RO-ILS Data Elements

** This field is required.*
Data elements are listed in the order in which they appear in the RO-ILS Portal.

"SUBMIT EVENT" Page

101. Question: *Location:
Response Options: The response options are specific to each contract.
Branching Logic: None

102. Question: *Sub Location:
Response Options: The response options are specific to each contract.
Branching Logic: None

103. Question: *Additional Location:
Response Options: The response options are optional and at the discretion of the practice.
Branching Logic: If applicable, based on contract.

104. Question: *Event Classification:
Response Options:
- o Therapeutic Radiation Incident: Radiation dose not delivered as intended, with or without harm
- o Other Safety Incident: Event that reached the patient, not involving radiation dose, with or without harm (examples: collision, fall, etc.)
- o Near-miss: A safety event that did not reach the patient
- o Unsafe condition: Any condition that increases the probability of a safety event
- o Operational/Process Improvement: non-safety event

Branching Logic: None

105. Question: *Narrative: (Briefly describe the event, 4000 character limit)
Response Options: Free Text
Branching Logic: None

106. Question: *Treatment Technique Pertinent to Event: (Select all that apply)
Response Options:
- ☐ 2D
- ☐ 3D
- ☐ IMRT/VMAT
- ☐ SRS/SBRT
- ☐ Particles (Protons)
- ☐ Electrons
- ☐ Intraoperative
- ☐ kV x-rays (i.e. Orthovoltage and superficial)

- ☐ LDR
  - ▶ List LDR radioisotope (manufacturer, if applicable) and applicator:
- ☐ HDR
  - ▶ List HDR radioisotope (manufacturer, if applicable) and applicator:
- ☐ Radiopharmaceuticals
  - ▶ List Radiopharmaceutical radioisotope (manufacturer, if applicable):
- ☐ Total body irradiation (TBI)
- ☐ Not Applicable
- ☐ Other
  - ▶ *Specify 'Other' Treatment Technique:

Branching Logic: None

107. Question: Local Identifier:
Response Options: Free Text
Branching Logic: None

109. Question: *Date and Time the Event Occurred:
Response Options: MM/DD/YYYY, XX:XX AM/PM
Branching Logic: None

108. Question: Reporter's Name:
Response Options: Free Text
Branching Logic: None

"MY REVIEW" PAGE

201. Question: Event Title: (200 character limit):
Response Options: Free Text
Branching Logic: None

233. Questions: *Problem Type:
Response Options:
- o Laterality incorrect
- o Anatomical site (excluding laterality) incorrect
- o Patient incorrect
- o Patient position, setup point, treatment isocenter, or shift change incorrect
- o Treatment accessories: incorrect, missing, mislabeled, misused or damaged
- o Prescription, dose, fractionation incorrect or not matching physician intent
- o Dose calculation error
- o Target or OAR contours incorrect or omitted
- o Planning margins incorrect
- o Treatment plan isodose distribution unacceptable
- o Treatment undeliverable: plan (dosimetrically acceptable) but not physically deliverable
- o Treatment undeliverable: staff unavailable (excluding patient factors)
- o Treatment undeliverable: hardware/software unavailable

o Hardware/software malfunction or product improvement/enhancement
o Imaging: excess, inadequate, or not matching physician intent
o Access to timely care issue (insurance, transportation, etc.)
o Decision-making suboptimal or made on clinical information which is insufficient or incorrect
o Coordination with other health care providers inadequate
o Delay/issue in workflow or error in RT scheduling
o Fall, patient injury, or acute medical event
o Other
▶ *Specify 'Other' Problem Type:

Branching Logic: None

Note: This data element has been adapted with permission from the National System for Incident Reporting – Radiation Treatment Minimum Data Set (Ottawa, Ont.: CIHI, 2022).

202. Question: Role of Person Who Discovered the Event: (Select all that apply)

Response Option:

☐ Administrator
☐ Dosimetrist
☐ Nurse, NP or PA
☐ Patient or Patient Representative
☐ Physician
☐ Physicist
☐ Radiation Therapist
☐ Other
▶ *Specify 'Other' Discoverers' Role:

Branching Logic: None

203. Question: Patient's Age:

Response Options:

o 0-28 days
o 29 days to less than 1 year
o 1-12 years
o 13-17 years
o 18-64 years
o 65-74 years
o 75-84 years
o 85+ years
o Unknown
o Report not patient related

Branching Logic: None

204. Question: Patient's Gender:

Response Options:

o Female
o Male
o Non-binary
o Unknown
o Report not patient related

Branching Logic: None

205. Question: Supplemental Information/Additional Follow-up to Event Narrative:

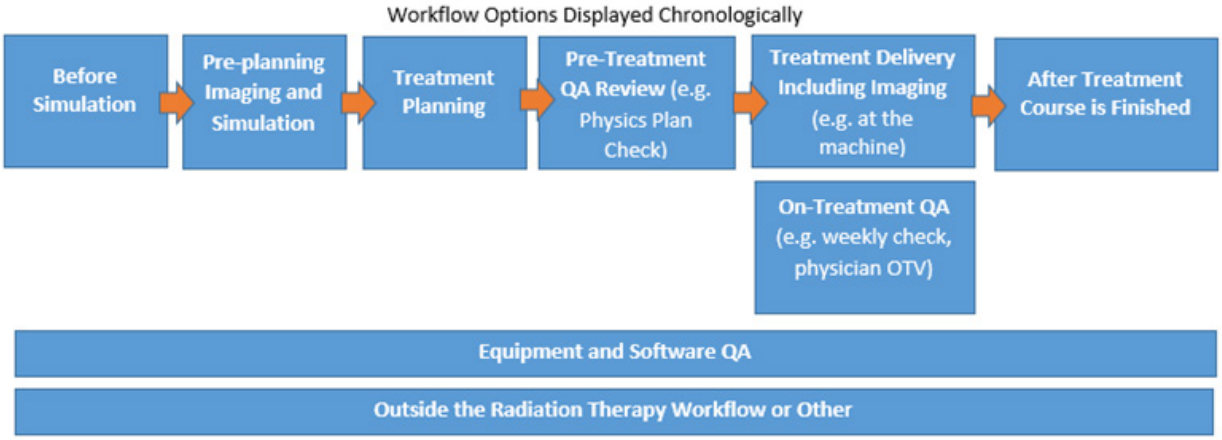
Response Options: Free Text

Branching Logic: None

206. Question: How was the event discovered?

Response Options: Free Text

Branching Logic: None



207. Question: *In what workflow step was the event first discovered?

Response Options:

o Before Simulation
o Pre-planning Imaging and Simulation
o Treatment Planning
o Pre-Treatment QA Review (e.g. Physics Plan Check)
o Treatment Delivery Including Imaging (e.g. at the machine)
o On-Treatment QA (e.g. weekly check, physician OTV)
o After Treatment Course is Finished
o Equipment and Software QA
o Outside the Radiation Therapy Workflow or Other
▶ *Specify 'Other' Workflow Step of Discovery:

Branching Logic: None

208. Question: *In what workflow step(s) did the event occur? (Select all that apply)

Response Options:

- ☐ Before Simulation
- ☐ Pre-planning Imaging and Simulation
- ☐ Treatment Planning
- ☐ Pre-Treatment QA Review (e.g. Physics Plan Check)
- ☐ Treatment Delivery Including Imaging (e.g. at the machine)
- ☐ On-Treatment QA (e.g. weekly check, physician OTV)
- ☐ After Treatment Course is Finished
- ☐ Equipment and Software QA
- ☐ Outside the Radiation Therapy Workflow or Other
  - ▶ *Specify 'Other' Workflow Step of Occurrence:

Branching Logic: None

209. Question: Treatment Imaging Being Used: (Select all that apply)

Response Options:

- ☐ kV or MV radiographs
- ☐ kV or MV Cone-beam CT
- ☐ Ultrasound
- ☐ Electromagnetic Transponders
- ☐ Optical (surface) imaging
- ☐ MRI
- ☐ None
- ☐ Not Applicable
- ☐ Other
  - ▶ *Specify 'Other' Imaging:

Branching Logic: If "Therapeutic Radiation Incident" selected for #104

210. Question: *Was this a systematic error that affected multiple patients?

Response Options:

- o Yes
- o No

Branching Logic: If "Therapeutic Radiation Incident" **OR** "Other Safety Incident" selected for #104

211. Question: How many patients were affected by the error?

Response Options: Free Text

Branching Logic: If "Yes" selected for #210

212. Question: *What was the dose deviation for the course of treatment between the planned total prescription and the delivered dose? (Select all that apply)

(Note: If you need to unselect an answer option, unselect **ALL** options before reselecting the correct option(s). This will ensure that you receive the follow-up questions.)

Response Options:

- ☐ ≤5% maximum dose deviation to target
- ☐ >5% but ≤25% maximum dose deviation to target

- ☐ >25% but ≤100% maximum dose deviation to target
- ☐ >100% maximum dose deviation to target
- ☐ OAR(s) received more than intended but within tolerance levels
- ☐ OAR(s) received more than intended and exceeded tolerance levels
- ☐ Not Applicable

Branching Logic: If "No" selected for #210

213. Question: How many fraction(s)/treatment(s) were delivered incorrectly?
Response Options: Free Text
Branching Logic: If response options 1-6 selected for #212

214. Question: How many total fractions were prescribed for the course of treatment?
Response Options: Free Text
Branching Logic: If response options 1-6 selected for #212

232. Question: *Was a dosimetric change to the plan (e.g., replanning) made as a result of the event?
Response Options:
o Yes
o No
Branching Logic: None

215. Question: *Was this event equipment related?
Response Options:
o Yes
o No
Branching Logic: None

216. Question: Simulator (Manufacturer: Type) related to this event, if applicable:
Response Options: A standardized list is provided. Practices can choose to display a subset of the list.
Branching Logic: If "Yes" selected for #215

217. Question: Treatment Planning System (Manufacturer: Model) related to this event, if applicable:
Response Options: A standardized list is provided. Practices can choose to display a subset of the list.
Branching Logic: If "Yes" selected for #215

218. Question: Treatment Management System: OIS (Manufacturer: Model) related to this event, if applicable:
Response Options: A standardized list is provided. Practices can choose to display a subset of the list.
Branching Logic: If "Yes" selected for #215

234. Question: Treatment Management System: EHR (Manufacturer: Model) related to this event, if applicable:
Response Options: A standardized list is provided. Practices can choose to display a subset of the list.
Branching Logic: If "Yes" selected for #215

219. Question: Treatment Delivery Equipment: External Beam Photon/Electron (Manufacturer: Model) related to this event, if applicable:
Response Options: A standardized list is provided. Practices can choose to display a subset of the list.
Branching Logic: If "Yes" selected for #215

220. Question: Treatment Delivery Equipment: Particles (Manufacturer: Model) related to this event, if applicable:
Response Options: A standardized list is provided. Practices can choose to display a subset of the list.
Branching Logic: If "Yes" selected for #215

235. Question: Treatment Delivery Equipment: Brachytherapy (Manufacturer: Type/Model) related to this event, if applicable:
Response Options: A standardized list is provided. Practices can choose to display a subset of the list.
Branching Logic: If "Yes" selected for #215

221. Question: Other Equipment: QA, Accessories, Devices (Manufacturer: Type/Model) related to this event, if applicable:
Response Options: A standardized list is provided. Practices can choose to display a subset of the list.
Branching Logic: If "Yes" selected for #215

236. Question: Please specify any additional information (e.g., version, secondary equipment) regarding the equipment involved in this event.
Response Options: Free Text
Branching Logic: If "Yes" selected for #215

222. Question: *Do you want to report this event to the PSO?
(Note: **"Yes" is the default answer. Unless you affirmatively select "No," your event will be reported to the PSO.** Once reported to the PSO, you cannot retract the information. Reports will be updated if/when additional data are added after submission to the PSO. All information remains in the RO-ILS portal.)
Response Options:
o Yes
o No
Branching Logic: None

223. Question: *Have you reported, or do you anticipate reporting, this event outside of RO-ILS/PSES?
(Note: If information about this event is needed outside of RO-ILS/PSES, HHS recommends that providers should maintain at least two separate systems, one for PSWP and one for maintaining records for external obligations.)
Response Options:
o Yes
o No
o Don't know

Branching Logic: None

224. Question: To whom was the event reported? (Select all that apply)

Response Options:

- ☐ FDA
- ☐ NRC
- ☐ State
- ☐ Vendor/Manufacturer
- ☐ Other
  - ▶ *Specify 'Other' External Entity:

Branching Logic: If "Yes" selected for #223

225. Question: *In terms of risk to patient safety, how significant was this event?

Response Options:

- o Mild
- o Moderate
- o Severe

Branching Logic: None

226. Question: What might prevent future events like this?

Response Options: Free Text

Branching Logic: None

227. Question: What changes, if any, has the facility made in response to the event?

Response Options: Free Text

Branching Logic: None

228. Question: Please provide any additional details in the space provided below:

Response Options: Free Text

Branching Logic: None

229. Question: You may use this space for your internal use (i.e. internal tags):

Response Options: Free Text

Branching Logic: None

230. Question: *Status:

Response Options:

- o Submitted
- o Closed

Branching Logic: None

Note: "Submitted" is the default answer. User should change event status to "Closed" when the

event review and investigation has been completed.

231. Question: Contributing factors: (Select all that apply)

Response Options:

1. Organizational Management

a. Inadequate Resources

- ☐ Inadequate human resources
- ☐ Inadequate capital resources

b. Policies, Procedures, Regulations

- ☐ Relevant policy nonexistent
- ☐ Policy inadequate
- ☐ Policy not followed
- ☐ Conflicting policies
- ☐ External regulation (e.g. state/federal) not followed

c. Training

- ☐ Facility training inadequate
- ☐ Vendor-provided training inadequate
- ☐ Inadequate assessment of staff competencies
- ☐ Lack of continuing education

d. Leadership and Culture

- ☐ Inadequate safety culture
- ☐ Failure to remedy past known shortcomings
- ☐ Hostile work environment
- ☐ Inadequate supervision
- ☐ Lack of peer review
- ☐ Outdated practices

e. Physical Environment

- ☐ Physical environment inadequate
- ☐ Distractions or Interruptions in the environment

2. Communication

- ☐ Poor, incomplete, unclear or missing
- ☐ Lack of timeliness
- ☐ Inadequate communication patterns designed
- ☐ Failure to request needed information
- ☐ Written documentation in EMR incorrect/incomplete/absent
- ☐ Verbal instructions inconsistent with documentation

3. Procedural issues

a. Failure to detect a developing problem or appreciate its nature/importance

- ☐ Environmental masking (e.g. noise or obscuring interference)
- ☐ Distraction and loss of attention
- ☐ Lack of information
- ☐ Expectation Bias (e.g. expecting to observe a certain effect and therefore being biased toward seeing it)

b. Failure to interpret the nature of the developing problem

- ☐ Inadequate search
- ☐ Missing information
- ☐ Incorrect information

c. Failure to develop an effective plan to combat the problem

- ☐ Information not seen or sought
- ☐ Information misinterpreted
- ☐ Inappropriate assumptions
- ☐ Unintended consequences

d. Failure to execute the planned action

- ☐ Plan started but not completed
- ☐ Plan misinterpreted
- ☐ Plan too complicated

- ☐ e. Inadequate quality assurance and quality control

4. Technical

a. Acceptance testing and commissioning

- ☐ Not following or reviewing established best-practice (AAPM TG reports, ASTRO, ACR, IPEM, COMP, etc.)
- ☐ Lack of independent review
- ☐ Lack of effective documentation (vendor or self)

b. Equipment design and operations

- ☐ Inadequate policies and procedures for quality assurance and quality control
- ☐ Poor human factors engineering
- ☐ Interoperability problem
- ☐ Networking (IT) or Software problems
- ☐ Treatment machine downtime (non-software/IT)
- ☐ Other equipment/hardware failure (non-software/IT)

c. Equipment maintenance issues

- ☐ Failure to report problems to vendor
- ☐ Failure to follow vendor notices (field change orders)
- ☐ Failure to provide adequate preventive maintenance
- ☐ Failure on the vendor's part to share failure/safety issues in a timely manner
- ☐ Unavailability of local and field support

d. Environment (within the facility and external)

- ☐ Ergonomics (room layout, equipment setup)
- ☐ Machine collision issues (room specific)
- ☐ Environment (water, HVAC, electrical, gas)

- ☐ Natural environment/disasters and hazards

5. Human behavior involving staff
   - ☐ Compressed time scale, rushing
   - ☐ Acting outside one's scope of practice
   - ☐ Slip causing physical error (failure in performance of highly developed skills as intended or maintained)
   - ☐ Intentional rules violations (sabotage/criminal acts, criminal intent, intentional violation)
   - ☐ Negligence (risky behavior, poor judgment in failure to address issues or extreme demands, lack of vigilance; recklessness)
   - ☐ Failure to follow through

   - ☐ 6. Patient-focused circumstances

   - ☐ 7. Other
   - ▶ *Specify 'Other' Contributing Factor:

Branching Logic: None