SLOVENSKI STANDARD
SIST ENV 13728:2003

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Zdravstvena informatika ï Vmesniki kliniļ nih analizatorjev do laboratorijskih informacijskih sistemov

Health informatics - Clinical analyser interfaces to laboratory information systems

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Health informatics - Clinical analyser interfaces to laboratory information systems

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 "Health informatics", the secretariat of which is held by SIS.

This European Prestandard Working Document has been produced by CEN/TC 251/PT36 "Instrument Interfaces to Laboratory Information Systems" under mandate M/255 from the European Commission and EFTA.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Prestandard describes messages for the transfer of data between Analytical Instruments (AIs) and Laboratory Information Systems (LISs).

Analytical Instruments (AIs) in European Laboratories

AIs are mainly used in hospital laboratories to analyse samples from patients. Most of these are interfaced to LISs that process the result data and produce reports for use by healthcare practitioners. In the absence of standards for the interface, each LIS supplier must write a new interface for each new analytical instrument. The cost of writing these interfaces can amount to between 10% and 20% of the total cost of the LIS. One of the most effective ways of reducing this cost is to implement a standard interface between the AI and the LIS.

In the early 1990s, the E31 committee of the American Society for Testing and Materials published a standard "Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems (ASTM E1394 - 91)". This improved the situation by standardising the format of the message and the syntax. It also attempted to standardise the data transferred in the messages, but suffered from implementation problems because:

- The vast choice of data items available gave implementers the choice to send the same data in many different ways.
- The relative lack of implementation guidelines meant that different implementers interpret the same clauses of the standard in different ways.
- Much of the information that is defined in the standard is intended for use in North America and does not cover European requirements.

The result of this is that each AI supplier has produced his own "standard", based loosely on ASTM E1394. Whereas this has made interfacing easier for the analytical instrument suppliers, the LIS suppliers are still faced with the need to write a different interface for most of the analytical instruments installed in a particular laboratory.

In particular, the LIS interface designer must - in theory - allow for any implementation allowed by ASTM E1394. This means that even simple AIs are normally handled by using a hugely complex interface on the LIS.

ASTM E1394 - 91 was reissued with minor revisions in 1997 as ASTM E1394 - 97.

This European Prestandard

This European Prestandard is intended to make interfaces between AIs and LISs simpler to implement by:

- Defining standard ways of conveying the same information in the same circumstances
- Defining a series of levels of complexity so that it is possible to interface a simple AI using only simple, easy to implement messages
- Adapting the original standard to cover European requirements
- Giving advice and guidance on how particular data items and functions should be implemented so as to reduce misinterpretation.

This is done by defining a series of standard messages, each of which is a subset of a comparable ASTM E1394 message. These are detailed in clause 6. Examples of scenarios covered by this European Prestandard, together with models and sequence diagrams, are given in Annex B. An informative implementation guide for both ASTM E1394 and this European Prestandard is given in Annex C.

Quality Management

There is a trend for all European clinical laboratories to be certified or accredited under a suitable quality management scheme. In most European countries the scheme is based on EN 45001: 1989 General criteria for the operation of testing laboratories, and/or ISO/IEC Guide 25: 1990 General Requirements for the Competence of Calibration and Testing Laboratories. Both these documents are currently being revised. A document for medical laboratories (ISO TC 212, ISO/IEC 17025) is currently at a draft stage. EN 45001 and ISO/IEC DIS 17025 require the laboratory to keep records of certain data. This means that, for the support of the users in conforming to the standard, the instruments and LIS must be capable of handling this data (input, storage, validation, output), and also transmitting it. This is especially important in functions that produce large amounts of data that cannot be handled effectively without automated processing. Typically, this is a task for the LIS, but certain items must originally come from the instrument. ASTM E1394 does not explicitly handle data required for quality management. In principle it is capable of doing so, but the required fields must be defined.

This has been achieved in this ENV by making recommendations as to which fields shall be implemented in order to satisfy the needs of quality management. These are identified in the implementation guideline included as Annex C.

This European Prestandard includes provisions for using existing ASTM E1394 records and fields to meet European quality requirements.

Compatibility with ASTM E1394

This European Prestandard defines records that are subsets of records defined in ASTM E1394. Therefore, all implementations conforming to this European Prestandard also conform to ASTM E1394. It should be noted, however, that not all implementations that conform to ASTM E1394 will conform to this European Prestandard.

How to Read this Document

Those not familiar with some of the concepts, e.g. profiling, described here should first read Annex A *How to Read this European Prestandard*.

1. SCOPE

1.1 Clinical Areas

This European Prestandard specifies general messages for electronic information exchange between AIs and LISs within a clinical laboratory. It is intended to be applicable within the following specialties:

- Clinical Chemistry/Biochemistry
- Haematology
- Toxicology
- Microbiology
- Virology and Immunology

It is not intended to apply in the following specialty:

- Blood Transfusion and Blood Bank

1.2 Messages, Syntax and Transport

This European Prestandard is concerned only with the specification of messages used by communicating parties and the syntax in which they are communicated. It is not concerned with the transport mechanisms used for the message interchange.

1.3 Data Types

This European Prestandard is applicable only to character-based message information. It is not applicable to the communication of graphical or image information.

1.4 Domains

User Domain - This standard has been specifically created to provide common conventions for interfacing AIs and LISs in a clinical laboratory environment. It will also be applicable to the interfacing of AIs to computers in other clinical practice settings, such as physicians' offices, clinics, and satellite laboratories. The standard is not applicable to applications with a continuous flow of results from only one (or a few) implicitly identified subjects of investigation, such as is found in the monitoring of vital signs. It may not be applicable to situations where the AI is remote from the laboratory that controls it, i.e. Near Patient Testing (NPT) or Point of Care (POC) AIs.

Interface Domain - This European Prestandard is intended for communication between communication parties where one party will assume the role of an AI and the other party will assume the role of an LIS. The standard is therefore also intended for communication involving independent workstations in the laboratory environment where these are capable of performing functions of communication between AIs and LISs. Such workstations may assume the dual role of both posing as an LIS to an AI, and as an AI to an LIS.

1.5 Validation

The provisions for this European Prestandard have been validated in the domains and for the purposes described above. However, messages conforming to this European Prestandard may be considered by some user communities to meet their needs for purposes outside this scope. Use of the messages in these circumstances is not precluded by the scope.

2. NORMATIVE REFERENCES

ISO 2955: 1993	Information Processing-Representation of SI and Other Units in Systems with Limited Character Sets.
ISO 5218	Information Interchange - Representation of Human Sexes.
ISO 8601	Data elements and interchange formats - Information interchange - Representation of dates and times.
ISO 8859-1	Information Processing - 8-bit single-byte coded graphic character sets- Part-1: Latin alphabet No. 1.
EN 45001: 1989	General criteria for the operation of testing laboratories.
ISO/DIS 15189: 1999	Quality Management in the Medical Laboratory.
ISO/IEC DIS 17025	General requirements for the competence of testing and calibration laboratories (Revision of ISO Guide 25:1990)
ASTM E1394 - 97	Standard Specification for Transferring Information between Clinical Instruments and Computer Systems (available from www.astm.org).

3. TERMS AND DEFINITIONS

3.1
analyte
component indicated in the name of a measurable quantity

3.2
analytical instrument (AI)
named set of equipment that provides implementations of laboratory services

NOTE 1 In the ASTM E-1394 the term "Clinical Laboratory Instrument" or "Clinical Instrument" is used.

NOTE 2 Workstations in laboratories may be capable of performing communication between AIs and LISs. Such workstations may assume the dual role of both posing as an LIS to an AI, and as an AI to an LIS. Therefore a workstation connected between an AI and an LIS may in some circumstances be considered as an AI, or in other circumstances as a LIS.

3.3
battery
group of analytical instrument investigations ordered together

NOTE this supplies a convention by which the user (the laboratory information system) can order multiple analytical instrument investigations by specifying a single name.

3.4
component
single data element or data elements that express a finer aggregation or extension of data elements that precede it

NOTE for example, parts of a field or repeat field entry. As an example, the patient's name is recorded as three components: last name, first name, and middle initial, each of which is separated by a component delimiter. Components cannot contain repeat fields.

3.5
download
transmission of data from an LIS to an AI

3.6
field
specific attribute of a record that may contain a single data element or aggregates of data elements

3.7
laboratory information system
information system which can provide services to one or more analytical instruments

NOTE 1 in ASTM 1394 the term "Computer System" is used.

NOTE 2 Workstations in laboratories may be capable of performing communication between AIs and LISs. Such workstations may assume the dual role of both posing as an LIS to an AI, and as an AI to an LIS. Therefore a workstation connected between an AI and an LIS may in some circumstances be considered as an AI, or in other circumstances as a LIS.

3.8
loadlist
subset of one or more worklists specifically assigned to an analytical instrument

3.9
order
set of one or more analytical instrument investigation requests submitted to an analytical instrument

3.10
profile
restricted subset of a standard intended for a particular purpose

3.11
record
aggregate of fields describing one aspect of the complete message

3.12
repeat field
field containing one or more data elements, each of which is to be treated as having equal priority or standing

NOTE used for demographics, requests, orders and the like, for example the repeat field "Test ID" may contain the three individual test IDs "Na" "K" "Ca".

3.13
request
request for a single laboratory service and a corresponding analytical instrument procedure to be carried out in respect of a specified subject of investigation

3.14
result
set of information including all essential or useful data relevant to the result of a single analytical instrument investigation and a corresponding analytical instrument procedure

3.15
sample
one or more parts taken or to be taken from a system and intended to provide information on that system or on a subsystem, or to provide a basis for decision on either of these

NOTE in this context "system" refers to a system under investigation, e.g. a human body, rather than a computer system.

3.16
specimen

NOTE used in ASTM E1394 to denote **sample**.

3.17
test

determination of a single analyte or a combination of values from other determinations or observations that constitute a measure of a single system attribute

NOTE in this context "system" refers to a system under investigation, e.g. a human body, rather than a computer system.

3.18
trigger event
action or event causing a message to be sent

3.19
upload
transmission of data from an AI to an LIS

3.20
worklist
defined set of requested analytical instrument investigations that can be assigned to an analytical instrument

4. SYMBOLS AND ABBREVIATIONS

AI	analytical instrument
ASTM	American Society for Testing and Materials
LIS	laboratory information system

5. NORMATIVE REQUIREMENTS

5.1 Messages for transmission of information between Analytical Instruments and Laboratory Information Systems, covered by this European Prestandard, shall use only the message types, records, fields and values specified in clause 6.

5.2 Implementations conforming to this European Prestandard shall conform to one of the Profiles defined in Clause 6.

5.3 Conformance to a Profile as defined in clause 6 shall mean support of the messages and records defined for that Profile in Clause 6.2, and the sequence of messages for that Profile defined in Clause 6.3.

5.4 When claiming conformance to this European Prestandard, implementations shall state which of the Profiles defined in clause 6 the messages conform to.

6. PROFILE TABLES

6.1 Introduction

This clause specifies the Profiles to which implementations shall conform. For each Profile it specifies:

- The messages that shall be supported
- The message sequence that shall be supported
- The records allowed within each message
- The optionality of the fields within the message
- The values allowed within each field.

Table 1 gives an overview of each message.

Table 2 specifies the messages included in each Profile, the direction of message flow and the records included in each message. Clause 6.3 specifies the sequence of messages that shall be supported by each Profile. Table 3 specifies the optionality and allowed values.

Table 1: Message Descriptions

Message identifier	Message title	Comment
M1	Result	for sending results from AI to LIS
M2	Results by Query	for sending results from AI to LIS in response to a Query for Results message (M6) sent from LIS to AI[a]
M3	Results by Query	for sending results from LIS to AI in response to a Query for Results message (M6) sent from AI to LIS[a]
M4	Order	for sending orders from LIS to AI, either unsolicited or in response to a Query for Order message (M5)
M5	Query for Order	for sending a query for an order from AI to LIS
M6	Query for Results	for sending a query for results from LIS to AI, or AI to LIS
[a] ASTM E1394 requires different fields to be supported for records containing results in response to queries, and different fields depending on the direction of the response message. There are no such requirements for order messages.		

6.2 Profiles

Table 2: Profiles

Profile	Description	Direction[a]	Messages[b]	Records[c]
P1	Simple profile for the transfer of results from AI to LIS	AI → LIS	M1: Result	H, L, P, O, R, C
P2	Simple profile for the transfer of orders from the LIS to the AI, and for the transfer of results from the AI to the LIS.	LIS → AI	M4: Order	H, L, P, O, C
		AI → LIS	M1: Result	H, L, P, O, R, C
P3	Bi-directional query profile for the transfer of order queries from the AI to the LIS, orders from the LIS to the AI, and results from the AI to the LIS.	AI → LIS	M5: Query for Order	H, L, Q
		LIS → AI	M4: Order	H, L, P, O, C
		AI → LIS	M1: Result	H, L, P, O, R, C
P4	Bi-directional query profile for the transfer of order queries from the AI to the LIS, orders from the LIS to the AI, result queries from the LIS to the AI, orders from the LIS to the AI, and results from the AI to the LIS.	AI → LIS	M5: Query for Order	H, L, Q
		LIS → AI	M4: Order	H, L, P, O, C
		AI → LIS	M1: Result	H, L, P, O, R, C
		LIS ↔ AI	M6: Query for Results	H, L, Q
		AI → LIS	M2: Results by Query	H, L, P, O, R, C
		LIS → AI	M3: Results by Query	H, L, P, O, R, C
P5	Implementation compliant only with ASTM E1394.	either/both	(no restrictions)	(no restrictions)

[a] The sequence of messages that shall be supported by each Profile is detailed in Clause 6.3

[b] The message identifiers correspond to the entries in Table 1.

[c] H = Message Header Record; L = Terminator Record; P = Patient Information Record; O = Test Order Record; R = Result Record; C = Comment Record; Q = Request Information Record

6.3 Sequence Diagrams

6.3.1 Profile P1

Implementations of Profile P1 shall support the following sequence of messages: