

# 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

<sup>1</sup> Licence holders must keep a record of medical radiation incidents.

→ CIRS

<sup>2</sup> 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

<sup>3</sup> 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

<sup>4</sup> 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

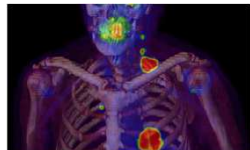


Multisite Hospital



## Radiation Oncology:

- 2 Hospitals
- ~ 800 treatments/year



## Nuclear Medicine:

- 2 Hospitals
- ~ 8K exams/year



## Radiology (diagnostic and interventional):

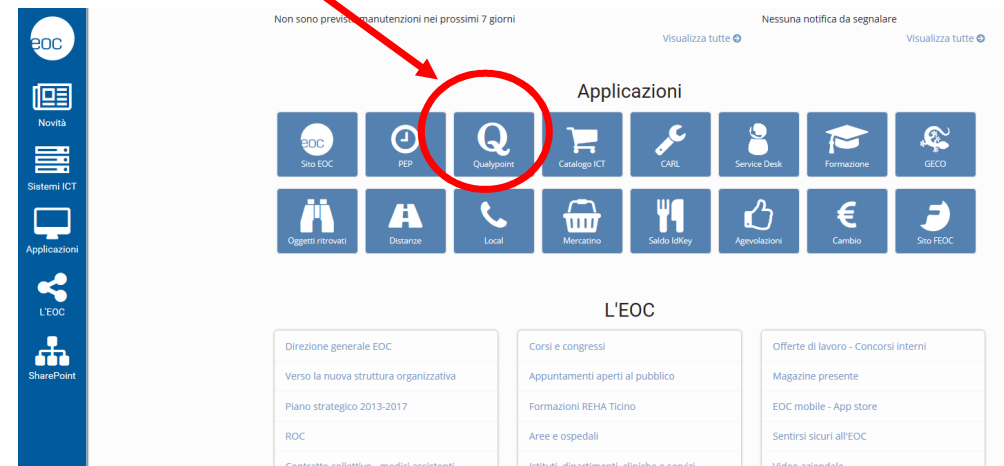
- 5 Hospitals
- ~ 230K exams/year



## 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 Aggiungi  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

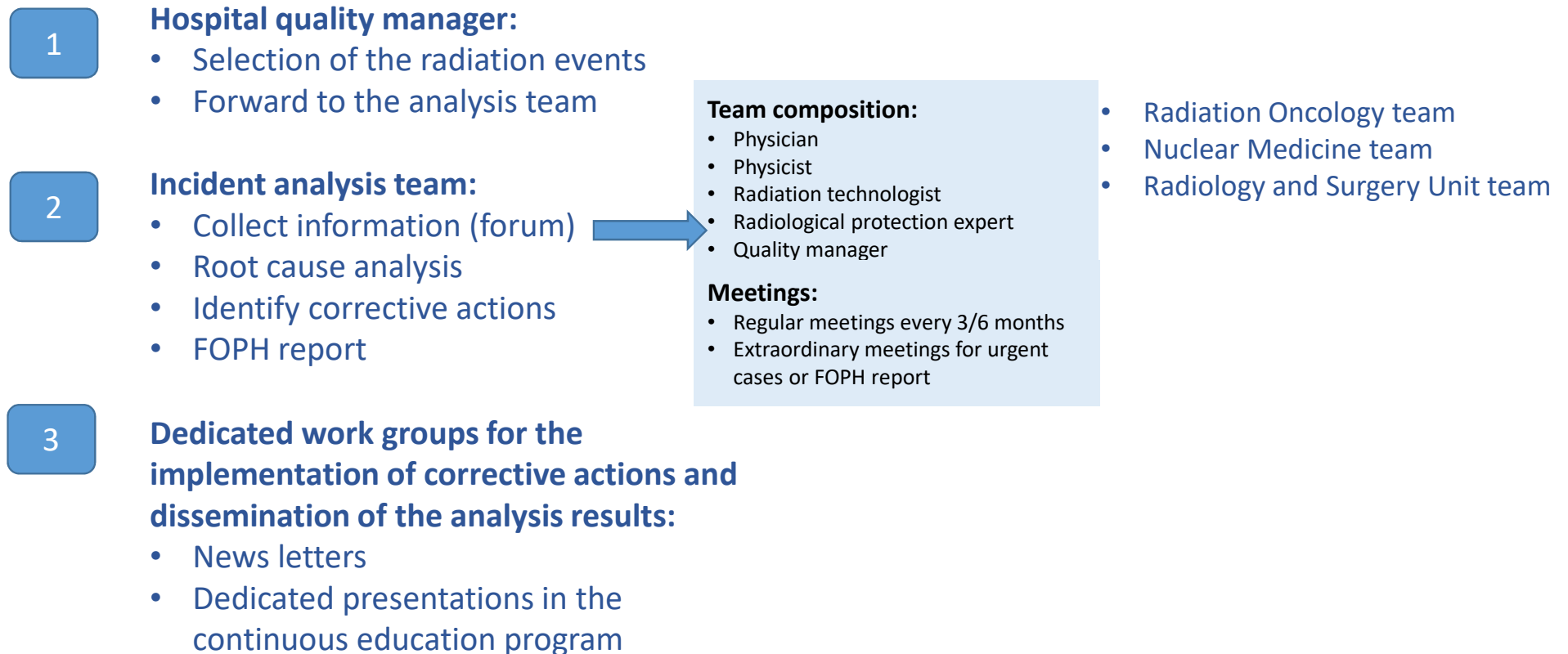
## 3. Other radiation incidents

### 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

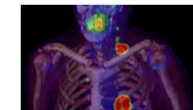


Segnalazione e gestione degli eventi radiologici in radiologia



Segnalazione e gestione degli eventi radiologici in Medicina Nucleare

21 giugno 2018

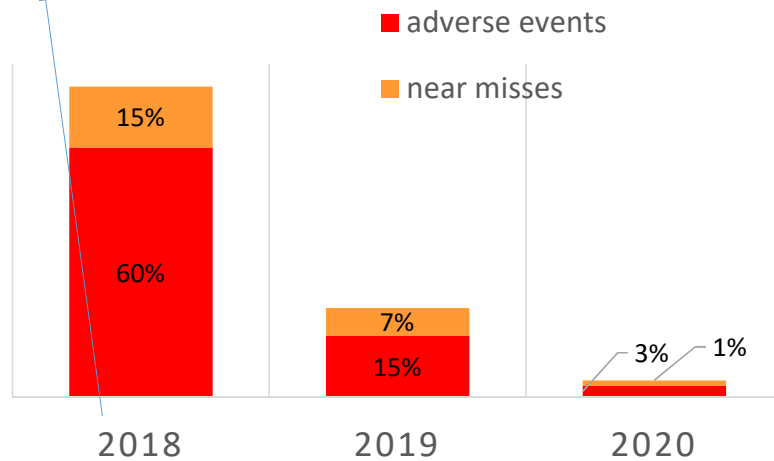


Dr.ssa Margherita Casiraghi  
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Servizio di Medicina Nucleare EOC

Credits for continuous education in radiation protection

# Incidents in Radiation Oncology

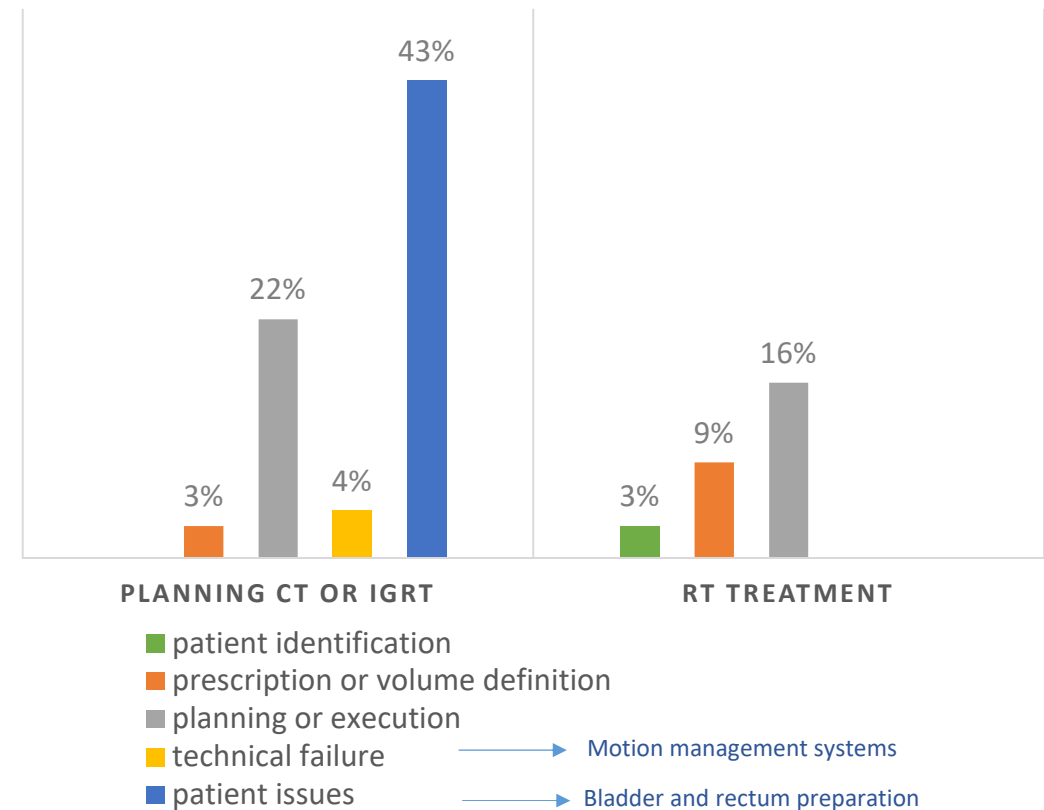
*Incident record introduction  
and education*



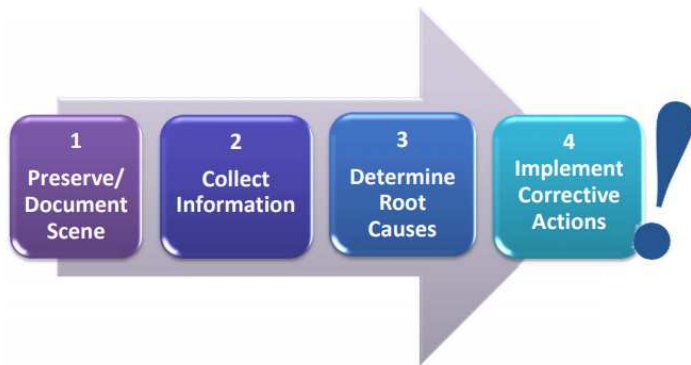
Reduction of the number of reports:

- actual incident decrease?
- need of refresher training!

## Medical radiation incidents



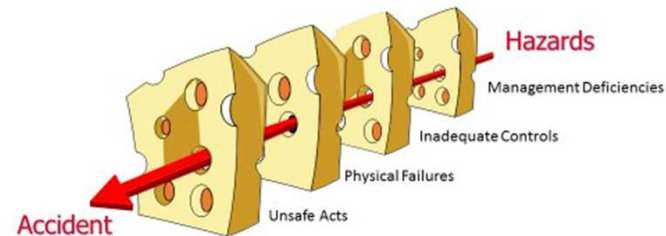
# Analysis approach



- 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?

WORKFLOW  
CHECK LISTS  
AUTOMATION

INSTRUCTIONS  
CHECK LISTS

INSTRUCTIONS  
AUTOMATION

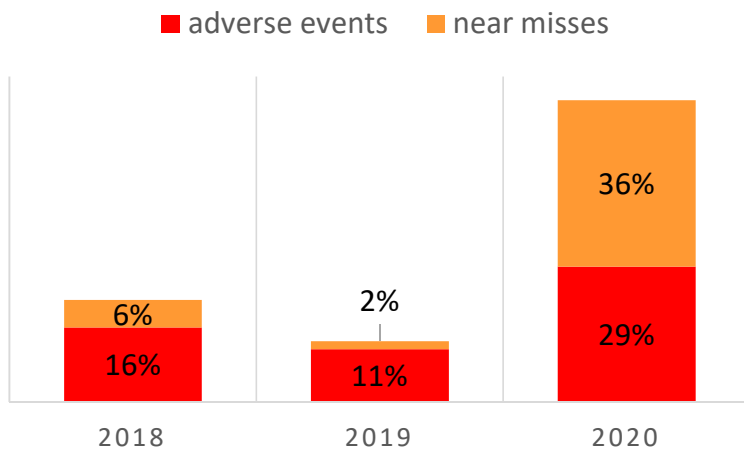
WORKFLOW  
PATIENT  
INFORMATION

## PROCESS CORRECTION

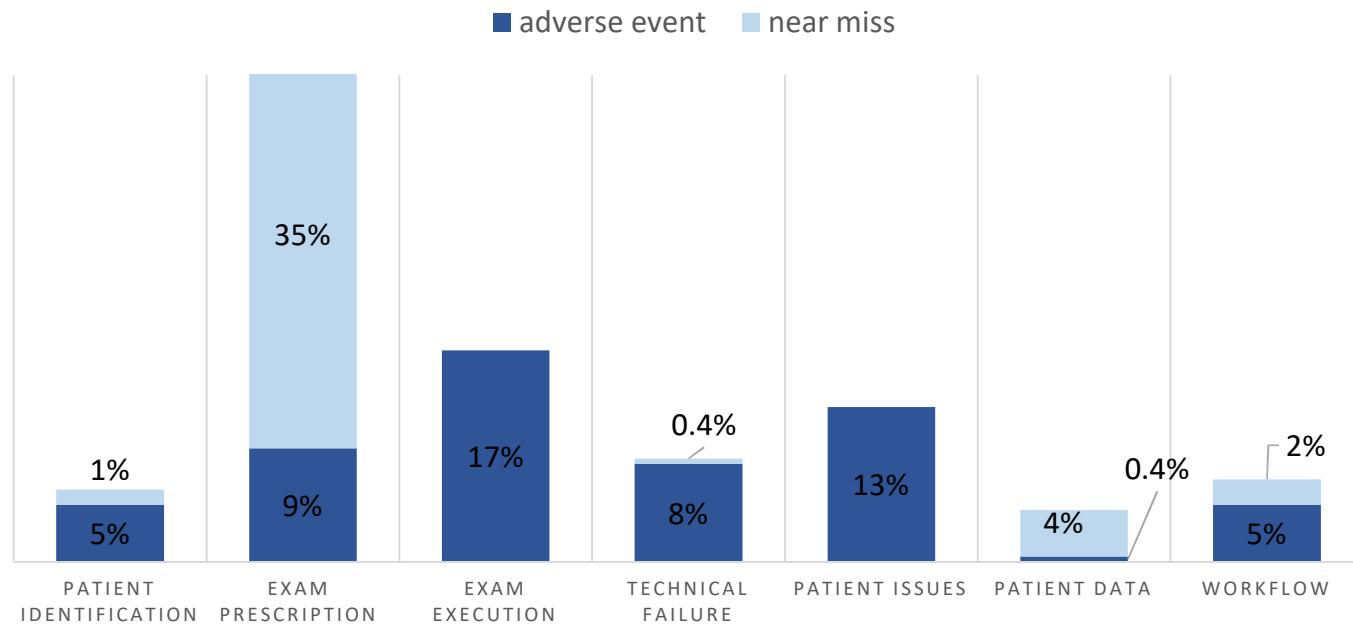
- ✓ ARIA prescription draft
- ✓ Prescription double check at the morning meeting
- ✓ ARIA prescription templates
- ✓ Instruction for delta couch shift corrections
- ✓ Check lists for electron and brachytherapy treatment approval
- ✓ Staff awareness – double check
- ✓ Surface imaging system
- ✓ Improve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

# Incidents in Radiology

## Medical radiation incidents

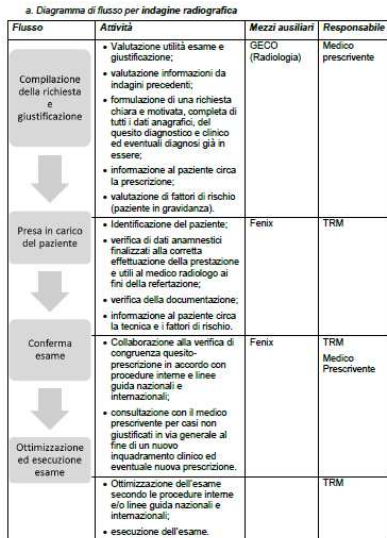


4 education appointments per year

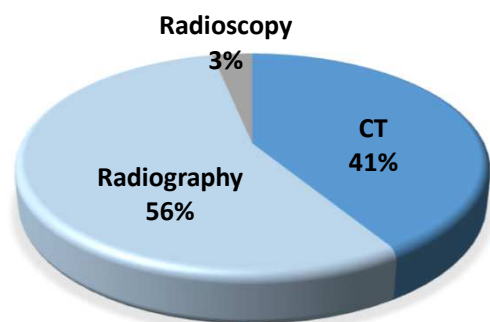


# Root cause analysis and corrective actions

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



# 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	ICRP 10 9.6	SSDE -	CTDIvol (mSv) 9.1	CTDIvol (mSv) -
Unknown CT THORAX test THORAX test Eseguito: 07/01/2021 16:20 Brilliance Big Bore HOST-7372	ICRP 10 4.5	SSDE -	CTDIvol (mSv) 5.1	CTDIvol (mSv) -

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

Istituto Nazionale della Sanità Italiana  
Servizio di fisica medica

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
  - Personale coinvolto (specificare quanti pazienti sono stati coinvolti)
  - Cause accertate o ipotizzate dell'evento
- Provvedimenti urgenti
  - Provvedimenti immediatamente adottati
- Valutazione ed evoluzione medica
  - Stime dosimetriche 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
  - Precisare se i pazienti sono stati informati (forma, grado di dettaglio)
  - Precisare se l'evento è stato incluso nella cartella clinica del paziente
- Risultati e comunicazione
  - Circostanze attribuibili all'evento
  - Conseguenze tratte dall'evento
  - Conseguenze acquisite in seguito all'evento (lesioni, danni)
  - Precisare a chi è stato notificato l'evento (CIRS, azienda, medico curante, altri servizi, ecc.)

Data emissione: 23.07.2018  
Data aggiornamento: 15.02.2020

Firma \_\_\_\_\_  
Firma \_\_\_\_\_

Page 1 of 2  
Data di revisione: 15.02.2020

- Private conversation with the BAG RP Officer: report all CT incidents in short list at the end of the year

# 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.