Patient safety

Paving the way for progress

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How to analyse your significant radiation protection events?

Newsletter for radiotherapy professionnals

asn Autorité de sûreté nucléaire

afppe

sfpm Société Française de Physique Médicale

Société Française de Radiothérapie Oncologique SFRO

Patient safety - Paving the way for progress is edited by the French Nuclear Safety Authority (ASN) in the framework of the multidisciplinary working group dedicated to experience feedback to radiotherapy professionals.
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>Editorial

The lessons drawn from the analysis of significant radiation protection events are a real opportunity to provide radiotherapy patients with safer care. This reactive process is useful for identifying risks and adopting preventive measures. Together with preliminary risk analysis, it is the basis of safety and quality management, which was made compulsory by ASN decision, 2008-DC-103. Analysing an event requires method, know-how and time.

While making no claim to be exhaustive, the purpose of this third newsletter is to present the methods of analysis which are most often used by radiotherapy departments. Other methods may be used.

It also serves to remind us of the importance of significant radiation protection event reports and what is expected of them. The quality of the feedback given to professionals concerned analysed events depends on the quality of the information given to ASN.

The Editor

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>Key figures

Every year, almost 180,000 patients receive radiotherapy treatment and four million radiotherapy sessions are carried out.

In 2011, ASN received 243 event reports concerning patients undergoing radiotherapy.
Since the reporting system was introduced in 2007, 90% of radiotherapy departments have informed ASN of at least one significant radiation protection event (SRPE). Fifty percent of radiotherapy departments have reported at least one SRPE per year since 2009.

Most events are caused by the incorrect identification of the patient or a positioning anomaly and have no effect on the patient's health. These events are ranked as level 0 or level 1 events on the ASN-SFRO scale.

Of the 243 reports, 139 events were ranked as level 1 events on the ASN-SFRO scale. Three events were ranked as ASN-SFRO level 2 events (seven in 2010).

>Methodologies

1. Aims and stages of an analysis

Significant events must be analysed in order to prevent events, incidents and accidents from occurring in the future (French Public Health Code Section R.1333-109).
Analysis is aimed at identifying the (immediate and root) causes of the events, the lines of defence which have and have not worked and those which are missing. It seeks ways of making improvements (not the guilty party). It is the basis on which internal and external feedback is gathered by the centre in which the event occurred. The lessons learned strengthen the measures in place to prevent such events from reoccurring.

An analysis comprises four key stages:

1. detailed compilation of the chronology of the facts,
2. identification of deviations from regulations, the internal quality reference or good professional practices,
3. identification of causes (human and/or technical errors, context and influencing factors),
4. description of actual consequences for the patient.

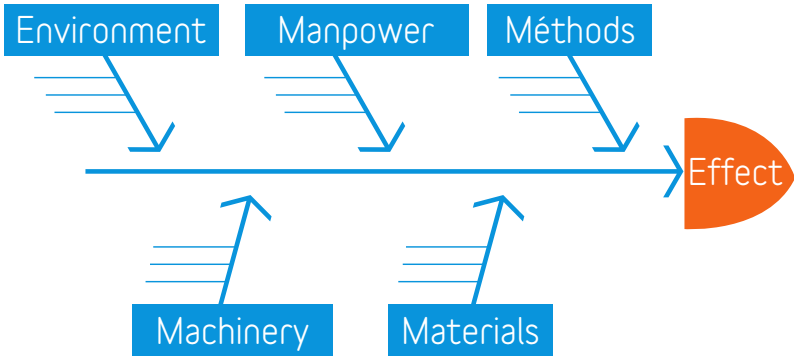
Once the analysis is finished, corrective actions are defined.

2. Analytical methods

In this newsletter, nine ESRs which occurred in 2011 have been selected in light of the analyses performed. One of the following five methods was used to analyse the events in question:

Ishikawa diagram (or cause-and-effect diagram)

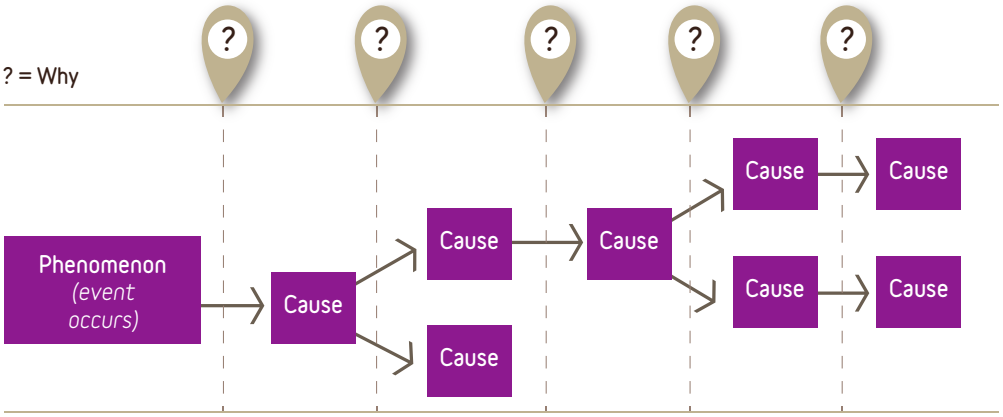
The Ishikawa diagram is a collective analysis tool that identifies the causes of an event from among five categories: Environment, Manpower, Methods, Materials, Machinery.
Two other categories can be added: Financial means and Management.



5 Whys?

This method involves asking the question 'why' five times in a row to identify the main cause behind a problem.

It is a participatory process involving the people concerned and affected by its consequences. It is often used in addition to the Ishikawa method to consider the multiple causes behind an event.



Root cause analysis
(see HAS 2012 guide sheet no. 24)

A root cause analysis has been developed by INRS, the French National Research and Safety Institute, to prevent occupational accidents and diseases.
This deductive method uncovers the immediate causes and goes so far as to identify the underlying (or root) causes by systematically searching for cause-and-effect relationships.
It addresses the 'multi-causality' of an event by considering the causes of that event as necessary and sufficient.

ALARM
(see ANAES 2003 guide, HAS 2012 guide sheet no. 23)

The ALARM method (Association of Litigation and Risk Management), which is specially designed for the healthcare sector, provides a guide to identify latent errors in organisation or governance.

This in-depth research technique strives to uncover contributing causes/factors, the accumulation of which creates a risk.

Its formalised analytical approach, inspired by clinical practices, is the guarantee of a systematic enquiry which does not apportion blame and which reduces the risk of a simplistic or routine explanation.

ORION©
(see MeaH 2008 guide)

This five-step method is used to find the causes of a precursor event and decide on the corrective action to be taken.

The five steps are:

1. collecting information on the event,
2. reconstructing the chronology of the event (without comments or judgements), while highlighting inappropriate actions and deviations and distinguishing between the three stages of the event (before, during and after),
3. identifying factors that contribute to each cause (technical, organisational, human or environmental factors),
4. identifying influencing factors,
5. proposing corrective action.

Like the ALARM method, the ORION method focuses on influencing factors and contributing factors.

> Decoding

All five methods are based on a collective process.
These shared discussion or diagnostic tools aim to identify the underlying causes of a radiation protection event.
It should be noted that the quality and depth of analysis depend on how well the facts have been collected and their chronology reconstructed.

Comparison of the five methods

The colours provide an indication of how easy (green = easier, orange = more difficult) a method is to implement in terms of the amount of time that radiotherapy department feedback teams usually spend analysing a radiation protection event (around two hours).

	Advantages	Disadvantages
5 Whys?	• Method based on systematic questioning to identify the main cause; • Schematic description; • Easy to implement.	• Generally used as a complement to a cause and effect diagram; • Partial analysis due to the focus on linking an event's causes; • No chronology.
Ishikawa diagram	• Questions focus on five to seven aspects: machinery, materials, method, manpower, environment, etc. • Graphic representation of causes; • Cause and effect relationships and ranking of causes.	• No representation of logical relationships; • No chronology.
ALARM	• The analyst is steered towards finding latent errors in organisation and governance; • Questions focus on six factors: environment, team, individual, institution, organisation, management of patients, tasks to be performed; • Reconstruction of the chronology of the facts and consideration of multiple causes; • Understanding of the complexity of the causes.	• Method designed for a hospital's clinical activities; • The actions to be taken are more complicated (addressing latent errors); • Factors not ranked; • No schematic description.
Root cause analysis	• Schematic description; • Reconstruction of the chronology of the facts; • Consideration of multiple causes: linking of causes to their effects; • Accessible method (a few hours of training).	• Factors not ranked; • Schematic description is not easy to understand for those who did not create it.
ORION	• Systemic method of analysis; • Recreates the context surrounding the event; • Factual analysis of the chronology of the event; • Identification of contributing factors: system errors, failure of barriers, etc.	• Initial analyses require support; • No schematic description.

> Steps for progress

Good practices

Data collection:

- **Gather information on the event**: this should preferably be done by somebody who was not involved in the event.
- **Involve all those concerned** by the occurrence of the event.
- **Reconstruct the facts accurately (account of activities)**: consider all points of view, look for consistencies and inconsistencies in the accounts provided, remove reconstruction effects.
- **Look for similar events which have occurred** at the radiotherapy centre.

Choice of method:

- **Define the amount of time to be spent gathering and analysing information** in line with the severity of the event, and not the availability of analysts.
- **Do not make do with the simplest method,** which is also the least comprehensive when it comes to looking for the causes.
- **Make sure that you fully understand the method chosen.** In healthcare facilities, the care risk management coordinator[1] is, in this respect, an excellent contact.

1. Section R.6111-4 of the Public Health Code
• Decree no. 2010-1408 of 12 November 2010 regarding the fight against undesirable care-related events in healthcare facilities,
• Order No. DGOS/PF2/2011/416 of 18 November 2011 relating to the application of Decree no. 2010-1408 of 12 November 2010 regarding the fight against undesirable care-related events in healthcare facilities.

Analysis of the event:

- **Select an independent analyst** to study the event to reduce the risk of a biased interpretation.
- **Do not judge the actions**: focus on understanding how the system has failed.
- **Highlight formal barriers and fortuitous actions** which made it possible to detect and remedy certain dysfunctions and mitigate their impact.
- **Identify and analyse the specific context** surrounding the event, the (latent) failures which led to the main inappropriate action as well as recovery failures.

Improvement actions:

- **Draw up the lines** for organisational and technical improvement.
- **Decide on priorities** and put forward a realistic and limited number of corrective actions.
- **Explain the actions** related to the underlying causes to decision makers as these are the most difficult to implement.
- **Introduce a follow-up system**: identify the coordinators, assess the relevance of the actions and ensure that they are implemented over time.
- **Inform the teams of analysis results** and measures taken.
- **Improve the preliminary risk analysis** in accordance with continuous improvement and system safety principles.

The success of the process greatly depends on management's support for the event analysis process and the implementation of improvement measures.

>Experience of the centres

'The root cause analysis, to find targeted solutions for complex events'

Interview with Elisabeth Boulaye, quality engineer, and Jean-Christophe Codez, radiotherapy manager of the radiotherapy department at Limoges university hospital.

Event analysed: Error in the definition of catheters at the time of planning high dose rate brachytherapy treatment (August 2011)

Why was the root cause analysis method chosen?
The hospital usually uses the Ishikawa diagram but the event was complex and multifaceted. The quality engineer attached to the hospital's radiotherapy department pointed us towards this method to uncover the root causes.

How many people in the department are trained to use this method?
It was the first time that we had used the root cause analysis method. We got to know the method thanks to the input provided by the quality specialist and through working group meetings.

The quality process which has been implemented over the past two years also let us undertake the search for the event's causes in an objective manner.

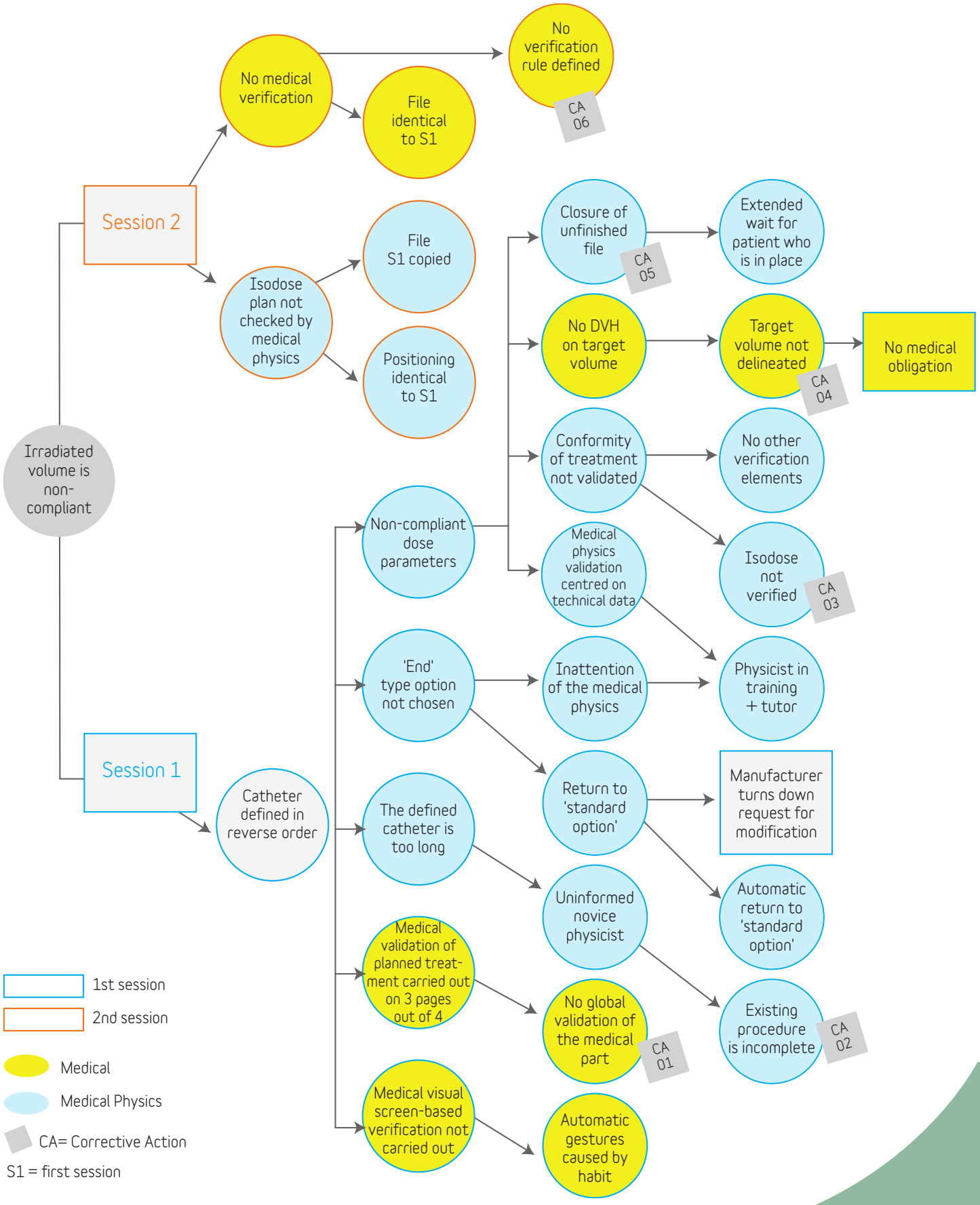
Who took part in the analysis?
The working group comprised seven people who represented those concerned by or involved in the event: the department head and manager, the quality engineer, a radiation oncologist, a radiographer and two medical physicists.

How much time was required to carry out the analysis?
Nine hours over an analysis period lasting 20 days.
Three meetings appear to be enough to collect information, present the method and analyse and correct the causes and define corrective actions. Keeping meetings to two hours ensures no loss of impetus and focuses attention on identifying the solution rather than the causes.

What do you consider to be the advantages and disadvantages of this method?
The root cause analysis is a rigorous and tried and tested method. It facilitates a targeted search for solutions.
It is difficult to carry out an objective analysis within a short period of time without apportioning blame and looking for immediate solutions. At the end of the analysis, you have to fight against the inclination to introduce a large number of corrective actions that you may not be able to implement.

What is key to a successful significant radiation protection event analysis?
During the analysis phase, everybody's participation, the management of the group and remaining objective are important. You then have to select the corrective measures, assign responsibilities and ensure that measures are implemented correctly and within the deadlines.

Root cause analysis and six corrective actions ('CA'), *Radiotherapy department, Limoges University Hospital (August 2011)*



'The Ishikawa method is simple and suitable for radiotherapy'

Interview with Chrystèle Chaab, medical physicist, Medical Physics Department, Beauvais Hospital

Event analysed: power cut during a thunderstorm, shutting down of computers and loss of patient data during the irradiation process (August 2011)

Why was the Ishikawa method chosen?
It is one of the methods used by Beauvais Hospital. The radiotherapy department systematically uses the Ishikawa method. It is simple to use and understand and very suitable for radiotherapy.

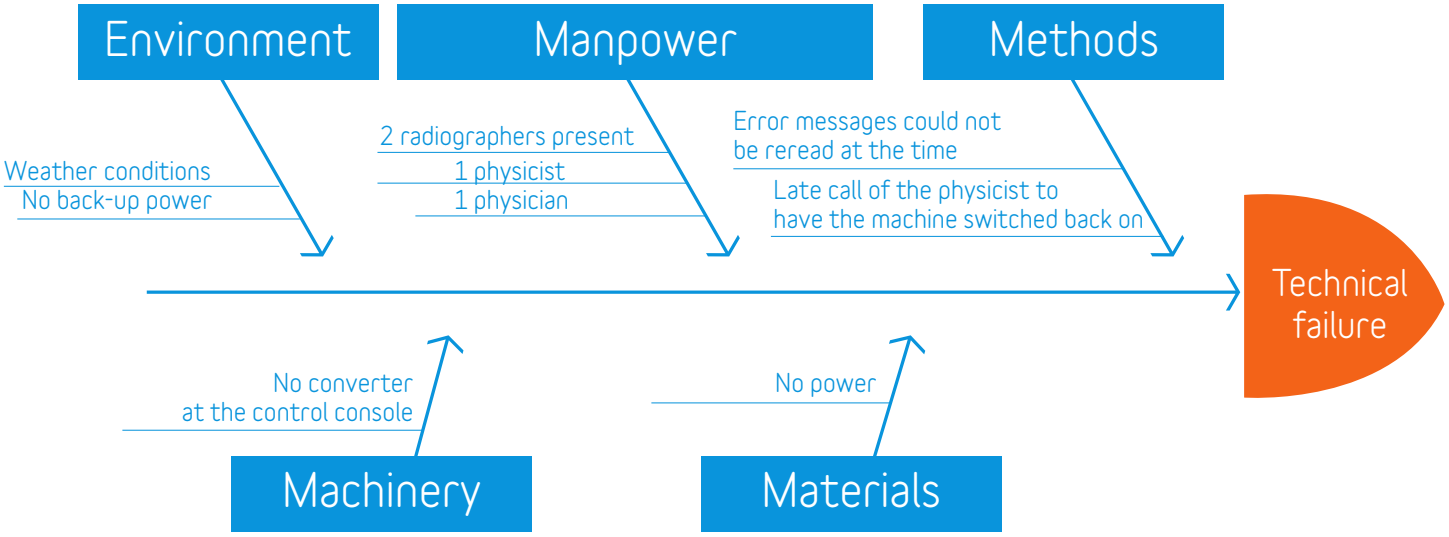
How many people in the department are trained to use this method?
Six people have received in-depth quality training in the department: the department manager, one radiographer, two physicists, one physician and one secretary.

Who takes part in the analysis?
In general, the hospital's risk manager, the six people who have been trained and the radiographers present at the time of the event in question.
In this case, eight people were involved in the analysis.

How much time was required to carry out the analysis?
Analysing this type of event, which is 'simple', is very fast (around 30 minutes). More complex significant radiation protection events take longer (at least one hour).

What do you consider to be the advantages and disadvantages of this method?
Often, only one clear cause is apparent (in this case, the thunderstorm). Creating an Ishikawa diagram reveals other more relevant causes and contributing factors which are sometimes important (in this case, no converters at the control consoles). Ranking the causes identified under the five categories is the main difficulty.

What is key to a successful significant radiation protection event analysis?
All professions must be represented. It is essential that the members of the team trust one another so that they can speak freely without fear of being judged.



Ishikawa diagram, *Beauvais Hospital (August 2011)*

>Further reading

Ishikawa method:

Methods and tools for quality procedures in healthcare facilities
ANAES guide (July 2000)
http://www.has-sante.fr/portail/upload/docs/application/pdf/2009-10/methodes.pdf

ORION© method:

Improving safety in healthcare facilities. Making the most of feedback
MeaH report, tool 9, p.87 (February 2008)
http://www.anap.fr/uploads/tx_sabasedocu/SECURITE_RADIO.pdf

Organisation of radiotherapy - Collection of good organisational practices - Book 3
MeaH report (February 2009)
http://www.anap.fr/uploads/tx_sabasedocu/RADIOTHERAPIET3_bpo.pdf

Feedback committees and the Orion analysis in radiotherapy: towards a pooling of corrective actions.
Article by E. Lartigau, A. Vitoux, F. Debouck.
Journal: Cancer Radiotherapie No. 13 pages 458-460 (2009)

Orion® method: simple and effective systemic analysis of clinical events and precursors arising in medical practices in hospitals
Article by F. Debouck et al.
Journal: Cancer Radiotherapie (March 2012)

ALARM method:

Methodological principles for the management of risks in healthcare facilities
ANAES guide (January 2003)
http://www.has-sante.fr/portail/jcms/c_436577/principes-methodologiques-pour-la-gestion-des-risques-en-etablissement-de-sante

Patient safety - Managing the risks associated with care in healthcare facilities: from theory to practice.
HAS guide - sheet No. 23 (March 2012)
http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-04/okbat_guide_gdr_03_04_12.pdf

Root cause analysis method:

Patient safety - Managing the risks associated with care in healthcare facilities: from theory to practice.
HAS guide - sheet No. 24 (March 2012)
http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-04/okbat_guide_gdr_03_04_12.pdf

Other publications

Creation of a post-accident technical survey reference
INERIS study report (April 2011)
http://www.ineris.fr/centredoc/memento-enquete-accident-2011-web.pdf

The frequency, preventable nature and accessibility of serious undesirable events in healthcare facilities
DREES study (May 2011)
http://www.drees.sante.gouv.fr/IMG/pdf/er761.pdf

Accreditation of physicians: user manual
HAS guide (May 2007)
http://www.has-sante.fr/portail/jcms/c_548535/accreditation-des-medecins-mode-d-emploi

Event of the month
Every month, HAS, the French National Authority for Health, publishes on its website an event that raises a risk (EPR) and is a good example of recovery, namely, a case full of lessons explaining why there were no serious consequences for the patient.
http://www.has-sante.fr/portail/jcms/c_1149405/tableau-de-bord-de-laccreditation-des-medecins

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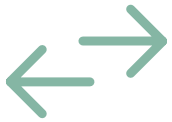

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