Our experience from using Excel to using myQA PROactive.

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myQA PROactive workshop

17/04/2023

Introduction

Regulations require integration of a risk assessment

DIRECTIVES

COUNCIL DIRECTIVE 2013/59/EURATOM

of 5 December 2013

Article 63

Accidental and unintended exposures

Member States shall ensure that:

(a) all reasonable ability and exposures c

(b) for radiot programme unintended

(c) for all med appropriate events invo unintended radiological

(30) Accidental source of devices p Council D competent the prever exposure a In this resp including a incidents sh analysis and corrective action should be required in such cases.

(d) arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis;

(e) (i) the undertaking declares as soon as possible to the competent authority the occurrence of significant events as defined by the competent authority;

BELGISCH STAATSBLAD — 20.02.2020 — MONITEUR BELGE

Afdeling 6. — Accidentele en onbedoelde blootstellingen

Art. 56.

Alle redelijke maatregelen worden genomen om de waarschijnlijkheid en de omvang van accidentele en onbedoelde blootstellingen in het kader van medische blootstellingen tot een minimum te beperken.

Art. 57.

Bij radiotherapeutische handelingen moet het programma voor kwaliteitsborging een proactieve analyse bevatten van het risico op accidentele en onbedoelde blootstellingen, rekening houdend met internationale aanbevelingen hieromtrent. Een dergelijke risicoanalyse laat toe de mogelijke risico's, hun waarschijnlijkheid en potentiële impact te identificeren en beschrijft de maatregelen om deze risico's te beheersen.

Section 6. — Expositions accidentelles et non intentionnelles

Art. 56.

Toutes les mesures raisonnables sont prises pour limiter au maximum la probabilité et l'ampleur des expositions accidentelles et non intentionnelles dans le cadre des expositions médicales.

Art. 57.

Pour les pratiques radiothérapeutiques, le programme d'assurance de qualité doit inclure une analyse proactive du risque d'expositions accidentelles et non intentionnelles en tenant compte des recommandations internationales en la matière. Cette analyse de risque permet d'identifier les risques potentiels, leur probabilité et leur impact potentiel, et elle décrit les mesures destinées à maîtriser ces risques.

REGULATIONS

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Manufacturers shall establish, implement, document and maintain a risk management system.

Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating. In carrying out risk management manufacturers shall:

(a) establish and document a risk management plan for each device;

(b) identify and analyse the known and foreseeable hazards associated with each device;

(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;

(d) eliminate or control the risks referred to in point (c) in accordance with the requirements of Section 4;

(e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and

(f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.

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Introduction

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

FMEA

TABLE II. Descriptions of the O, S, and D values used in the TG-100 FMEA.

Rank	Occurrence (O)		Severity (S)		Detectability (D)
	Qualitative	Frequency in %	Qualitative	Categorization	Estimated Probability of failure going undetected in %
1	Failure unlikely	0.01	No effect		0.01
2		0.02	Inconvenience	Inconvenience	0.2
3	Relatively few failures	0.05			0.5
4		0.1	Minor dosimetric error	Suboptimal plan or treatment	1.0
5		<0.2	Limited toxicity or tumor underdose	Wrong dose, dose distribution, location, or volume	2.0
6	Occasional failures	<0.5			5.0
7		<1	Potentially serious toxicity or tumor underdose		10
8	Repeated failures	<2			15
9		<5	Possible very serious toxicity or tumor underdose	Very wrong dose, dose distribution, location, or volume	20
10	Failures inevitable	>5	Catastrophic		>20

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How we used to work…

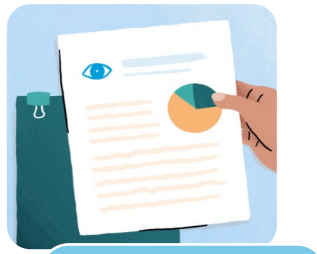
Form a multidisciplinary team

Process mapping

Identify potential FM

Scoring the FM

Formulate actions



Make a Report

1. Multidisciplinary team

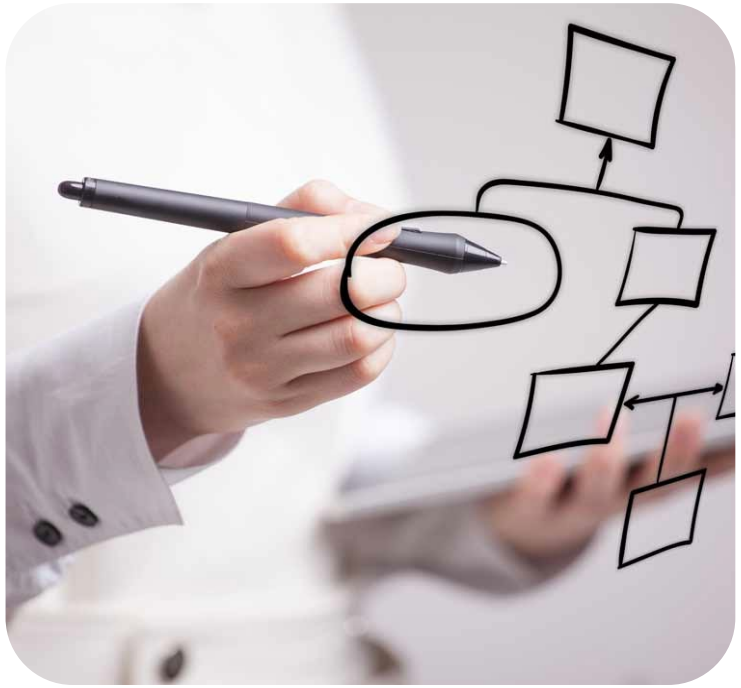
See it as a project or subtask of an project

Form a dedicated team of expertise

At least one person of each discipline

Facilitated by QM

2. Process mapping



First draft foreseen by QM

Reviewed by each member of the team

3. Identify FM

Identify potential FM, their cause and effects.

Let each member of the team prepare it on their own.

Go through it together and discuss.

4. Let the scoring begin

Each member prepares the scoring on their own.

O x S x D = RPN

Go through it together and discuss.

5. Formulate actions

Prioritize the risks

Formulate actions to be taken to control/prevent the FM from happening

Dedicate each action to a person

Followed up by QM

Make a report.

Name of the involved ones.

Summary of the analysis.

Actions and their status.

Conclusion.

And now with myQA PROactive?

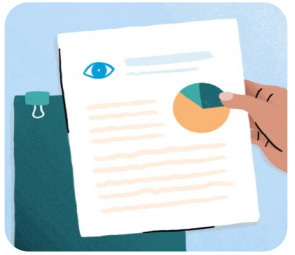
Form a multidisciplinary team

Process mapping

Identify potential FM

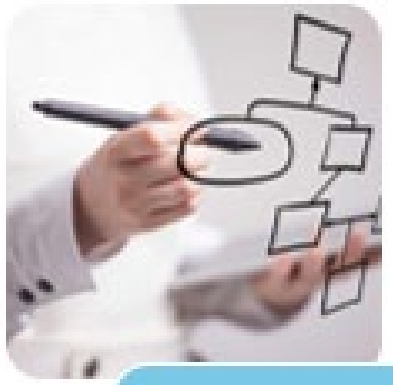
Scoring the FM

Formulate actions

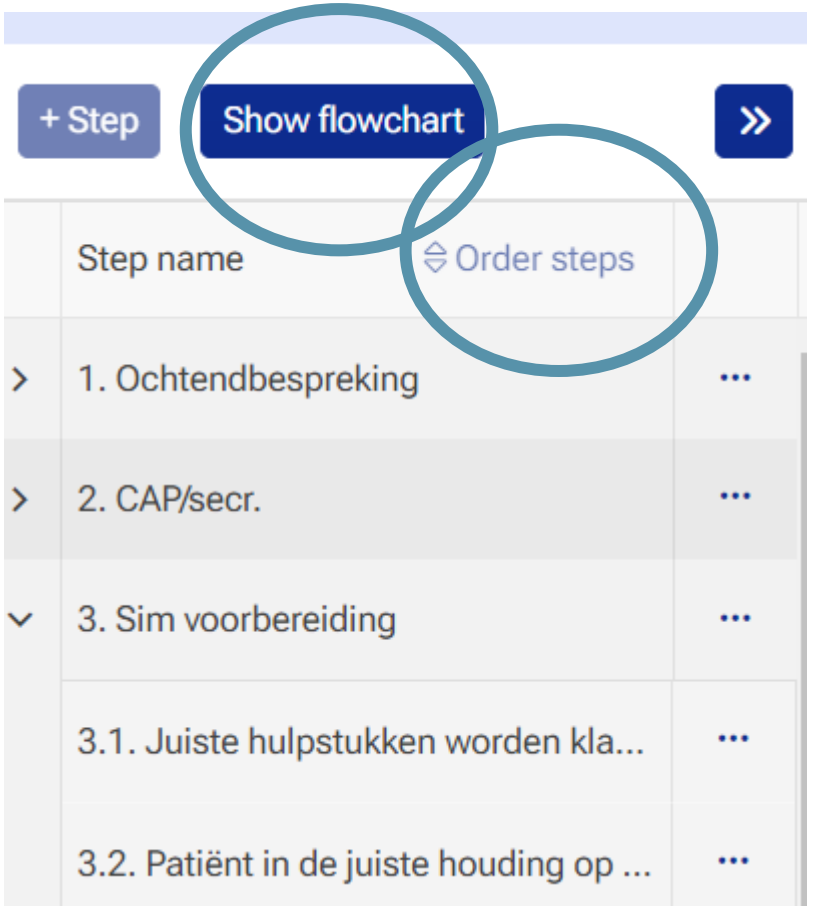


Make a Report

Process mapping



Process mapping



Identifying and scoring the potential FM

Identify potential FM

Scoring the FM

New failure mode

Name *

Cause *

Step *

Bepaal lokalisatie van de CT

Select an existing step or enter a new step

Effect

Select an existing effect or enter a new effect

Severity *

0

Occurrence *

0

Po c,i (%)*

0

Initial prevention *

Initial prevention

Detectability *

0

Pr iss,i (%)*

0

Initial barrier *

Initial barrier

* Required

Save

Cancel

Formulate actions

Formulate actions

For now we add it as a note to th

4.1. selectie scanprotocol + uitvoer scan
Scanrange niet lang (cranio-caudaal tekort)
Cause

Cause | Preventions | Barriers | Notes

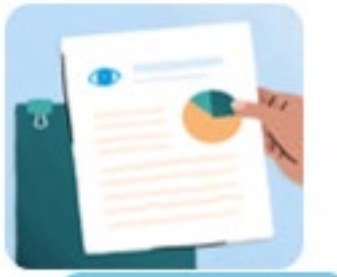
10.1. Patiënt positioneren volgens de initiële houding
Niet overeenstemmend met de initiële houding
Cause

Cause | Preventions | Barriers | Notes

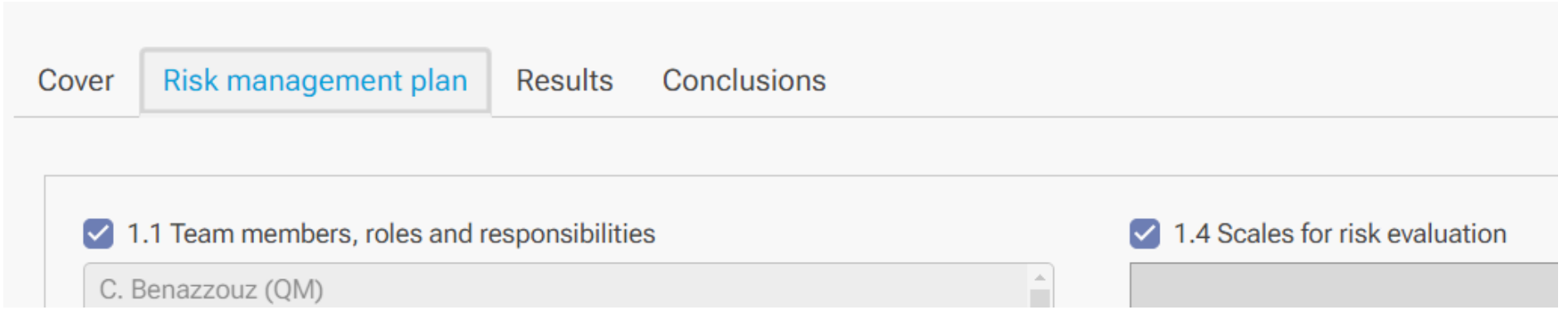
Initial barrier	Pmiss,i (%)	Di
Initial barrier	75	9.5

Added barriers	pmiss (%)	Status

Make a report



Make a Report



Select items you want in the report

Print out the report.

To summarize

- [ ] 1 Software only
- [ ] Gives in different ways an overview of your processes and their risks
- [ ] Process mapping + scoring
- [ ] Report
- [ ] Templates

- [ ] Not possible to have scorings of > 1 person (as preparation)
- [ ] Identifying FM and scoring at the same moment
- [ ] Formulating actions + status

Thank you for your attention!

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