Share2Care
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S2C DCB029

Philips Hazard Management Process &

Philips Hazard Management Guidelines

Contents

1 Implementation transition

This process is effective 30 days after authorization of the process. The date of work Instruction deployment may be different when this has been established via a separate Q&R transition plan, referencing this work Instruction number and revision.

2 Introduction

This Process Definition is used to describe the Hazard Management process used within Forcare related to the product hazards. The focus is to create a high level process that will contain the key elements of the process and it's expected in- and/or outputs. Hazard Management within Forcare adheres to the EN ISO 14971: 2012 and ISO 14971:2007 standard.

As described in the patient safety policy Forcare strives to safeguard patient safety by assessing how patients may be harmed and preventing or managing hazards. This process focuses on Product Hazards – Hazards in the product that need to be sufficiently controlled to prevent that these will occur when the product is used at customer site.

This process will be used by the product owner and (senior) software development engineers

3 Process flow

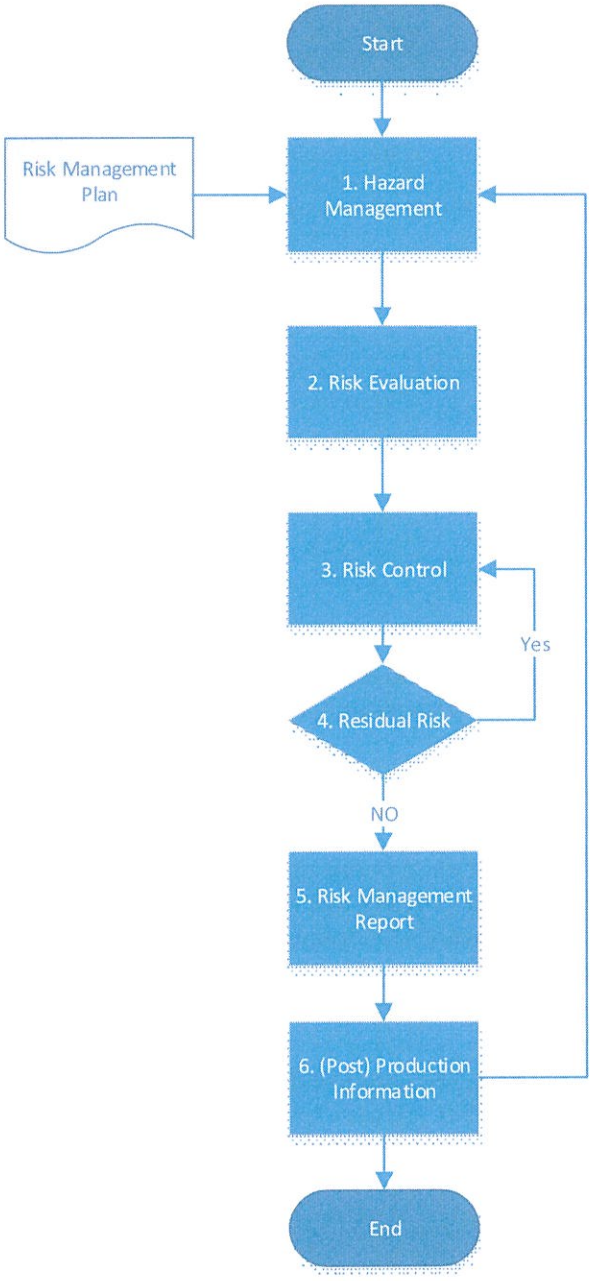

Figure 1: Process flow – Hazard Management Process

4 Process description

Box no.	Process Description

	Hazard Management Plan The hazard management activities shall be planned in a hazard management plan which is part of the Hazard management workbook. The workbook includes: 1. Hazard management plan 2. Snapshot of the Hazard database 3. Hazard report
1.	**Hazard analysis** Foreseeable hazards associated with the products are identified by a software development engineer, during the hazard brainstorm. The brainstorm results are documented in the Hazard database. Hazards could also be identified during other processes like: • *Product complaints process* • *Support process* • *Bug process* Hazards that are find within the processes logged during these processes are logged in the hazard database as brainstorm result with a link to the originating ticket. Based on the brainstorm results the product owner lead architect and support lead perform the hazard analysis. For each hazard the hazard exposure shall be estimated using available information or data. *Output:* Hazard register
2.	**Hazard Evaluation** The product owner and Integration consultant determine which hazard reduction is required for each of the identified hazards. If the hazard cannot be reduced this will be substantiated. *Output:* Decision for each hazard in the hazard register, stating if reduction is required and if the hazard is clinical or non-clinical.
3.	**Hazard Control** For each identified hazard that requires hazard reduction the appropriate control measure is identified by the Product owner and Integration consultant

	The hazard control measures are implemented and verified by the project teams and validated by the product owner. *Output:* The hazard register contains the control measures and verification of this measure
4.	**Residual Hazard** The hazards are evaluated to determine if the control measures were effective and to determine if new hazards were introduced by the control measures by the Product owner. In case the hazard has not been reduced sufficiently new control measures need to be set -> the hazard is residual. In case of a residual hazard, the hazard needs to be evaluated against its benefit. For hazards that are outweighed by the benefits, it shall be decided which information for safety is necessary to disclose the residual hazard. *Output*: Updated hazard register
5.	**Hazard Management Report** Prior to release of the product the hazard management plan is reviewed by the stakeholders to at least ensure that: • The hazard management plan was appropriately implemented • The overall residual hazard is acceptable • Appropriate measures are in place to obtain relevant (post) production information *Output*: Approved hazard register for the product to be released.
6.	**(Post) Production Information** Hazards in released products are identified by the CCB via: • (Critical) bugs identified in the released products • New or revised standards • Customer complaints In the processes mentioned above a check is built in, to accommodate identification of product hazards. If a hazard is found in a released product: • The impact on the previously implemented hazard management activities will be evaluated • A review of the hazard management file is conducted

	Output: Updated hazard register.

Table 1: Process Description – Hazard Management process

5 Tailoring

ISO14971:2007 requires hazards to be reduced to as low as reasonably practicable. While the standard refers to hazards to the patients' health (clinical hazards), it is common practice within Forcare to also document hazards that are not related to the patients' health (non-clinical hazards). It is not required to reduce the hazard as low as reasonably practicable for non-clinical hazards.

6 Measurements

6.1 New Product hazards

Title	**Newly introduced product hazards**
Goal	To determine the number of hazards found after the release of a product
Metrics	# customer incidents with a related hazards
Calculation	No calculation, trend analysis against time
Boundaries	To be set in the management review meeting
Point in Time	Management review meeting

Table 2: Metric - New Product Hazards

7 Records

Record	**Description**
Hazard Management Plan	Document containing the product including hazard control measures and the verification of this measure.

Table 3: Records

8 Document history

Rev	Author	Description of changes

01	Hoentjen, Wim	• Transferred document to HI Forcare QM. transitionplan nbr 2019-03-05
		• Next Sections updated:
		  ○ Review
		  ○ History
		  ○ Approval
		  ○ Table of Content
		  ○ Header and Footer
		• Added implementation transition section
		• Content of the document isn't changed.
		• Updated flowchart to visio format

02	Marielke Nieuwerth – van den Akker	• Corrected Standard reference

9 Review and Approval

Name Author	Function Author
Nieuwerth-van den Akker, Marielke	*Program / Release Manager*

Name Reviewer(s)	Function Reviewer(s)	Review Date(s) *DD-MMM-YYYY*	Signature(s)
Verwoert, Sven	*Manager Software Development*	06-jan-2020	
Al. Crainic, Dacina	*Product Manager interoperability Solutions*	06-Jan 2020	Dacina Crainic

Name Approver(s)	Function Approver(s)	Approval Date(s) *DD-MMM-YYYY*	Signature(s)
Hoentjen, Wim	*QMS Manager*	06-Jan 2020	
Nieuwerth-van den Akker, Marielke	*Program / Release Manager*	06-Jan 2020	ANieuwerth

End of Document

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1 Implementation transition

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2 Introduction

This guideline describes the terms used in the hazard management process.

3 Probability

Probability	Meaning	Integer Value
Frequent	It is anticipated that the risk will occur daily - weekly during the operation life of a product	5
Probable	It is anticipated that the risk will occur weekly-monthly during the operation life of a product	4
Occasional	It is anticipated that the risk will occur monthly - once per half a year during the operation life of a product	3
Remote	It is anticipated that the risk will occur yearly during the operation life of a product	2
Improbable	It is not anticipated that the risk will occur a few times in the life of an entire system.	1

4 Severity – Clinical hazards

Severity	Meaning	Integer Value
Catastrophic	Death or serious irreversible injury	4
Significant	Reversible serious injury	3
Marginal	Marginal inconvenience	2
Negligible	-	1

5 Severity – Non-clinical hazards

Severity	Meaning	Integer Value
Catastrophic	The system is unavailable OR Patient data is accessible without user authorization	4
Significant	The system is partly available or a work around is required OR Patient data can be accessible without user authorization in specific cases	3
Marginal	System is available with minor inconvenience in general use	2
Negligible	The system is available with minor inconvenience in very specific cases	1

6 Hazard Index

The following table shows the risk index, calculated from the multiply of the severity and the probability factors. The colors indicate the different acceptance criteria that follow according the table "Hazard Risk Index".

	Catastrophic (4)	Significant (3)	Marginal (2)	Negligible (1)
Frequent (5)	20	15	10	5
Probable (4)	16	12	8	4
Occasional (3)	12	9	6	3
Remote (2)	8	6	4	2
Improbable (1)	4	3	2	1

Hazard Index	Acceptance Criteria
1-5	Acceptable without review
6-9	Acceptable upon completion of quality assurance review
10-15	Undesirable: Written and reviewed decision required to proceed
16-20	Unacceptable

7 Hazard actions

Risk Action	Description
Design	Change product design to reduce probability or severity of risk
Protective measures	Apply design controls to reduce probability or severity of risk
Labels	Warn the user through screen or manual alerts

8 Hazard categories

The following hazard outcome categories are defined for further analysis.

Outcome (harm done)	Hazards (causes harm)
Mixing up documents from different patients	Source system used wrong Patient ID
	PIX lookup failed
	PIX lookup returns wrong PID
	Merging patient records
	Create new patient based on incorrect HL7 ADT message
	Patient ID and patient demographics differ from existing patient in registry
	Receiving images from multiple patients over a single DICOM association
Incorrect document displayed	Previous version of documents still in cache
	Old document in repository still contains "old" patient details
	External repository serves up wrong document
	WADO proxy serves up wrong document
	Invalid configuration for custom actions in viewer
Documents incorrectly displayed	Rendering pipeline error
	Wrong style sheet applied
	Error while displaying current document
	Wrong version of web browser used
	Document mime type incorrectly handled
Information corruption	Document submitted multiple times
	Document stored incorrectly in repository
Missed updates on documents	Source system change source data after document submission
	Same document received from different source
Loss of information	Database corruption
	File system corruption

	Hard disk failure
Unauthorized access to patient information	Session hijacking
	Sniffing communication to/from server
	SQL insertion
	User credential guess using automated logon script
	Unauthorized re-use of existing user session
	Unauthorized use of cached user credentials
	Use of unprotected web interface
System unavailable	Network failures
	Denial of Service attack
	System failures
	Disk full
Compromised patient privacy	Missing information in audit trail.
	A user may gain access information about types of exported imaging studies without explicit authorization.
	A user may expose information about a particular patient when exporting imaging studies.
	Document can be read by a wider audience, so more people can see patient information.
Unreachable information	Patient information that is not referenced in the registry
	Patient (meta) data that can only be set but not fetched
Unintended diagnostic use	Use of our DICOM viewer for measurements
	Medical interpretation of DICOM images

9 References

Reference Number	Document Title	Document ID
1	Hazard Management process	FOR-P-063

10 Document history

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01	Hoentjen, Wim	• Transferred document to HI Forcare QMS. transitionplan nbr 2019-03-05
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		• Updated flowchart to visio format

02	Bosman, Rogier	• Updated the outcome list

11 Review and Approval

Name Author	Function Author
Nieuwerth-van den Akker, Marielke	*Program / Release Manager*

Name Reviewer(s)	Function Reviewer(s)	Review Date(s) *DD-MMM-YYYY*	Signature(s)
Verwoert, Sven	*Manager Software Development*	29-Oct-2019	
Bosman, Rogier	*Product Owner*	29-Oct-2019	

Name Approver(s)	Function Approver(s)	Approval Date(s) *DD-MMM-YYYY*	Signature(s)
Cases-Villar, Marta	*Haed Q&R Forcare*	04-NOV-2019	
Hoentjen, Wim	*QMS Manager*	31 october 2019	
Nieuwerth-van den Akker, Marielke	*Program / Release Manager*	30 october 2019	

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