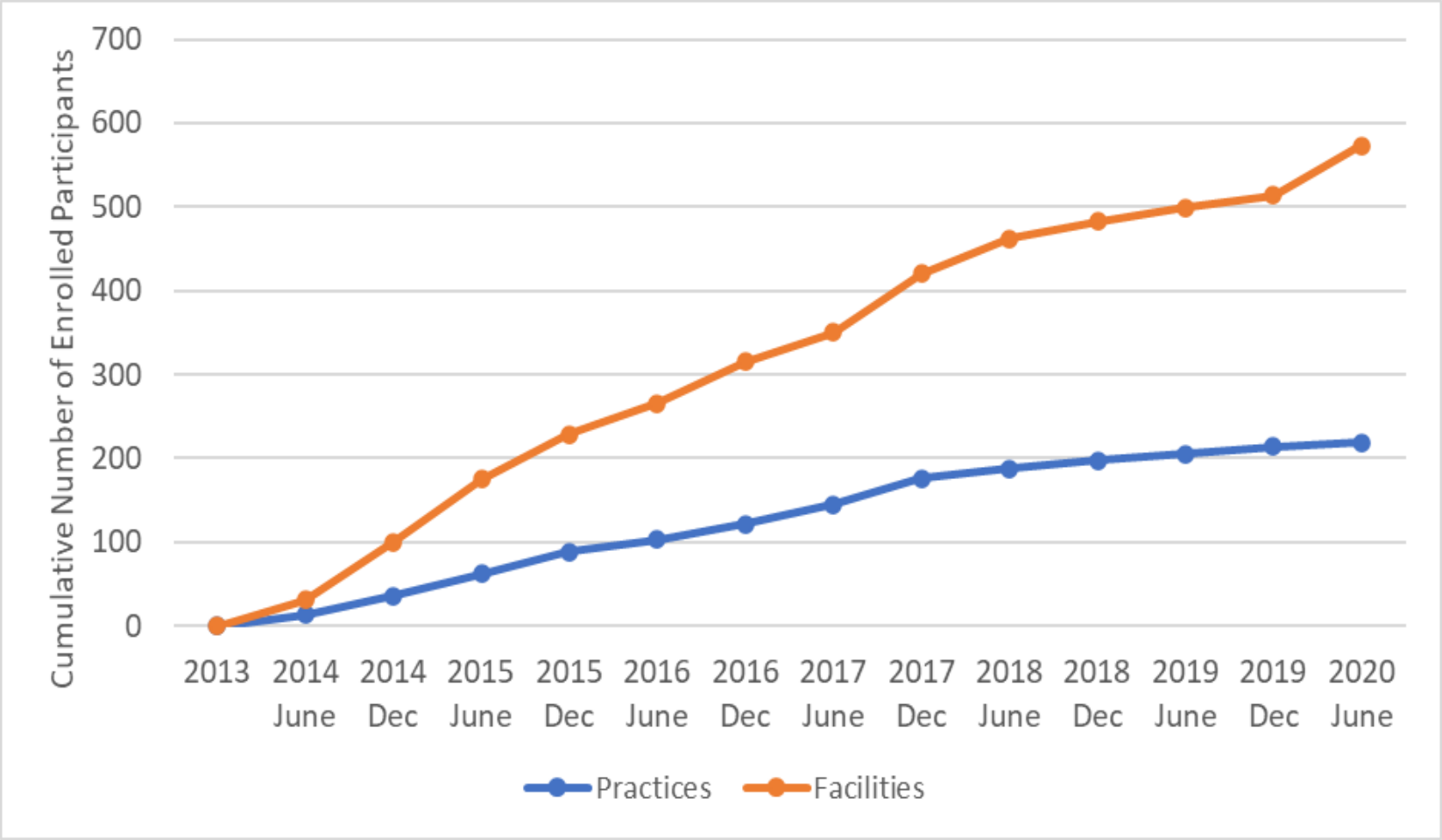
Implementation

-Share RO-ILS access with all staff and empower staff to report.

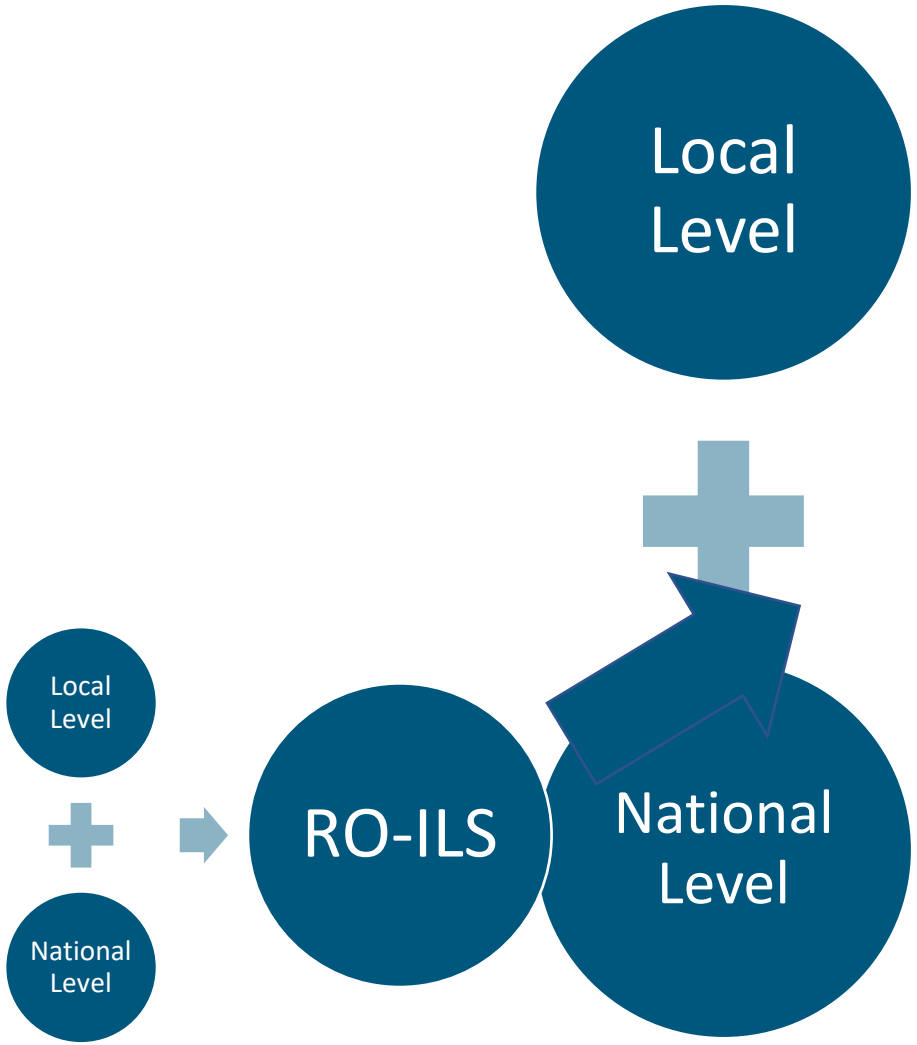
-Develop a detailed process and workflow for incident learning.

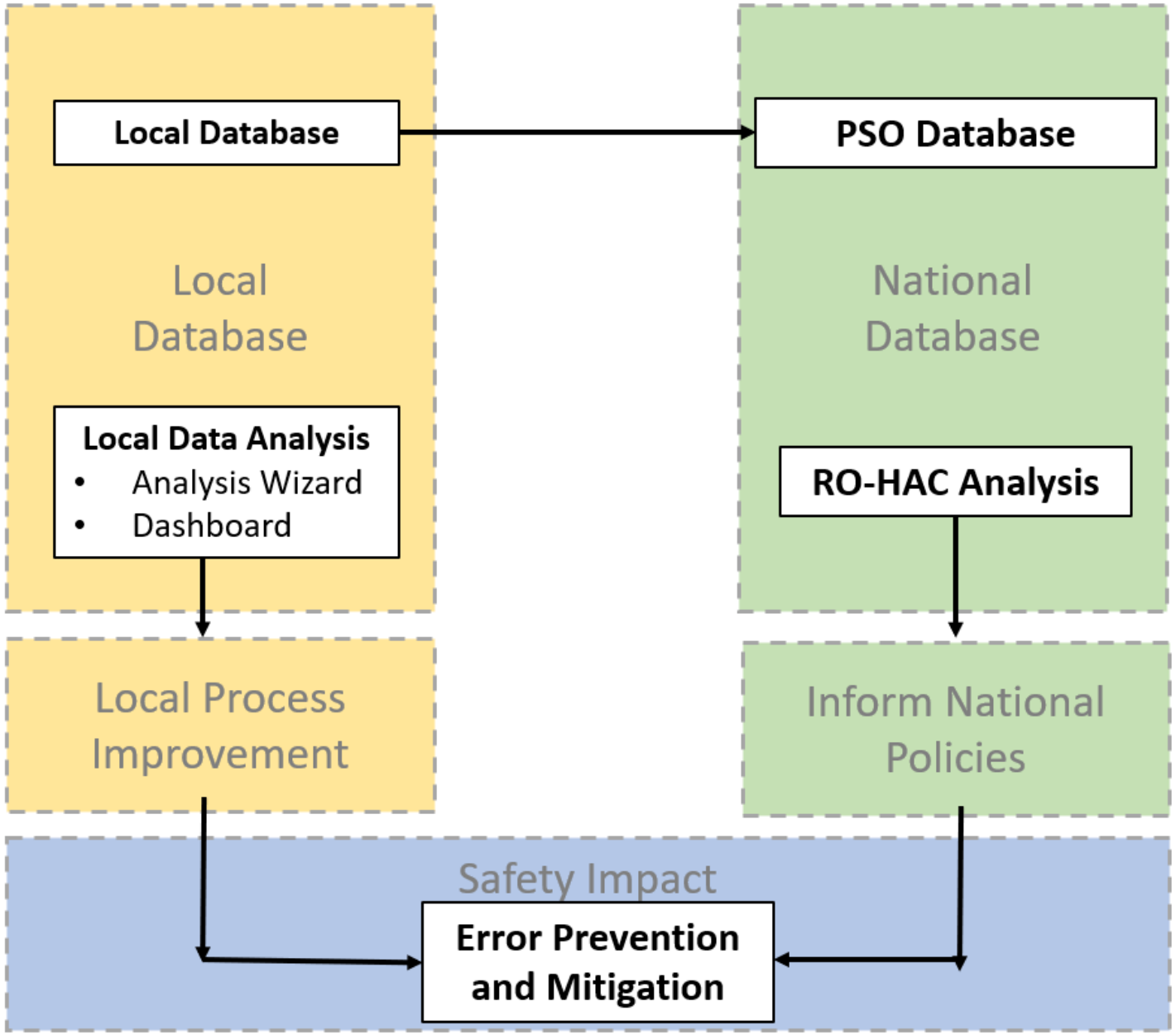
RO-ILS Overview

- Launched June 2014
- 219 Practices; 573 Facilities Enrolled
- Free to Participate
- Web-based Portal

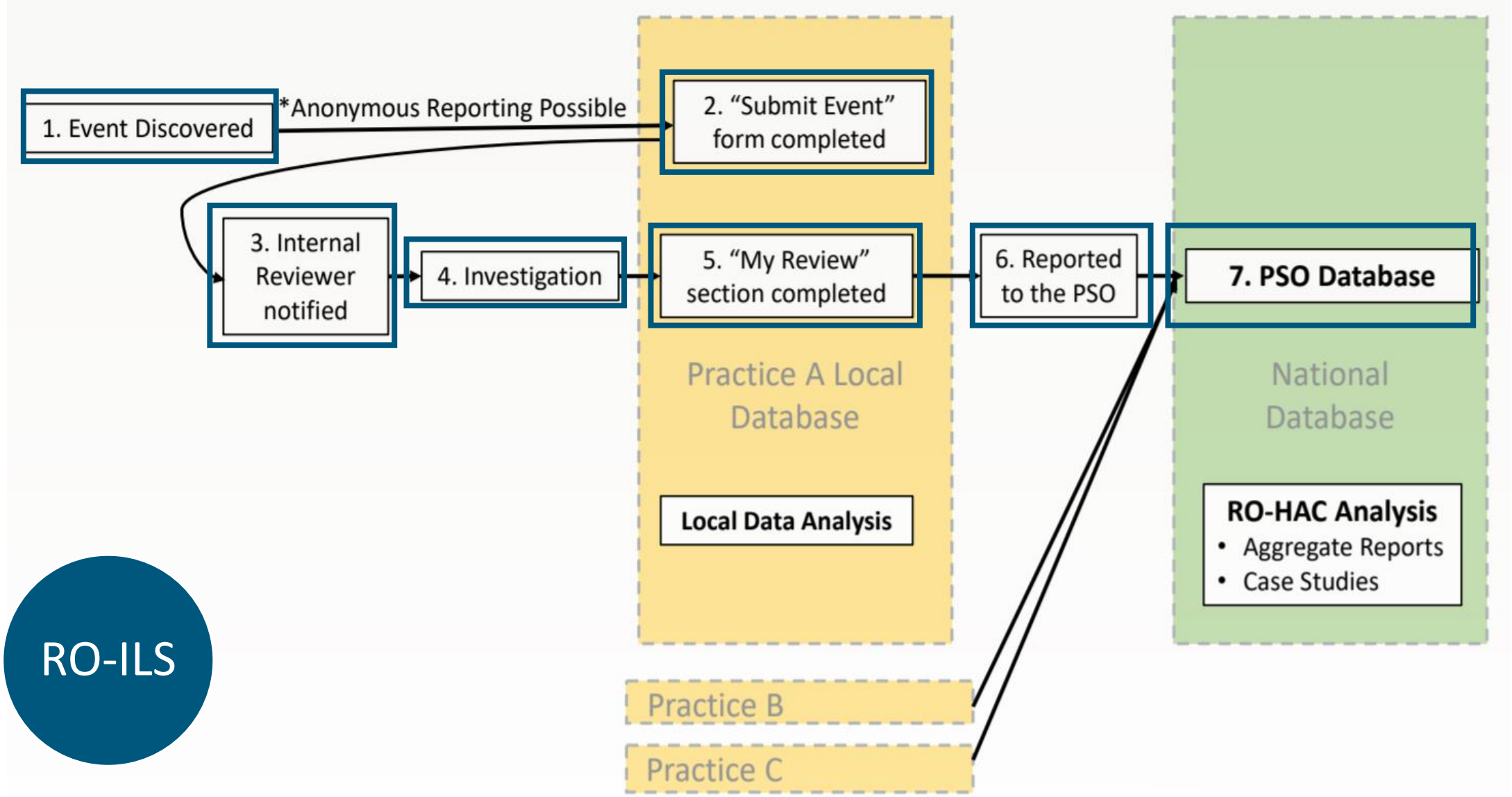


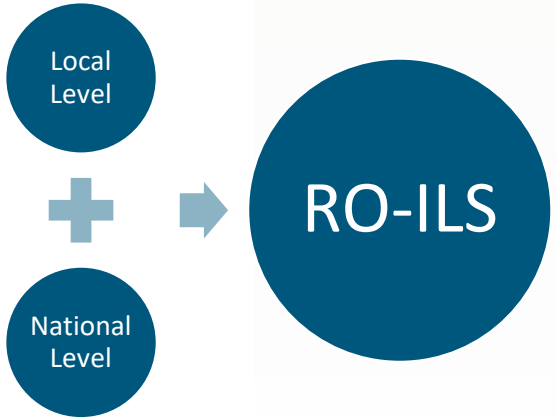
Safety Program





RO-ILS Submission & Reporting Workflow





Incident Learning Cycle

RO•ILS®

Investigate Event

-Reviewers investigate that event and enter additional information into RO-ILS (i.e., "My Review") .

-Report Event to the PSO.

Review Trends

-Local: Utilizing the Analysis Wizard in the RO-ILS Portal, reviewers analyze trends.

-National: Read RO-ILS Aggregate Reports and additional education.

Mitigation Strategies

-With multidisciplinary staff, develop mitigation strategies to address issues.

-Proactively assess processes and identify areas for quality improvement (QI).

Report Findings to All Staff

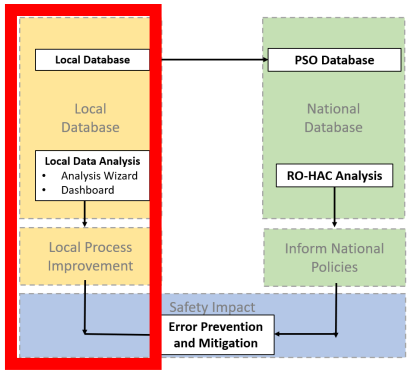
-Discuss case studies.

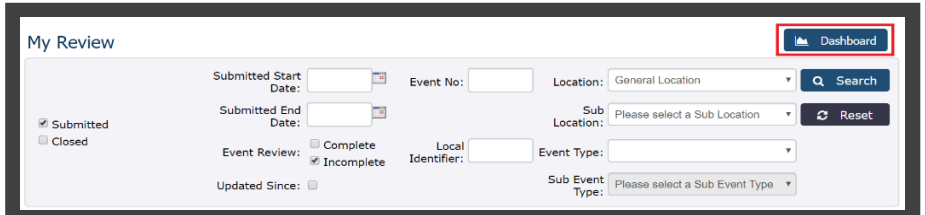
-Present national (e.g., Aggregate Report slide deck) and local findings at staff meetings.

-Engage all staff in incident learning and QI implementation.

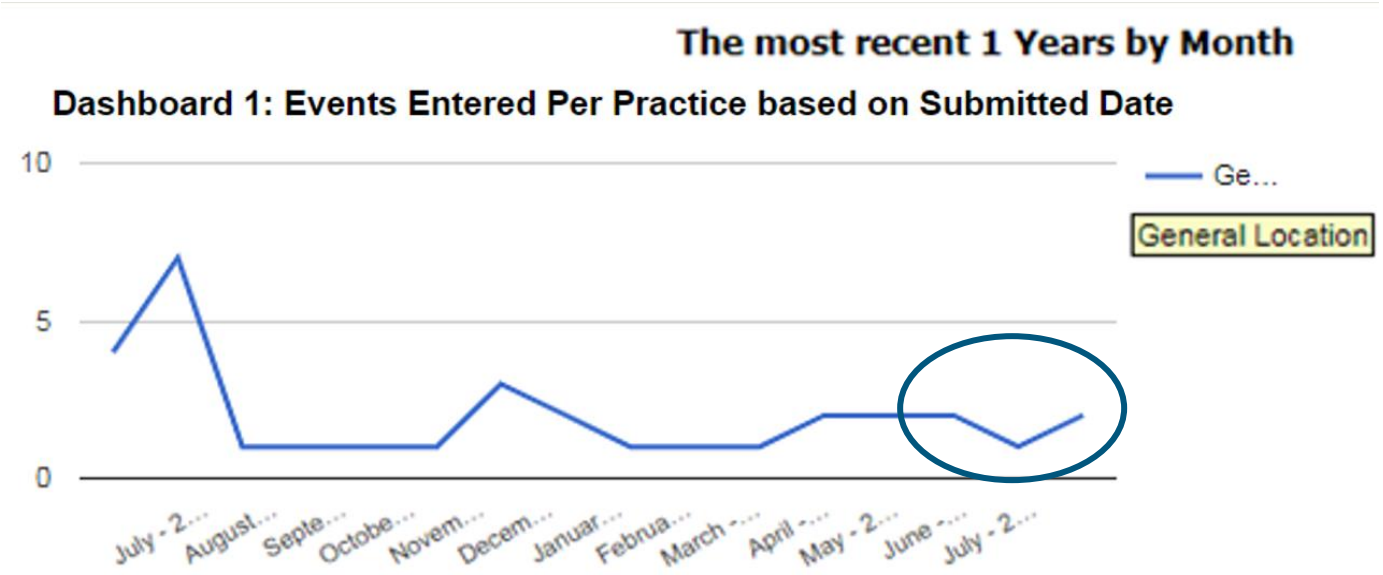
Submit Event

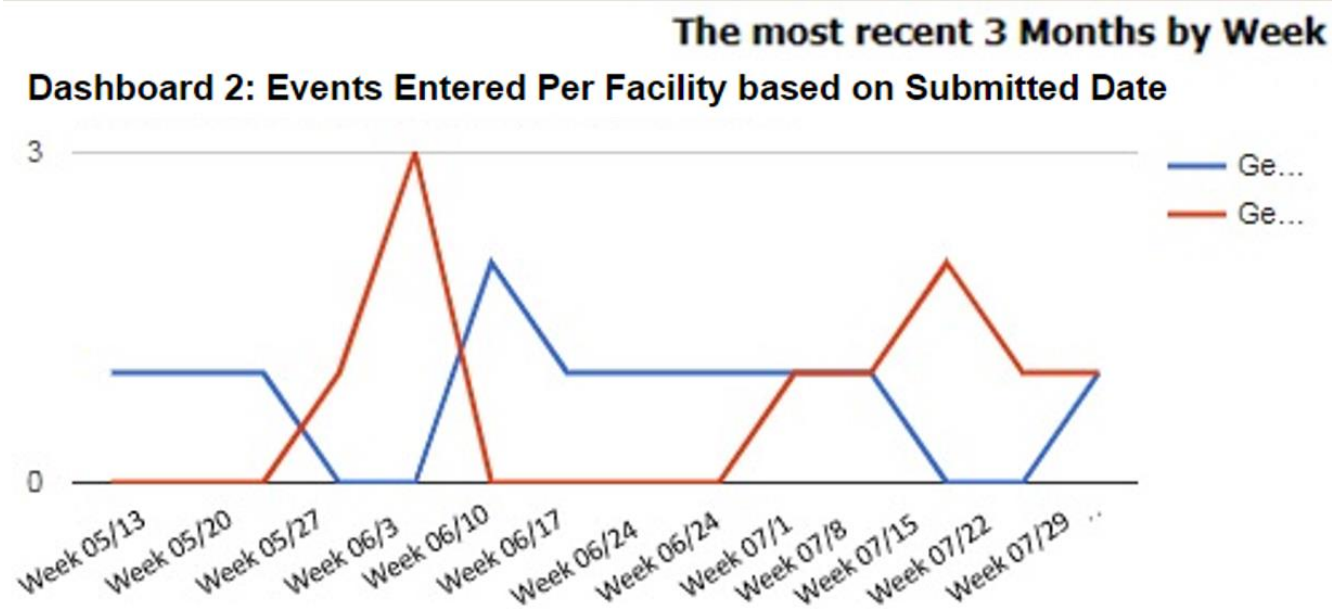
- User enters an event into RO-ILS (i.e., "Submit Event") upon discovery.





Dashboard 1&2: Submitted Events

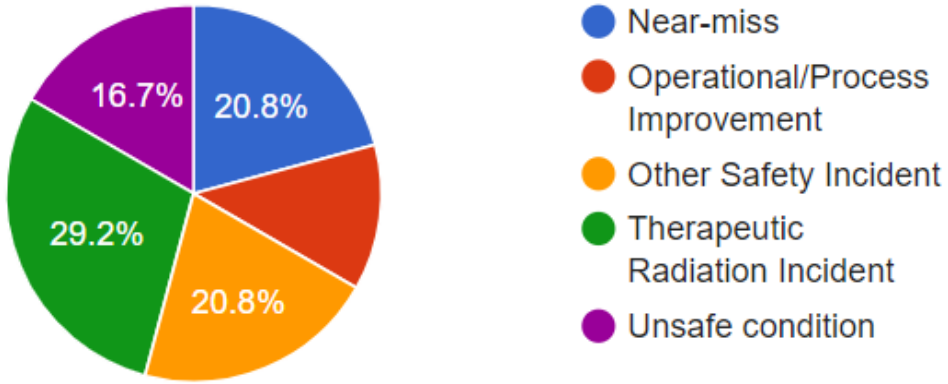




Dashboard 3-6

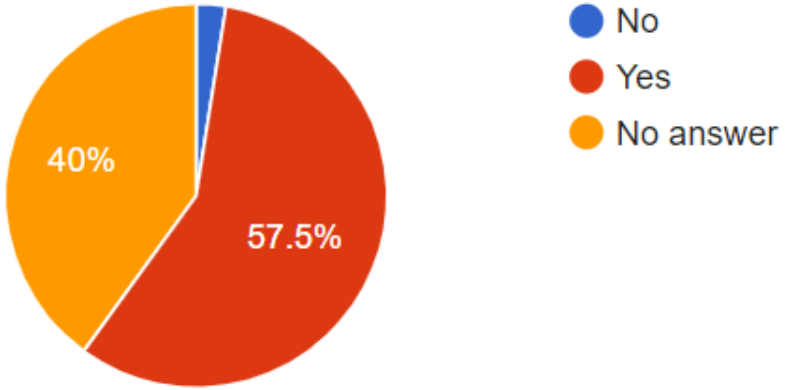
The most recent 1 Years

Dashboard 3: Event Classification of All Entered Events



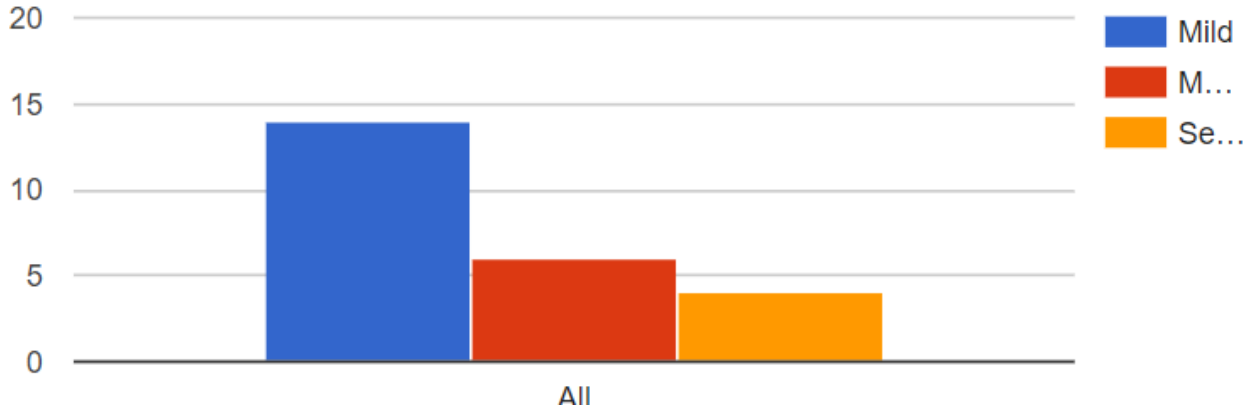
The most recent 1 Years

Dashboard 4: PSO Submission of All Entered Events



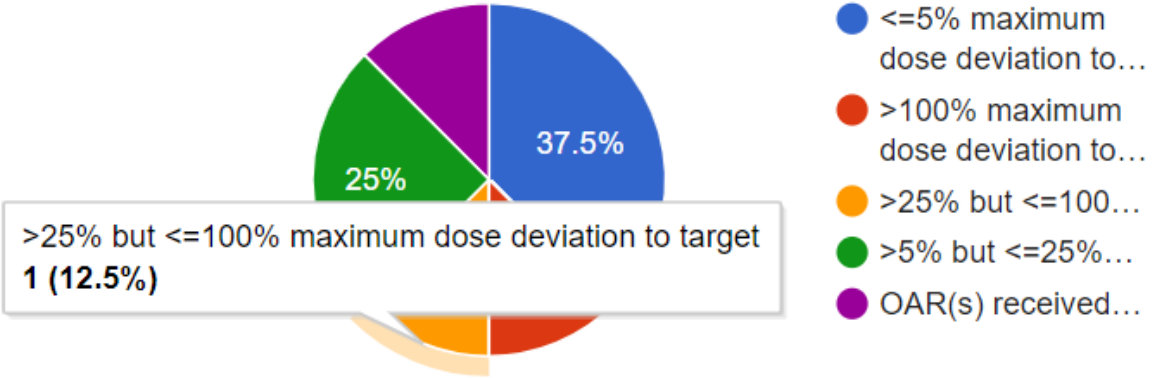
The most recent 1 Years

Dashboard 5: Significance Scale of All Reviewed Events



The most recent 1 Years

Dashboard 6: Dose Deviation of Therapeutic Incidents



Reviewing Trends: Analysis Wizard

Saved Templates | Scheduled Reports

Previous | Next | Reset Search Criteria

- Home
- Time Frame
- Forms
- Event Type
- Primary Locations
- Secondary Locations
- Result Set
- Sorting
- Columns
- Filter
- Export To Excel
- Export To PDF
- Graphing
- Create Saved Template
- Create Scheduled Report

Analysis Wizard

Date Option: Submitted Date / Event Date

Include closed date: Yes / No

Start Date: 06/03/2020

End Date: 06/03/2020

Days: Sunday, Monday, Tuesday, Wednesday, Thursday, Friday, Saturday

Start Time: : AM

End Time: : AM

Previous | Next | Reset Search Criteria

Saved Templates | Scheduled Reports

Form Name: Event Form

Reset Search Criteria

- Home
- Time Frame
- Forms
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- Secondary Locations
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- Create Scheduled Report

40 Record(s) Found **Page Size:** 100

Event Number	10X.Date_Time_Submitted	104.Classification	102.Location_Sub	233.Problem_Type	225.Significance_Scale
34172	5/26/2020 11:19:59 AM	Near-miss	General 1		
34147	5/22/2020 3:20:01 PM	Therapeutic Radiation Incident	General 1	Wrong side (laterality)	Mild
34146	5/22/2020 3:19:39 PM	Unsafe condition	General 2	Wrong anatomical site (excluding laterality)	Mild
34145	5/22/2020 3:19:14 PM	Unsafe condition	General 1	Treatment not delivered: personnel/ hardware/ software failure	Moderate
34144	5/22/2020 3:18:54 PM	Operational/Process Improvement	General 1	Treatment not delivered: personnel/ hardware/ software failure	Moderate
34143	5/22/2020 3:17:49 PM	Near-miss	General 2	Systematic hardware/software (including dose–volume) error	Mild
34142	5/22/2020 3:17:25 PM	Unsafe condition	General 1	Treatment not delivered: personnel/ hardware/ software failure	Mild
34141	5/22/2020 3:17:04 PM	Near-miss	General 1	Inappropriate or poorly informed decision to treat or plan	Moderate
34140	5/22/2020 3:16:32 PM	Other Safety Incident	General 2	Excess imaging	Mild
34139	5/22/2020 3:15:45 PM	Other Safety Incident	General 2	Radiation therapy scheduling error	Severe

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Submit Event

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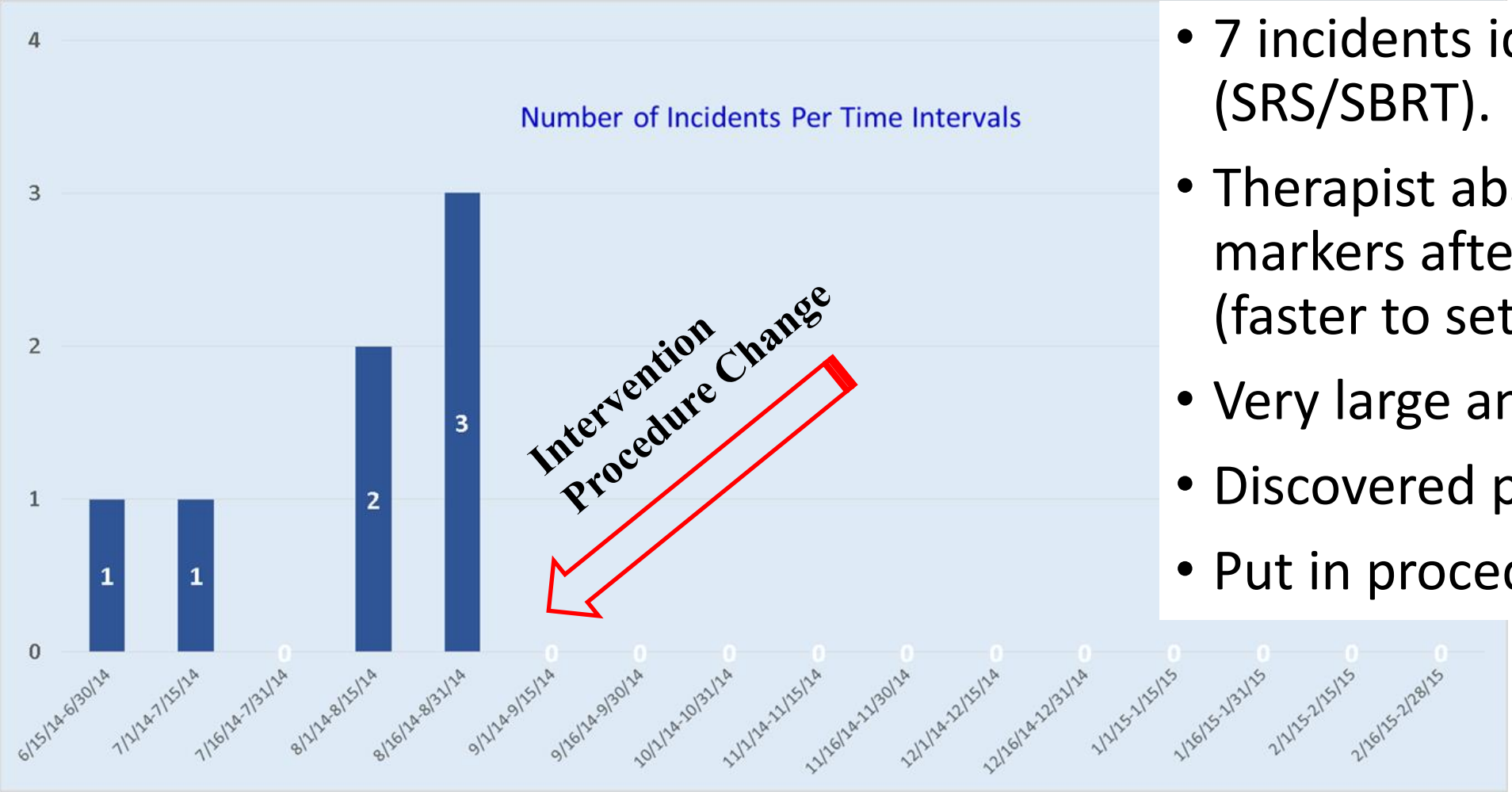
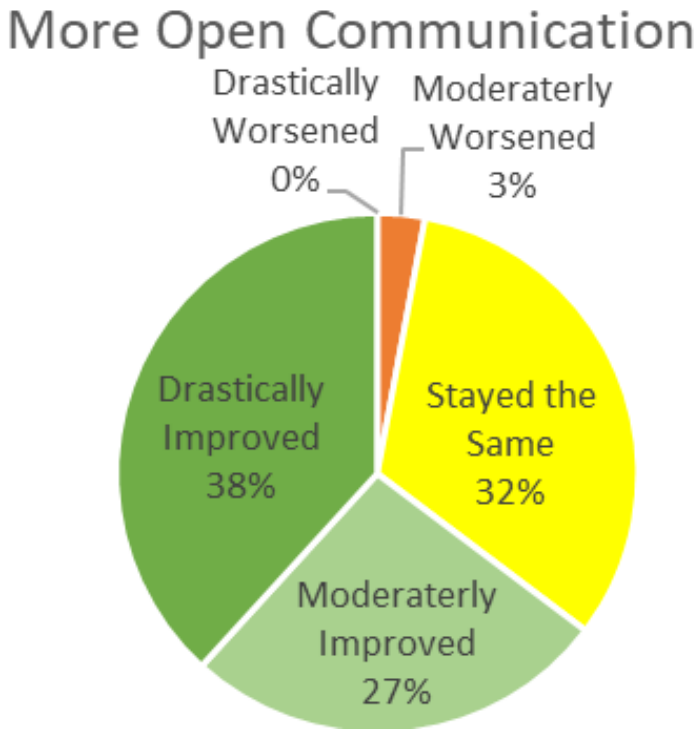
Local Change: RO-ILS Practice Example



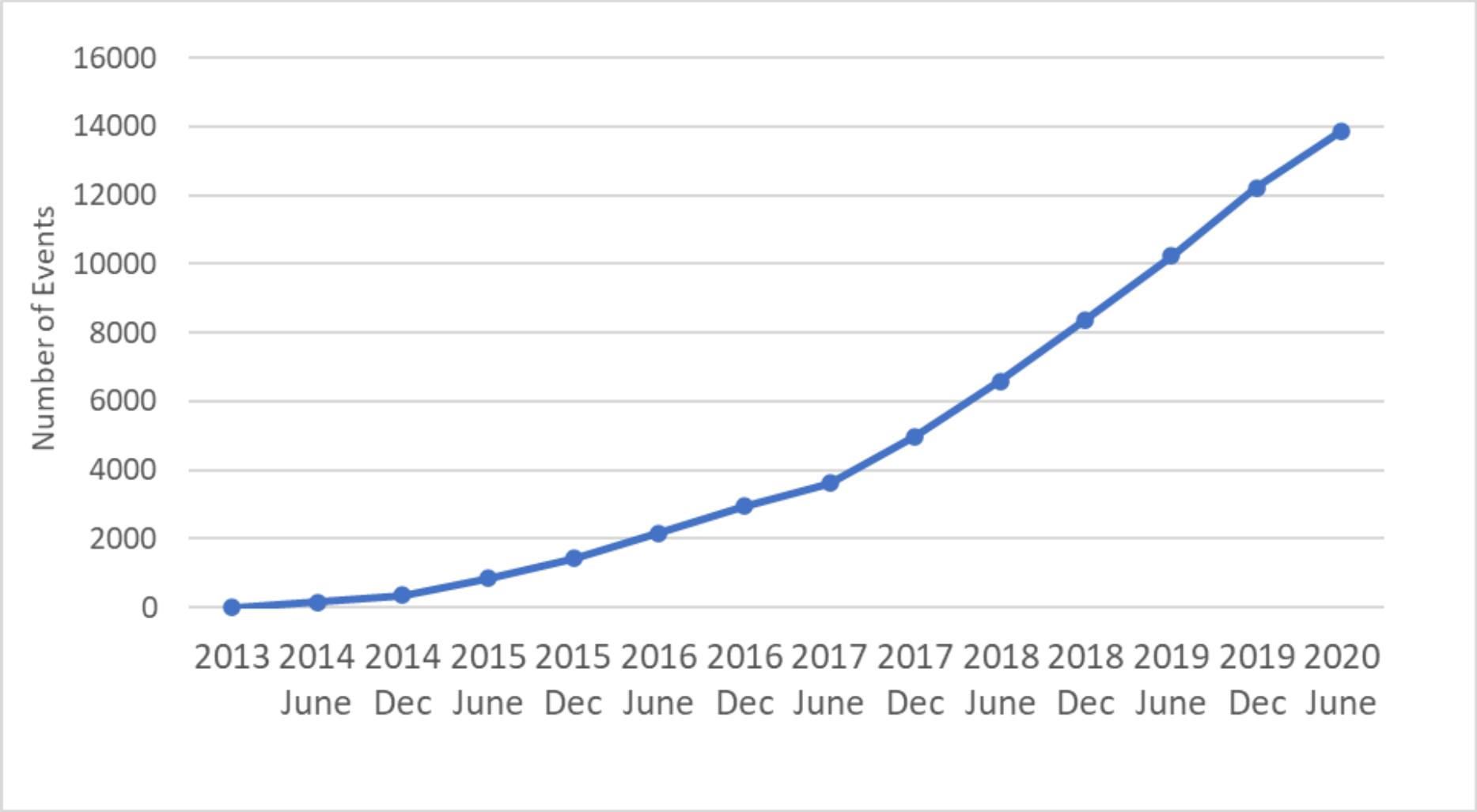
- 7 incidents identified (SRS/SBRT).
- Therapist abandoned infrared markers after the first tx day (faster to set up to lasers).
- Very large and unusual shifts.
- Discovered protocol breach.
- Put in procedural change.

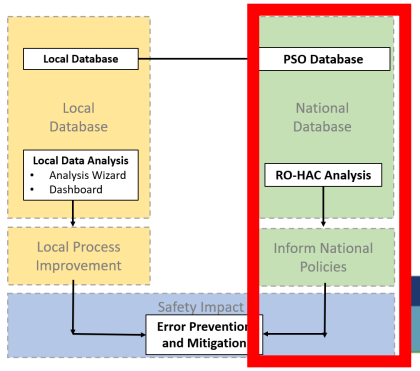
Local Change: Process and Culture

- 2018 RO-ILS User Survey
- Changes or creation of new policies:
  - Example: “overdue contour policy”
- Safety Culture component:
  - More Open Communication
  - More Frequent Reporting of Events
  - More People Involved in Reporting
  - Improved Systems for Responding to Events
  - Higher Expectation that Internal Changes will be Made



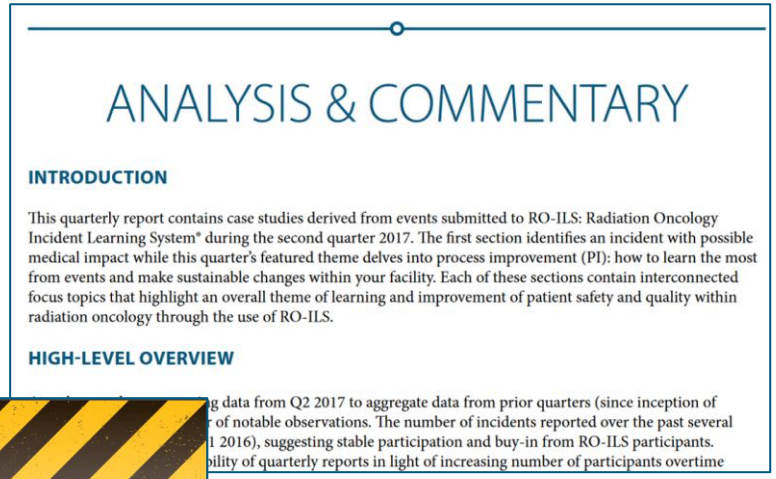
Events Reported to the PSO





National PSO Work

- RO-HAC:
  - 12 radiation oncology experts.
  - Blind review of escalated events reported to the PSO.
  - Analyze trends and identify aggregate findings.
- Aggregate Education:
  - Themed Data Reports
  - Case Studies
  - Safety Notices
  - Continuing Education



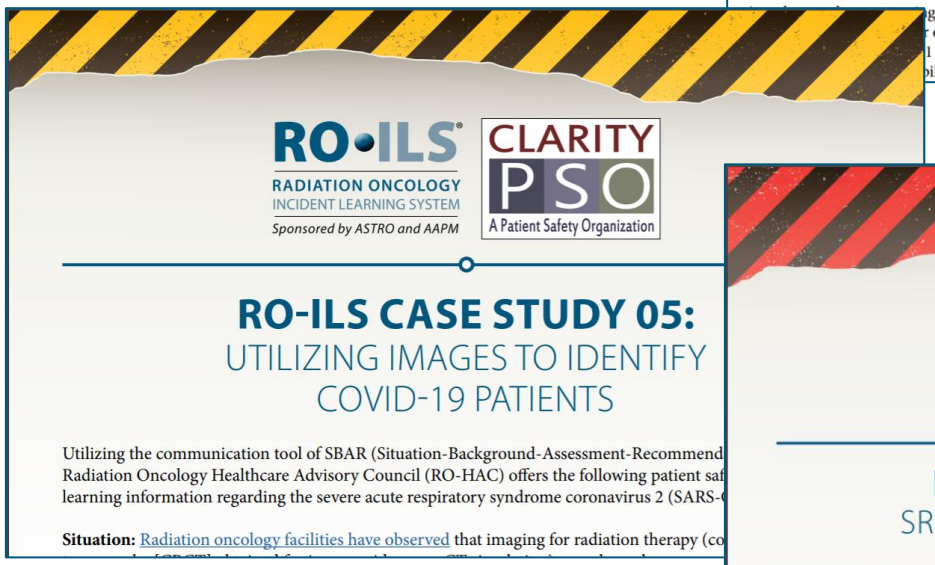
ANALYSIS & COMMENTARY

INTRODUCTION

This quarterly report contains case studies derived from events submitted to RO-ILS: Radiation Oncology Incident Learning System* during the second quarter 2017. The first section identifies an incident with possible medical impact while this quarter's featured theme delves into process improvement (PI): how to learn the most from events and make sustainable changes within your facility. Each of these sections contain interconnected focus topics that highlight an overall theme of learning and improvement of patient safety and quality within radiation oncology through the use of RO-ILS.

HIGH-LEVEL OVERVIEW

g data from Q2 2017 to aggregate data from prior quarters (since inception of
of notable observations. The number of incidents reported over the past several
1 2016), suggesting stable participation and buy-in from RO-ILS participants.
bility of quarterly reports in light of increasing number of participants overtime



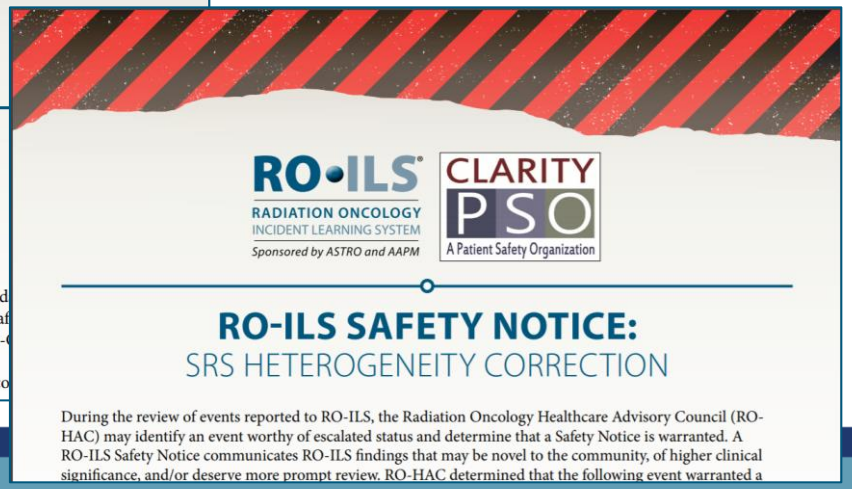
RO-ILS RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM Sponsored by ASTRO and AAPM

CLARITY PSO A Patient Safety Organization

RO-ILS CASE STUDY 05:
UTILIZING IMAGES TO IDENTIFY COVID-19 PATIENTS

Utilizing the communication tool of SBAR (Situation-Background-Assessment-Recommend
Radiation Oncology Healthcare Advisory Council (RO-HAC) offers the following patient saf
learning information regarding the severe acute respiratory syndrome coronavirus 2 (SARS-

Situation: Radiation oncology facilities have observed that imaging for radiation therapy (co



RO-ILS RADIATION ONCOLOGY INCIDENT LEARNING SYSTEM Sponsored by ASTRO and AAPM

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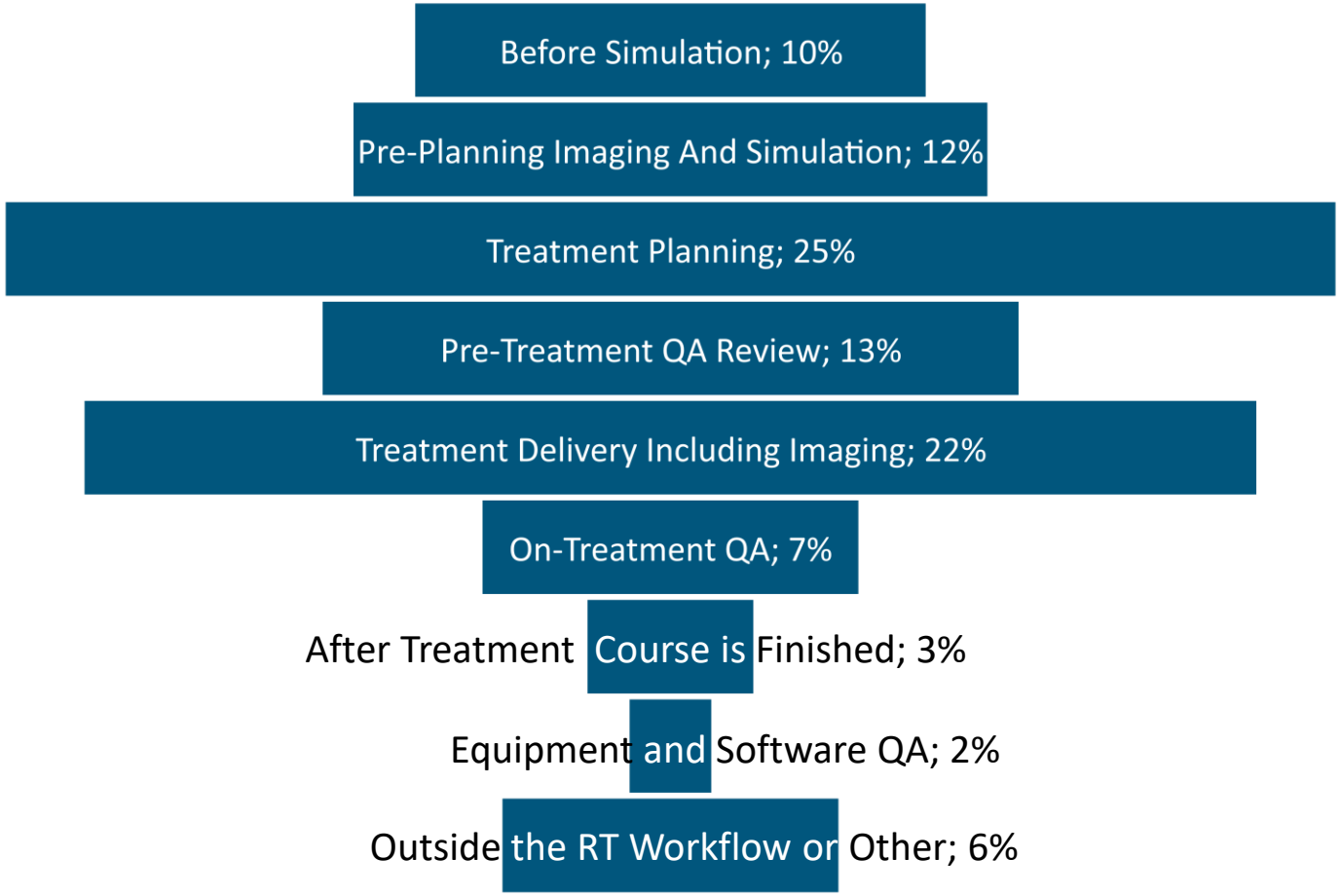
RO-ILS SAFETY NOTICE:
SRS HETEROGENEITY CORRECTION

During the review of events reported to RO-ILS, the Radiation Oncology Healthcare Advisory Council (RO-HAC) may identify an event worthy of escalated status and determine that a Safety Notice is warranted. A RO-ILS Safety Notice communicates RO-ILS findings that may be novel to the community, of higher clinical significance, and/or deserve more prompt review. RO-HAC determined that the following event warranted a

Treatment Planning

Event Occurrence (n=13,871)



Safety Notice 2020

- New SRS program
  - Immobilization included a substantial base plate and accessories.
- Planner contoured equipment in order to account for this new density device in the beam path.
- Physics staff assumed that heterogeneity corrections were accounted for in the new planning software, but they were not.
- ~10% deviation in dose for patients.

Fault Tree Analysis

- 396 events out of 2344 (17%) received a RO-HAC event severity score of 3.5 or higher.
- 173 events fell into one of three major error categories:
  1. Problematic plan approved for treatment.
     A. Problem with imaging used for planning.
     B. Poor plan quality.
  2. Wrong shift instructions given to therapists.
  3. Wrong shift performed at the treatment unit.

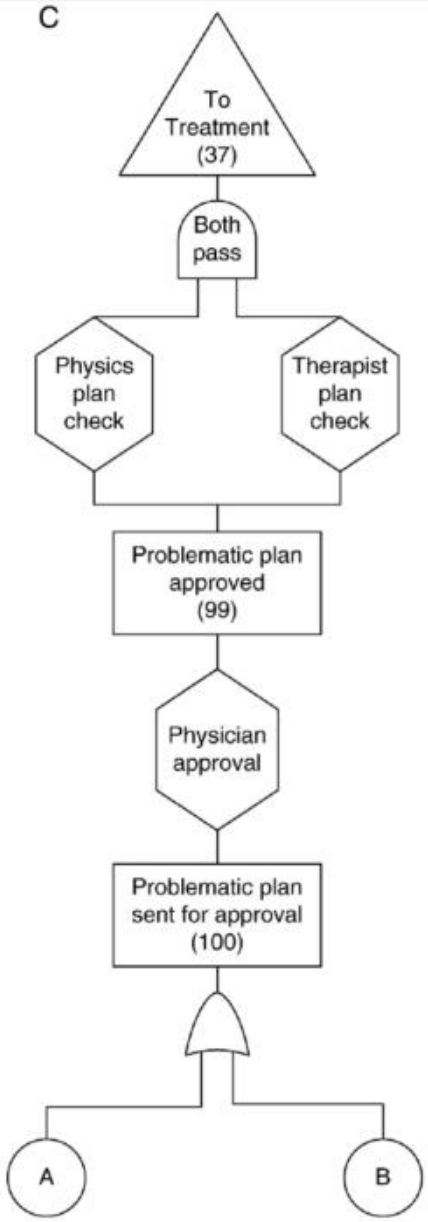
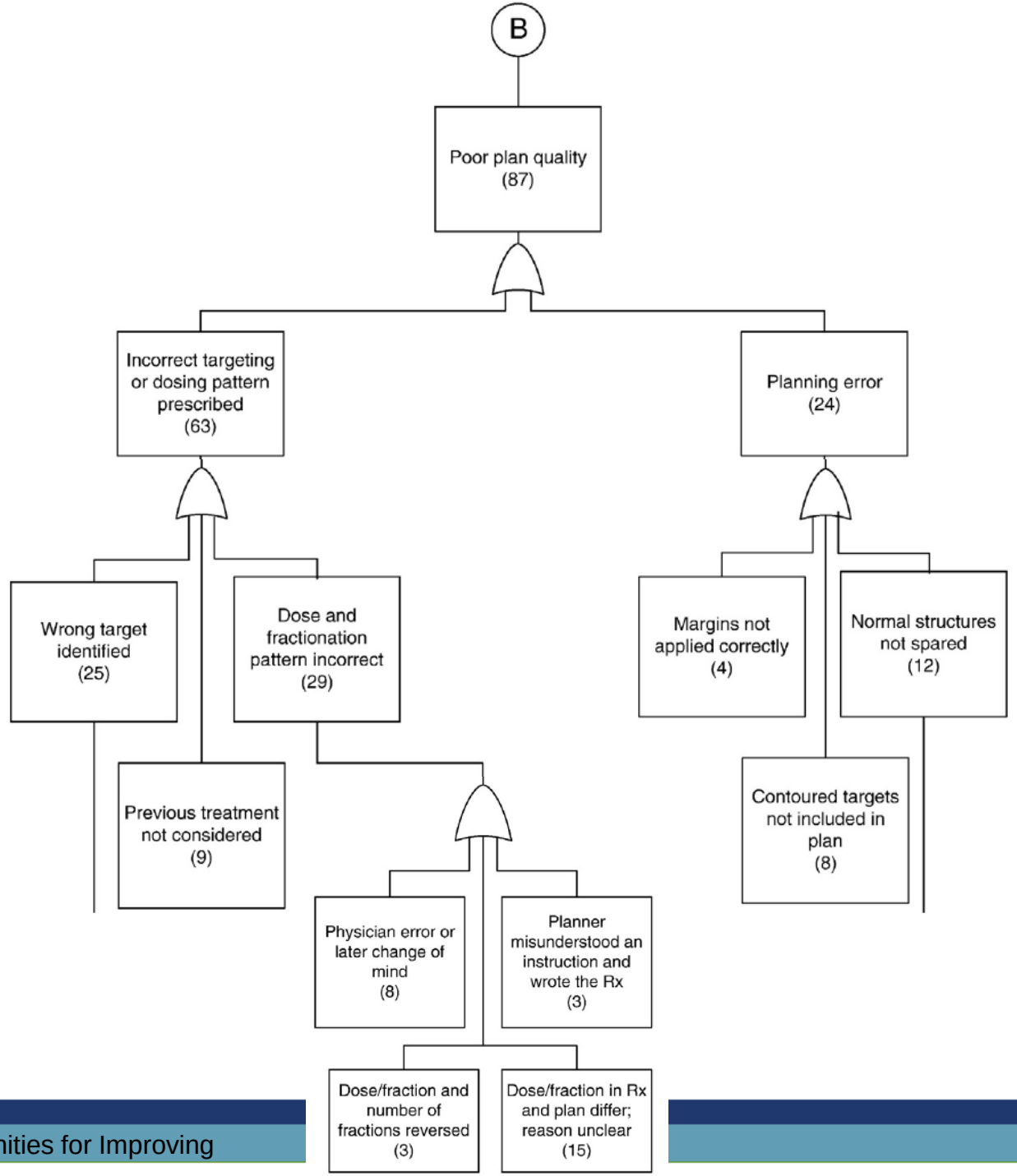


Figure 1 *(continued.)*

Ezzell et al, Common Error Pathways Seen in the RO-ILS Data That Demonstrate Opportunities for Improving Treatment Safety.
Pract Radiat Oncol. 2018; 8(2): 123-132

Fault Tree Analysis

- Case Example:
  - Planner received a verbal order from the physician for a dose of “12 in 2”
    - Interpreted as 6 fx of 2 Gy
    - Physician intended 2 Fx of 6 Gy
  - Planner prepared the plan and Rx for physician to sign. After 2 treatments were delivered, the error was detected in chart rounds.



Ezzell et al, Common Error Pathways Seen in the RO-ILS Data That Demonstrate Opportunities for Improving Treatment Safety. *Pract Radiat Oncol*. 2018; 8(2): 123-132

Trends: Prescription Errors

- RO-ILS Survey 2017
- 41% respondents indicated that verbal instructions are communicated.
- 48% respondents reported *only* the attending physicians drafts formal Rx.
- ASTRO Standard Rx White Paper

Tx Site	Delivery Method	Dose per Fraction	Fraction Number	Total Dose

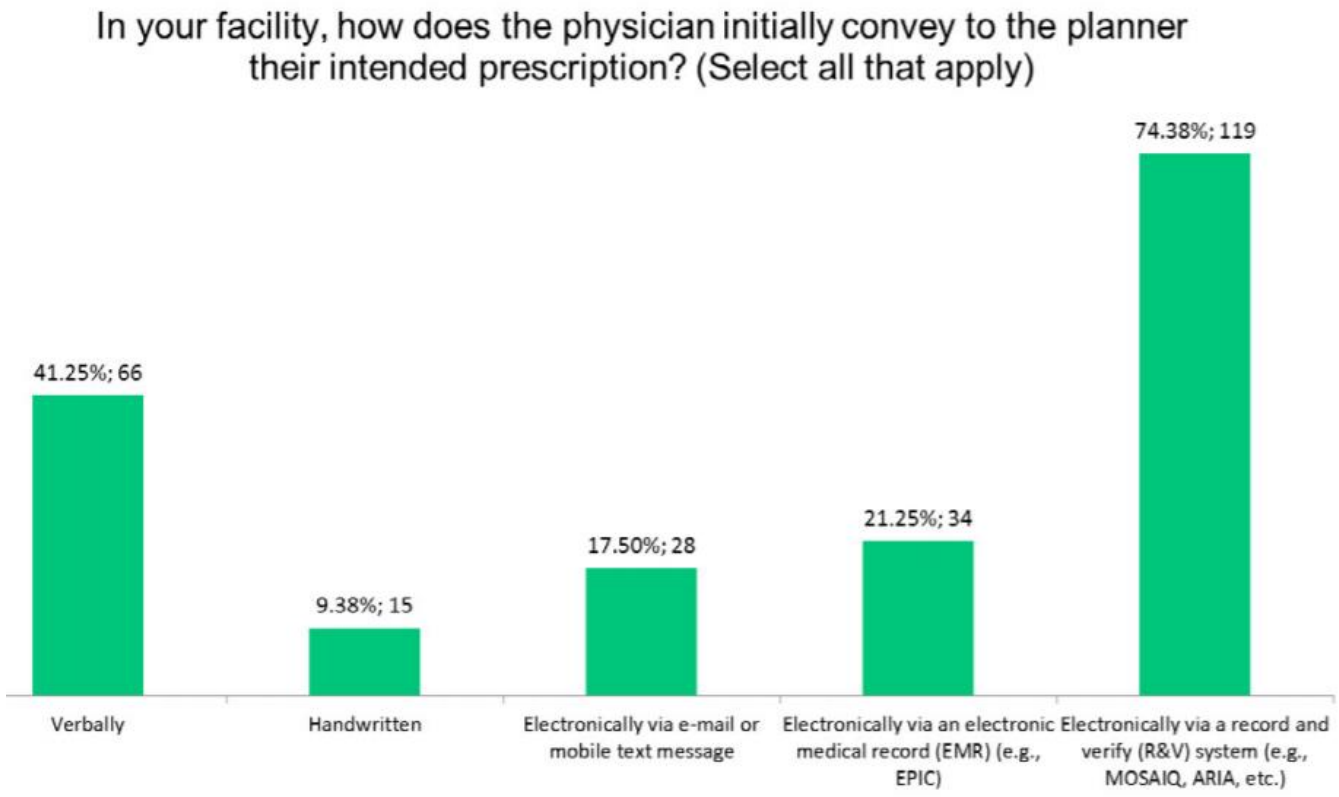


Figure 6. Initial Method of Prescription Communication (n=160)

Why Incident Learning? Why RO-ILS?

- Collect safety data.
- Identify and address error pathways.
- Educate the community.
- Reduce adverse events.
- Promote safety culture.

Quality Improvement Tools

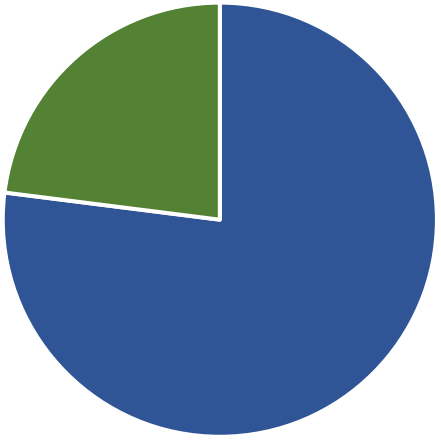
- Incident learning
- Plan-Do-Study-Act cycle
- AAPM TG-100 report
- Safety Profile Assessment (SPA) tool
- Lean, Six Sigma, Kaizen methodology
- Flow charts, process mapping, checklists
- **Accreditation**

APEx- Accreditation Program for Excellence®

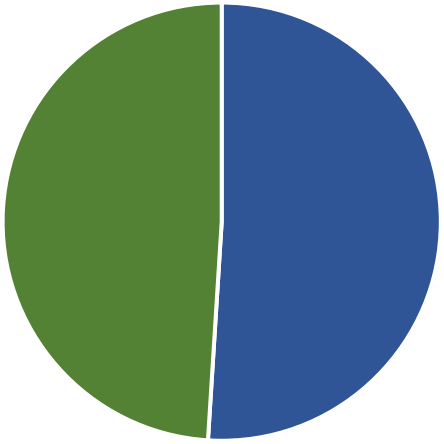
An ASTRO Quality Improvement Initiative

APEx Overview

Practice type



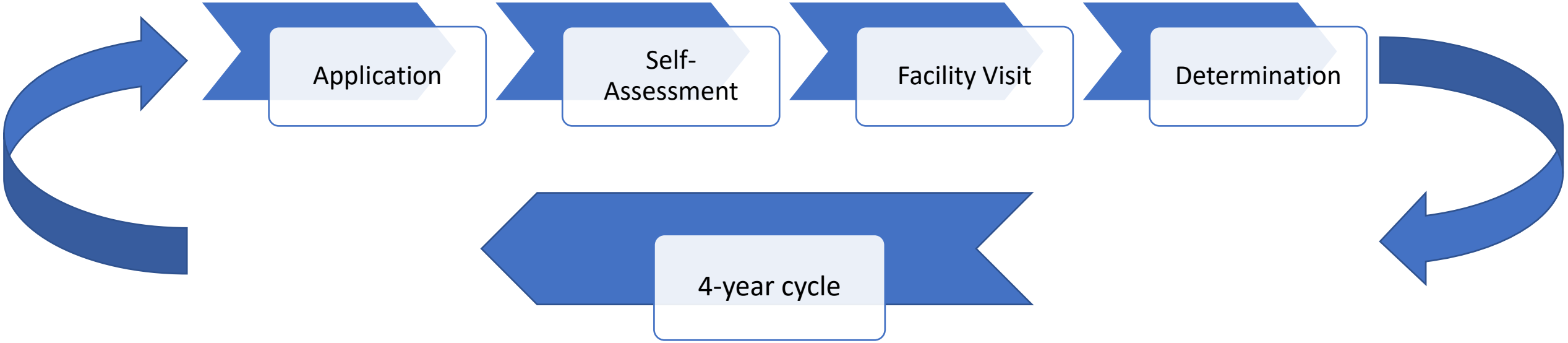
Applicant type



■ Community/Private ■ Academic

■ Single facility ■ Multi-facility

APEx Accreditation



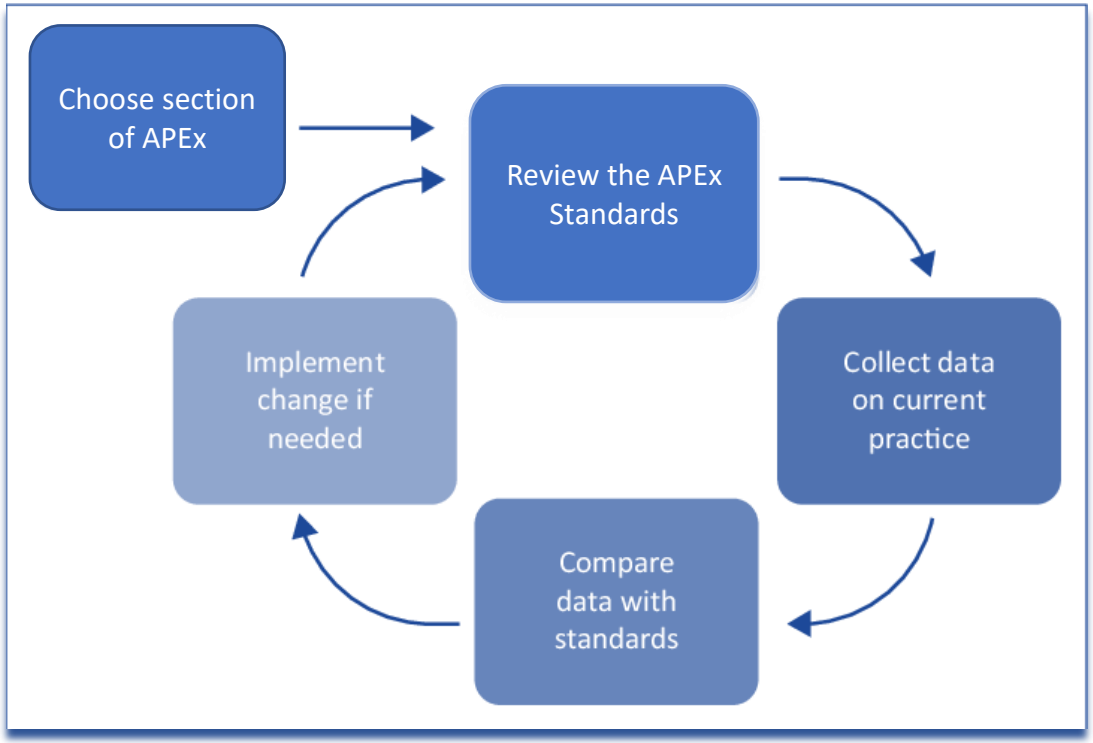
APEx Program

Self-Assessment

3 sections:

- **Medical Record Review**
- **Document Uploads**
- **Interview Preparation**

3 attempts



APEx Standards

233 Program requirements

- Dosimetry focus areas:
  - Pre-treatment
  - Data transfer
  - Treatment planning
  - Quality management
  - Board certification and training
  - On-boarding and competency assessment
  - Culture of safety
  - Peer review

Dosimetry Focus Areas

- **Pretreatment**
  - Simulation directive/order
  - Patient preparation
  - Simulation process
- **Data transfer**
  - DICOM transfer between sim and TPS
  - Data input/transfer between systems
  - Previous treatment to new providers
- **Treatment planning**
  - Prescription and planning directive
  - Treatment plan generation
  - Approvals/checks
- **Supervision**
  - Non board-certified dosimetrists
  - Students
- **Training**
  - Board certification
  - On-boarding and competency assessment
  - On-going training
- **Quality management**
  - Standard operating procedures
  - Data deviations
- **Culture of safety**
  - Policies and environment
  - Leadership
  - Event reporting, investigation and feedback
  - Learning
- **Peer review**
  - Dosimetrist-to-dosimetrist

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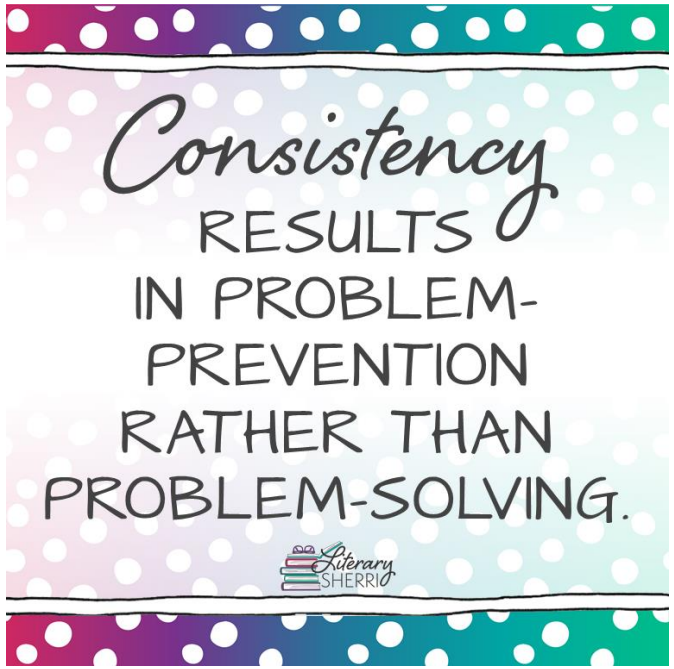
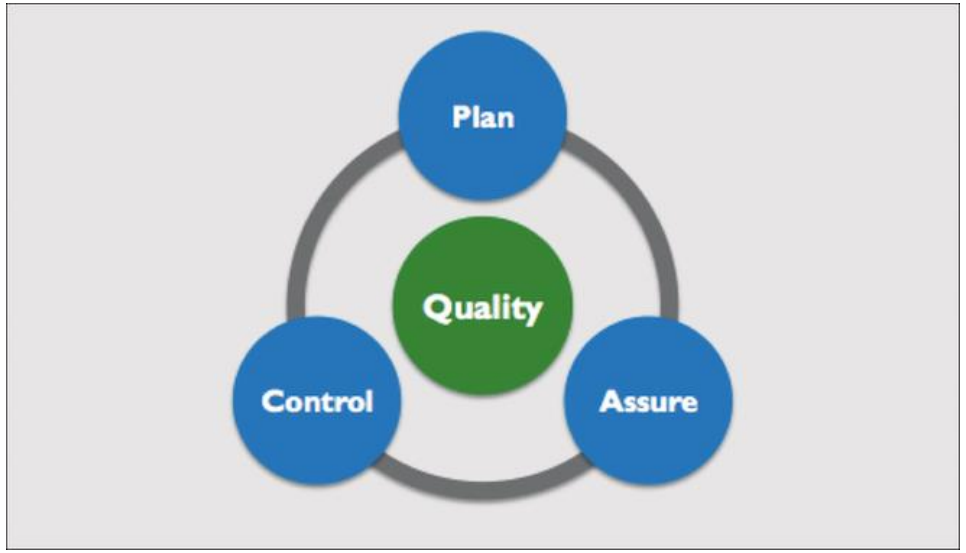
  - Prescription and planning directive
  - Treatment plan generation
  - Approvals/checks
- **Supervision**
  - Non board-certified dosimetrists
  - Students
- **Training**
  - Board certification
  - On-boarding and competency assessment
  - On-going training
- **Quality management**
  - Standard operating procedures
  - Data deviations
- **Culture of safety**
  - Policies and environment
  - Leadership
  - Event reporting, investigation and feedback
  - Learning
- **Peer review**
  - Dosimetrist-to-dosimetrist

Quality Improvement

Quality Management



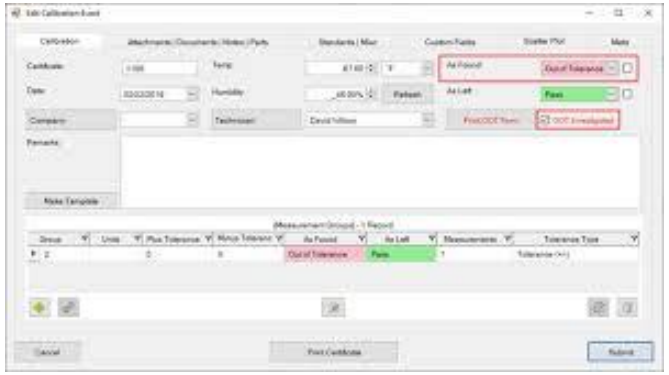


Quality Management

- **Standard operating procedures (SOPs)**
  - Define and set expectations
  - Provide guidance
  - Encourage compliance
  - Promote consistency and efficiency
  - Reduce incidents

Quality Management

- **Data deviations**
  - Set tolerances
  - Define a process for deviations

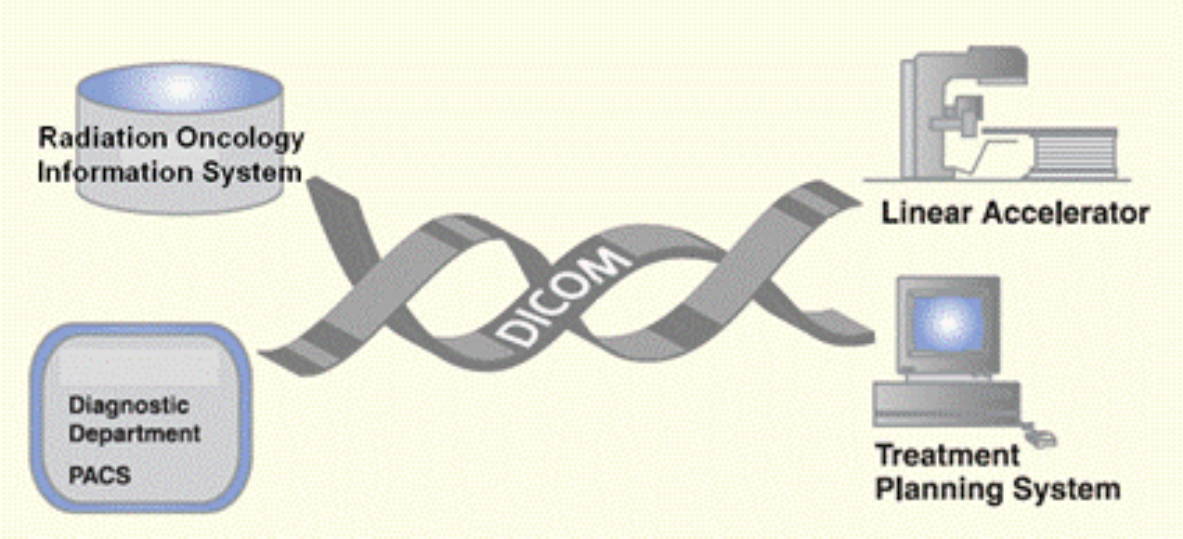


Data transfer

- DICOM transfer between systems
- Data input/transfer between systems
- Previous treatment to new providers

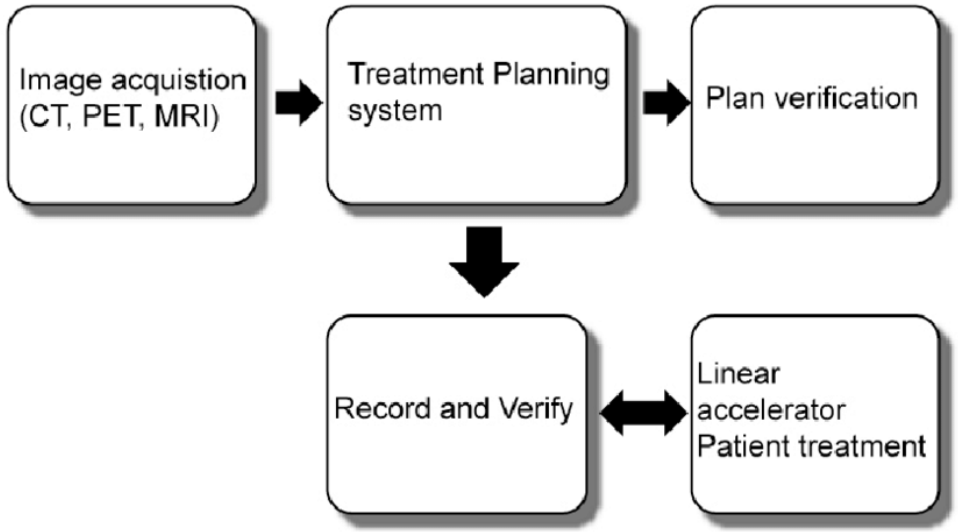
Data transfer

- DICOM transfer between systems



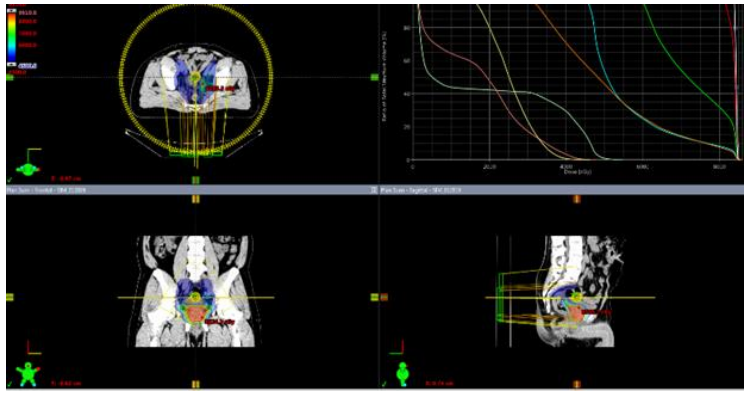
Data transfer

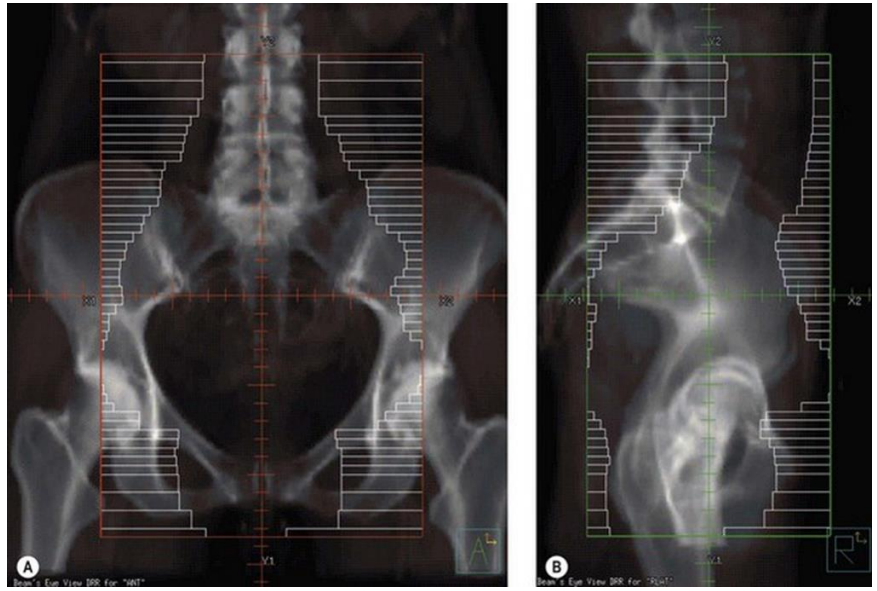
- Data input/transfer between systems

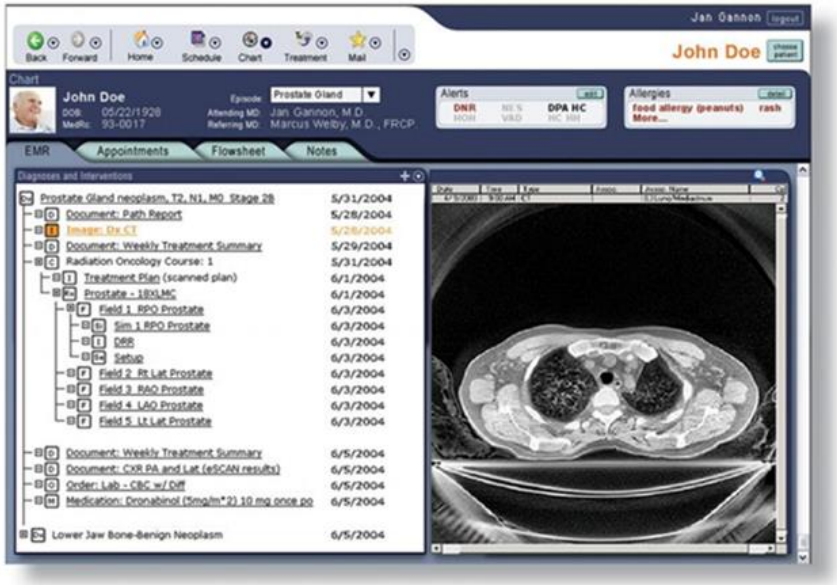


Data transfer

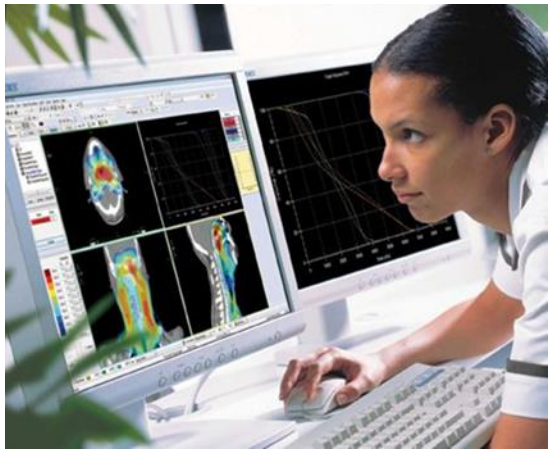
- Previous treatment to new providers







Treatment planning directive



"Pre-op" Rectum Treatment Planning Directive

Primary Physician: <Primary Care Physician-Name (Default)>

Imaging: Tx planning CT

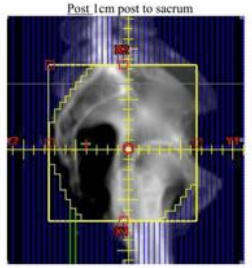
Target(s):	Priority:	Drawn by:	Dataset:	Instructions:
GTV	____	MD	CT	____
____	____	____	____	____

Normal Structures:	Priority:	Drawn by:	Dataset:	Planning Limits:
____	____	____	____	____
____	____	____	____	____

Plan Parameters: ☐ **3 field standard**

Post Field :
Sup Border mid L5
Inf Border mid tuberosity or 2cm below GTV & exclude anal marker
Lat Borders 1.5cm wider than bony pelvis

Lateral Fields:
Same Sup and Inf borders
Ant 2cm ant to vertebral body
Post 1cm post to sacrum



Standard Dose to Initial Fields: ☐ 1.8Gy/fx to 45Gy or ____

Standard Boost Fields: ☐ For all fields, close superior border to bottom of SI joints
☐ ____

Boost Dose: ☐ 1.8Gy/fx to 5.4Gy for total dose of 50.4Gy or ☐ ____

Medical Necessity: Reason to justify extra Special Treatment Procedure Charge 77470 and IMRT
Extra effort Choose One ____ Choose One ____ Choose One ____ Choose One ____

Other Instructions: ____

Completed by: <Authored By> <Current Date>

Attending Signature: <Approved By> <Approved date time>
Electronically signed by controlled access password

Normal Structures: (check all to be contoured)	Priority	Parameter	Goal	Notes/Comments
☐ Lungs-GTV	1 or	Bio-NTCP (α/β=2.5) [Med Phys Consult]	<15% or	
☐ Lungs-ITV	1 or	Mean	<15.0 Gy or	
	1 or	V20.0 Gy	<35% or	
	1 or	V5.0 Gy*	<65% or	
☐ Esophagus*	1 or	Max (0.1 cc)	<105% Rx or	
	1 or	Mean	<34 Gy or	
☐ Heart	1 or	Max (0.1 cc)	<105% Rx or	
☐ Pericardium	1 or	Mean	<30 Gy or	
	1 or	V30.0 Gy	<50 % or	
	1 or	V40.0 Gy	<35 % or	
☐ SpinalCanal	1 or	Max (0.1 cc)	<45.0 Gy or	
☐ SpinalCanal _PRV5	1 or	Max (0.1 cc)	<50.0 Gy or	
☐ BrachialPlex_R	1 or	Max (0.1 cc)	<60.0 Gy or	
☐ BrachialPlex_L				
☐				
☐				

Note: Limits based on RTOG 1106 or more conservative
*For IMRT/VMAT Plans

Target Coverage & Conformality Goals:

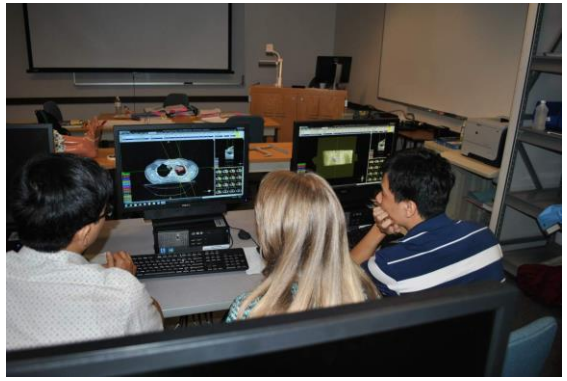
Name	Priority	Parameter	Goal	Notes/Comments
PTV(s)	2 or	Dose covering 95% PTV	Rx Dose	
	2 or	Min Dose (0.1 cc)	93% Rx Dose	
	2 or	Max Dose (0.1 cc)	107% Rx Dose	
Conformity Index	2 or	Rx Isodose Vol/PTV	< 1.5 (If not met, consider IMRT)	

Dose Prescription:
Choose

Peer Review

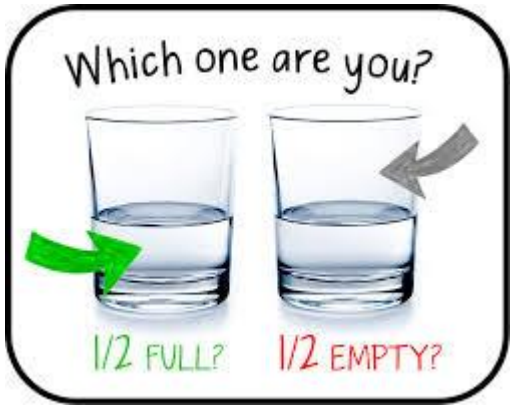
- Multi-disciplinary
  - Between specialties in oncology
  - Radiation oncology, medical oncology, surgical oncology
  - e.g. tumor boards
- Inter-disciplinary
  - Between professions in radiation oncology
  - Radiation oncologists, medical physicists, therapists, dosimetrists, nurses
  - e.g. chart rounds, safety meetings, huddles
- **Intra-disciplinary**
  - Between colleagues
  - Dosimetrist-to-dosimetrist

Peer review



Final thoughts on APEx

Dosimetrists that initiate and lead the APEx process at their facility.



ASTRO estimates there are approximately 2300 radiation oncology practices in the US. Half of them are accredited.

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  - MIPS
  - RO-APM
- TJC/NAPBC
- CE/MOC
- Public Message

Thank you!

We hope you enjoyed this presentation.

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