

Chapter XVII

Standardization in Health and Medical Informatics

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INTRODUCTION

When things go well then often it is because they conform to standards (ISO, 2005). According to the Oxford Dictionary of Modern English, there is a lot of explanation of what standard means, but, in context of the first sentence, the best meaning is «standard is a thing or quality or specification by which something may be tested or measured». Personal computer is a standardized computer. It means that any of its components is made according to strictly defined specification. Consequently, it does not matter who produces components and where they are produced.

Industry put the first demand for standards. Especially standardization is extremely important for electronics, for information and communication technology (ICT), and its application in different areas. Nowadays developing of standards is organized on global, international level, but it exists also on national level, well harmonized with international one.

Developers of standards are organizations and groups working on this matter. The leading standard developer in the world is International

Standards Organization (ISO). ISO is a non-governmental organization established on 23 February 1947. Its mission is to promote the development of standardization and related activities in the world with a view to facilitating the international exchange of goods and services, and to developing cooperation in the spheres of intellectual, scientific, technological and economic activity (ISO, 2005). ISO collaborates with its partners in international standardization, the International Electrotechnical Commission (IEC), a non-governmental body, whose scope of activities complements ISO's. The ISO and the IEC cooperate on a joint basis with the International Telecommunication Union (ITU), part of the United Nations Organization and its members are governments. The ISO standard can be recognized by the ISO logo, ISO prefix and the designation, "International Standard".

European developer of standards is the European Committee for Standardisation (Comité Européen de Normalisation – CEN). It was founded in 1961 by the national standards bodies in the European Economic Community and EFTA countries. CEN promotes voluntary technical

harmonization in Europe in conjunction with worldwide bodies and its partners in Europe and the conformity assessment of products and their certification (CEN, 2005). CEN cooperates with the European Committee for Electrotechnical Standardization (CENELEC), and the European Telecommunications Standards Institute (ETSI). Product of this cooperation is the European standard which can be recognized by the prefix EN. Any added prefix to the existing one, for both ISO and CEN standard, means that this standard is result of cooperation with other standardization group or organization. The prefix ENV in European standardization means that this standard is not yet a full standard (it is under development by CEN).

ISO and CEN have Technical Committees working in the specific areas. ISO/TC215, established in 1998, and CEN/TC251, established in 1991, are corresponding technical committees working on standardization in health and medical informatics in ISO and CEN. Both standardization bodies, the ISO and CEN cooperate, and they mutually exchange their standards.

There are also a variety of organizations and groups developing standards, cooperating with ISO and CEN or acting as administer and coordinator in standardization. For example, there are Health Level 7 (HL7), Digital Imaging and Communications in Medicine (DICOM), American National Standards Institute (ANSI), non-profit organization that administers and coordinates the U.S. voluntary standardization and conformity assessment system, etc.

BACKGROUND

Definition: A standard is a set of rules and definitions that specify how to carry out a process or produce a product, or more precisely standard is a document established by consensus, and approved by a recognized body, that provides, for common and repeated use, guidelines or char-

acteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

The main role of standard is in raising levels of quality, safety, reliability, efficiency and interchangeability, and consequently in lower cost (ISO, 2005).

Standard creation process: There are several *phases* in the process of standardization: The first phase of this process is characterized by demand for standard. There must be someone who needs standard. Most standards are prepared at the request of industry. The European Commission can also request the standards bodies to prepare standards in order to implement European legislation. This standardization is ‘mandated’ by the Commission, through the Standing Committee of the Directive, in support of the legislation. Group of users can also ask for standard in the field of their interest. The second phase of standardization means developing of standards by following specification based on needs defined in the first phase. Experts of specific field are working on related standards. After the standard has been approved by standardization body, it becomes prototype which goes to testing and evaluation. Positive test results imply dissemination of standards and they start to live. It should be highlighted that standard is dynamic category and it changes time after time. Most standards require periodic revision. Several factors combine to render a standard out of date: technological evolution, new methods and materials, new quality and safety requirements. To take account of these factors, the general rule has been established that all standards should be reviewed at intervals of not more than several, predefined time period. On occasion, it is necessary to revise a standard earlier (Hammond and Cimino, 2001).

Standardization in health and medical informatics - why and what: Standardization has been a major factor in the company’s financial and clinical success, enabling faster implementation, greater quality control and significant cost-sav-

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