

# Data Coordination Board

## Information Standards Notice – Change

Acting under delegated authority from the Secretary of State for Health and Social Care, the Data Coordination Board (DCB) has approved a change to an existing information standard for publication under section 250 of the Health and Social Care Act 2012.

You must comply with the change to this standard by the full conformance date specified below.

Standard details	
DCB unique identifier	DCB0129 Amd 24/2018
Name	Clinical Risk Management: its Application in the Manufacture of Health IT Systems, 2018 Update
Approval date	29 May 2018
Publication date	7 June 2018
Standard definition	
Description	<p>This information standard provides a set of requirements suitably structured to promote and ensure the effective application of clinical risk management by those organisations that are responsible for the development and maintenance of Health IT Systems for use within the health and care environment.</p> <p>The standard forms part of the NHS Digital Clinical Safety Standards; it is accompanied by the related standard for the application of clinical risk management in the deployment and use of Health IT Systems (<a href="#">DCB0160</a>).</p>
About this change	<p>Following the publication of the Medical Devices Regulation (<a href="#">EU 2017/745</a>) in May 2017 and evidence of the need for clinical risk assessment of medical devices using software, a decision has been made to extend the scope of the standard to now include medical devices.</p> <p>Previously medical devices have been excluded from the scope of the Clinical Safety Standards.</p>
Scope (Health and Social Care Act 2012)	Health Services, NHS Services, Adult Social Care
Impacts upon	This Notice is addressed to Manufacturer personnel who are responsible for ensuring clinical safety in the development and modification of Health IT Systems through the application of clinical risk management.
Legal authority	This information standard is published under section 250 of the Health and Social Care Act 2012.
Link to further documentation	The Change Specification, Requirements Specification and Implementation Guidance are available on the NHS Digital website: <a href="http://www.digital.nhs.uk/isce/publication/dcb0129">www.digital.nhs.uk/isce/publication/dcb0129</a>

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Dates	
Implementation dates	1 July 2018
Post Implementation Review date	31 December 2018

The controlled version of this Information Standards Notice is published on the NHS Digital website: <http://www.digital.nhs.uk/isce/publication/isns>