

Health informatics standards — Status as of July 2001 — Guide

ICS 35.240.80

Confirmed November 2008

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee IST/35, Health informatics, upon which the following bodies were represented:

- AMS Consulting
- Association of Anaesthetists of GB and Ireland
- BCS — British Computer Society
- BCS — Nursing Specialist Group
- BMA — British Medical Association
- BMA — IT Committee
- BUPA
- British Institute of Radiology
- British Nuclear Medicine Society
- CAT Limited
- Computing Services and Software Association
- Conference of Royal Colleges Information
- DTI
- Health Systems Co-ordination
- ISSD
- Institute of Medical Laboratory Science
- Intellect
- NHS Executive
- Nine Tiles
- Nottingham City Hospital NHS Trust
- Royal College of Radiologists
- Royal Hospital for Sick Children
- Royal Pharmaceutical Society of GB
- Society for Computing and Technology in Anaesthesia
- University of Anaesthesia

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 28 November 2003

© BSI 28 November 2003

Amendments issued since publication

Amd. No.	Date	Comments

The following BSI references relate to the work on this British Standard
Committee reference IST/35
Draft for comment 02/653351 DC

ISBN 0 580 42772 2

Contents

	Page
Committees responsible	Inside front cover
Foreword	ii
1 Scope	1
2 Terms definitions, acronyms and abbreviations	1
3 How standards are developed	3
4 Application areas	5
5 Healthcare informatics standards	10
Annex A International Organization for Standardization (ISO)	43
Annex B Joint Technical Committee One (JTC1)	44
Annex C Comité Européen de Normalisation (CEN)	45
Annex D (informative) National Standards Bodies	46
Annex E (informative) Consortia and Professional Bodies	46
Annex F (informative) Other Standardization Bodies	48
Bibliography	49
Table 1 — General healthcare	5
Table 2 — System architecture	5
Table 3 — Vocabulary, terminology and coding schemes	6
Table 4 — Security	6
Table 5 — Patient administration and electronic records	6
Table 6 — Diagnostic services	7
Table 7 — Pharmacy	7
Table 8 — Medical imaging and multimedia	7
Table 9 — Medical devices	7
Table 10 — Patient/health cards	8
Table 11 — Standards for standards developers	8
Table 12 — Superseded standards	9
Table 13 — PMEP specifications	41

Foreword

This British Standard Guide has been prepared by Technical Committee IST/35.

Since the end of the 1980s there has been considerable activity in the health informatics sector resulting in the publication of a large number of standards. These standards have been produced by a variety of formal standards bodies, covering a single country (e.g. BSI, ANSI), a region (CEN) or globally (ISO). In addition to these formal standards various industry consortia, professional bodies and similar organizations, e.g. DICOM (ACR/NEMA), HL7, ASTM and IEEE have issued informal standards. Additionally, many formal standards bodies have introduced a less formal standard, known as Industry Workshop Agreements or International Technical Agreements.

The scope of this guide is limited to those standards and publications approved by 9 July 2001.

This British Standard Guide details the most important health informatics standards and equivalent publications relevant to the UK and explains how they relate to each other.

There are a number of ways of using this Guide depending on the readers' knowledge and understanding of standards, and what they wish to discover. The most common scenarios are.

— **I have seen a reference to a standard and wish to find out more**

— If it is an ISO standard, e.g. ISO/IEC 12345, find the ISO entry in the list in Clause 5, and look in the appropriate sub-section. Where standards are numbered, each section is in ascending order.

— **I am working in a particular area of healthcare (e.g. electronic healthcare records) and wish to find out which standards are relevant**

— Find your field of interest in Clause 4, then look in the tables in the appropriate subsection. For instance, if your interest is in the communication of electronic patient records, find the appropriate area listed in Clause 4, i.e. "Patient administration and electronic records". Then follow the reference to the appropriate table (Table 1) and find one or more standards concerning communication of electronic records (i.e. ENV 13606). Then look up this standard in Clause 5 to find further information on that standard.

— **I am interested in standards concerning a particular subject, e.g. EDIFACT messages**

— Look up the subject in the index in Clause 4. Then either check the master reference to Clause 4 and follow the scenario above, or check the references to individual standards in Clause 5.

— **I wish to find out more about who creates standards and why**

— Read the annexes.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 51 and a back cover.

The BSI copyright notice displayed in this document indicates when the document was last issued.

1 Scope

This British Standard gives guidance on the most important health informatics standards (and equivalent publications) in use in, or appropriate for use in, the UK. The scope of this guide is limited to those standards and publications approved by 9 July 2001.

It deals only with standards (either approved or in course of development) developed specifically for use in healthcare. For example, even though lower-layer communications standards are widely used in health, their use is more or less exactly the same as in fields other than health, and they are therefore omitted. Conversely, where a standard has been developed specifically for use in healthcare – even though the standard is of more general applicability – it has been included.

This Guide is intended to be of use to:

- procurers of systems incorporating health informatics standards;
- implementers of such systems;
- suppliers of such systems;
- those responsible for selecting and approving health informatics standards, e.g. NHS Information Standards Boards.

It is also intended to be of use to:

- standards developers;
- policy makers;
- consultants;
- those with an interest in the development of health informatics standards.

2 Terms definitions, acronyms and abbreviations

2.1 Terms and definitions

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

2.1.1

health informatics

application of information technology to healthcare

2.1.2

publicly available specification (PAS)

standard not produced by a formal standards body

NOTE Formal standards bodies, e.g. ISO, might publish PAS's with a view to their becoming formal standards in due course.

2.1.3

laboratory information system (LIS)

computer system for the processing results of tests performed in a hospital or other clinical laboratory

2.1.4

profile

subset of a standard defined for particular purpose

2.2 Acronyms and abbreviations

For the purposes of this guide, the following acronyms and abbreviations apply.

ACR	American College of Radiologists
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
BS	British Standard
BSI	British Standards Institution
CAP	College of American Pathologists
CDA	Clinical Document Architecture
CDS	Commissioning Data Set
CEN	Comité Européen de Normalisation (Europäisches Komitee für Normung/European Committee for Standardization)
CENELEC	Comité Européen de Normalisation Electrotechnique (Europäisches Komitee für Elektrotechnische Normung/European Committee for Electrotechnical Standardization)
CPP	Communication Protection Profile
CR	CEN Report
CWA	CEN Workshop Agreement
DICOM	Digital Imaging and Communications in Medicine
DISP	Draft International Standardized Profile
DTR	Draft Technical Report
EDI	Electronic Data Interchange
EDIFACT	Electronic Data Interchange for Administration, Commerce and Transport
e-GIF	e-Government Interoperability Framework
EHR	Electronic Health Record
EN	Européenne Norme (European Standard/Europäische Norm)
ENV	Européenne Normes Voraussage (European Pre-standard)
EPR	Electronic Patient Record
ETG	EWOS Technical Guide
EWOS	European Workshop for Open Systems
FTP	File Transfer Protocol
GP	General Practitioner
HDF	HL7 Message Development Framework
HIF	Healthcare Information Framework
HIS	Hospital Information System
HL7	Health Level 7
ICD	Intermittently Connected Device
IEC	International Electrotechnical Commission
IEEE	The Institute of Electrical and Electronics Engineers
IETF	Internet Engineering Task Force
ISO	International Organization for Standardization
ISSS	Information Society Standardization System
ITA	Industry Technical Agreement
ITU	International Telecommunications Union
IWA	International Workshop Agreement
JTC1	Joint Technical Committee 1
LIS	Laboratory Information System

LOINC	Logical Observation Identifiers Names and Codes
MIVOC	Medical Informatics Vocabulary
NEMA	National Electronic Manufacturers' Association
NWCS	NHS-wide Clearing Service
OSI	Open Systems Interconnection
PACS	Picture Archiving and Communication System
PAS	Publicly Available Specification
PKI	Public Key Infrastructure
QoS	Quality of Service
RFC	Request for Comment
RIS	Radiology Information System
SNOMED	Systemized Nomenclature of Medicine
SNOMED CTSNOMED	Clinical Terms
SNOMED RTSNOMED	Reference Terminology
TC	Technical Committee
TF	Task Force
TR	Technical Report
TS	Technical Specification
UML	Unified Modelling Language
WD	Working Draft
WG	Working Groups
WI	Work Item

3 How standards are developed

3.1 Overview

Many organizations produce standards. These can be divided into a number of broad groups:

- formal standards bodies (see 3.2);
- consortia and professional bodies (see 3.3);
- other standardization bodies (including national health services) (see 3.4).

3.2 Formal standards bodies

3.2.1 General

Formal standards bodies are set up by national or international agreement.

Neither national standards bodies nor international or European standards organizations have the legal authority to make the use of their standards mandatory. Although a specification takes the form of requirements, a legally binding obligation to comply is only created if conformity to it:

- a) is claimed in the trade description of a product, process or service;
- b) becomes a contractual requirement;
- c) is made mandatory by law or regulation.

For example, the use of European standards (EN's) may be mandatory in public sector procurements within the European Union. Formal bodies fall into three main categories:

- international (see 3.2.2);
- regional (see 3.2.3);
- national (see 3.2.4).

3.2.2 International standards bodies

There are three principal international standards bodies:

- the International Telecommunications Union (ITU);
- the International Organization for Standardization (ISO);
- the International Electrotechnical Commission (IEC).

The ITU is principally produces telecommunications and associated standards. Though these can be used in healthcare, none are healthcare specific and hence no further information on ITU is included in this standard.

ISO (see Annex A) is responsible for the production of a number of healthcare standards. There is also a joint ISO/IEC committee (JTC1) (see Annex B), which, mainly for historical reasons, is responsible for a number of healthcare standards.

The IEC produces electrotechnical standards (e.g. electrical safety) and, while these are relevant to healthcare, none are healthcare specific and hence no further information on IEC is included in this standard.

3.2.3 Regional standards bodies

CEN is the principal regional standards body (see Annex C). The vast majority of standards produced for healthcare in Europe to date are European Pre-Standards (ENV's) rather than EN's. Unlike EN's, ENV's need not be mandated in procurement.

3.2.4 National standards bodies (NSB)

Many national standards bodies publish their own local healthcare informatics standards. National standards can be used or adopted by other countries if they are particularly useful. Further information on national standards bodies is given in Annex D.

3.3 Consortia and professional bodies

A number of professional bodies produce standards within their own field of expertise. Similarly, consortia can be formed to produce standards where there is a particular need. These standards have no significance unless adopted by a formal standards body – as many are – but can in appropriate circumstances be specified in procurement. Details of relevant health informatics consortia and professional bodies are given in Annex E.

3.4 Other standardization bodies

In theory, any type of organization can produce a standard and enforce its use, provided it does not conflict with a standard that has legal significance. In practice this is done mainly where the organization has specific standards, e.g. data items or message structures. Details of other standardization bodies relevant to health informatics can be found in Annex F.

4 Application areas

Clause 4 details which standards have been published for use in specific areas of healthcare. The areas are:

- *General healthcare*: Standards for general use across the healthcare domain (see Table 1);
- *System architecture*: Standards concerning the design of healthcare IT systems (see Table 2);
- *Vocabulary, terminology and coding schemes*: Standards defining/describing the use of healthcare vocabularies terms lists or coding schemes (see Table 3);
- *Security*: Standards concerned with security of healthcare systems and information (see Table 4);
- *Patient administration and electronic records*: Standards used for exchanging administrative information and electronic healthcare records (see Table 5);
- *Diagnostic services*: Standards for use within or in conjunction with the major healthcare disciplines designed to produce data to aid healthcare professionals in the diagnosis and management of clinical conditions, e.g. pathology, blood transfusion, radiology (except imaging functions) (see Table 6);
- *Pharmacy*: Standards for use within or in conjunction with hospital or community pharmacy departments (see Table 7);
- *Medical imaging and multimedia*: Standards for use within or in conjunction with healthcare imaging departments (see Table 8);
- *Medical devices*: Standards for use in conjunction with medical devices, e.g. vital signs monitors (see Table 9);
- *Patient/health cards*: Standards for use on or in conjunction with patient cards and health cards (see Table 10);
- *Standards for standards developers*: Standards intended to be used in the production of healthcare standards rather than in healthcare systems (see Table 11);
- *Superseded standards*: Standards no longer used (see Table 12).

NOTE This section is not intended to be a definitive list of all aspects of healthcare but to provide a convenient way of finding standards in a particular area of healthcare.

Table 1 — General healthcare

Document identifier	Document title	Clause
ENV 12435:1999	<i>Expression of results of measurements in health sciences</i>	5.2.2.20
HL7 Version 2	<i>HL7 Version 2</i>	5.3.1.1
HL7 Version 3	<i>HL7 Version 3</i>	5.3.1.2

Table 2 — System architecture

Document identifier	Document title	Clause
ENV 12967	<i>Healthcare Information System Architecture (HISA)</i>	5.2.2.33

Table 3 — Vocabulary, terminology and coding schemes

Document identifier	Document title	Clause
ISO DTS 17117	<i>Controlled health vocabularies — Vocabulary structure and high-level indicators</i>	5.2.1.6
ISO WD 18104:2001	<i>Integration of a reference terminology model for nursing</i>	5.2.1.8
ENV 1828:1995	<i>Structure for classification and coding of surgical procedures</i>	5.2.2.7
ENV 13940:2000	<i>System of concepts to support continuity of care</i>	5.2.2.47
NHS Data Dictionary and Manual	<i>NHS Data Dictionary and Manual version 1.2</i>	5.4.1.1
NHS Commissioning Dataset Manual	<i>NHS Commissioning Dataset Manual version 1.4</i>	5.4.1.2
Clinical Terms (The Read Codes)	<i>Clinical Terms (The Read Codes) version 3</i>	5.4.1.3
SNOMED RT	<i>SNOMED Reference Terminology</i>	5.4.2.1
SNOMED CT	<i>SNOMED Clinical Terms</i>	5.4.2.2
The LOINC Database	<i>Logical Observation Identifiers Names and Codes (LOINC)</i>	5.4.3

Table 4 — Security

Document identifier	Document title	Clause
ISO WD 17090	<i>Public Key Infrastructure</i>	5.2.1.4
ENV 12251:2000	<i>Secure user identification for healthcare: management and security of passwords</i>	5.2.2.15
ENV 13608	<i>Security for healthcare communication</i>	5.2.2.37
ENV 13729:1999	<i>Secure user identification for healthcare — Strong authentication using microprocessor cards</i>	5.2.2.41
CR 13694:1999	<i>Safety and security related software quality standards for healthcare (SSQS)</i>	5.2.2.39

Table 5 — Patient administration and electronic records

Document identifier	Document title	Clause
ENV 12538:1997	<i>Messages for patient referral and discharge</i>	5.2.2.23
ENV 13606	<i>Electronic healthcare record communication</i>	5.2.2.35
ENV 12612:1997	<i>Messages for the exchange of healthcare administrative information</i>	5.2.2.28
HL7 Version 2	<i>HL7 Version 2</i>	5.3.1.1
HL7 Version 3	<i>HL7 Version 3</i>	5.3.1.2
HL7 CDA - I	<i>The Clinical Document Architecture — Release I</i>	5.3.1.3

Table 6 — Diagnostic services

Document identifier	Document title	Clause
ISO DIS 18812:2001	<i>Clinical Analyser Interfaces to Laboratory Information Systems — Use Profiles</i>	5.2.1.11
ENV 1613:1995	<i>Messages for exchange of laboratory information</i>	5.2.2.5
ENV 1614:1995	<i>Structure for nomenclature, classification and coding of properties in clinical laboratory sciences</i>	5.2.2.6
ENV 12435:1999	<i>Expression of results of measurements in health sciences</i>	5.2.2.20
ENV 12539:1997	<i>Request and report messages for diagnostic service departments</i>	5.2.2.24
ENV 13609	<i>Messages for maintenance of supporting information in healthcare systems</i>	5.2.2.38
ENV 13728:1999	<i>Clinical analyser interfaces to laboratory information systems</i>	5.2.2.40
ENV 13730	<i>Blood transfusion related messages</i>	5.2.2.42
ASTM E1394-97	<i>Standard Specification for Transferring Information between Clinical Instruments and Computer Systems</i>	5.2.6.1
HL7 Version 2	<i>HL7 Messaging Standard Version 2</i>	5.3.1.1
HL7 Version 3	<i>HL7 Messaging Standard Version 3</i>	5.3.1.2
NHS Requirements for Pathology Messaging	<i>NHS Requirements for Pathology Messaging v1.002, July 2000</i>	5.4.1.4

Table 7 — Pharmacy

Document identifier	Document title	Clause
ENV 13607:1999	<i>Messages for the exchange of information on medicine prescriptions</i>	5.2.2.36
HL7 Version 2	<i>HL7 Messaging Standard Version 2</i>	5.3.1.1
HL7 Version 3	<i>HL7 Messaging Standard Version 3</i>	5.3.1.2

Table 8 — Medical imaging and multimedia

Document identifier	Document title	Clause
ENV 12052:2002	<i>Health Informatics — Digital Images — Communication, workflow and data management</i>	5.2.2.12
ETG 068	<i>Multimedia medical data interchange</i>	5.2.3.1
ACR/NEMA: The DICOM Standard	<i>Digital Imaging and Communications in Medicine (DICOM)</i>	5.3.2

Table 9 — Medical devices

Document identifier	Document title	Clause
ISO 11073	<i>Health informatics — Point-of-care medical device communications</i>	5.2.1.3
IEEE 1073	<i>Standard for Medical Device Communications — Overview and framework</i>	5.3.3.1
ENV 1064:1993	<i>Standard communications protocol — Computer-assisted electrocardiography</i>	5.2.2.1

Table 10 — Patient/health cards

Document identifier	Document title	Clause
ISO/IEC WD 20301:2001	<i>Health cards — General characteristics</i>	5.2.1.12
ISO/IEC WD 20302:2001	<i>Health cards — Numbering system and registration procedure for issuer identifiers</i>	5.2.1.13
ISO WD 21549	<i>Patient healthcard data</i>	5.2.1.14
ENV 1387:1996	<i>Machine readable cards — Health care applications — Cards: General characteristics</i>	5.2.2.4
ENV 1867:1997	<i>Machine readable cards — Health care applications — Numbering system and registration procedure for issuer identifiers</i>	5.2.2.8
ENV 12018:1997	<i>Identification, administrative and common clinical data structure for Intermittently Connected Devices used in healthcare (including machine readable cards)</i>	5.2.2.10

Table 11 — Standards for standards developers

Document identifier	Document title	Clause
ISO DIS 17113:2001	<i>Method for develop development of messages</i>	5.2.1.5
ISO DIS 17120	<i>Country identifier mechanism in healthcare</i>	5.2.1.7
ISO DTR 18307:2001	<i>Key characteristics for interoperability in messaging and communications standards</i>	5.2.1.9
ISO WD 18308:2001	<i>Functional requirements for the Electronic Health Record reference architecture</i>	5.2.1.10
ISO/IEC WDTS 21667:2001	<i>Health indicators: conceptual framework</i>	5.2.1.15
ENV 12017:1997	<i>Medical informatics vocabulary (MIVoc)</i>	5.2.2.9
ENV 12264:1997	<i>Categorical structures of systems of concepts — Model for representation of semantics</i>	5.2.2.16
ENV 12381:1996	<i>Time standards for healthcare specific problems</i>	5.2.2.18
ENV 12443:1999	<i>Medical informatics healthcare information framework (HIF)</i>	5.2.2.21
ENV 12537	<i>Registration of information objects used for EDI in healthcare</i>	5.2.2.22
CR 12587:1996	<i>Methodology for the development of healthcare messages</i>	5.2.2.25
ENV 12610:1997	<i>Medicinal product identification</i>	5.2.2.26
ENV 12611:1997	<i>Categorical structure of systems of concepts — Medical devices</i>	5.2.2.27
CR 14300:2001	<i>Interoperability of healthcare multimedia report systems</i>	5.2.2.45
CR 12161:1995	<i>A method for defining profiles for healthcare</i>	5.2.2.14

Table 12 — Superseded standards

Document identifier	Document title	Clause
ISO/IEC DISP 15127	<i>Information technology – International Standardized Profiles — MEDI-1n-C</i>	5.2.1.1
ISO/IEC ISP 15128	<i>Information technology – International Standardized Profiles — MEDI-2n-C</i>	5.2.1.2
ENV 1068:1993	<i>Healthcare information interchange — Registration of coding schemes</i>	5.2.2.2
CR 1350:1993	<i>Investigation of syntaxes for existing interchange formats to be used in healthcare</i>	5.2.2.3
ENV 12052:1997	<i>Medical Imaging Communication (MEDICOM)</i>	5.2.2.11
CR 12069:1995	<i>Profiles for medical image interchange</i>	5.2.2.13
ENV 12265:1995	<i>Electronic healthcare record architecture</i>	5.2.2.17
ENV 12388:1996	<i>Algorithm for digital signature services in health care</i>	5.2.2.19
ENV 12623:1997	<i>Media interchange in medical imaging communications (MI-MEDICOM)</i>	5.2.2.29
CR 12700:1997	<i>Supporting document to ENV 1613:1994 — Messages for exchange of laboratory information</i>	5.2.2.30
ENV 12922	<i>Medical image management</i>	5.2.2.31
ENV 12924:1997	<i>Security categorisation and protection for healthcare information systems</i>	5.2.2.32
CR 13058:1997	<i>Mapping between the models specified in ENV 12539:1997 and NEMA PS3 supplement 10</i>	5.2.2.34
ENV 13734:1999	<i>Vital signs information representation</i>	5.2.2.43
ENV 13735:1999	<i>Interoperability of patient connected medical devices</i>	5.2.2.44
ENV 13939:2000	<i>Medical data interchange: HIS/RIS-PACS and HIS/RIS — Modality interface</i>	5.2.2.46
ETG 075	<i>Quality of Service requirements for Healthcare Information Interchange</i>	5.2.3.2
IEEE 1157	<i>Draft Standard for Healthcare Data Interchange</i>	5.3.3.2

5 Healthcare informatics standards

5.1 Introduction

5.1.1 Summary

This clause gives information on the standards developed for use in the field of healthcare informatics. It is divided into the following subclauses:

- **5.2** Standards from official standard bodies
 - **5.2.1** ISO standards
 - **5.2.2** CEN standards
 - **5.2.3** EWOS standards
 - **5.2.4** British standards
 - **5.2.5** ANSI standards
 - **5.2.6** ASTM E31 standards
- **5.3** Standards from industry consortia and similar bodies
 - **5.3.1** HL7
 - **5.3.2** ACR/NEMA: the DICOM standard
 - **5.3.3** IEEE standards
- **5.4** Standards from healthcare organizations
 - **5.4.1** NHS standards
 - **5.4.2** College of American Pathologists (CA) standards
 - **5.4.3** The LOINC database

For each standard listed, the following information is given.

- A summary of the scope and purpose of standard.
- Implementation status – whether systems or software based on the standard are known to have been implemented in the UK or elsewhere.
- Relevance to healthcare in the UK.

And where applicable;

- Further information.

5.2 Standards from official standards bodies

5.2.1 ISO standards

General information on each standard can be found at the web sites listed in **A.4**. Where supplementary information is available for a particular standard, a reference is included under the entry for that standard.

5.2.1.1 ISO/IEC DISP 15127

5.2.1.1.1 Title

*Information technology — International Standardized Profiles — **MEDI-1n-C** — Medical image interchange profiles using the connection mode Transport Service – simple point-to-point image transfer — Part 1: **MEDI11-C (AFT11-C)** — File transfer of unstructured binary data*

5.2.1.1.2 Scope and purpose of standard

This is one of a series of OSI profiles based on the FTAM (File Transfer, Access and Management) standard ISO 8571:1988 and the FTAM profile ISO/IEC 10607 allowing the transfer of medical images from one location to another. This is the only published part of the standard and is a simplification of the profile ISO/IEC 10607-3:1995 permitting the transfer of unstructured (binary) files.

5.2.1.1.3 Implementation status

None, as far as is known.

5.2.1.1.4 *Relevance to healthcare in the UK*

Since the publication of this standard, the use of FTAM has largely been superseded by Internet File Transfer Protocol (FTP). Therefore the standard is now obsolescent and is no longer relevant to healthcare in the UK.

5.2.1.2 *ISO/IEC ISP 15128*

5.2.1.2.1 *Title*

Information technology — International Standardized Profiles — MEDI-2n-C — Medical image transfer — Part 1: MEDI222-C (AMH21-C, AMH22-C, AMH23-C, AMH24-C) — Interpersonal messaging — Externally defined body part

5.2.1.2.2 *Scope and purpose of standard*

This is one of a series of OSI profiles based on the FTAM (File Transfer, Access and Management) standard (ISO 8571:1988) and the FTAM profile ISO/IEC 10607 allowing the transfer of medical images from one location to one or more locations using store-and-forward messaging (email). This part (the only one to be published) allows the transfer of an arbitrary file.

5.2.1.2.3 *Implementation status*

None, as far as is known.

5.2.1.2.4 *Relevance to healthcare in the UK*

Since the publication of this standard, the use of FTAM has largely been superseded by the Internet FTP and so the standard is now obsolescent and is no longer of relevance to healthcare in the UK.

5.2.1.3 *ISO 11073*

5.2.1.3.1 *Title*

Health informatics — Point-of-care medical device communications

5.2.1.3.2 *Parts*

ISO DIS 11073-00000:2001	<i>Framework and overview;</i>
ISO DIS 11073-10101:2001	<i>Nomenclature;</i>
ISO DIS 11073-10201:2001	<i>Domain Information Model;</i>
ISO DIS 11073-10301:2001	<i>Device specialization — Infusion device;</i>
ISO DIS 11073-10303:2001	<i>Device specialization — Ventilator;</i>
ISO DIS 11073-20000:2001	<i>Application profiles — Framework and overview;</i>
ISO DIS 11073-20101:2001	<i>Application profiles — Base standard;</i>
ISO DIS 11073-20102:2001	<i>Application profiles — MIB elements;</i>
ISO DIS 11073-20201:2001	<i>Application profile — Polling mode;</i>
ISO DIS 11073-20202:2001	<i>Application profile — Baseline;</i>
ISO DIS 11073-20301:2001	<i>Application profile — Optional package, remote control;</i>
ISO DIS 11073-30200:2001	<i>Transport profile — Cable connected;</i>
ISO DIS 11073-30300:2001	<i>Transport profile — Infrared wireless;</i>
ISO DIS 11073-90100:2001	<i>Analytical instruments — Point-of-care test.</i>

5.2.1.3.3 *Scope and purpose of standard*

The professional organization IEEE (Institute of Electrical and Electronics Engineers) Project 1073 is concerned with medical device communications and has produced a wide range of standards under the auspices of the USA National Standards Body, ANSI. The majority of these standards have been submitted to ISO for international standardization.

The standard covers communications between point of care medical devices, other devices and one or more network nodes.

5.2.1.3.4 Implementation status

Various parts of the standard (in the guise of the ANSI/IEEE standard) have been implemented widely. There is a strong commitment by the relevant manufacturers to implement new parts of the standard as they emerge.

5.2.1.3.5 Relevance to healthcare in the UK

This standard is highly relevant to the UK since it is the dominant (and, effectively, the only) standard in this field.

5.2.1.3.6 Further information

In order to retain the same taxonomy as the IEEE standards, a five-digit part number has been used and the International Standard number reflects the IEEE number; for example, IEEE 1073-1.2.1 has become ISO DIS 11073-10201

This standard will be adopted by CEN as EN ISO IEEE 11073.

5.2.1.4 ISO WD 17090

5.2.1.4.1 Title

Public Key Infrastructure

5.2.1.4.2 Parts

- ISO DTS 17090-1:2001 *Part 1: Framework and overview;*
- ISO DTS 17090-2:2001 *Part 2: Certificate profile;*
- ISO DTS 17090-3:2001 *Part 3: Policy management of certification authority.*

5.2.1.4.3 Scope and purpose of standard

This three-part document is a Technical Specification (TS) that describes the various requirements to allow Public Key Infrastructures (PKIs) to be used to protect the security of healthcare information being exchanged (whether within one domain, between domains or across jurisdictional boundaries). PKIs are generic and span various sectors; this TS provides healthcare-specific security profiles (profiling formal – ISO/IEC – standards as well as Internet – Internet Engineering Task Force (IETF) – specifications).

Part 1 defines the basic concepts for a healthcare PKI and defines interoperability requirements.

Part 2 specifies healthcare specific profiles of digital certificates based on the ITU-T/X.509 Recommendation/International Standard ISO/IEC 9594-8 (*Information technology – Open Systems Interconnection – The Directory – Authentication framework*) and the profile of this specified in the Internet specification Request for Comment (RFC) 2459 (*Internet X.509 Public Key Infrastructure Certificate and CRL profile*) for different types of certificates.

Part 3 deals with management issues involved in implementing and operating a healthcare PKI and is based on RFC 2527 (*Internet X.509 Public Key Infrastructure Certificate Policy and Certification Practices Framework*) including requirements for cross-border communication.

5.2.1.4.4 Implementation status

None as far as it is known.

5.2.1.4.5 Relevance to healthcare in the UK

Not yet determined.

5.2.1.5 ISO DIS 17113:2001

5.2.1.5.1 Title

Method for development of messages

5.2.1.5.2 Scope and purpose of standard

This standard defines a general method for developing messaging standards for the exchange of information between healthcare information systems. It is derived from joint work by CEN and HL7 on the HL7 Message Development Framework (MDF).

5.2.1.5.3 Implementation status

This is a standard for use by standards makers and hence is not used in the development of software for use in healthcare informatics.

5.2.1.5.4 Relevance to healthcare in the UK

The standard is indirectly relevant in that it will be used in order to define other standards that are likely to be implemented in the UK. However, it is of real relevance only to message developers.

5.2.1.6 ISO DTS 17117**5.2.1.6.1 Title**

Controlled health vocabularies — Vocabulary structure and high-level indicators

5.2.1.6.2 Scope and purpose of standard

This standard (TS) is concerned with clinical concept representation. It is intended to provide vocabulary developers and authors with the quality guidelines needed to construct useful, maintainable controlled health vocabularies.

5.2.1.6.3 Implementation status

None.

5.2.1.6.4 Relevance to healthcare in the UK

This is a standard for standards developers and may form the basis of other standards relevant to the UK.

5.2.1.7 ISO DIS 17120**5.2.1.7.1 Title**

Country identifier mechanism in healthcare

5.2.1.7.2 Scope and purpose of standard

This standard specifies country identifier standards suitable for use within health informatics applications and standards development.

5.2.1.7.3 Implementation status

This is a standard for standards developers and hence will not be used in the development of software for use in healthcare informatics.

5.2.1.7.4 Relevance to healthcare in the UK

BSI voted against progression of this standard on the basis that there were fully adequate international standards for this purpose. These standards will continue to be used in the UK.

5.2.1.8 ISO WD 18104:2001**5.2.1.8.1 Title**

Integration of a reference terminology model for nursing

5.2.1.8.2 Scope and purpose of standard

This standard is intended to establish a nursing reference terminology model that is consistent with other specific health terminology models in order to provide a more unified reference health model. It includes reference terminology models for nursing diagnoses and nursing actions.

5.2.1.8.3 Implementation status

This standard is still in an early draft.

5.2.1.8.4 Relevance to healthcare in the UK

No direct relevance although it is likely to provide the basis for the development of further standards that are of direct relevance.