

Health software: a new CEI Guide for software management in medical environment

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Abstract

Introduction. The increasing spread of software components in the healthcare context renders explanatory guides relevant and mandatory to interpret laws and standards, and to support safe management of software products in healthcare.

Methodology. In 2012 a working group has been settled for the above purposes at Italian Electrotechnical Committee (CEI), made of experts from Italian National Institute of Health (ISS), representatives of industry, and representatives of the healthcare organizations.

Results. As a first outcome of the group activity, Guide CEI 62-237 was published in February 2015. The Guide incorporates an innovative approach based on the proper contextualization of software products, either medical devices or not, to the specific healthcare scenario, and addresses the risk management of IT systems.

Conclusions. The Guide provides operators and manufacturers with an interpretative support with many detailed examples to facilitate the proper contextualization and management of health software, in compliance with related European and international regulations and standards.

Key words

- medical devices
- software
- reference standards

INTRODUCTION

The widespread dissemination of electronic systems in all healthcare fields parallels the unrestrainable development of the most common consumer electronics. Since almost all electronic systems – from mobile devices to computers, up to diagnostic instrumentation – contains some form of programmability, the pervasiveness of software components in consumer devices life and, similarly, in the healthcare context, has assumed crucial relevance. This requires some considerations about the professional use of software systems in healthcare settings: i) other, more established and older technology categories like constructions, installations, or even the non-programmable electronic instrumentation, underwent a relatively slow introduction and spread, in general and in the healthcare context as well; ii) with respect to such categories, health professionals proceeded through an adequate process of familiarization, education and training to use; iii) conversely, programmable systems have appeared more recently in the daily use and in the context of health, and their fast dissemination and continuous updating perhaps anticipated and partly prevented a proper adaptation of working routines and management methodologies; iv) as a consequence, supporting actions are needed in or-

der to exploit the great potentials of such a technology properly, consciously, efficiently and safely.

To cope with such a disruptive penetration of information technology (IT) and information and communication technology (ICT) in healthcare settings – hospitals, clinics as well as daily-care structures and, in general, all those facilities used to carry out activities related to the delivery of care – Italian Electrotechnical Committee (CEI) has settled a technical working group aiming at delivering descriptive and interpretative documentation intended as a support for the appropriate implementation of software management in healthcare settings, in compliance with European Regulations [1-4] and Standards.

As a first outcome of the initiative, the CEI Guide 62-237 has been published – February 2015 – which deals with the management of software and IT-medical networks in the healthcare settings, with a special focus on the critical aspects of assessment and management of such technology. The Guide adopts and further develops an approach similar to that introduced by the recent Standards of the IEC 80001 series, *i.e.* the phenomenon of the introduction of ICT in healthcare is investigated by introducing the concept of risk management in information systems in healthcare, and by

tuning it, where necessary, to the particular context of European legislation.

This paper aims at describing the inspiring concepts of the working group, the implemented methodology, and main contents of the Guide.

METHODS

The technical working group

Since 2012 CEI has been hosting a group of CEI Members and invited experts in the field of software products/systems and IT network used in healthcare scenarios, as well as of Medical Device and Software Regulations. As a CEI usual recruitment procedure, the new group activities and goals were disseminated through the official CEI website and residential events; potential contributors to the group were asked to submit a short CV and, once recruited, were informed about CEI policy and ethics. The experts are representatives of Industry, Healthcare Responsible Organizations, Standardization and Notified Bodies, and Research Organizations. Even though stemming out of the Italian context, the group's subject deals with matters pertaining to the European and International levels, both on the market and in standardization contexts: the work conducted within CEI has a more general applicability and interest, and this is the reason why it is hopefully worth to disseminate the approach and the activities conducted up to now.

In the period 2012-2014 the CEI group organized residential meetings on an almost regular basis every 2 months, also using web conferences for extraordinary activities. At the end of 2014 the first document underwent the CEI official publication process which includes a rigorous peer-review and public inquiry processes. CEI, in fact, is responsible at national level for technical standardization, its activities being linked to the activities of the corresponding European and International standardization organizations (CENELEC and IEC, respectively). Formally recognized by the Italian Government and by the European Union, CEI proposes, elaborates, publishes and disseminates Technical Standards that, according to the Italian Law 186/1968, provide the presumption of conformity to the "in a good and workmanlike manner" concept for electrical products, systems, installations and processes following CEI Standards, as well as authoritative interpretation documents and Guides.

Since the publication of the CEI Guide 62-237, which this contribution focuses on, the working group has split its activities, now addressing both the preparation of the second part of the Guide – *i.e.* the part dealing with the management of medical IT networks – and the revision of the Guide itself, due to the incredibly fast development of ICT and ICT-related Standards.

The working group methodology

Main aim of the CEI working group is the delivery of interpretative documents to deal with the management of software and IT-medical networks in the healthcare setting. Experts in the group agreed on the adoption and further development of the approach introduced by the recent Standards of the IEC 80001 series, *i.e.* the

ICT in healthcare should be investigated by introducing the concept of risk management in information systems in healthcare, and by tuning it to the particular context of European legislation.

The group first focused on the critical aspects of identification, management and use of software products/systems in the healthcare context, and on the way to advise on those requirements of such software products – whether Medical Devices or not – that should be guaranteed by their Manufacturers and requested by Users. Such aspects are difficult to cope with, due to the complexity of correctly placing software products/systems in the existing regulatory framework (as in the case of the European Directives on Medical Devices [1, 2]): unlike other technologies, software systems are available in such a variety of configurations and functions that it is often very difficult to make comparisons between "similar" systems from different Manufacturers; equally difficult is to assign a commercial product to a specific category. A typical example of the hospital sector may help clarify the concept: software systems like Laboratory Information System (LIS), Radiographic Information System (RIS) and Picture Archiving and Communication Systems (PACS) have so much grown over time, by increasing the number of their functions and the number and kind of interactions with other systems, that it is now very difficult to identify functional boundaries between one system and another. At a European level, a very common question regarding the above systems is whether or not they should fall under the European Directives on Medical Devices: this question is simply misplaced, since the answer depends on what functionality or software modules are present in the specific system concerned. The CEI group stressed that this difficulty should be conjugated to the other critical issue specific of software products/systems, *i.e.* the dependence on the context of use. Unlike other industrial products, in fact, some of the performances of software systems are not completely and uniquely defined at the time they leave the Manufacturer premises; rather, they can be more or less influenced by the specific environment in which they will be installed and where they will carry out their functions.

Key-point to stress was thus found to be the encouragement and the instruction of the final user to perform an accurate analysis of the specific context in which the software product/system will be – or already is – used. In fact, in this regard, only the Healthcare Responsible Organization (RO, the final user), has the full knowledge of the needs and features of the "environment" where the specific software product/system will be – or already is – hosted.

This concept was then developed by outlining a path for ROs, applicable to each type of software they use, which consists of two phases: a first phase of *software identification*, and a second phase of *software management*.

RESULTS

As a first outcome of the CEI group activity, the CEI Guide 62-237 "Guida alla gestione del software e delle reti IT-medicali nel contesto sanitario. Parte 1: gestione del software (Guide to management of software and

medical IT-networks in the healthcare context. Part 1: software management) has been published on February 2015. Originated from the specific needs of the industry and of ROs, it is rather configured as an interpretative document, completed with broad sets of examples to facilitate the proper use of the relevant Standards, for all people acting in healthcare, thus including Manufacturers, Notified Bodies, Regulatory and Standardization Institutes, Healthcare ROs and Professionals, Health Authorities.

The Guide is a substantial document of 74 pages, made of 8 chapters and an annex containing examples from healthcare settings.

To properly address all the topics in the Guide, the Authors considered it appropriate to use, whenever possible, the terms defined in the existing legislation. In particular, all European directives on medical devices and *in vitro* diagnostic [1, 2] were taken into account, together with the most relevant International Standards; among these it is worth to mention the following ones: IEC 62304 entitled “Software for medical devices” [6]; IEC 60601-1 entitled “Medical electrical equipment – Part 1: General requirements for basic safety and essential performance” [7]; IEC 80001-1 entitled “Application of risk management for IT networks incorporating medical devices. Part 1: Roles, responsibilities and activities” [5]. Other relevant Standards were checked in case of missing definitions or discrepancies, too [8-10]. As a general rule, the use of new definitions was minimized; however since the Guide aimed at addressing the management of all software that can be reasonably used in the healthcare environment – *i.e.* both software marketed as a medical device and software for general use – some additional definitions were delivered, regarding relevant concepts for both health and non-health scenarios.

As anticipated in the Methods section, the Guide suggests ROs to follow a path, applicable to each type of software they use, which consists of two phases: a first phase of *software identification*, and a second phase of *software management*.

Software “identification”: essential parameters

In the identification phase, the suggested approach is to start the process by assessing 5 relevant parameters partly provided by the Manufacturer of the software product/system and partly associated with the specific context of use. These parameters, hereby described and commented, are: the intended use; the context of destination; the actual use; the actual context of use; the possible impact on health and/or safety.

The first parameter to consider is the *Intended Use*: it is defined by the manufacturer, and is needed to identify the purpose for which a product/system is provided. Under EU legislation, for Medical Devices and other types of products/systems, the Manufacturer is obliged to provide an explicit and direct indication of the intended use. For the remaining products/systems, the Intended Use can be obtained from the overall information/descriptions provided by the Manufacturer. At this stage of the assessment, it is important to understand if the Manufacturer has given the software a health pur-

pose (see Glossary for definition of health purposes), a general purpose, or even a destination which explicitly excludes its use for health purposes.

The second parameter to be derived from the set of information provided by the Manufacturer is the *Context of Destination*: the Manufacturer often declares if the product/system is intended for a particular environment (industrial, healthcare, domestic etc.). The context of destination can also be specified “in a negative mode”, *i.e.* the Manufacturer explicitly excludes the use of his product/system in a particular context. With regard to this parameter, it is important to clarify whether a software product/system is intended by the Manufacturer to be used in a healthcare context or, equally important, the Manufacturer has excluded the use of his product/system in the healthcare setting.

The parameters described so far are established by the Manufacturer only; conversely, the remaining three parameters the Guide suggests to evaluate are only obtainable by ROs.

The third parameter is the *Actual Use* of the software product/system, which depends on the true context in which the same is used, on the application/use mode chosen by its user, and on its features (or potentialities). The concept of “true” use therefore refers to the actual use of the software product/system within the specific healthcare organization.

The correct definition of the actual use of the product/system is a crucial and mandatory step, since it allows to highlight the possible impact on health, any risks to manage, and any related regulations to take into account. The actual use must therefore be defined by the RO, which is the only body able to understand the intrinsic features of the product/system as well as the needs and the wishes of the end user. It is worth to stress here that the concept of actual use will be exploited to cover the information gap that should be assumed by granting that the manufacturer’s prescriptions (intended use, installation and maintenance procedures etc.) cannot, even if carefully designed, cover every single detail of the user environment and settings. Especially important, the RO assessment must also include a careful analysis aimed at determining whether or not the software might assume, even unintentionally, health purposes due to its actual use, *i.e.* regardless any Manufacturer’s declarations.

This detailed analysis will allow the RO on one side to become aware of the actual use of the software under test, and on the other side to identify potentially dangerous or even not acceptable conditions (as in the case of a medical device software, if as a result of this analysis the actual use is found to be not compliant with the intended use specified by the Manufacturer).

Simultaneously with the Actual Use, the RO will also assess (fourth parameter) the *Context of Use*: similarly to the Actual Use, the Context of Use refers to the context of the actual use of the product/system, rather than to the context of destination as identified by Manufacturer. In this regard the RO will assess, for example, whether or not the product/system will be used in a healthcare setting. The following explanation might help to share light on the usefulness of this parameter.

It is frequently found, in real life experience, that the maximum level of patient protection from technology-associated risks is sought in places where patients are actually allowed, and where a medical treatment will be possible. This, in turn, means that any other setting could be implicitly considered at a lower risk, and will receive less managerial effort in evaluating all safety issues arising from – or related to – the activities therein done. This assumption can turn exceptionally wrong in the IT world, where patient data can travel, be analyzed, used and treated in physical (or virtual) places that we may not recognize as part of an “healthcare setting”.

The last (fifth) parameter that the RO should take into account is represented by the *Possible Impact on Health and/or Safety*. It should be assessed on the basis of the other four parameters, to understand whether or not a product/system, used in the specific RO context of use and aimed at the actual use outlined by the user, might have the ability to impact – either directly or indirectly – on health or safety of individuals. It is probably the parameter whose determination will require the greatest efforts by the RO because, especially in the case of general purpose software, its assessment may be done only by those who have a deep knowledge of both the software product/system under examination and company assets and processes.

Once the parameters have been determined, the RO can easily identify which category (as in *Figure 1*, adapted from *Figure 1* of the Guide) the software under test belongs to. The figure shows all possible combinations of the above software parameters in healthcare settings. Scrolling through the categories in the *Figure* from top to bottom, *i.e.* from C1 to D4, the level of attention should increase, since the safe use of the software under test in the specific conditions essentially requires an increasingly strict risk management process.

As a practical example, the general purpose software which, due to the way it is used – *i.e.* not for its peculiar features – does assume health purposes, is positioned at the bottom of the figure, corresponding to the maximum possible risk. In fact, the Manufacturer of such a generic product/system could in no way take into account the possible risks of using its product for health purposes. Two effective examples of software products belonging to this category may be: i) a statistical software package used in combination with a patient’s data in order to extract complex indicators for the diagnosis or therapy of the patient; ii) a general purpose database engine or a general purpose data storage system used to store patients’ clinical parameters, in view of their subsequent use for medical purposes. The reason why such software products/systems should be subjected to a more stringent process of risk management than that used, for example, for the category of software medical devices is clear: in the latter case, in fact, the Manufacturer of the software has been already obliged to undertake a risk assessment and management process as a standard process in its development cycle.

Software management operational procedures

The Guide then provides, for each of the 6 software categories, a pattern of initial management processes;

by implementing them, the RO will briefly document that: i) the 5 previously described parameters have been gathered – *i.e.* intended use, context of destination, actual use, context of use, possible impact on health and/or safety; ii) the actual conditions of use have been analyzed and found consistent with the Manufacturer’s instructions; iii) the possible effects on health and safety are consistent with those expected by any software product/system belonging to the same category. In case the above analyses bring to conclusions other than those reasonably expected – as in the case, for example, of a medical device software product/system whose actual use is not consistent with the recommendations given by the Manufacturer – possible alternatives are suggested *i.e.* recession from product/system commissioning, interruption of the use and withdrawal of product/system (when already in use), proper change of the actual use, supplementary risk analysis according to ISO 14971 or ISO 31000 [11, 12], and so on.

In support of the description of the initial management processes, the Guide also provides clarification on some standard operational processes associated with software products/systems management in healthcare settings, namely: composition of the product/system file; checks during software testing or commissioning; maintenance and periodic reevaluation; withdrawal of a software product/system. Concepts in this part of the Guide are not in-

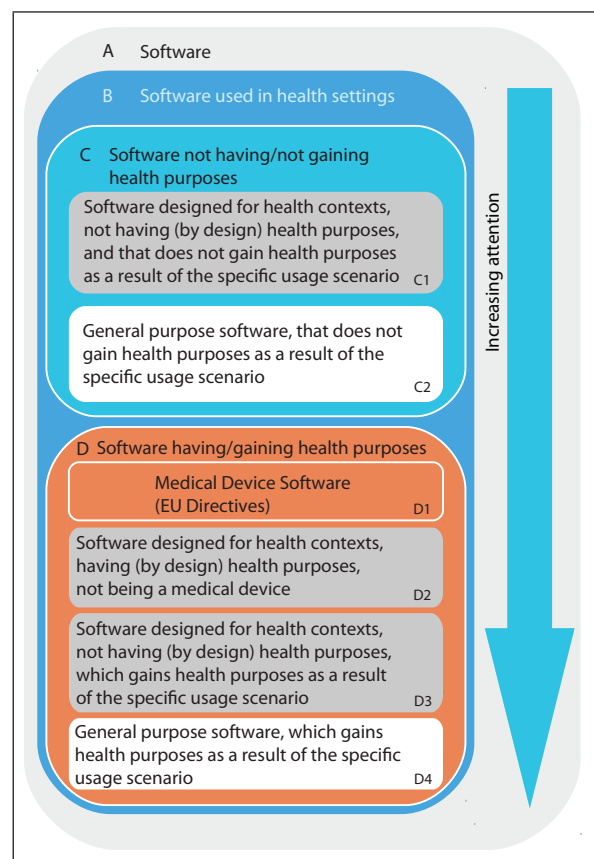


Figure 1

Scheme to identify the proper risk category for each software product/system used in a healthcare scenario. Source: authors’ adaptation of CEI Guide 62-237.

novative; however, these paragraphs restate that software products/systems, while being very peculiar elements of the healthcare scenario, still represent a strategic asset of the RO healthcare structure, and as such they must be included in usual management processes.

Special cases

Last section of the Guide briefly analyses some special cases: the “apps” for mobile systems; healthcare systems interfacing; risk management during software decommission in a healthcare setting. Some basic guidelines are provided, to address the safe use of software systems in these particular cases.

The safe use and management of software applications for mobile systems – briefly referred to as “mobile apps” – in the healthcare context, is of extremely high interest and relevance at a worldwide level. Several doubts and concerns and, of course, different approaches have been reported up to now in the relevant literature and regulatory documentation [13-16]. A first, quite common approach retrievable in EU as well as US documents, focuses on mobile apps intended by the Manufacturer as software applications with medical purposes (thus identified as medical mobile apps); with respect to those apps, of course, conformity is claimed with regulations in force in the healthcare context and in software engineering, and those preserving personal data and privacy of individuals [1-4]. However, confusion is still existing with respect to those mobile apps that, according to the categorization proposed in the CEI Guide 62-237, may play a role and introduce not negligible risks in a healthcare context even if not originally intended for such a specific scenario. The Guide suggests to try and follow the same approach as for the other software products/systems used in the healthcare context; however, work is still in progress at the working group to soon revise the Guide with the inclusion of a wider set of practical examples and discussion related to mobile apps.

The Guide Annex

The Guide is completed with a rich Annex that compares, for a relevant set of examples of software products currently used in the healthcare settings, the main indications and comments – about qualification, classification and categorization – delivered by the authors of the Guide and by two authoritative reference documents, *i.e.* i) the European guideline MEDDEV 2.1/6 2012 “Qualification and classification of standalone software” (prepared by representatives of the European Competent Authorities, the European Commission, Notified Bodies and Industry) [17], and ii) the Swedish guideline “Medical Information Systems – guidance for qualification and classification of standalone software with a medical purpose” (prepared by the Medical Products Agency of the Swedish Competent Authority) [18]. Care has been paid in the Annex to highlight the different approach of the two documents with respect to certain types of software, thus further showing the need to further investigate some critical, fast developing issues.

The example hereby reported is extracted from the Annex to the Guide, section c.1.3, and is focused on RISs, *i.e.* Radiologic Information Systems. Briefly, a RIS

consists of a software-based database which is used in Hospital Radiology Units to store and transfer radiological images and patients' data.

According to the European Guideline MEDDEV 2.1/6, a RIS is commonly qualified as a *non medical device*. However, if it includes additional modules with specific medical purposes, the latter may be qualified as *medical devices*.

According to the Swedish Guideline – which is more recent with respect to the previous document – a RIS in the simplest configuration, as those available up to the early '90s, might be considered as a “borderline” product between a *medical* and a *non medical device* (the decision depending on its specific functions), while currently available RISs are conceived to be used in patients' diagnosis and treatment, thus they must be qualified as *medical devices*.

Finally, CEI Guide Authors clarify that a RIS will likely fall within category D1 of the categorization scheme in *Figure 1* or, in case of simpler configurations which allow to qualify it as a *non medical device*, within category D2 (software product/system intended for a healthcare context, with intended health purposes not falling under the definition of a *medical device*).

DISCUSSION AND CONCLUSIONS

The whirling evolution, the uncontrolled availability on the market and the disruptive penetration of information and communication technology in healthcare settings is likely to introduce, together with undeniable potential for optimizing resources and improving the quality of care, a number of critical issues relating to software products/systems management and tracking of changes; such criticalities may put ROs into serious difficulties, compromising the quality management of the healthcare structures, and increasing the potential risks for the patient's health. Despite a relevant framework of rules is already in force at a European level, and both harmonized and not harmonized standards had already been published or are currently under preparation on such specific and urgent issue, nevertheless its complexity requires the production of explanatory documents and interpretations that help clarifying and better using the existing rules. A similar need is faced at a worldwide level, with continuous delivery and update of official Guides [19, 20].

The innovative approach of the CEI Guide 62-237, based on the identification of the key parameters of a software product/system as described in the previous paragraphs, renders the document a valuable support to ROs while assigning each software product/system to the appropriate category. Namely, the Guide aims at assisting ROs in: easily identifying any residual critical issue both in the actual use and in the context of destination; avoiding underestimation of potential risks for health; implementing clear, reproducible and traceable operational management procedures for each product. A wide set of examples, taken from actual healthcare settings and reported experience not only on the Italian territory but rather at an International level, is given and commented in the Guide. Hopefully, the Guide may represent an added value not only for ROs but

also for all other actors playing in the software-related healthcare setting.

Glossary and acronym list

CEI: Italian Electrotechnical Committee. It is a non-profit association of private law, which is in charge at a national level for technical standardization in electrical engineering, electronics and telecommunications; under the mandate of the Italian Government, it has direct participation into the corresponding European and International Standardization organizations (CENELEC, Comité Européen de Normalisation Electrotechnique; IEC, International Electrotechnical Commission).

Health Context: any place, condition or context in which actions are taken dealing – directly or indirectly – with health (source: definition delivered in the CEI Guide).

Health Purpose: an action has a medical purpose if it is performed in order to have – even indirectly – an effect on or a control/monitoring of the health status or,

more generally, on the physical, mental and social status of one or more individuals. A product has an intended medical purpose if the Manufacturer has intended its use in an action for medical purposes (source: definition delivered in the CEI guide).

Responsible (Healthcare) Organization (RO): the body who is in charge for the use and maintenance of a medical electrical equipment (EM), an EM system, an IT medical network or a software used in a healthcare context (source: definition adapted from CEI EN 60601 and CEI EN 80001-1). In other words, it refers to the legal bodies of the Healthcare Organization *i.e.* Hospitals, Medical Centers, private or public Clinics, private Medical Doctors, and so on.

Conflict of interest statement

No conflict of interest.

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