

Medical Radiological Events (RPO art 49-50): first outcomes from a multidisciplinary group analysis of the registry

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Outline

- Introduction on the FOPH requirements (RPO 2017 revision)
- Stages of the implementation of the radiation incident reporting system and incident analysis in our institute
- Analysis of the medical radiation incidents in a Radiation Oncology Department
- Analysis of the medical radiation incidents in a Radiology Department
- Summary

FOPH requirements - definitions

- Radiological Protection Ordinance (*in force since 1.1.2018*)

Art. 49 Definition

A medical radiation incident is an unplanned event in the form of a careless or inappropriate action, with or without actual consequences, which, as a result of deficiencies in the quality assurance programme, technical malfunctions, operator error or other incorrect behaviour, led or could have led to unintended exposures of patients.

- **Adverse event:** any event related to the care process **leading to patient harm**, which is unintentional and unwanted.
- **Near miss:** any event that **could have caused patient harm but did not**. However, a recurrence of this event carries a significant chance of adverse outcome (an error was committed but the patient did not experience any clinical harm, either by chance or timely intervention).

For radiation protection purposes: **harm = unplanned exposure**

FOPH requirements – duties

Art. 50 Duties

¹ Licence holders must keep a record of medical radiation incidents.

→ CIRS

² They must, with an interdisciplinary working group, regularly analyse any incidents which have occurred and make the operational adjustments required to prevent similar incidents.

→ Interdisciplinary team for incident analysis

³ They must report the following medical radiation incidents to the supervisory authority within 30 days:

- a. unplanned exposures which led or could have led to moderate organ damage, moderate functional impairment or more serious damage in the patient;
- b. confusion of patients or organs in therapeutic exposures or in diagnostic exposures in the high-dose range;
- c. unplanned exposures where the patient received an effective dose of more than 100 mSv.

→ Report to UFSP:

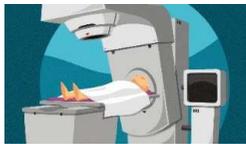
- Patient harm
- Confusion of patients or organs
- Effective dose > 100 mSv

⁴ In the case of medical radiation incidents as specified in paragraph 3, the licence holder must conduct an investigation and submit a report in accordance with Article 129.

Implementation of the radiation incident record and analysis

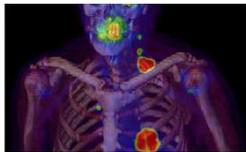


Multisite Hospital



Radiation Oncology:

- 2 Hospitals
- ~ 800 treatments/year



Nuclear Medicine:

- 2 Hospitals
- ~ 8K exams/year



Radiology (diagnostic and interventional):

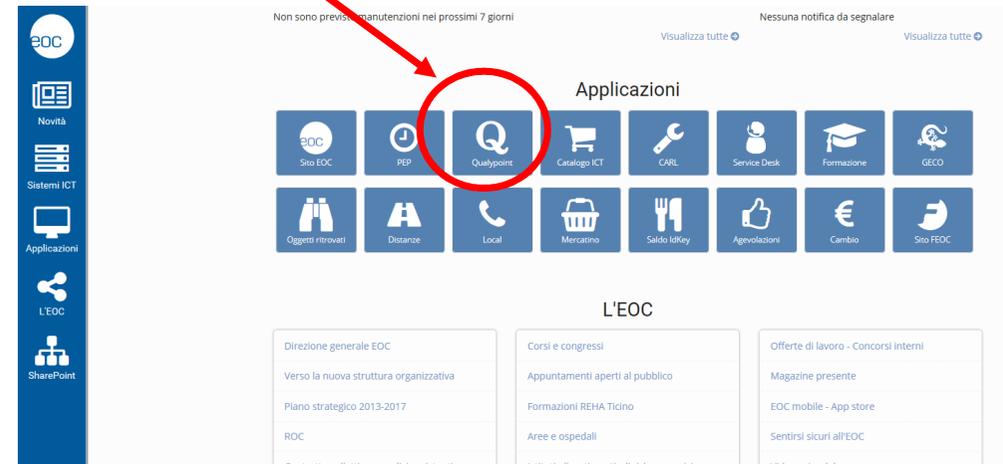
- 5 Hospitals
- ~ 230K exams/year



Surgical Unit:

- 5 Hospitals
- 17 fluoroscopes

- QualyPoint: CIRS already in use in our institute accessible by all the employees



Incident reporting form

QUALYPOINT
PORTALE QUALITA'



Ospedale in cui si è verificato l'evento:

OSPEDALE REGIONALE BELLINZONA E VALLI

Utente collegato:

Documentazione:

DocQ

Segnalazioni:

- Non conformità/Near miss/Evento avverso (segnalazione interna)
- Reclamo (segnalazione esterna: solo per segnalazioni ricevute dai pazienti o visitatori)
- Idea di miglioramento
- Apprezzamento
- Cadute (degenti e ambulant)
- Aggressioni
- Notifica di furto - smarrimento - danneggiamento
- Materiovigilanza

Lista segnalazioni effettuate

Eventi assegnati

Non conformità/Near miss/Evento avverso (segnalazione interna) id:

Data segnalazione (gg.mm.aaaa)*

Data in cui si è verificato l'evento (gg.mm.aaaa)* Ora (hh:mm)

Argomento segnalazione*

Nome e cognome del segnalatore

Ruolo di chi ha segnalato*

Reparto/servizio di chi ha segnalato*

Luogo in cui si è verificato l'evento

Reparto/servizio coinvolto (che ha causato la NC)*

Descrizione dei fatti*

Azioni immediate intraprese

Proposte di miglioramento

ALLEGATI Sfoglia... Titolo

*) Campi obbligatori
ATTENZIONE: per la compilazione del modulo si dispone di 60 minuti di tempo, trascorsi i quali il contenuto inserito sarà automaticamente cancellato

→ When

→ Where

→ What happened

→ Immediate actions taken

Incident Classification

- Radiation Incident
- FOPH report

1. Unplanned exposure of a patient

- 1.1 prescription of the procedure
 - 1.1.1 lack of prescription
 - 1.1.2 lack of justification
 - 1.1.3 error in the prescription
- 1.2 planning or execution of the procedure
 - 1.2.1 wrong therapy plan or exam
 - 1.2.2 error in the positioning
 - 1.2.3 patient issues
- 1.3 technical failure
- 1.4 incorrect patient
- 1.5 information and informed consent
- 1.6 data management
- 1.7 Other

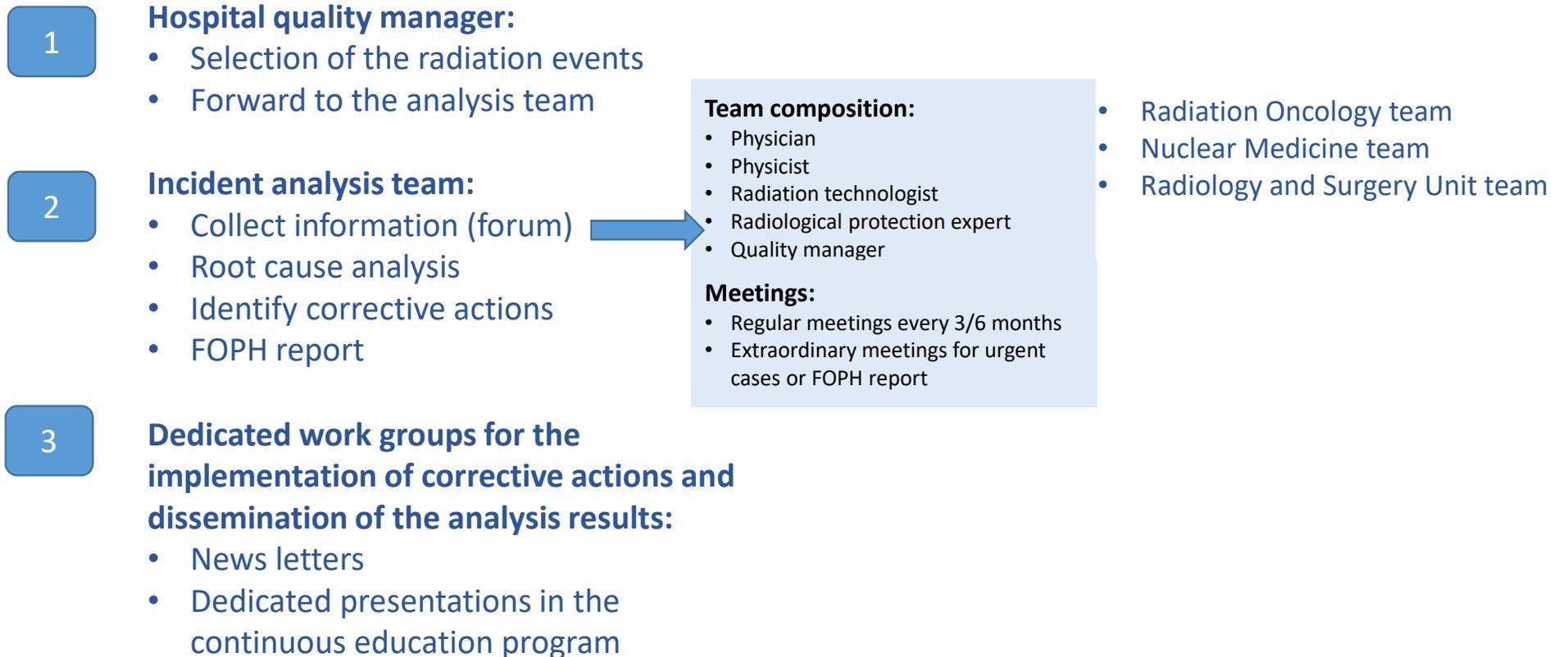
2. Unplanned exposure of workers or visitors

- 2.1 occupationally exposed workers
 - 2.1.1 exceedance of a reporting threshold
 - 2.1.2 technical failure
 - 2.1.3 wrong use of DPI
 - 2.1.4 pregnant workers
- 2.2 non exposed workers or visitors
- 2.3 Other

3. Other radiation incidents

- 3.1 management of radioactive waste
- 3.2 loss or theft of a radioactive source
- 3.3 Other

Workflow for the incident analysis



Staff education

- Dedicated presentations on the introduction of the medical radiation incident reporting system in the three departments + continuous education of MD prescribing radiological applications.
- Focus on:
 - What is a medical radiation incident (examples for each department)
 - Refresh on how to use QP application
 - **Safety culture and purpose of the reporting system**



- All the staff members of the different professions are involved in radiation protection of the patient
- All the staff members shall be aware of the risks related to the medical applications of radiation
- The contribution in reporting incidents from different professions is important to find vulnerabilities at all levels
- Importance of reporting all events including near misses to prevent incidents
- No fear of blame
- The goal is to learn from mistakes and correct the causes to avoid incident recurrences



Segnalazione e gestione degli eventi radiologici in Radioterapia

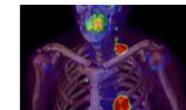


Segnalazione e gestione degli eventi radiologici in radiologia



Segnalazione e gestione degli eventi radiologici in Medicina Nucleare

21 giugno 2018

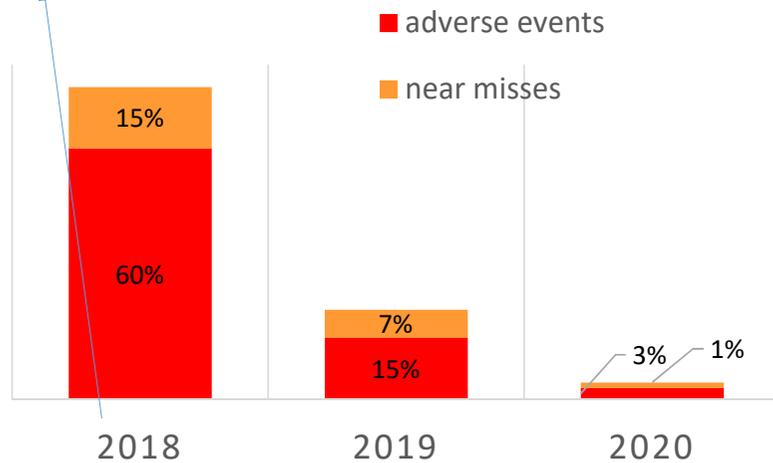


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➔ Credits for continuous education in radiation protection

Incidents in Radiation Oncology

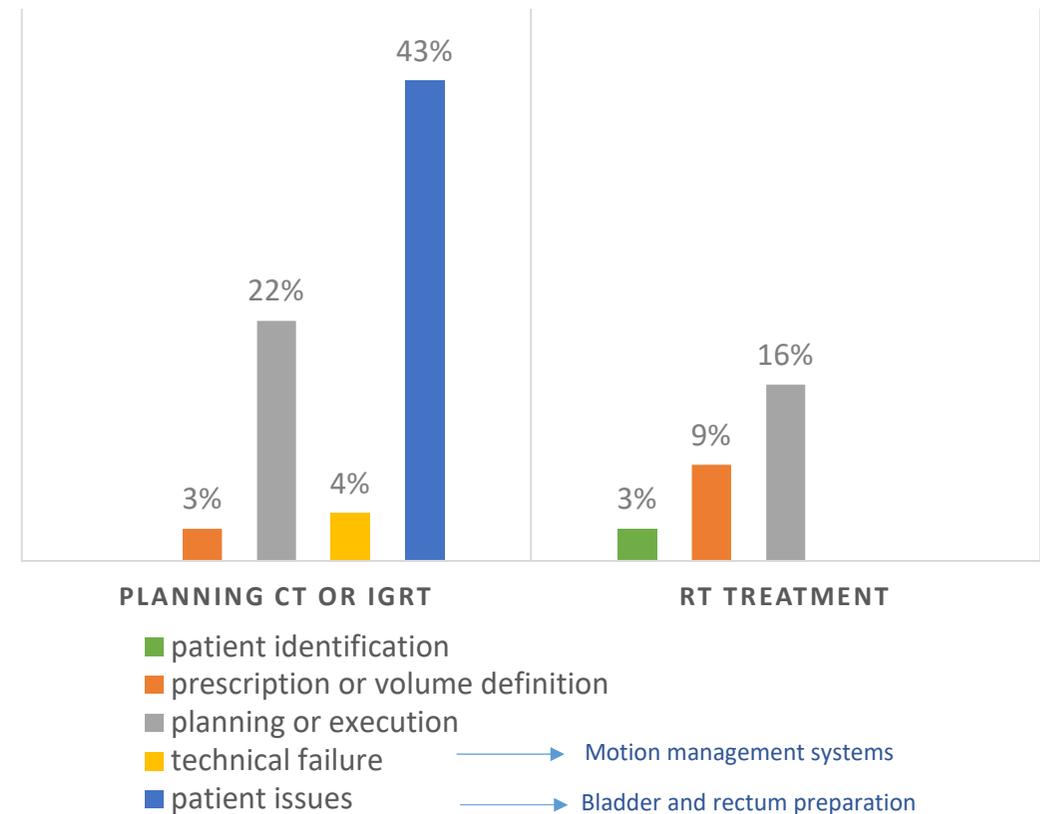
Incident record introduction and education



Reduction of the number of reports:

- actual incident decrease?
- need of refresher training!

Medical radiation incidents



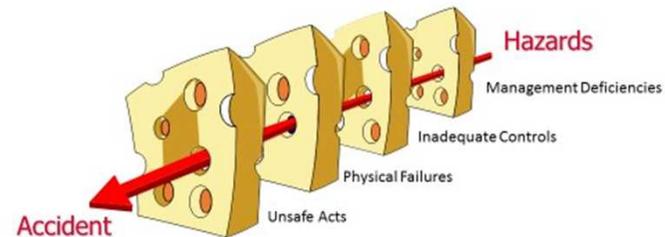
Analysis approach



- What happened?
- How did it happen?
- Why did it happen?
- What needs to be corrected?

Root cause analysis:

- the focus of the analysis should not be on the error itself but on the causes leading to the error
- an incident is often the conclusive event of a complex chain of organizational, structural, environmental and human failures



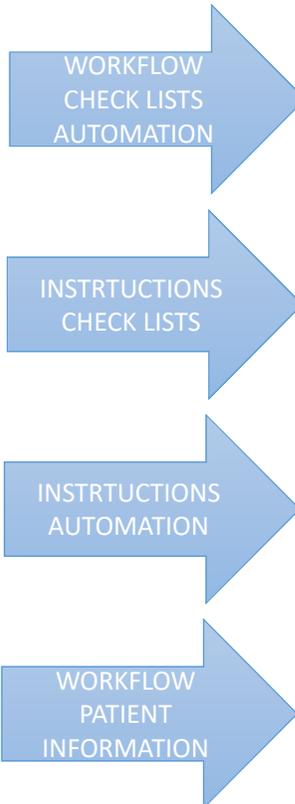
Goal:

- implement corrective actions at all levels:
 - Workflows
 - Structural changes
 - Control procedures /check lists
 - Technology upgrade, automation
 - Education and training

Root cause analysis and corrective actions

INCIDENT CAUSES

- **PRESCRIPTION:**
last minute prescription changes
- **PLANNING AND EXECUTION:**
lack of written instructions and check lists
- **PATIENT IDENTIFICATION:**
human error
- **PATIENT ISSUES:**
patient information?, wrong instructions?

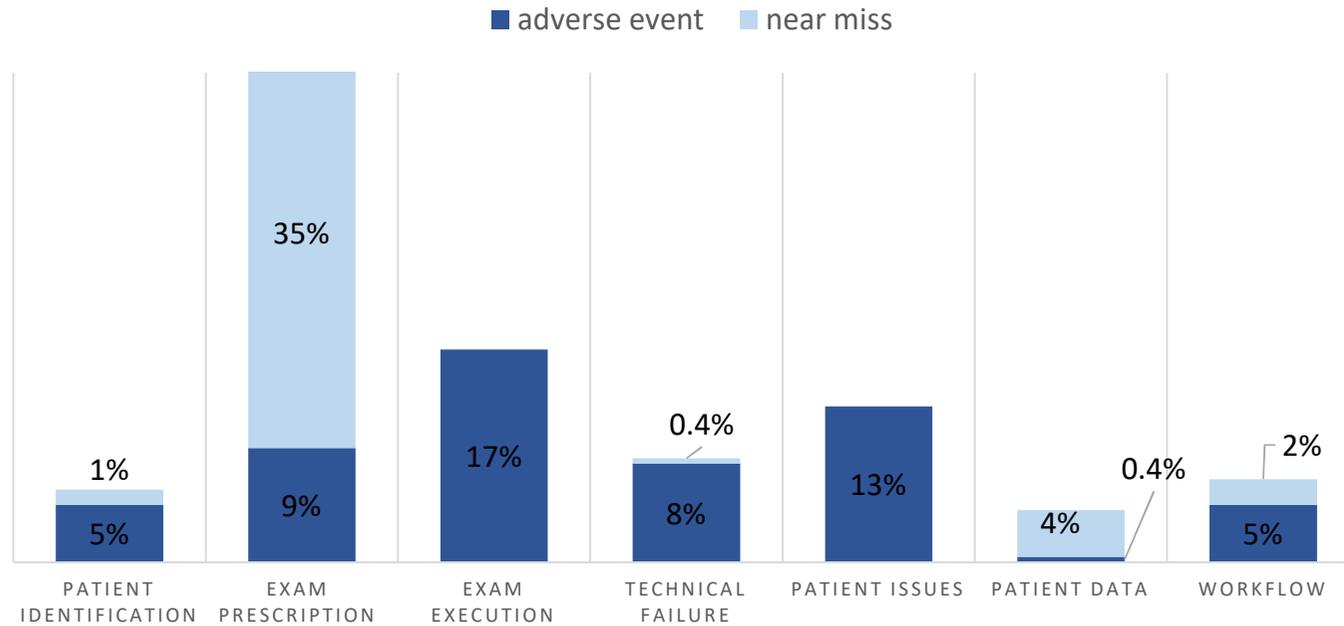
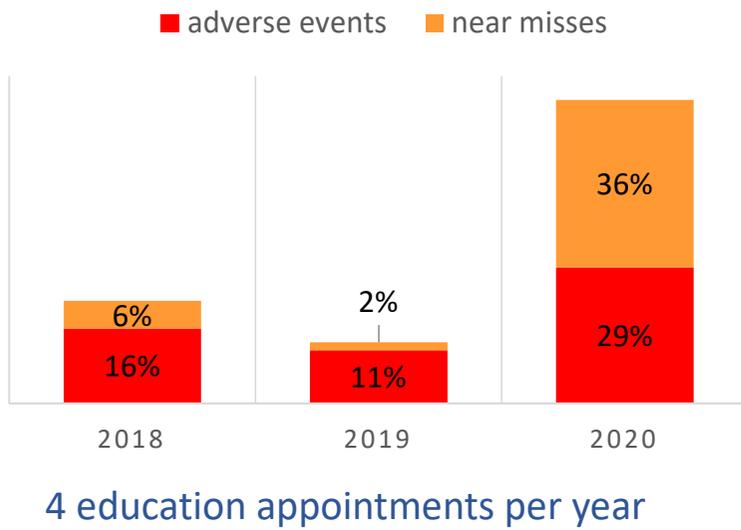


PROCESS CORRECTION

- ✓ ARIA prescription draft
- ✓ Prescription double check at the morning meeting
- ✓ ARIA prescription templates
- ✓ Instruction for delta couch shift corrections
- ✓ Check lists for electron and brachytherapy treatment approval
- ✓ Staff awareness – double check
- ✓ Surface imaging system
- ✓ Improve patient information (additional nurse appointments)
- ✓ Easier instructions (liquid amount, diet)

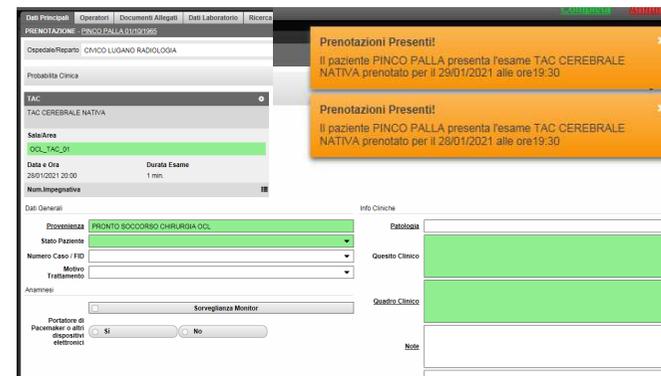
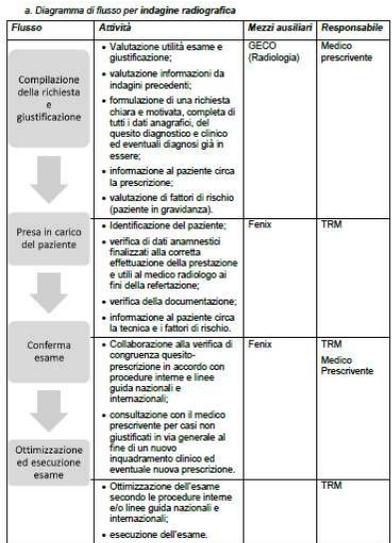
Incidents in Radiology

Medical radiation incidents

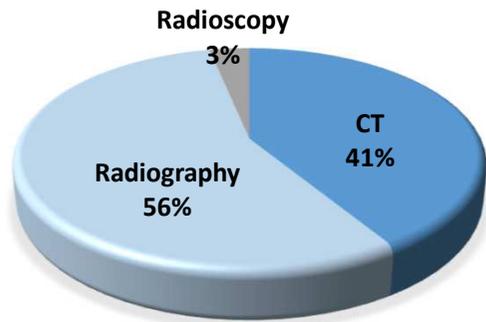


Root cause analysis and corrective actions

Event category	Event description	Root cause analysis	Corrective actions
Medical prescription	RADIOGRAPHY •Wrong exam (body site, protocol) •Lack of justification	<ul style="list-style-type: none"> •Unclear workflow for radiography exam and justification process •Referral physicians need to improve the radiation protection knowledge 	<ul style="list-style-type: none"> • Written Instructions: <ul style="list-style-type: none"> ○ Definition of minimum information for the prescription ○ Workflow definition clarifying the justification process • Education: <ul style="list-style-type: none"> ○ Continuous education in radiation protection of referring physicians: examples of the incidents
	•CT repetition	<ul style="list-style-type: none"> •Referring physician forgets to delete the previous request •The radiologist/referring physician are not aware of previous exams 	



Radiology incidents - FOPH report



- RPO: report within 30 days – high dose range

Radimetrics radiation dose management platform.

	Unknown CT THORAX test THORAX test Eseguito: 07/01/2021 16:26 Brilliance Big Bore HOST-7372	
	Unknown CT THORAX test THORAX test Eseguito: 07/01/2021 16:20 Brilliance Big Bore HOST-7372	

- Patient identification
- Wrong CT protocol
- CT repetition

SSRMP position statement on art.	
Category	Radiological procedures
Low-dose E<1mSv	<ul style="list-style-type: none"> All X-ray radiographies except: abdomen, pelvis, lumbar spine radiography Dental radiography Bone densitometry CT of lower limbs Arthrography Lymphangiography Mammography*
Medium-dose 1mSv<E<5mSv	<ul style="list-style-type: none"> Abdomen, pelvis and lumbar spine radiography Head CT Neck CT CT of upper limbs Diagnostic procedures performed under fluoroscopy guidance (e.g. operating theatre)
High-dose E>5mSv	<ul style="list-style-type: none"> Chest CT Abdomen CT Pelvis CT Therapeutic procedures performed under fluoroscopy guidance (e.g. therapeutic ERCP, etc.) Interventional procedures under fluoroscopy guidance (e.g. cardiology, radiology, vascular) Interventional procedures performed under CT guidance

M-SFM-001/B

Rapporto inchiesta evento radiologico

- Motivazione della notifica
 - Evento radiologico medico/incidentale/altro
- Descrizione dettagliata dell'evento
 - Data e luogo dell'evento
 - Apparecchiatura utilizzata
 - Come è stato scoperto l'evento
 - Quando è stato scoperto l'evento
 - Chi ha scoperto l'evento
 - In che fase lavorativa è stato scoperto l'evento
 - Persone coinvolte (specificare quali pazienti sono stati coinvolti)
 - Cause accertate o ipotizzate dell'evento
- Provvedimenti urgenti
 - Provvedimenti immediatamente adottati
- Valutazione ed evoluzione medica
 - Stima dosimetrica per gli individui coinvolti (volume bersaglio, organi a rischio, organi coinvolti, dose efficace)
 - Descrizione delle conseguenze immediate o tardive aspettate
 - Valutazione medica dettagliata riguardo l'entità del danno
 - Descrizione delle cure mediche pianificate per il paziente coinvolto
 - Specificare se i pazienti sono stati informati (forma, grado di dettaglio)
 - Specificare se l'evento è stato incluso nella cartella clinica del paziente
- Risultati e comunicazione
 - Circostanze attribuibili all'evento
 - Conseguenze tratte dall'evento
 - Conoscenza acquisita in seguito all'evento (lezioni)
 - Specificare a chi è stato notificato l'evento (DIRS, azienda, medico curante, altri servizi, ecc.)

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 Data aggiornamento: 13.02.2020 Approvato da: RESP SFM Data di revisione: 13.02.2020

Summary

- A medical radiation incident reporting system is a great tool for improving the safety of medical applications of radiation
- The contribution of all the staff members is important to find the system vulnerabilities and identify hazards related to the radiation protection of the patient
- Communication of the incident analysis results is important to diffuse the safety culture and promote a conscious introduction of the corrective actions
- Sharing the lessons learned from radiation incidents also outside the own institute (e.g: by reporting the events to BAG) could lead to the implementation of national guidelines for improvement of the processes related to the radiation protection of the patient.