Cliniques universitaires SAINT-LUC
UCLouvain BRUXELLES

Impact of the new medical device regulation on quality management

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17/04/2023

What is MDR?

- Defines a regulatory framework for medical devices (MD)
- European level standard for quality and safety
- (re)Defines the term medical device

New definition of MD:

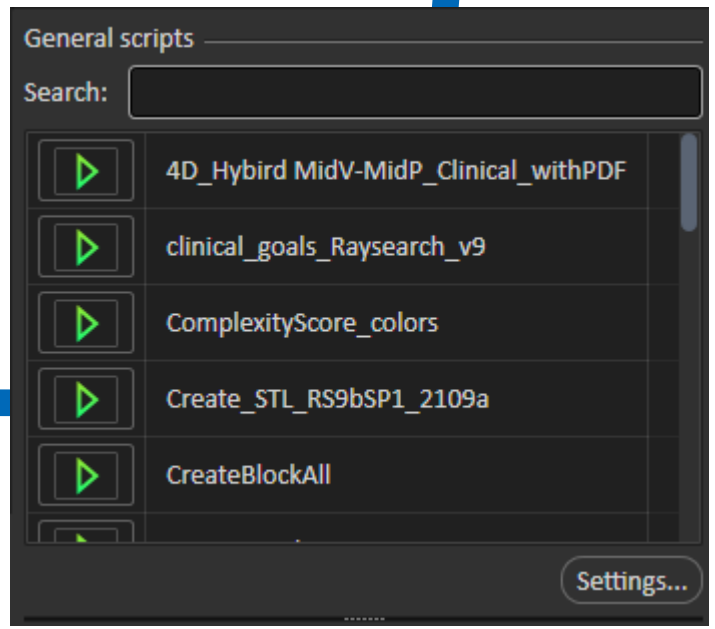
Art.2 (1): "medical device" means any instrument, […], software, […], material or other article intended by the manufacturer to be used, alone or in combination, […] for one or more of the following specific medical purposes:

diagnosis, prevention, monitoring, prediction, prognosis, treatment […]

Art.2 (4): "active device" means any device, the operation of which depends on a source of energy […]

Software shall also be deemed to be as active device;

Home-made medical devices are also targeted (e.g. scripts, …)



MDR 745 - HIE

Article 5

Placing on the market and putting into service

5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used only within health institutions established in the Union, provided that all of the following conditions are met:

(a) the devices are not transferred to another legal entity,

(b) manufacture and use of the devices occur under appropriate quality management systems,

(c) the health institution justifies in its documentation that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance by an equivalent device available on the market,

(d) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

(e) the health institution draws up a declaration which it shall make publicly available, including:

(i) the name and address of the manufacturing health institution;

this Regulation shall not apply to devices, manufactured and used only within health institutions

I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor,

(f) the health institution draws up documentation that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met;

(g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in point (f), and

(h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

This paragraph shall not apply to devices that are manufactured on an industrial scale.

➡ No CE marking but…

MDR 745 - HIE

No CE marking but:

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With the exception of the relevant general safety and performance requirements

(iii) a declaration that the devices meet the general safety and performance requirements set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor,

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ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

CHAPTER I

3. 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.

QA managers be like:

FMEA

MDR 745 - HIE

No CE marking but:

the devices are not transferred to another legal entity,

appropriate quality management systems,

equivalent device available on the market,

justification of their manufacturing, modification and use;

draws up a declaration

draws up documentation

reviews experience gained from clinical use

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IEC norms

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IEC 62304 Medical device software – Software life cycle processes

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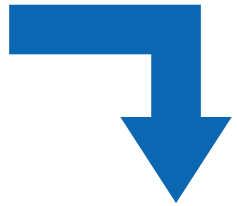
Classify software according to related health risk:

Class A - if the software cannot harm health.

Class B - if the software can cause minor health damage.

Class C - serious health damage or even death.



Adapted documentation level by class:

Class determination by FMEA

IEC 62304:2006/Amd.1:2015				
Section	Title	Class A	Class B	Class C
5	***Software development PROCESS***			
5.1	**Software development planning**			
5.1.1	Software development plan	X	X	X
5.1.2	Keep software development plan updated	X	X	X
5.1.3	Software development plan reference to SYSTEM design and development	X	X	X
5.1.4	Software development standards, methods and tools planning			X
5.1.5	Software integration and integration testing planning		X	X
5.1.6	Software VERIFICATION planning	X	X	X
5.1.7	Software RISK MANAGEMENT planning	X	X	X

FMEA I used to do

Adaptation for the radiotherapy domain of level definition:

frequency (F)

non-detection probability (D)

gravity (G)

Level	Criteria on clinical consequence	Impact on the activity performance criteria	Impact on the perceived quality criteria	Gravity	ASN Grade	Number of implicated people
Minor	Event without consequences for the patient or staff	Slight impact on the activity performance (lightly late)	Slight impact on the perceived quality.	1	0	Several people +1

According to :

- Joint Commission on Accreditation of Healthcare Organizations (JCAHO).
- ASN. Guide d'autoévaluation des risques encourus par les patients en radiothérapie externe. Guid ASN N°4 2008:186.
- Huq MS, Fraass BA, Dunscombe PB, Gibbons JP, Ibbott GS, Mundt AJ, et al. The report of Task Group 100 of the AAPM: Application of risk analysis methods to radiation therapy quality management. Med Phys 2016;43:4209–62. https://doi.org/10.1118/1.4947547.

FMEA I used to do

Double-layer FMEA (with and without actions)

C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U
oftware System	Potential failure modes	Potential causes of failure	Hazardous situation	Potential effects of failure	Gravity (G)	Frequency (F)	non-Detection rate (D)	F*D	Criticity Index (IC)	Acceptability	Remark	Risk reduction actions	GP	FP	DP	F*D	IC	Acceptability class
Infinity - Daily QA - "QuickCheck (Infinity)" test list												Infinity - Daily QA - "QuickCheck (Infinity)" test list						
ackend	Wrong result	Error in corresponding script	The script is displaying results from an anterior date	Error in the reporting and trending of results	1	3	1	3	3	4	Data is already checked within the PTW QuickCheck software and compared with appropriated tolerance level. The sole purpose of the QuickCheck test list is the reporting and trending of the calculated machine parameters	Today's date is displayed to the user in the right format (YYYY-MM-DD) to enable easy copy/paste filling. Script will not display result in data does not exist at that date or if the date is written in the wrong format	1	2	1	2	2	2
rontend	Wrong display																	
ackend	No result	Missing file	Data file is saved in a different directory than expected	No reporting is possible for that date	1	2	1	2	2	2			1	2	1	2	2	2
Infinity - Weekly QA - "Output poly Infinity E08" test list												Infinity - Weekly QA - "Output poly Infinity E08" test list						
ackend	Wrong result	Error in corresponding script	The script is displaying wrong results	An out-of-tolerance output displayed as passing the tolerance will not warn the physicist about offset in dose output. The consequence might be an under/over-dosage to the patient.	4	3	4	12	48	59		CE-marked PTW QuickCheck is used every other day for daily output check. Hence, output variation would be seen the next day.	4	3	2	6	24	42
rontend	Wrong display			An in-tolerance output displayed as not-passing the tolerance will lead the physicist	1	3	1	3	3	4	In case of test failure, an appropriate dose output measurement in water will							
Infinity - Weekly QA - "Output poly Infinity E10" test list												Infinity - Weekly QA - "Output poly Infinity E10" test list						
ackend	Wrong result	Error in corresponding script	The script is displaying wrong results	An out-of-tolerance output displayed as passing the tolerance will not warn the physicist about offset in dose output. The consequence might be an under/over-dosage to the patient.	4	3	4	12	48	59		CE-marked PTW QuickCheck is used every other day for daily output check. Hence, output variation would be seen the next day.	4	3	2	6	24	42
rontend	Wrong display			An in-tolerance output displayed as not-passing the tolerance will lead the physicist	1	3	1	3	3	4	In case of test failure, an appropriate dose output measurement in water will							
Infinity - Weekly QA - "Output poly Infinity E10" test list												Infinity - Weekly QA - "Output poly Infinity E10" test list						
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rontend	Wrong display			An in-tolerance output displayed as not-passing the tolerance will lead the physicist	1	3	1	3	3	4	In case of test failure, an appropriate dose output measurement in water will							
Infinity - Weekly QA - "Output poly Infinity E12" test list												Infinity - Weekly QA - "Output poly Infinity E12" test list						
ackend	Wrong result	Error in corresponding script	The script is displaying wrong results	An out-of-tolerance output displayed as passing the tolerance will not warn the physicist about offset in dose output. The consequence might be an under/over-dosage to the patient.	4	3	4	12	48	59		CE-marked PTW QuickCheck is used every other day for daily output check. Hence, output variation would be seen the next day.	4	3	2	6	24	42
rontend	Wrong display			An in-tolerance output displayed as not-passing the tolerance will lead the physicist	1	3	1	3	3	4	In case of test failure, an appropriate dose output measurement in water will							
Infinity - Weekly QA - "Output poly Infinity E15" test list												Infinity - Weekly QA - "Output poly Infinity E15" test list						
ackend	Wrong result	Error in corresponding script	The script is displaying wrong results	An out-of-tolerance output displayed as passing the tolerance will not warn the physicist about offset in dose output. The consequence might be an under/over-dosage to the patient.	4	3	4	12	48	59		CE-marked PTW QuickCheck is used every other day for daily output check. Hence, output variation would be seen the next day.	4	3	2	6	24	42
rontend	Wrong display			An in-tolerance output displayed as not-passing the tolerance will lead the physicist	1	3	1	3	3	4	In case of test failure, an appropriate dose output measurement in water will							
Infinity - Weekly QA - "Output poly Infinity E18" test list												Infinity - Weekly QA - "Output poly Infinity E18" test list						
ackend	Wrong result	Error in corresponding script	The script is displaying wrong results	An out-of-tolerance output displayed as passing the tolerance will not warn the physicist about offset in dose output. The consequence might be an under/over-dosage to the patient.	4	3	4	12	48	59		CE-marked PTW QuickCheck is used every other day for daily output check. Hence, output variation would be seen the next day.	4	3	2	6	24	42
rontend	Wrong display			An in-tolerance output displayed as not-passing the tolerance will lead the physicist	1	3	1	3	3	4	In case of test failure, an appropriate dose output measurement in water will							
Infinity - Weekly QA - "Output poly Infinity EX6" test list												Infinity - Weekly QA - "Output poly Infinity X6" test list						
ackend	Wrong result	Error in corresponding script	The script is displaying wrong results	An out-of-tolerance output displayed as passing the tolerance will not warn the physicist about offset in dose output. The consequence might be an under/over-dosage to the patient.	4	3	4	12	48	59		CE-marked PTW QuickCheck is used every other day for daily output check. Hence, output variation would be seen the next day.	4	3	2	6	24	42
rontend	Wrong display			An in-tolerance output displayed as not-passing the tolerance will lead the physicist	1	3	1	3	3	4	In case of test failure, an appropriate dose output measurement in water will							

FMEA I used to do

Document with explanations

Written document explaining:

- FMEA description and related definitions
- Evaluation criteria
- Risk and control measures

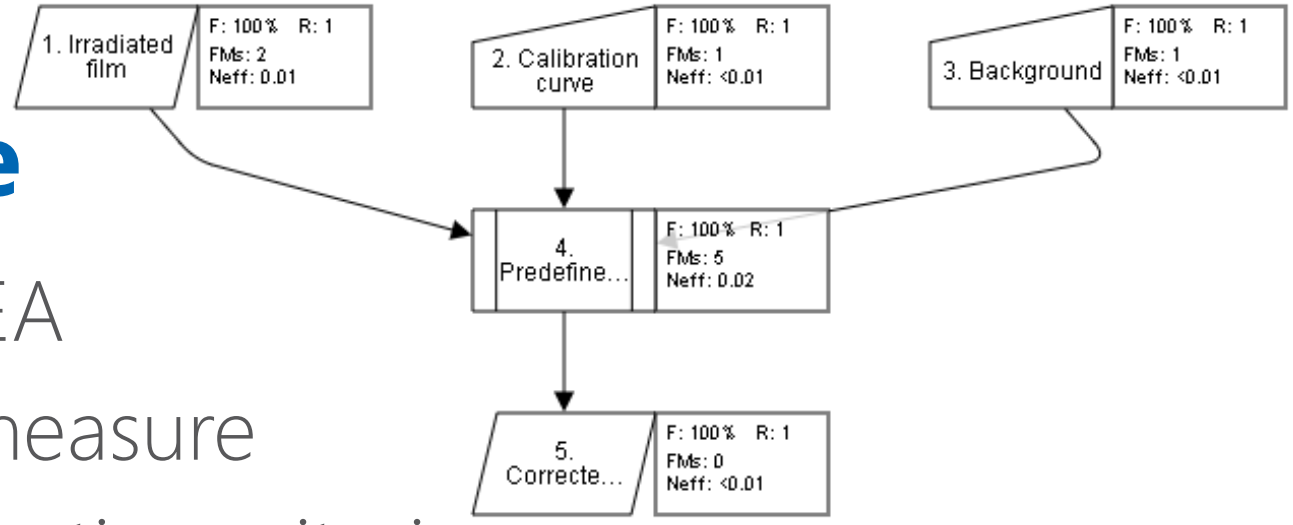
ID	Software System	Failure Mode
1	Backend	Wrong result
2	Frontend	Wrong display
3	Backend	Missing file

ID	Description	Type	Gravity reduction	Frequency reduction	Non-detection rate reduction
1	Color-coded tolerance	Protective Measure	-	-	1
2	Link to procedure	Inherent safety by design	-	1	-
3	Test description	Inherent safety by design	-	1	-

Criticity classes	Class name	Decisions and actions
C1	Acceptable	No action needed
C2	Tolerable under control	Organize a following in terms of risk management
C3	Unacceptable	Refuse situation and take actions to reduce risks. Otherwise one should refuse part or totality of the activity

With MyQA PROactive

- Integrated double-layer FMEA
- Integrated risk and control measure
- Clear and standardized evaluation criteria



Process view | Cost/Benefit view | Effect view

In-house film post-processing software

Home | Configure | Export

Throughput
T=100 patients/y

+ Step

Show Flowchart

Steps

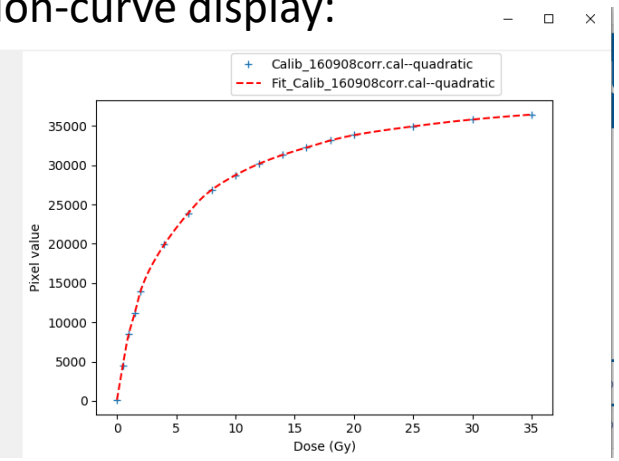
Steps	F [% of patients through the step]	R [step repetitions per patient]	
1. Irradiated film	100	1	...
2. Calibration curve	100	1	...
3. Background	100	1	...
4. Predefined process	100	1	...
5. Corrected film	100	1	...

+ Failure Mode | Filter | Show All

Step / Failure Mode	Cause	Effect	Severity (S)	Occurrence (O)	Detectability (D)	RPN	Impact neff (patients/y)	
1.Irradiated film **Wrong film image**	Cause	Delivered dose distribution does not matched planned dose distribution	7.00	1.00 (2)	9.00 (1)	63.00	<0.01	(0) ...
1.Irradiated film **Film is not scanned along the full flatbed scanner width**	Cause	Delivered dose distribution does not matched planned dose distribution	5.00	7.00 (1)	4.00 (1)	140.00	0.01	(0) ...
2.Calibration curve **Wrong calibration curve data**	Cause	Delivered dose distribution does not matched planned dose distribution	8.00	4.00 (2)	4.00 (2)	128.00	<0.01	(0) ...
3.Background **Wrong background data**	Cause	Delivered dose distribution does not matched planned dose distribution	7.00	5.00 (1)	5.00 (1)	175.00	<0.01	(0) ...
4.1.Film image selection **Process the film of another patient**	Cause	Delivered dose distribution does not matched planned dose distribution	8.00	1.00 (2)	2.00 (1)	16.00	<0.01	(0) ...
4.2.Imaging processing **Film is not rotated**	Cause	Time lost rotating the film in the right direction	2.00	7.00 (1)	1.00 (2)	14.00	<0.01	(0) ...
4.2.Imaging processing **Wrong output**	Cause	Delivered dose distribution does not matched planned dose distribution	8.00	1.00 (2)	10.00 (1)	80.00	<0.01	(0) ...
4.4.Background selection **Wrong film processing**	Cause	Delivered dose distribution does not matched planned dose distribution	7.00	1.00 (3)	10.00 (1)	70.00	<0.01	(0) ...
4.5.Calibration curve selection **Wrong film processing**	Cause	Delivered dose distribution does not matched planned dose distribution	8.00	3.00 (3)	10.00 (1)	240.00	0.01	(0) ...

With MyQA PROactive

Add film and film calibration-curve display:



2.Calibration curve **Wrong calibration curve data**	Cause	Delivered dose distribution does not matched planned dose distribution	8.00	4.00 (2)	4.00 (2)
3.Background **Wrong background data**	Cause	Delivered dose distribution does not matched planned dose distribution	7.00	5.00 (1)	5.00 (1)
4.1.Film image selection **Process the film of another patient**	Cause	Delivered dose distribution does not matched planned dose distribution	8.00	1.00 (2)	2.00 (1)
4.2.Imaging processing **Film is not rotated**	Cause	Time lost rotating the film in the right direction	2.00	7.00 (1)	1.00 (2)
4.2.Imaging processing **Wrong output**	Cause	Delivered dose distribution does not matched planned dose distribution	8.00	1.00 (2)	10.00 (1)
4.4.Background selection **Wrong film processing**	Cause	Delivered dose distribution does not matched planned dose distribution	7.00	1.00 (3)	10.00 (1)
4.5.Calibration curve selection **Wrong film processing**	Cause	Delivered dose distribution does not matched planned dose distribution	8.00	3.00 (3)	10.00 (1)

Conclusion

- European legislation evolves
- Stricter rules for increased safety
- Home-made devices targeted
- FMEA is part of requested QMS
- Now you have a software for that !

Thank you for your attention