Funded by the European Commission
Contract No ENER/11/NUCL/S12.612.180
Julian Malicki,
Project co-ordinator

Europejskie wytyczne dotyczące analizy ryzyka i rejestracji ‘adverse error-events’ i ‘near misses’ w radioterapii

Funded by the European Commission
Contract No ENER/11/NUCL/S12.612.180
Project co-ordinator

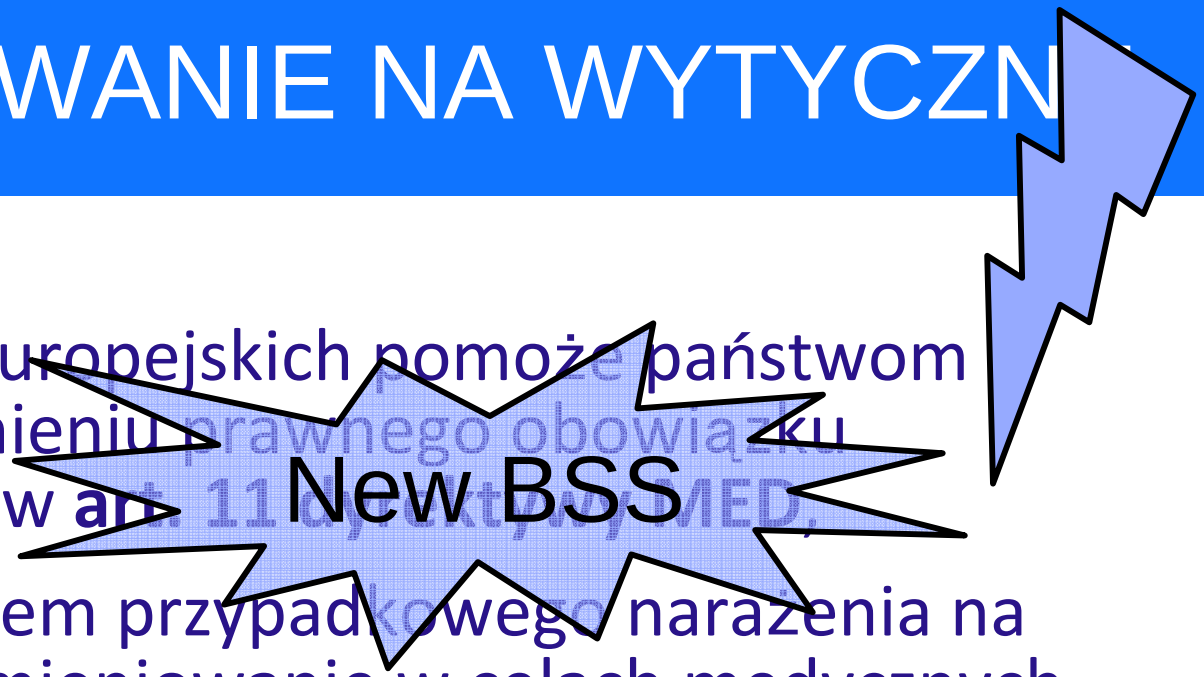
Projekt zakończony
Guidelines będą wkrótce opublikowane przez Komisję Europejską

Europejskie wytyczne dotyczące analizy ryzyka i rejestracji ‘adverse error-events’ i ‘near misses’ w radioterapii

ZAPOTRZEBOWANIE NA WYTYCZNE

- publikacja wytycznych europejskich pomoże państwom członkowskim w wypełnieniu prawnego obowiązku wynikającego z przepisów **art. 11 dyrektywy MED**,
- rozwój badań nad ryzykiem przypadkowego narażenia na promieniowanie na promieniowanie w celach medycznych uznano za jeden z podstawowych kroków na drodze do poprawy bezpieczeństwa,
- projekt powstał na podstawie rekomendacji grupy roboczej ds. narażenia na promieniowanie w celach medycznych działającej w ramach grupy eksperckiej powołanej na podstawie art. 31 traktatu EURATOM.

ZAPOTRZEBOWANIE NA WYTYCZN



- publikacja wytycznych europejskich pomoże państwom członkowskim w wypełnieniu prawnego obowiązku wynikającego z przepisów **art.** 11 dyrektywy MED,
- rozwój badań nad ryzykiem przypadkowego narażenia na promieniowanie na promieniowanie w celach medycznych uznano za jeden z podstawowych kroków na drodze do poprawy bezpieczeństwa,
- projekt powstał na podstawie rekomendacji grupy roboczej ds. narażenia na promieniowanie w celach medycznych działającej w ramach grupy eksperckiej powołanej na podstawie art. 31 traktatu EURATOM.

O DOKUMENCIE (I)

- Zawiera kompleksowy opis najlepszych praktyk w zakresie badania ryzyka - przypadkowego i niezamierzonego narażenia na promieniowanie.
- Przedstawia proaktywne metody określania newralgicznych aspektów radioterapii z wykorzystaniem:
  - matrycy ryzyka lub probabilistycznej oceny bezpieczeństwa oraz precyzuje powiązania między analizą ryzyka, zasadą ochrony wielopoziomowej i opinią zwrotną użytkownika badając przy tym korzyści płynące z efektywnej wymiany wyników analiz ryzyka między producentami sprzętu i użytkownikami.

O DOKUMENCIE (II)

- W swojej treści powołuje się na dokumenty wydane przez Światową Organizację Zdrowia **(WHO)**, Międzynarodową Komisję Ochrony Radiologicznej **(ICRP)**, Międzynarodową Agencję Energii Atomowej **(IAEA)** oraz inne.
- Ponadto, zostały uwzględnione informacje ogólne istotne dla projektu pochodzące z realizowanych projektów wspólnotowych, takich jak MPE czy MEDRAPET.

O DOKUMENCIE (III)

- Wytyczne europejskie to efekt 2,5 - letniej pracy Konsorcjum, które składa się z 6 partnerów (WCO, ESTRO, TUDOR, STUK, ASN, FIB HCSC) oraz jednego podwykonawcy (SECTOR).
- Dokument składa się z następujących części:
  - Introduction
  - Purpose and Scope
  - Regulatory and normative basis
  - Risk Management (Basic concepts, Organisation and Resources, Proactive Risk Assessment , Reactive analysis of events, Classification and reporting of adverse error-events and near misses iradiotherapy, Other preventive measures/ Risk reduction interventions)
  - **Recommendations on risk assessment and analysis and reporting of events**

Guidelines on a Risk Analysis of Accidental and Unintended Exposures in Radiotherapy

www.accirad.eu

ADRESACI WYTYCZNYCH

- Management team
- Various professional groups at radiotherapy institutions
- Risk managers and other people directly involved with risk management
- Radiation protection and regulatory authorities
- Organisations charged with establishing and promoting the use of reporting and learning systems
- Manufacturers, who have an important role related to the impact of equipment design on proactive risk assessment and reporting and learning from events.

Legal Basis

97/43/EURATOM (Medical Exposure Directive, MED) defining the European legal requirements for radiation protection.

➢**Article 11** of MED: *„Member States shall ensure that all reasonable steps to reduce the probability and the magnitude of accidental or unintended doses of patients from radiological practices are taken (…) and stipulates that the main emphasis in accident prevention should be on the equipment and procedures in radiotherapy"*.

Council Directive: 96/29/EURATOM/1: **Basic Safety Standards (BSS)** for radiation protection of the workers and the members of the public was **was published.**

COUNCIL DIRECTIVE 2013/59/EURATOM

of 5 December 2013

laying down … g from exposure to ionising ra… …, 96/29/Euratom,

On *5 D*… …l adopted specific … …on of the probabil… …herapy.

Council Directive 2013/59/EURATOM
Art 63

Member states shall ensure that
(b) For radiotherapeutic practices the quality assurance programmes include **a study of the risk** of accidental or unintended exposures
(c) For all medical exposures the undertaking implements an appropriate system for the record keeping and **analysis of events** involving or potentially involving accidental or unintended medical exposures

…ed exposures

(30) Accidental an… source of co… devices post-… Council Direc… competent au… the preventio… exposure and the follow-up in case of their occurrence. In this respect, the role of quality assurance programmes including a study of risks in radiotherapy, to avoid such incidents should be emphasised, and recording, reporting, analysis and corrective action should be required in such cases.

… quality assurance …isk of accidental or unintended exposures;

(c) for all medical exposures the undertaking implements an appropriate system for the record keeping and analysis of events involving or potentially involving accidental or unintended medical exposures, commensurate with the radiological risk posed by the practice;

Guidelines składają się z 2 dokumentów

General guidelines

- Main concepts
- Short general review of
  - Proactive risk assessment
  - Reactive analysis of events
  - Event classification, reporting and learning systems
  - Other preventive measures or risk reduction interventions.
- Recommendations
  - RT institutions
  - Authorities
  - Reporting and learning systems

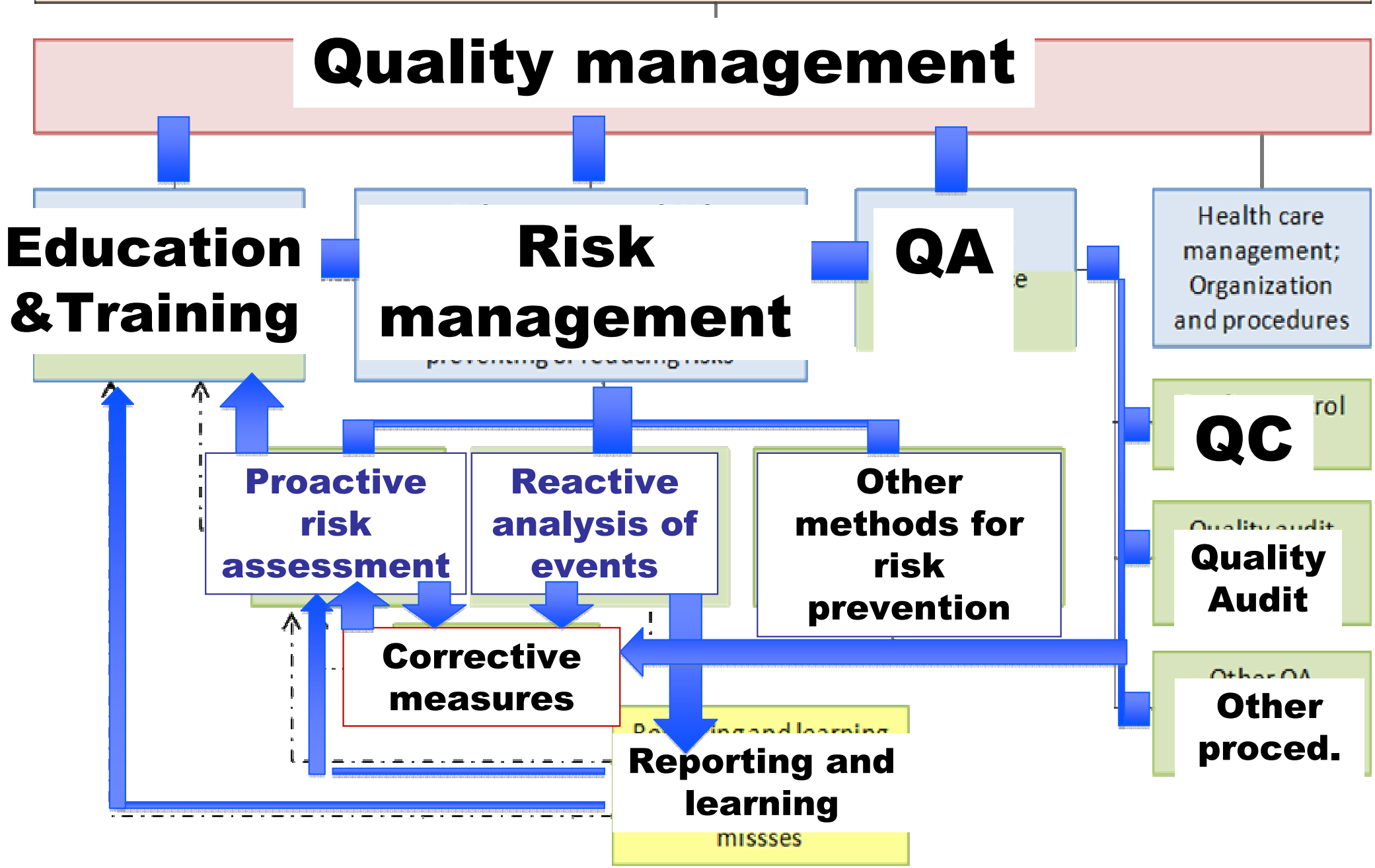
Technical supplement

- Detailed information
  - Legislative and normative basis
  - Methods for proactive risk assessment and reactive analysis of events,
  - Event classification, reporting and learning systems
  - Preventive measures
  - Summaries of the results of the two questionnaires (**Status of risk management in EU member states**).

Risk = Radiation Risk

- Risk of all the various ways in which a patient could be harmed in the context of using radiation for the treatment, which is considered to be an **adverse error-event**.
- This includes the risk of
  - administering a radiation **overdose** (higher than intended) or an **underdose** (lower than intended; reducing cure rate)
  - delivering the right dose to the wrong site (**geographical miss**).

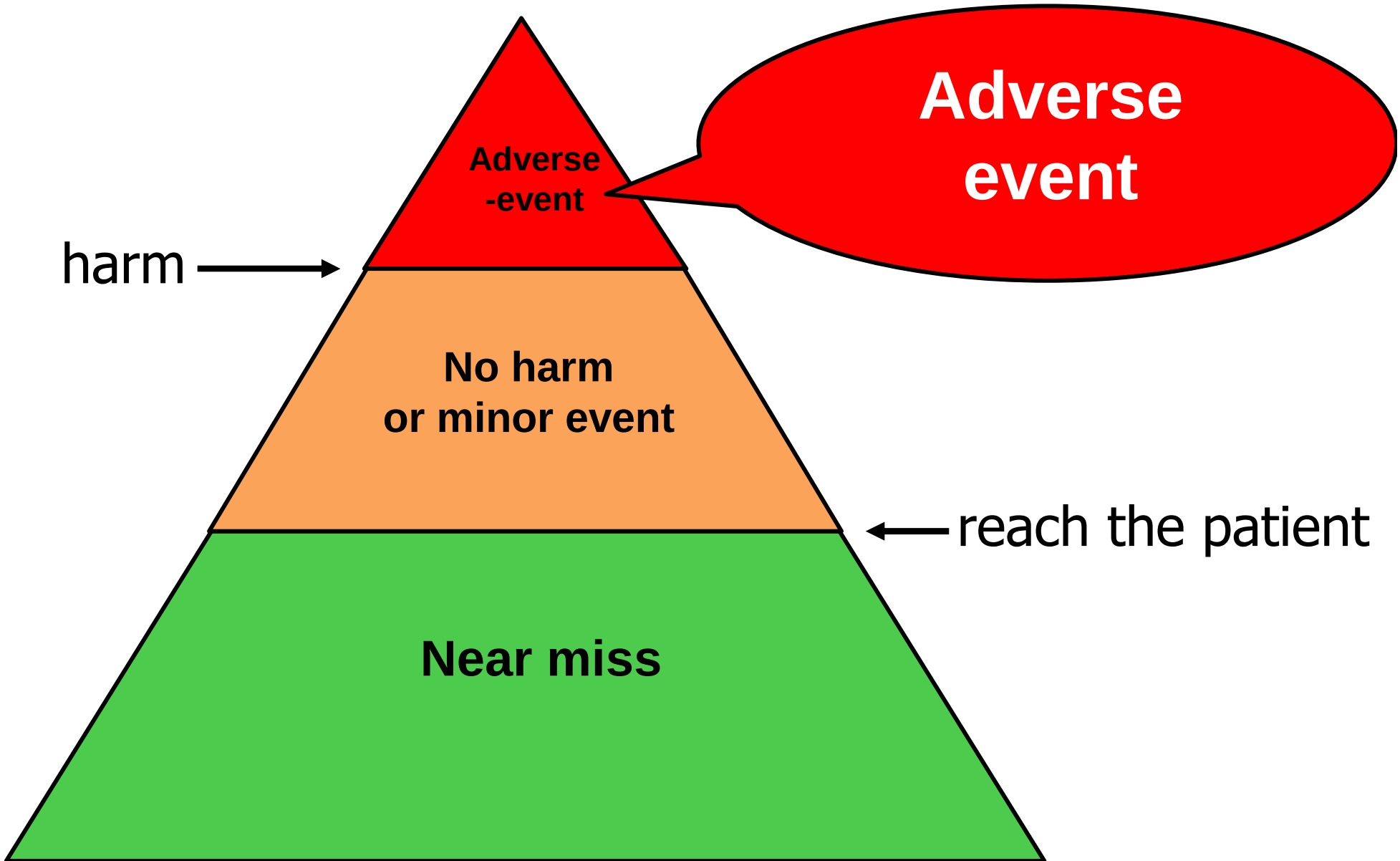
- **NOT included:**
  - **side effects (= adverse reactions)** of radiotherapy, regardless of their severity, because these are unrelated to any treatment errors.
  - medication errors and other types of errors not directly related to the use of radiation



Simplified relationships of basic concepts

Terminology 1st approach

Eliminate term ACCIDENT

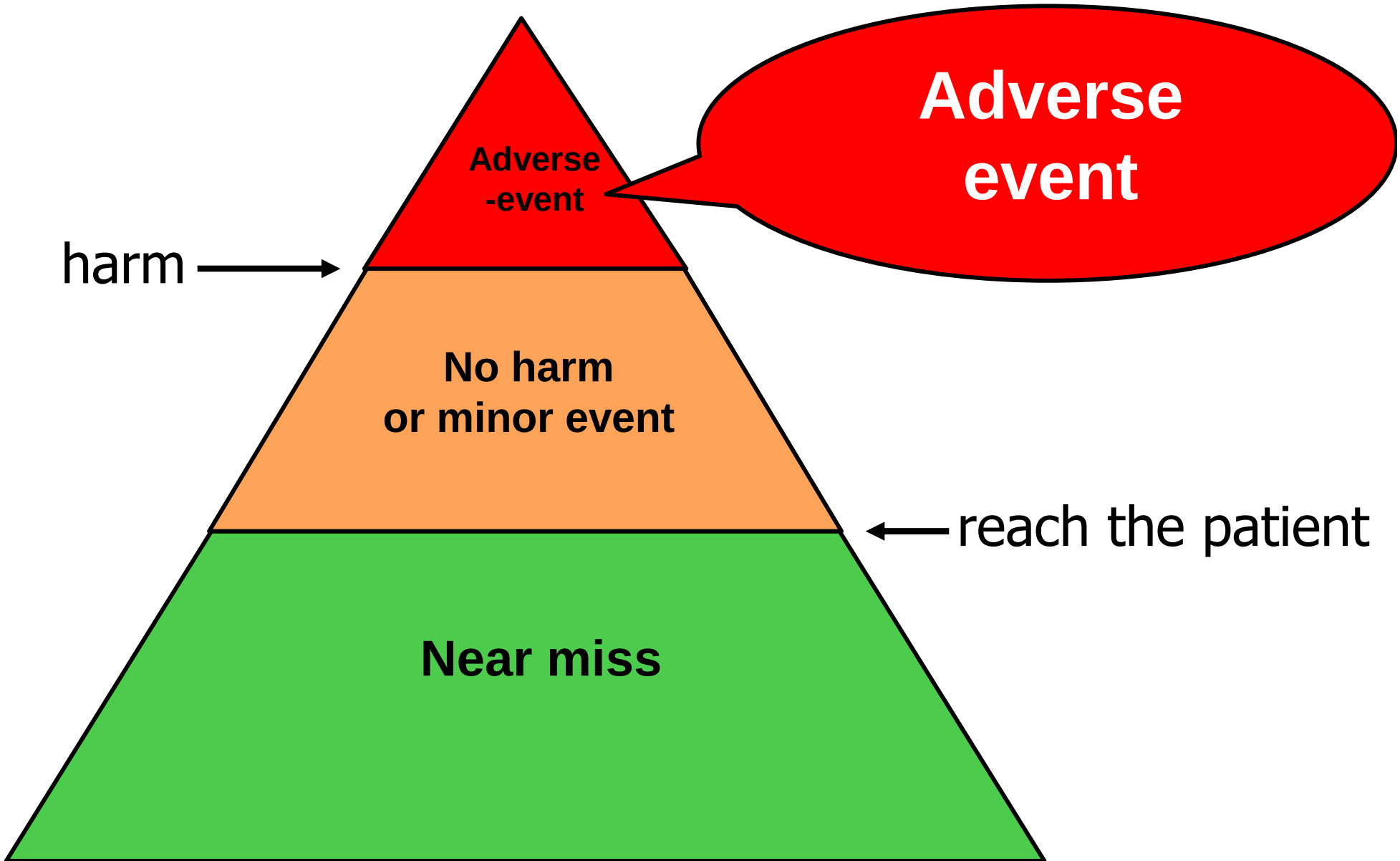


Terminology – critical point

- Term **adverse event** is intuitively used for any type of severe complications
- is used sometimes for side effects and the difference is not clearly marked
- Moreover FDA uses term of adverse event for any type of reportable severe side effects – not related to error.
- **Therefore, to avoid confusion with the general use of the term "adverse event", a new term "adverse-error event" is defined and used for the purposes of the Guidelines.**

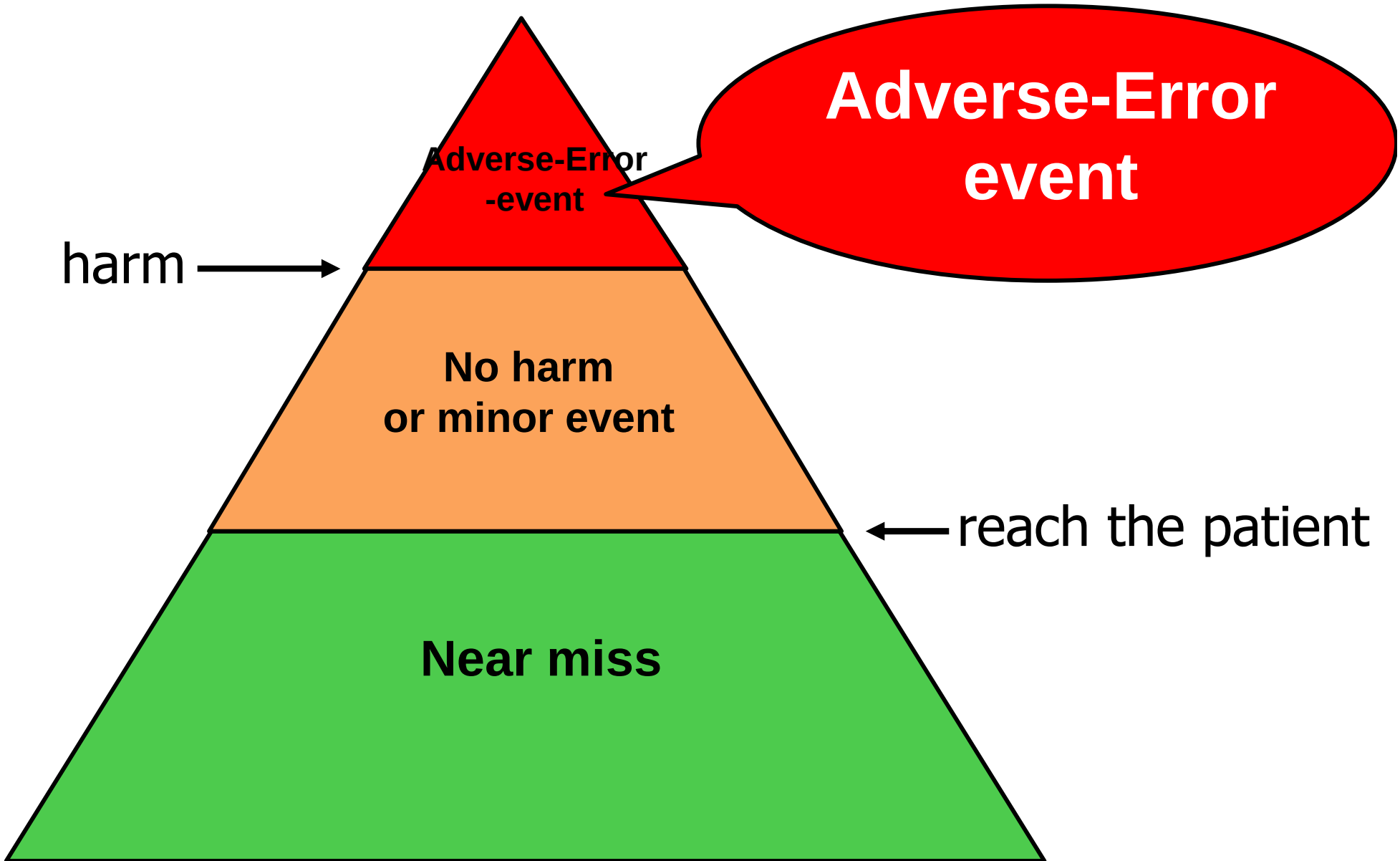
Terminology 1st approach

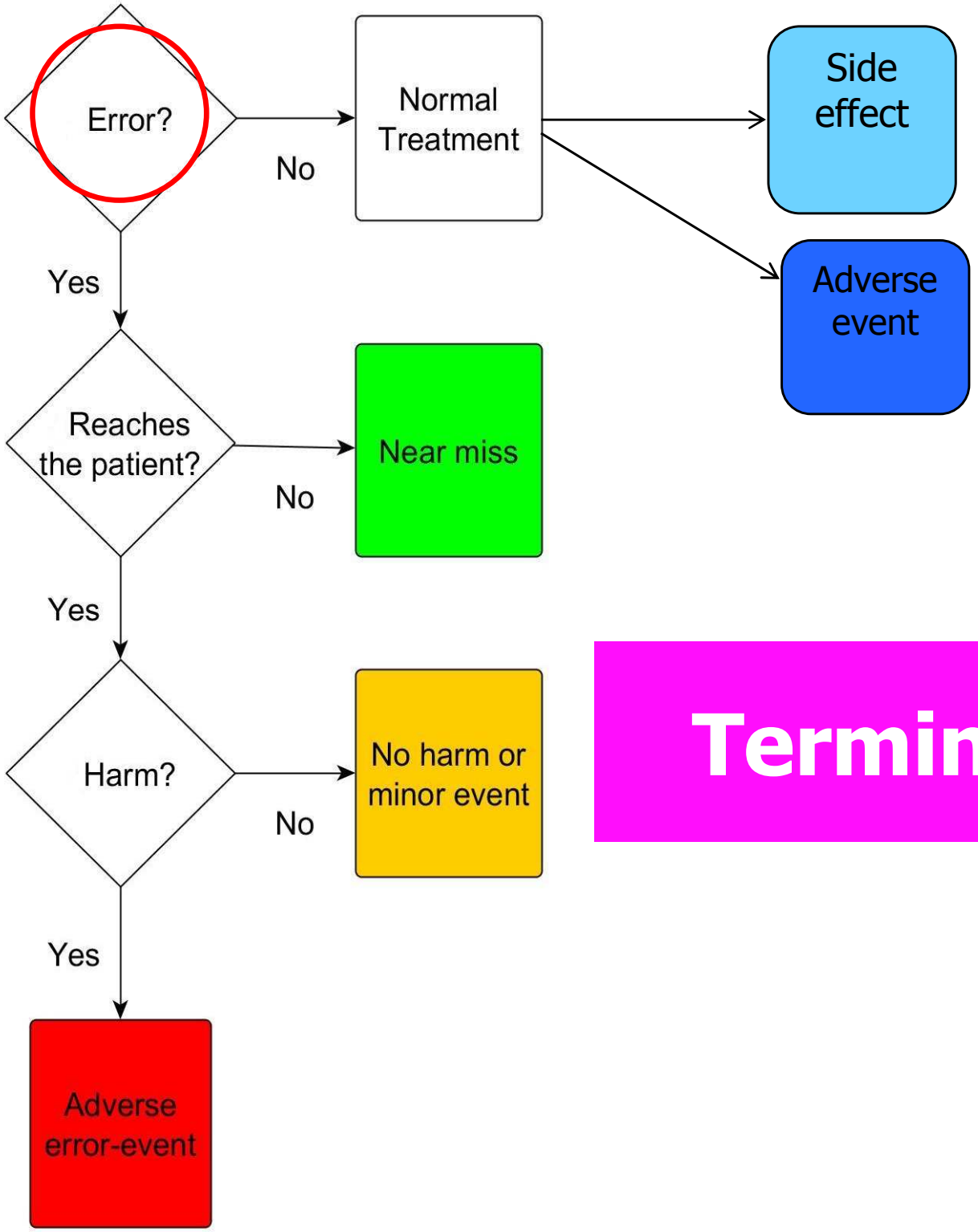
Eliminate term ACCIDENT



Terminology 2nd approach

Eliminate term ACCIDENT

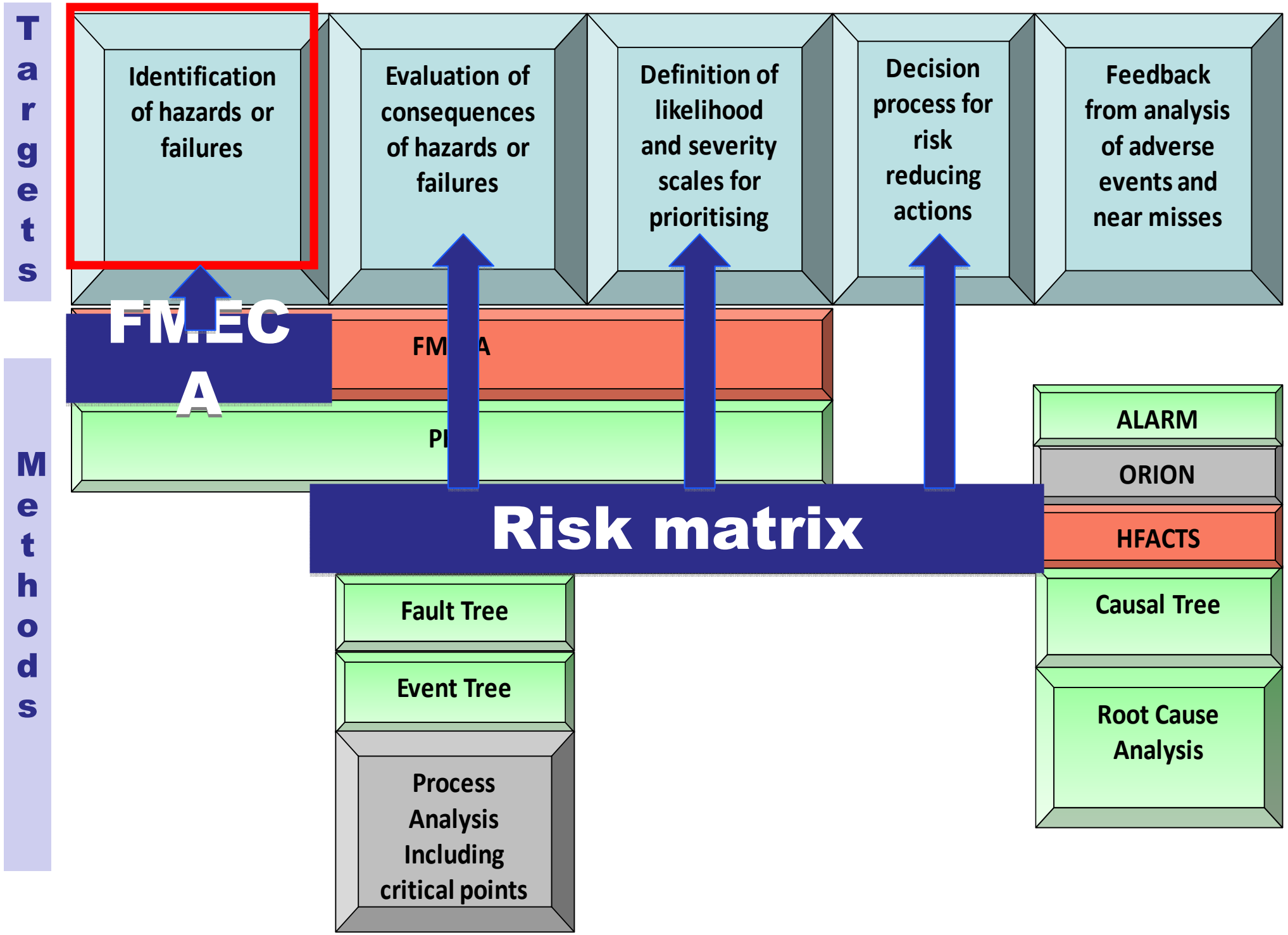




Terminology update

EQUIVALENCE OF TERMS

ACCIRAD Guidelines	Euratom BSS
Proactive risk asessment, risk asessment	Study of risk
Analysis of events	Analysis of events
Adverse error-event	Event involving accidental or unintended medical exposure
Near miss	Event potentially involving accidental or unintended medical exposures


Targets
Identification of hazards or failures
Evaluation of consequences of hazards or failures
Definition of likelihood and severity scales for prioritising
Decision process for risk reducing actions
Feedback from analysis of adverse events and near misses
Methods
FMECA
FM A
PI
Risk matrix
ALARM
ORION
HFACTS
Causal Tree
Root Cause Analysis
Fault Tree
Event Tree
Process Analysis Including critical points

RECOMMENDATIONS TO RADIOTHERAPY INSTITUTIONS

5 points for organization

Key point	Action
1	Ensure leadership and commitment of the top management and allocation of specific resources
2	Ensure establishment of general provisions: quality management system, promotion of safety culture, process descriptions
3	Establish risk management committee and define the process of risk management, including methods to be used
4	Ensure involvement of an experienced risk manager
5	Establish a multidisciplinary working group with the requisite skills and radiotherapy professionals needed to implement the methods

RECOMMENDATIONS TO RADIOTHERAPY INSTITUTIONS

Illustration of personel resources needed

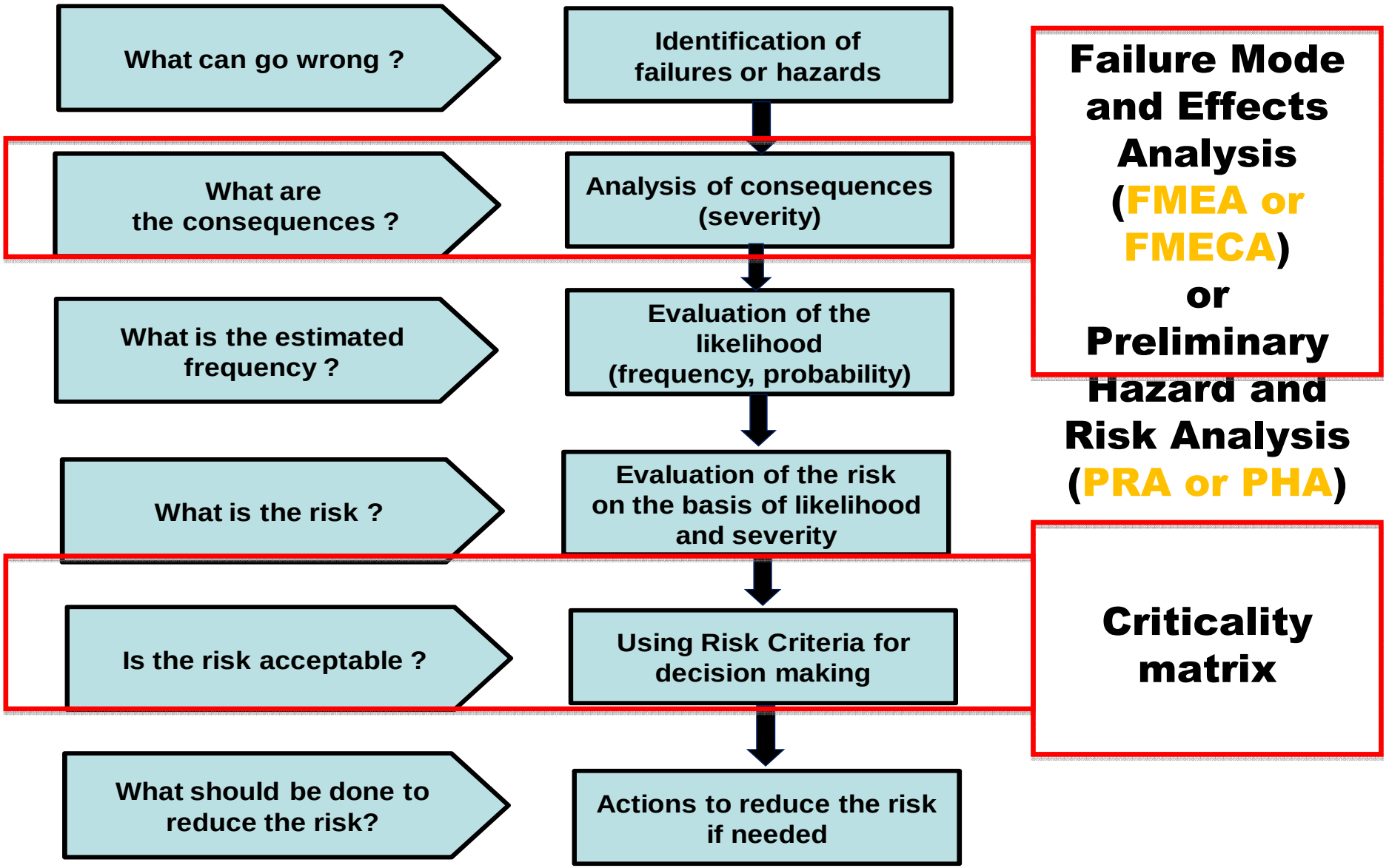
Task	Minimum resources
Initial work for risk assessment (creating the resources and selecting methods, organizing training, carrying out a process description, defining scales etc)	6 man-months
First proactive risk assessment based on the minimum approach	3 man-months
Continuous development and updating of the risk assessments	2 man-months/year
Analysis of events with reporting and feedback actions	One day/month

RECOMMENDATIONS TO RADIOTHERAPY INSTITUTIONS

5 key points for practical procedures

	Action
1	Implement risk assessment according to the minimum approach and apply lessons learned from published reports of events to the system
2	Implement risk assessment according to the defence in depth approach
3	Implement analysis of events and prepare and send reports to internal and/or external reporting systems for all events considered significant
4	Use the results of proactive risk assessment and reactive analysis of events to implement improvements to working practices (e.g. new barriers)
5	Include the results of proactive risk assessment and reactive analysis of events in the internal quality documentation and in staff training programs

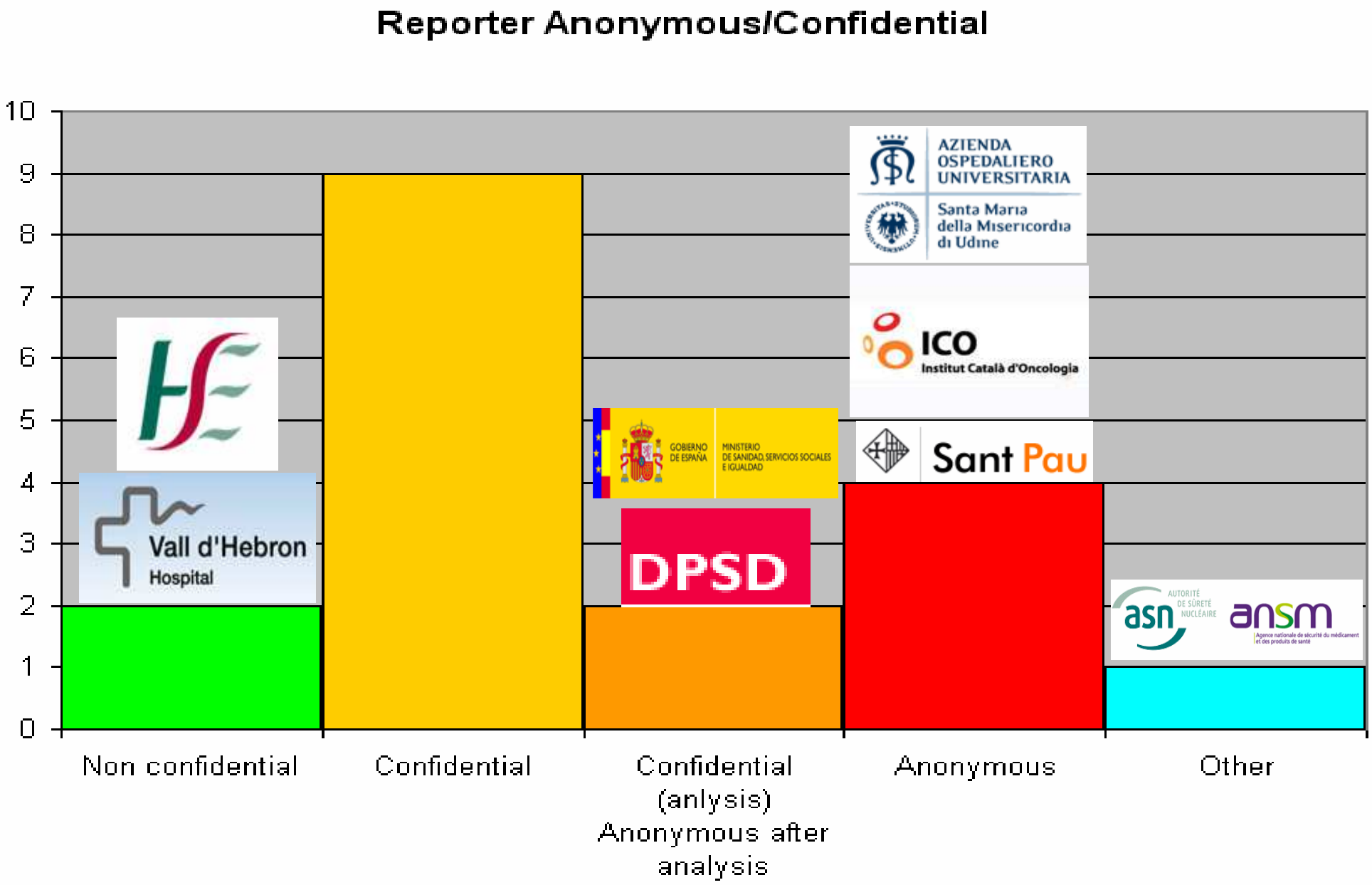
MINIMUM APPROACH FOR RISK ASSESSMENT



Reporting systems

- All adverse-error events with significant consequences should be reported to internal and/or external (national or international) reporting and learning systems as soon as sufficient information, based on the analysis of the event, is available, unless local QA documents or national regulations impose more urgent and stringent reporting procedures.
- Near misses that offer a significant learning opportunity should also be reported, at the very least, to voluntary reporting and learning systems.
- Reporting to the international system of SAFRON is encouraged, to promote worldwide learning of events and improvement of safety

Reporting systems



RECOMMENDATIONS TO NATIONAL AUTHORITIES

- The novel requirements in EURATOM BSS → opportunity to establish or update a comprehensive strategy on quality and risk management in RT.
- Strong collaboration needed between RT institutions, authorities, professional societies and manufacturers

Main components of the recommended strategy	
1	Updated legislation incl. criteria for significant event
2	Methodology for QM and RM
3	Dissemination of information on RM
4	Training on RM and safety culture
5	Informing patient and public
6	Clinical audit
7	Regulatory inspections

Partners

- European Society for Radiotherapy and Oncology (ESTRO)
- Public Research Centre Henry Tudor (TUDOR) Luxembourg
- Nuclear Safety Authority (ASN), Paris, France with SECTOR as a sub-contractor,
- Fundación Investigación Biomédica Hospital Clínico San Carlos (FIB HCSC), Madrid, Spain
- Radiation and Nuclear Safety Authority (STUK), Helsinki, Finland
- Greater Poland Cancer Centre (GPCC), Poznan, Poland.

Acknowledgement (1)- Working Team

Andreas Jahnen	Luxembourg		
Jean-Luc Godet	Paris		
Marc Valero	Paris		
Carlos Prieto Martin	Madrid		
Ritva Bly	Helsinki		
Hannu Järvinen	Helsinki		
Marco Krengli	Novarra	-	ESTRO
Philippe Maingon	Dijon	-	ESTRO
Julian Malicki	Poznan	-	Chair
Kamila Przybylska	Poznan		
Agnieszka Skrobała	Poznan		

EC Project Officer: Remigiusz Barańczyk till IX.2013,
Georgi Simeonov since X.2013

Acknowledgement (1)- Working Team

Andreas Jahnen	Luxembourg
Jean-Luc Godet	Paris
Marc Valero	Pari
Carlos Pri	
Ritva B	
Hann	
Mal	
Philip	
Julia	
Kamila Przyb	
Agnieszka Skrobała	Poznan

Wiele z pokazanych slajdów zostało przygotowanych przez Hannu Jarvinen

EC Project Officer :Remigiusz Barańczyk till IX.2013,
Georgi Simeonov since X.2013

Acknowledgement (2) - Panel of Experts

No	Name	Affiliation, country
1	Jean Marc Cosset	ICRP, France
2	Frank Andre Siebert	Department of Radiation Therapy University of Kiel, Germany
3	Mary Coffey	ROSIS, Ireland
4	Pierre Scalliet	ESTRO, Belgium
5	Tommy Knöös	Skåne University Hospital and Lund University, Sweden
6	Andrew Nisbet	Royal Surrey County Hospital, University of Surrey , UK.
7	Will van der Putten	EFOMP, Ireland
8	Pedro Ortiz Lopez	ICRP, IAEA, Austria
9	Costas Hourdakis	GAEC, Greece
10	Maria Perez	WHO
11	Ola Holmberg, Debbie Gilley	IAEA

Acknowledgement (3)

COUNCIL DIRECTIVE 2013/59/EURATOM

of 5 December 2013

… **basic safety standards** ….

replacing 97/43 Euratom