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Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems – Change Specification

Document Management

Reviewers

This document must be reviewed by the following people:

Reviewer name	Title / Responsibility	Date	Version
	NHS Digital Clinical Safety Group	02.05.2018	3.3

Approved by

This document must be approved by the following people:

Name	Title	Date	Version
Dr Manpreet Pujara	Clinical Director for Patient Safety	02.05.2018	3.2
Debbie Chinn	Director of Solution Assurance	02.05.2018	3.2
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Data Coordination Board

This information standard (DCB0160) has been approved for publication by the Department of Health and Social Care under section 250 of the Health and Social Care Act 2012.

Assurance that this information standard meets the requirements of the Act and is appropriate for the use specified in the specification document has been provided by the Data Coordination Board (DCB), a sub-group of the Digital Delivery Board.

This information standard comprises the following documents:

- Requirements Specification
- Implementation Guidance
- Change Specification.

An Information Standards Notice (DCB0160 Amd 25/2018) has been issued as a notification of use and implementation timescales. Please read this alongside the documents for the standard.

The controlled versions of these documents can be found on the NHS Digital website. Any copies held outside of that area, in whatever format (e.g. paper, email attachment), are considered to have passed out of control and should be checked for currency and validity.

Date of publication: 7 June 2018

Contents

1 Purpose

To inform those who have already implemented the standard what the changes are and how to implement those changes.

2 Description

This change focuses on aligning NHS Digital Clinical Safety standards with the new medical devices regulations for standalone software. The change provides clarity and removes uncertainty among users and developers with regard to the registration of software as a medical device and compliance with this standard. The evidence of this statement comes from academic and industry advisors, and recent experiences with devices in use that are decision making or supporting and integrated into unregulated software.

The new Medical Devices Regulation[1] was published by the European Commission in May 2017. A brief of it is:

- Software is specifically identified as a type of medical device. This will broaden the number of software solutions that are a medical device.
- Classification now includes risk as a component, in line with the NHS Digital Clinical Safety standards. This is important to note.
- The regulation includes additional essential requirements in the fields of:
    - IT environment
    - Interoperability
    - Cybersecurity
    - Mobile platforms
    - IT network and IT security.

This change in scope of the clinical risk management of health IT within the NHS Digital Clinical Safety standards provides a means of asserting compliance with this standard for the design, build, deployment and maintenance of software in conformance to a “harmonised” manner and in line with the medical devices regulations. A harmonised standard is a European standard developed by a recognised European Standards Organisation following a request from the European Commission.

Implementation Completion Date is 01/07/2018

[1] https://eur-lex.europa.eu/eli/reg/2017/745/oj

3 Future Consultation and Maintenance

In line with the approval by NHS Digital leadership teams to proceed with this change request and the endorsement of MHRA; the clinical safety team in NHS Digital are leading on the rewrite of ISO standards for clinical risk management of medical device software. The team will be monitoring implementation effectiveness within 6 months of publication and periodically as part of the quality function of this standard.