



Position Statement

Subject: Advisory Statement on "legacy debt" for Healthcare Organisations

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The NHS Information Standard DCB0160 has been in existence in one form or another since 2012 and is legislated under section 250 of the Health and Social Care Act (2012). DCB0160 provides a set of requirements to promote and ensure the effective application of clinical risk management by health organisations that are responsible for the deployment, use, maintenance or decommissioning of Health IT Systems within the health and care environment. It is evident that, historically, DCB0160 has at times received limited consideration for software within its scope, although in recent years the standard is being applied more rigorously for new products. The result is that a lot of NHS Trusts will have what is referred to as "legacy debt" of DCB0160 risk assurance, having produced no hazard logs and safety case reports for historical software that has been in their Trust for a number of years.

The issue of tackling "legacy debt" is compounded by the fact that digital growth has been exponential in the last few years and Clinical Safety Officers (CSOs) sometimes finite resources have been used to concentrate on these new systems. The result is that the legacy debt never gets tackled and there will always be an amount of clinical software within NHS Trusts that has had no risk assurance.

NHS England does not give any specific advice within the DCB0160 standard or implementation guidance on legacy debt but the following statements within DCB0160 can be used to offer some advice:

 "The extent of clinical risk management needs only to be commensurate with the scale, complexity and level of clinical risk associated with the deployment" -DCB0160 The first tasks that a Trust is able to do today is assess the size of their legacy debt and perform an exercise to identify each system and prioritise these in order of urgency, based on the clinical risk of that product.

To that end, stable, long term clinical software that has been in a Trust for a number of years without any previous issue or clinical risk assurance, the scale of clinical risk is likely lower. Therefore, the Trust could make an informed decision to produce only a focussed hazard log for this product, focussing on key aspects of the software that had the potential to cause harm to a patient.

The second important line in the DCB0160 standard is shown below:

 Top management must make available sufficient resources for clinical risk management – DCB0160

If a Trust identifies they have a number of legacy products with no DCB0160 risk assurance then this needs highlighted to "top management"; likely in the form of an entry on a Risk Register. This should then necessitate a plan for top management to ensure CSOs are wellresourced in their role and able to provide support to new products and also legacy debt. If the role of a CSO cannot be resourced adequately then this risk sits with "top management" rectify, not with the CSO performing the role of risk to assurance.

References: <u>DCB0160</u>: Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems - NHS England Digital