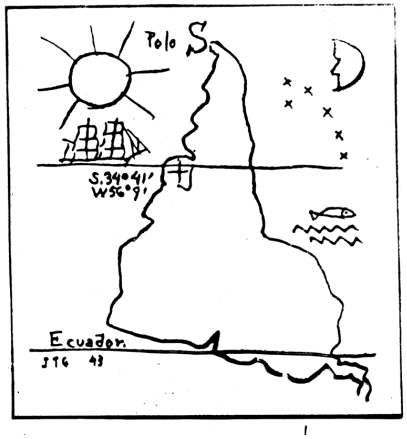
Security and safety in medical applications: diagnosis and therapies

Gabriel González Sprinberg,
Instituto de Física
Facultad de Ciencias
Universidad de la República
Montevideo, Uruguay



Gabriel.Gonzalez-Sprinberg@fcien.edu.uy

Security and safety in medical applications: diagnosis and therapies

Security and safety represent important elements within medical radiation applications, encompassing both in **therapies and diagnostics** procedures. However, the procedures and policies concerning these aspects remain underdeveloped across some of our countries. For one hand, at the **educational** level security and safety may not be properly included in the curricula and postgraduate studies. Moreover, several issues pertaining to **regulatory** authority policies warrant consideration within these practices. In this presentation, I will examine the challenges facing the field of **medical physics** concerning security and safety, while also exploring the intricate relationship between these elements and regulatory policies.

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NUCLEAR SECURITY:

prevention of unauthorized actions with radiation sources (theft, terrorism, etc..)

NUCLEAR SAFETY:

refers to the appriopriate use of techniques and equipment taking into account the protection for public, workers, patients, and environment from undue radiation hazards (also “radiation security” and “radiation protection”).

BONN CALL for ACTION 2012

JOINT POSITION STATEMENT **IAEA WHO**

10 Actions to Improve Radiation Protection in Medicine in the Next Decade

Careful balance between the benefits of enhancing human health and welfare, and the risks related to the radiation exposure of people

Holistic approach which includes partnership of **national governments, civil society, international agencies, researchers, educators, institutions and professional associations** aiming at identifying, advocating and implementing solutions to address existing and emerging challenges.

Leadership, harmonization and coordination of activities and procedures at an international level are also needed.

The **aims** of the Bonn Call-for-Action for the safe and appropriate use of ionzing radiation in medicine are to

a) strengthen the radiation protection of patients and health workers overall;

b) attain the highest benefit with the least possible risk to all patients by the safe and appropriate use of ionizing radiation in medicine;

c) aid the full integration of radiation protection into health care systems;

d) help improve the benefit/risk-dialogue with patients and the public; and

e) enhance the safety and quality of radiological procedures in medicine.

10 Actions to Improve Radiation Protection in Medicine

01 **Enhance** the implementation of the principle of justification

02 **Enhance** the implementation of the principle of optimization of protection and safety

03 **Strengthen** manufacturers' role in contributing to the overall safety regime

04 **Strengthen** radiation protection education and training of health professionals

05 **Shape** and **promote** a strategic research agenda for radiation protection in medicine

06 **Increase** availability of improved global information on medical exposures and occupational exposures in medicine

07 **Improve** prevention of medical radiation incidents and accidents

08 **Strengthen** radiation safety culture in health care

09 **Foster** an improved radiation benefit-risk-dialogue

10 **Strengthen** the implementation of safety requirements globally

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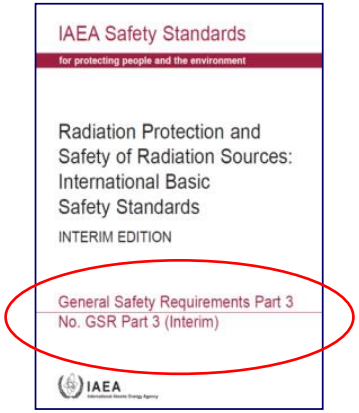
INTERNATIONAL ATOMIC ENERGY AGENCY (IAEA)

IAEA'S RADIATION SAFETY STANDARDS

- **IAEA Safety Standards are not legally binding on Member States but may be adopted by them, at their own discretion**

however...

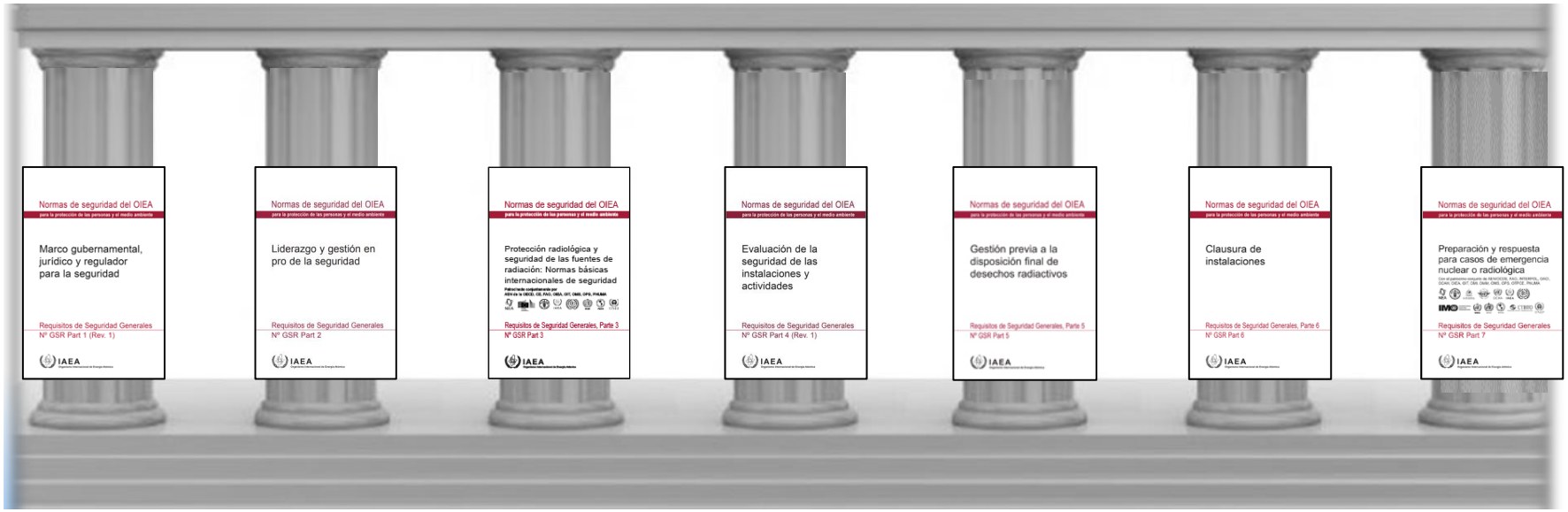


- IAEA Safety Standards are binding on IAEA in relation to its own operations and to operations assisted by the IAEA; and

- Member States receiving IAEA assistance are obliged to apply IAEA Safety Standards

General Safety Requirements/Documents

1. Governmental, Legal and Regulatory Framework for Safety
2. Leadership and Management for Safety
3. Radiation Protection and Safety for Radiation Sources
4. Safety Assessment for Facilities and Activities
5. Predisposal Management for Radioactive Waste
6. Decommissioning of Facilities
7. Preparedness and response for a Nuclear or Radiological Emergency



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Radiation safety is structured in Thematic Safety Areas (TSA):

- **TSA 1: Regulatory Infrastructure for Radiation Safety**
- **TSA 2: Occupational Radiation Protection**
- **TSA 3: Medical Exposure Control**
- **TSA 4: Public & Environmental Exposure Control**
- **TSA 5: Emergency Preparedness and Response**
- **TSA 6: Education and Training**
- **TSA 7: Transport Safety**

- **Each TSA has a standard set of "essential elements" used to identify country situation, identify assistance needs and monitor progress.**
  - **Information is managed in RASIMS**

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International Atomic Energy Agency

ELEMENTS FOR TSA 1: REGULATORY INFRAESTRUCTURE FOR RADIATION SAFETY

The regulatory control shall be commensurate with the radiation risks associated with facilities and activities, in accordance with a graded approach. To cover these topics 14 infrastructure elements constitute TSA 1:

Legislative framework:

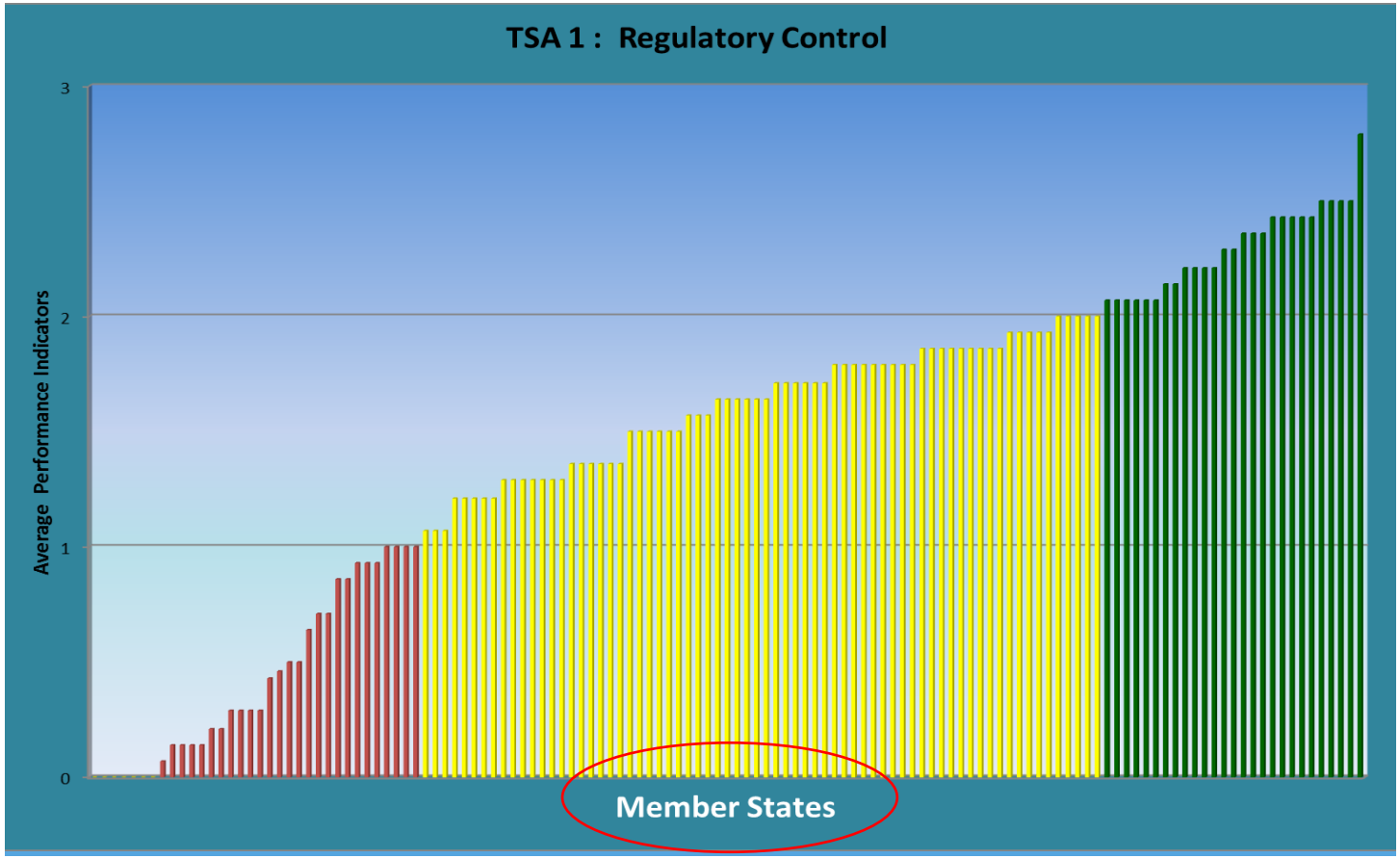
Legislation
Regulations and Guidance,
Regulatory Body Establishment and independence.
Regulatory Body Staffing and Training.
Regulatory Body Funding.
Coordination and Cooperation and the National Level.
International Cooperation.

Regulatory Body activities:

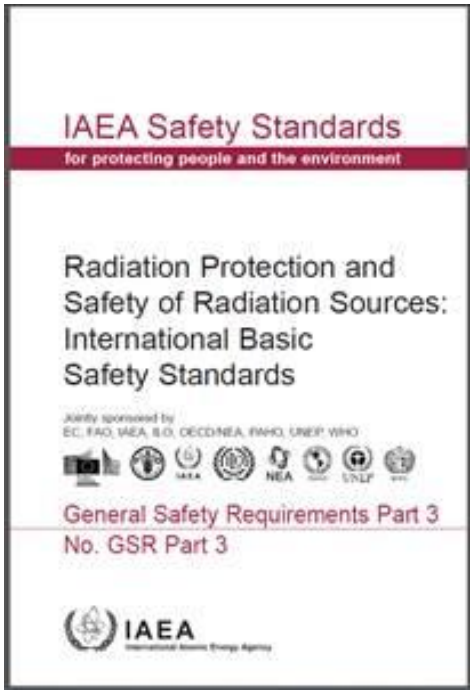
8. Notification and National Register of Radiation Sources
9. Authorization
10. Safety and Security of R.S
11. Inspection
12. Enforcement
13. Information management
14. Quality Management

THEMATIC SAFETY AREA 1 (REGULATORY)

40 % Low progress | 56 % Medium progress | 4 % High progress



Basic Safety Standards GSR Part 3



3 exposure situations

- **Planned**
- **Existing**
- **Emergency**

3 different exposure situations

- **Occupational**
- **Medical**
- **Public**

Specific Safety Guide SSG 46

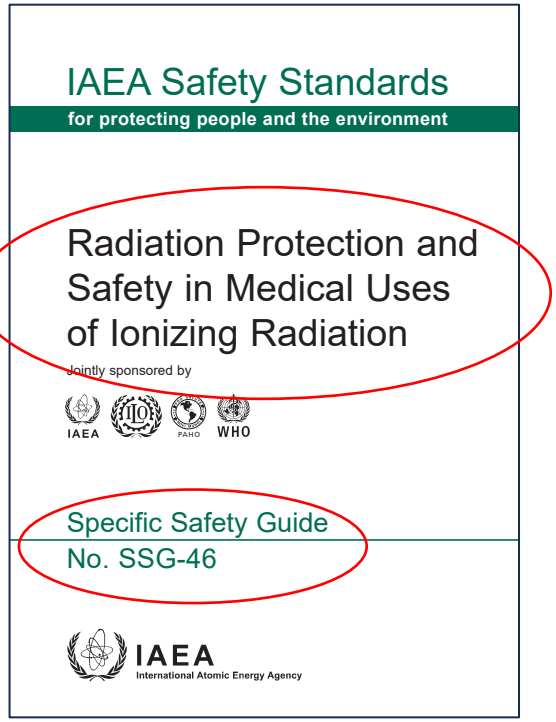
MEDICAL PROCEDURES WITH IONIZING RADIATION IN DIAGNOSIS AND TREATMENT

- **DIAGNOSTIC RADIOLOGY AND IMAGE GUIDED INTERVENTIONAL**
  (X-RAYS, TOMOGRAPHY, MAMOGRAPHY, FLUOROSCOPY, ANGIOGRAPHY,…)

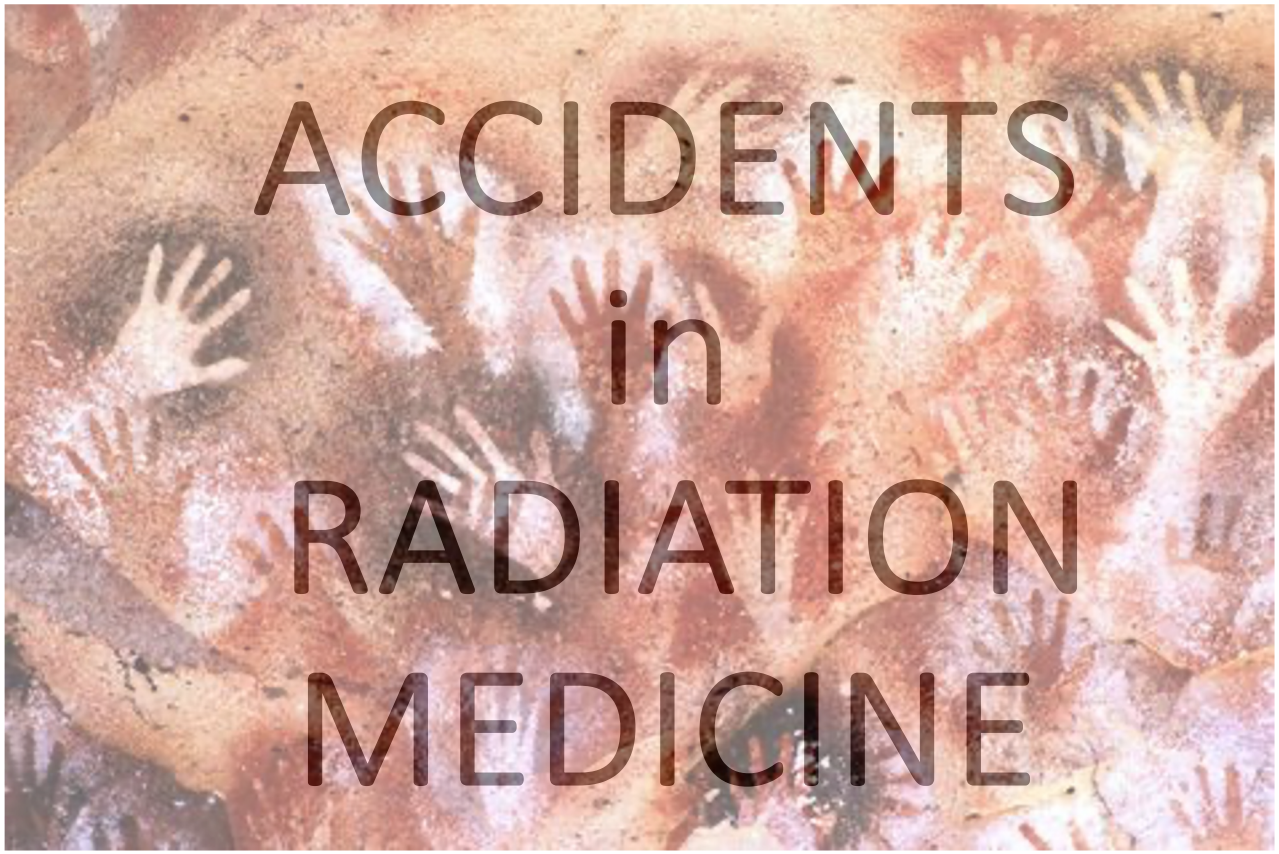
- **NUCLEAR MEDICINE**
  (DIAGNOSIS AND TREATMENT WITH SOURCES; GAMMA-CAMARA, PET, SPECT,…)

- **RADIATION THERAPY**
  (TREATMENT, SOURCES AND RADIATION BEAMS, LINAC,…)

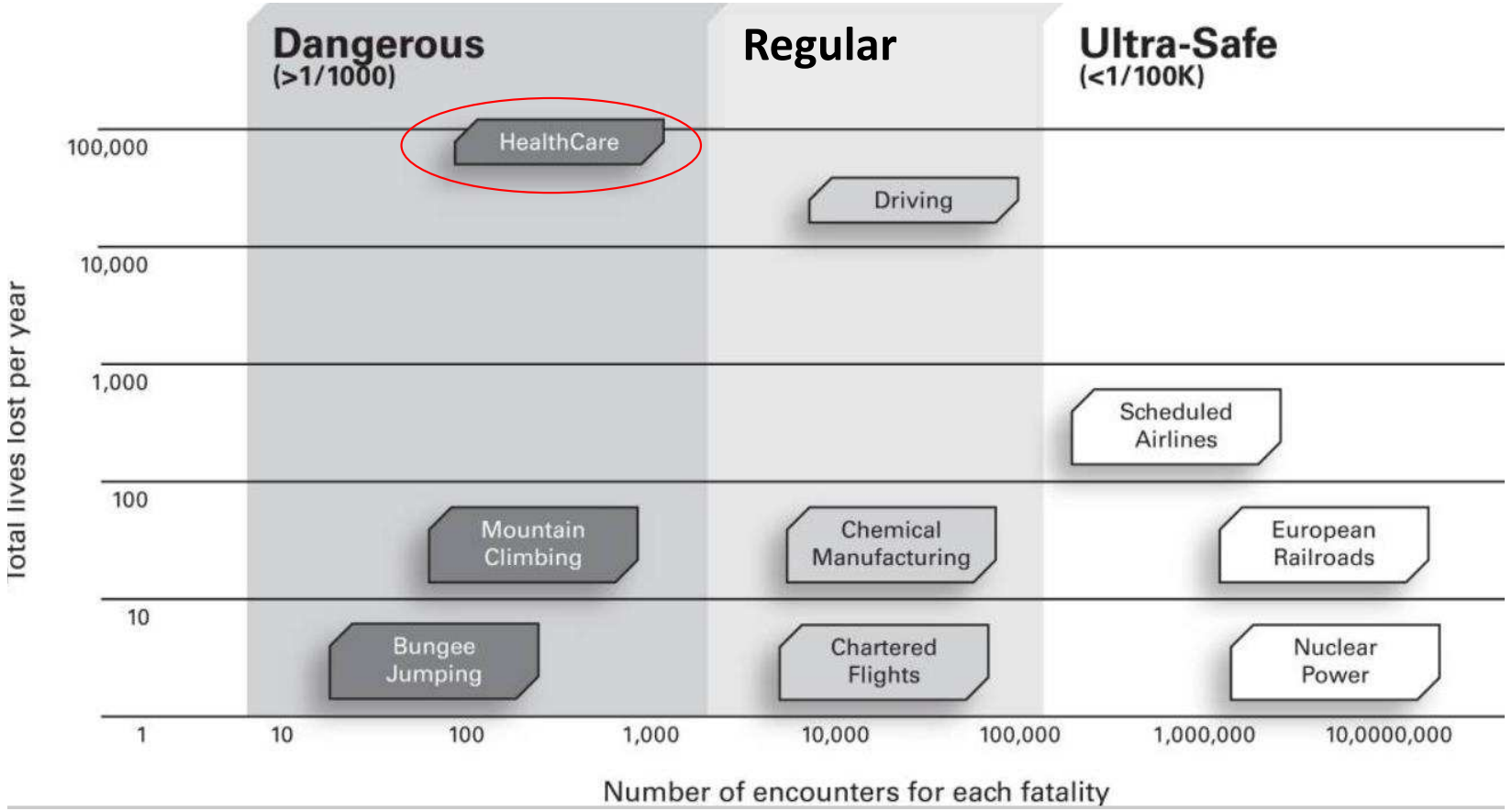
Specific Safety Guide SSG 46



- GENERAL RECOMMENDATIONS FOR RADIATION PROTECTION AND SAFETY IN **MEDICAL USES** OF RADIATION
- SPECIFIC RECOMMENDATIONS FOR RADIATION PROTECTION AND SAFETY IN **DIAGNOSTIC RADIOLOGY AND IMAGE GUIDED INTERVENTIONAL** PROCEDURES
- SPECIFIC RECOMMENDATIONS FOR RADIATION PROTECTION AND SAFETY IN **NUCLEAR MEDICINE**
- SPECIFIC RECOMMENDATIONS FOR RADIATION PROTECTION AND SAFETY IN **RADIATION THERAPY**

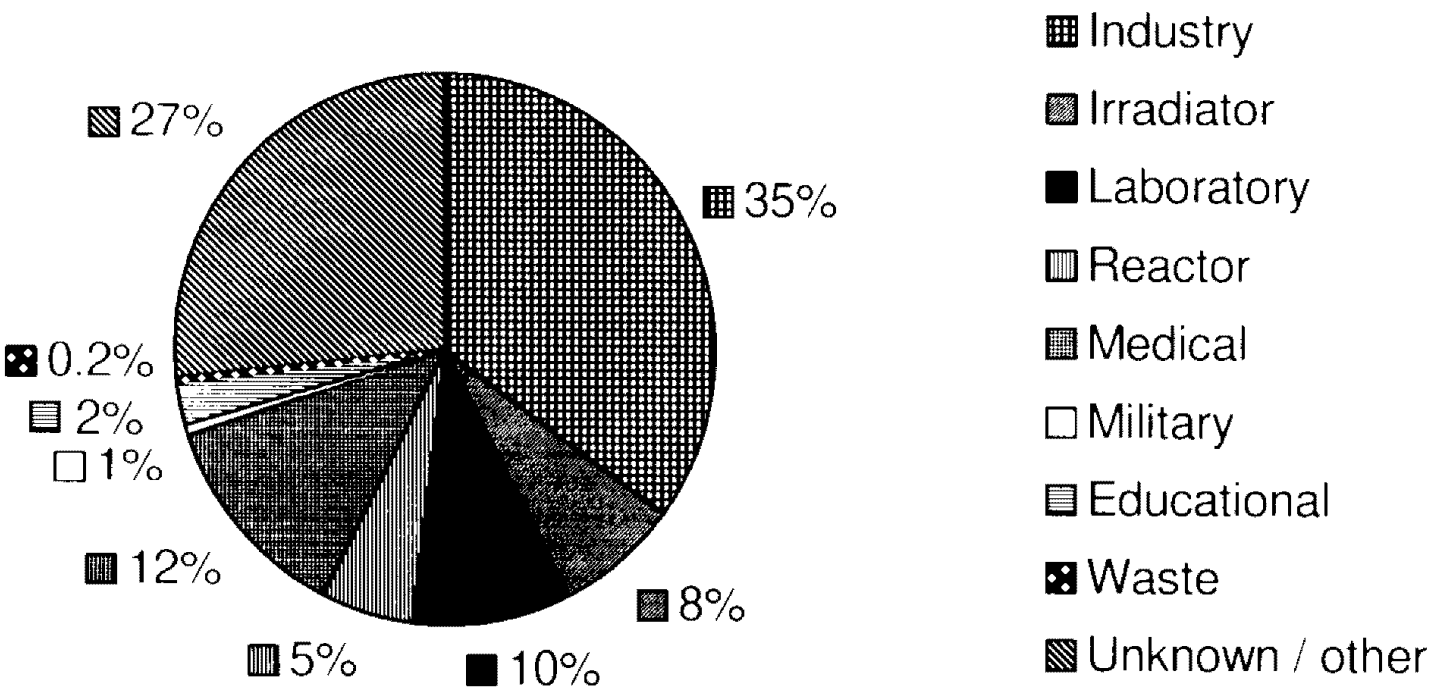

ACCIDENTS
in
RADIATION
MEDICINE

Security and Safety : how dangerous is dangerous



Agency for Healthcare Research and Quality

Types of Accidents Involving Radiation



IAEA Accidents Reports

Lessons learned in radiological accidents/emergencies

Circumstances and consequences are detailed for nuclear and radiological accidents

More than 20 reports are available

These reports lessons and hints to improve safety, preparedness and response to radiological emergencies

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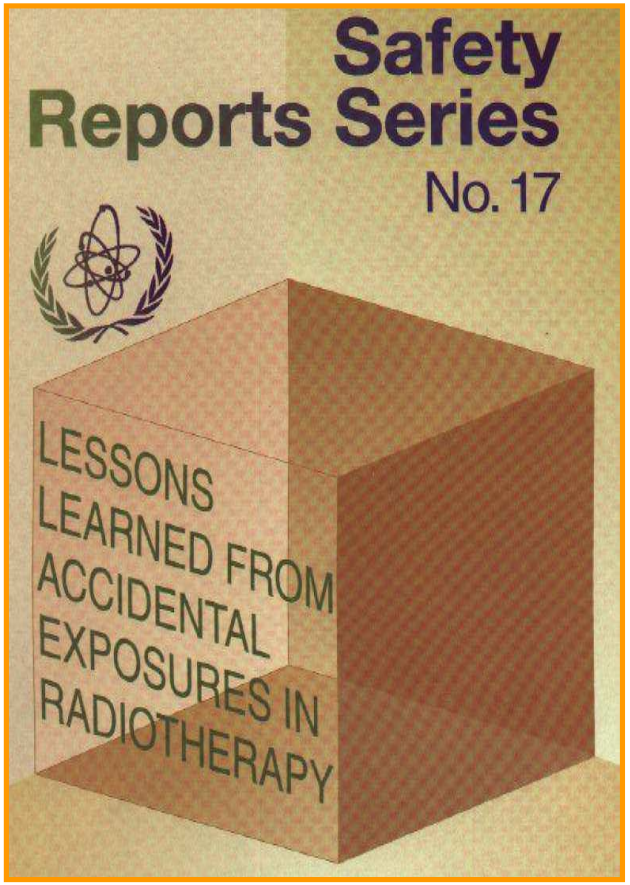
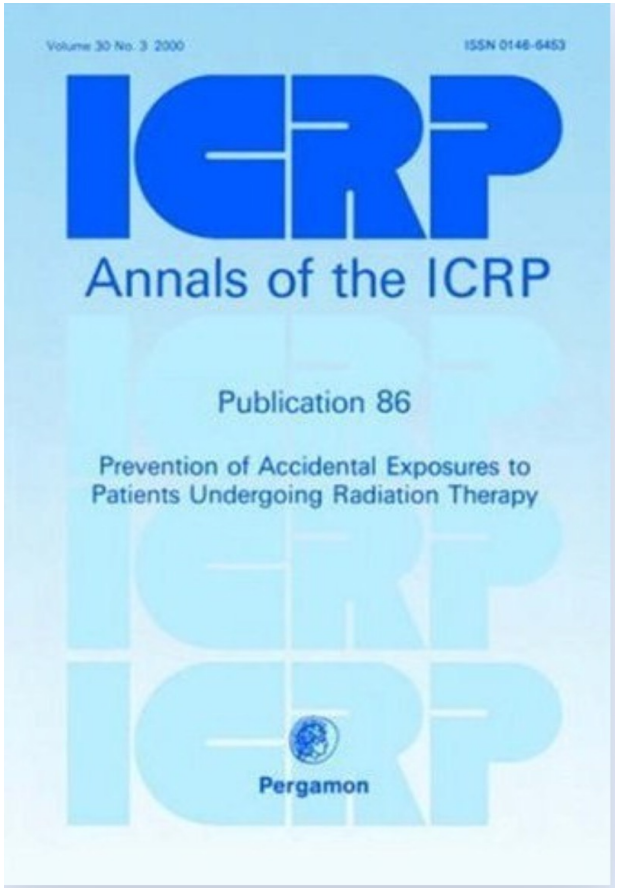
Adverse event/outcome (accident): injuries related to medical managment



IAEA 2000



ICRP 2000

Accident: word might suggest that / may be interpreted that it could be unpreventable

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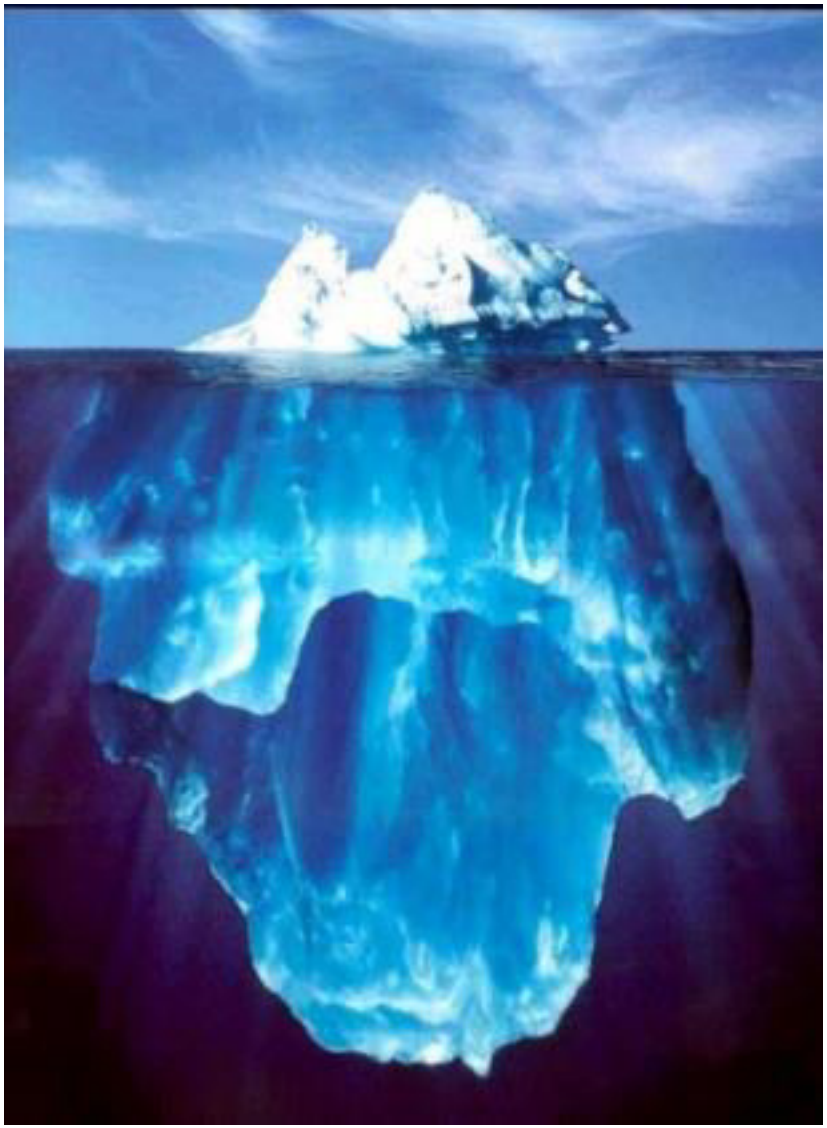
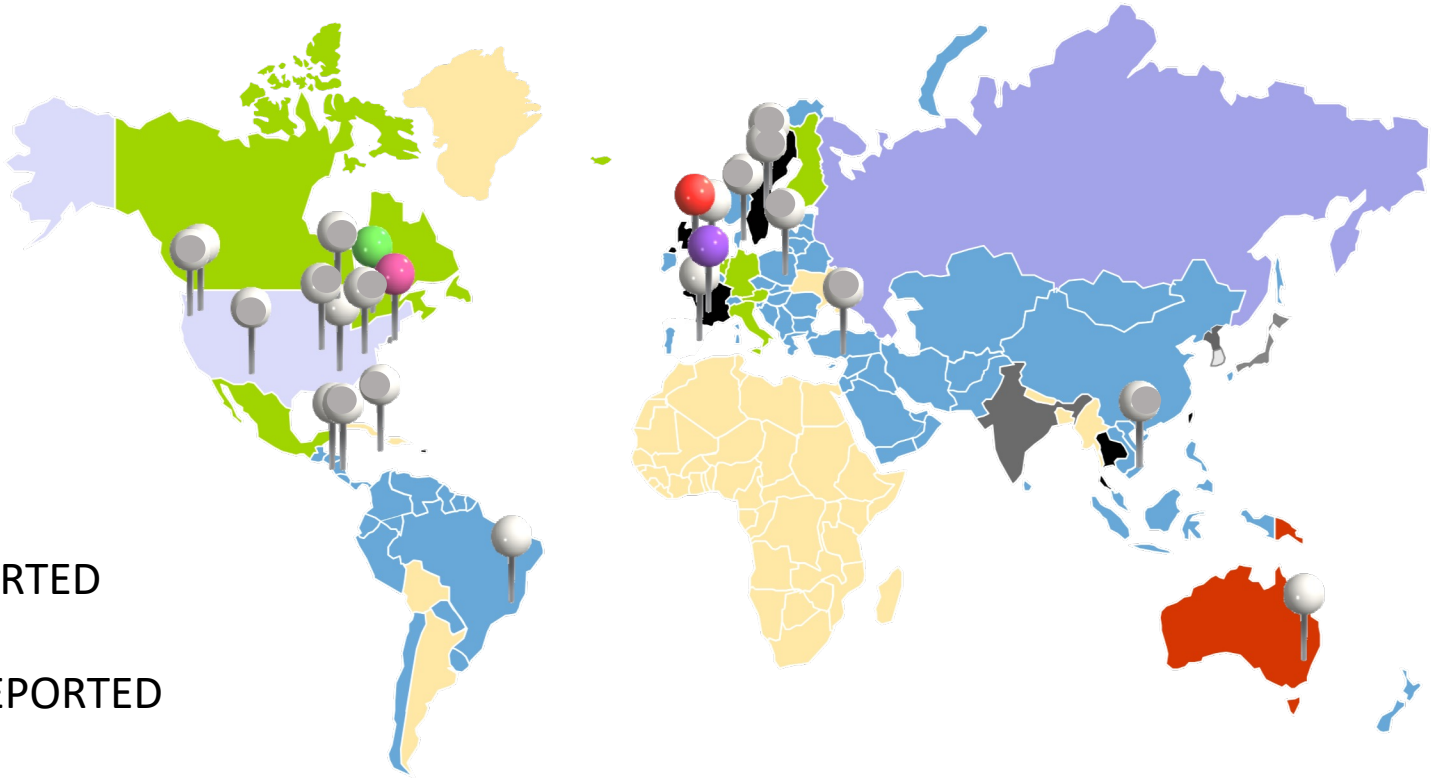
Reported

Unreported



Accidents in radiotherpay around the world



REPORTED

UNREPORTED

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IAEA Accident Reports: Región Latinoamericana

Evento	País/Año	Práctica / Actividad de la fuente	Fuente involucrada: Industrial o Médica	Personas afectadas	Lugar de origen del evento
Goiania	Brasil/1987	Teleterapia ***Cs-137 50,9 TBq***	Médica	Miembros del público: ***4 muertos*** ***129 expuestos (19 lesiones piel)***	Clínica abandonada
San Salvador	El Salvador/1989	Irradiador ***Co-60 660 TBq***	Industrial	Trabajadores: ***1 muerto*** ***2 expuestos (amputaciones)***	Irradiador industrial
San José	Costa Rica/1996	Teleterapia ***Co-60***	Médica	Pacientes: ***17 muertos*** ***63 sobreexpuestos***	Hospital
Yanango	Perú/1999	Gammagrafía ***Ir-192 1,37 TBq***	Industrial	Trabajadores: ***2 expuestos (lesiones en el cuerpo)***	Sitio industrial (faena)
Cochabamba	Bolivia/2002	Gammagrafía ***Ir-192 0,22 TBq***	Industrial	Trabajadores y Público: ***4 trabajadores sobreexpuestos*** ***55 personas público expuestas***	Medio de transporte/faena
Nueva Aldea	Chile/2005	Gammagrafía ***Ir-192 3,33 TBq***	Industrial	Trabajadores: ***3 sobreexpuestos (lesiones graves)***	Sitio industrial (Faena)
Chilca	Perú/2012	Gammagrafía ***Ir-192 3,65 TBq***	Industrial	Trabajadores: ***4 sobreexpuestos (lesiones graves)***	Sitio industrial (Faena)
Hueypoxtla	México/2013	Teleterapia ***Co-60 95,24 TBq***	Médica	Miembros del público y Respondedores: ***59 expuestos***	Transporte/robo/ desmantelamiento
Ventanilla	Perú/2014	Gammagrafía ***Ir-192 1,22 TBq***	Industrial	Trabajadores ***3 sobreexpuestos (lesiones graves)***	Sitio industrial (Faena)

RADIOTHERAPY INCIDENTS

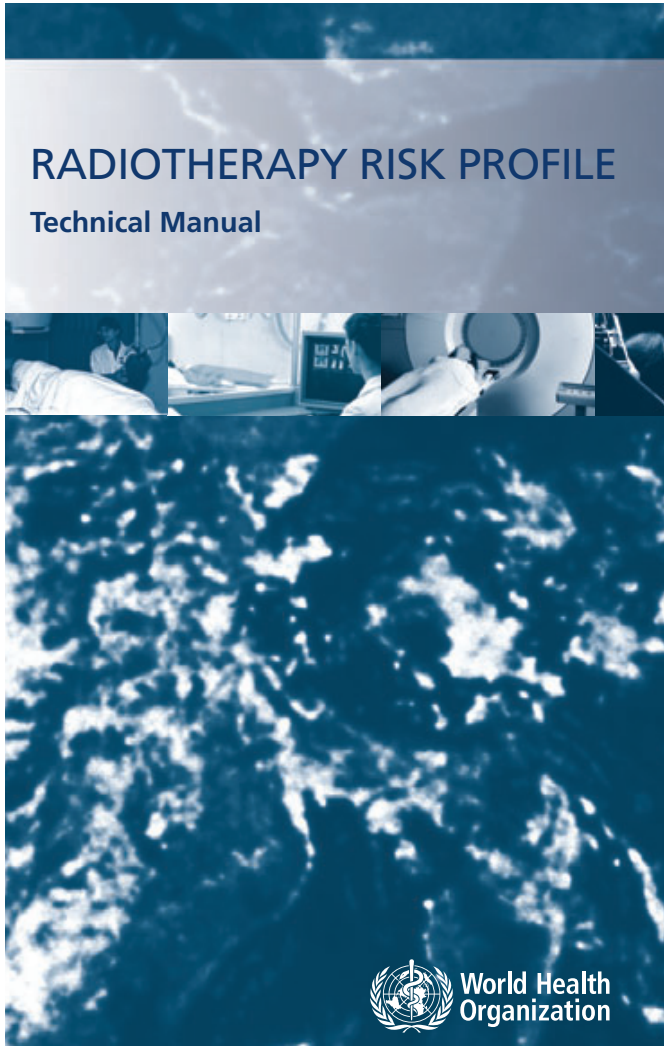
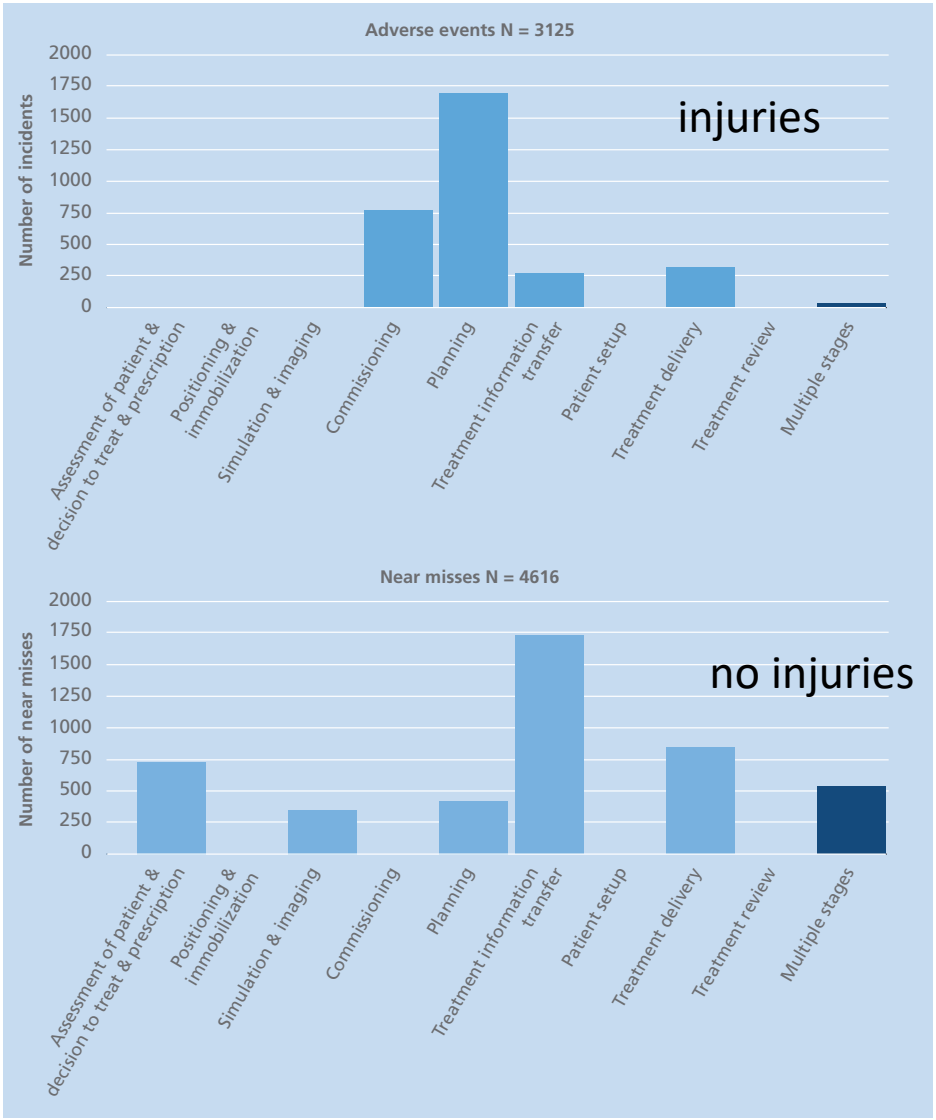
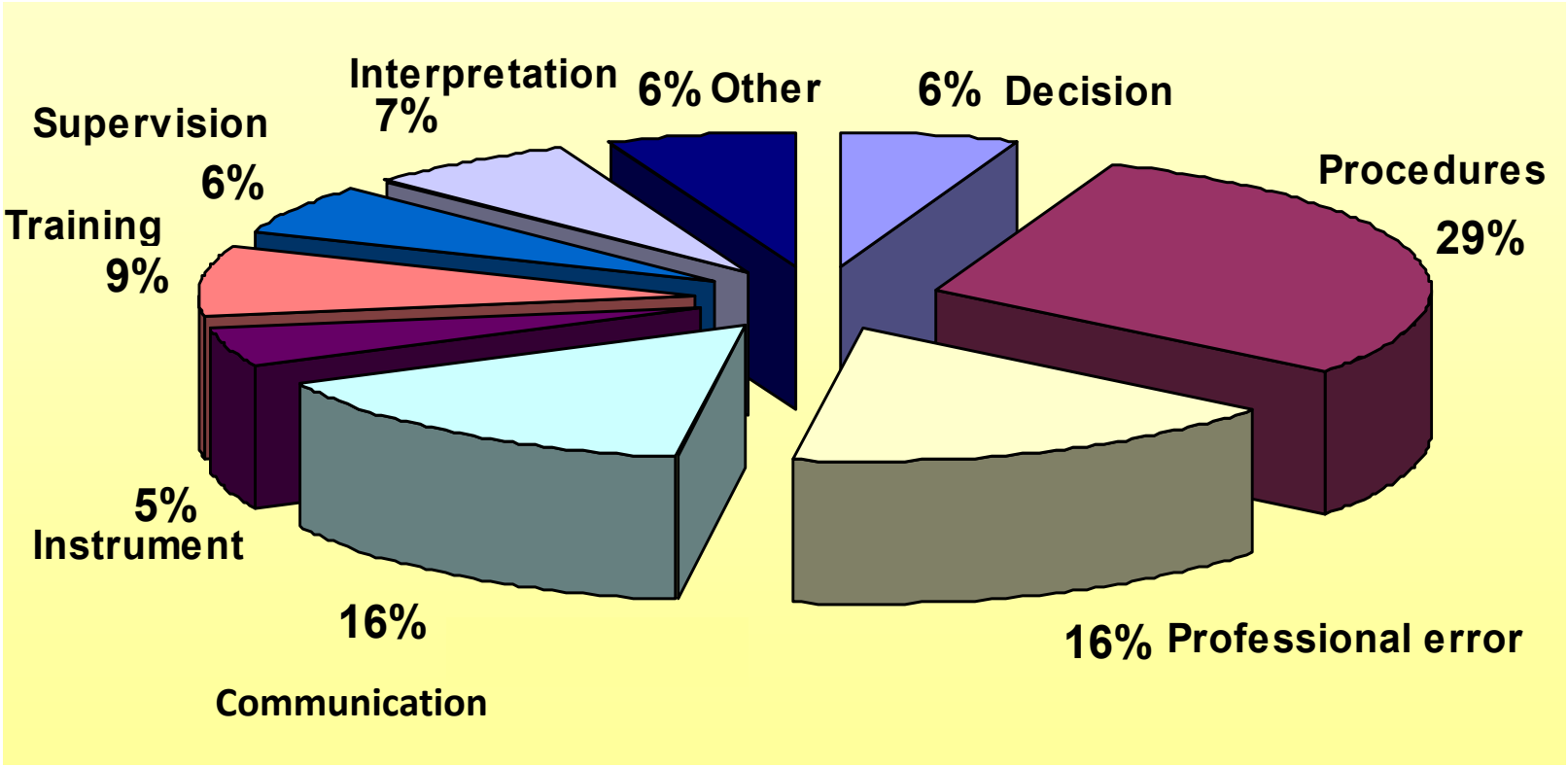


Figure 4: Radiotherapy incidents (1976-2007) by the stages of treatment process



Errors in radiotherapy: 90 % human errors

May result in overdose and underdose



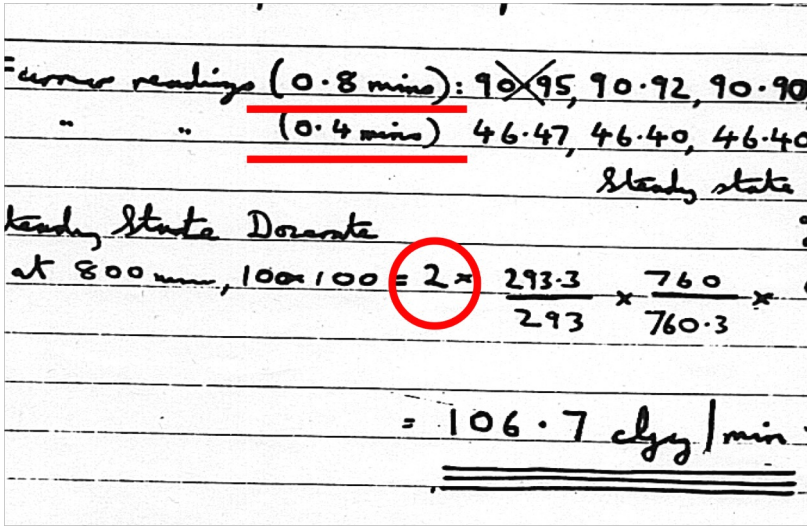
Healthcare errors occur in around 10% in hospitalisation

Radiotherapy example - Erroneous calibration Exeter, Uk, 1988

New cobalt source (similar for accelerators)

A physicist, working on his own,
calibrated the new source

1min/0.4 min= 2.5, NOT 2.0



Resulted in 106.7 cGy/min instead of 133.4 Cgy/min

25% overdose for 205 patients

+ increased morbidity and possible deaths as a consequence

Accident discovered by external audit

LESSONS: check and recheck, cross check, repeat over time, external audit, …

Complexity: techniques + equipment

Radiotherapy: 100/200 sub-processes + parameters

Assume: 1/1000 error probability in each:

Naive estimate for just 100

Prob. error = $1 - 0.999^{100} = 1 - 0.9 = 10\%$

10 % error probability (1 in 10 PATIENTS !!!!)

If 1/100 instead : 63% error prob.

For 200 processes and 1/1000 error prob.: 18% !!!!

For 200 parámetros and 1/100 error prob.: 87% !!!!

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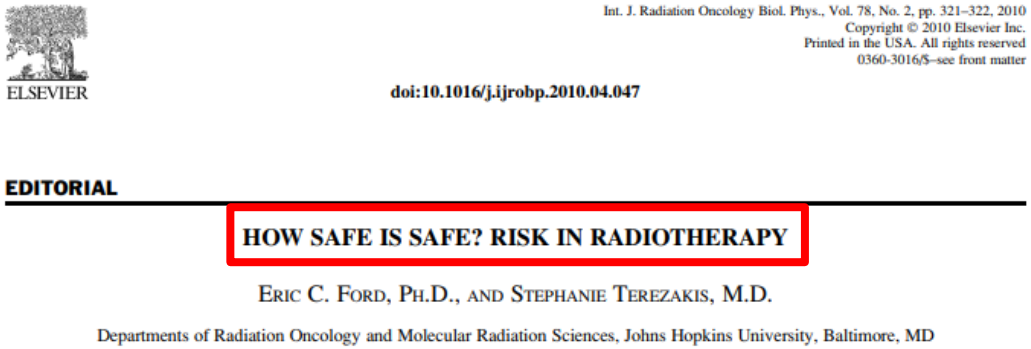


ELSEVIER

Int. J. Radiation Oncology Biol. Phys., Vol. 78, No. 2, pp. 321–322, 2010

0360-3016/$–see front matter

doi:10.1016/j.ijrobp.2010.04.047

EDITORIAL

HOW SAFE IS SAFE? RISK IN RADIOTHERAPY

ERIC C. FORD, PH.D., AND STEPHANIE TEREZAKIS, M.D.

Departments of Radiation Oncology and Molecular Radiation Sciences, Johns Hopkins University, Baltimore, MD

1/10.000 clinically significant events (estimation)

ONLY 3-10/100.000 are informed

This is 1000 times scheduled airlines flights reports

In medicine, anesteshia / blood transfusion procedures have similar profile as schduled airlines

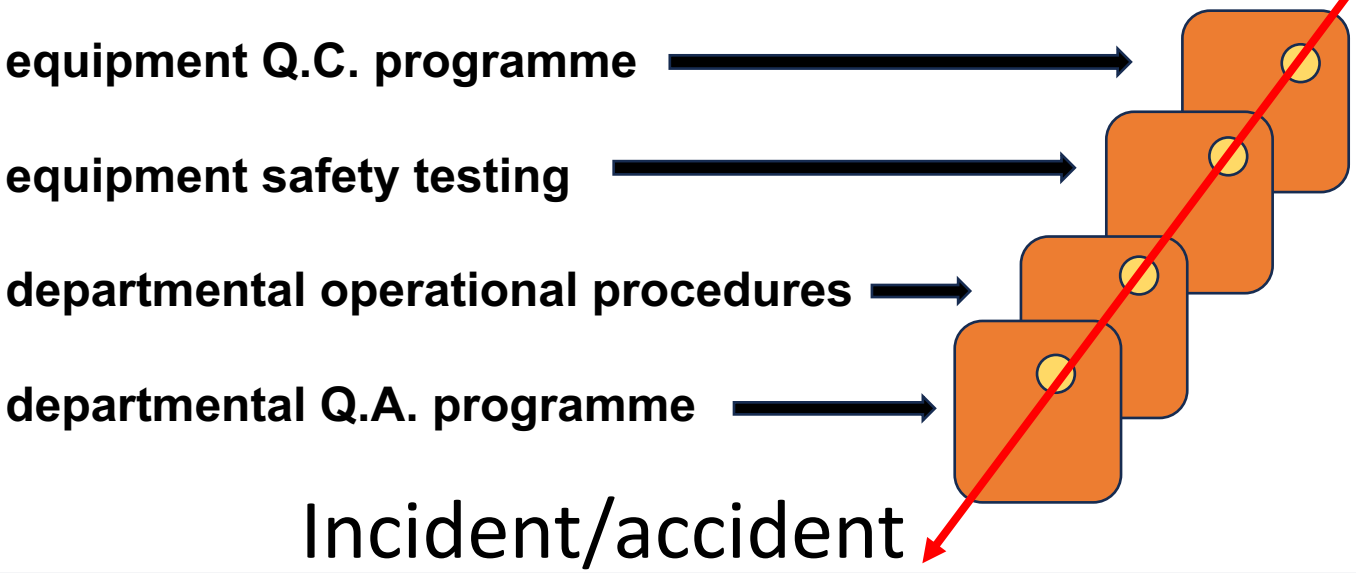
New techniques and complex equipments have more precision but more controls, redundancy and training are needed.

Factors / interplay of different elements in adverse events

- human errors
- equipment malfunctions
- calibration errors
- treatment planning errors
- data transfer errors

Prospective analysis

Hazard situation



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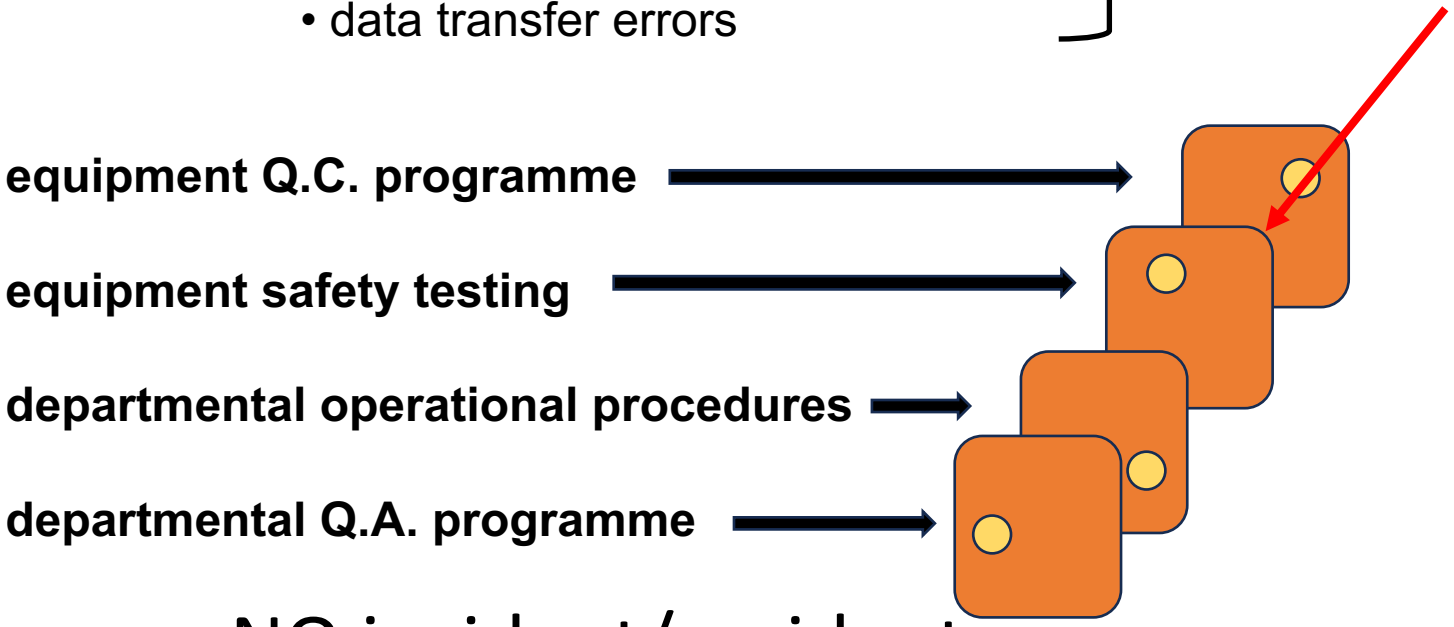

NO incident/accident

Errors in RT: Contributing Factors

- Insufficient education/training
- Lack of procedures/protocols as part of
- Comprehensive QA program
- Lack of supervision of compliance with QA program
- Lack of training for “unusual” situations
- Lack of a “safety culture”

The background of a well established regulatory body contributes for all this elements to improve

Incidences, mistakes and near misses may happen in every radiotherapy department

Radiotherapy treatment techniques get more complex everyday and poses a chellenging scenario

The same applies to other procedures, with the appropriate weigth of dose and risks

FINAL COMMENTS

- Security and Safety occur in a context where Medical Physics is still under construction in many LA countries
- No specific postgraduates degrees in Medical Physics or academic training in most areas of Medical Physics (radiotherapy, nuclear medicine, radiology,…) exist in many countries, and the same for a formal clinical training progamme
- Besides, harmonizad education is still lacking in the region, and this leads to different background of Medical Physicists in order to face the challenges from complex and demanding techologies and techniques, frequently not aligned with the standards
- Education and training in Medical Physics should include, from the beggining, the culture of security and safety

FINAL COMMENTS

- Regulatory bodies in LA countries are not always well established, and many of their legal mission is shared beween different institutions, with a different degre of success

- Lack of independence, not enough funding, low level of capacities and training is also found in the regulatory bodies in some coutries in LA

- Regulations and not only Regulatory bodies are still under construction, and this poses a challenge for Security and Safety

FINAL COMMENTS

- The Safety culture is to be shared within the multidiciplinary team responsible for the medical radiation process

- The particular role of Medical Physicists, related to the physical good understanding of equipment and radiation benefits/risks, deserves a leading role in this team, related to radiation protection and security

- Dialogue/interplay between the different roles/responsabilities in regulation and professional practice contribute to the improvement of Safety

Charles Darwin:

Ignorance more frequently begets confidence than does knowledge

G.K.Chesterton

It isn't that they cannot find the solution. It is that they cannot see the problem

THANKS FOR YOUR ATTENTION