

# Safety Standards for Safer Systems

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# NHS Safety Standards for Health IT

- Two standards approved through NHS Information Standards Board for Health and Social Care [NHS ISB]
- One for manufacturers and one for health organisations
- Based on the formal Clinical Safety Management System [CSMS] used in NHS Connecting for Health (NHS CFH) since 2005

## DSCN 14/2009

- Standard for manufacturers
- Based on development of a safety case from a structured hazard assessment
- Hazards need to be considered from perspective of the clinical context in which product will be used
- Hazards assessed, logged and those within the domain of the manufacturer are mitigated or designed out
- Downstream hazards formally passed on to healthcare organisation

# DSCN 18/2009

- Standard for healthcare organisations
- Organisations required at risk assess products with significant clinical impact and plan for safe implementation
- Organisations required to nominate 'suitably trained and qualified professional' who has clinical governance responsibility for implementation

## **Blood Glucose Telehealth Scenario**

- Blood glucose monitoring in the home
- Results collected and transferred electronically to family physician

## Components Involved

- Existing medical device – glucose meter
- Home PC
- Results collection package interfacing with glucose meter
- Home hub and domestic broadband connection
- Firewall and router at family practice
- Results display and altering package

## Specific Regulatory Issues

- Which components are medical devices?
- Which software is medical software?
- Which supplier classifies which component?
- Is end to end system a 'medical network' under IEC8000-2?
- How are COTS components dealt with?
- What are responsibilities of healthcare organisation under DSCN 18/2009? [NHS]

## General Regulatory Issues

- Aim should be for proportionate and effective regulation
- Telehealth will operate where there are interfaces between home and multiple healthcare settings
- Needs to be clear ownership of safety responsibilities
- Is IEC8000-2 the answer?





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# Thank You

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