International Safety Requirements in Medical Exposure

Vesna Gershan, PhD

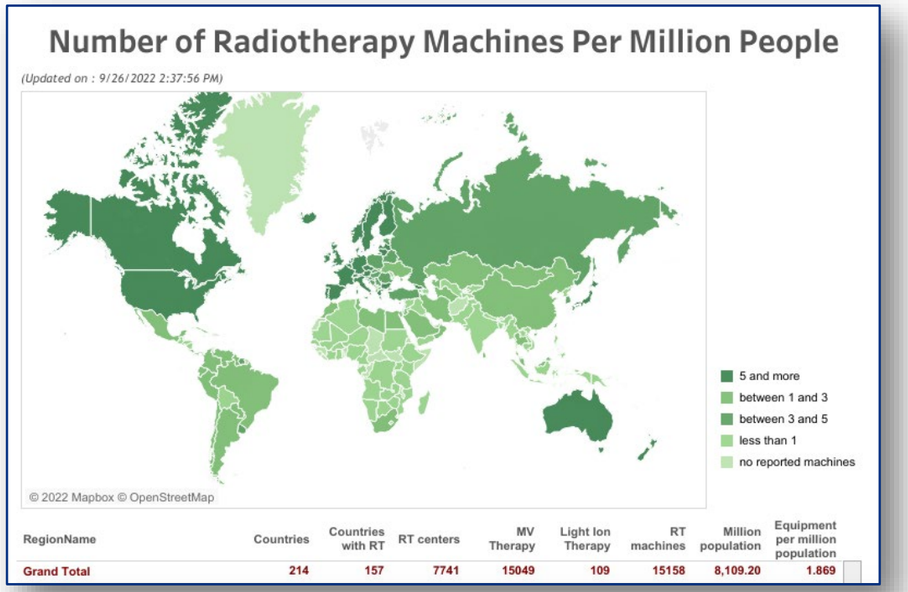
ACCESS RADIOTHERAPY TECHNOLOGIES

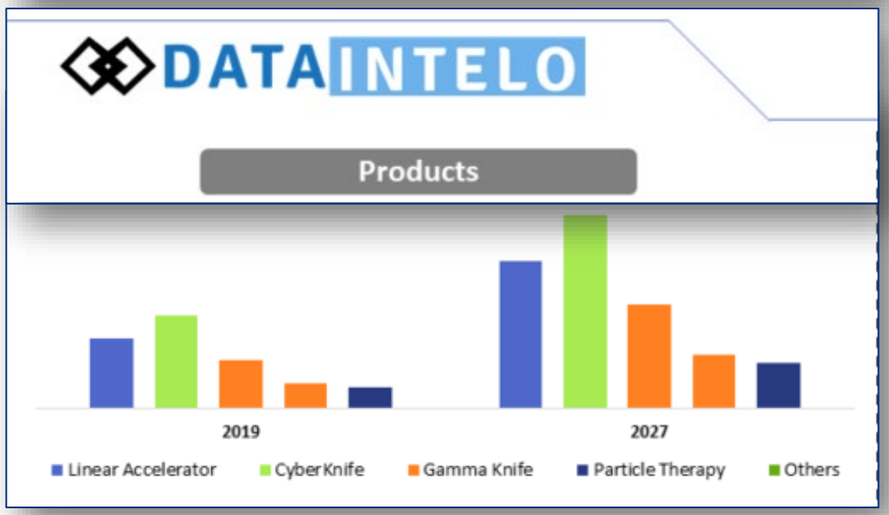
International Cancer Expert Corps

ORS Office of Radiological Security
Protect · Remove · Reduce

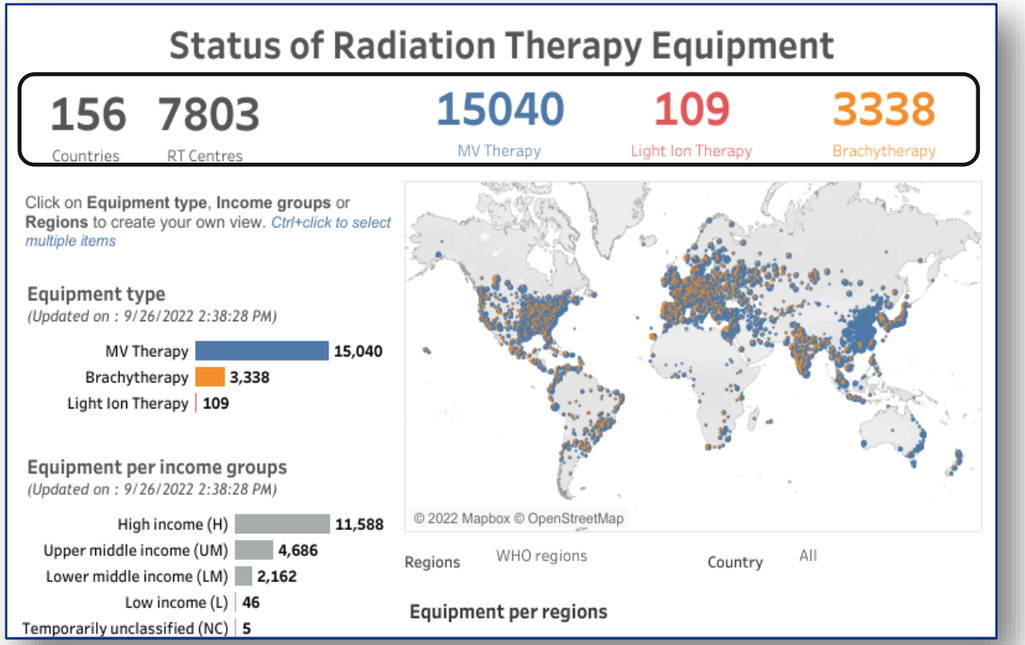
Global increase of available radiotherapy equipment

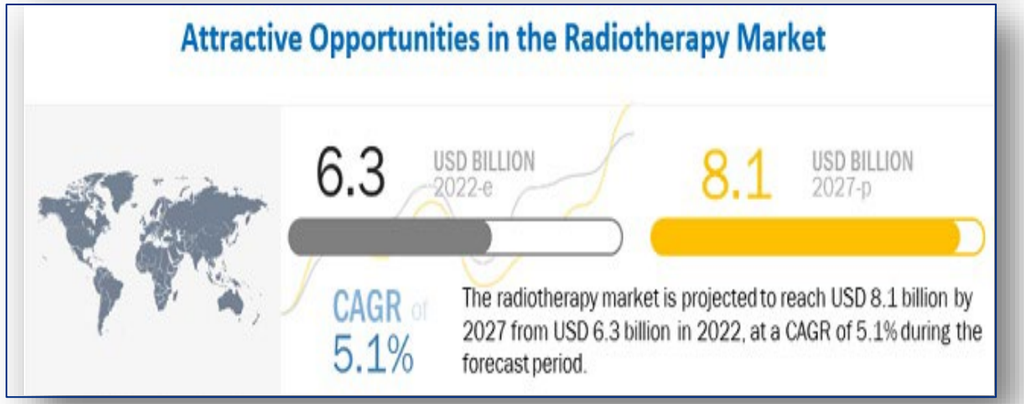
IAEA DIRAC Data base





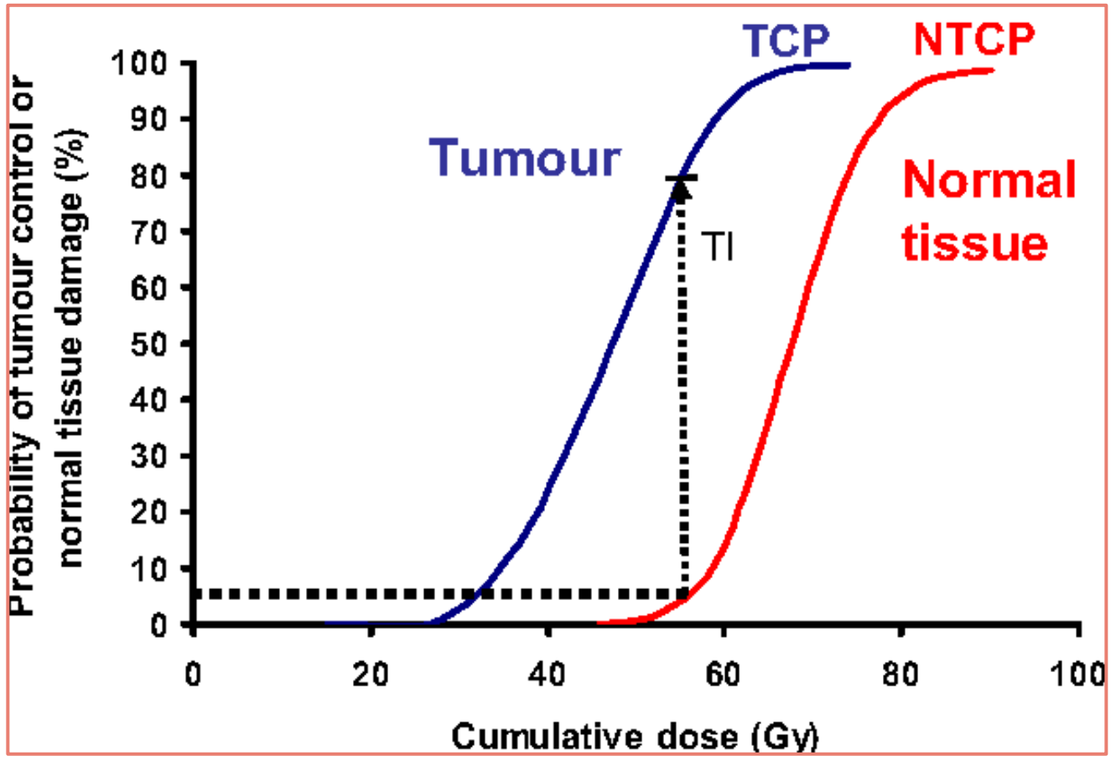
Radiation Therapy Equipment Market Size | Industry Report, 2026 (dataintelo.com)





Radiotherapy Market Size, Share | 2022 - 2027 | MarketsandMarkets

Importance of radiation protection in Radiotherapy (1/4)



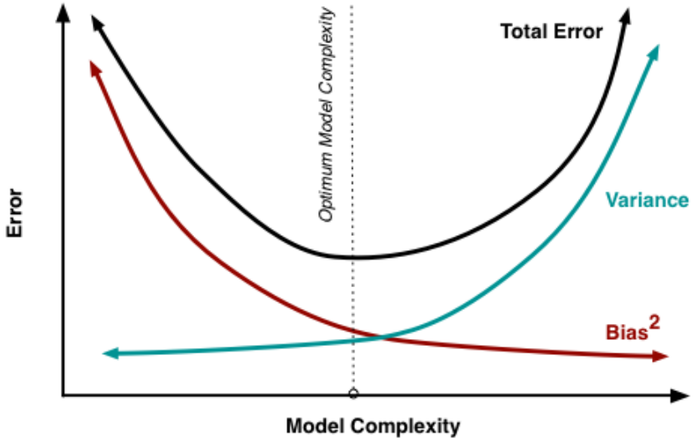
Karsten Eilertsen Imaging the Beams Eye View in External Beam Radiotherapy : Geometric and Dosimetric Precision, K. Eilertsen, T. Tung, Published 2012, Physics

https://wonderopolis.org/wonder/can-you-walk-the-tightrope

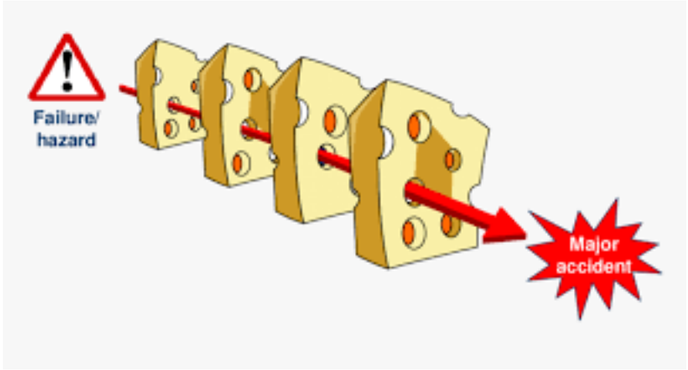
✓ For a given radiation schedule and technique, a high probability of tumour of control (TCP) can be reached **at a dose level that does not inflict severe normal tissue complications** (NTCP).

Importance of radiation protection in Radiotherapy (2/4)

- ✓ Radiotherapy is a highly complex, multi – step process that requires the input of many different staff groups in the planning and delivery of the treatment.



scikit-learn : Bias-variance tradeoff - 2020 (bogotobogo.com)



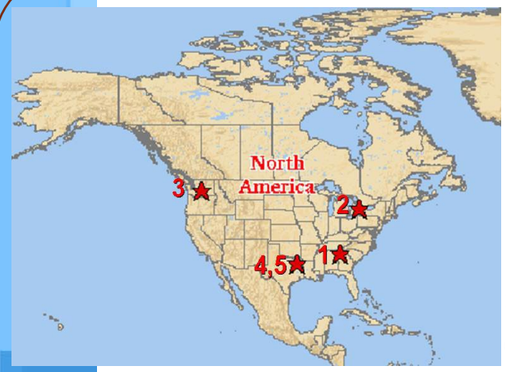
Physical and Radiobiological Evaluation of Radiotherapy Treatment Plan | IntechOpen

Importance of radiation protection in Radiotherapy (3/4)

- ✓ Though errors are rare, when they do occur the consequences can be significant for the patient.

Incorrect repair of accelerator (Spain)
15 of 27 patients died as a consequence of overexposure

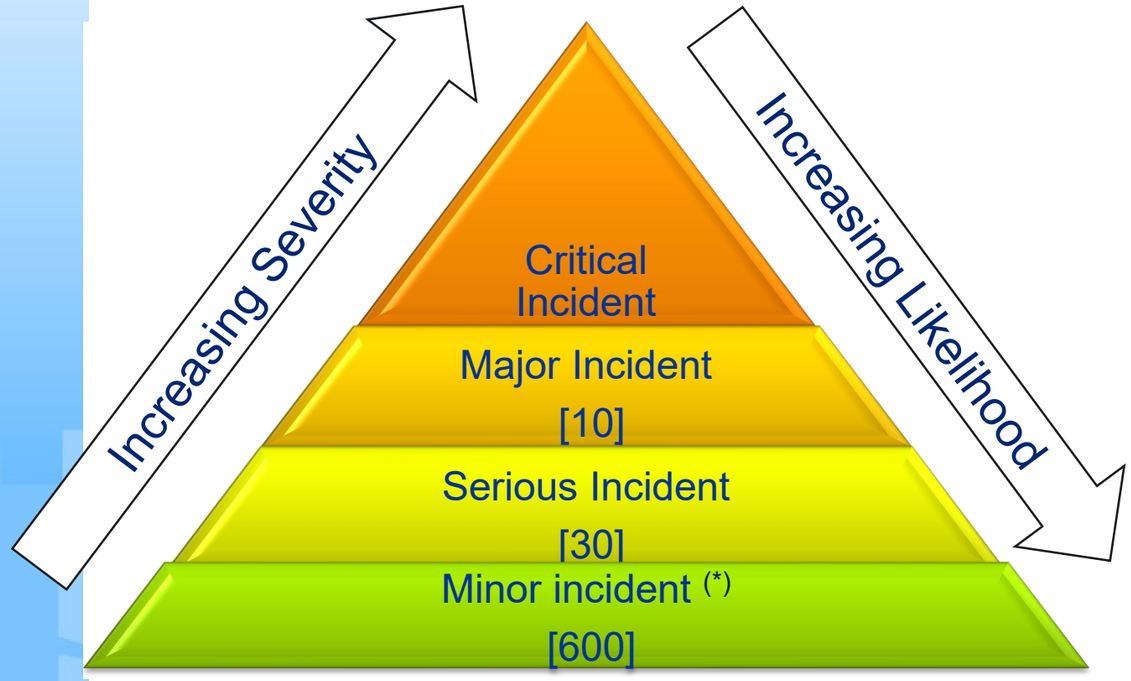
Wrong treatment planning (Panama)
8 of 28 patients died



Accelerator software problems (USA & Canada)
6 accidents, 4 patients died, 2 left with severe disability
(2 – 100 times higher dose delivered in 1-3 sec)

Accelerator interlock failure (Poland)
5 patients severely affected, 3-37 times higher doses

Importance of radiation protection in Radiotherapy (4/4)



Bird F E and Germain G L 1992 Practical Loss Control Leadership (Loganville, GA: International Loss Control Institute)

~90 % human factors associated!

- The New York State experience:
  Serious incident rate: 0.012 % per course
  (12 in every 100 000 courses)

  Huang G, Medlam G, Lee J, Billingsley S, Bissonnette J-P, Ringash J, Kane G and Hodgson D C 2005 Error in the delivery of radiation therapy: results of a quality assurance review *Int. J. Radiat. Oncol. Biol. Phys.* **61** 1590–5

- The UK experience:
  Serious incident rate: 0.003 % per course
  (3 in every 100 000 courses)

  www.rcr.ac.uk/system/files/publication/field_publication/files/Towards_saferRT_final.pdf

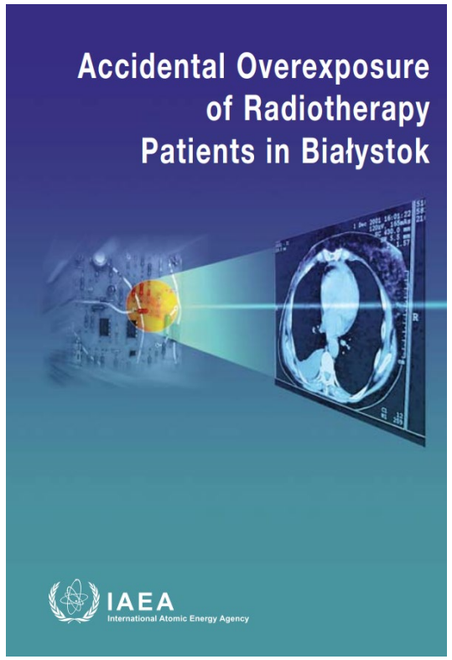
- The chance of death on a commercial flight:
  0.000005% Safety Reports (icao.int)

- The risk for fatal consequences in radiotherapy is ~1000 times higher then in a commercial flight.

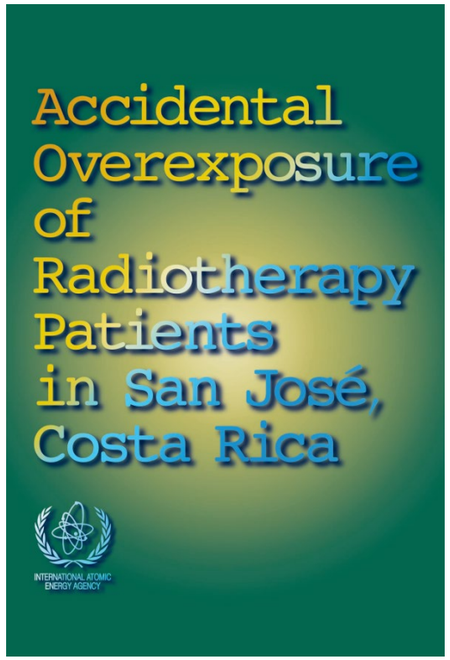
SAFETY IS AN ISSUE IN RADIATION THERAPY!

(*) Different categorization of the type of incidents

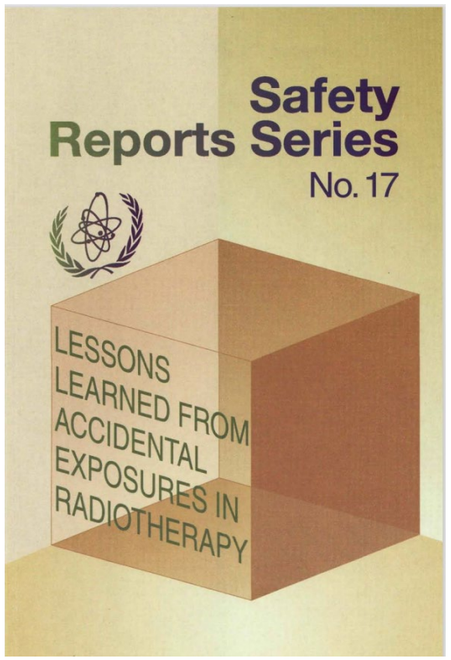
Unintended and accidental exposure of patients – some reports



STI/PUB/1180 (iaea.org)



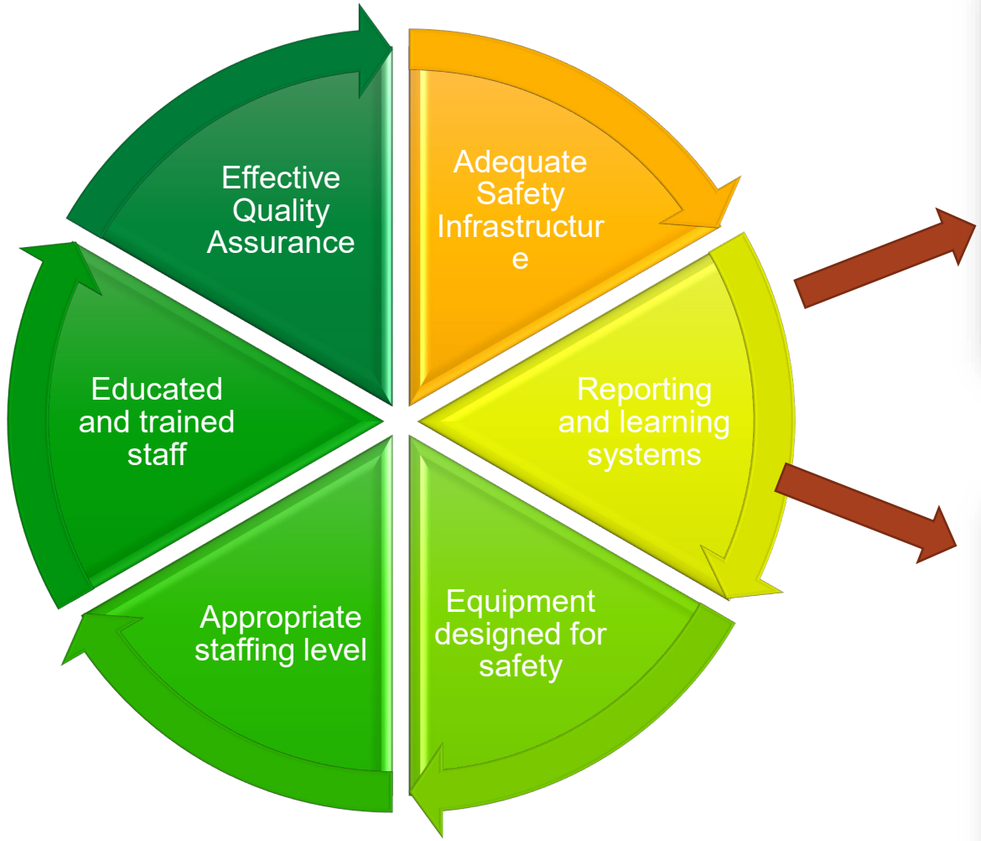
P027_scr.pdf (iaea.org)

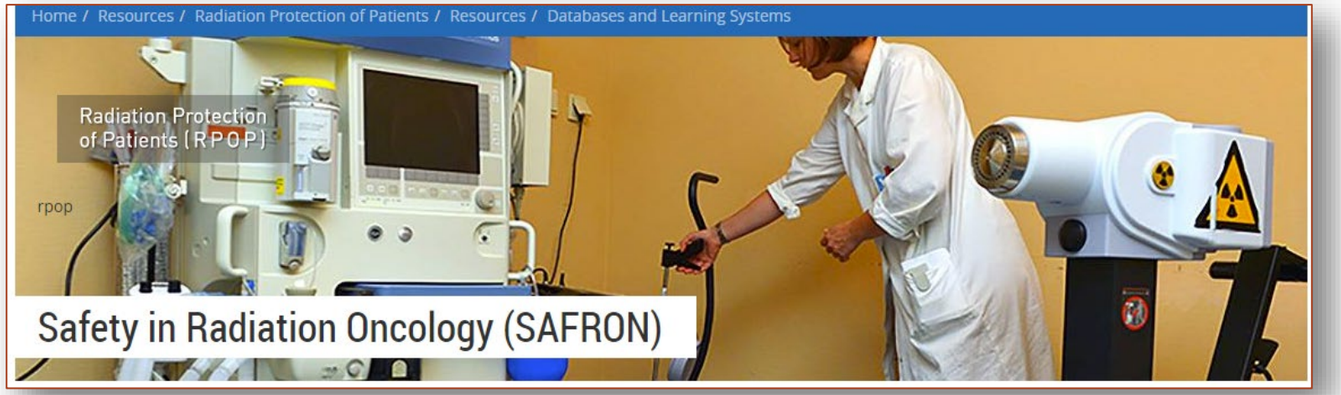


Pub1084_web.pdf (iaea.org)

Unintended and accidental exposure of patients - platforms

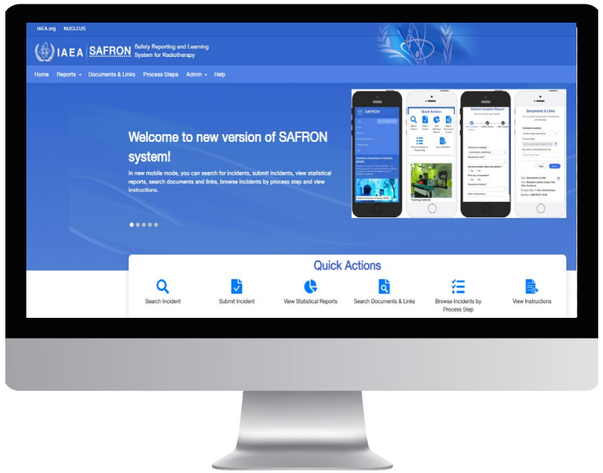
IAEA Safety improvement initiatives





IAEA Safety Reporting and Learning System for Radiotherapy (SAFRON)

- ✓ Safety in Radiation Oncology (SAFRON) is an integrated voluntary reporting and learning system for radiotherapy (external beam radiotherapy and brachytherapy) and radionuclide therapy **incidents and near-misses.**
- ✓ The main goal of SAFRON is to improve the safe planning and delivery of radiotherapy and radionuclide therapy **by sharing safety-related events** and safety analysis around the world.
- ✓ To establish **a database** of safety related resources;
- ✓ To provide users with the ability **to analyse and benchmark** safety improvement efforts.

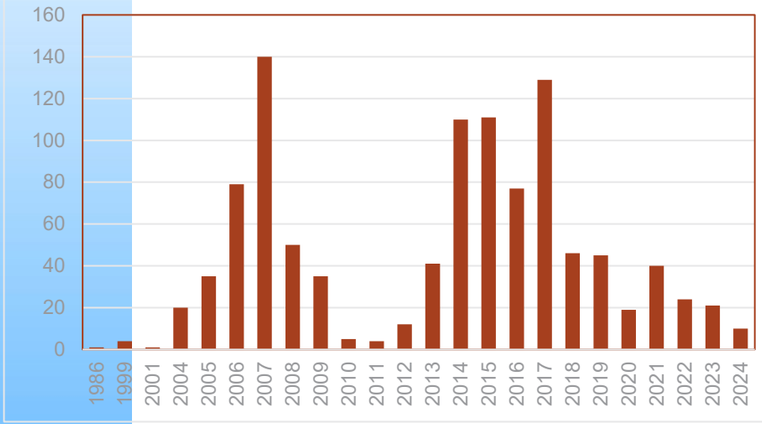


Register your hospital

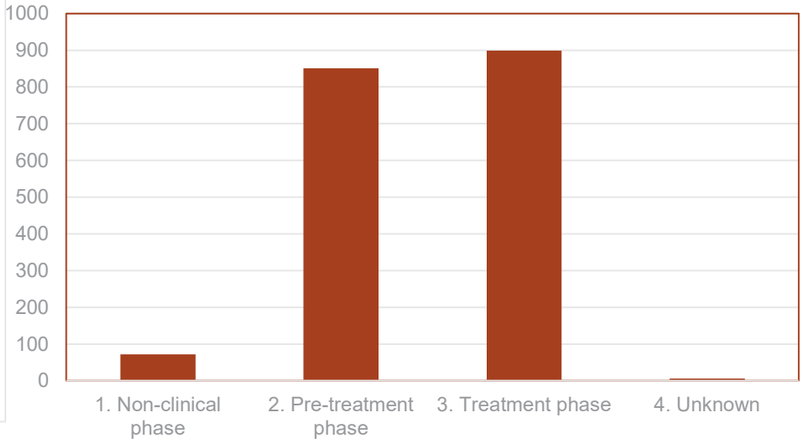
Total of 1831 reported incidents (status 3 July 2024)

IAEA Safety Reporting and Learning System for Radiotherapy (SAFRON)

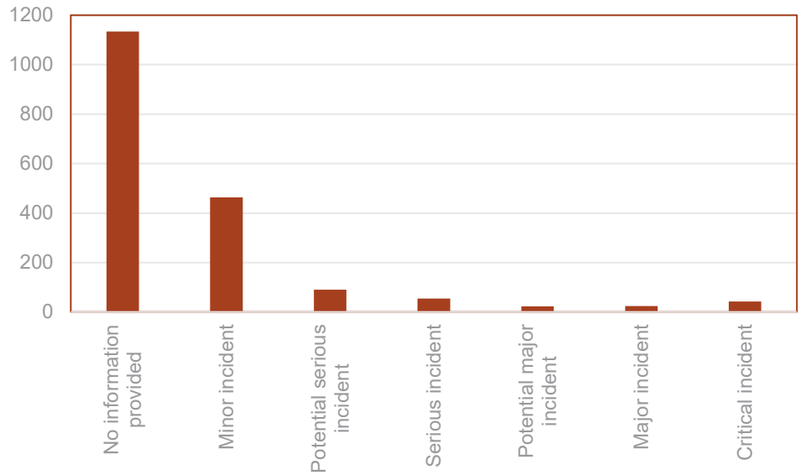
Repoted incidents over time



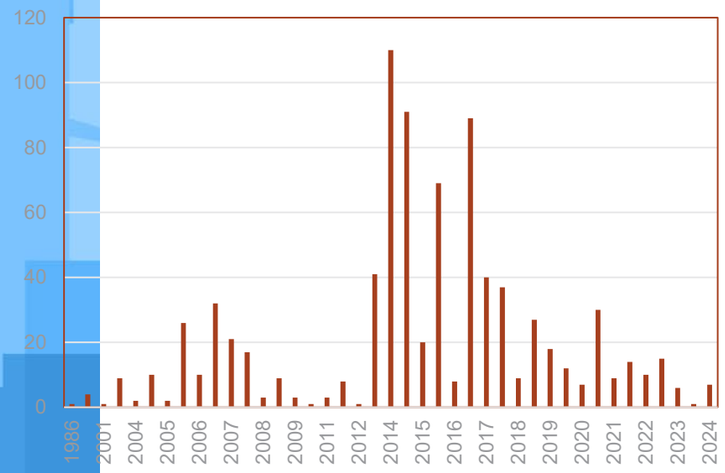
Incidents by Process Phase



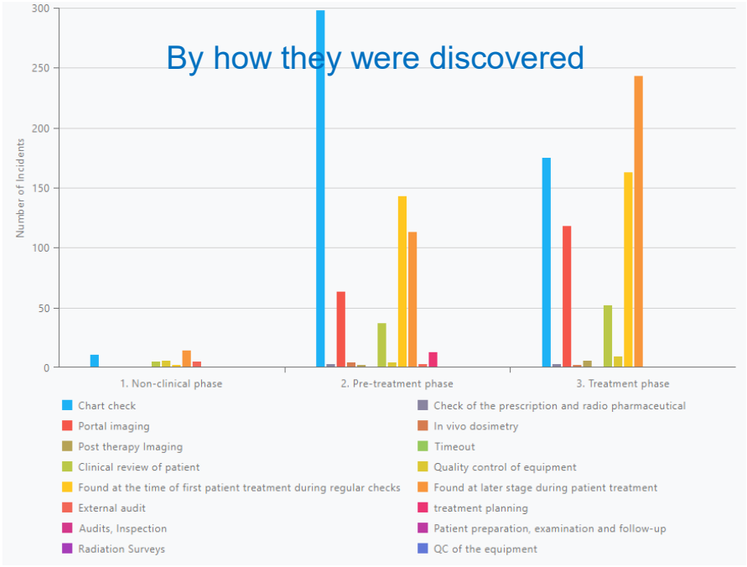
By Clinical Incident Severity



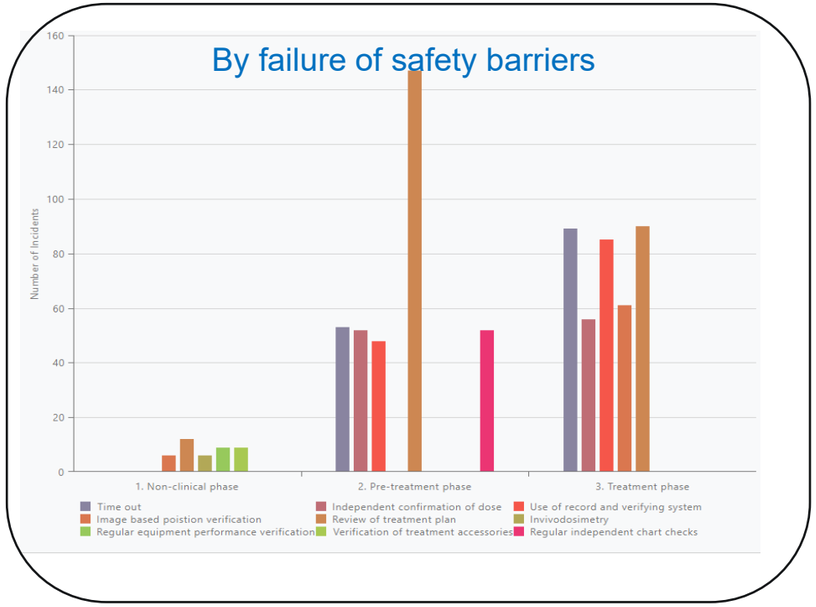
Reaching patient vs near misses



By how they were discovered



By failure of safety barriers



Safety in radiation oncology (SAFRON):
Learning about incident causes and safety barriers in external beam radiotherapy

Purpose:

To examine whether any discernible **patterns exist in the causes of reported incidents and safety barriers** within the SAFRON system concerning external beam radiotherapy.

ELSEVIER

Contents lists available at ScienceDirect

Physica Medica

journal homepage: www.elsevier.com/locate/ejmp

Original paper

Safety in radiation oncology (SAFRON): Learning about incident causes and safety barriers in external beam radiotherapy

Maryam Zarei *, Vesna Gershan, Ola Holmberg

Radiation Protection of Patients Unit, Radiation Safety and Monitoring Section, Division of Radiation, Transport and Waste Safety, International Atomic Energy Agency, Vienna, Austria

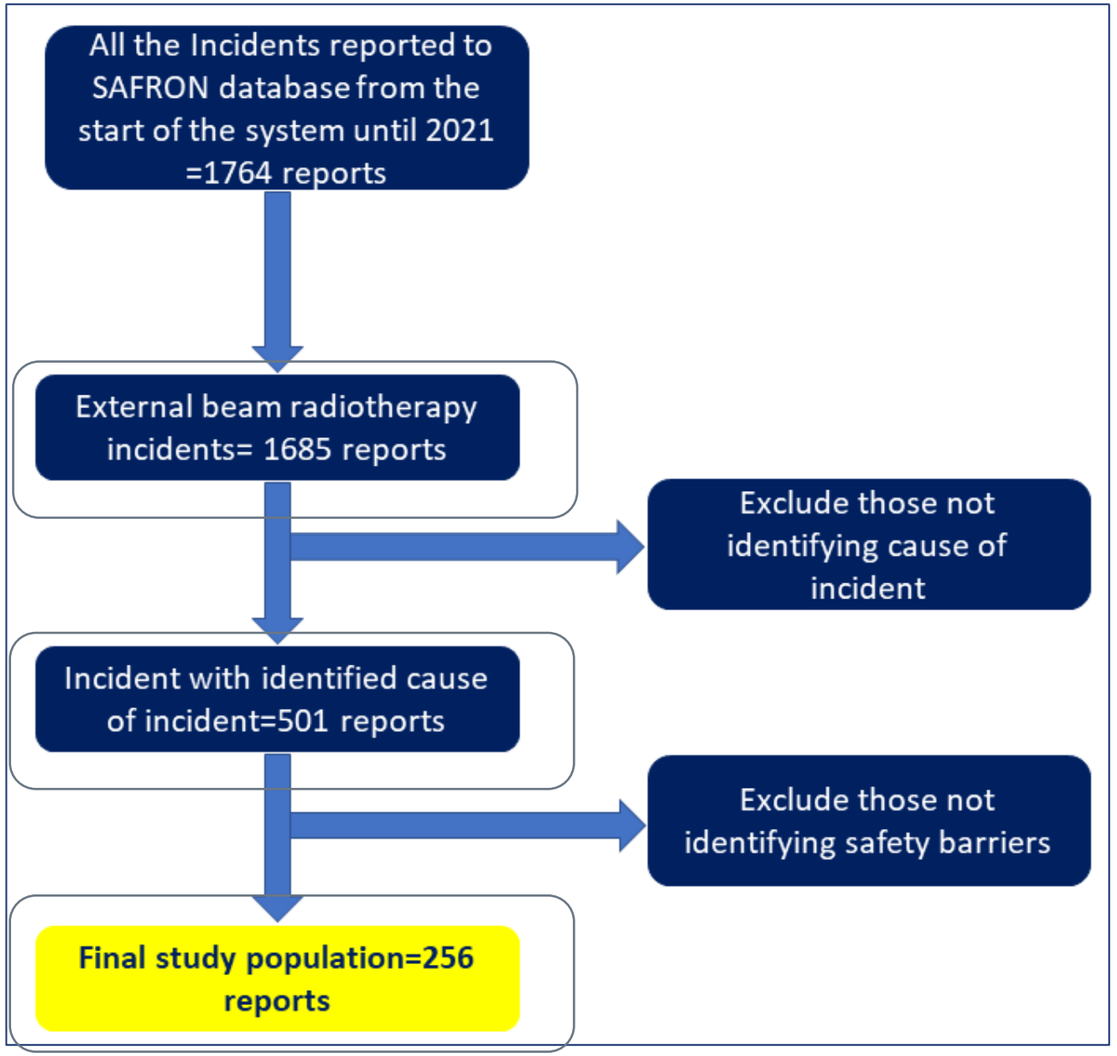
Safety in radiation oncology (SAFRON):
Learning about incident causes and safety barriers in external beam radiotherapy

Methods and materials:

This study focuses on external beam radiotherapy incidents, reviewing **1685 reports** since the inception of SAFRON until December 2021.

Simple 2D RT - 97 reports,
3D Conformal RT - 39 reports,
Modulated arc therapy - 12 reports,
IMRT - 11 reports,
Stereotactic radiosurgery - 4 reports
Radiotherapy with protons or other particles - 1 report,

No information on treatment method had been provided in 92 reports.



Flowchart of sample identification

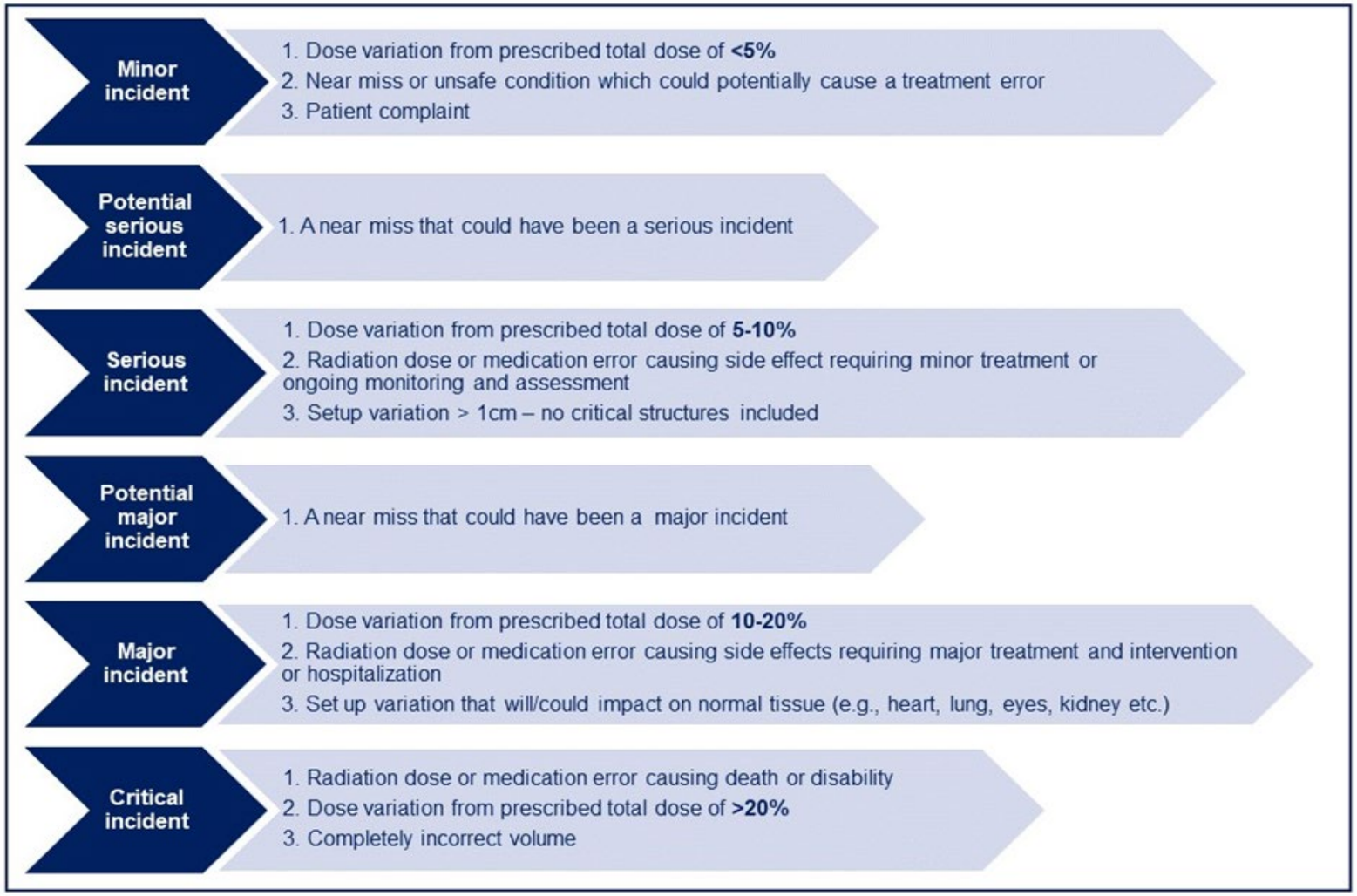
Safety in radiation oncology (SAFRON):
Learning about incident causes and safety barriers in external beam radiotherapy

Methods and materials:

Severity metrics in SAFRON system;

Safety barriers are determined by the reporters.

The SAFRON system allows for the reporting of incidents with multiple safety barriers

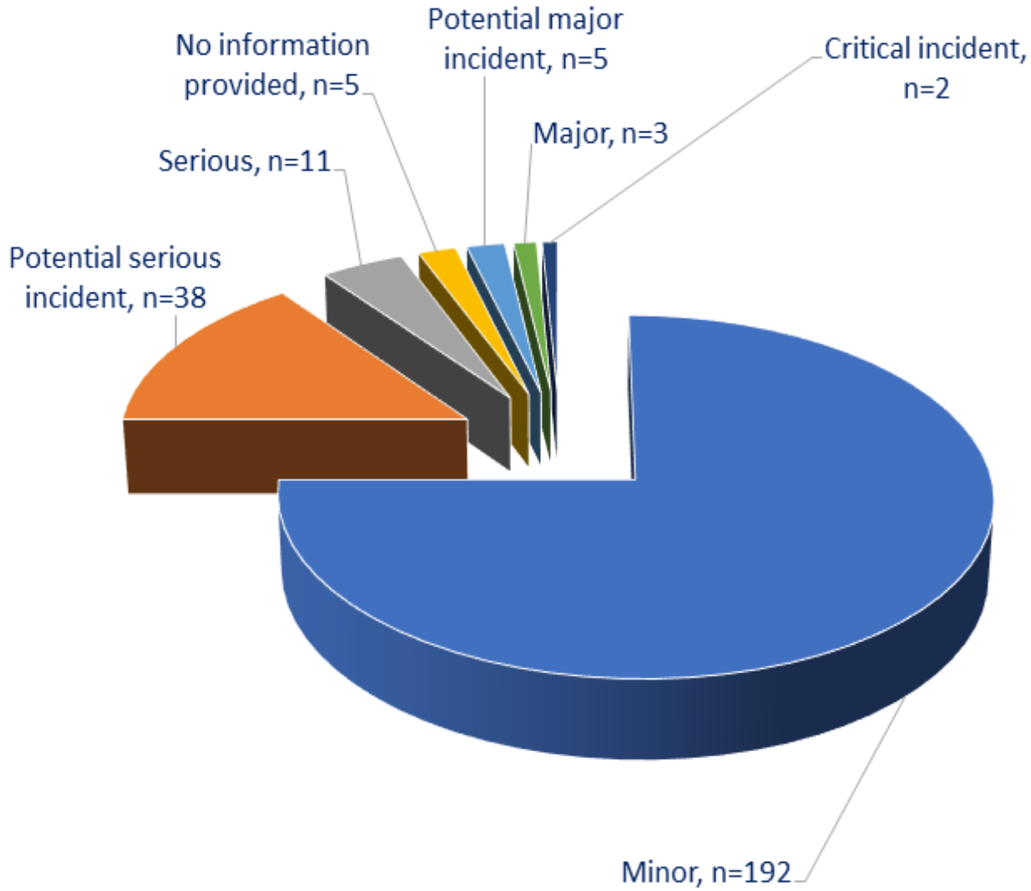


Safety in radiation oncology (SAFRON):
Learning about incident causes and safety barriers in external beam radiotherapy

RESULTS

<u>Category of incidents:</u>

Most of the reported incidents (192) were **minor incidents** and were discovered by the **radiation therapist.**



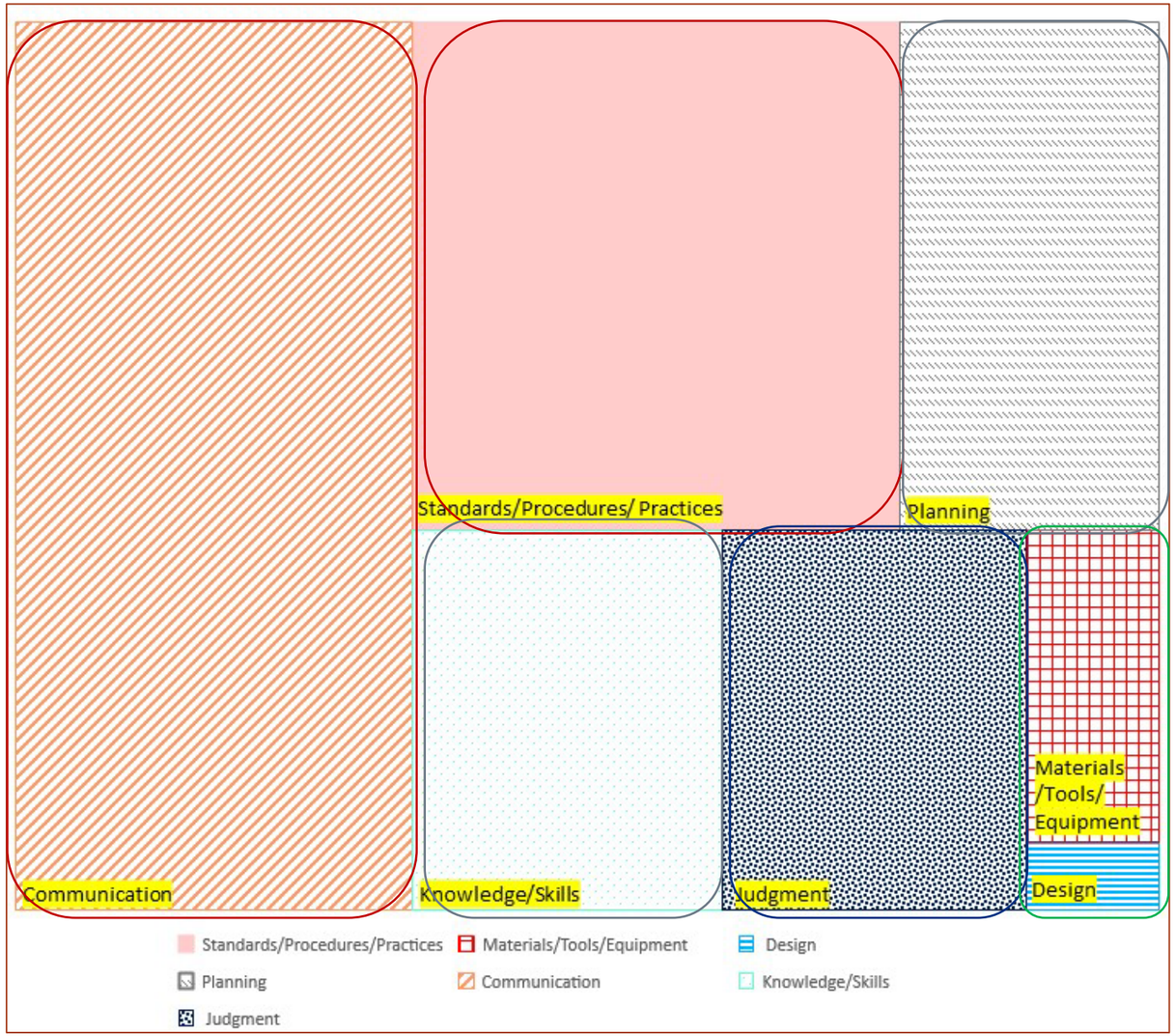
Distribution of categories of actual or potential incidents in the final study population from SAFRON's reporting system

Safety in radiation oncology (SAFRON):
Learning about incident causes and safety barriers in external beam radiotherapy

RESULTS

Cause of incidents:

- Communication
- Standards / Procedures / Practices
- Planning and Knowledge / Skills
- Judgement
- Material / Tools / Equipment
- Design



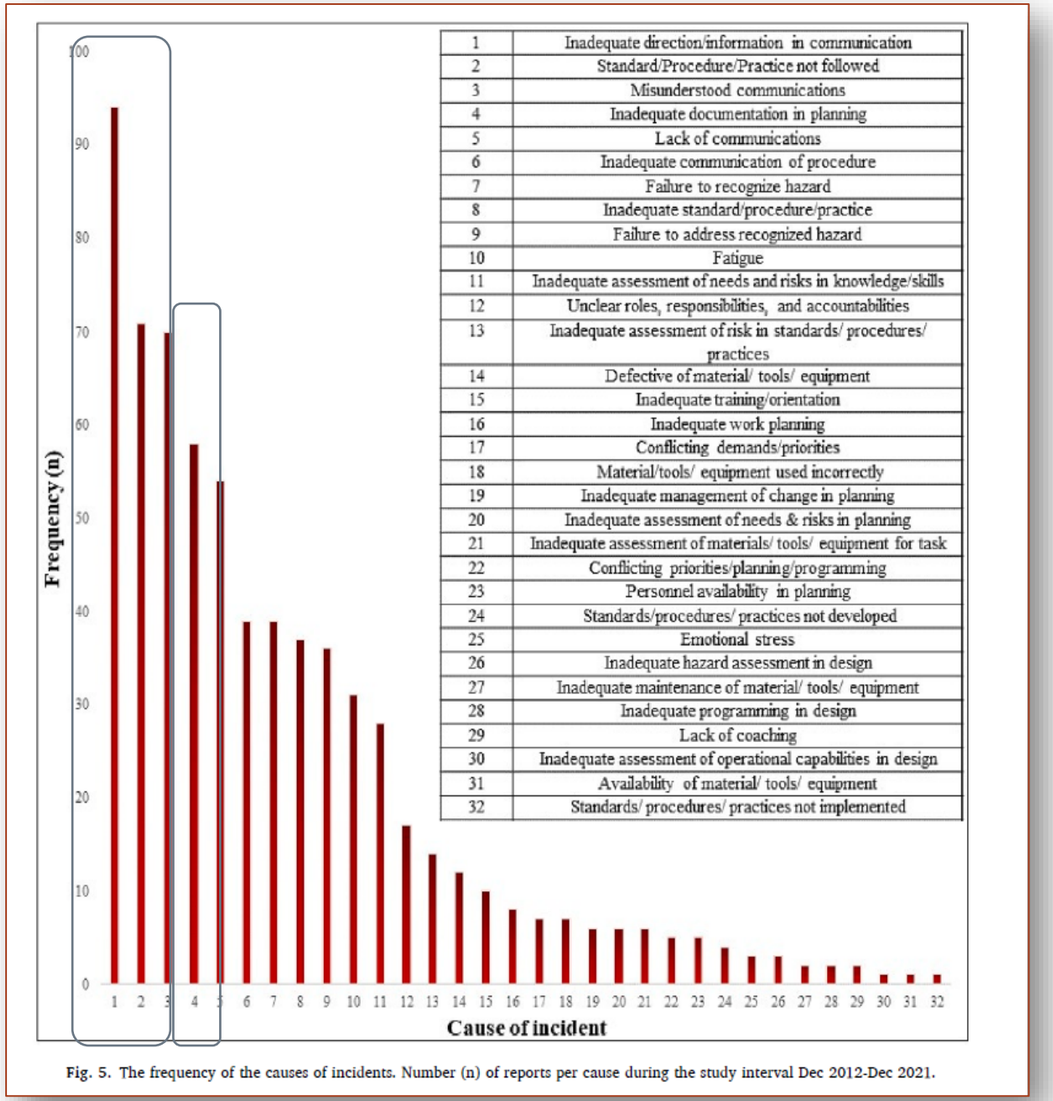
Tree-map chart on all categories of causes of incidents in the reports

Safety in radiation oncology (SAFRON):
Learning about incident causes and safety barriers in external beam radiotherapy

RESULTS

Frequency of the Cause of incidents:

- **Communication problems** and **failure to follow standards/ procedures/practices** were the most frequent causes of incidents [1-3]
- Furthermore**, inadequate documentation in planning** was the most frequent cause of incidents [4]



1	Inadequate direction/information in communication
2	Standard/Procedure/Practice not followed
3	Misunderstood communications
4	Inadequate documentation in planning
5	Lack of communications
6	Inadequate communication of procedure
7	Failure to recognize hazard
8	Inadequate standard/procedure/practice
9	Failure to address recognized hazard
10	Fatigue
11	Inadequate assessment of needs and risks in knowledge/skills
12	Unclear roles, responsibilities, and accountabilities
13	Inadequate assessment of risk in standards/ procedures/ practices
14	Defective of material/ tools/ equipment
15	Inadequate training/orientation
16	Inadequate work planning
17	Conflicting demands/priorities
18	Material/tools/ equipment used incorrectly
19	Inadequate management of change in planning
20	Inadequate assessment of needs & risks in planning
21	Inadequate assessment of materials/ tools/ equipment for task
22	Conflicting priorities/planning/programming
23	Personnel availability in planning
24	Standards/procedures/ practices not developed
25	Emotional stress
26	Inadequate hazard assessment in design
27	Inadequate maintenance of material/ tools/ equipment
28	Inadequate programming in design
29	Lack of coaching
30	Inadequate assessment of operational capabilities in design
31	Availability of material/ tools/ equipment
32	Standards/ procedures/ practices not implemented

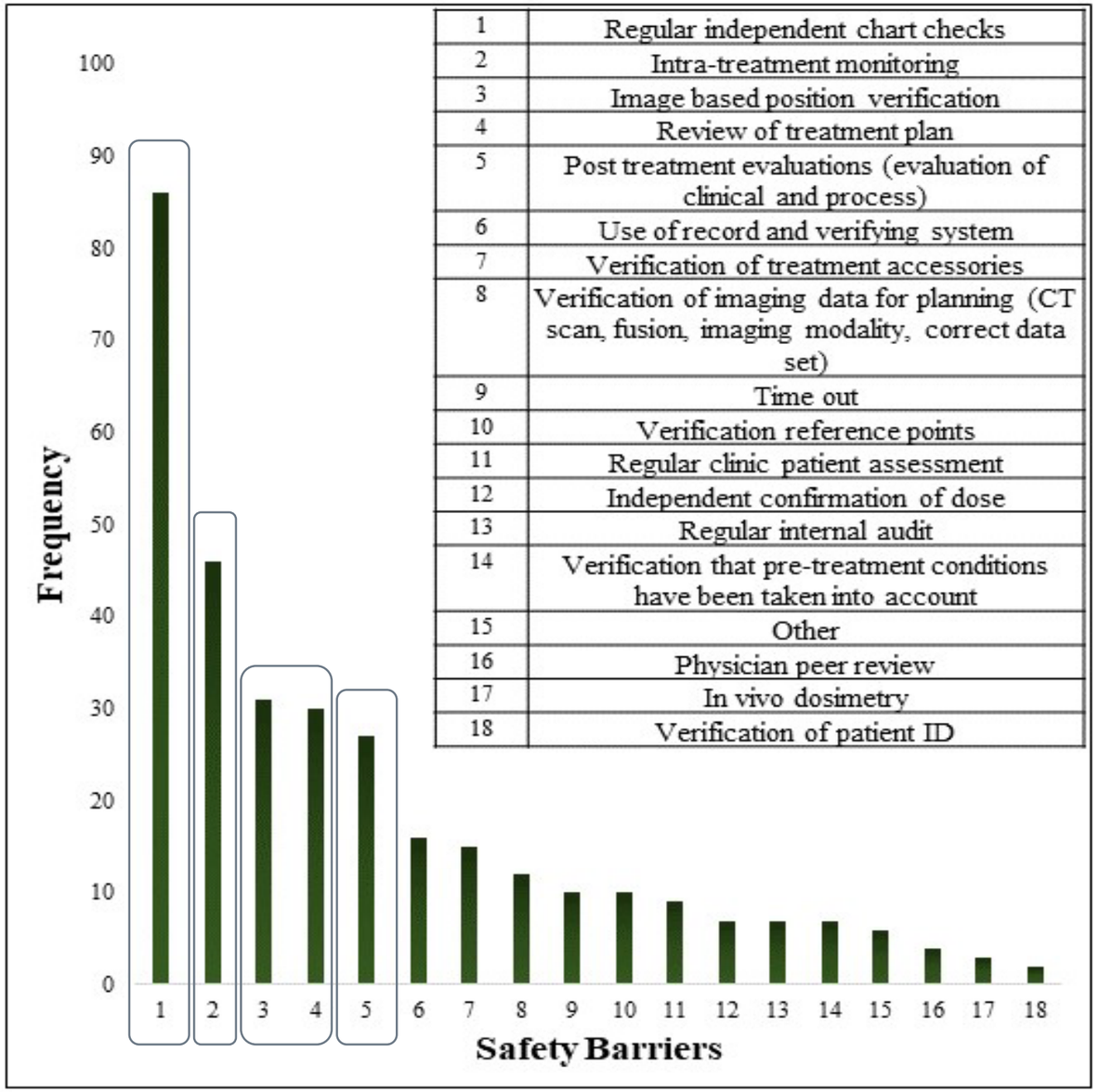
Fig. 5. The frequency of the causes of incidents. Number (n) of reports per cause during the study interval Dec 2012-Dec 2021.

Safety in radiation oncology (SAFRON):
Learning about incident causes and safety barriers in external beam radiotherapy

RESULTS

Safety barriers failed:

- Regular independent chart checks [1]
- Intra – treatment monitoring [2]
- Image based position verification and Review of treatment plan [3-4]
- Post treatment evaluation (evaluation of clinical and process) [5]



1	Regular independent chart checks
2	Intra-treatment monitoring
3	Image based position verification
4	Review of treatment plan
5	Post treatment evaluations (evaluation of clinical and process)
6	Use of record and verifying system
7	Verification of treatment accessories
8	Verification of imaging data for planning (CT scan, fusion, imaging modality, correct data set)
9	Time out
10	Verification reference points
11	Regular clinic patient assessment
12	Independent confirmation of dose
13	Regular internal audit
14	Verification that pre-treatment conditions have been taken into account
15	Other
16	Physician peer review
17	In vivo dosimetry
18	Verification of patient ID

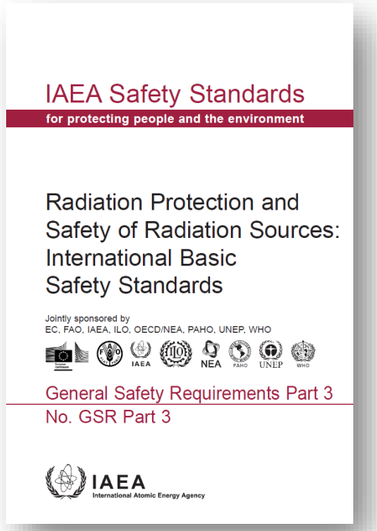
Safety in radiation oncology (SAFRON):
Learning about incident causes and safety barriers in external beam radiotherapy

Findings:

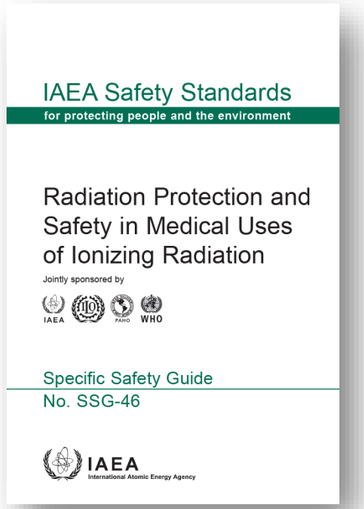
- ✓ The importance of **education and training radiation therapists** in incident prevention and patient safety in radiotherapy should not be underestimated since **they have discovered almost two-thirds** of the reported incidents.
- ✓ Although the majority of the reported incidents were minor, **they could provide numerous learning opportunities and may aid in the prevention** of more serious events.
- ✓ Different types of **communication-based issues**, such as insufficient communication direction or information, misunderstood communications and a lack of communication were frequently the causes of incidents.
- ✓ Regular **independent chart checking was the most effective type of safety barrier** in the identification of the reported incidents, and they highlighted the significance of awareness required during the chart check.

IAEA standards

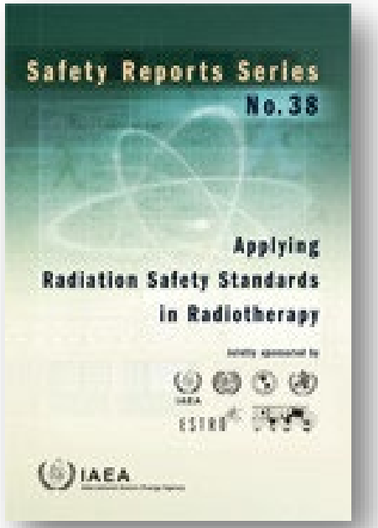
- ✓ Before initiating construction of a radiotherapy facility, approval has to be obtained by the national regulatory authority.
- ✓ The BSS can only be implemented through an effective radiation safety infrastructure that includes **adequate laws and regulations, an efficient regulatory system,** supporting experts and services, and a ‘safety culture’ shared by all those with responsibilities for protection, including both management and workers.
- ✓ Guidance on the practical implementation of the standards of safety in medical exposure as established by the BSS can be found in **GSR Part 3 and SSG 46**
- ✓ More specific guidance for regulators and users of radiation sources in radiotherapy can be found in SRS 38



RADIATION PROTECTION AND SAFETY OF RADIATION SOURCES:INTERNATIONAL BASIC SAFETY STANDARDS (iaea.org)



17-24431_PUB1775_book.indb (iaea.org)



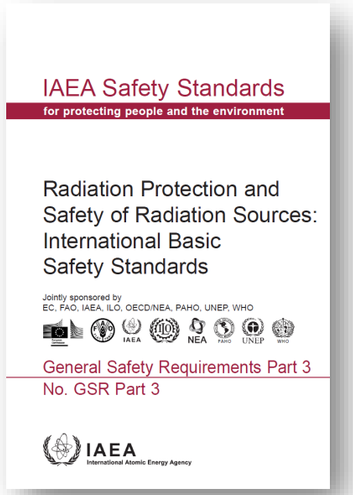
Applying Radiation Safety Standards in Radiotherapy | IAEA

Medical exposure (GSR Part 3)

	Occupational exposure	Public exposure	Medical exposure
Planned exposure situations	Section 2; Section 3: paras 3.5–3.67 and paras 3.68–3.116	Section 2; Section 3: paras 3.5–3.67 and paras 3.117–3.144	Section 2; Section 3: paras 3.5–3.67, 3.145-3.185
Emergency exposure situations	Section 2; Section 4	Section 2; Section 4	Not applicable
Existing exposure situations	Section 2; Section 5	Section 2; Section 5	Not applicable

- **Medical uses of ionizing radiation are a planned exposure situation.**
- This includes situations of **potential exposure.**

3.145. The requirements in respect of medical exposure in planned exposure situations (paras 3.146–3.185) apply to all medical exposures, including intended, unintended and accidental exposures.



Radiation Protection in Medical Exposure (TSA-3)

TSA 3 in RASIMS 2.0 includes **14 elements under 4 groups**:

I. Governmental and legal framework for radiation protection in medical exposure (7 PQs and 27 SQs)

- Element 1. Legal and regulatory framework (4 SQs)
- Element 2. Education, training and competence (3 SQs)
- Element 3. Justification (7 SQs)
- Element 4. Optimization (5 SQs)
- Element 5. Female patients (3 SQs)
- Element 6. Unintended or accidental medical exposures (2 SQs)
- Element 7. Radiological reviews and records (3 SQs)

Radiation Protection in Medical Exposure (TSA-3)

✓ I. Governmental and legal framework for radiation protection in ✓ Medical Exposure (7 PQs and 27 SQs)

✓ Element 1. Legal and regulatory framework (4 SQs)

- ✓ Provides the statutory basis for requirements for protection and safety specific to medical exposure.
- ✓ Requires the establishment of a regulatory body with responsibilities and functions for control of medical exposure.
- ✓ Specified responsibilities of relevant parties (such as radiological medical practitioner, referring medical practitioners, medical physicists and medical radiation technologists) in relation to medical exposure.
- ✓ Provides for coordination between authorities with responsibilities relevant to medical exposure (regulatory bodies, health authority, and relevant professional bodies) to ensure that relevant parties can adequately assume their roles and responsibilities.

Radiation Protection in Medical Exposure (TSA-3)

I. Governmental and legal framework for radiation prot medical exposure (7 PQs and 27 SQs)

Education, training and competence (3 SQs)

- ✓ The requirements that health professionals with responsibilities for medical exposure are specialized in the appropriate area (as acknowledged by the relevant professional body, health authority or appropriate organization) are established by regulatory body.
- ✓ There are requirements in place related to education, training and competence in radiation protection of health professionals with responsibilities for medical exposure.
- ✓ Requirements for formal assessment of the competence of medical physicists to practice independently in one or more of the subfields (specialities) of medical physics are in place.

Radiation Protection in Medical Exposure (TSA-3)

I. Governmental and legal framework for radiation protection in medical exposure (7 PQs and 27 SQs)

Element 4. Optimization (5 SQs)

- ✓ Requirements that consider design of medical radiological equipment and software that could influence the delivery of medical exposure.
- ✓ Requirements that require medical physicist to ensure that: all sources giving rise to medical exposure are calibrated, independently validated prior to clinical use, and calibration procedure is traceable to a standards dosimetry laboratory.
- ✓ Establishment of a quality assurance programme for medical exposure.
- ✓ Requirement for using dose constraints in the optimization of protection and safety for carers and comforter.
- ✓ Requirements for using dose constraints in the optimization of protection and safety of persons subject to exposure as part of a programme of biomedical research.

Radiation Protection in Medical Exposure (TSA-3)

I. Governmental and legal framework for radiation protection in medical exposure (7 PQs and 27 SQs)

Element 6. Unintended or accidental medical exposures (2 SQs)

- ✓ Requirements to ensure that measures are taken to minimize the likelihood of unintended or accidental medical exposures which arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error.
- ✓ Requirements to ensure that any unintended or accidental medical exposures is promptly investigated, and that all the corrective actions under their own responsibility are implemented and written record is submitted to the regulatory body.

Radiation Protection in Medical Exposure (TSA-3)

II. Patient protection in diagnostic and interventional radiology

Element 8. Qualified medical personnel in diagnostic and interventional radiology (4 SQs; 5IQs)

Element 9. Optimization in diagnostic and interventional radiology (4 SQs; 5 IQs)

III. Patient protection in nuclear medicine

Element 10. Qualified medical personnel in nuclear medicine (5 SQs; 4 IQs)

Element 11. Optimization in nuclear medicine: PQ on diagnostic NM (4 SQs; 3 IQs)

PQ on therapeutic NM (3 SQs; 2 IQs)

Element 12. Release of patient (2 SQs)

IV. Patient protection in radiotherapy

Element 13. Qualified medical personnel in radiotherapy (4 SQs; 3 IQs)

Element 14. Optimization in radiotherapy (7 SQs)

Radiation Protection in Medical Exposure (TSA-3)

IV. Patient protection in radiotherapy

Element 13. Qualified medical personnel in radiotherapy (4 SQs; 3 IQs)

- ✓ Regulatory requirements which establish responsibility of licensees to ensure sufficient medical professionals are available in facilities that perform radiation therapy.
- ✓ Availability of or access to qualified medical physicists in radiation therapy is required.
- ✓ Regulatory requirements to ensure sufficient availability of qualified radiation oncologists in radiation therapy facilities.
- ✓ Requirements to ensure sufficient availability of qualified medical radiation technologists (radiographers) in radiation therapy.
- ✓ Requirements for formal education for radiotherapy technologists.

Radiation Protection in Medical Exposure (TSA-3)

IV. Patient protection in radiotherapy

Element 14. Optimization in radiotherapy (7 SQs)

- ✓ There are requirements in place to ensure that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances.
- ✓ There are regulatory requirements to ensure that all sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols.
- ✓ Requirements to ensure that calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the regulatory body are established.
- ✓ Requirements for dosimetry to determine absorbed doses to the planning target volume for each patient treated with external beam therapy and/or brachytherapy and absorbed doses to relevant tissues or organs.
- ✓ Requirements to ensure that comprehensive quality assurance programmes are established for radiation therapy are in place.

IAEA - Radiation Protection of Patients unit (RPOP)

http://rpop.iaea.org

- Annually: 1.5 million pageviews
- Contains useful information and FAQs for health professionals, patients and public
- Links to resources: training material, posters, webinars, videos, etc.

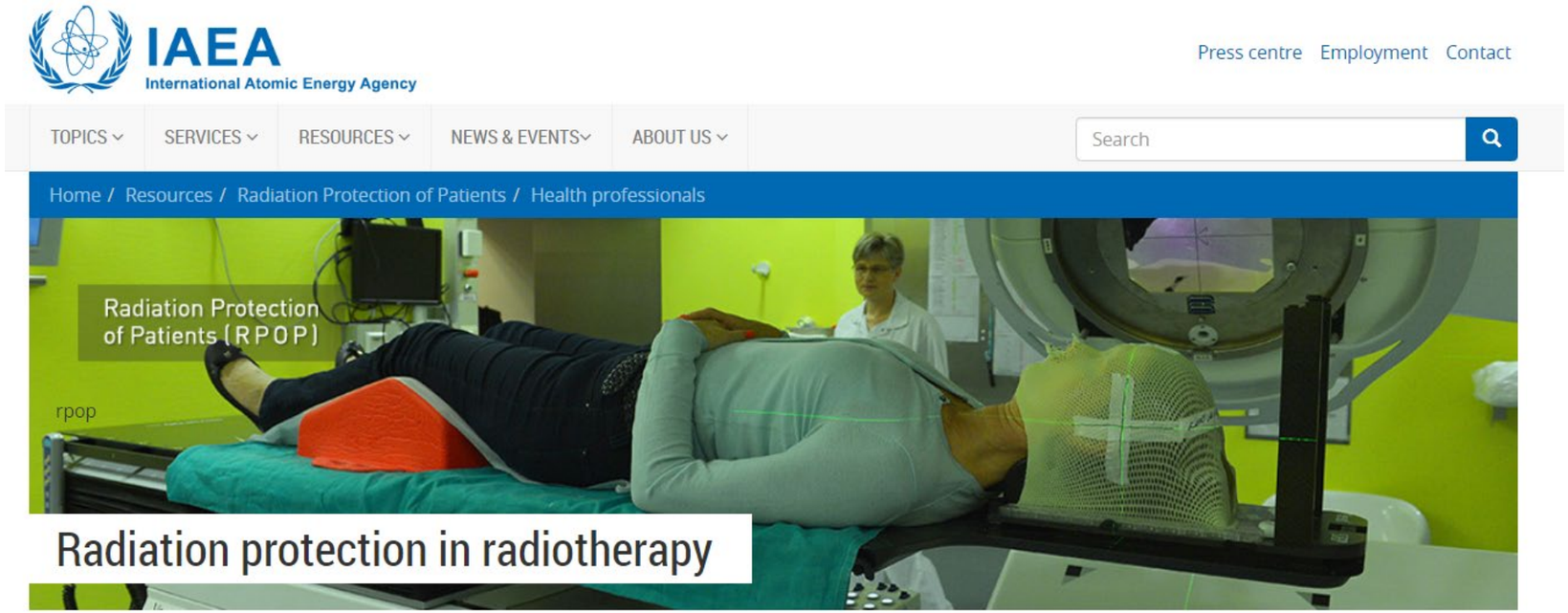
IAEA - Radiation Protection of Patients unit (RPOP)

http://rpop.iaea.org

2 entries – 2 different audiences

IAEA - Radiation Protection of Patients unit (RPOP)

Radiotherapy | IAEA



Health professionals

- RPOP Home
- Radiology
- Radiotherapy
  - Responsibilities of health professionals
  - Pregnant women
  - Accident prevention
  - Brachytherapy
  - External beam radiotherapy
  - Endovascular brachytherapy
- Nuclear medicine

Radiotherapy is one of the main types of cancer treatment. It uses ionizing radiation to destroy cancer cells and limit cell growth. It is applied by a team of qualified experts with the appropriate education and many years of experience in radiation oncology, medical physics and radiation therapy technology.

Radiotherapy can be delivered externally or internally. In external beam radiotherapy, radiation beams originating externally to the patient are directed towards the treatment site. These beams are usually created through the use of a linear accelerator or a cobalt unit. In brachytherapy, small and encapsulated radioactive sources are placed directly into or near the volume to be treated. Endovascular brachytherapy, finally, is used for prevention of restenosis in arteries following coronary arterial angioplasty.

Related resources

- Radiotherapy - what patients need to know
- Safety in Radiation Oncology (SAFRON)

Training resources

- Online training: safety and quality in radiotherapy
- Online training in radiation protection
- Training material: radiotherapy

IAEA Radiation Protection of Patients – RPOP website

Radiation Protection of Patients (RPOP) | IAEA

IAEA launches new E-learning

The IAEA has created e-learning program - *Safety and Quality in Radiotherapy* designed to provide continuing education to radiotherapy professionals regarding safety and quality in radiotherapy. The e-learning offers participants from all around the world the opportunity to improve their understanding of safety in radiotherapy, learn techniques to reduce and avoid radiotherapy incidents and understand the value and use of incident learning systems.

Throughout this e-learning course, the participants are expected to:

- Improve their understanding of safety in radiotherapy
- Learn techniques to reduce and avoid radiotherapy incidents;
- Understand the value and use of incident learning systems;
- Learn about useful sources of information to enhance safety in radiotherapy;
- Gain insight into improving safety culture in medical clinics/facilities.

The course is organized into twelve modules, each with a short quiz at the end. These quizzes serve as a self-check for participants to review their own understanding of the material.

The estimated time for the entire course is 5 hours. After completing the course, participants can receive a certificate of completion. This e-learning is provided in English.

IAEA launches new E-learning

12 modules

Radiation protection challenges

Cooperation with IRPA, WHO and IOMP -2021

Building Radiation Safety Culture in Medicine (1/2)

Handbook for students

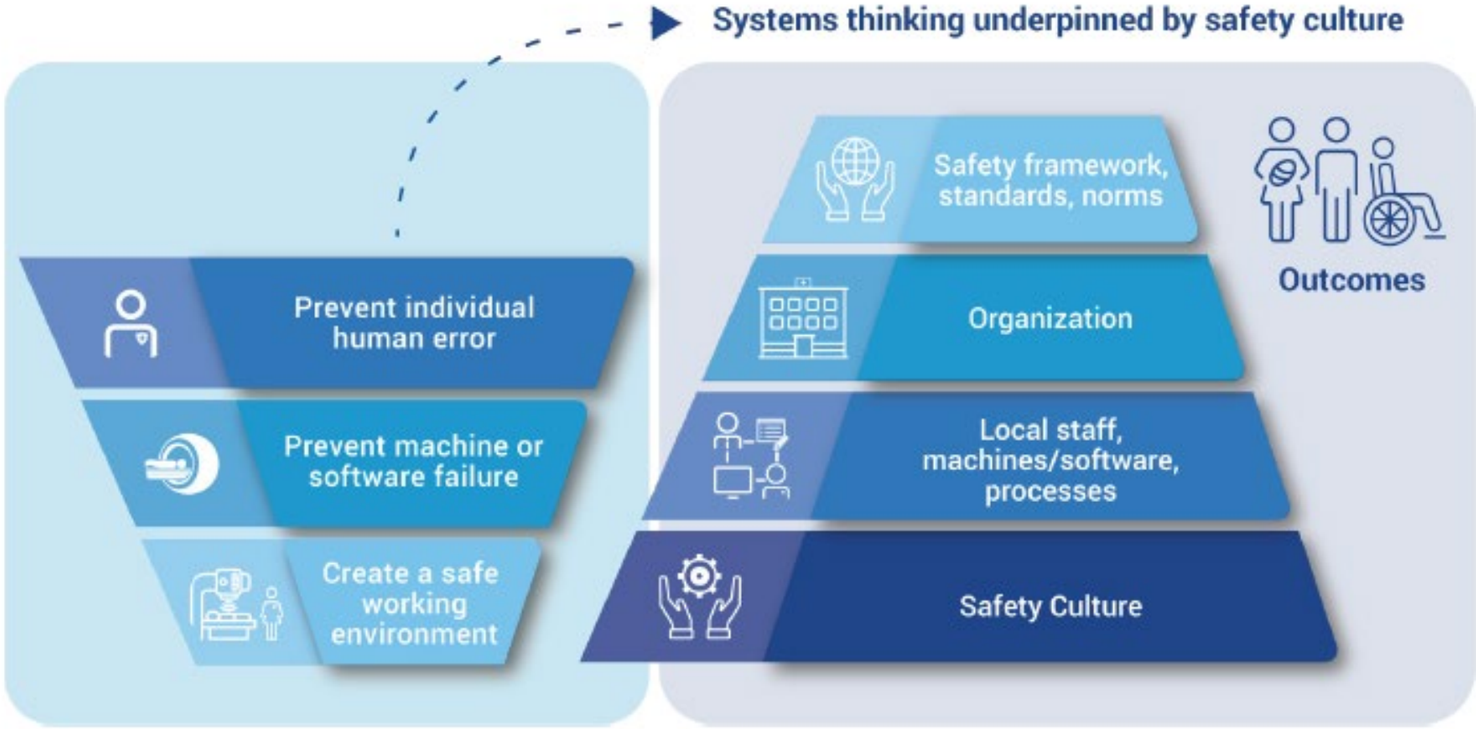
Complemented by digital presentations on how medical facilities address improvements in safety culture in practice

Radiation protection challenges

Cooperation with WHO, IAEA and IOMP

Published 10 July 2024

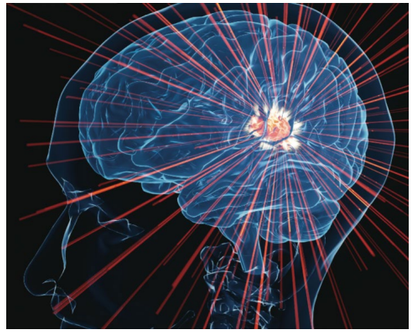
Building Radiation Safety Culture in Medicine (2/2)



Quantitative indicators that can be related to radiation safety culture traits Safety Culture in Medicine

EXAMPLES OF INDICATORS	RELATED TRAITS
Percentage of procedures for which local Diagnostic Reference Levels are in place	• Decision-making • Problem identification and resolution • Work processes
Percentage of staff included in accreditation programmes for their specific roles	• Continuous learning • Individual responsibility
Number of services accredited	• Work processes
Reported errors/incidents	• Problem identification and resolution • Environment for raising concerns
Number of audits performed	• Problem identification and resolution
Number of hours training in radiation protection	• Continuous learning
Number of procedures suspended for safety concerns	• Decision making
Recorded staff doses	• Leadership responsibility
Compliance with personal monitoring	• Work processes
Compliance with wearing PPE	• Individual responsibility

To conclude:



- The delivered dose to the treated volume in radiotherapy is very high;
- Any accident or incident can have a significant impact on the patient's outcome.
- Radiation protection infrastructure and practices should be implemented in line with the highest safety standards.


IAEA
International Atomic Energy Agency
Thank you!
https://www.iaea.org/resources/rpop