
RT-IDEA
iba
DOSIMETRY
The hitchhiker's guide
to Risk Analysis
Carlos Rodrigues
Director of Innovation
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Are you aware of local or intergalactic highways ?

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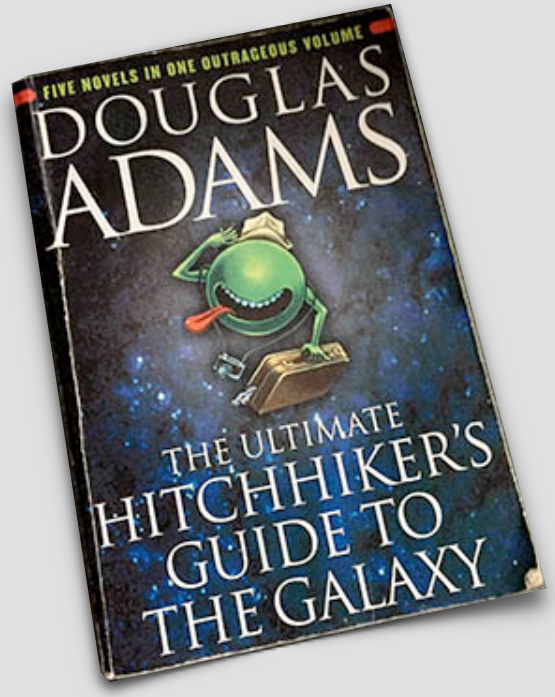
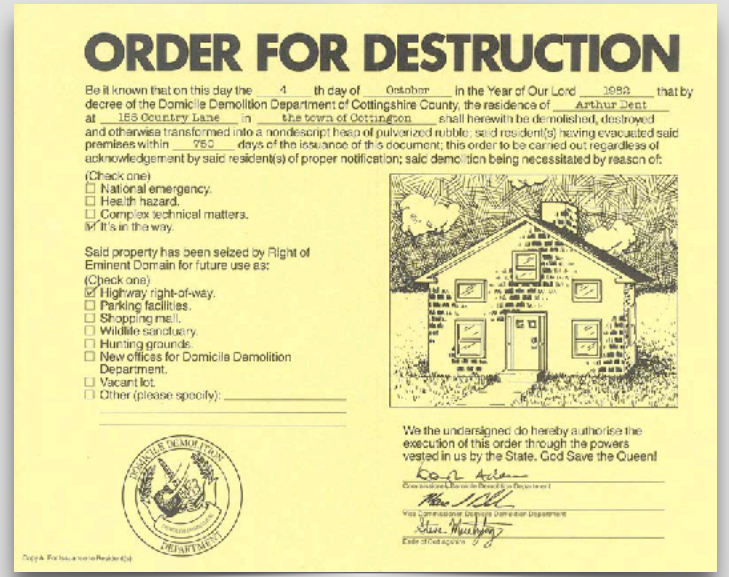
In the book hitchhiker's guide to the galaxy, the earth is to be destroyed since it is in the path of an intergalactic highway and no-one on earth knew about it ... so, no-one interjected or prepared to this plan.



On Apha Centuri

a.k.a "nationally or Internationally"

On Earth



a.k.a. “in your institution”

Are you aware of your Risk Analysis intergalactic highways ?

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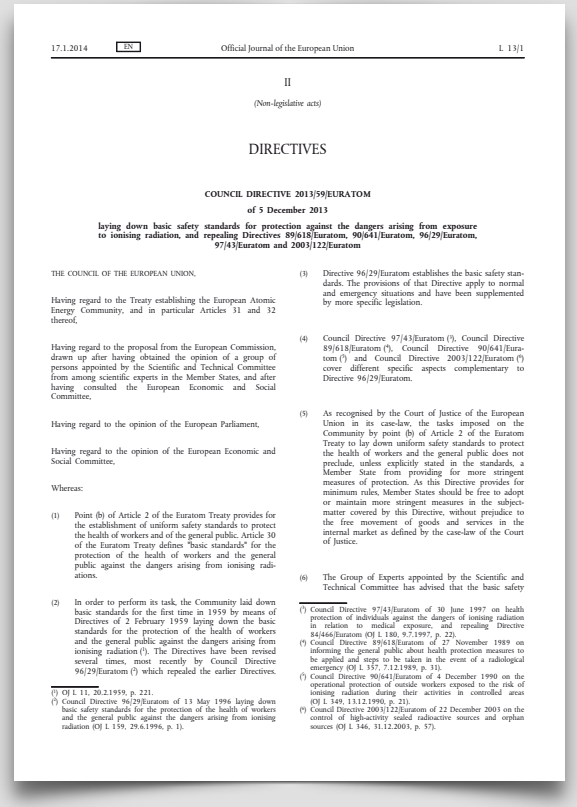
EURATOM 2013/59



17.1.2014 EN Official Journal of the European Union L 13/1

II

(Non-legislative acts)

DIRECTIVES

COUNCIL DIRECTIVE 2013/59/EURATOM

of 5 December 2013

laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular Articles 31 and 32 thereof,

Having regard to the proposal from the European Commission, drawn up after having obtained the opinion of a group of persons appointed by the Scientific and Technical Committee from among scientific experts in the Member States, and after having consulted the European Economic and Social Committee,

Having regard to the opinion of the European Parliament,

Having regard to the opinion of the European Economic and Social Committee,

Whereas:

(1) Point (b) of Article 2 of the Euratom Treaty provides for the establishment of uniform safety standards to protect the health of workers and of the general public. Article 30 of the Euratom Treaty defines "basic standards" for the protection of the health of workers and the general public against the dangers arising from ionising radiations.

(2) In order to perform its task, the Community laid down basic standards for the first time in 1959 by means of Directives of 2 February 1959 laying down the basic standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (1). The Directives have been revised several times, most recently by Council Directive 96/29/Euratom (2) which repealed the earlier Directives.

(3) Directive 96/29/Euratom establishes the basic safety standards. The provisions of that Directive apply to normal and emergency situations and have been supplemented by more specific legislation.

(4) Council Directive 97/43/Euratom (3), Council Directive 89/618/Euratom (4), Council Directive 90/641/Euratom (5) and Council Directive 2003/122/Euratom (6) cover different specific aspects complementary to Directive 96/29/Euratom.

(5) As recognised by the Court of Justice of the European Union in its case-law, the tasks imposed on the Community by point (b) of Article 2 of the Euratom Treaty to lay down uniform safety standards to protect the health of workers and the general public does not preclude, unless explicitly stated in the standards, a Member State from providing for more stringent measures of protection. As this Directive provides for minimum rules, Member States should be free to adopt or maintain more stringent measures in the subject-matter covered by this Directive, without prejudice to the free movement of goods and services in the internal market as defined by the case-law of the Court of Justice.

(6) The Group of Experts appointed by the Scientific and Technical Committee has advised that the basic safety

(1) OJ L 11, 20.2.1959, p. 221.
(2) Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation (OJ L 159, 29.6.1996, p. 1).
(3) Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionising radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJ L 180, 9.7.1997, p. 22).
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a.k.a "nationally or Internationally”

Your Quality Department

a.k.a. “in your institution”

EURATOM 2013/59 | Mandatory in all EU member states

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- Since 2018, the application of the EURATOM directive 2013/59 is mandatory in all member states
- Some member states are late in transposing it in their national regulation and in enforcing it
- Some professional bodies are still interjecting on the local transpositions/implementations

Staatsblad
van het Koninkrijk der Nederlanden

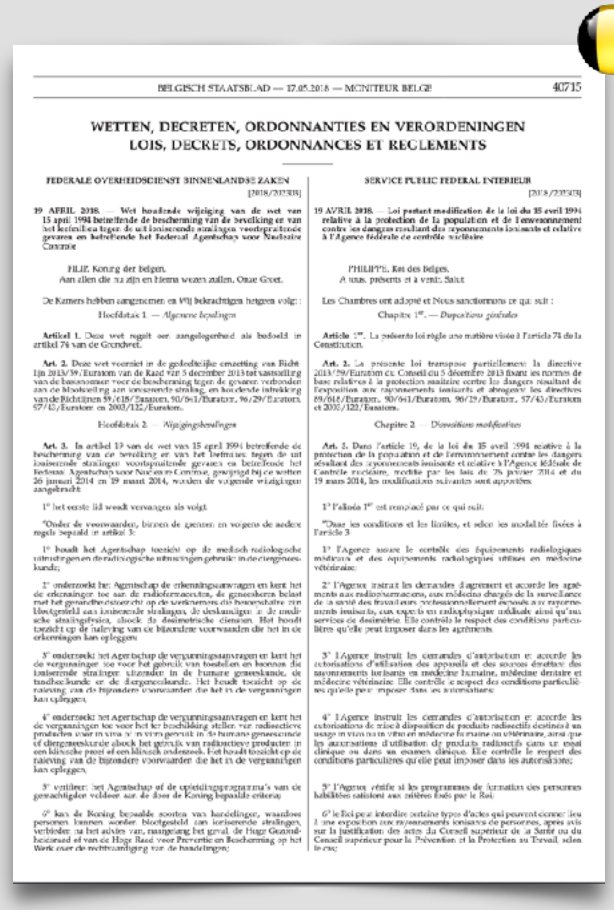
Jaargang 2017

404

Besluit van 23 oktober 2017, houdende vaststelling van regels ter bescherming van personen tegen de gevaren van blootstelling aan ioniserende straling (Besluit basisveiligheidsnormen stralingsbescherming)

Wij Willem-Alexander, bij de gratie Gods, Koning der Nederlanden, Prins van Oranje-Nassau, enz. enz. enz.

Staatsblad 2017 404



BELGISCH STAATSBLAD — 17.05.2018 — MONITEUR BELGE 40715

WETTEN, DECRETEN, ORDONNANTIES EN VERORDENINGEN
LOIS, DECRETS, ORDONNANCES ET REGLEMENTS

FEDERALE OVERHEIDSDIENST BINNENLANDSE ZAKEN

SERVICE PUBLIC FEDERAL INTERIEUR

19 APRIL 2018. — Wet houdende wijziging van de wet van 15 april 1994 betreffende de bescherming van de bevolking en van het leefmilieu tegen de uit ioniserende straling voortspruitende gevaren en betreffende het Federaal Agentschap voor Nucleaire Controle

19 AVRIL 2018. — Loi portant modification de la loi du 15 avril 1994 relative à la protection de la population et de l'environnement contre les dangers résultant des rayonnements ionisants et relative à l'Agence fédérale de contrôle nucléaire

Some interjections can be seen as “details”.

“art. 84º/3: RP Unit can be external or Internal”

“art. 159º/5: RP Unit is internal”

Some interjections are definitely not “details”

“Euratom 2013/59 doesn’t refer to RP174”

“Clinical licences are now bound to implementing RP174 staffing level within 5 years”

1 EURATOM 2013/59 | Nationally still a work in progress

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- Still “WIP nationally ” …

Infringement for transposition failure

2018

2019

European Commission at work

2021

European Commission > .. > Applying EU law > Infringements > Infringement decisions

Infringement number	Decision	Country	Policy area / Department in charge	Title	Active infringement cases	Non-communication cases
INFR(2018)2049	• 17/05/2018 Formal notice Art. 258 TFEU Memo • 27/11/2019 Reasoned opinion Art. 258 TFEU Memo	**Portugal**	Energy	**Failure to notify transposition measures under the council directive 2013/59/EURATOM**	Yes	Yes

The Commission has also highlighted **shortcomings in the full and complete transposition** of the Basic Safety Standards Directive (Council Directive 2013/59/Euratom) into national legislation, **sending reasoned opinions to** Malta, **Portugal**, Cyprus and Greece (following earlier letters of formal notice) and initiating the first step of infringements proceedings (letters of formal notice) to Belgium, Austria, Spain, Estonia and Hungary.

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EURATOM 2013/59 | Focus

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- Radiation Protection is the core of the directive
- Article 63 enshrines proactive actions to avoid accidental/unintended radiation exposures.

Article 63

Accidental and unintended exposures

Member States shall ensure that:

a) all reasonable steps to **minimize** the probability and magnitude of accidental or unintended exposures of persons undergoing medical exposure are adopted

b) **for radiotherapeutic practices, the quality assurance program includes a study of the risk** of accidental or unintended exposures,

c) for all medical exposures the undertaking implements a **proper system for recording and analysis of events** involving or potentially involving accidental or unintended medical exposures, that is commensurate with the radiological risk associated with the practice.

- ✓ Quality Assurance Plan
- ✓ Risk Analysis
- ✓ Incident reporting

> This brings (lots of) added work (that your management might not be fully conscious of)
> This creates ambiguities of ownership (*who is responsible for the result and for the task*)

2 Your Quality Department

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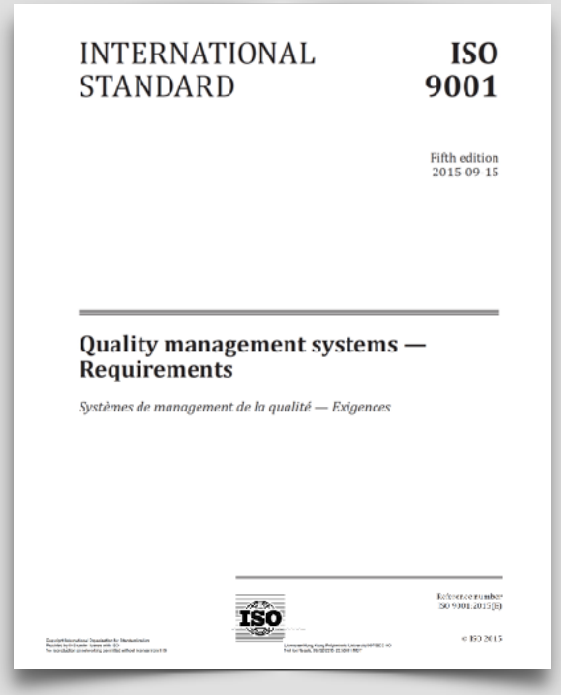
- The size of the institution defines how your quality department is structured and staffed.
- The Quality department wears different hats such as:

- ✓ health and safety
- ✓ environment
- ✓ information security
- ✓ regulatory affairs
- ✓ training requirements
- ✓ documentation control
- ✓ audit programs
- ✓ risk management
- ✓ ...

ISO 9001:2015

implicitly addressed risk through "preventative actions"

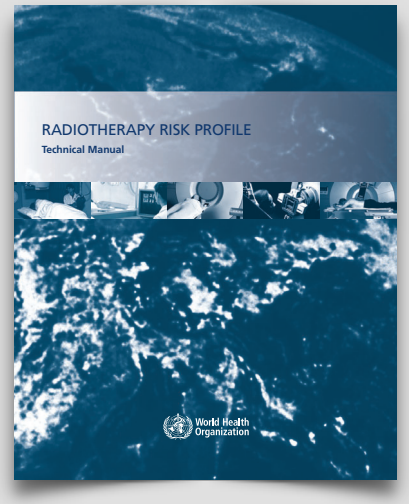


explicitly addressed risk with Clause 6.1 "actions to address risks and opportunities".

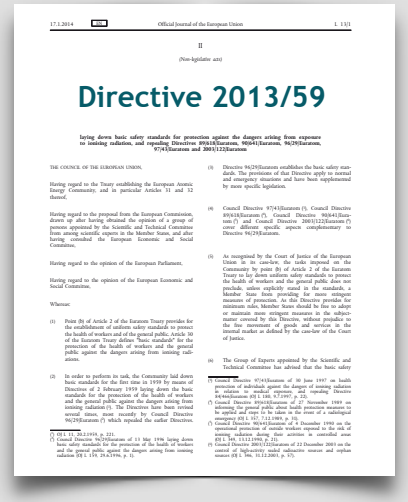
2015 → Now

😉 regulation in clinical operations didn't wait for ISO

WHO
World Health Organisation



EURATOM
European Atomic Energy Community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II

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Directive 2013/59

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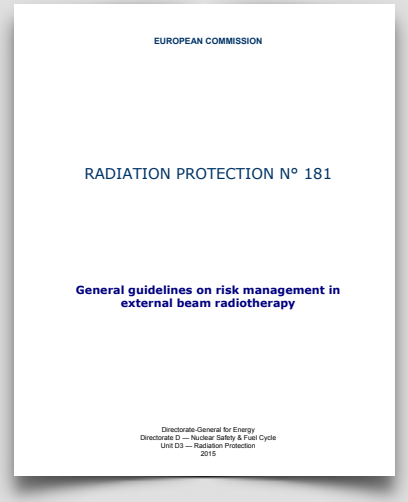
EC
European Commission


EUROPEAN COMMISSION

RADIATION PROTECTION N° 181

General guidelines on risk management in external beam radiotherapy

Directorate-General for Energy
Directorate D — Nuclear Safety & Fuel Cycle
Unit D3 — Radiation Protection
2015

EC
European Commission

Check of national transposition of EURATOM 2013/59

National bodies
AFCN/FANC - CSN - APA - ...

Check of compliance with art. 63 EURATOM 2013/59 (clinical practices)

- ✓ Quality Assurance Program
- ✓ Risk Analysis
- ✓ Incident Reporting

2008 — 2013 — 2015 — 2018 → Now

❷ How can we speak the same language | Use same form

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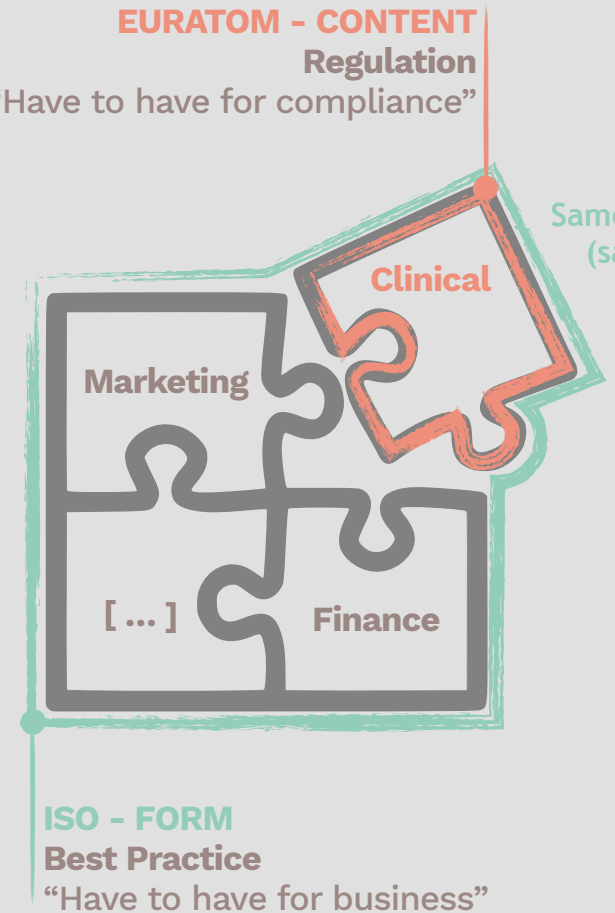

EURATOM 2013/59

Goal: Protect against the dangers from exposure to ionising radiation

ISO 9001:2015

Goal: Organisation to achieve standardisation and customer satisfaction

Departments:

- Management
- Human ressources
- Finance
- Business Development
- Marketing
- […]
- Operations (/Clinical Operations)

- Documentation control
- Processes
- Procedures
- Work Instructions
- Annexes

Quality Assurance Program

❷ How can we speak the same language | Use same form and our color coding

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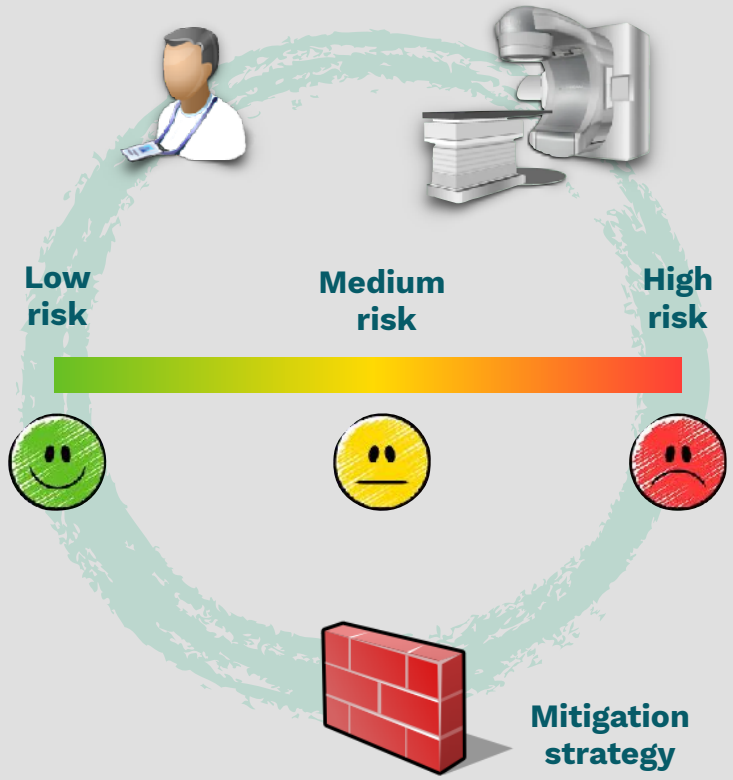

Likelihood
Frequency

Consequence
Harm

	Rare	Unlikely	Possible	likely	Almost certain
Severe					
Major					
Moderate					
Minor					
Minimal					

Let's use "our own risk analysis toolbox" to comply, in one stop, with regulation and ISO !

How do we look at incidents/accidents ?

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REACTIVE

Look back at what happened

Accident analysis

Feedback into the equipment and processes security systems.

a.k.a. Lessons learned, RCA

PROACTIVE

Anticipate what can happen

Equipment operation and processes analysis

Estimation of the probability of accidents and their consequences.

a.k.a. PSA, FMEA, Risk Matrices

How do we look at incidents/accidents ?

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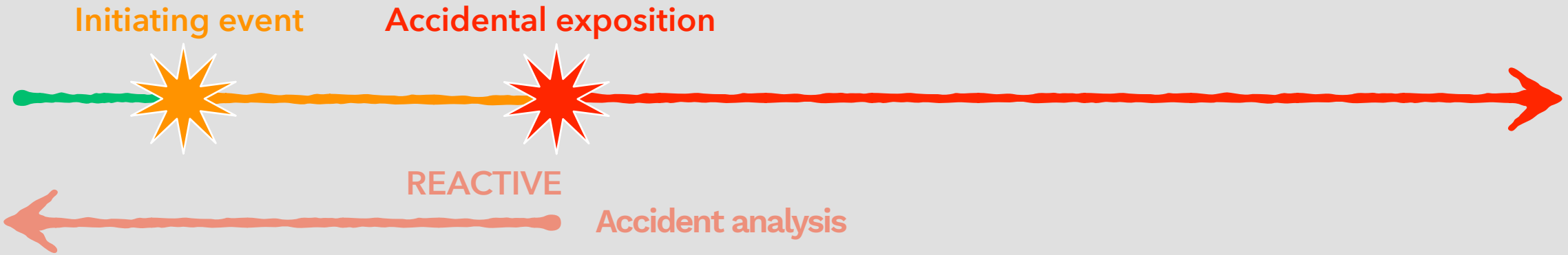

REACTIVE

Accident analysis

- Method most commonly used.
- The compliance with regulatory requirements and international standards uses this method.
- Based on using the lessons learned from documented accidental exposures that already occurred.
- Re-evaluating, in light of the lessons learned, the QA programs and existing procedures in the facilities..
- Very valuable to give practical solutions to real problems that have arisen and prevent them from happening again, not only in the installation where they occurred but also elsewhere

Methodologies

ORION

PRISMA

…

Notes:

- Only cover known events. They leave without considering other possible failures that although they have not happened or they have not been published, it does not mean that they can not happen.
- Feed on cases of catastrophic consequences and very low frequency; do not pay attention to more frequent but less serious events

How do we look at incidents/accidents ?

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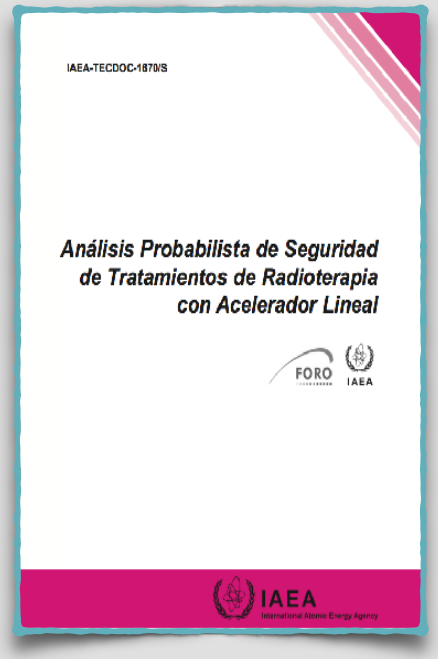
PROACTIVE

Equipment operation and processes analysis



Probabilistic Safety Analysis (PSA) - Quantitative

It provides quantitative information about the degree to which the risk is reduced by the existence or introduction of a security measure and allows to establish its priority.

Requires considerable effort and expert in the methodology itself, limited application in our field.

How do we look at incidents/accidents ?

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PROACTIVE

Equipment operation and processes analysis

The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management

M. Saiful Huq
Department of Radiation Oncology, University of Pittsburgh Cancer Institute and UPMC CancerCenter, Pittsburgh, Pennsylvania 15232

Benedick A. Fraass
Department of Radiation Oncology, Cedars-Sinai Medical Center,Los Angeles, California 90048

Peter B. Dunscombe
Department of Oncology, University of Calgary Calgary T2N 1N4, Canada

John P. Gibbons, Jr.
Ochsner Health System, New Orleans, Louisiana 70121

Geoffrey S. Ibbott
Department of Radiation Physics, UT MD Anderson Cancer Center, Houston, Texas 77030

Arno J. Mundt
Department of Radiation Medicine and AppliedSciences, University of California San Diego, San Diego, California 92093-0843

Sasa Mutic
Department of Radiation Oncology, Washington University Schoolof Medicine, St. Louis, Missouri 63110

Jatinder R. Palta
Department of Radiation Oncology, Virginia Commonwealth University, P.O. Box 980058, Richmond, Virginia 23298

Frank Rath
Department of Engineering Professional Development, University of Wisconsin, Madison, Wisconsin 53706

Bruce R. Thomadsen
Department of Medical Physics, University of Wisconsin, Madison Wisconsin 53705-2275

Jeffrey F. Williamson
Department of Radiation Oncology, Virginia Commonwealth University, Richmond, Virginia 23298-0051

Ellen D. Yorke
Department of Medical Physics, Memorial Sloan-Kettering Center New York, New York 10065

(Received 13 May 2015; revised 13 March 2016; accepted for publication 14 March 2016; published 15 June 2016)

The increasing complexity of modern radiation therapy planning and delivery challenges traditional prescriptive quality management (QM) methods, such as many of those included in guidelines published by organizations such as the AAPM, ASTRO, ACR, ESTRO, and IAEA. These prescriptive guidelines have traditionally focused on monitoring all aspects of the functional performance of radiotherapy (RT) equipment by comparing parameters against tolerances set at strict but achievable values. Many errors that occur in radiation oncology are not due to failures in devices and software; rather they are failures in workflow and process. A systematic understanding of the likelihood and clinical impact of possible failures throughout a course of radiotherapy is needed to direct limit QM resources efficiently to produce maximum safety and quality of patient care. Task Group 100 of the AAPM has taken a broad view of these issues and has developed a framework for designing QM activities, based on estimates of the probability of identified failures and their clinical outcome through the RT planning and delivery process. The Task Group has chosen a specific radiotherapy process required for "intensity modulated radiation therapy (IMRT)" as a case study. The goal of this work is to apply modern risk-based analysis techniques to this complex RT process in order to demonstrate to the RT community that such techniques may help identify more effective and efficient ways to enhance the safety and quality of our treatment processes. The task group generated by consensus an example quality management program strategy for the IMRT process performed at the institution of one of the authors. This report describes the methodology and nomenclature developed, presents the process maps, FMEAs, fault trees, and QM programs developed, and makes suggestions on how this information could be used in the clinic. The development and implementation

4009 Med. Phys. 43 (7), July 2016 0094-2405/2016/43(7)/4009/24/$30.00 © 2016 Am. Assoc. Phys. Med. 4009

Failure **M**ode and **E**ffect **A**nalysis and criticality (**FMEA**) - Qualitative

- Procedure of identifying potential failures in a process and analysis of the resulting effects.
- Generally a qualitative technique although a priority range can be established by assigning a number to the variables Severity (S), Occurrence (O) Detectability (D). Each variable has a range of 1 to 10.
- Product gives place to the denominated RPN (Risk Priority Number) that allows to classify the risk and set priorities.
- Method chosen by the AAPM TG100

How do we look at incidents/accidents ?

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Initiating event → Accidental exposition

PROACTIVE → Equipment operation and processes analysis

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Department of Radiation Oncology, Washington University Schoolof Medicine, St. Louis, Missouri 63110

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Failure Mode and Effect Analysis and criticality (**FMEA**) - Qualitative

$$RPN = S \times O \times D$$

Rank	Severity (S)
1	No effect
2	Inconvenient
3	
4	Minor dosimetric error
5	Minor toxicity or tumour underdose (wrong dose, dose distribution, location, or volume)
6	
7	Serious toxicity or tumour underdose
8	
9	Very serious toxicity of tumour underdose
10	Catastrophic

Rank	Occurrence (O)
1	Failure unlikely (1/10,000)
2	Unlikely (2/10,000)
3	Relatively few failures (5/10,000)
4	Few failures (1/1,000)
5	Few failures (<0.2%)
6	Occasional failures (<0.5%)
7	Occasional failures (<1%)
8	Failures more common (<2%)
9	Failures more common (<5%)
10	Failures inevitable (>5%)

Rank	Detectability (D)
1	Undetected in 0.01% of cases
2	Undetected in 0.2% of cases
3	Undetected in 0.5% of cases
4	Undetected in 1.0% of cases
5	Undetected in 2.0% of cases
6	Undetected in 5.0% of cases
7	Undetected in 10% of cases
8	Undetected in 15% of cases
9	Undetected in <20% of cases
10	Undetected in >20% of cases

Risk analysis in practice, SRS example | TG-100 XLS style

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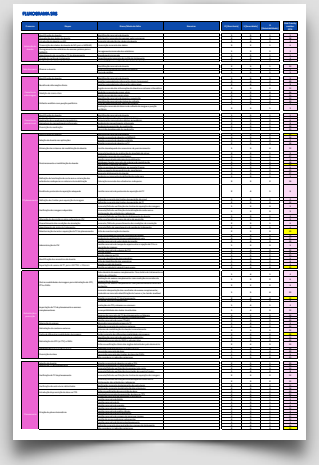
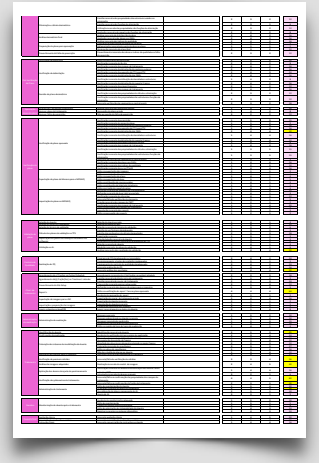
Processo	Etapas	Riscos/Modo de falha	O [Ocorrência]	S [Severidade]	D [Detectabilidade]	Risk Priority number RPN
Controlo de Qualidade	Realização do CQ	Programa de CQ desadequado ou incompleto	3	4	2	24
		Comissionamento e testes de aceitação inadequados	1	5	1	5
		Equipamento de controlo de qualidade desadequado	3	4	2	24
		Incorreta realização do CQ	2	4	2	16
		Incorreta análise dos resultados	2	4	4	32
Chart do tratamento	Agendamento do nº frações no *Patient Schedule*	Agendamento incorreto do nº de frações no p*atient schedule*	2	3	3	18
	Agendamento da(s) fração(ões) no *Treatment calendar*	Escolha incorreta do dia de início do tratamento	1	1	2	2
		Escolha incorreta do *course* de tratamento	2	4	3	24
	Preenchimento do *Site Setup*	Transcrição incorreta para as *setup notes*	3	1	4	12
		Definição incorreta dos desvios da origem para o isocentro	1	3	3	9
	R*eport* s	Falha na verificação do *report* face ao plano aprovado	4	4	4	64
		Ausência de aprovação do *report*	2	1	1	2
	Exportação de imagens para o XVI	Exportação do *course* de tratamento errado	1	4	4	16
		Exportação do doente incorreto	2	1	1	2
	Importação e preparação das imagens	Importação do doente incorreto	1	1	1	1
		Preparação incorretas das imagens	2	1	1	2
	Inserir o doente na HexaPOD	Inserir incorretamente os dados do doente	2	1	4	8





FMEA - TG 100

How do we look at incidents/accidents ?

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PROACTIVE

Equipment operation and processes analysis

Risk Matrices - Qualitative

- Created from a Probabilistic Safety Analysis made to a Radiotherapy service.
- Proposal of a set of initiating events and barriers that allows normalising the risk profile between different centers.
- Makes more elaborate study of the barriers than the FMEA.
- Although they do not quantify the risk numerically, it makes it possible to classify them into levels, which is enough to establish priorities without needing more accurate and costly risk analysis.
- Endorsed by the IAEA to facilitate the realisation of the Risk profile.

How do we look at incidents/accidents ?

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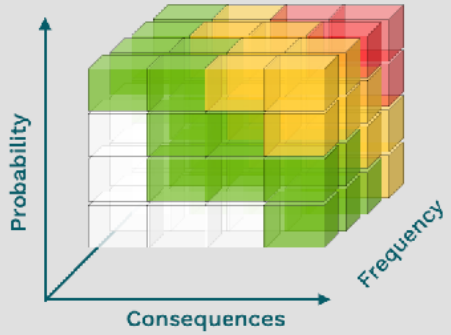
Initiating event → Accidental exposition

PROACTIVE → Equipment operation and processes analysis



Risk Matrices - Qualitative

Risk = C x F x P

Consequences| Incident

Consequences	Definition
Very high or Catastrophic (C_{MA})	Cause death or limiting damage to several patients. It is assumed that the magnitude of errors dose is higher than 25% compared to the prescribed dose. They can be bysubdoses or overdose.
High or Severe (C_{TO})	Cause death or limiting damage to a single patient, affecting all or much of the treatment. exposures affecting multiple patients whose dose errors are between 10 and 25% compared to the prescribed dose (including 25%) are also included in this level.
Mild or moderate (C_M)	Clinically do not endanger the patient's life, are exposures that affect a patient in a treatment session.
Low (C_B)	Decreased defense in depth. Dose not cause deviation.

Frequency | Incident

Frequency	Events / year (considering 500 patients per year)
High (FA)	More than 50 per year
Media (FM)	Between 1 and 50 per year
Low (FB)	Between 1 year and 1 every 100 years
Very Low (FMB)	Less than 1 per 100 years

Probability | Barrier failure

Probability	Definition
High (PA)	There is no safety barrier
Media (PM)	There are one or two safety barriers
Low (PB)	There are three safety barriers
Very Low (PMB)	There are four or more safety barriers. There is sufficient defense in depth

Risk analysis in practice, 3DCRT example | Risk Matrices XLS style

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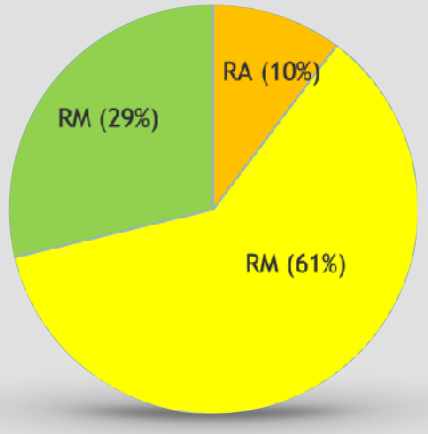
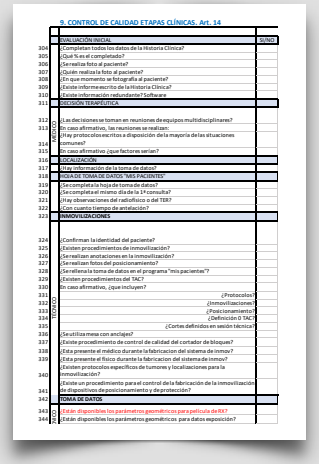
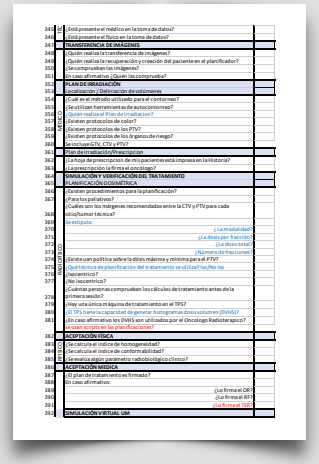
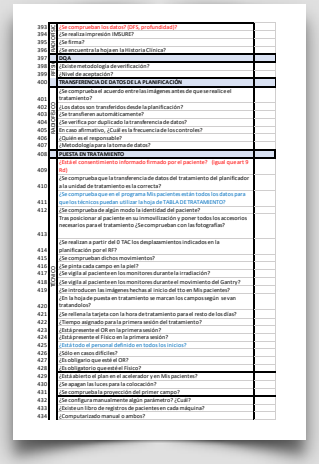
Núm.	Etapas clínicas	Total eventos iniciadores por etapa	Risco Muito Alto (RMA)	Risco Alto (RA)	Risco Médio (RM)	Risco Baixo (RB)
1	Instalação inicial do equipamento	2	0	0	2	0
2	Aceitação e Comissionamento	27	0	8	17	2
3	Manutenção do equipamento	3	0	0	3	0
4	Prescrição Clínica do tratamento	7	0	1	0	6
5	Aquisição de dados anatômicos do paciente	10	0	1	6	3
6	Delineamento dos volumes	5	0	0	4	1
7	Planejamento do tratamento	16	0	2	10	4
8	Confecção dos moldes	4	0	0	0	4
9	Início do tratamento	17	0	1	9	7
10	Posicionamento diário para tratamento	13	0	1	5	7
11	Execução do tratamento	42	0	1	33	8
Total #		146	0	15	89	42
Total %			0%	10%	61%	29%









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Risk Matrices

Conclusion

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- Compliance with european and national regulation is non negotiable.
- XLS is not a regulatory friendly tool.
- Continuous improvement requires to be objectively guided towards what presents risk in our practices. Risk analysis allows us to focus on what needs our truly needs our attention.
- The increase of regulatory workload requires platforms to pragmatically support periodic internal/ external risk analysis of practices.
- A simple handshake with Quality departments, to support their ISO needs, is needed on Quality Assurance Programs, Incident Reporting and Risk Analysis as well as on the platforms to be used.


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Thank you