This is a free page sample. Access the full version online.

NSAI Standards

Standard Recommendation
S.R. CEN/TR 15640:2007

Health informatics - Measures for ensuring the patient safety of health software

© NSAI 2007 No copying without NSAI permission except as permitted by copyright law.

This is a free page sample. Access the full version online.

S.R. CEN/TR 15640:2007

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces:	*This document is based on:* CEN/TR 15640:2007	*Published:* 8 August, 2007

This document was published under the authority of the NSAI and comes into effect on: 21 May, 2011	ICS number: 35.240.80

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W **NSAI.ie**

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

This is a free page sample. Access the full version online.

TECHNICAL REPORT

RAPPORT TECHNIQUE

TECHNISCHER BERICHT

CEN/TR 15640

August 2007

ICS 35.240.80

English Version

Health informatics - Measures for ensuring the patient safety of health software

Informatique de Santé - Mesures pour assurer la sécurité du patient vis à vis des logiciels de santé

Informatik im Gesundheitswesen - Sicherstellung der Patientensicherheit bei der Nutzung von Gesundheitsinformatikprodukten

This Technical Report was approved by CEN on 16 July 2007. It has been drawn up by the Technical Committee CEN/TC 251.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

© 2007 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. CEN/TR 15640:2007: E

This is a free page sample. Access the full version online.

Contents

Page

Foreword 3

Introduction 4

1 Scope 6

2 Terms and definitions 6

3 Symbols and abbreviations 7

4 Outline of the issues 8

5 General position on medical device controls 9

6 The border between health software products and medical devices 10

7 Classifying health software products 10
7.1 Options 10
7.2 Conclusions 11

8 Options for control measures for health software products 11
8.1 General 11
8.2 Labelling and documentation 12
8.3 Clinical evidence 12
8.4 Incident reporting 13
8.5 Quality Systems 13
8.6 Design control 15
8.7 Risk management 16

9 Standards specific to risks of a particular nature 17
9.1 Conclusions 17

10 Observation on safety and risks in the user domain 17
10.1 Conclusions 17

11 Taxonomies 17
11.1 Conclusions 17

12 Summary of conclusions 18

Annex A (informative) **Position regarding medical devices in different countries** 20
A.1 The EU, Australia and Canada 20
A.2 USA 21
A.3 The Global Harmonization Task Force (GHTF) 22

Annex B (informative) **Analysis of classification procedures** 24
B.1 EU, Australian, Canadian and GHTF Medical Device Classification 24
B.2 USA Medical Device Classification 25
B.3 USA FDA guidance related to software classification 25
B.4 CEN classification of health software products 26
B.5 Conclusions 29

Annex C (informative) **Risk management** 30
C.1 Attributes necessary for successful uptake of risk management processes 30
C.2 Minimum components for an effective risk management process 30
C.3 'Enterprise risk management' processes 31
C.4 'Healthcare related' risk management standards 34
C.5 Related risk management standards 36
C.6 Overall conclusions regarding risk management standards 39

Bibliography 41

This is a free page sample. Access the full version online.

Foreword

This document (CEN/TR 15640:2007) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by NEN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This is a free page sample. Access the full version online.

Introduction

The threat to patient safety

In the past health-related software was primarily applied to relatively non-critical administrative functions where the potential for harm to the patient, as distinct from disruption to the organisation, was low. Clinical systems were generally unsophisticated often with a large administrative, rather than clinical, content and little in the way of decision support. Even clinical decision support systems tended to be ‘light touch’, relatively simple and understandable in their logic and used as a background adjunct to decisions, rather than a major influence on which to rely routinely. This has changed and will continue to change substantially. The nature of these changes will increase the potential for risks to patients.

There have been some high profile adverse incidents related to clinical software e.g. in the area of screening and patient call and/or recall where software malfunctions have resulted in failure to ‘call’ ‘at-risk’ patients. Such incidents have not only caused anguish for the patients concerned but may also have led to premature deaths. The trust of the general public has been severely affected. The scope for screening for diseases is increasing significantly and it is in such applications involving large numbers of subjects that there will be heavy reliance, administratively and clinically, on software to detect normals and abnormals and to ‘call’ or ‘process’ those deemed to be at-risk. Such software needs to be safe for purpose.

Chief Executives and others responsible for healthcare organisations need to recognise that:

— health software products have the potential to harm patients;

— this potential is growing as the complexity of implementations grow;

— healthcare organisations are increasingly reliant on health software products.

This means that, unless these risks are recognised and controlled, harm to patients may result with consequent damage to the reputation of a health organisation and substantial financial consequences in terms of legal damages.

There is mounting concern around the world about the substantial number of avoidable clinical incidents which have an adverse effect on patients of which a significant proportion result in avoidable death or serious disability [1] [2] [3] [4] [5] [6]. A number of such avoidable incidents involved poor or ‘wrong’ diagnoses or other decisions. A contributing factor is often missing or incomplete information or simply ignorance e.g. of clinical options in difficult circumstances or cross-reaction of treatments.

It is increasingly claimed that information systems such as decision support, protocols, guidelines and pathways could markedly reduce such adverse effects. If for no other reasons – and there are others – this will lead, and is leading, to increasing utilisation of decision support and disease management systems which inevitably will increase in sophistication and complexity. It can also be anticipated that, due to pressures on time and medico-legal aspects, clinicians will increasingly rely on such systems with less questioning of their ‘output’. Indeed, as such systems become integrated with medical care any failure to use standard support facilities may be criticised on legal grounds.

Increased decision support can be anticipated not only in clinical treatment but also in areas just as important to patient safety such as referral decision-making, where failure to make a ‘correct’ referral or to make one 'in time’ can have serious consequences.

Economic pressures are also leading to more decision support systems. The area of generic and/or economic prescribing is the most obvious, but economy in number and costs of clinical investigative tests is another.

This is a free page sample. Access the full version online.

Systems such as for decision support have considerable potential for reducing clinical errors and improving clinical practice. For example a large body of published evidence gives testimony to the reduction in errors and adverse incidents resulting from the deployment of electronic prescribing. However all such systems also carry the potential for harm. Harm can of course result from unquestioning and/or non-professional use albeit that designers and suppliers can mitigate such circumstances through, for example, instructions for use, training and on-screen presentation techniques, guidance or instruction. The potential for harm may equally lie in the system design such as:

— poor evidence base for design;

— failure in design logic to properly represent design intentions;

— failure in logic to represent good practice or evidence in the design phase;

— poor or confusing presentation of information or poor search facilities;

— failure to update in line with current knowledge.

Some of these system deficiencies are insidious and may be invisible to the user.

Failures and deficiencies in health software products can, of course, have adverse impacts other than causing harm to patients. They may, for example, create administrative inconvenience or even administrative chaos, with a range of impacts on the organisation including financial loss. Harm to a patient may also have a consequent impact on the organisation such as financial loss resulting from litigation. Whereas these adverse organisational impacts will be significant to an organisation they are not the subject of this document unless they result in harm to a patient. For example the failure of a hospitals central patient administration system will certainly cause substantial administrative inconvenience but that adverse impact is not in itself within the scope of this document unless it has the potential to cause harm to a patient (which is possible). It is the potential harm to the patient which is the subject of this document.

Controlling the risks

The safety of medicines and of medical devices is ensured in many countries through a variety of legal and administrative measures. In the European Union it is subject to several EU directives [7] [8] [9]. These measures are often backed by a range of safety related standards from a number of sources, both national and international, including the European Standards Organisation (CEN), the International Standards Organisation (ISO) and the International Electrotechnical Committee (IEC). Some software such as that necessary for the proper application or functioning of a medical device is often encompassed by these legislative controls. However other software applied to health of a stand-alone nature is not usually covered or is encompassed in a less than clear manner. This document is concerned with software applied to health excluding that which is encompassed by medical device controls.

A necessary precursor for determining and implementing appropriate design and production controls to minimise risks to patients from product malfunction or inadequate performance, is a clear understanding of the hazards which a product might present to patients if malfunction or an unintended event should occur, and the likelihood of such a malfunction or event causing harm to the patient. Additionally if guidance is to be given to designers and producers of health software products as to design and production control (and corresponding standards produced) then it will need to be recognised that the controls necessary for products presenting low risks will not be the same as for those presenting high risks. Controls need to match the level of risk which a product might present to a patient. For these purposes many standards, legislation and specifications dealing with control of risks in design and production, group products in to a limited number of classes or types according to the risk they might present. Controls are then tailored to the class or type. This document follows that philosophy.

There is a wide range of controls which might be exerted on the design, development, production, distribution, installation, up-grading/version control/up-dating of a health software product etc. This document starts with considering how those controls are applied to medical devices and offers practical solutions how to adapt them to health software products.”

This is a free page sample. Access the full version online.

1 Scope

This document considers the control measures required to ensure patient safety in respect to health software products. It does not apply to software which is:

— necessary for the proper application of a medical device or

— which is an accessory to a medical device or

— which is a medical device in its own right.

The document is aimed at identifying what standards might best be used or created, and their nature, if health software products were to be regulated or controlled in some other formal or informal or voluntary manner whether national, regional or local. However it is not the purpose of this document to recommend whether or not health software products should be regulated.

This document applies to any health software product whether or not it is placed on the market and whether or not it is for sale or free of charge. It is addressed to manufacturers of health software products.

NOTE The scope is intended to cover health software products which are not, in practice, covered by medical device regulations. Annex A considers this matter in detail. This TR acknowledges that, on the boundary, there are health software products which are encompassed by medical device regulations in some countries but not in others and that some definitions of medical devices may appear to cover health software products in general but in practice do not.

2 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

2.1
harm
death, physical injury and/or damage to health or well being of a patient

[ISO/IEC Guide 51:1999 modified] [65]

2.2
hazard
potential source of harm

[ISO/IEC Guide 51:1999] [10]

2.3
health software product
software product for use in the health sector for health related purposes but excluding software which is:

— necessary for the proper application of a medical device or

— is an accessory to a medical device or

— is a medical device in its own right.

NOTE For the purposes of this standard software includes firmware.

2.4
Manufacturer
natural or legal person with responsibility for the design, manufacture, packaging or labelling of a health software product, assembling a system, or adapting a health software product before it is placed on the

SAI GLOBAL

This is a free preview. Purchase the entire publication at the link below:

Product Page

Looking for additional Standards? Visit Intertek Inform Infostore

Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation