EC Tender project contract N° ENER/2022/NUCL/SI2.880751

SAMIRA Study on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology

Survey Methodology and Results of Questionnaires and Expert Interviews

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MARLIN Project Workshop
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Online Surveys

- **Competent authorities:** The Heads of the European Radiological Protection Competent Authorities (HERCA) is a member of the project Advisory Board and as such made available its network of national CAs and distributed the survey among the members of the Working Group on Medical Applications (WG MA). The consortium reached out to health authority contacts available through other quality and safety projects (e.g., QUADRANT, EU-REST), as in some countries health authorities have competence in the field of ILSs. At the request of the European Commission, the members of the SAMIRA SGQS were not invited to complete the survey.
- **National professional societies:** To understand the implementation of the BSSD requirements at member state level from the perspective of the professional stakeholders, the European PSs represented in the consortium (ESTRO, EFOMP) as well as in the Advisory Board (EANM, ESR, CIRSE, EAPCI, EFRS) were asked to distribute the survey among their national professional member societies, via their national delegates in quality & safety committees or similar depending on their organisational structures. As the European PSs have long-standing contacts with their national counterparts, qualified responses from the EU-27 as well as Norway and Switzerland were obtained.

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Online Surveys

- **Individual hospitals:** To understand the implementation of ILSs from a practical point of view, it was considered important to survey and evaluate the situation directly in a representative sample of European hospitals, taking into account discipline variation as well as potential gaps, barriers, common issues and the need for European action and guidance. In order to ensure a structured approach and to avoid bias (e.g. by contacting the EuroSafe Imaging Stars network only), the consortium decided to ask EFOMP to contact its national member organisations to identify a representative selection of 5-10 hospitals in their country, covering all radiation risk areas as well as the public and private sectors and including a relevant contact person, e.g., the medical physicist in charge of incident reporting.

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Online Surveys (CA)

The content of the survey to the CAs included the following.

- National legal provisions for the implementation of regulatory ILSs for significant events after the BSSD transposition
- Organization of the CAs for the management of significant events
- Areas where an ILS is working (radiotherapy, nuclear medicine, diagnostic and interventional radiology)
- Type of incidents reported (only significant events or also other minor events or near miss for learning purposes)
- Definition of significant events, minor events and near misses in every area
- Evidence of functioning: Number of significant events reported annually, events analysed by the regulator, example of safety measures implemented
- Mechanisms for the timely dissemination of information, relevant to radiation protection in medical exposure, regarding lessons learned from significant events. Frequency of feedback
- Existence of regulatory systems to identify those facilities with no or few reports submitted and analysed in the local ILSs
- Composition of the group in charge of the analysis and feedback of the lessons learned from significant events. Support from experts
- Main gaps and barriers found in the implementation of the regulatory ILSs
- Collection of references of available guidance, resources, and good practices

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Online Surveys (PS and Hospitals)

The content of the survey to national PSs and selected hospitals on the development of local ILSs included the following.

- National legal provisions for the implementation of hospital or department ILS after Council Directive 2013/59/Euratom transposition
- Areas where an ILS is currently in place (e.g., radiotherapy, nuclear medicine, diagnostic and interventional radiology, interventional cardiology)
- Type of incidents reported (radiation exposure significant events, near misses, both, events not concerning radiation exposure)
- Criteria to report significant events in every area to the national authority. Number of significant events reported in the last years
- Evidence of functioning: number of reports in every area, criteria to analyse events, percent of events analysed, example of safety measures implemented as a consequence of the analysis
- Composition of the patient safety and quality team in every area. Frequency of meetings. Dependency of the team within the organisation
- Information about training of staff both to enable correct reporting at ground level and to allow for adequate analysis/feedback/learning
- Internal feedback and learning after the analysis
- Criteria or recommendations followed for the harmonisation of fields, structure and coding system of the ILS
- Arrangements to inform the referrer, the practitioner and the patient about unintended or accidental exposures
- Contribution to anonymous voluntary external ILSs. Other means of communicating and sharing lessons learnt externally
- Main gaps and barriers found in the implementation of the local ILSs
- Collection of references of available guidance, resources, and good practices (for national PSs)

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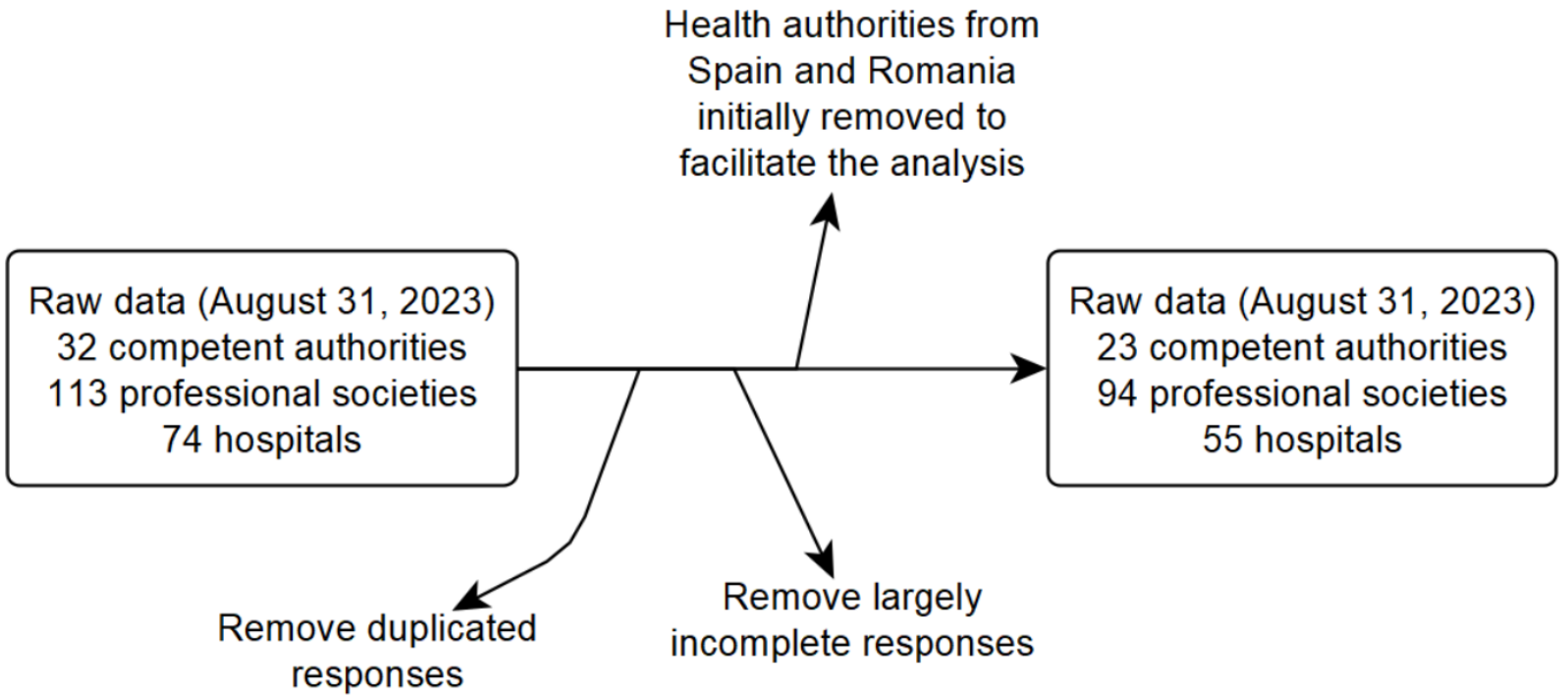
Online Surveys



- CAs: 23 from 23 countries
- PSs: 94 from 28 countries
- Hospitals: 55 from 19 countries

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Online Surveys

Competent authorities

Fig. 2: Countries represented among responses from CAs (dark green)

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Online Surveys

Table 2: Replies from national PSs considered for data analysis

	IR	MP	NM	RG	RY	RT	IC	RY & NM	other	Total
AT	1		1		1	1				4
BE			1	1		1				3
BG			1							1
HR	1	1	1	1						4
CY		1	1			1				3
CZ			1			1				2
DK	1		1	2	1	1				6
EE			1	1						2
FI	1		1		1				1	4
FR		1			1	1				3
DE	1	1	1		1	1				5
GR	1		1			1				3
HU			1		1					2
IE		1	1	1	1					4
IT		1	1		1	1				4
LV			1							1
LT	1				1	1				3
LU										0
MT		1						1		2
NL	1		1	1			1			4
NO		1		1	1					3
PL		1	1			1				3
PT	1		1	1	1		1			5
RO	1		1							2
SK					1					1
SI						1	1			2
ES	1	1	1	1	2	2				8
SE		2	1		1	1			1	6
CH	1		1	1			1			4
	12	**12**	**22**	**11**	**15**	**15**	**4**	**1**	**2**	**94**

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Online Surveys

Hospitals

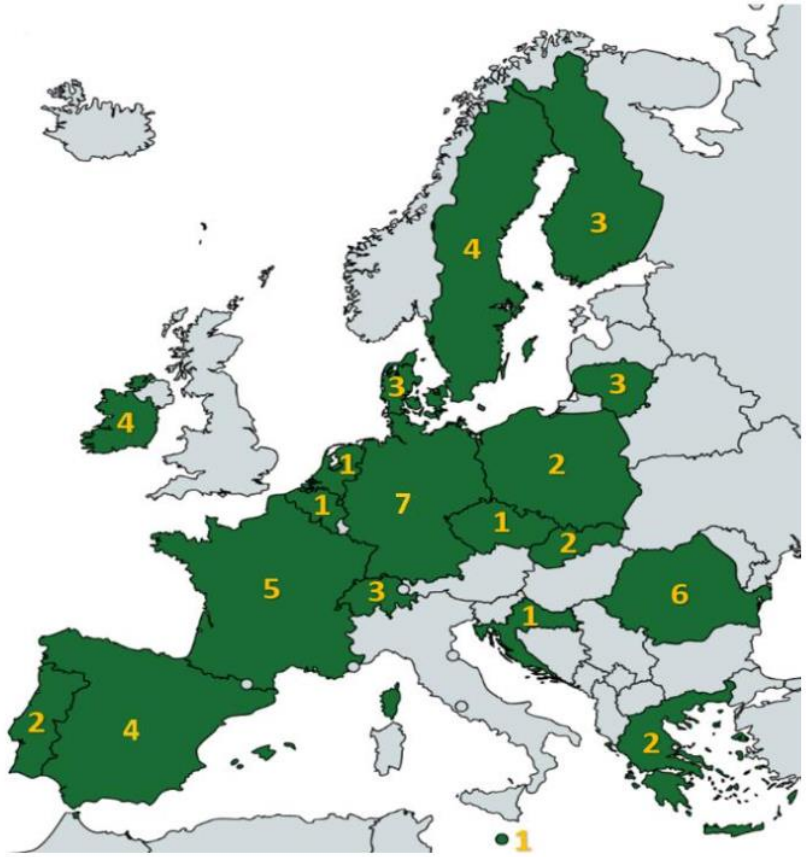

Fig. 10: Countries represented among responses from hospitals (dark green), including the number of replies per country

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Online Surveys (CA)

3.3 Analysis of Survey to Competent Authorities

The survey was targeted for radiation protection and health authorities, referred to as CAs.

All 23 countries have transposed the BSSD regarding incident reporting of significant events involving ionising radiation for patients into their national legislative framework.

In all countries that replied to the survey, the regulatory system of reporting and learning applies to the following.

- External beam radiotherapy
- Brachytherapy
- Therapeutic nuclear medicine (vectorised internal radiation therapy)
- Diagnostic nuclear medicine
- Diagnostic radiology
- Fluoroscopically-guided interventional radiology
- Interventional cardiology

Denmark, France and Ireland also indicate that they have a reporting and learning system for dental imaging.

All 23 countries have a national/regional authority specifically designated as CA for the management of declared significant events involving ionising radiation.

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Online Surveys (CA)

Despite all the countries having a CA for the management of declared significant events involving ionising radiation, some differences exist regarding the kinds of events reported (Table 4), namely for the following five types of events.

- Events involving accidental medical exposures
- Events involving unintended medical exposures
- Events involving potentially accidental (near misses) medical exposures
- Events involving potentially unintended exposures
- Events involving malfunction of medical devices

Belgium, Czechia, Denmark, Finland, France, Germany, Greece, Lithuania, Norway, Portugal and Sweden are the countries that include all five listed events, while Estonia is the only country that did not report any.

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Online Surveys (CA)

The CAs were asked whether they had defined specific criteria for reporting by hospitals that undertook the radiation modalities above (see the summary in appendix 4). One CA had delegated the task of developing modality specific criteria to the relevant national PSs.

For the high-risk areas of external beam radiotherapy (EBRT) and brachytherapy, 16 out of 23 CAs had issued specific criteria (see the summary in appendix 4).

For nuclear medicine services, the picture was as follows: 9 out of 23 CAs had specific criteria for therapeutic nuclear medicine and diagnostic nuclear medicine and, respectively, 6 out of 23 and 4 out of 23 had generalised criteria, while 8 out of 23 and 10 out of 23 had no answer or no criteria.

In diagnostic radiology, 11 out of 23 CAs had specific criteria, 3 out of 23 had generalised criteria, and 9 out of 23 had no criteria or did not answer the question. Of the 11 CAs that answered "Yes" to this question, one CA only had criteria for foetal dose.

In interventional radiology and cardiology, the picture was exactly the same for all CAs, with none having different criteria for interventional radiology compared to interventional cardiology. The situation was as follows: 12 out of 23 had specific criteria (again with 1 CA only having foetal dose as a criteria), 4 out of 23 had generalised criteria, and 7 out of 23 had no criteria or no answer to the question.

Of the CAs that did not report criteria, 2 out of 23 reported that they were developing such criteria.

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Online Surveys (CA)

In the last 5 years (2018–2022) there have been 2964 significant events reported to the CAs, although some of the systems were not operational in 2018 and started to collect data later. External beam radiotherapy, diagnostic nuclear medicine and diagnostic radiology are amongst the modalities with higher numbers reported.

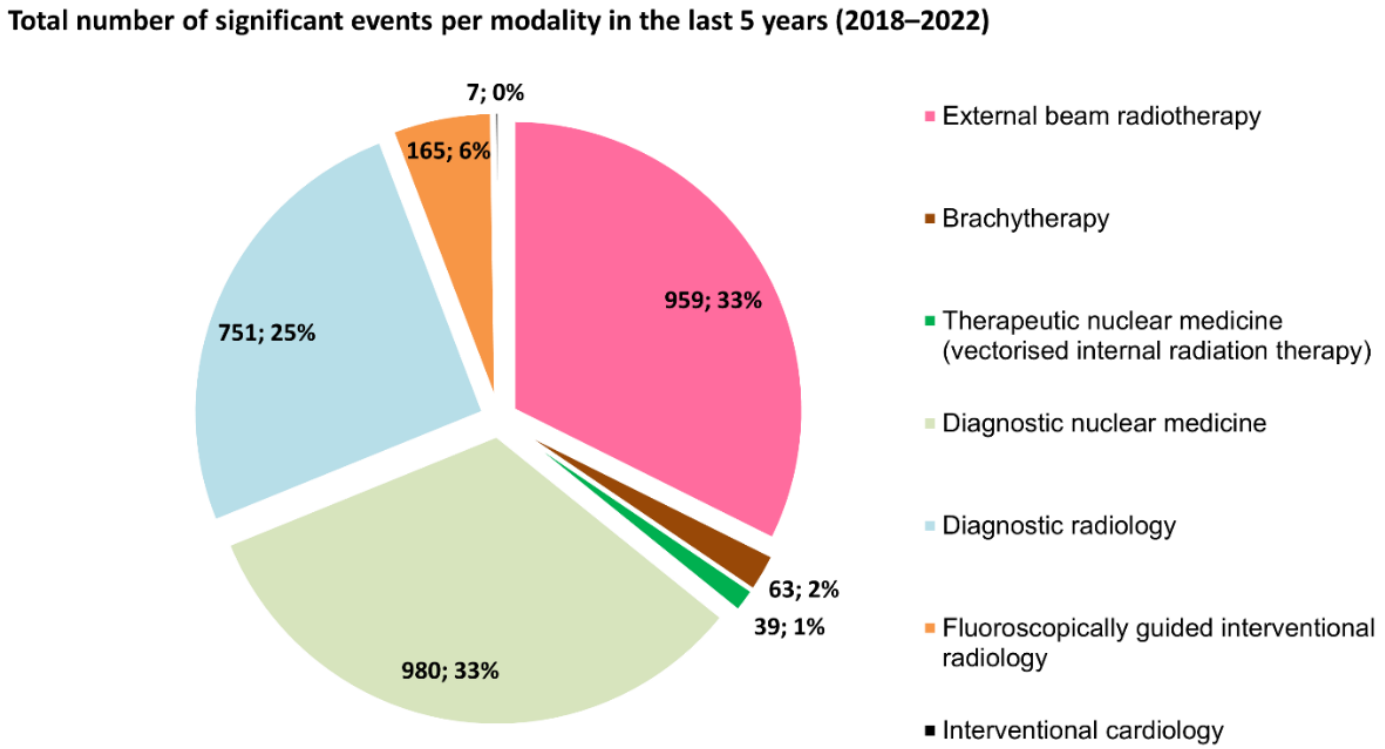

Fig. 11: Total number of significant events per modality in the last 5 years (2018–2022)

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Online Surveys (CA)

External beam radiotherapy (total 5 years 2018–2022) per country

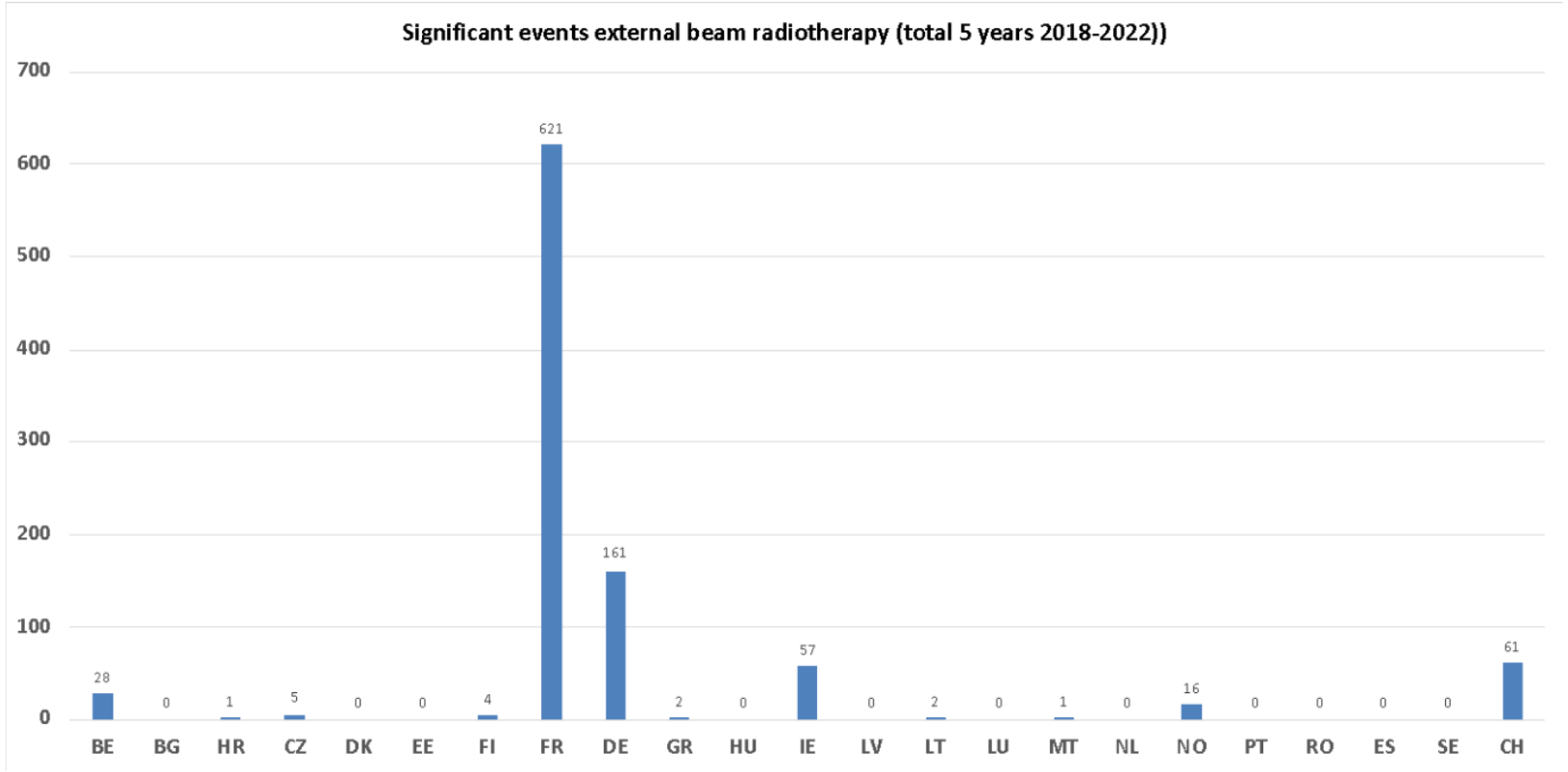

Fig. 12: Significant events in EBRT (total 5 years 2018–2022)

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Online Surveys (CA)

The role of the CA in managing reported significant events varies between countries.

The survey asked specifically about the following.

- Event report analysis
- Adopting corrective measures
- Inspections
- Soliciting experts
- Carrying out periodic reviews
- Dissemination of lessons learned

The results per each country are presented in Table 6. Belgium, Czechia, France, Luxembourg, Norway and Portugal are among the countries that have a role in all the areas defined.

Table 6: Role of the CA in managing reported significant events (✓ - with role; ✗ - no role)

Country	Event Report Analysis	Adopting Corrective Measures	Inspections	Soliciting Experts	Performing Periodic Reviews	Dissemination of Lessons Learned	✓	✗
✓	21	13	21	9	11	17		
✗	2	10	2	14	12	6		

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Online Surveys (CA)

Table 7: Estimation of the possible rate of underreporting of significant events

	On a national level, can you estimate the possible rate of underreporting of significant events involving ionising radiation?
BE	Common
BG	Rare
HR	I don't know
CZ	Common
DK	I don't know
EE	None
FI	Common
FR	I don't know
DE	I don't know
GR	Common
HU	I don't know
IE	I don't know
LV	Common
LT	I don't know

	On a national level, can you estimate the possible rate of underreporting of significant events involving ionising radiation
LU	I don't know
MT	I don't know
NL	I don't know
NO	Common
PT	Common
RO	Common
ES	Common
SE	Common
CH	Common

Common	11
Rare	1
None	1
I don't know	10

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Online Surveys (PS)

3.4 Analysis of Survey to Professional Societies

This survey was addressed to various European PSs involved with medical applications of ionising radiation. Included were PSs in the fields of medical physics, radiotherapy, clinical oncology, cancer nursing, nuclear medicine, radiography, radiology, interventional radiology, and interventional cardiology. A few PSs also represented a combination of these medical fields.

The main good practices from answers to the survey question "Please specify any additional means of support to the competent authority (CA) for managing reported significant events provided by the society?" are listed below.

- Official publications in the form of reports and recommendations, at least annually
- Newsletter and email dissertation of information, mostly monthly
- Recording presentations for dissemination

The survey queried the respondents on whether their organisation was somehow involved with quality and risk management. The results are shown in Table 8.

Table 8: An overview of PSs that have active quality and risk management initiatives within their respective societies

Area of professional society	Quality and risk management
Interventional cardiology (IC)	1 out of 4
Interventional radiology (IR)	2 out of 12
Medical physics (MP)	6 out of 12
Nuclear medicine (NM)	7 out of 22
Radiography (RG)	7 out of 11
Radiology (RY)	9 out of 15
Radiology and Nuclear Medicine (RYNM)	0 out of 1
Radiotherapy (RT)	7 out of 15
Other	0 out of 2
Total	**39 out of 94**

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Online Surveys (PS)

Table 12: An overview, by PS area, of the answers to the question: "Has the society cooperated/contributed somehow in the process of revising this provision?"

Area of Professional society	Yes	No	Don't know	No answer	Total
Interventional cardiology (4)	0%	50%	50%	0%	100%
Interventional radiology (12)	8%	42%	50%	0%	100%
Medical physics (12)	50%	33%	8%	8%	100%
Nuclear medicine (22)	36%	23%	32%	9%	100%
Radiography (11)	55%	9%	27%	9%	100%
Radiology (15)	40%	33%	20%	7%	100%
Radiology and Nuclear Medicine (1)	100%	0%	0%	0%	100%
Radiotherapy (15)	13%	40%	27%	20%	100%
Other (2)	0%	50%	50%	0%	100%
Average	**34%**	**31%**	**29%**	**6%**	**100%**

From the survey replies, MP and RG societies seem to have a higher level of involvement in the national regulatory process, Furthermore, many PSs of all types indicated in free-text answers that they were involved in the drafting stage of national regulations in many ways, including the following.

- Reviewing drafts
- Meetings with regulators to discuss issues
- Contributing to expert advisory groups
- Co-option on to the drafting team for new regulations
- Part of the general consultation with stakeholders

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Online Surveys (PS)

Table 14 PS answers to the question: "Is there a national/regional authority specifically designated as competent to be in charge of the management of declared significant events?"

Area of Professional society	Yes	No	Don't know	No answer	Total
Interventional cardiology (4)	50%	50%	0%	0%	100%
Interventional radiology (12)	50%	8%	42%	0%	100%
Medical physics (12)	92%	0%	0%	8%	100%
Nuclear medicine (22)	68%	9%	14%	9%	100%
Radiography (11)	78%	11%	0%	11%	100%
Radiology (15)	82%	9%	0%	9%	100%
Radiology and Nuclear Medicine (1)	100%	0%	0%	0%	100%
Radiotherapy (15)	67%	7%	7%	20%	100%
Other (2)	100%	0%	0%	0%	100%
Average	**76%**	**10%**	**7%**	**6%**	**100%**

For the 67 PSs that answered "Yes" (76%), one society did not specify the name of the CA as required by the survey, and one society gave an unusable answer. In general, these survey replies from PSs indicate that the knowledge of CAs in charge of the management of declared significant events is good.

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Online Surveys (PS)

Table 16: An overview, by PS area, the number of respondents who indicated that their society supports CAs in managing reported significant events

Area of Professional Society	The PS Supports the CA
Interventional cardiology	3 out of 4
Interventional radiology	5 out of 12
Medical physics	3 out of 12
Nuclear medicine	8 out of 22
Radiography	2 out of 11
Radiology	5 out of 15
Radiology and nuclear medicine	0 out of 1
Radiotherapy	5 out of 15
Other	0 out of 2
Total	**31 out of 94**

Table 17: An overview by country of how PSs supports CAs in managing reported significant events (note that more than one answer per respondent was possible)

Country	Event report analysis	Adopting corrective measures at national level based on events analysis	Dissemination of lessons learned	Clinical audit of the reporting institution
Total	16	15	27	12

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Online Surveys (PS)

Table 19: Summary of the survey respondents free-text answers to the question "In your experience, what are the main supports in implementing an incident/reporting and learning system"

Main Supports in Implementing an Incident-Reporting and Learning System	
Local Level	**National Level**
Having a quality department supporting safety, reporting, events analysis and lessons dissemination, and having the expertise of medical physics experts to also support	Having specific provisions protecting reporters
Having specific "no blame, no shame" policy supporting learning culture	Online and easily accessible reporting systems
Staff education in reporting	Education and training in reporting and safety culture
Easy to use electronic reporting system	

Table 20: Summary of the survey respondents' free-text answers to the question "From your own experience, which are the main barriers in implementing an incident-reporting and learning system?"

Main Barriers in Implementing an Incident-Reporting and Learning System	
Local Level	**National Level**
Fear of sanctions / litigations / repercussions if declaring significant events.	Fear of sanctions / litigations / repercussions if declaring significant events.
Lack of safety culture and education in reporting.	Lack of funding incentives.
Lack of time and "easy to use" reporting systems.	Lack of communication/feedback.
	Lack of education training in safety culture and reporting.

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Online Surveys (PS)

Table 22: An overview by PS area of respondents' survey replies to the question: "Do you carry out initiatives to promote safety through incident reporting systems?"

Area of Professional society	Yes	No	No answer	Total
Interventional cardiology (4)	0%	100%	0%	100%
Interventional radiology (12)	33%	42%	25%	100%
Medical physics (12)	33%	50%	17%	100%
Nuclear medicine (22)	36%	45%	18%	100%
Radiography (11)	55%	27%	18%	100%
Radiology (15)	33%	47%	20%	100%
Radiology and Nuclear Medicine (1)	0%	100%	0%	100%
Radiotherapy (15)	47%	20%	33%	100%
Other (2)	50%	50%	0%	100%
Average	**32%**	**54%**	**15%**	**100%**

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Online Surveys (PS)

Table 24: By PS area, the answers to the question: "Do you think that the competent authority should share information about significant events involving ionising radiation in a more systematic way?"

Area of Professional society	Yes	No	No answer
Interventional cardiology (4)	50%	25%	25%
Interventional radiology (12)	67%	8%	25%
Medical physics (12)	75%	8%	17%
Nuclear medicine (22)	82%	5%	13%
Radiography (11)	64%	18%	18%
Radiology (15)	67%	20%	13%
Radiology and Nuclear Medicine (1)	100%	0%	0%
Radiotherapy (15)	80%	0%	20%
Other (2)	100%	0%	0%
Average	**76%**	**9%**	**15%**

Survey respondents also gave examples of how CAs could share information about significant events involving ionising radiation more systematically, which can be summarised in three distinct actions.

- Official publications in the form of reports and recommendations, at least annually
- Newsletter and email dissemination of information on a monthly basis
- Recording presentations for dissemination in the community

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Online Surveys (PS)

The final question in the PS survey gave the respondents the opportunity to provide general comments within the field of reporting and learning from significant events. The comments selected by the WP team as most prominent include the following items.

- "I would really be happy if the competent authority would be able to give us more professional support (via publications, organising national meetings with international experts in the field, direct discussions with institutions, etc). At the moment there is no regular activity on that; hence, an unmet need"
- "Creation of a European data repository register in which to record ionising radiation-based significant events and incidents"
- "It would be desirable to have standardisation in incident reporting and common guidelines across EU countries"
- "I think it's important to explain that radiation incidents are an important part of learning. Particularly in small centres, there may be a fear of disclosing incidents. In my opinion, in small centres it is easier to keep the event a secret than in large ones"
- "Patient safety requires training and time to dedicate to it. It is difficult to free up time to devote to these issues, especially in healthcare facilities with high healthcare activity. I believe that external audits organised by the government in collaboration with scientific societies can be of great help to improve patient safety and quality, however the logistics involved in organising such audits are not easy to implement"
- "Spain is an almost federal country, a common policy should be applied for the declaration, registration and evaluation of incidents. In addition a continuous learning system should be implemented with the collaboration of the national societies. The investments of the EC should be reviewed in countries where there is no clear commitment on this issue"
- "Incidents are reported to and handled by the national authority. Their mission could be extended to developing a system for incidence learning on a national level"

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Online Surveys (Hospitals)

3.5 Analysis of Survey to Hospitals

Hospitals within the survey area were identified according to the methodology described in Section 2.2 via PSs. The survey structure is given in Annex 1. There were 58 responses from hospitals, three of which were distinct survey responses from different departments within the same hospital. This means 55 separate hospital responses were received from 19 countries out of 29 possible. No replies were received from Austria, Bulgaria, Cyprus, Estonia, Hungary, Italy, Latvia, Luxembourg, Norway and Slovenia. The types of hospitals that responded are summarised in Table 25 below. Please note multiple answers regarding the type of facility were possible, hence the totals in the table are higher than the number of hospital replies received.

Table 25: Summary of types of hospital within the survey respondents

	Public	Private	University Hospital	Cancer Hospital	General Hospital
Total	**32**	**10**	**27**	**21**	**19**

All responding hospitals had implemented an ILS of some sort. When asked what type of local radiation event recording system they had implemented the vast majority were using electronic ILSs (35 out of 55). Of the remaining hospitals, 18 used a paper-based system, one hospital declared a local system for radiotherapy and a generic regional system, one hospital reported a general, non-specific system, and one hospital reported the use of multiple paper and electronic ILSs depending upon the department/clinic. However, it is likely that, from the 35 out of 55 hospitals reporting electronic-based ILSs, many of these will also be generic reporting systems where staff are able to report all types of local incidents.

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Online Surveys (Hospitals)

Reporting of significant events to

- Radiation safety authority
- Device regulatory agency
- Pharmaceutical agency
- Both regional and national reporting

Who can be a reporter of events?

- 34/55 any staff member
- 21/55 some restrictions (certain experts, managers, etc.)

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Online Surveys (Hospitals)

Staff protection and mode of reporting

- 13/55 complete anonymity
- 14/55 reporter discretion
- 21/55 restricted access to reporter identity
- 4/55 open systems

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Online Surveys (Hospitals)

Analysis of reported events

- 43/55 significant events
- 35/55 near misses
- 35/55 repeated events

Where events are analysed:

- 29/54 clinical service level
- 33/54 quality and safety department (or equivalent)

Most report findings to hospital management (graded approach)

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Online Surveys (Hospitals)

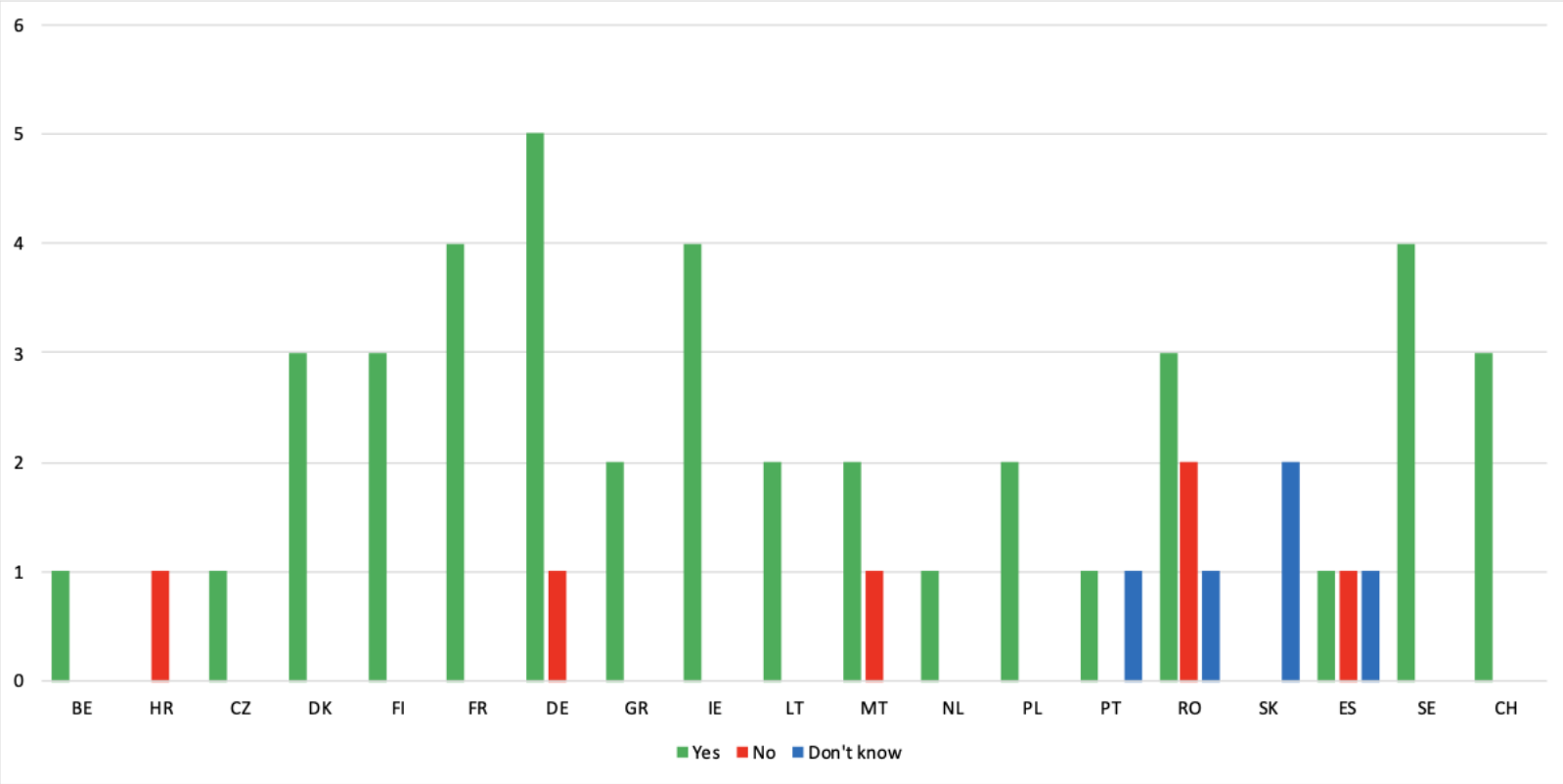

Fig. 19: Summary by country of numbers of hospitals regarding the status of their regularly reviewing of reported radiation events

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Online Surveys (Hospitals)

Staff involved in review and analysis of reported events

- Medical physicists
- Physicians
- Radiographers
- Radiation protection officer/expert
- Quality and risk managers (less than 50%)

Training for staff

- Most for reporters, less common for review/analysis

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Online Surveys (Hospitals)

Service improvement following reported events

- Improvements in written procedures
- Training of staff
- Improvements in workflow
- 2nd check of patient identity
- Standardised nomenclature and colour coding
- Double check of procedure to be performed

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Online Surveys (Hospitals)

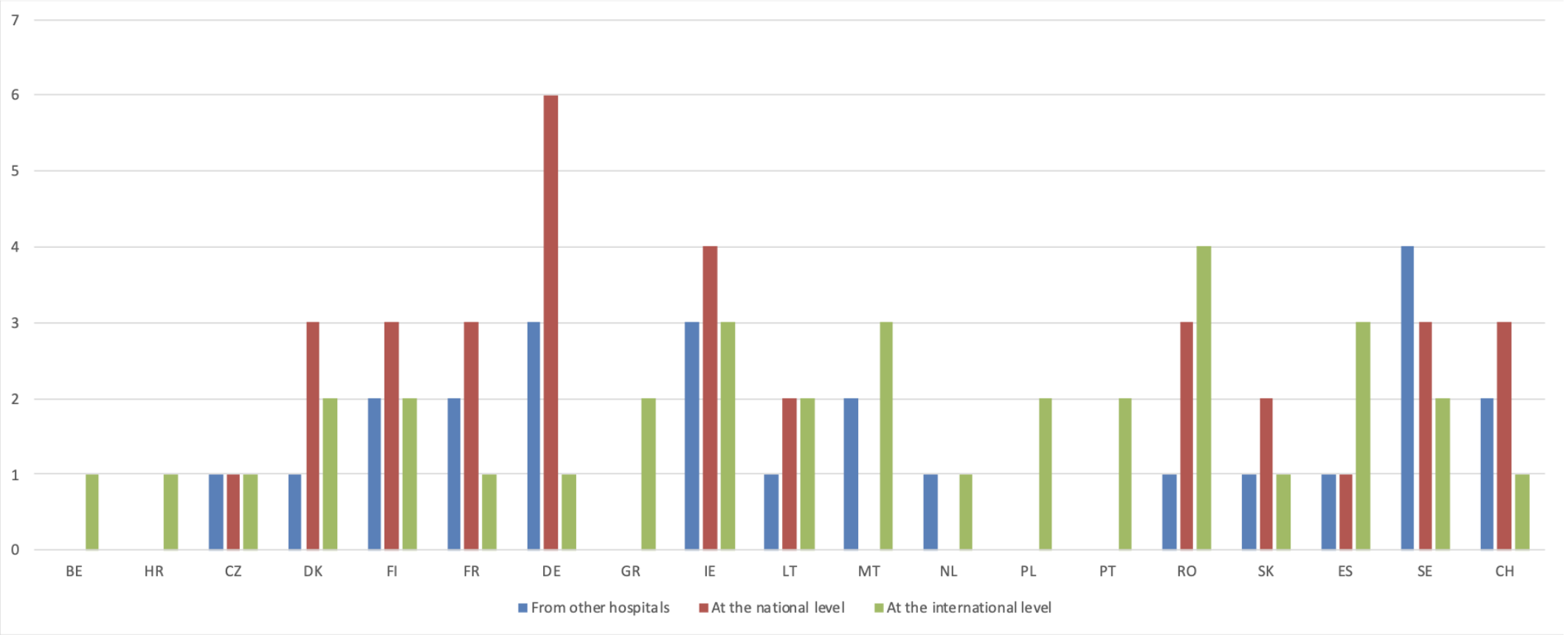

Fig. 21: Summary of sources of learning for hospitals by country

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Online Surveys (Hospitals)

In terms of the free-text request for additional comments some of the more notable ones were the following.

- "A desire to more strongly couple two disparate reporting systems so that the radiation protection authority also sees the reported radiation incidents"
- "Many hospitals are not aware of what they would have to report"
- "We are trying to encourage more near misses to be reported as there is great learning from these"
- "All of the nationally reported incidents have shown a 'Swiss cheese' effect with several points of failure"
- "We have increased our emphasis on incidents reporting and in 2023 have seen an uptick in reported incidents and near misses"
- "We have a national cooperation between the hospitals in Denmark where we share knowledge from the incidents to learn from each other. We meet twice per year"

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

Online Surveys (Summary)

3.6 Comparative Analysis of the Three Surveys

When comparing the survey results for CAs, PSs and hospitals, the following items were identified as important to pursue in the MARLIN project final guidance document.

- The criteria for reporting events shows some hospitals were mistaken in their responses regarding who set the criteria. For instance all Swedish hospitals said criteria were set locally. However, we know from the CA survey that Sweden has set such national criteria. The Dutch hospital, though, was correct in saying there is no CA setting criteria, as these are set by the relevant PS. One hospital stated criteria were set locally and specified exactly what these criteria were. There is no way to corroborate this response, as the relevant CA did not respond to the CA survey.
- In final guidelines the MARLIN project will analyse events reported by hospitals to CAs as a function of criteria to try to answer the question "Why does France have so many reported events compared to other countries." Do countries with low numbers have vague criteria, or is there something else standing in the way of reporting events?
- Regarding CA opinions on under-reporting, some hospitals said they or other hospitals in their country were reluctant to report for reputational reasons, and also staff in some hospitals were reluctant to report to local ILS due to fear of disciplinary action by management. Definitely a culture issue. Furthermore, some replies indicated a fear of economic consequences from reporting events to CA, which will also be addressed in the final guidance document.

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

Online Surveys (Summary)

3.6 Comparative Analysis of the Three Surveys

When comparing the survey results for CAs, PSs and hospitals, the following items were identified as important to pursue in the MARLIN project final guidance document.

- Professional societies indicated that the CAs should share information about significant events involving ionising radiation in a more systematic way, while CAs indicated that dissemination of information on significant events involving ionising radiation is part of their duties.
- A strong majority of PSs declared they are not directly requested by members of their society (hospitals) to assist with reported significant events.
- In summary, the survey results underline that there is a need for more interaction between CAs and PSs, as well as PSs and hospitals, i.e., the entire community, in order to efficiently use incident-reporting and learning systems to promote a safety culture within medical applications using ionising radiation.

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

Expert Interviews

4. Expert Interviews

4.1 Methodology

The methodology for selecting themes and questions for interviews was linked to survey replies, i.e., no predetermined themes and questions before we had received a majority of survey replies. This decision was made to be able to reflect good and suboptimal practices, as well as particularly interesting items, that were identified from survey replies. As a strategy we decided to focus on fewer interviews to allow a more in-depth exploration of items.

A decision was made to focus the interviews on CAs and hospitals. Seven CAs and eight hospitals were selected for interviews based on their survey replies. While some participants have been unresponsive, the consortium has completed interviews with four of each group.

Interviews were conducted with the following CAs.

- National Centre of Radiobiology and Radiation Protection, Bulgaria
- Nuclear Safety Authority (ASN), France
- Portuguese Environment Agency, Portugal
- Federal Office of Public Health, Switzerland

Additionally, interviews were carried out with the following hospital personnel.

- Eeva Boman, Head of Radiotherapy Physics who provides medical physics input to all event analyses and feedback to staff and managers via annual reports, Tampere University Hospital, Tampere, Finland
- Esther Angulo Pain, medical physicist responsible for patient safety strategy in Andalusia, Hospital Universitario Puerta del Mar, Cádiz, Spain
- Nadja Rystedt, Head of the Radiation Physics Department, University Hospital of Umeå, Umeå, Sweden
- Margaret Moore, Head of Radiotherapy Physics, University Hospital Galway, Ireland

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

Expert Interviews

Competent authorities

- Transposition of BSSD -> boost in reporting
- No concrete evidence of underreporting
- Initiate inspections based on reporting
- Main role should be dissemination of knowledge
- There should be legal protection for reporters

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

Expert Interviews

Hospitals

- Non-significant events outnumber significant
- Harmonisation of criteria for significant events is critical
- Most use anonymised approach for reporting
- Systems used are focused on reporting (not learning)
- EU wide communication would be appreciated

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

Thank you!

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

EC Tender project contract N° ENER/2022/NUCL/SI2.880751

SAMIRA Study on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology

Success Factors for Deploying a Reporting and Feedback System: The French Experience

Carole ROUSSE, ASN

Director - Ionising Radiation and Health Department

MARLIN Project Workshop
September 5 & 6, Brussels

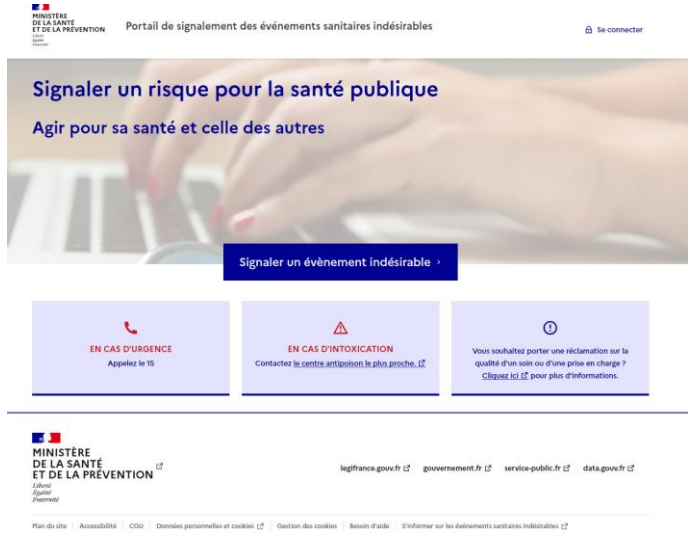
Presentation summary

1. **Characteristics of the French reporting and feedback system**
2. **Some key figures**
3. **What does feedback mean ?**
4. **Success factors for deploying a reporting and feedback system**

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

1. Characteristics of the French reporting and feedback system

- Set up in 2007 in the context of a serious radiotherapy accident, with **strong health ministerial support** and the involvement of all stakeholders
- Initially a joint portal between ANSM[1] and ASN, then integration into a **single portal** for reporting events covering all health vigilances.
- **Procedures defined with stakeholders** to investigate and learn from reported events (ASN, ANSM, Ministry of health and regional health agencies, HAS[(2)], Professional societies, …)



(1) National Agency for the Safety of Medication and Health Products (2) French National Authority for Health

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

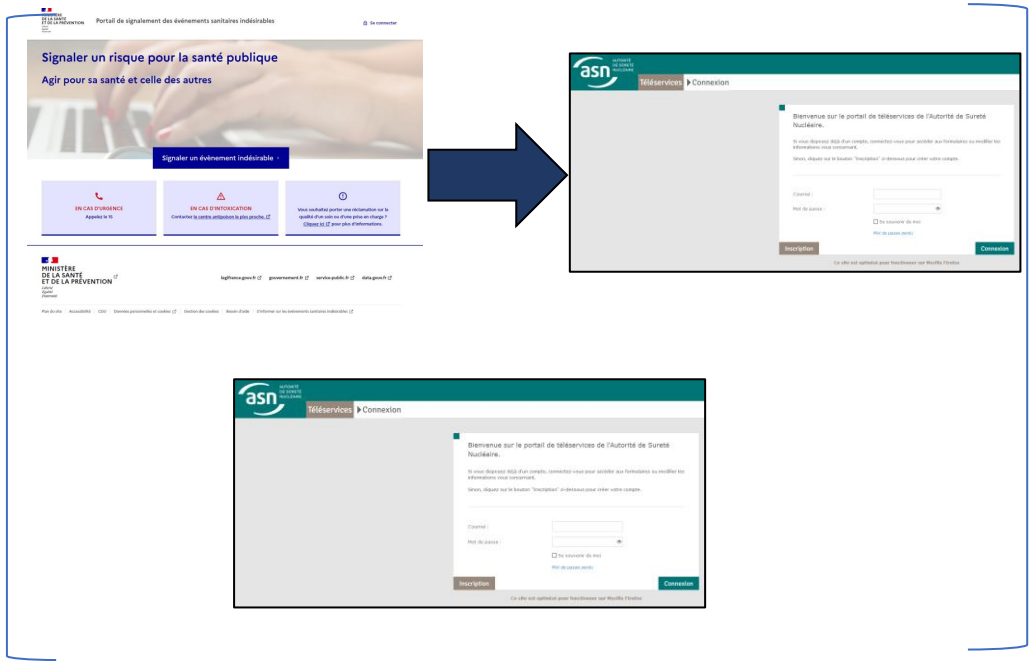
1. Characteristics of the French reporting and feedback system : the event reporting circuit

Type of event to be reported

ESR (1)

ESR
And
Health products event

ESR
and
Medicines event



Reporting authority

asn ars Agence Régionale de Santé

asn ars Agence Régionale de Santé ansm Agence nationale de sécurité du médicament et des produits de santé

asn ars Agence Régionale de Santé ansm Agence nationale de sécurité du médicament et des produits de santé

L.1333-13
Public Health Code

Immediate notification (2 working days)

possibility of notifying events via the single vigilance portal or directly via the ASN teleservice

ESR report to be submitted within 2 months

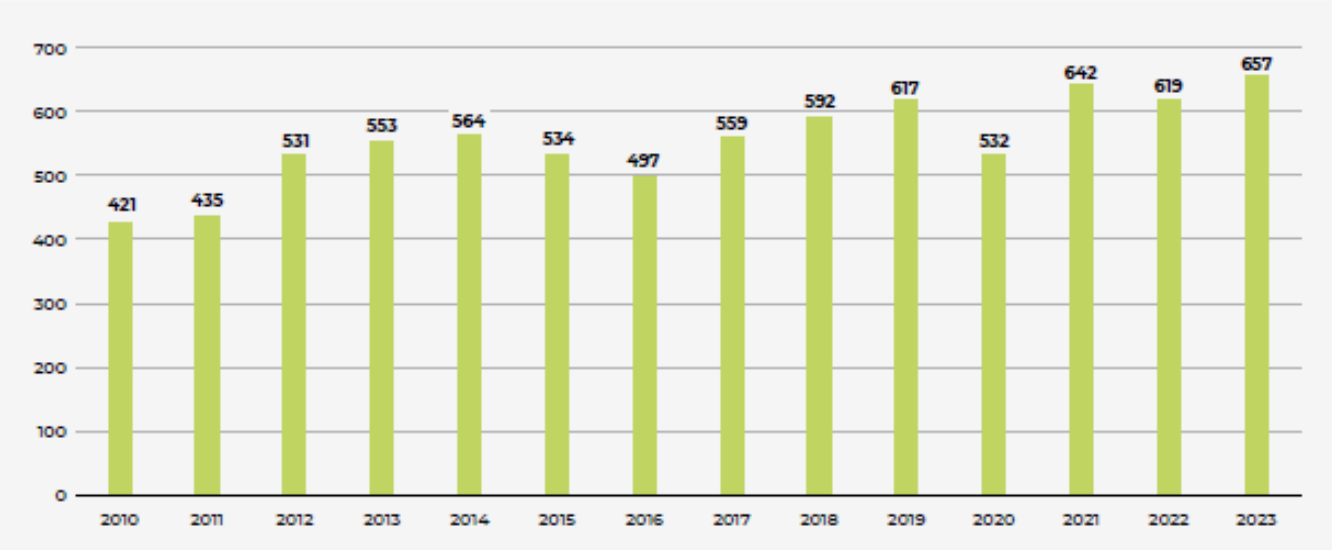
See ASN guide n°11 for the notification criteria : Guide n°12 : Déclaration des événements significatifs dans les domaines des installations nucléaires - 09/11/2023 - ASN

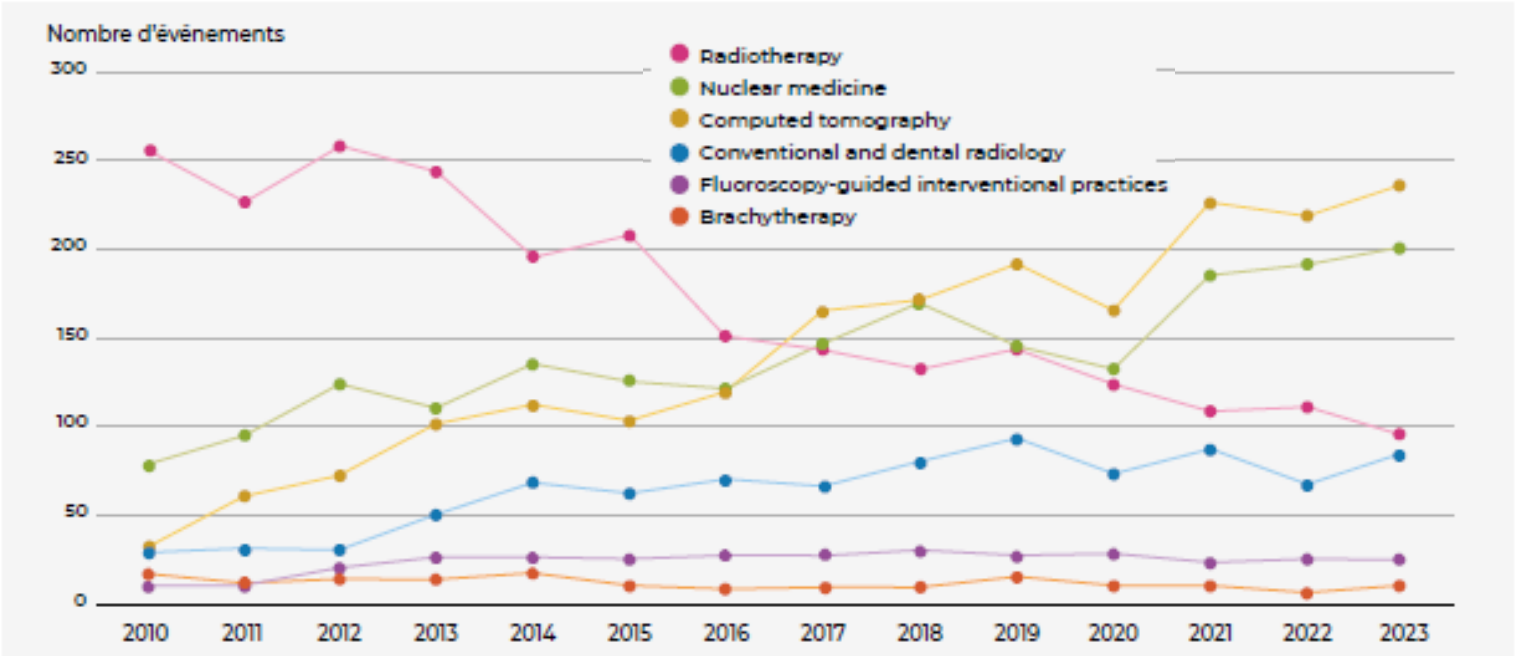
(1) ESR =significant radiation protection event : event to be declared to the authorities

2. Some key figures

Evolution of the number of annual ESR notified from 2010 to 2023

More than 8,000 events reported since 2007 in tne medical field





Number of ESRs by activity category during the 2010-2023 period

- **Half of reported events concerns patients**
- A quarter of reported events concerns women ignoring their pregnancy
- A steady decline in radiotherapy and an increase in nuclear medicine and CT since 2010

MARLIN,Project Workshop, Brussels

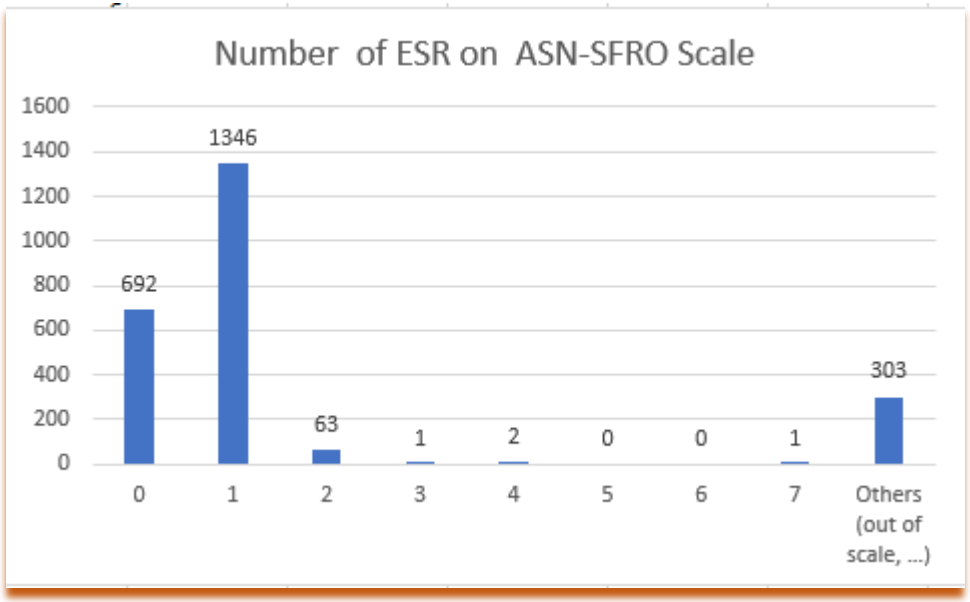
This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

2. Some key figures : communication

Radiotherapy ASN-SFRO Scale

CALE	EVENTS (UNPREDICTED, UNEXPECTED)	CAUSES	CONSEQUENCES (CTCAE V3.0 GRADE)
5 to 7* ACCIDENT	Death	Dose (or irradiated volume) much greater than normal resulting in complications or sequelae incompatible with life	Death
4** ACCIDENT	Serious life-threatening event, disabling complication or sequela	Dose or irradiated volume much greater than the tolerable doses or volumes	Serious unexpected or unpredictable acute or delayed effect, grade 4
3** INCIDENT	Event resulting in severe alteration of one or more organs or functions	Dose or irradiated volume greater than the tolerable doses or volumes	Severe unexpedted or unpredictable acute or delayed effect, grade 3
2** INCIDENT	Event resulting in or likely to result in moderate alteration of an organ or fuction	Dose greater than the recommended doses, or irradiation of a volume that may lead to unexpected but moderate complications	Moderate unexpedted or unpredictable acute or delayed effect, grade 2, minimal or absence of alteration of quality of life
1 EVENT	Event with dosimetric consequences but no expected clinical consequence	Dose or volume error (e.g. dose error or target error in a session not compensable over the treatment as a whole)	No symptom expected
0 EVENT	Event with no consequence for the patient	Dose error (number of monitor units, filter, etc.) compensated over the treatment as a whole. Error of identification of a patient treated for the same pathology (compensable)	

* In the case of deaths of several patients:
• the minimum level 5 is raised to 6 if the number of patients is greater than 1 but less than or equal to 10;
• the minimum level 5 is raised to 7 if the number of patients is greater than 10.
** If the number of patients is greater than 1, a + sign is added to the assigned level (example: 3 become 3+).



•Needed after a severe accident to provide the public with accessible information and to facilitate the understanding of the severity of an event
•Elaborated in July, 2007 by ASN with SFRO
•Referring to CTCAE scale

Incident notice : ≥ 2 or >1 for a cohort of patients

No patient scale outside radiotherapy

16 indicent notices (patient event) published: mainly interventional radioguided procedures and nuclear medicine

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

3. What does feedback mean?

Feedback at the clinical facility level

Internal ASN feedback

Feedback at the national level and dissemination

Appropriate handling of the event by the clinical facility

Evolution of ASN control

New inspection guidelines

Training improvement

Exchanges between authorities and professional societies to build on experience feedback

2 incidents learning committees on imaging and therapy

Incident notices, case report of an incident (serious one), information during inspection

Circular letters sent to all services

Bulletin « The safety of the patient », feedbacks sheets

Recommandations from health authorities or professional societies

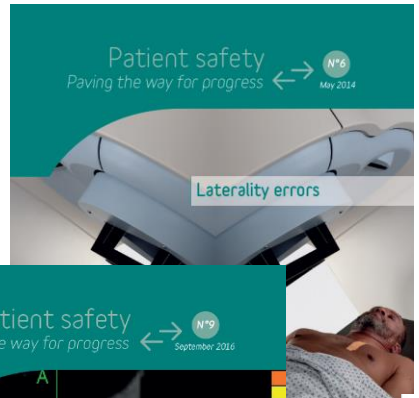
Publication of scientific articles

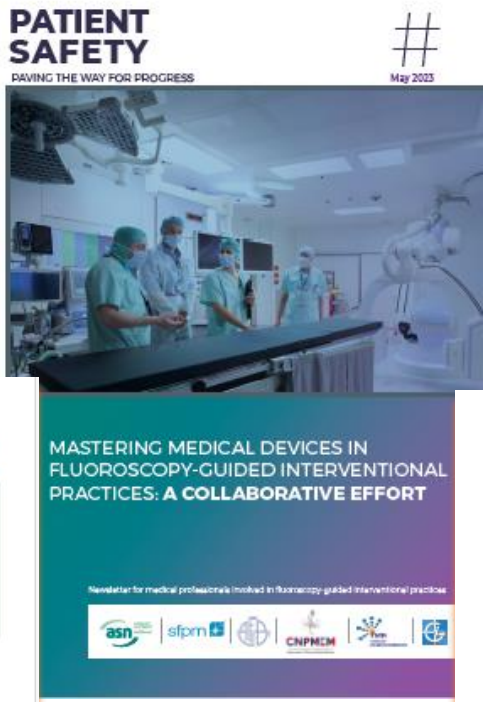
Participation in congresses or seminars

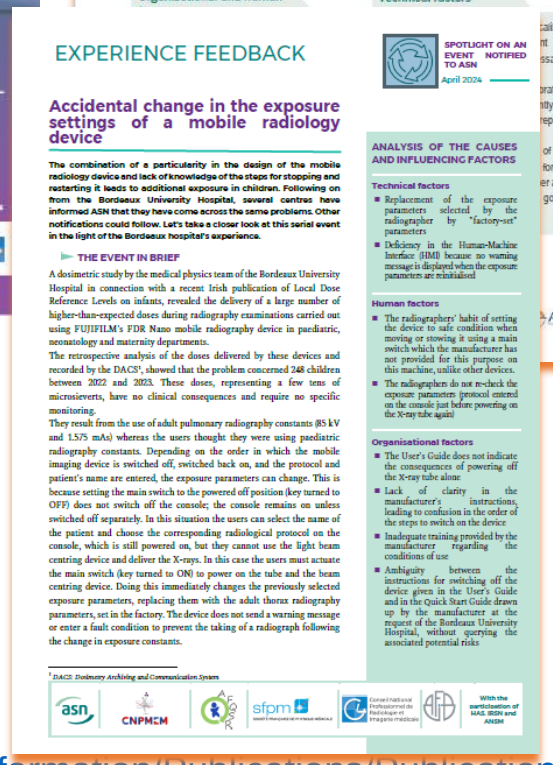
Changes in regulation, trainings improvement

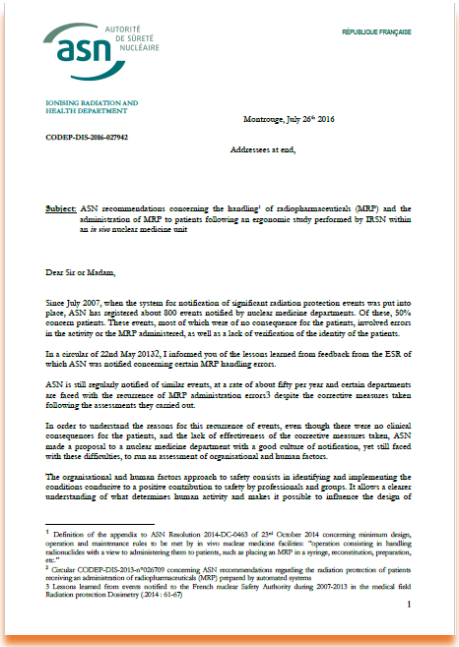
This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

3. What does feedback mean ? Bulletin « The safety of the patient », feedbacks sheets, circular letters radiotherapy and brachytherapy others









Circular letters concerning the handling of radiopharmaceuticals and the administration of MRP to patients following an ergonomic study performed by IRSN within an in vivo nuclear medicine unit

http://www.french-nuclear-safety.fr/Information/Publications/Publications-for-the-professionals

3. What does feedback mean? Recommandations from health authorities or professional societies

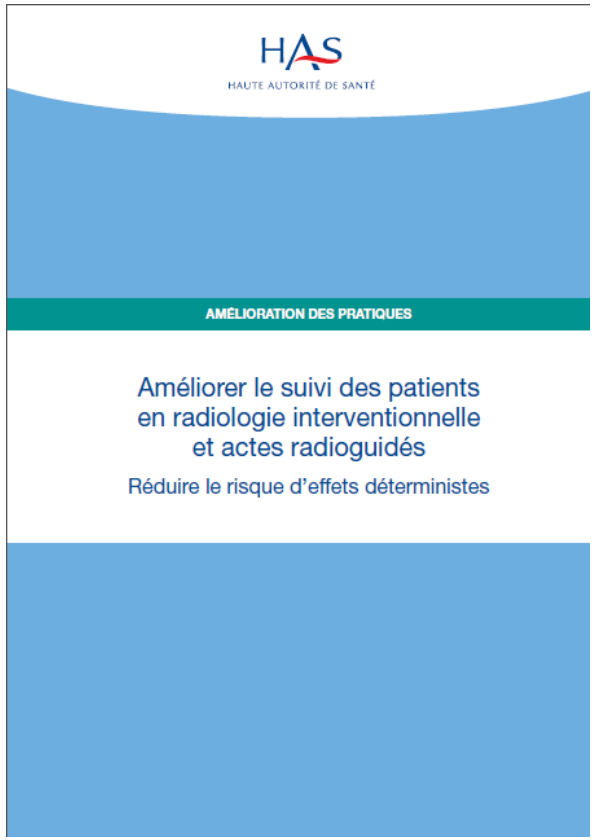
le 13 juin 2016

Recommandations
relatives à la formation à l'utilisation des dispositifs médicaux émetteurs de rayonnements ionisants

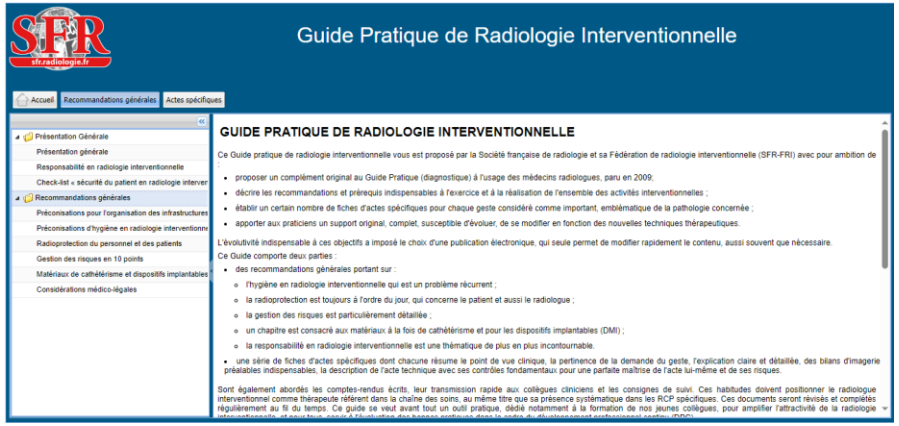
Domaine d'application :
Dispositifs médicaux émetteurs de rayonnements ionisants, équipements utilisés en imagerie médicale notamment pour la radiologie conventionnelle, la scanographie, la radiologie interventionnelle, l'imagerie interventionnelle et actes radioguidés

Contexte

✓ **Recommendations for training users of medical devices using ionizing radiation**



✓ **Improving patient follow-up in interventional radiology and radioguided procedures: reducing the risk of deterministic effect**



✓ **Interventional radiology practical guide published in 2009 by SFR**

Introduction of an Extended Competence Diploma in Stereotactic Radiosurgery and Radiotherapy by the French Society of Neurosurgery

3. What does feedback mean? Publications : articles, posters, presentations at national and international levels

Radiation Protection Dosimetry Advance Access published October 1, 2014

Radiation Protection Dosimetry (2014), pp. 1–4 doi:10.1093/rpd/ncu295

LESSONS LEARNED FROM EVENTS NOTIFIED TO THE FRENCH NUCLEAR SAFETY AUTHORITY DURING THE PERIOD 2007–13 IN THE MEDICAL FIELD

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Received 27 June 2014; revised 25

The analysis of events is crucial for acc events. The majority of them concern extent, occupational exposures and the radiological procedures and nuclear me respectively. Deterministic effects in p events involve leakage of radioactive ef effluent facilities. The causes are main the role of medical physicists and radia and to conduct clinical audits.

INTRODUCTION

Lessons must be drawn from each diation protection (technical an from procedures, etc.) in order t sures to prevent recurrence of the such events plays a fundamental vention in the field of radiation July 2007, ASN set up a system cant radiation protection events activities in the medical field. The cations from WHO[1], IAEA[2, 3], the critical need to disemina lessons learned from events. Ma system failures rather than the ac Ensuring that staff are properly written procedures, improving ris couraging manufacturers to des their machines, conducting regul toring unusual reactions in patie ples of the lessons learned.

The objectives of this paper are t tion requirements, to give an overvi fied to ASN during the period 200 the lessons learned in order to imp radiation protection during medica ginality of this paper is to present the events occurring in radiation m

FRENCH REGULATORY RE

According to the provisions of A the Public Health Code, 'the in

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Radioprotection
© EDP Sciences 2013
DOI: 10.1051/radiopro/2013096

SFRP

Disponible en ligne :
www.radioprotection.org

ARTICLE

Retour d'expérience sur les évènements déclarés à l'Autorité de sûreté nucléaire (ASN) dans le domaine médical

C. Rousse[a], P. Cillard et J.-L. Godet

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Reçu le 17 octobre 2013 – Accepté le 17 octobre 2013

Résumé – L'ASN a mis en place en juillet 2007 un sys radioprotection. Les ESR déclarés à l'ASN dans le domaine total cumulé de 2300. Les enseignements montrent que les tion les plus importantes sont, pour les professionnels, la ra de doses, la curiethérapie et la médecine nucléaire avec des des effets radio-induits sont observés en radiologie interv nucléaire, lorsque les processus de délivrance des radiophar grave une ablation partielle de la thyroïde. De nombreux é soulignent la nécessité de renforcer la maintenance et la s fortes perturbations de l'activité des services avec des retard tance de donner les moyens aux physiciens médicaux et per des démarches de management de la qualité et de gestion de

Abstract – Experience feedback of events notified to July 2007 a system of notification of significant events deali to the ASN in the medical field have been increasing sin are that medical activities with the most important implic interventional radiology with dose limits overruns, brachy of operators. For patients, deterministic effects were obse nuclear medicine, when the process of issuing radiopharm partial removal of the thyroid . Many events involve leaks the maintenance and monitoring facilities and can cause r care. The feedback emphasizes the importance of empow implement steps of quality management and risk manageme

Keywords: event / feedback / medical / radioprotection /

1 Introduction

À la suite d'un dysfonctionnement, il y a lieu de tirer les enseignements afin de renforcer les dispositions qui permet-tront d'éviter sa répétition ou la survenue éventuelle d'un évè-nement de gravité plus importante. La détection et l'analyse des événements sont donc fondamentales en matière de pré-vention des accidents dans le domaine de la radioprotection. L'ASN a mis en place en juillet 2007 un système de déclaration d'événement significatif de radioprotection pour les activités nucléaires. L'objectif d'un tel système est de pouvoir capita-liser les enseignements issus de l'analyse de ces événements afin de faire progresser collectivement la radioprotection. Cet article a pour objet, après avoir rappelé brièvement les obli-gations réglementaires relatives à la déclaration d'événements

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IMdR

20e Congrès de maîtrise des risques et de sûreté de fonctionnement - Saint-Malo 11-13 octobre 2016

L'ANALYSE ORGANISATIONNELLE AU SECOURS DES CREX
UNE EXPERIENCE EN MEDECINE NUCLEAIRE.
ORGANIZATIONAL ANALYSIS HELPING FEEDBACK COMITEE
A NUCLEAR MEDICINE EXPERIENCE

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Résumé

La médecine nucléaire permet d'étudier le fonctionnement des organes en utilisant les rayonnements ionisants émis par les radionucléides et produits ou dispositifs en contenant (dont les Médicaments Radio-Pharmaceutiques (MRP)). Parmi les exigences s'appliquant à cette activité, figure l'obligation de déclaration aux autorités de tout incident ou accident susceptible de porter atteinte à la santé des personnes par exposition aux rayonnements ionisants. Dans ce cadre tout Evénement Significatif de Radioprotection (ESR) doit être déclaré à l'ASN et faire l'objet d'une analyse et d'actions correctives décidées en Comité de Retour d'Expérience (CREX). Depuis juillet 2007, l'ASN a enregistré environ 800 événements déclarés concernant la médecine nucléaire et a constaté que ces événements sont souvent similaires et que certains services sont confrontés à la récurrence d'ESR malgré les actions correctives mises en place. Afin de comprendre cette récurrence et le manque d'efficacité des actions correctives décidées suite aux CREX, l'ASN a proposé à un établissement, ayant une bonne culture du signalement, confronté à ces difficultés, de mener une analyse sous l'angle des facteurs organisationnels et humains (FOH). Les résultats montrent que l'analyse FOH offre une solution au CREX lorsque la diversité des ESR observés nécessitant d'investiguer le champ organisationnel, voire un moyen de se prémunir des impacts de futures modifications techniques ou organisationnelles de l'activité. Les enseignements issus de cette analyse ont permis d'émettre des recommandations, non seulement pour l'établissement ayant fait l'objet de l'étude, mais également pour l'ensemble des services de médecine nucléaire in vivo par la diffusion d'une lettre circulaire adressée par l'ASN en 2016.

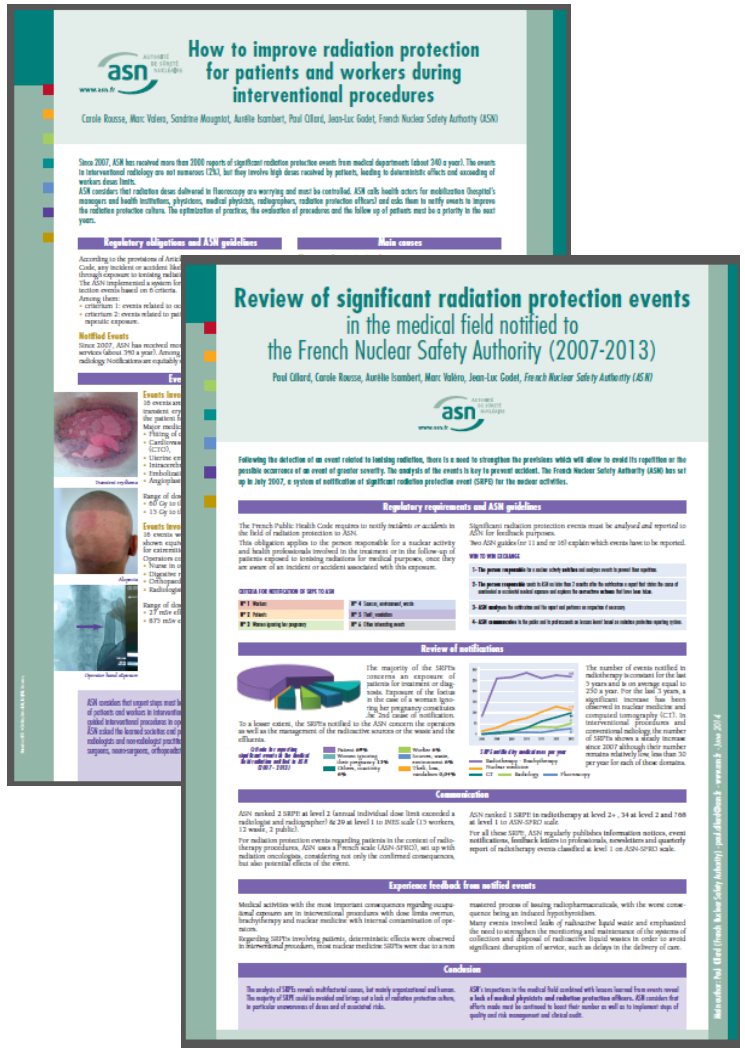
Summary

Nuclear medicine is used to study organ function using ionizing radiation emitted by radionuclides and products or devices containing (including Radio-Pharmaceutical). Among the requirements for this activity include an obligation of reporting to the authorities of any incident or accident likely to affect human health by exposure to ionizing radiation. In this context any Significant Event of Radiation Protection (ESR) must be reported to the Nuclear Safety Authority (ASN) and be analyzed and corrective actions decided by a specific Committee (CREX). Since July 2007, ASN recorded 800 events reported for nuclear medicine and found that these events are often similar and that some nuclear medicine units are facing the recurrence of ESR despite corrective actions implemented. To understand this recurrence and lack of effectiveness of corrective actions decided following CREX, ASN suggested an hospital with a good reporting culture, faced with these difficulties, to conduct an organizational and human factors analysis (FOH). The results show that the FOH analysis offers a solution to CREX when observed diversity of ESR need to investigate the organizational field, see a way to protect from the impacts of future technical and organizational changes in the activity. The lessons learned from this analysis allowed to make recommendations not only to the institution that is the subject of the study, but also for all the in vivo nuclear medicine services by a letter circular sent by the ASN in 2016.

1. Introduction

La médecine nucléaire concerne le plus souvent le diagnostic, le pronostic et le suivi thérapeutique d'un grand nombre de pathologies. Elle permet d'étudier le fonctionnement des organes en utilisant les rayonnements ionisants émis par les radionucléides et produits ou dispositifs en contenant dont les Médicaments Radio-Pharmaceutiques (MRP)). Lors des examens d'imagerie, le MRP est administré au patient par voie intraveineuse le plus souvent, en quantité adaptée au poids du patient, à l'indication et à la machine utilisée. Sa nature est spécifique de l'organe et de la fonction étudiés. Il se répartit dans l'organisme ou dans l'organe cible à explorer, en émettant un rayonnement ionisant détecté, après un temps variable (instantané à quelques jours), à l'aide d'appareils d'imagerie appelés « caméras ». Les images ainsi produites sont ensuite analysées par des médecins spécialisés en médecine nucléaire.

International Conference on Radiation Protection in Medicine - Setting the Scene for the Next Decade,-Déc 2012



How to improve radiation protection for patients and workers during interventional procedures

Carole Rousse, Marc Valero, Sandrine Mougnot, Aurélie Isambert, Paul Cillard, Jean-Luc Godet, French Nuclear Safety Authority (ASN)

Review of significant radiation protection events in the medical field notified to the French Nuclear Safety Authority (2007-2013)

Paul Cillard, Carole Rousse, Aurélie Isambert, Marc Valero, Jean-Luc Godet, French Nuclear Safety Authority (ASN)

IRPA 2012, 2014

4. Success factors for deploying a reporting and feedback system

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

EC Tender project contract N° ENER/2022/NUCL/SI2.880751

SAMIRA Study on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology

The German Incident Reporting System

Erik Mille

MARLIN Project Workshop
September 5 & 6, Brussels

The Basis

Federal level

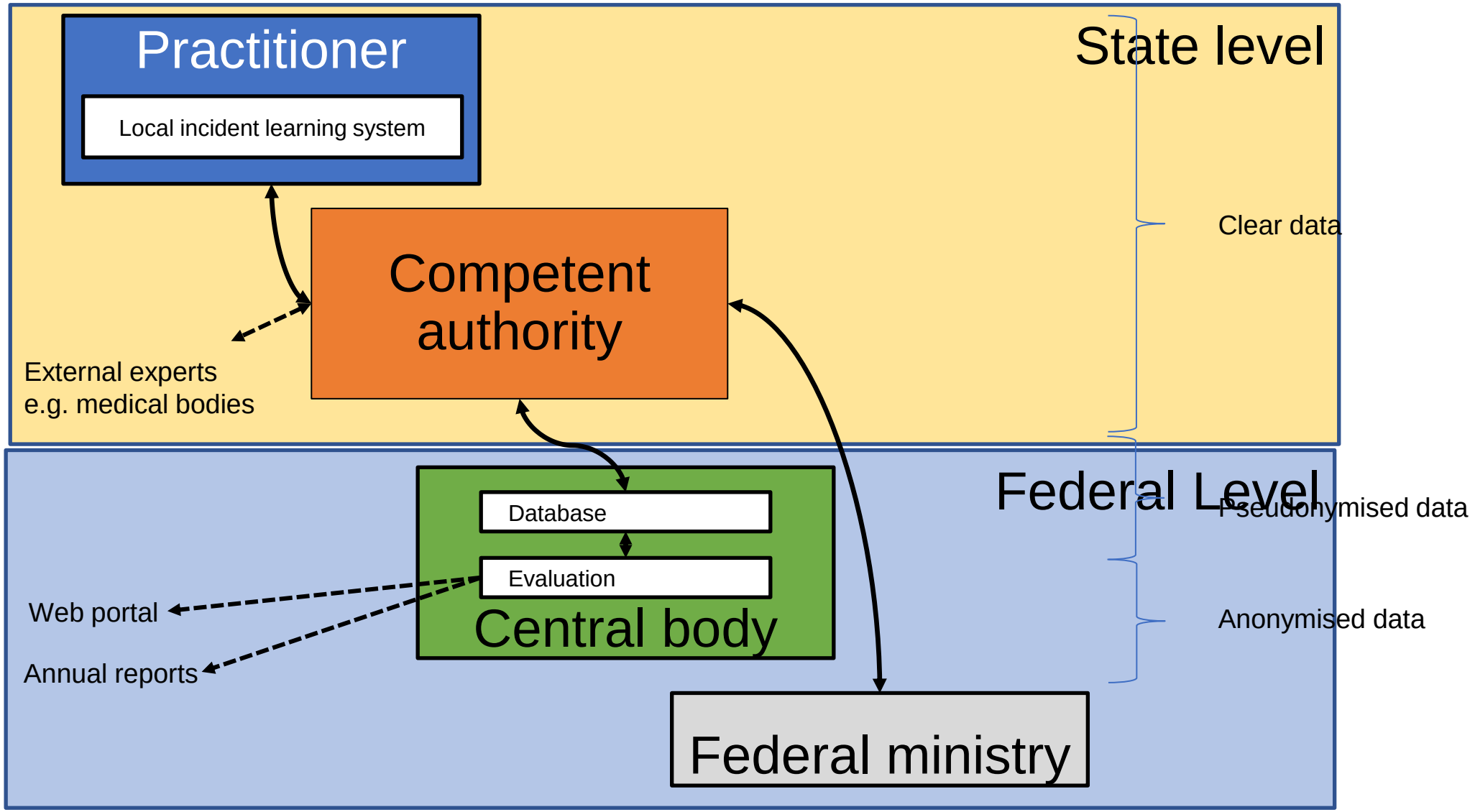
- Radiation Protection Act
- Radiation Protection Ordinance "Strahlenschutzverordnung" (StrlSchV)
- Central body at the Federal Office for Radiation Protection

State level (16 States)

- State administration on behalf of the federation
- Regional competent supervisory authorities (n = 46)

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

The Structure



This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

D

One size fits all

Medicine is a planned exposure situation

Without individual justification

Near-misses

Incident (sect. 1, subsect. 2

- Event in a pla ure situation
- that led, could have led or could lead to an unanticipated exposure
- including hazardous incidents and emergencies

Reporting a sign (sect. 108 StrlSchV)

Non-exlusive

Medicine

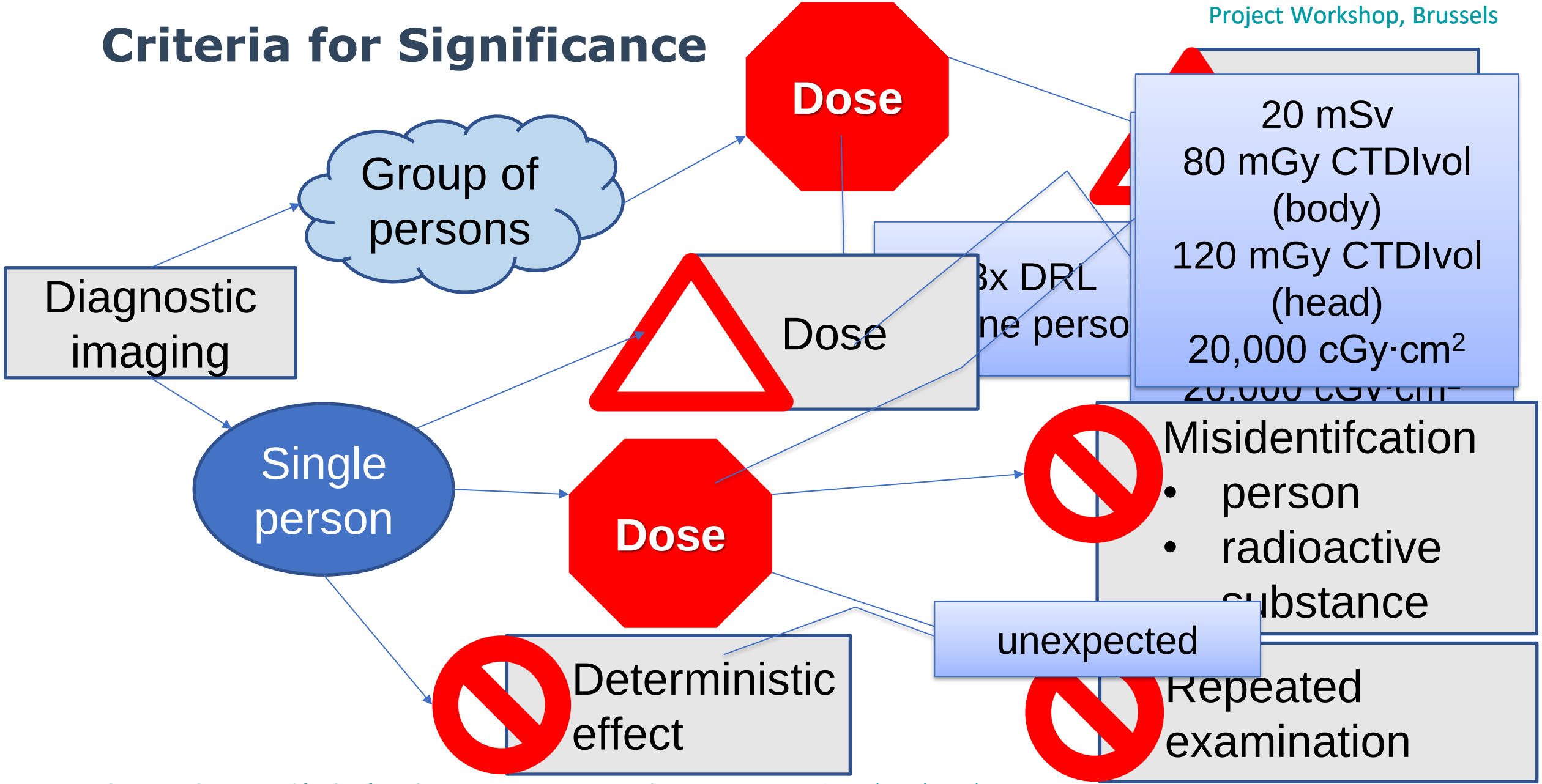
- particular deemed significan criteria in Annex 14 or 15 is satisfied

Vague legal concept

- Report to the competent authority without undue delay
- Summary report to the competent authority within 6 month

This project has received funding from the European Commission under Service Contract N°ENER/2022/NUCL/SI2.880751

Criteria for Significance



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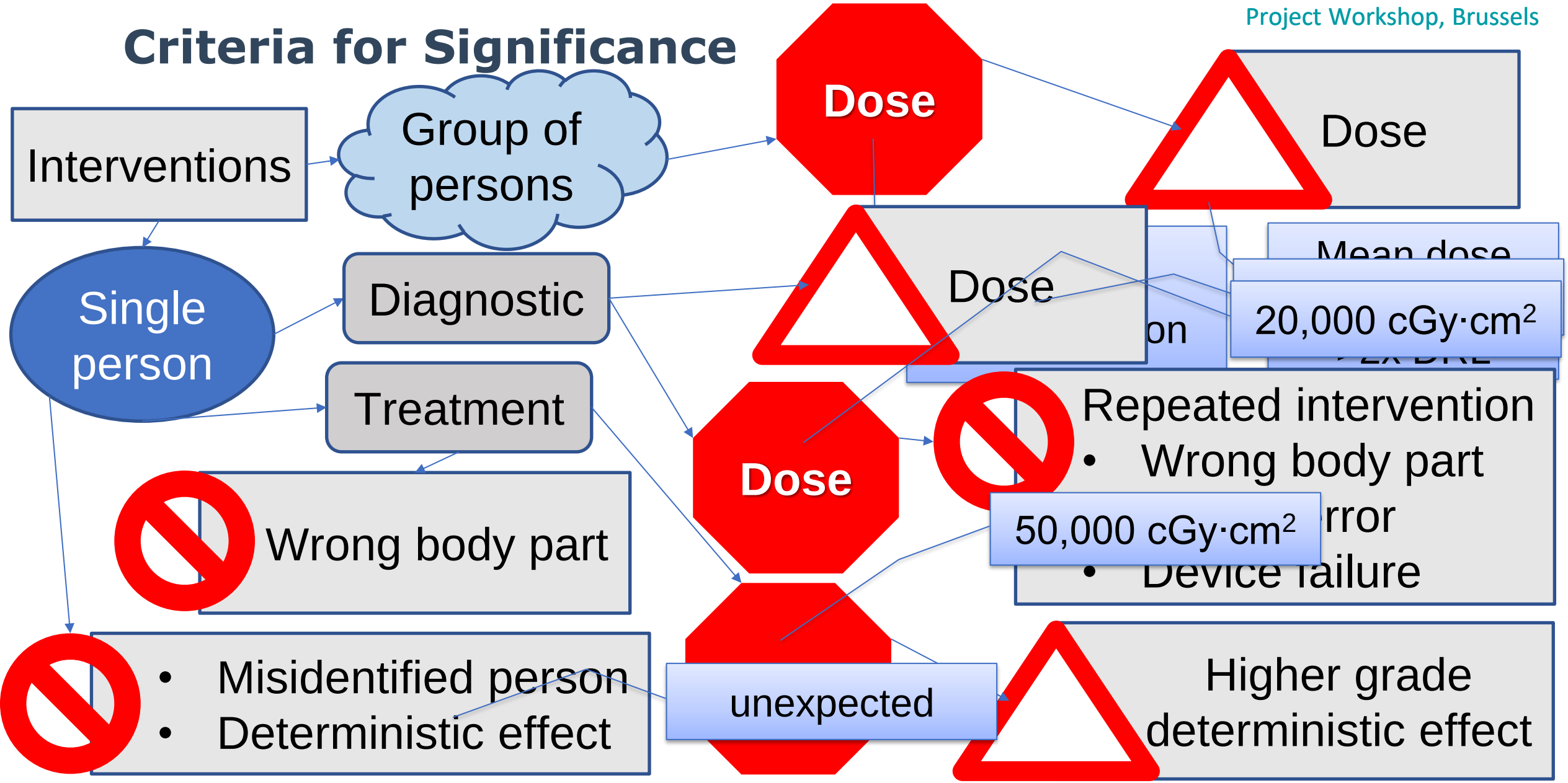

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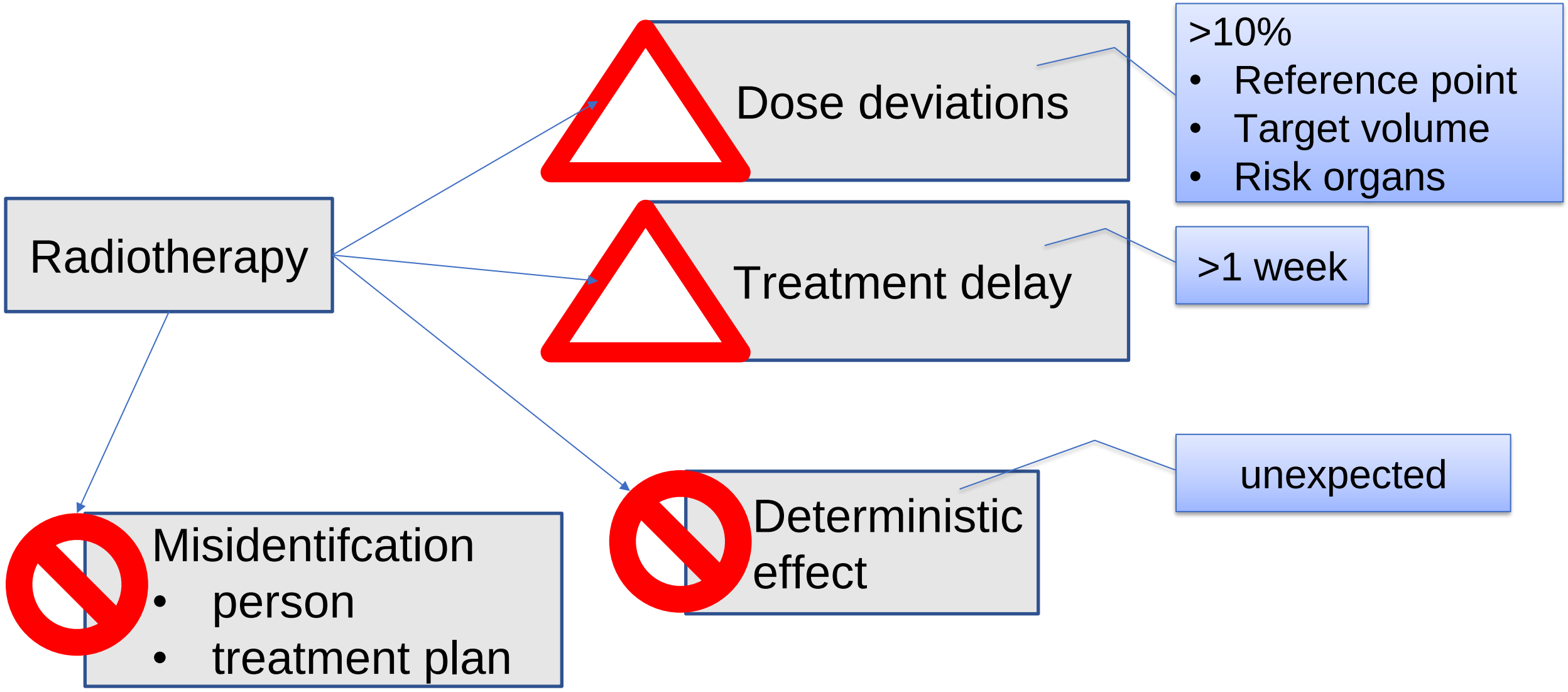

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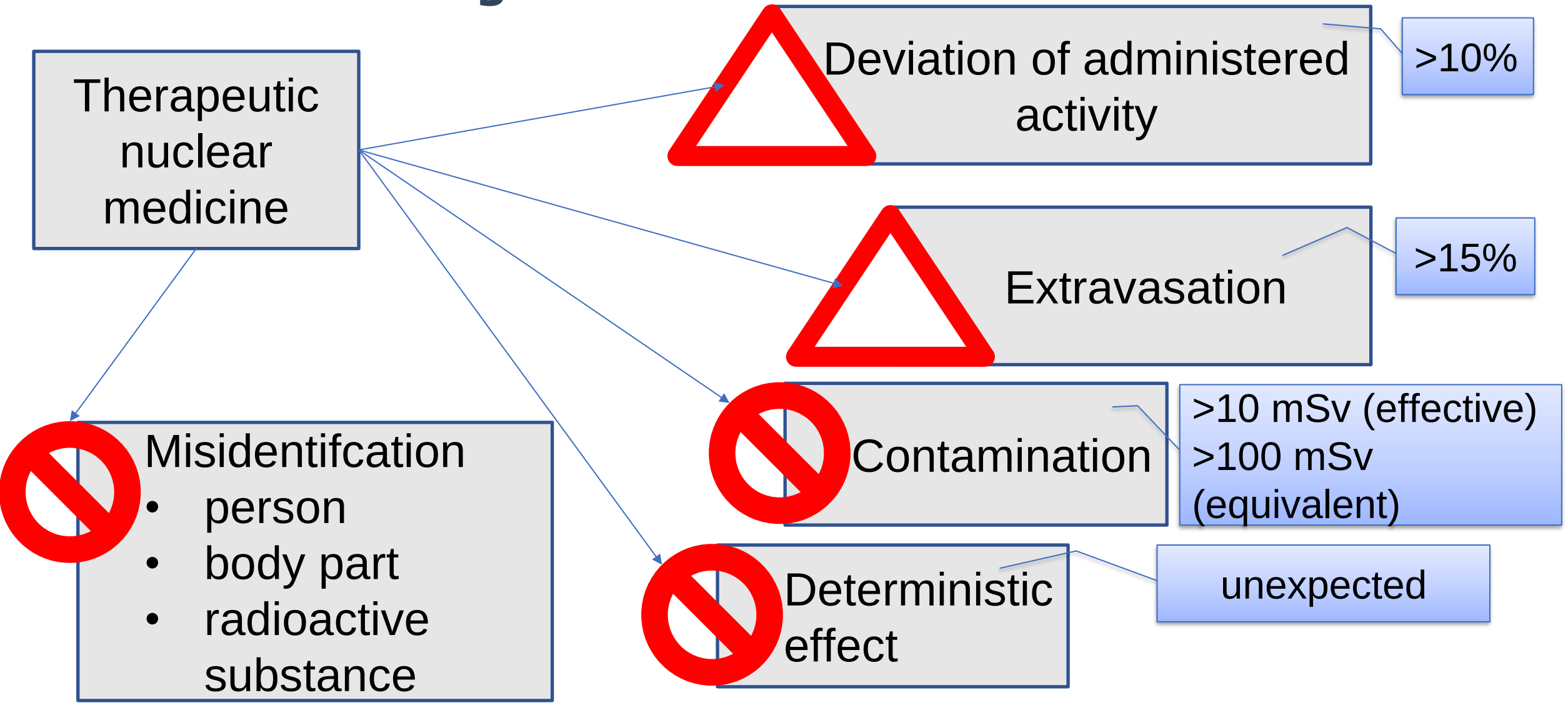

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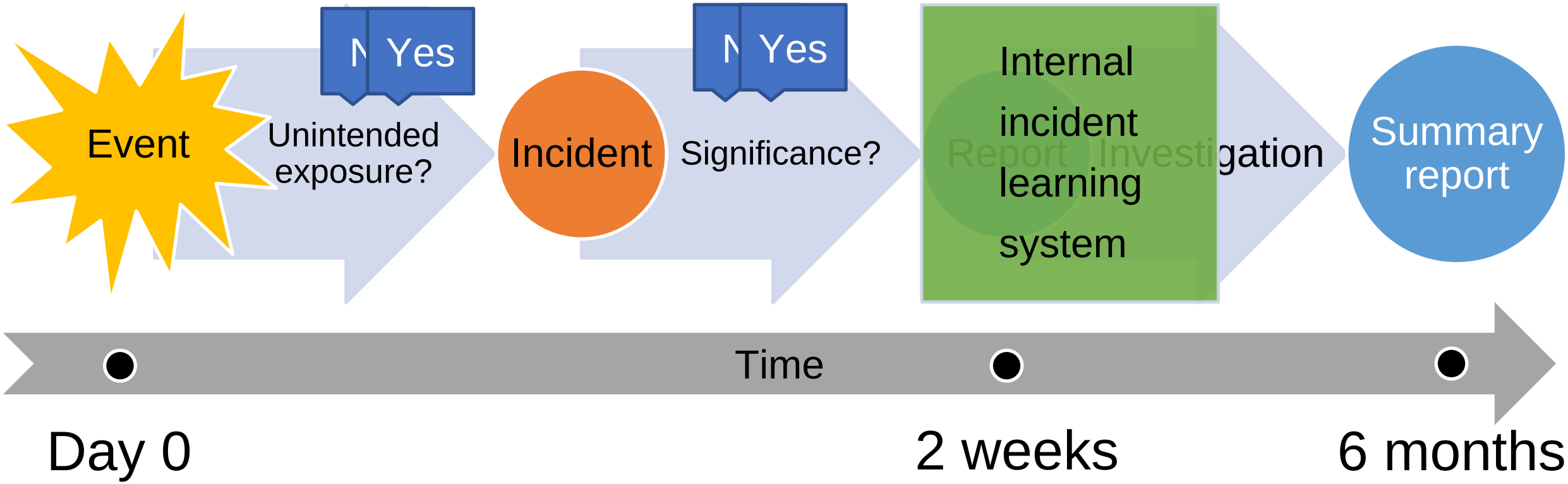
Workflow (Practitioner's View)



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EC Tender project contract N° ENER/2022/NUCL/SI2.880751

SAMIRA Study on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology

PRISMA-RT in Belgium: A Common Methodology to Analyse All (Near)-Incidents in Radiotherapy

Aude Vaandering

(Cliniques Universitaires St Luc, Brussels, Belgium)

MARLIN Project Workshop
September 5 & 6, Brussels

Context

Belgian National Regulatory body (AFCN/FANC)

- **Mandatory notification** of all significant events* in radiology, nuclear medicine, interventional radiology and radiotherapy
- **Voluntary notification** of events that are of potential interest to other departments

→ Anonymized reports (with content of event and set improvement actions) is sent to all departments (++ for RT)

→ MAY lead to a visit of the department by the FANC/AFCN

Clearly defined by Rx specialty: https://www.jurion.fanc.fgov.be/jurdb-consult/consultatieLink?wettekstId=27933&publicatieId=39795&appLang=fr&wettekstLang=fr

Radiotherapy

- **2010 National Cancer Plan** financed:
  - One FTE quality manager per RT department
  - A national platform for incident reporting and learning

Radiotherapy

- **2010 National Cancer** plan financed:
  - One FTE quality manager per RT department
  - A national platform for incident reporting and learning

→ Decision to use the **PRISMA-RT platform**

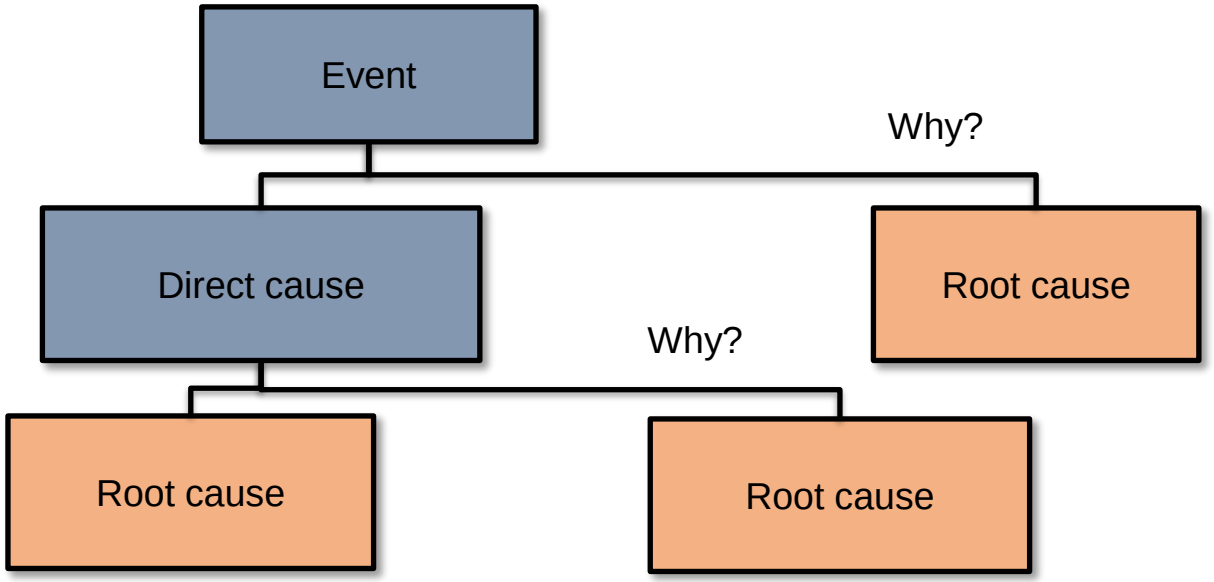
PRISMA-RT

PRISMA-RT.be

PRISMA-RT

- PRISMA-**RT***= methodology for the retrospective analysis of reported events developed for RT (MAASTRO)

→ Methodology focusing on the identification of **causes** that lead events



*Vuuren, W. van, Shea,C.E., Schaaf, T.W. van der (1997) The Developmenent of an incident analysis tool for the medical field. Eindhoven: Technische Universiteit Eindhoven
Dusncombe, P.Taxonomies and Classification Schemes In Incident Learning Systems Taxonomies : Incident Learning Systems

PRISMA-RT

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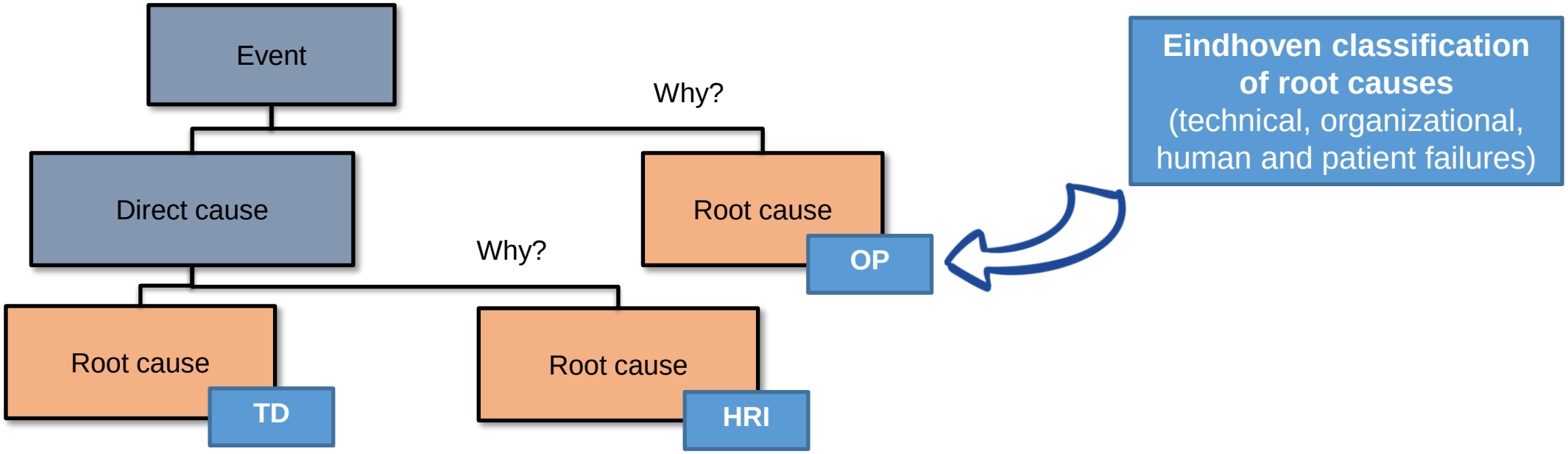

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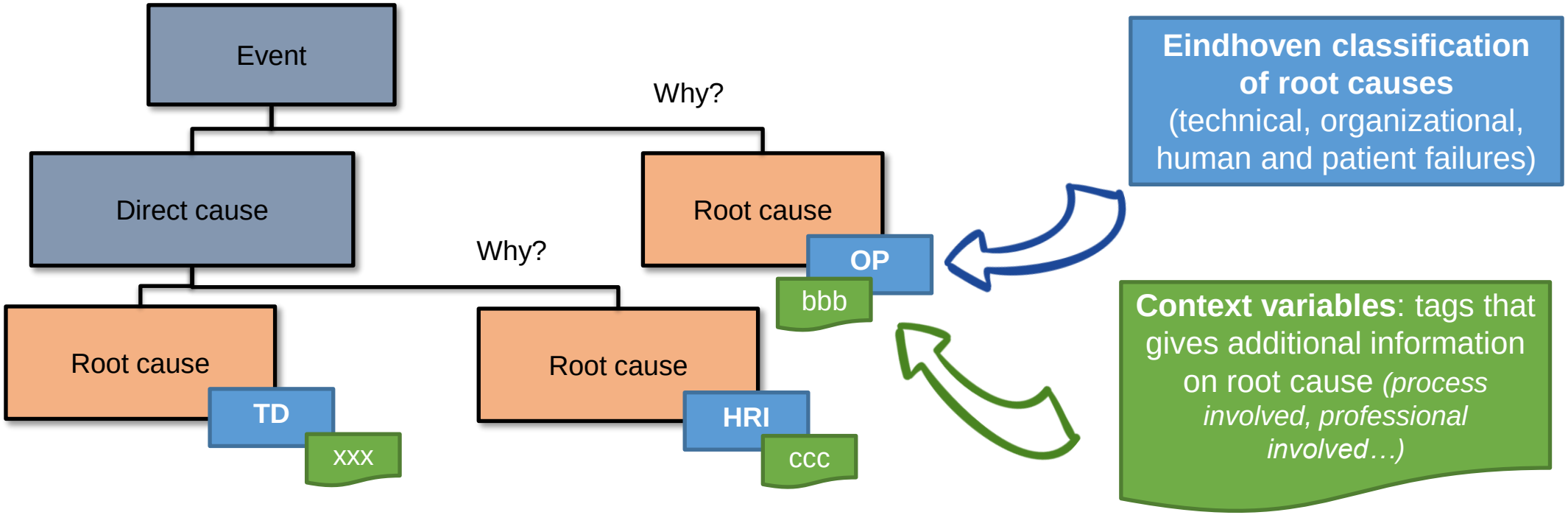

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Practical Benefits

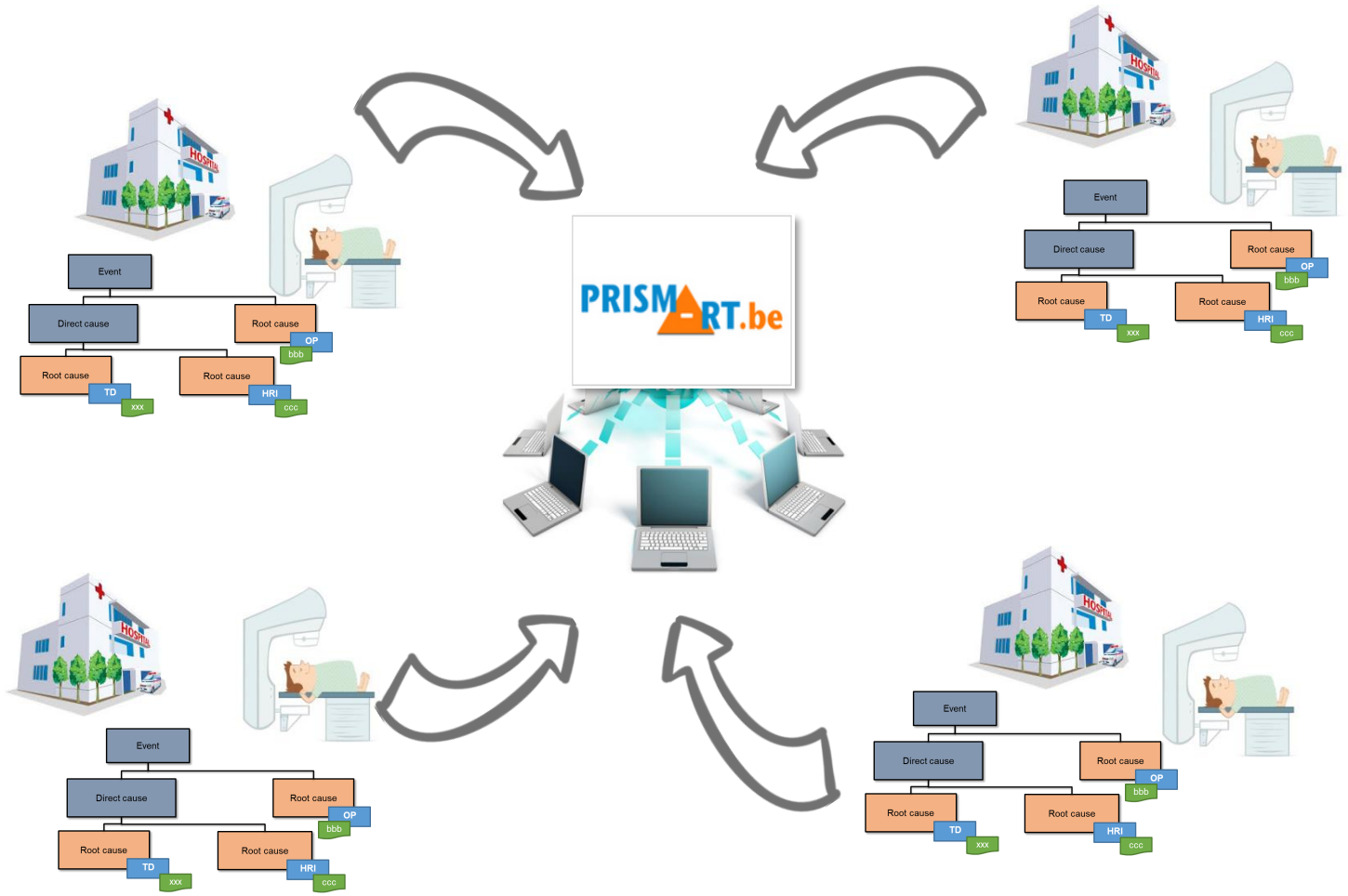
- Common analysis methodology used by all RT departments
  → Common language to discuss adverse events, issues and projects
  → Encouraged collaboration between departments and quality managers (QMs)

QMRT.BE
Belgian Quality Managers in Radiotherapy

Practical Benefits

- Common analysis methodology used by all RT departments
  - → Common language to discuss adverse events, issues and projects
  - → Encouraged collaboration between departments and quality managers (QM)
- Analysis methodology that is also used for the mandatory declarations of events
- Allows for (potential) benchmarking between departments

PRISMA-RT.BE



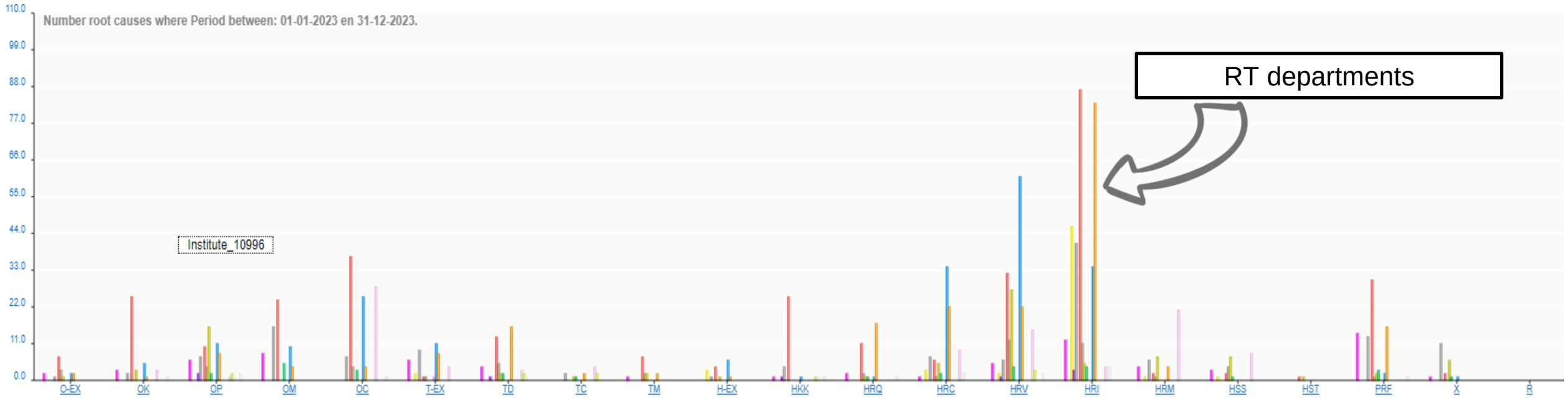
PRISMA-RT platform:

- Importation of:
  - Date of events
  - Root causes classifications
  - Context variables

!! *Sharing of root cause analyses of events, **not** of events themselves*

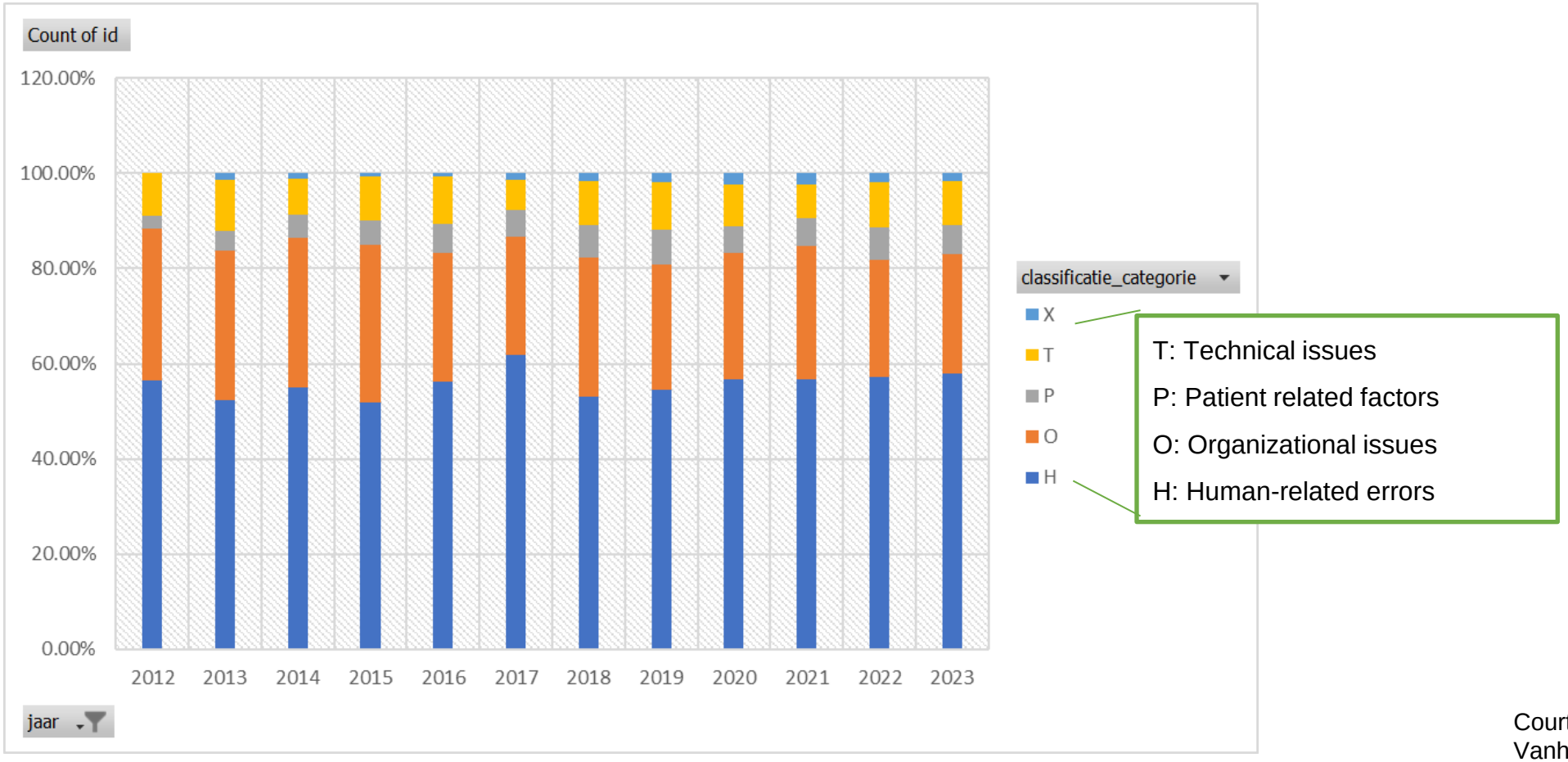
Benchmarking

1. Allows for the visualization of a dept's data versus other depts



Benchmarking

2. Allows for trending analysis on a national basis



Courtesy of Frederik Vanhoutte (UZ Gent)

Benchmarking

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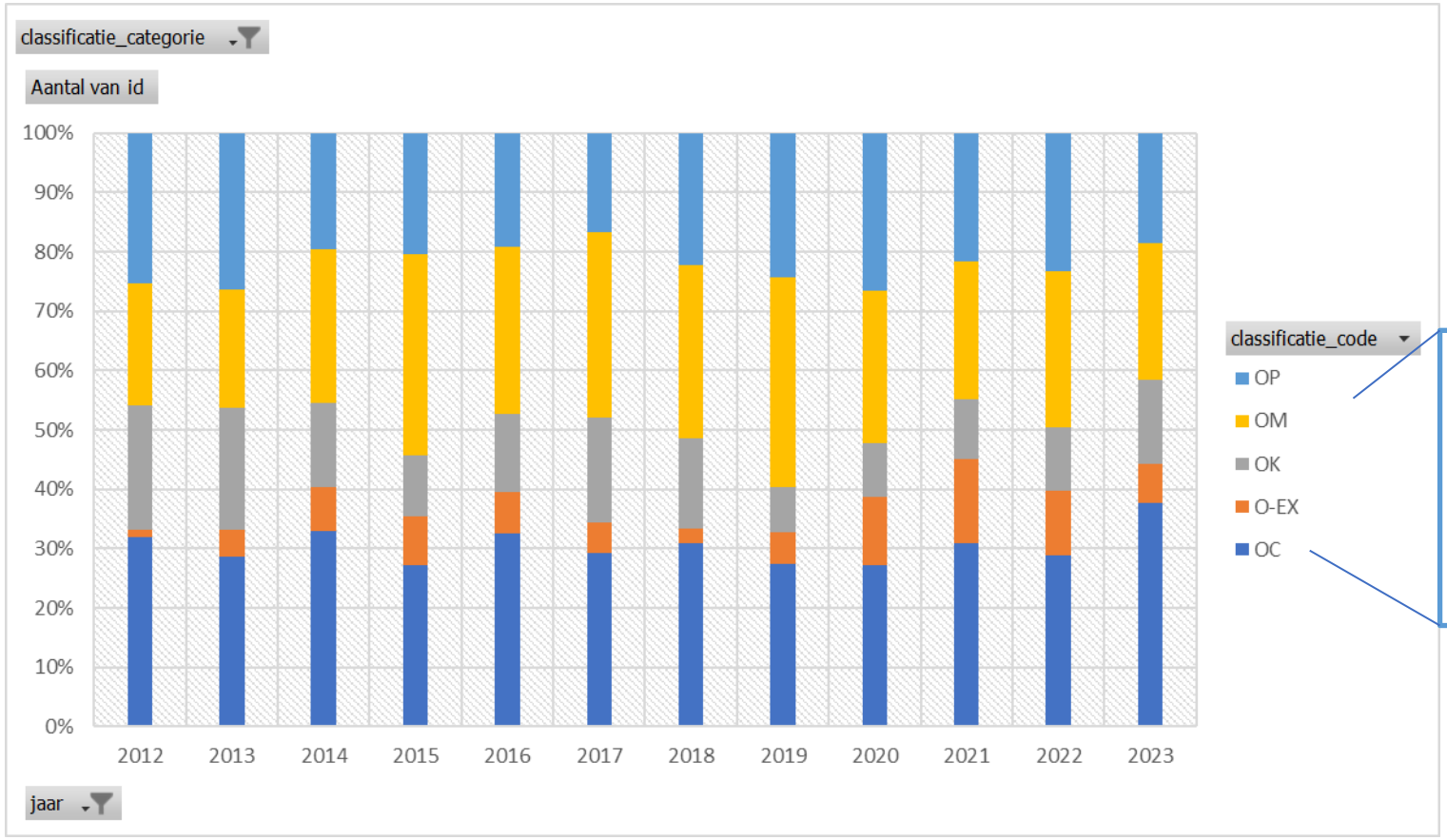


OP: Procedural issues

OM: Management factors

OK: Knowledge transfer issues

O-EX: External organizational issues

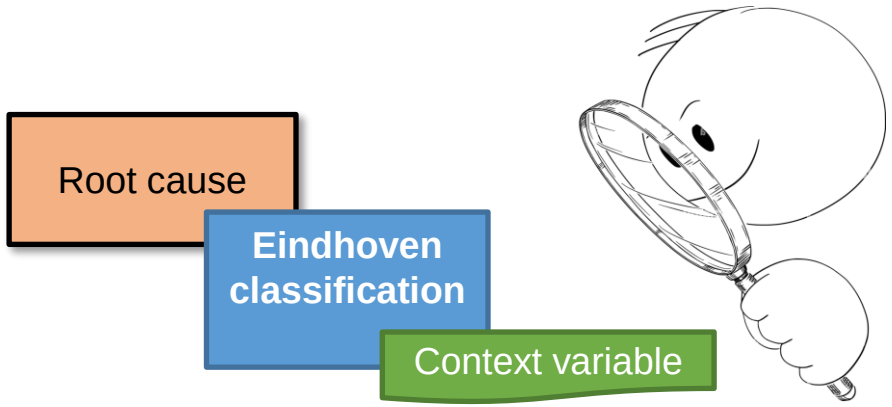
OC: Cultural issues

Courtesy of Frederik Vanhoutte (UZ Gent)

Benchmarking

2. Allows for trending analysis on a national basis

→ Can facilitate the setup of national quality/safety improvement projects



PRISMA-RT

de eerste vereniging in de gezondheidszorg die incidentdata benchmarkt

Petra Reijnders[1], Margreet Bijl[2], Monique Roozen[3], Jo Duvivier[4], Rogier Wessel[5], Ulrike Neuerburg[6], Oda Wijers[7], Jørgen Bojaard van den[1]

1: MAASTRO clinic (afdeling radiotherapie) Maastricht
2: Erasmus MC (afdeling radiotherapie) Rotterdam
3: Catharina Ziekenhuis (afdeling radiotherapie) Eindhoven
4: ZRTI (afdeling radiotherapie) Vlissingen
5: VUmc (afdeling radiotherapie) Amsterdam
6: AMC afdeling radiotherapie) Amsterdam
7: RIF afdeling radiotherapie) Leeuwarden

PRISMA-RT

De ontwikkeling van een nationaal patiëntveiligheid netwerk voor de Nederlandse Radiotherapie genaamd PRISMA-RT. Dit is gebaseerd op de benchmark van incident analyses (PRISMA) tussen 17 radiotherapie-instellingen. De weg ernaar toe en ervaringen worden in deze publicatie gedeeld.

Samenvatting

In 2008 is de vereniging PRISMA-RT opgericht, een samenwerking van 17 van de 21 Nederlandse radiotherapie instellingen.
Deze radiotherapie instellingen ontwikkelden een nationale database. Dit veiligheidsnetwerk is ontstaan uit 2 samenwerkingsprojecten op het gebied van procesvergelijking tussen instellingen. Het doel is primair het verbeteren van processen en verhogen van patiëntveiligheid in de radiotherapie door het vergelijken van basisoorzaken van incidenten. Naast veiligelijkingen op instellingsniveau is dit nu ook op nationaal niveau mogelijk. Alle instellingen gebruiken de PRISMA-methode om hun (bijna)-incidenten te analyseren.

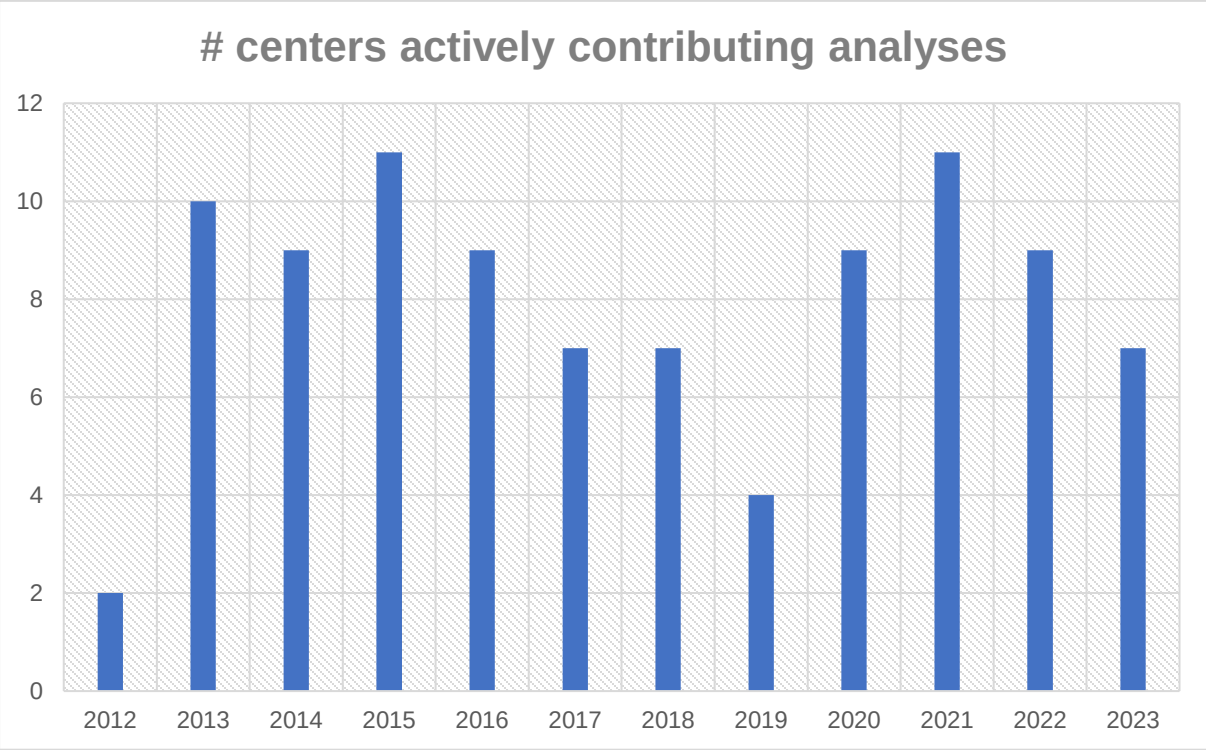
Naast de standaarddatabase van TPSC (The Patient Safety Company), werd speciaal voor deze samenwerking een benchmark module ontwikkeld. Daarnaast is er een website ontwikkeld (www.prisma-rt.nl).

jul 2010 | jaargang 60 | nummer 3 | pagina 7

https://www.prisma-rt.org/wp-content/uploads/2016/07/PRISMA-RT-de-eerste-vereniging-in-de-gezondheidszorg-die-incidentdata-benchmarkt-NL.pdf

Use of PRISMA-RT in Belgium

- 100% of departments (n=26) have been trained in using the methodology
  → Continuous training is required
- 67% of department send in reports (=date of event)
- 30% of departments actively contribute to PRISMA-RT platform



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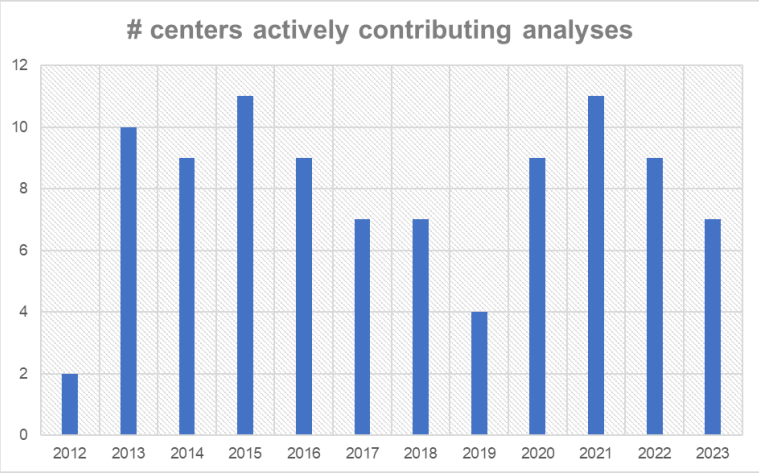
WHY?

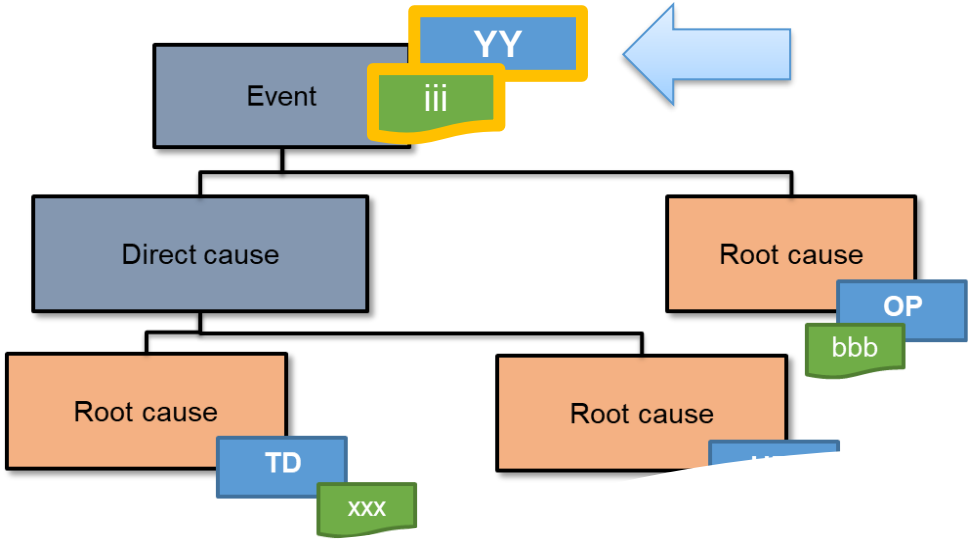
- Issues with third party hospital incident reporting systems (technical issues, bugs…)
- Absence/no quality managers
- No dedicated PRISMA-RT benchmark project/data manager

↓ Incentive



Future Prospects

- Dedicated project manager?
- Event level classification and benchmarking



- Adding proactive risk analysis at a benchmarking level

Conclusions

- PRISMA-RT methodology has been implemented in **all** Belgian RT departments
  - → Common language and best practice exchange amongst departments
  - → Facilitated by the existence of dedicated personnel (quality managers) in RT departments
- Constructive national/multicentric benchmarking requires dedicated resources

- Potential to further develop the national platform to include event level information and proactive risk analysis tools

Thank you

INSTITUT ROI ALBERT II
CANCER ET HÉMATOLOGIE
Cliniques universitaires SAINT-LUC
UCLouvain BRUXELLES

QMRT.BE
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Aude Vaandering Aude.vaandering@saintluc.uclouvain.be

EC Tender project contract N° ENER/2022/NUCL/SI2.880751

SAMIRA Study on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology

Discussion

16:30–17:15

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Conclusions & Recommendations

G. Paulo

MARLIN Project Workshop
September 5 & 6, Brussels

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SAMIRA Study on reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, nuclear medicine and interventional and diagnostic radiology

See you tomorrow at 09:00!

Wrap-up of day 1

J. Andersson

MARLIN Project Workshop
September 5 & 6, Brussels