

## Information Standards Notice – Conversion

Following recommendation by the Standardisation Committee for Care Information (SCCI), NHS England has provided authority to publish the following information standard under section 250 of the Health and Social Care Act 2012.

This information standard was formerly approved by the Information Standards Board for Health and Social Care (ISB).

Standard details	
SCCI unique identifier	SCCI0129 Amd 39/2012
Name	Clinical Risk Management: its Application in the Manufacture of Health IT Systems
Acceptance date	13 April 2016
Approval date	26 April 2016
Publication date	05 May 2016
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 includes implementation guidance and is supported by the related standard for the application of clinical risk management in the deployment and use of Health IT Systems (<a href="#">SCCI0160</a>).</p> <p>Version 2.0 of this information standard was approved by ISB in February 2013. In April 2014, SCCI replaced ISB; it makes recommendation to the Department of Health and / or NHS England on the publication of information standards. In this instance, SCCI has worked with the developer to assure that this information standard is fit to be published under section 250 of the Health and Social Care Act 2012 without making changes to the content of the information standard.</p> <p>Note that Version 2.0 has been updated to Version 4.0 to align with the developer's configuration management.</p>
Scope (Health and Social Care Act 2012)	NHS Services
Applies to	<p>This information standard 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.</p> <p>It applies to those Health IT Systems that are not controlled by medical device regulations, though the requirements defined in this standard are broadly consistent with the requirements of ISO 14971.</p>

Legal authority	This information standard is published under section 250 of the Health and Social Care Act 2012.
Link to further documentation	The specification and implementation guidance documents are available on the HSCIC SCCI website: <a href="http://www.hscic.gov.uk/isce/publication/scci0129">www.hscic.gov.uk/isce/publication/scci0129</a>
<b>Contacts</b>	
Sponsor	Rob Shaw, Director of Operations & Assurance Services, Health and Social Care Information Centre
SRO	Rob Shaw, Director of Operations & Assurance Services, Health and Social Care Information Centre
Business Lead	Sean White, Senior Safety Engineer, Health and Social Care Information Centre
Help Desk	<a href="mailto:enquiries@hscic.gov.uk">enquiries@hscic.gov.uk</a>
<b>Dates</b>	
Full conformance date	Conformance with this information standard was due by 30 June 2013. This Notice does not extend this conformance date.
Post Implementation Review date	31 March 2017

The controlled version of this Information Standards Notice is available on the HSCIC website: [www.hscic.gov.uk/isce/publication/isn](http://www.hscic.gov.uk/isce/publication/isn)