LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

approvals • authorisation • clinical trials • communication • competence • cosmetics • dialogue • directives • efficacy • environment • evaluation • guidelines • harmonisation • health economics • herbals • homeopathics • information • inspection laboratory analysis • market surveillance • medicinal products • medical devices • narcotics • public health • quality • registration • regulations • reliability • risk/benefit • safety • scientific • standardisation • transparency • vigilance • approvals • authorisation • clinical trials • communication • competence • medical devices • dialogue

Medical Information Systems

– guidance for qualification and classification of standalone software with a medical purpose

Content

Content

Preface

This is an unconfirmed translation from Swedish of the report "Medicinska informationssystem – vägledning för kvalificering och klassificering av programvaror med medicinskt syfte", dated 2012-10-31.

The latest update of Directive 93/42/EEC on medical devices, which came into force on 21 March 2010, clarifies that the directive also applies to so called standalone software and that they can be medical devices. Not much more is mentioned in the regulatory text about the requirements for standalone software and how to determine whether the software is a medical device or not.

To help manufacturers, organisations and authorities, some Swedish interested parties, led by the Medical Products Agency, proposed a guideline for standalone software. The document was published in June 2009 and was positively received in Sweden and internationally.

The Medical Products Agency thereafter initiated an EU guideline for standalone software. The agency participated in the work together with other EU authorities and industry organisations. The document was approved in January 2012 by the European Commission, referred to as MEDDEV 2.1/6. It contains a number of important clarifications but must be viewed in the light of that the use and apprehension of sophisticated information systems still differ significantly between the European member states. This means that the presented examples do not entirely reflect or describe the systems that are presently available on the Swedish market.

The Medical Products Agency has developed this guideline due to the development in this area having increased rapidly and to clarify remaining ambiguities.

The purpose of the guideline is:

- To clarify the relevant criteria for qualification of standalone software that is a medical device, and the application of classification criteria for such software
- To help manufacturers, health care providers and other interested parties to better understand what determines a standalone software a medical device
- To clarify the Medical Products Agency's expectations on the manufacturers
- To harmonise the interpretation of the regulatory requirements for standalone software.

It must be pointed out that the guideline is completely based on the medical device directives, contains clarifications and interpretations but does not formulate any further requirements. It is also synchronised with the MEDDEV 2.1/6 guideline and the intention is that there should be no conflicts between the documents.

This guideline reflects many of the questions that the Medical Products Agency has received over the last couple of years. The guideline also contains some product examples for a number of medical information systems. The examples are intended to describe those systems that are available on the Swedish market at present, but they shall also be helpful for qualification and classification for similar and future systems.

The scope of the guideline is limited to issues that the Medical Products Agency can be accountable for. It is however clear that patient safety related to standalone software depends on a mutual understanding between manufacturers and health care providers. This applies especially at procurement. This is discussed in a number of informative annexes that are intended to increase the awareness of necessary collaboration and mutual understanding on risks between the market players.

The guideline only handles standalone software. Software that is included in a medical device is not covered.

The new guideline is intended for:

- Manufacturers
- Manufacturing organisations
- Notified bodies
- Health care institutions
- Authorities
- Other parties.

The guideline is not a legally binding document, but rather an interpretation of the medical device directive. However, legislations, rules and regulations that are referenced in the guideline are legally binding. Even though the Medical Products Agency is the formal owner of the guideline, several other organisations have been invited to participate in the development. The Medical Products Agency is grateful for all parties that have participated in developing this guideline.

Project members

The Medical Products Agency has been in charge of developing the guideline. The following persons have participated in the project:

Mats Ohlson, Project Leader, Medical Products Agency

Morgan Andreasson, Swedish operations network for Medical Devices (Region of Västra Götaland)

Lars Asteborg, National Board of Health and Welfare

Git Eliasson, Swedish Standards Institute

Hans Ericsson, Intertek

Björn-Erik Erlandsson, Royal Institute of Technology, school of technology and health

Ronnie Lundström, MTF, Northern University Hospital

Peter Löwendahl, Swedish Medtech (Elekta AB)

Ulrika Boström, Medical Products Agency

Sandra Brolin, Medical Products Agency

Helena Dzojic, Medical Products Agency

Per Gillblom, Medical Products Agency

Brita Liljestrand, Medical Products Agency

Alf Öhman, Medical Products Agency

1. Background

The latest update of the Medical Device Directive 93/42/EEC came into force on 21 March 2010 by the amending Directive 2007/47/EC. The amending Directive includes, among other things, a clear statement of standalone software.

> *"It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device".*

The European Commission has in this context developed a guideline for manufacturers of standalone software that, among other things, describes criteria for whether a product is considered to be a medical device, and therefore needs to be CE marked. In general the guideline, referred to as MEDDEV 2.16/, follows the draft guideline that was introduced in Sweden in 2009. Principally, a system shall be CE marked if the manufacturer has described the product to have a medical purpose and therefore fulfils the definition of a medical device, according to article 1 in Directive 93/42/EEC on medical devices. A user must then be able to expect that the manufacturer has taken patient risks and patient benefits into account in the design.

2. Abstract

Software is qualified as **medical device** if the manufacturer's stated purpose of the software complies with the definition in article 1 of Directive 93/42/EEC on medical devices.

Among other things, the following requirements must then be met:

- The product shall have the adequate features that support the intend use.
- Patient safety shall be considered in the risk assessment.
- The manufacturer shall demonstrate that the performance of the product really meets the medical purpose, for example by evaluation.
- The product must be CE marked.

The opinion of the Medical Products Agency is that a program intended for a medical purpose must be regarded as a "product", and terms such as "project", "service" and similar must be avoided when describing a medical information system. This approach has advantages since a product safety regulation, in this case the medical device directive, can be applied.

The product will then have:

- A defined intended use
- Defined and documented specifications
- A manufacturer with a clear responsibility for the product
- A controlled "Post Market" surveillance.

Furthermore, the Medical Products Agency emphasizes:

- That the medical device directive shall be applicable for software and systems that fulfils the definition of a medical device.
- That the manufacturer of the designated systems shall follow the appropriate verification method in the medical device directive.
- That the level of risk shall be assessed, justified and control the classification and verification method.
- That applicable standards should be followed for design, verification and validation of software and information system that are medical devices
- That there is no legal requirement that manufacturers of devices in the lowest device class must have certification for their operational processes to fulfil the medical device directive. Therefore, the Medical Products Agency cannot in these cases require a formal certification, e.g. such as ISO 13485, Medical devices – Quality management systems - Requirements for regulatory purposes. However, in reality it is still necessary to have some form of a functional quality management system to manage a proper design process for software systems as well as the necessity to fulfil the Post Market Requirements including Vigilance reporting.
- That a controlled and standardised verification method for installation in a user's network, supported by the manufacturer, is an essential supplement to the manufacturer's CE marking and a prerequisite for an acceptable safety level when in use.

The Medical Products Agency has, as a result of market surveillance, questions asked to the agency, etc. identified a need for increased understanding on the intended use of a product, clarifying that it is the intended use in combination with the mode of action that decides whether it shall be defined as a medical device or not. It is the responsibility of the manufacturer to describe the intended use. If the manufacturer has described that the system can be used for a medical purpose then it must be CE marked accordingly. A user must be able to expect that the manufacturer has taken patient risks and patient benefits into account when designing the system. If a system is not described as a medical device but only has a technical and administrative description, one cannot automatically assume that the manufacturer has taken the patient safety aspects into account.

Users must then bear in mind to implement the software fully in accordance with the intended use stated by the manufacturer. The Medical Products Agency experiences that there is a great need to develop the relationship between manufacturer and client in this respect, to ensure that devices are being used in the proper way. Requirement specifications, procurement, configuration and training are important tasks that must be managed properly.

3. Regulations, definitions and terms

Requirements for manufacturers, including risk management, validation and post market surveillance, are stipulated in the European regulations on product safety, based on a concept called '**The new approach**'. This applies to the medical devices directives, and many manufacturers state an intended use of their medical information system that fit the definition of a medical device, as described below.

The medical device regulatory framework is based on EU legislation, which means that the same rules apply throughout all of EU/EES. The legislation consists of three EU directives: directive 90/358/EEC on active implantable medical devices (AIMDD), directive 93/42/EEC on medical devices (MDD) and directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD).

In Sweden the directives have been implemented by the Medical Devices Act (1993:584) and the Medical Products Agency's regulations LVFS 2001:5 on active implantable medical devices, LVFS 2003:11 on medical devices and LVFS 2001:7 on *in vitro* diagnostic medical devices.

Products that do not fall under the medical devices directives can still fall under other legislation. Such legislation is for instance the Product Safety Act (2004:451) that is applicable for products supplied to consumers.

Medical Device

Article 1 93/42/EEC
(1 § Medical Devices Act)
A medical device means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
1. diagnosis, prevention, monitoring, treatment or alleviation of disease,
2. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
3. investigation, replacement or modification of the anatomy or of a physiological process,
4. control of conception.

And which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

The definition of a medical device has a wide scope and applies to many devices that are intended to be used within the entire health care sector. The term is applicable for both small simple devices as well as for large advanced systems. This guideline sometimes uses the abbreviation MD for Medical Device.

It is important to point out that it is the intended use, as stated by the manufacturer, in combination with the mechanism of action of the product, not the design or user, that determines whether it shall be defined as a medical device or not. This means that a product is not qualified as a medical device solely by how it is denominated. What determine whether e.g. an electronic patient record system is a medical device, is whether the manufacturer's intended use of a system conforms to the definition of a medical device or not.

Intended purpose

Article 1 (2) (g) 93/42/EEC
(2 § d) LVFS 2003:11)
Means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

The intended use of a medical device, as specified by the manufacturer, is the basis for determining the regulatory requirements that shall apply for the medical device.

Accessory

Article 1(2) (b) 93/42/EEC
(3 § Medical Devices Act)
Means an article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

Definition of accessory for IVD medical devices
Article 1 (2 (c) 98/79/EC
Means an article which, whilst not being an in vitro diagnostic medical device, is intended specifically by its manufacturer to be used together with a device to enable that device to be used in accordance with its intended purpose.

Many medical devices require accessories to function according to its intended purpose. Standalone software that is an accessory to a medical device is not in itself a medical device but must still meet the applicable requirements for medical devices in the respective regulation.

Placing on the market

Article 1 (2) (h) 93/42/EEC
(2 § e) LVFS 2003:11)
Means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished.

When a device is made available for use it is considered to be placed on the market. This also applies if the device can be downloaded over the Internet or made available over a network. The device is considered to be placed on the market if it is used in a clinical demonstration setup but not if it is presented at an exhibition or being used at a clinical trial, then specific rules apply.

Putting into service

Article 1(2) (i) 93/42/EEC
(2 § f) LVFS 2003:11)
Means the stage at which a device has been made available to the final-user as being ready for use on the Community market for the first time for its intended purpose.

This applies both when the device is provided to the health care provider as well as the individual user.

In vitro diagnostic medical device

Article 1 (2) (c) 93/42/EEC
(2 § a) LVFS 2003:11)
Means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information;

- concerning a physiological or pathological state, or
- concerning a congenital abnormality, or
- to determine the safety and compatibility with potential recipients, or
- to monitor therapeutic measures.

Specimen receptacles are considered to be in vitro diagnostic medical devices. "Specimen receptacles" are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

Products for general laboratory use are not *in vitro* diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

For software to qualify as an IVD medical device it must first fulfil the definition of a medical device.

Active medical device

Section 1.4 Chapter I Annex IX 93/42/EEC
(Section 1.4 Annex 9 LVFS 2003:11)
Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, is not considered to be active medical devices. Stand alone software is considered to be an active medical device.

Article 1 (2) (b) 90/385/EEC
(2 § b) LVFS 2001:5)
Active medical device means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

An active medical device has it own source of energy to perform what it is intended to do, such as infusion pumps or ventilators. Software is an active medical device.

Active implantable medical device

Article1 (2 c) 90/385/EEC
(2 § b) LVFS 2001:5)
Means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

What determines the definition of an active implantable medical device is whether it is intended with its source of energy to be introduced into the human body and remain there. Such devices are typically pacemakers, implantable defibrillators and nerve stimulators.

Active therapeutical device

Section 1.5 Chapter I Annex IX 93/42/EEC
(Section 1.5 Annex 9 LVFS 2003:11)
Any active medical device, whether used alone or in combination with other medical devices, to support, modify, replace or restore biological functions or structures with a view to treatment or alleviation of an illness, injury or handicap.

Active device for diagnosis

Section 1.6 Chapter I Annex IX 93/42/EEC
(Section 1.6 Annex 9 LVFS 2003:11)
Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

A typical feature of standalone software used within the health care sector is the provision of information that contributes to diagnosis and treatment. This is an important medical feature that falls under the directive's definition of a medical device.

The definition of an active medical device clarifies that the term does not necessarily mean that the product must generate the diagnosis, but it can provide health care professionals with information that could be used for a medical procedure.

Standalone software

The term ”Standalone software” means in this guideline software that is not part of a medical device when it is placed on the market or made available for use.

Decision support system

Decision support system means in this guideline software intended to provide information to health care professionals, or others, for a medical purpose. See e.g. the definition of Active device for diagnosis: … *“to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities”.*

Expert system

Expert system means in this guideline advanced decision support systems. The term includes software which can analyse existing information to create new specific information in accordance with the intended use of the software.

Qualification

Qualification means in this guideline the decision making that determines whether a product shall be considered to be a medical device or not and ,if so, which product category it shall belong to under general medical devices, *in vitro* diagnostic medical devices or active implantable medical devices.

Classification

Classification means in this guideline the decision making that determines which risk class under each medical device directive a product shall belong to, such as class I, II or III for general medical devices or Common, list A, list B for *in vitro* diagnostic medical devices.

4. Qualification – when is standalone software to be considered a medical device?

4.1. Qualification criteria

4.1.1 Intended purpose

According to the medical device directive the manufacturer is responsible for defining the product's intended purpose.

A medical device must have a medical purpose. This is the case if the manufacturer has specified and described the product such that it can be regarded as having one or more of the purposes described in the definition in Article 1 of Directive 93/42/EEC on medical devices. The key is whether the intended purpose involves the patient benefit as expected in the directives.

In respect of the intended purpose the following also needs to be met:

- The product shall have the adequate features that support its intended use
- It shall involve a patient whose safety has been considered in a risk management process
- The manufacturer shall demonstrate by an evaluation that the performance of the product really meets the medical purpose
- The product must be CE marked.

With the intended purpose the manufacturer defines what the software is intended to be used for. The instructions for use shall further specify the different features and modes of the software. One must also consider any claims made in the marketing material and expressions made by sales personnel in respect to how the software can be used.

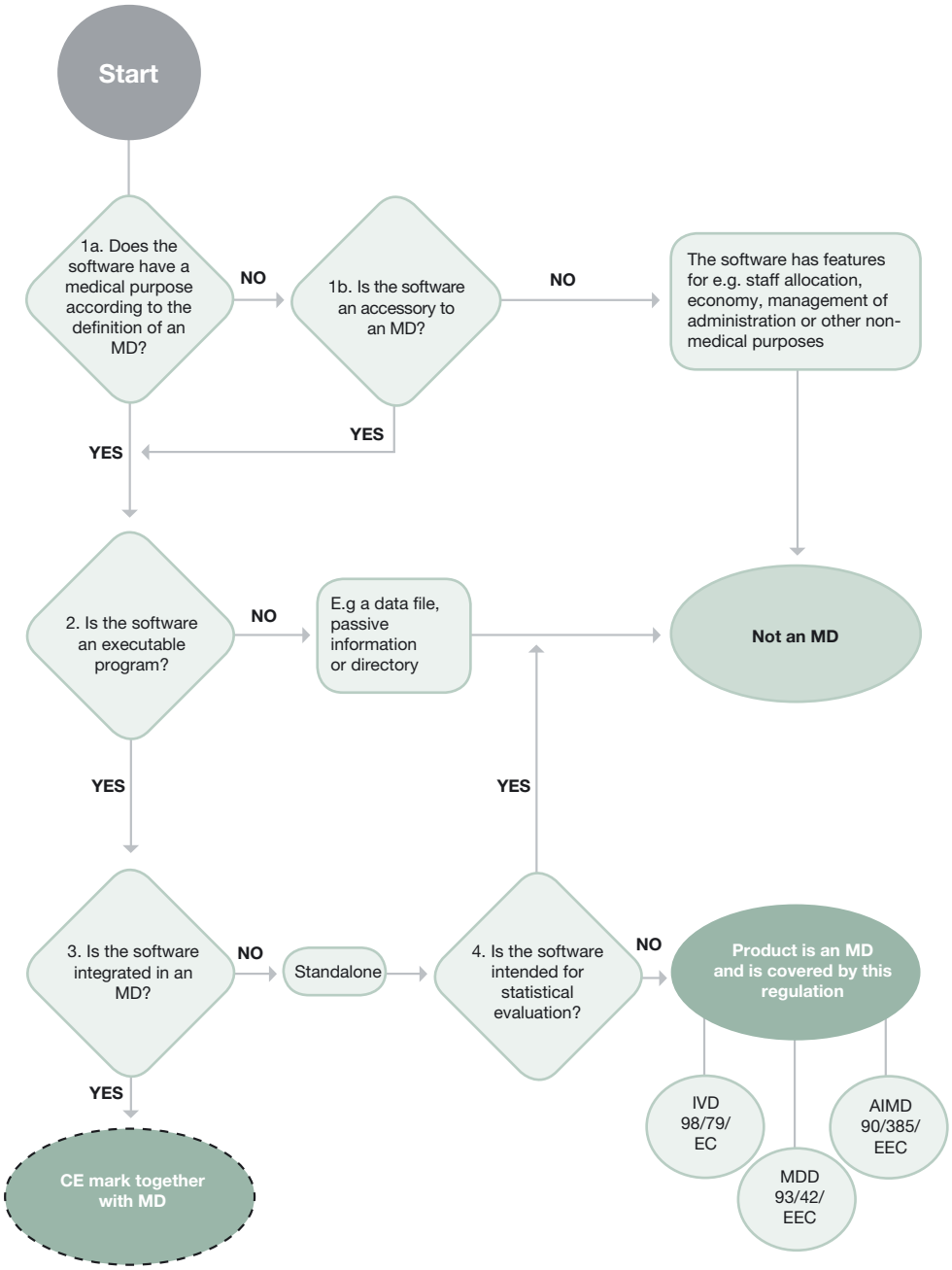
Operating systems or virtual environments that are required to operate the product does not affect the qualification criteria.

What is not considered a qualification criteria?

- Name: A product does not qualify as a medical device by virtue of the way it may be called.
- Technical description: If a manufacturer only describes the system in general technical terms, without mentioning the patient benefit, this cannot be considered sufficient to conclude that the system is a medical device.
- Real use: It is not relevant how a user chooses to use the product.
  Risks: Risks associated with a product are not qualifying conditions.

4.1.2 Software qualification flow chart

Figure 1.



Explanations

Step 1a. Does the software have a medical purpose according to the definition of an MD (Medical Device)?

See the definition of a medical device in Article 1 of Directive 93/42/EEC on medical devices, chapter 3.

Many software applications used in health care have an important medical function since it provides health care professionals with information that contributes to a medical procedure. A typical feature of standalone software used within the health care sector is the provision of information that contributes to diagnosis and treatment.

It is important to bear in mind that it is both the functionality of a product as well as the intended purpose stated by the manufacturer that determines whether software is qualified as a medical device. However, the name of the software or how it may be called is not relevant.

Software which is intended to create or modify medical information might qualify as a medical device. If such alterations are made to facilitate the perceptual and/or interpretative tasks performed by health care professionals when reviewing medical information (e.g. when searching the image for findings that support a clinical hypothesis as to the diagnosis or evolution of therapy) the software could be a medical device.

The display of images usually involves alterations to the representation because techniques are used such as contrast stretching, edge enhancement, grey scale manipulation, smoothing, sharpening, zooming and re-sizing. Alterations may include reconstruction, loss compression, filtering, pattern recognition, modelling, interpolation, transformation, classification (e.g. scoring of tumours against specific criteria), segmentation, registration (e.g. mapping a data set to a model or atlas or to another data set, e.g. registering an MRI image on a CT image), calculations, quantification, qualification (e.g. comparison of data against references), rendering, visualisation, interpretation, etc.

Not all standalone software used within health care can be qualified as a medical device. To qualify as a medical device it must first have a medical purpose, as described in chapter 3.

Individual tasks such as e-mailing, internet access or voice messaging, data parsing, word processing, and back-up is by itself not considered as being a medical purpose. However, refer to chapter 5 regarding systems - modules and components.

Systems that have a purely **administrative purpose**, to improve the efficiency of business processes, such as staff allocation systems, payroll systems, inventory, accounting systems, billing systems between health care providers etc. are not considered to have the purpose matching the definition of a medical device and shall therefore not be regulated under the medical device directive.

However, there are information systems for the health care sector where the manufacturer has not defined their device as a medical device, but still it could affect the safety for patients under certain conditions. Health care providers should in these instances still consider if those systems should be handled with the same awareness of safety as if it had been a medical device.

A specific issue concerns systems such as general Patient Administrative Systems (PAS), Radiological Information Systems (RIS) or Laboratory Information Systems (LIS). These systems typically have functions for booking medical appointments, admission or managing waiting lists, medical decisions based on the priority of the clinical need. Previously these types of systems did not used to be seen as medical devices. However, the earlier purely administrative systems have been developed into more and more advanced medical devices. It is not unusual that modern systems have many complex additional features, apart from the traditional ones, and with an intended function that fulfils the criteria of a medical device. On the Swedish market most RIS are for instance CE marked as medical devices.

It is important to reassess the qualification of a software application if a product has been upgraded, customized or subjected to any other changes. A medical purpose might have appeared. Qualification (and possible classification) should be included in the development process.

Step 1b. Is the software a medical device accessory?

Standalone software can, without having a medical purpose of its own, be essential to maintain an intended function of another medical device. It can then be an accessory to a medical device. By definition it is not a medical device, but still it needs to meet the requirements for a medical device. See the definition of accessory in chapter 3.

Step 2. Is the software an executable program?

The medical device directive is a product safety regulation. It is applicable for devices that have been released on the market, meaning that it has been transferred from a manufacturer to a user. However, not all software can be regarded as a product in the sense of what a product safety regulation is intended to regulate.

If the standalone software is an executable computer program, then it may be a medical device. If the software is not a *computer program*, then it is a *digital document* and not a product. Therefore, a digital document is not a medical device.

Examples of *computer programs* are software applications, macros, scripts, dynamically linked libraries, batch files, style sheets and any document containing active formatting or filtering instructions.

It shall be noted that even though an electronic patient record (EPR) is not usually a computer program, but a digital document, the *EPR system*, i.e. the software writing, retrieving, representing, etc. the information in the *EPR*, is a computer program. This is similar as for DICOM files vs. a PACS (Picture Archiving and Communication System).

Other typical examples of *digital documents* that are generated from medical device computer programs are images, digital ECG recordings and numerical test results.

The intended purpose according to what is expressed by the manufacturer is an important starting-point. A particular problem is how to define appropriate and useful methods for the distinctions towards systems and devices which certainly are used for diagnosis or treatment of patients, and therefore possibly could fulfil the medical devices definition, but still for other reasons should not be defined as medical devices.

The Medical Products Agency has determined that the following products, such as software with passive information, should not be subjected to the regulation of medical devices:

- Literary works, scientific literature
- Cell phone apps providing general health advice, about exercise, diet etc.
- Raw data in data bases
- Registers, tables and forms
- Digital transmission of manual counselling services
- Medical atlases, models and templates
- Electronic library, such as Eira, Effective Information Retrieval and Acquisition
- Supply databases of medical devices, for instance at vendors
- HSA, the Swedish list of addresses within health care.

Step 3. Is the software integrated in an MD?

If the software is integrated with equipment that is a medical device, then it is not standalone software, but must be regarded as part of the equipment and shall therefore be included in that product's verification procedure.

Step 4. Is the software intended for statistical evaluation of clinical or epidemical studies?

Although it is not clearly expressed in the legislation, the view of the Medical Products Agency is that the definition should not cover products intended for the diagnosis, treatment, etc. **intended for a population**.

Examples of software not regarded to be typically useful for individual patients are:

- Gathering of statistical data of the population
- Programs for epidemiological studies
- Compilation of medical data for a specific method such as quality registries stored in databases
- Programs providing generic diagnosis or treatment procedures.

Even though such databases are intended to be used for diagnosis or treatment of patients, they are not intended for individual patients. They contain a compilation of experiences and information that the health care provider or other systems can use directly or use as a reference source.

However, if for instance a database can be updated with an interface allowing for functions to sort information, select parameters and present results for a specific patient according to predefined conditions, or if it can be connected to other systems (e.g. electronic patient record system) then these features might be considered to be covered, as described in the definition of a medical device.

4.1.3 Office programs and operating systems

Standalone software may run on different operating systems or in virtual environments. These operating systems or virtual environments do not impact the qualification criteria. The software is also dependent on different components available on the market for general purposes such as operating systems, word processors, communications programs or browsers. They are referred to by IEC as SOUP (Software Of Unknown Provenance). These are not medical devices and their manufacturers cannot be expected to have taken into account any medical safety aspects. A manufacturer of a medical application must in the risk assessment consider the uncertainty in these general programs and allow for this in the risk assessment, according to annex I, clause 9.1, of Directive 93/42/EEC on medical devices.

> *If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system must be safe and must not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use.*

Office programs such as applications for word processing, browsers, registration and calculation software, such as Microsoft Office, cannot be seen as medical devices, even though they are used in the process to document clinical findings, diagnosis or other patient information. However, if one develops an application, e.g. in MS Excel, with the intent to use such program according to the definition of a medical device, it may fall under that definition.

Office programs, e.g. browsers or word processors, may also be part of a medical device as SOUP software. It will be the responsibility of the medical device manufacturer to decide if the SOUP software's specifications and safety is sufficient enough to fulfil the expressed intended purpose.

4.1.4 Hardware

The question of what hardware the software runs on is important but often overlooked. General hardware such as computers, servers, networks, nodes, switches, etc. are not medical devices. However, they have a great impact on the proper functioning of the software. Based on the risk management process, the manufacturer of the medical software is to predict and describe the requirements for suitable hardware environment and the need for regular safety measures.

The user then has to either abide by the manufacturer's recommendations or take own responsibility for the alternate solutions. The manufacturer can only take responsibility for what is covered in the risk management process.

4.1.5 Software via the Internet

The definition of "putting into service" requires that a device is made available to the end-user/operator and ready for use on the Community market. Software made available for the user via the Internet (online or download) or via different setups of commercial services, and that fulfils the definition of a medical device, is subjected to the medical device regulation. Instead of installing it on their own servers or computers, a health care provider may choose to use the software over networks, such as the Internet, from a server located at the manufacturer's premises.

This is sometimes referred to as *Software as a service* and means that the owner of the server is responsible for operation and maintenance. The user "only" uses the product. From a regulatory perspective, such software, if it has a medical purpose, becomes subject to the medical device directives and must be CE marked since it is made available to the user.

4.1.6 "Cell phone apps"

Cell phones have proven to have a positive impact on health care for patients, and their use in clinical environments has become more widely accepted. Although cell phones are primarily intended for communication their ability to run standalone software is a feature that strengthens their position as a health care aid.

"Apps" or "cell phone apps" is often the name of small applications which run as part of a larger and a more complex digital environment, usually on a cell phone, on an e-reader, tablet PC or Laptop. There are cell phone apps for both those intended to be used by health care staff and those intended to be used by patients and non-professionals. The later is either a standalone application or an application used to communicate via a server with a health care professional. There has been a rapid increase of health apps that can be downloaded, but the regulation in this area, and what it covers, has not yet been very well known.

Cell phone apps shall also be CE marked if they are considered to have a medical purpose according to the definition of a medical device.

Examples of cell phone apps that shall be CE marked are those which transfer data from the human body, such as body temperature, weight, pulse, pulse/oxygen in combination, various types of ECG, irrespectively if data has been entered from a sensor with body contact or implanted, or if data has been entered manually. If the purpose is to collect data for diagnosis to influence the health of the individual who sends the information, then the app has a medical purpose and shall be CE marked. Apps are usually interactive in such a way that an occurrence in the app, or non-occurrence, generates a message, an alert to someone about something. Cell phone apps with a medical purpose can also be of a kind that they support medication treatment by coaching the patient to follow the recommendation and then communicate this to the health care provider.

A cell phone or "smartphone" that the software is run on, or through, however, is not a medical device unless it is converted for an explicit medical purpose. Otherwise, what is said in section 4.1.4 about hardware applies. Nor shall the cell phone be seen as a medical device even though it has an app that calculates a medical result.

4.2 Qualification criteria as IVD medical device

To qualify as IVD medical device, the software must first of all fulfil the definition of a medical device.

Standalone software fulfilling the definition of a medical device and is intended to be used for the purpose of providing information derived from *in vitro* examination of a specimen derived from the human body falls under Directive 98/79/EC on *in vitro* diagnostic medical devices.

Provided that standalone software is intended specifically by its manufacturer to be used together with an IVD medical device, the standalone software falls under the scope of the IVD directive and shall be treated as an IVD medical device.

Standalone software may provide analysis and interpretation of the optical density delivered by an ELISA reader, line or spot pattern of a blot from a DNA sample, provide information on e.g. differential diagnosis, predict the risk to get a certain disease, predict the efficiency or failure risk (e.g. from a treatment) or identify different types of bacteria.

The information managed by the software can be obtained from different sources. The qualification as a general medical device or an IVD medical device is based on the intended purpose:

- If the intended purpose of the software fulfils the definition of a medical device and processes data that only is obtained from medical devices then it is considered to be a medical device.
- If the intended purpose of the software fulfils the definition of an IVD medical device and processes data that only is obtained from IVD medical devices then it is considered to be an IVD medical device.
- If the intended purpose of the software fulfils the definition of a medical device but doesn't fulfil the definition of an IVD medical device, then the software is a medical device irrespectively whether data is obtained from IVD medical devices/other sources or not.
- If the intended purpose of the software fulfils the definition of an IVD medical device and contains data obtained from IVD medical devices, medical devices and/or general laboratory analysers, then it is considered to be an IVD medical device.

If standalone software is intended to be used in combination with other devices or equipment, then the whole combination must be safe and must not impair the specified performances of the devices. Clinical evaluation of the combination shall be performed for each of the medical devices from which the data is obtained. A manufacturer that claims that a specific combination is possible shall ensure this in the risk management process.

4.3 In-house manufacture

Software that a health care provider has developed for their own internal use is not considered to be placed on the market and shall therefore not be CE marked. If software has an intended use that corresponds to the definition of a medical device it must, according to *National Board of Health and Welfare's regulations (SOSFS 2008:1) on the use of medical devices in health and medical care*, fulfil the same requirements as for CE marked medical devices. The health care provider is obliged to ensure that software is

safe and that the appropriate routines and processes are in place in order to meet the safety requirements. Software that complies with these requirements is referred to as "In-house manufacture". If a health care provider chooses to sell, donate or in any other way share software outside the organisation it is considered to be placed on the market. It should then be CE marked and someone needs to take the responsibility as a manufacturer according to the medical devices directives.

5. Systems – modules, components and accessories

A medical device has traditionally often been seen as a standalone technical product. Meaning, a product including software that is designed for a specific purpose that it is not intended for interconnection or interaction with other products.

Many software solutions however consist of combinations of various features and components, sometimes referred to as systems. The whole idea of the software is often to process complex combinations and operations with clinical information, and thus refine this information into a valuable aid for diagnosis and treatments of patients.

It also common to combine software components from different manufacturers, e.g. software for data acquisition, processing, calculation, communication and storage.

Just like the rest of society, health care is moving towards an interactive and integrated culture. This leads to the boundaries between individual products' functionality becoming more difficult to define and that several individual medical devices and non-medical devices are interconnected, which in some sense can create a new functionality that may not have been intended from the beginning.

5.1 What is a system?

There are several different definitions of what a system is supposed to be. Definitions can depend on the situation or of device type, e.g. IT systems, electrical medical devices, alarm systems or mechanical systems. With device systems, one typically means a group of devices and accessories, intentionally related to each other or not, that are interconnected to perform coordinated or method specific activities.

Two specific definitions

- According to the international standards committee IEC, a Medical Electrical System is a combination of several devices, or parts of devices, where at least one must be a medical equipment, that is functionally interconnected.
- The medical device directive use the term “systems” to describe a combination of devices that are marketed together by a vendor.

Some typical examples of common software systems that are used nowadays are laboratory information systems, electronic patient record systems, alarm systems, patient monitoring systems and radiotherapy systems.

5.2 Specific risks with systems

New functionality can occur, intentionally or unintentionally, when several devices are interconnected into a system. In addition, new unpredicted risks can arise. Operations within the system are difficult to monitor by single persons and several activities can be multitasked in a way that they affect both patient and operator safety.

Since individual components in an interconnected system may have individual intended purpose not qualifying them as medical devices, the formal requirements may also differ between different parts the systems. User interfaces on different devices, but with equal requirements, may have different design and use different terms for similar functions which may lead to confusion for the user.

Typical difficulties with interconnected systems could be to define the responsibility for the entire, or parts, of the system.

- Who takes responsibility for the system - the hospital or vendors?
- Who will guarantee that the devices still are compatible after e.g. software upgrades?
- How can it be assured that different devices that are interconnected to a unit don't interfere with each other?
- How is the risk management process for the entire combination?

Manufacturers of software intended to be combined with other software or devices must also consider the compatibility requirements towards other modules, as stated in annex I, clause 9.1, of Directive 93/42/EEC on medical devices. The requirement means that the manufacturer of a module, that is a medical device intended to be used in combination with other devices or equipment, shall assure that the whole combination, including the interconnected system, is safe and will not impair the specified performances of the devices. Any restrictions on use must be indicated on the label or in the instructions for use, according to annex I, clause 13.6, of Directive 93/42/EEC on medical devices.

5.3 Division into modules

In preparation for CE marking, a software manufacturer may choose to either define the product as a system that combines various features from different software components or broken down to modules with more limited functionality. This affects the CE marking in different ways. One must question whether it is possible that the whole or parts of a software system can be CE marked when not all software modules have a medical purpose, for instance acquire and store administrative patient information, managing invoicing and other accounting tasks or interfacing with insurance systems.

The directives offers two possibilities:

a) Module solution

A solution for the manufacturer is to screen out software components or modules that have a general or purely administrative purpose and not include them in the CE marking. Modules with a medical purpose are subjected to the medical device directives and must be CE marked. A module without a medical purpose of its own, but that is necessary and intended for the proper function of other software with a medical purpose, can be an accessory (see the definition in chapter 3).

Non-medical modules are not subjected to the medical device directive and shall therefore not be CE marked as medical devices.
The manufacturer must define delimitations and interfaces for the various modules and can demonstrate that the module in question has a sufficiently independent role in relation to the rest of the combination. Delimitations for any modules that are subjected to the medical device directive shall be clearly described and must be based on the intended use.

A risk with too far-reaching division into modules is however that the combined functionality in the system and clinical use will not be evaluated in the risk assessment. Another risk connected with too far-reaching division into modules is that it might lead to the exclusion of risk assessment of modules with apparently purely administrative functions but which may have a significant impact on combined functionality and safety.

b) System solution

If a manufacturer chooses to CE mark the software solution as a whole system, the system might include parts with a purely administrative function. If they constitute a minor part of the system, they need not burden the CE marking process since they can be handled more easily in the risk management process.

Some components that are used together with a system can be seen as accessories, i.e. software without its own medical purpose but that is necessary for the proper function and of a system according to its intended use.

The Medical Products Agency does not recommend one solution over the other. This needs to be determined on an individual basis. It is however strongly recommended that the designer of the system, whether it is a manufacturer or a health care provider, considers and assesses the clinical functionality of the combined system.

6. Classification

6.1 About classification in general

Medical devices that fall under Directive 93/42/EEC shall be classified according to risk classes (I, IIa, IIb or III). IVD medical devices under Directive 98/97/EC are not classified in that way, instead they are arranged in risk based device lists (list A or list B), devices for self-testing, devices for performance evaluation and devices other than those covered by Annex II. Implantable devices under Directive 90/385/EEC are not divided into groups.

All medical devices, irrespective of their class or group, shall comply with the essential requirements. It is the responsibility of the manufacturer to verify that the design of a device fulfils the essential requirements, and to comply with the appropriate conformity route (as described in the annexes) to verify that manufactured and distributed devices comply with the type of device that has been designed. The requirement to demonstrate that a device fulfils the essential requirements applies regardless of what annex is chosen.

6.2 Characteristics that determine the classification of a medical information system

6.2.1 Medical devices

Annex IX in Directive 93/42/EEC on medical devices describe a number of classification rules applicable for medical devices. The following could be of interest for software:

Standalone medical device software is referred to as **active medical devices**. This means that rule 9, 10 and 12 is applicable in most cases. Clause 2.3 in the annex states that software which drives a medical device or influences the use of a device, falls automatically into the same class.

Therefore, software intended to control a device that **administers or exchanges energy** is in Class IIa according to rule 9. However, if the function of the medical device is potentially hazardous it is Class IIb. Naturally, the software depends on a modality (equipment) to actively transfer the energy. This means that no standalone software exists.
Software intended to **control and/or monitor the performance** of active therapeutic devices in Class IIb, or intended to directly influence the performance of such devices, are in Class IIb. This type of software could for instance control or monitor X-ray or radiotherapy equipment. However, such software is often strongly connected to the modality itself.

Rule 10 could be more interesting. According to this rule, software **intended for diagnosis** is in Class IIa under certain conditions. One of these conditions is that the device shall be intended to allow direct diagnosis or monitoring of vital physiological processes. This means that equipment for measuring vital parameters allowing measurements to be reviewed on/inside the device itself, e.g. ECG measurements, when the system shall be classified as traditional ECG monitoring equipment, is Class IIa.

However, if the devices are intended especially for **monitoring of vital physiological parameters** where the nature of variations is such that it could cause immediate danger for the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are Class IIb. Typically this means software in patient monitoring systems intended for intensive care. Depending on the intention expressed by the manufacturer and the intended use, such ECG system for pre-hospital use can belong to either IIa, according to last paragraph, or IIb.

Software intended to emit **ionizing radiation** and intended for diagnostic and therapeutic interventional radiology including devices which control and/or monitor such devices, or which directly influence their performance, are in Class IIb. Standalone soft-

ware such as for instance software intended for image enhancement in X-ray equipment, is considered to directly influence its performance and automatically therefore belong to the same class as the X-ray equipment.

Rule 12 is applicable for all other software that has not been subjected to any other rule. All of those devices are in Class I. Most systems identified by the Medical Products Agency will most likely belong to this class.

Some guiding examples can be found in the European Commission's guidance document MEDDEV 2.4/1: Guidelines for the classification of medical devices.

6.2.2 Active implantable medical devices

Software that supports the function of **active implants**, e.g. PC software for programming a pacemaker, is treated as active implants according to Directive 90/385/EEC on active implantable medical devices. No classification is applicable.

6.2.3. IVD medical devices

IVD medical devices or accessories of IVD medical devices are regulated according to Directive 98/79/EC on *in vitro* diagnostic medical devices. The devices are divided into

- Two risk based product lists (list A or list B) according to Annex II
- Device for self-testing
- Device for performance evaluation
- Devices other than those covered by Annex II.

List B contains for instance "Reagents and reagent products, including related calibrators, control materials and software, designed specifically for evaluating the risk of trisomy 21". Standalone software that is qualified as IVD medical devices should generally be considered to be devices other than those covered by Annex II and devices for performance evaluation.

6.3 Choice of verification method in the directives

The annexes in each directive describe various routes to verification. The chosen verification route must be based on the risk classification of the system – based on which patient harm a system can cause – and shall give acceptable evidence that a finished device is safe enough.

A software manufacturer of medical devices in the lowest risk class shall ensure that the devices fulfil the essential requirements, but the manufacturer is not required to have a formal quality management system in place or consult a notified body.

A software manufacturer of IVD medical devices that are devices other than those covered by Annex II and devices for performance evaluation shall ensure that the manufactured devices fulfil the essential requirements and the software manufacturer shall have a functioning quality management system in place but he software manufacturer doesn't need to consult a notified body.

A software manufacturer in the highest MD/IVD groups and AIMD shall follow a verification method that requires a complete and certified quality management system. A software manufacturer of other intermediate class/group shall have a certified quality management system in place and a verification method with sufficient safety level.

Some of the verification methods that are described in the Directive 93/42/EEC offer different types of quality assurance such as quality assured design, production quality assurance and/or quality assured type testing. These are described in annexes II, V and VI. Annexes V and VI describes limited quality management systems and does not require the design phase to be quality assured. The annexes are applicable in theory for devices in Class

IIa or IIb but are not always suitable for software. Safety of software is implemented in the design phase and can therefore not be achieved with tests only. Production and reproduction of devices such as for physical medical devices is not a central issue when it comes to standalone software. Hence, for software that falls under Class IIa, IIb or III it is reasonable to assume that the appropriate verification method would be a full quality assurance system, as described in annex II.

7. Discussion – international development

The development is vast when it comes to collecting, managing, processing and presentation of data for medical purposes. Regular computer systems are connected with mobile units, smart phones, tablets and so on. Furthermore, mobile units are affordable which makes it possible to buy large quantities. Since many mobile units have small screens it leads to significant challenges for developers and users. The development will most likely accelerate within this area and it is of great importance that manufacturers, users and authorities can handle the issues that arise.

The ambition of the Medical Products Agency is to have a proactive approach to support manufacturers and health care providers to develop new safe and effective devices and software for clinical use. This is sensible since Sweden has for many years now been fast to adopt new technology, both at work and in personal life.

In parallel to the work within EU and Sweden, several other countries have individual organisations that have developed guidelines and/or recommendations for standalone software and medical device software. The American Food and Drug Administration, FDA, have proposed a guidance which provides a very good overview, but since the American and EU regulation differs, the FDA guidance is not fully applicable within Europe.

References

EU directives

- Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices.
- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.
- Directive 2007/47/EC of the European Parliament and the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.

Acts

- Medical Devices Act (1993:584)
- Product Safety Act (2004:451) (the Swedish implementation of Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety).

Ordinances

- Medical Devices Ordinance (1993:876)

Regulations

- Medical Products Agency's regulations(LVFS 2001:5) on active implantable medical devices
- Medical Products Agency’s regulations (LVFS 2001:7) on in vitro diagnostic medical devices
- Medical Product Agency's regulations (LVFS 2003:11) on medical devices
- National Board of Health and Welfare's regulations (SOSFS 2011:9) concerning management system for quality
- National Board of Health and Welfare's regulations (SOSFS 2008:1) on the use of medical devices in health and medical care
- National Board of Health and Welfare’s regulations (SOSFS 2008:14) on information management and record keeping in health and medical care (being revised).

Guidelines

- The Medical Product Agency’s guideline on manufacturers' obligation to report accidents and near-accidents with medical devices; guidelines on the Medical Product Agency’s regulations LVFS 2003:11 on medical devices, LVFS 2001:5 on active implantable medical devices and LVFS 2001:7 on in vitro diagnostic medical devices and their associated appendix Guidance on a medical devices vigilance system , MEDDEV 2.12-1
- Proposal for guidelines regarding classification of software based information systems used in health care, Medical Products Agency 2009.

- Guidelines related to the application of: Council Directive 90/385/EEC on Active Implantable Medical Devices, the Council Directive 93/42/EEC on Medical Devices, MEDDEV 2.1/1.
- Guidelines on the qualification and classification of stand alone software used in healthcare within the regulatory framework of medical devices, MEDDEV 2.1/6.
- Guideline for the classification of medical devices, MEDDEV 2.4/1.
- Manual on borderline and classification in the community regulatory framework for medical devices.

Some standards and technical reports for software

(International reference numbers)

- ISO 13485:2003 Quality management systems – Requirements for regulatory purposes
- ISO 14155 Clinical investigation of medical devices for human subjects
- ISO TR 14969:2004 Medical devices – Quality management systems – Guidance on the application of ISO 13485:2003
- ISO 14971 Medical Devices – Application of Risk Management to Medical Devices – 2007
- CEN/TS 15260 CEN Health informatics – Classification of safety risks from health informatics products
- CEN/TR 15640 CEN Health informatics – Measures for ensuring the patient safety of health software
- ISO/IEC 20000-series Information technology -- Service management (ITIL-related set of standards)
- CEN/TS 25238 CEN Health informatics – Classification of safety risks from health informatics products
- ISO/IEC 27000-series, LIS Information security management systems
- ISO/IEC 27799, Health informatics - Information security management in health using ISO/IEC 27002
- CEN/TR 27809 CEN Health informatics – Measures for ensuring the patient safety of health software
- IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 62304, Ed. 1: Medical device software – Software life cycle processes, computer software.
- IEC 62366 Medical devices – Application of usability engineering to medical devices (2007)
- IEC 80001 Application of risk management for IT-networks incorporating medical devices
- IEC TR 80002 Medical device software – Guidance on the application of ISO 14971 to medical device software
- ISO/IEC 90003:2004 Software engineering – Guidelines for the application of ISO 9001:2000 to computer software.

Appendix

Annex 1. Risk management

Annex 2. Standards and recent development of standards

Annex 3. Clinical evaluation of medical information systems

Annex 4. Networks

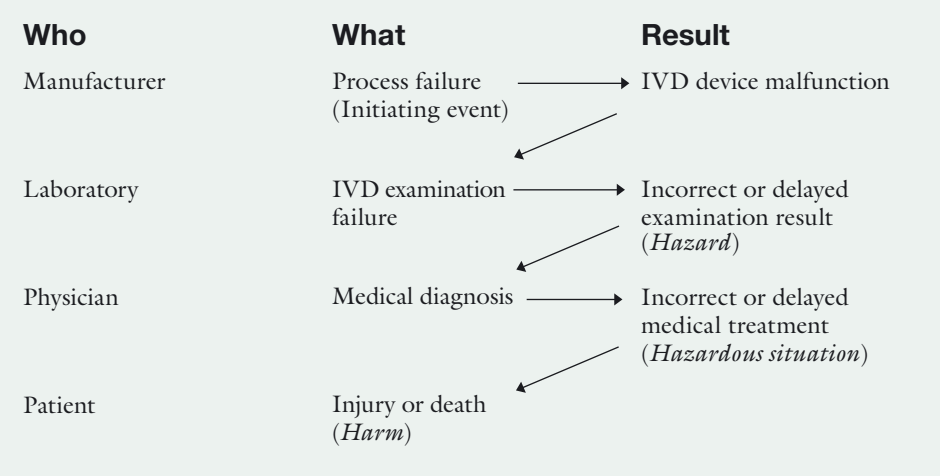
Annex 5. Procurement and issues referring to CE marking

Annex 6. Product examples

Annex 1. Risk management

Direct and indirect risks

Risks with standalone software are often related to its performance as decision support. This means that the possible harm which is a consequence of a failure does not occur instantly, but instead as a series of actions due to problems with the information. In the risk management standard ISO 14971 this scenario is described for IVD medical devices with an illustrative example in annex H. The illustration is generally applicable for all software for diagnosis, not just IVD medical devices.



Patient safety or information security

Patient safety and information safety (security) issues are often separated. This is not always entirely correct. The medical device requirements focus on safety for patients and individuals. The concept for information safety is defined in information safety standards and is intended to cover confidentiality, accuracy and access.

- Poor access can mean loss or delay of information and that the information has not been communicated or presented in a manner that makes sense for the intended user.
- Loss of accuracy can mean distortion, miscalculation or mix-up of information.
- The confidentiality requirement involves mandatory secrecy, protection against disclosure and assurance that the information only is made available for those who are qualified.

Accordingly, the patient safety concept, when used for medical information systems, should therefore be covered by the information safety concept and should therefore be considered in organisations that claim to have systems for managing information safety.

Methods for risk assessment

Several attempts have been made to introduce methods or models to describe how to evaluate different types of risks with software.

The standard for medical electrical equipment, IEC 60601-1, describes a risk classification that is based on how long time it takes from fault occurrence until a patient could be harmed. The faster and more instantly, the higher risk class. The longer time, the more likely the failure could be detected before any harm occurs.

The medical device software standard, IEC 62304, states that software should initially be grouped into three classes based on severity of harm depending on if death, personal injury or impaired health could occur. If the harm could occur due to the software the

likelihood will be set to 1.
The indirect harm if an information failure occurs, which would typically apply for diagnostic devices, is better addressed in the risk management standard ISO 14971 and the annex for IVD medical devices.

Decision matrix

The matrix below points out a few additional aspects to the risk assessment that contributes to that a medical information system may cause harm for a patient.

Risk of maltreatment due to information failure:

Factor/severity	1	2	3
Device complexity	Everything is visible. Like manual mode	Hidden automatic function	Many hidden functions and processes
Device take over human responsibility	Only presents basic data	Presents calculations	Provides suggestions and conclusions
Risk for maltreatment or injury	Failure that always can be detected	Failure is possible to detect to some extent	Failure cannot be detected until it is to late

Explanations to the matrix

The risk due to a software failure is not within itself a criterion to qualify as a medical device or not. However, the risk is important to consider at classification.

The way a *device is part of diagnosis and treatment*, can be directly or indirectly. In that respect the arguments do not differ from those used for traditional medical devices. Software can directly control a device, e.g. radiotherapy device. Most medical devices used for diagnosis, including IVD medical devices, has an indirect function since it provides decision support for health care staff, e.g. ECG equipment or blood sugar counters. Many software based systems are in the same way a decision support tool while the final responsibility for evaluation still rests with the health care staff.

The same applies if the device is intended to be used for monitoring or to compensate for a disability.

The following is a set of parameters or characteristics that are often issues in classification discussions, which does not solely determine if a device is to be seen as a medical device or not, but that is important for *risk analysis or risk classification*.

- The complexity of a device and the user's possibility to verify proper functionality

The complexity and the user's possibility to verify proper functionality are important factors to consider. Many functions can be hidden for the user. For that reason the developer/manufacturer of a system must take great responsibility for the proper function of a system since this is difficult for the user to do. The intention is to describe the difference between, for instance, older paper based patient records and systems for new electronic patient record systems.

The description of device complexity describes, with the same purpose, in what degree the software refines the entered information.

- The risk for maltreatment, what harm can occur and how this is instantly connected to the patient

The risk for maltreatment, what harm can occur and how this is instantly connected to the patient provides fundamentals for risk classification. If the feedback towards the patient is strong then the device, in reality, overrules many parts of the health care staffs' responsibility for health care decisions. The time from when a problem occurs, as well as the possibility of detecting it, and to when it leads to personal injury is a critical parameter that some standards use as a fundamental for risk classification.

- Risks for several persons

When analysing risks for maltreatment, the number of persons who are exposed to the failure must be evaluated. Software in health care has the potential to have impact on a large number of patients, e.g. plenty of diagnostic data and X-ray images disappear or several patients are diagnosed with the same faulty software and receive the wrong diagnosis.

- Interaction between manufacturer and health care provider

Information safety involves both administrative and technical aspects. Consequently, information safety involves more than just securing software systems. Other resources, not at least personal and organisational ability, are also important components to include in the information safety concept.

The manufacturer's interaction with the health care provider in the risk management process is explained in the IEC 80001 standard. Parts of the risk management process, e.g. communicating residual risks, should be expressed to the health care providers so that they can decide if the system is safe to use with their own routines, their own risk management process, to mitigate the risk for failure when the system is operated.

Annex 2. Standards and recent development of standards

Relevance between the European directives and standards

One way to comply with the essential requirements in the directives is to follow harmonised standards. If one fulfils a requirement in a harmonised standard it is then assumed that the corresponding requirement is fulfilled in the European directive and corresponding Swedish regulations. To qualify as a harmonised standard the standard must be based on a mandate from the European Commission, and to be valid for use it must first have been published in the Official Journal of the European Union. If the standard is harmonized or not, can be read from the content, first it is mentioned in the introduction, and then also mentioned in an Annex Z that links the requirements of the standard with the essential requirements of applicable directive. The harmonised standards are excellent and useful tools for demonstrating conformity with the requirements in the medical device directives.

The standards are therefore helpful tools to comply with most of the regulatory requirements. In public procurement it is important that the requests for proposals are specific and include essential requirements to obtain the device that is requested. The Swedish Act on public procurement emphasises that technical specifications (if available) must be included in the request for proposal. The requirements will then be applicable whether they are harmonised or not.

Standards offer universal solutions on repetitive problems. Manufacturers, users, authorities, test houses, professional associations and other interested parties within the health care sector meet on a neutral platform at standard organisations, to discuss the lowest requirements that can be expected of devices, services and processes, such as e.g. medical devices, management systems and risk assessment. Standards for software, manufacturing of IT systems and installation of IT networks have been developed. Some of these consensus documents are described in this chapter with emphasis on purpose, scope and for whom they are aimed.

ISO 13485:2012

Medical devices – Quality management systems – Requirements for regulatory purposes

The standard specifies requirements for a quality management system where the organisation needs to demonstrate the ability to provide medical devices and related services to continually satisfy customer demands and regulatory requirements applicable for medical devices and related services.

The primary goal of ISO 13485:2012 is to facilitate the harmonisation of the legal requirements on quality management systems for medical devices. As a result, it includes a number of specific requirements for medical devices and excludes some of the requirements in ISO 9001 that are not applicable.

All requirements in ISO 13485:2012 are applicable to organisations that provide medical devices, irrespectively of organisational structure or size.

The standard covers manufacturing, design, final quality control and final testing. Documentation requirements, management responsibility, resource management, product realization, measurement, analysis and improvement are parts that are included. The latest issue includes a justification of the foreword and Annex ZA, ZB and ZC have been updated to comply with the new directive. The standard from 2003 is translated into Swedish.

ISO 27799:2008

Health informatics – Information security management in health using ISO/IEC 27002

The standard defines guidance to support interpretation and application of ISO/IEC 27002 and is a complement to that standard.

The specified set of detailed security measures in the standard is intended to aid health care providers to ensure an appropriate security level to sustain confidentiality, accuracy and accessibility for personal information within health care.

ISO 14971: 2012

Medical devices – Application of risk management to medical devices

ISO 14971 is primarily aimed for manufacturers of medical devices that need to comply with the essential requirements in the Directive 93/42/EEC on medical devices.

This standard describes a process for management and mitigation of risks associated with development and monitoring of medical devices. ISO 14971 is helpful for the manufacturer to analyse, assess and evaluate any risks related to their products, and to mitigate those risks as well as monitoring the efficiency of the measures. The standard describes different processes to manage risks, mainly for the patient, but also for operators, other persons, other equipment and environment.

It is important that the risk assessment concept is also understood by health care providers in order to justify various measures for patients and the public. The decision to use a medical device for a certain clinical procedure requires that any residual risks, as described by the manufacturer in the instructions for use, must be weighed against the expected benefits for a procedure in each individual case.

The requirements in this standard apply to all phases in the life cycle of a medical device and also apply for risk management of in vitro diagnostic medical devices (IVD). The standard does not require that the manufacturer has a functional quality management system implemented. Risk management can on the other hand be integrated in a quality management system.

The latest issue includes a justification of the foreword and Annex ZA, ZB and ZC have been updated to comply with the new directive. The standard from 2000 is translated into Swedish.

ISO/TR 80002-1:2009

Medical device software – Guidance on the application of ISO 14971 to medical device software

This is a technical report that covers manufacturers risk management and software development when software is part of a medical device or a system and describes how to apply ISO 14971 (see above) together with the IEC 62304 standard (see below). The report gives a good description in quite a simple way, of how a software designer of medical devices can adopt a proactive instead of a reactive approach to mitigate problems.

EN 62304: 2007

Medical device software – Software life cycle processes, computer software

This standard applies for both manufacturers and users and was approved in Sweden in the autumn of 2008. It demonstrates a systematic approach for design and maintenance of medical device software.

Validation and the release of a medical device are not covered in the standard.

EN 80001-1

Application of risk management for IT-networks incorporating medical devices

Medical devices are often part of IT networks to achieve desired performance (e.g. interoperability). This standard is typically aimed for health care providers and is intended to be used as guide when a health care provider has acquired a medical device and plans to implement it in an IT network.

The standard defines roles, areas of responsibility and activities that are essential to risk management of IT networks that include medical devices and deals with safety, efficiency and data and system security.

The standard is applicable for all parts in the life cycle of an IT network with medical devices.

The risk analysis has clear references to ISO 14971 and also defines a medical IT network which is helpful for how to determine and delimitate the application.

Hospitals that are going to apply the standard, and collaborate with vendors that are aware of the content, can with the identified and communicated residual risks provide a safer network. For medical devices with software connected to a network this allows for the intended use to be fulfilled in a safer way.

The first edition of the standard was published in December 2010. The standard was translated into Swedish in 2011.

Explanations to EN 80001-1

Application of risk management for IT-networks incorporating medical devices

At present five technical reports (TR) are under development from ISO and IEC, in cooperation. The first three will most likely be published in spring 2013. They contain typical examples of what is intended with the requirements in ISO/IEC 80001-1. So far the following drafts are available:

- Step by Step Risk Management of Medical IT-Networks; Practical Applications and Examples
- Guidance for the communication of medical device security needs, risks and controls
- Guidance for wireless networks
- General implementation guidance for Healthcare Delivery Organizations
- Guidance on distributed alarm systems.

ISO DTR 17791 NWIP (new proposed standard)

Health Informatics – Guidance on standards for enabling safety in health software

This new initiative aims to identify a coherent view of international standards in need for the safe development, implementation and use of health software for patients. The mapping also intends to find existing gaps and overlaps and which standards that are relevant and how they can be best applied.

The report will most likely be published in autumn 2013.

EN 62366:2008

Medical devices – Application of usability engineering to medical devices

This standard describes a process for a manufacturer to analyse, specify, design, verify and validate the usability since this is closely related to the safe use of a medical device. It is a process standard intended to evaluate and mitigate risks from problems arising at correct use and foreseeable use error of a medical device, i.e. normal use. It is also useful for identification, but not for evaluation or mitigation, of risks due to abnormal use.

ISO/IEC Guide 63

Guide to the development and inclusion of safety aspects in International Standards for medical devices

The ISO/IEC Guide 63 intends to be a compliment to ISO/IC Guide 51 for a harmonised view on the safety term when developing international standards. ISO/IEC Guide 63 is a standard typically developed for the safety of medical devices.
This guide is intended to be used within the framework for risk management according to ISO 14971.

EN 60601-1

Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

This is a central standard for all electrical medical devices and it contains requirements on everything from electrical and mechanical safety to software and instructions for use, all with focus on patient safety. This is the main standard in a family of standards for product specific requirements and standards that deals with general features for equipment, such as EMC, usability, radiation safety or home use. The standard is based on the concept where a risk management process according to ISO 14971 and usability process according EN 623 66 is in place. It covers software in equipment and the requirements are related to EN 623 04. At present there is also an initiative to treat standalone software in a particular standard connected to EN 60601-1.

Annex 3. Clinical evaluation of medical information systems

Why clinical evaluation?

Clinical evaluation involves analysis and evaluation of clinical data about a medical device to verify the clinical safety and performance of a device. Clinical evaluation is a continuous process that shall be carried out during the entire life cycle of a device. It starts during the design phase, before the device is placed on the market, and is thereafter continuously updated at regular intervals with new clinical experiences about the device's safety from daily use. This information is fed back to the manufacturer's risk management process where it is used. Additional information is available in the European Commission's guidance on clinical evaluation of medical devices, MEDDEV. 2.7/1

There is doubt about how clinical evaluations shall be treated, if medical information systems are qualified as medical devices, especially in the light of the stricter wording in the amending directive 2007/47/EEC.

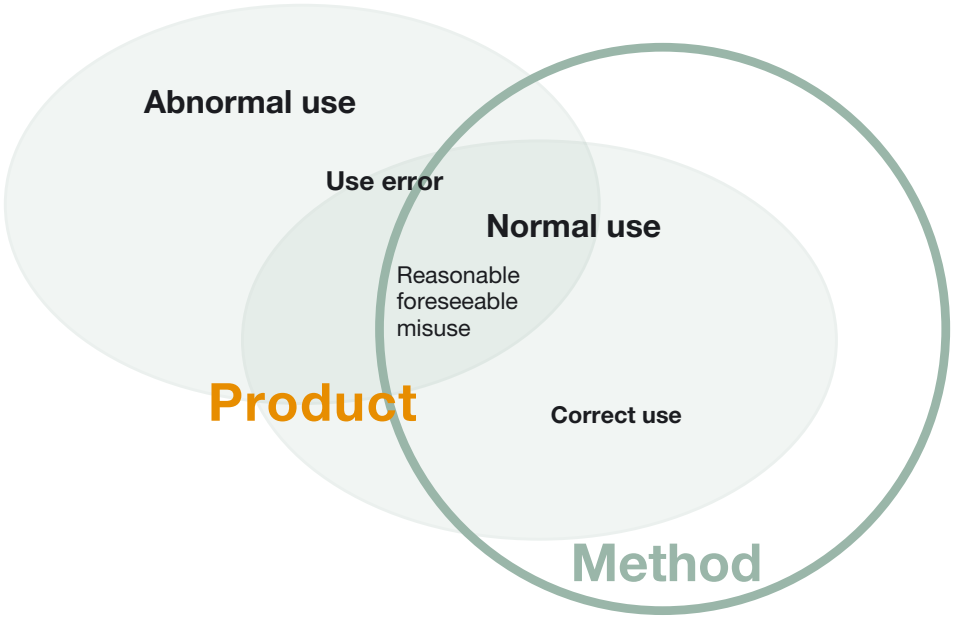
All medical devices, irrespectively of class, must have a clinical evaluation, unless the manufacturer can demonstrate that it is not necessary or appropriate. The clinical evaluation shall verify the clinical purpose and capabilities that are being claimed for a medical device. The clinical evaluation must be based on one or more questions that shall be answered by the evaluation. These questions are identified in the manufacturer's risk management process and usability analysis (Usability Engineering Process according to IEC 62366) and checked against the essential requirements in the directives.

A clinical evaluation must be based on relevant clinical data. Relevant clinical data can be found in the records of own previous experiences, scientific or other trustworthy documentation for the same or similar devices that can confirm the performance of the actual device. If such relevant information is deemed necessary, but doesn't exist, the manufacturer must conduct a clinical trial. Clinical data is needed to fulfil some of the essential requirements in the directives. In reality this means that the specific questions in the risk management process must be answered and hopefully the issues can be solved. In that respect a clinical evaluation for medical information systems does therefore not differ from a clinical evaluation of other medical devices. The risk management process and usability analysis, based on the essential requirements, determines which questions need to be answered.

Separate concepts "device" and "method"

Medical devices are normally used in a context, in a method, established and applied by the health care provider. Extensive medical information systems have a tendency to control the medical methods. Although the methods need to be adapted to the technical tools that are available, it is in this context important to make clear who shall be responsible for the device and who shall be responsible for the method. A great deal of the reported incidents is due to misunderstandings and vague roles of responsibility in this respect. The problem applies to all medical devices but has proven to be especially important to clarify when it concerns medical information systems.

This model below illustrates the problem:



Explanation in figure:

Both grey ovals together represent the device as a whole.

The light green oval in the middle represents what the manufacturer specifies as intended use for a device, according to the description in the instructions for use, and for which the manufacturer is responsible for, here referred to as ***normal use****.*

The top light green oval demonstrates ***use errors****, partly what the manufacturer has already assessed in the risk analysis and has evaluated as* ***reasonably foreseeable misuse****, and partly* ***abnormal use*** *such as severe use errors and abuse that the manufacturer not always can prevent in the risk management process.*

The green oval describes the situation, the method used in health care where the device is a tool for reaching the medical purpose. The responsibility for the method lies with the health care sector.

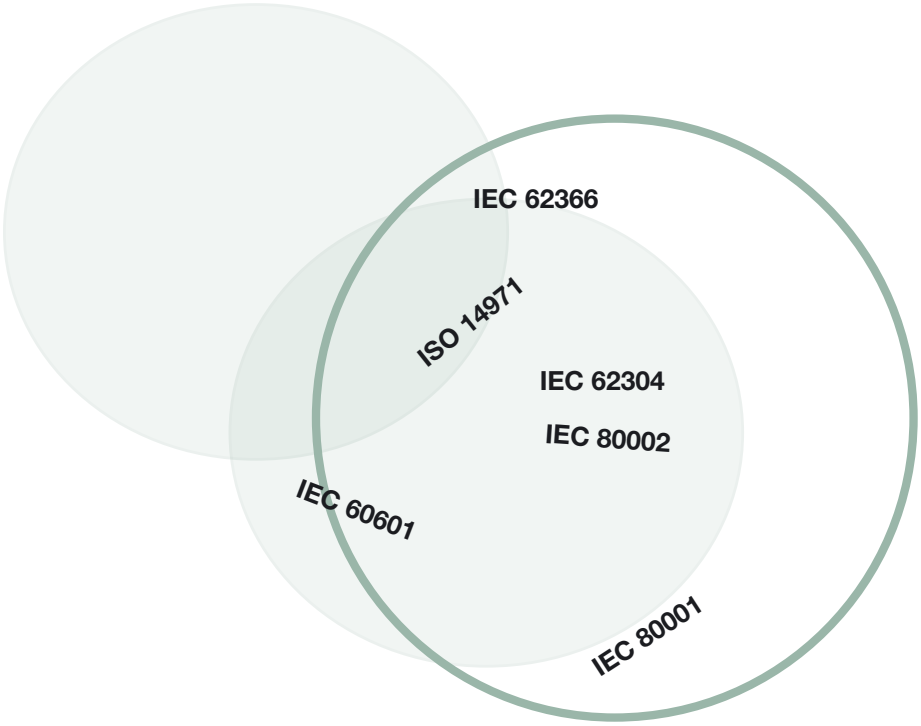
A medical information system has been provided with a specification for its intended use, as expressed by the manufacturer. Its *Normal use* must be identified in the risk management process and documented in the instructions for use or other information intended for the user. A user problem could still occur, so called *reasonable foreseeable misuse.* Use errors may happen even though the user has followed the instructions for use and used the device according to Normal use. This is due to human errors, forgetfulness, pushing the wrong button, etc. It is the responsibility of the manufacturer to foresee, monitor and minimise the consequences of such actions as far as reasonably possible.

Furthermore, there are also use error that could not have been foreseen or where the manufacturer has limited possibilities to be prepared for, so called abnormal use. This means anticipated risks, taking shortcuts, using the device for the wrong purpose and so on. The liability here rests fully on the user but does not automatically free the manufacturer from updating the risk evaluation, monitoring and minimising the consequences for possible use error if it is reasonable.

Additionally, the manufacturer should have been able to foresee in which Method the device is likely to be used. The term method can in this context include routines, other devices, staff, competence, facilities, etc. Methods could for instance be “Record keeping at anaesthesia”, “Patient monitoring” and likewise. A device shall not be equipped with functions that are directly inappropriate for the intended method. It is also the responsibility of the user to check that any devices and systems that are going to be used really are specified for the actual method.

This is often where it fails. The health care provider uses the system in their operations, either without taking into account the specification from the manufacturer or due to missing specifications. A manufacturer that resists seeing its system as a device with defined specifications has limited possibilities to meet and assess any specific requests that the health care provider may have. If the manufacturer has little understanding of the methods used in health care, then certain functions or configurations could lead to harmful situations.

Different guidelines such as standards for instance, may be useful tools to address the issues in the correct manner. The standard IEC 62366 about Usability Engineering is helpful to analyse and design a customised system.



Explanation in figure:

The manufacturer of medical information systems can use several different standards, which are useful tools to meet the essential requirements in the medical device directive. ***ISO 14971*** *is the general risk management standard for medical devices.* ***IEC/TR 80002*** *is guidance for how to apply the standard ISO 14971 when designing medical device software.*

IEC 60601 *is a general safety standard for medical electrical equipment, and the relevant annex H includes overall guidance for PEMS Programmable Electrical Medical Systems, description of structure, development life cycle plan and documentation. The most relevant standard to be used for designing software is* ***IEC 62304*** *Medical device software - Software life cycle processes. These standards also relates to the awareness of applying risk management according to ISO 14971.*

The user of medical information systems can apply the standard ***IEC 80001****, Application of risk management for IT-networks incorporating medical devices.*
IEC 62366 describes the process of usability engineering which is important in the design phase to assure that medical devices fulfil usability. It is also relevant for the user to have some insights in this process.

Annex 4. Installation and maintenance of medical information systems in networks

Infrastructure systems/Buildings

It is important that systems for infrastructure and support functions are as robust as it would be expected. These support and infrastructure systems, when they function properly, allow for the operation of IT systems by providing electrical power, networks, heating, ventilation, etc.

If such infrastructure systems are not planned carefully and properly implemented, including risk management, other systems may fail, which can lead to severe safety risks for both patients and staff. The bigger structures that are dependent on support and infrastructure systems, the bigger losses will be suffered when they fail. The trend to achieve effectiveness by coordinating different systems, leads to a situation where society and health care will become more vulnerable.

For infrastructure systems we see a convergence towards other non-medical IT systems with unclear borderlines. Electronic access control systems are linked to other password protected systems and can create barriers for instance allocating resources for treating patients with acute illness.

Medical information systems communication with other systems

One problem with medical information systems is that they often to a large extent rely on the environment in which they are installed. It is normal that these systems share information with other systems and therefore also depend on the interaction with other systems. In a complicated user network it will be more or less impossible for a single manufacturer to understand the overall picture. It is therefore an obligation of an individual manufacturer to design a system which is as robust as possible, by applying all existing knowledge. In the risk management process the manufacturer identifies possible weaknesses, establishes acceptance criteria and makes his best attempt to verify the requirements in a controlled environment where no patients are facing any risks from possible problems.

Managing residual risks, verification of installation

The validation of a system and how to use the devices is of significance for the function. The manufacturer shall perform the validation in a controlled environment, as far as possible similar to the intended environment of the user. Any residual risks that the manufacturer cannot control and where the result depends on a final installation in the client's network shall be explained to the user. The manufacturer should then be able to expect that the installation in the client's network is done in a structured way and that the information about any residual risks that have been expressed have been taken into account.

The installation and "verification" should be carried out according to a standardised method that is known to both manufacturer and user. This also means that the health care provider shall have a risk management process to be able to do a validation based on the proper information about the device, including the intended environment where it is often linked to other devices in a network and is depending on other systems or software to check the correct function. (This is especially important when interacting with operating systems, databases, anti-virus software, etc.) Function and safety for patients and staff can then be guaranteed in a better way.

The purpose of the verification is to identify problems that could occur due to combinations that are unpredictable. The verification shall have a higher level of attention in the initial phase and focus on the mitigation on the consequences from an error. Emphasise shall be put on the residual risks identified by the manufacturer.

The client's organisation is responsible for any additional installation or configurations in the network to be done with the same level of attention and monitoring regarding any residual risks as those expressed by each system manufacturer.

This verification process shall not be seen as a clinical evaluation or clinical investigation as described and intended in the medical devices directives.

Verification after changed prerequisites in the installation environment

After the procurement of a medical information system, that is a medical device, and after verifying the installation in its environment including an approved delivery, the system shall be maintained. The applicable prerequisites for the original installation and verification constantly change. These changes can affect the system properties negatively and may impair the performance or cause operational disturbances and thereby jeopardize patient safety. When appropriate management routines are missing, then both the health care provider and the manufacturer might not be aware of any ongoing changes in the network or if, for example, more systems have been added.

The Medical Products Agency believes that there are appropriate guidelines and terminology for verifying changes in the installation environment, as described in the standard *IEC 80001 Application of risk management for IT-networks incorporating medical devices.* Furthermore, it is noted that there is a consistency between the standard and the Swedish National Board of Health and Welfare's regulation on information management and record keeping in health care "SOSFS 2008:14" (currently under revision). The description of the roles of responsibility for different participators is especially interesting.

Annex 5. Procurement and issues referring to CE marking

Procurement

When procuring information systems that are qualified as medical devices intended to be used in either the public or private sector, the requirements in the medical device directives must be considered.

In order to avoid ambiguities and appeals in the procurement process and possibly improve the requests for proposals, especially regarding the patient perspective and considering the medical device directives, it is important that both parties are clear about:

- Which parts of an information system should be CE marked
- Who is the contractor (seller) and procuring entity (buyer). Is it the manufacturer, distributor, subcontractor or other?
- Who will be registered at the Medical Products Agency (if applicable)
- Who is the subcontractor
- Who will be responsible for complaints
- Who will be responsible for the overall system or parts of the system
- How will the contract agreement be followed up during the contract period.

Preparations for tenders

One important aspect is how the relevant manufacturers have described their systems in the offer and that they match the expressed need of the health care provider. To avoid that tenders are ambiguous i.e. where the request for proposal and tender describes different or imprecise system properties, it is important that the health care provider has prepared a proper requirement specification. The health care provider that describes a device must put thought into whether one desires a product with a medical function that clearly benefits the patient or not.

The manufacturer decides

The Swedish Medical Devices Act stipulates that, it is the specification from the manufacturer that decides whether it is a medical device or not. The manufacturer may have expressed this as an explicit statement or by a device description in a way that it meets the definition in the law. However, a manufacturer can for some reasons avoid mentioning this, even though it is obvious that the device will be used for a purpose in accordance with the definition. The device will then not be under the supervision by the Medical Product Agency and no requirements for medical devices will be applicable.

In a possible procurement situation a vendor can claim in the tender that the information system, e.g. an electronic patient record system, not is classified as a medical device. A user can then not expect that the manufacturer has taken patient risks and patient benefits into account when designing the system. There is no guarantee that either the risk management process or post market follow up, which are required to mitigate patient risks, can be fulfilled. Therefore, it will be the responsibility of the health care provider and the clinic to avoid patients or staff becoming harmed when the system is used.

Definition of contractual party

In some requests for proposals it is apparent that the requirements are aimed for a party without mandate to affect the requirements. It is important to differ between vendor, distributor or manufacturer (unless they are the same) in the respect of who will be accountable for product safety.

The requirements in the medical device directives are primarily aimed for the manufacturers. It is expected that the requirements are fulfilled in all aspects. It is however necessary that requirements dealing with the manufacture's customer relations and feedback of experiences are known to distributors and representatives if they are the contractual party. This applies especially for vigilance reporting.

Distributors and representatives must also have knowledge of which demands they can impose on manufacturers.

There are often misunderstandings about the requirement for registration. Only Swedish manufactures and authorised representatives of medical devices in the lowest risk class, systems/procedure packs and some IVD medical devices shall be registered at the Medical Products Agency, not distributors.

Managing complaints and adverse events

One important requirement on a manufacturer of medical devices is that there is a system for monitoring experiences from the market, i.e. attend to complaints and adverse events such as side effects, accidents and incidents.

The request for proposal should include a request to describe how complaints and adverse events will be followed up and who will be responsible for this task.
One can also demand that the manufacturer states in the information to the user (e.g. in the instructions for use) how and who to contact in the case of complaints and adverse events.

A distributor/representative that indicates in an offer that there have been a number of accidents and incidents doesn't necessarily mean that the manufacturer has bad products, but rather a functioning system for monitoring experiences from the market.

Documentation

It is of great value that the tenders show the documentation from the quality management process in respect to process control, materials, traceability, subcontractor reviews and their competence.

Likewise, one shall demand access to instructions for use and safety information to users/patients with information on how to use the device and information on how to contact the manufacturer.

The request for proposal may contain a demand to include the "Declaration of conformity" of the CE marked device together with the tender documentation. The aim is to get assurance from the manufacturer that the medical device fulfils the essential requirements in the medical device directives.

Follow up of contracts

By following up contracts it is possible to contribute to further improvements which help both the distributor and client to sustain a safe device with the anticipated patient benefit. It is also of great importance to continually follow up that the distributor fulfils the requirements as decided in the procurement process, since an agreed contract may not be altered, by either party. The methods for following up a contract by doing supplier vendor evaluations, e.g. using questionnaires during the contract period, can however be further improved.

Annex 6. Product examples

This annex describes a number of different systems with options used within the Swedish health care sector. These systems include some kind of software, to a different extent, that could be seen to fulfil the medical device directive's definition of a medical device. Each device is described with a short text, justifying if and in what way the medical device directives is applicable. The section about risks is intended to be included in the device description to give a perspective on the use. It must be pointed out that the qualification discussion never should start with identifying associated risks of a device. This could instead be dealt with during the classification.

All together nineteen product examples have been developed, which naturally means that not all systems on the market can be covered. The product examples are intended to serve as descriptive examples of principles that can be applied on other systems that are not mentioned here, or even yet exist.

Qualification criteria

The basis for any qualification is the intended use according to the definition of a medical device in Article 1 of Directive 93/42/EEC on medical devices.

According to the directive, the definition of a medical device is a product, used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- Investigation, replacement or modification on the anatomy or of a physiological process,
- Control of conception.

Classification rules

Annex IV in Directive 93/42/EEC on medical devices describe a number of classification rules applicable for medical devices.

Standalone medical device software is referred to as active medical devices. This means that rule 9, 10 and 12 is applicable in most cases. Software that is a medical device is an active medical device.

Much software having such purposes can be seen as active medical devices, due to that, software is to be seen as active devices for diagnosis according to Annex IX clause 1.6 in Directive 93/42/EEC on medical devices.

> *Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.*

IVD medical devices

IVD medical devices or accessories of IVD medical devices are regulated according to Directive 98/79/EC on *in vitro* diagnostic medical devices. The devices are divided into

- Two risk based device lists (list A or list B)
- Device for self-testing
- Device for performance evaluation
- Devices other than those covered by Annex II.

The following product examples have been compiled

1. **Electronic Patient Record System**
2. **Anaesthetic Record System**
3. **Medication Module**
4. **Clinical Information System – CIS / Patient Data Management System – PDMS**
5. **CTG Central Station**
6. **Pre-hospital ECG**
7. **ECG Storage System**
8. **Retinal Imaging System**
9. **Picture Archiving and Communication Systems (PACS)**
10. **Radiological Information System (RIS)**
11. **Telemedicine System**
12. **Applications for cell phones and tablets**
13. **Advanced Decision Support System, Expert System**
14. ***In vitro* diagnostic (IVD) software: LIS & WAM**
15. **Transfusion Medicine Blood Data System**
16. **Web System for Monitoring Medical Devices**
17. **Quality Registries**
18. **Quality Indicators**
19. **National System**

1. Electronic Patient Record System

Electronic patient record systems and decision support systems are tools for managing patient information associated with care and treatment within the health care sector.

Patient record systems are involved in diagnosis and treatment since evaluations of a patient's condition, goals and care plans are registered in the system. Stored data is being used for decision support in booking appointments for future care and treatment and later on when the patient is visiting the clinic. The stored data consists of examination results from different laboratories and is essential to the patient's treatment. Decisions on drug prescriptions are being stored in a medication module which is often integrated in electronic patient record systems.

The electronic patient record system presents facts entered by the user or via imported data, e.g. laboratory test results. Responsibility for the evaluation of the presented data lies with health care staff. The staff makes an evaluation based on information where the integrity is guaranteed by the system. That is, the system guarantees accurate data if the data itself has been entered correctly.

At drug prescription, different support functions are used, such as interaction registries which can be seen as forms of decision making tools. The medication modules usually contain interaction registries with functions to make alerts for inappropriate combinations. Some systems also include specific expert support functions generating recommendations or suggestions to physicians or health care staff. If any kind of expert support is implemented, this may be done in two ways. It is either decided by the manufacturer, which means that the manufacturer has responsibility for the expert support functioning according to the relevant system specifications. Or, if the expert support function has a flexible construction based on rules that are defined by the client (health care staff), then they will have the full responsibility for all operational specifications.

The client is responsible for the environment meeting the necessary requirements for the device to be able to function as it is intended. Often integration also takes place with other systems when entering external patient information. Notification management concerning integration may require that specific products are connected to the electronic patient record system.

In Sweden electronic patient record systems must also follow the National Board of Health and Welfare's regulation (SOSFS 2008:14) on "Information management and record keeping in health and hospital care".

Qualification

Electronic patient record systems have various complexities and functionalities, and could be everything from a simple system such as a word processor on a PC to an advanced decision support system as described above. The system qualification is based on the purpose and functionality that the manufacturer has stated for the system. Advanced systems that comply with the description above are usually intended to provide information to support diagnosis and treatment of disease or injury of a patient, and have therefore such functions and medical purpose that falls under the medical device directive. Systems with such medical purpose, as stated by the manufacturer, shall be considered to qualify as medical devices and shall be CE marked.

The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Associated risks

As mentioned above, the information in an electronic patient record system is an important part of the feedback to the patient when it comes to future plans for care and treatment.

Electronic patient record systems are especially complex products that normally require extensive configuration work. The product is part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed.

If the electronic patient record system functions insufficiently, and not according to the intended use, then there are obvious risks for maltreatment. If incorrect information is presented to health care staff then the wrong measures could be taken. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

Classification

An electronic patient record system that is a medical device is an active diagnostic device and should fall under Class I according to rule 12.

2. Anaesthetic Record System

An anaesthetic record system is a software based system intended for anaesthetic clinics to store, manage and transfer patient information generated in connection to anaesthesia. Usually the system contains information about patient identity, vital parameters from the anaesthesia and other documented clinical observations.

An anaesthetic record system normally supports the following functions:

- Patient registration
- Patient identification
- Scanning of relevant documents
- Results documented on a specific template
- Acquisition of vital parameters from the anaesthetic work station and other medical devices (integrated with these devices)
- Report generator
- Support for quality review and statistical data
- Interface (usually HL7) towards other systems.

Anaesthetic record systems can be configured in different ways, depending on when they were developed and to what extent they are interfaced to medical devices. It is intended to be used for the patients' diagnosis and treatment.

Qualification

The purpose of an anaesthetic journal system, as described above, is to generate information that supports treatment of a disease, an injury or a handicap. Depending on how a manufacturer specifies a product, an anaesthetic record system can be considered to have a medical purpose according to the definition of a medical device.

Associated risks

Depending on system complexity, various functions are either built-in or integrated through an interface. The information presented to the user is complex and critical. The user has limited possibilities for checking whether the system presents accurate information. If the system fails the risk for maltreatment is obvious.

Classification

An anaesthetic record system that is a medical device is an active diagnostic device and should fall under Class I according to rule 12.

3. Medication Module

A medication module is a decision support system and a process support linked together with several activities by different parties. The medication module can consist of several components, often by different vendors, where the combination of all components constitutes the functionality.

The medication modules interact with other modules in an *electronic patient record system*, especially with *documentation* and *laboratory modules*. The *Warning module* has traditionally been a part of the medication module since severe hypersensitivity reactions have been essential. For specific patient groups that require scheduled treatments (e.g. oncology patients) the interaction with the *scheduling* and *booking module* will be essential to safely manage a complex chain of drug supply for outpatients.

A medication module can, among other things, include:

- Medication list with a compilation of all ongoing medication for a patient (including history)
- Warnings and hypersensitivity
- Prescription module (prescriptions)
- Prescription support
- Drug dispension module (for nurses)
- Pharmacy module (ordering of drugs)
- Pharmacist module (requires that the process is implemented with the pharmacist involved in the prescription)
- *Quality system, quality registry*
- *National databases (Swedish National Board of Health and Welfare)*
- *Clinical studies of medications*
- Communication with pharmacy.

ePrescriptions

The ePrescription feature can be seen as a part of the medication module. ePrescription does traditionally include a prescription module in an electronic patient record system with the possibility to transfer an electronic prescription. Usually the health care provider uses an incoming server (where information often is rearranged) before the prescriptions are transferred to the pharmacy for further distribution to the local pharmacies or to the national electronic mailbox. The pharmacy is finally using a handling system where the medication is handed out. In addition, there is also often software for encrypting and signing to ensure secure data transfer in the various networks. The information is transmitted in both directions, for instance to confirm received data or to generate an error message. An important part in the ePrescription chain is the data transfer in the different private or public networks, whether the services are internally operated or provided by an external operator. The situation for ePrescrition services is that software from different vendors is being used by different organisations at many different levels.

Qualification

The general purpose with a medication module is to provide information so that the patient gets the appropriate medication for e.g. treatment, alleviation or compensation for an injury or handicap. Depending on how the manufacturer specifies its product, a medication module can be considered to have a medical purpose according to the definition of a medical device.

Associated risks

Information transfer and security are essential for patient safety. Medication modules have raised expectations of increased patient safety, improvements in logistics and follow-up as well as cost effectiveness.

The earlier manual systems have had problems when it comes to follow ups and quality assurance. The handwriting and the interpretation of people's handwriting are daily challenges for nurses and pharmacists.

In Sweden there have been a number of documented severe incidents (even deaths) due to the malfunction of medication modules. Pharmacies, have reported problems in the e-prescriptions chain where patients have been handed the wrong medication. One problem in particular is that data bases and sources to the medication modules have differed in quality.

Classification

A medication module that is a medical device is an active diagnostic device and should fall under Class I according to rule 12.

4. Clinical Information System – CIS/ Patient Data Management System – PDMS

CIS/PDMS are software based decision support systems primarily intended for intensive care units to store, manage and transfer patient information generated in association with the patients' intensive care treatments. Usually the system contains information like patient identification, vital intensive care parameters and other documented clinical observations.

CIS/PDMS normally supports the following functions:

- Patient registration
- Patient identification
- Scanning of relevant documents
- Results documented on a specific template
- Acquisition of mainly vital parameters from most types of medical devices that are used in an intensive care unit
- Medication prescription, distribution, follow up and reminders
- Lab results
- Report generator
- Support for quality review and statistical data
- Interface (usually HL7) towards other systems.

The CIS/PDMS that are available on the market can be configured in different ways, depending on when they were developed and to what extent they are interfaced with medical devices. Depending on system complexity, various functions are either built-in or integrated through an interface.

Qualification

A CIS/PDMS system as described above is intended to support diagnosis and treatment of disease or injury of a patient, and have therefore such functions and medical purpose that fall under the medical device directive. Systems with such medical purpose, as stated by the manufacturer, shall be considered to qualify as medical devices and shall be CE marked.

The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Associated risks

CIS/PDMS systems are especially complex products that normally require extensive configuration work. The product is part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed. The information presented to the user is complex and critical. The user has limited possibilities for checking whether the system presents accurate information.

If the CIS/PDMS system functions insufficiently, and not according to the intended use, then there are obvious risks for maltreatment. If incorrect information is presented to health care staff then the wrong measures could be taken. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

Classification

A CIS/PDMS system that is a medical device is an active diagnostic device and should fall under Class I according to rule 12.

5. CTG Central Station

A CTG central station is a software based system intended for delivery rooms to store, manage and transfer patient information acquisitioned from CTG equipment (cardiotocography) about the foetus and mother in connection to childbirth. Usually the system contains information about patient identity, vital parameters from the delivery and other documented clinical observations.

A CTG central station normally supports the following functions:

- Patient registration
- Patient identification
- Scanning of relevant documents
- Results documented on a specific template
- Acquisition of vital parameters from CTG equipment and sometimes other medical devices
- Report generator
- Support for quality review and statistical data
- Interface (usually HL7) towards other systems.

The CTG centrals that are available on the market can be configured in different ways, depending on when they were developed and to what extent they are interfaced with medical devices. Depending on system complexity, various functions are either built-in or integrated through an interface.

Qualification

CTG centrals are normally decision support systems intended to support diagnosis and treatment of disease or injury of a patient, and have therefore such functions and medical purpose that fall under the medical device directive. Systems with such medical purpose, as stated by the manufacturer, shall be considered to qualify as medical devices and shall be CE marked.

The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Associated risks

CTG centrals are very complex products that normally require extensive configuration work. The product is part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed. The information presented to the user is complex and critical. The user has limited possibilities for checking whether the system presents accurate information.

If the CTG central functions insufficiently, and not according to the intended use, then there are obvious risks for maltreatment. If incorrect information is presented to health care staff then the wrong measures could be taken. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

Classification

A CTG central that is a medical device is an active diagnostic device and should fall under Class I according to rule 12.

6. Prehospitalt ECG

Systems for managing pre-hospital ECGs are software based decision support systems intended for ambulance services to store, manage and transfer patient information from patients that are connected to an ECG monitor. Usually the system contains information about patient identity, vital parameters from the transport and other documented clinical observations. The systems also transfer and often document prescriptions from the doctor at the admitting hospital to the paramedics to start the patient's treatment during the transportation.

A system for pre-hospital ECGs normally supports the following functions:

- Patient registration
- Patient identification
- Results documented on a specific template
- Acquisition of vital parameters from ECG monitors and sometimes other medical devices
- Report generator
- Support for quality review and statistical data
- Interface (usually HL7) towards other systems.

The systems for managing pre-hospital ECG that are available on the market can be configured in different ways, depending on when they were developed and to what extent they are interfaced to medical devices. Depending on system complexity, various functions are either built-in or integrated through an interface.

Qualification

Systems for managing pre-hospital ECGs are usually intended to support diagnosis and treatment of disease or injury of a patient, and have therefore such functions and medical purpose that fall under the medical device directive. Systems with such medical purpose, as stated by the manufacturer, shall be considered to qualify as medical devices and shall be CE marked.

The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Associated risks

Systems for managing pre-hospital ECGs are especially complex products that usually require extensive configuration. The product is part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed. The user has limited possibilities for checking whether the system presents accurate information. The information presented to the user is complex and critical.

If incorrect information is presented to health care staff then the wrong measures could be taken. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

Classification

Systems for managing pre-hospital ECGs that are medical devices are an *active diagnostic device* and should fall under class IIa according to rule 10. If the intended use includes monitoring of vital parameters it should fall under class IIb according to the same rule.

7. ECG Storage System

Systems for storing ECGs are software based decision support systems used by most clinics to store, manage and transfer information about patients' examinations from resting ECG or exercise ECG. The system normally contains information about patient identity, averaged ECG complexes, measurement results and a computerised ECG interpretation that have been reviewed, edited (if necessary) and finally approved by a physician.

ECG storage systems normally support the following functions:

- Patient registration
- Patient identification
- Results documented on a specific template
- Acquisitioned signals of averaged ECG complexes from ECG equipment
- Physician's signature
- Report generator
- Support for quality review and statistical data
- Interface (usually HL7) towards other systems.

Most ECG storage systems on the market are configured in similar ways. Depending on system complexity, various functions are either built-in or integrated through an interface.

Qualification

ECG storage systems are decision support systems and are normally intended to support diagnosis and treatment of disease or injury of a patient, and have therefore such functions and medical purpose that fall under the medical device directive. Systems with such medical purpose, as stated by the manufacturer, shall be considered to qualify as medical devices and shall be CE marked.

The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Associated risks

ECG storage systems are especially complex products that normally require extensive configuration work. The product is part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed. The information presented to the user is complex and critical. The user has limited possibilities for checking whether the system presents accurate information.

If the ECG storage system functions insufficiently, and not according to the intended use, then there are obvious risks for maltreatment. If incorrect information is presented to health care staff then the wrong measures could be taken. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

Classification

An ECG storage system that is a medical device is an active diagnostic device and should fall under Class I according to rule 12. If the manufacturer states that the system is the only place where an ECG can be reviewed for diagnosis, then instead it should be a Class IIa device according to rule 10.

8. Retinal Imaging System

Retinal imaging systems are software based decision support systems used by typically eye clinics to store, manage and transfer information about patients who have had the eye ground photographed. The system usually contains information about patient identity, stored images of the eye ground and measurement results.

A retinal imaging system normally supports the following functions:

- Patient registration
- Patient identification
- Results documented on a specific template
- Acquisition of images generated from a retinal camera or OCT-camera
- Report generator
- Support for quality review and statistical data
- Interface (usually HL7) towards other systems.

The retinal imaging systems on the market are usually configured in similar ways.

Depending on system complexity, various functions are either built-in or integrated through an interface. The quality of the screens is of importance at the work stations.

Qualification

Retinal imaging systems are normally intended to support diagnosis and treatment of disease or injury of a patient, and have therefore such functions and medical purpose that fall under the medical device directive. Systems with such medical purpose, as stated by the manufacturer, shall be considered to qualify as medical devices and shall be CE marked.

The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Associated risks

Retinal imaging systems are especially complex products that usually require extensive configuration. The product is part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed. The information presented to the user is complex and critical. The user has limited possibilities for checking whether the system presents accurate information.

If a retinal imaging system functions insufficiently, and not according to the intended use, then there are obvious risks for maltreatment. If incorrect information is presented to health care staff then the wrong measures could be taken. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

Classification

A retinal imaging system that is a medical device is an active diagnostic device and should fall under Class I according to rule 12.

9. Picture Archive Communication System (PACS)

Background

The following section is based on text from the Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices

Basically, a PACS (Picture Archiving and Communication System) workstation is specifically designed to be networked with a variety of diagnostic imagining systems, e.g. X-ray, nuclear medicine, magnetic resonance imaging (MRI) or ultrasound, as well as laboratory or patient record systems. It does not have control of the direct operation of a diagnostic imaging system and is designed to receive, archive and transmit data both on-line and off-line. It is typically located at a different site than the imaging systems and is designed to provide various possibilities for further processing, manipulation and/or viewing patient images and information collected from diagnostic imaging systems.

Generally speaking there are three types of PACS:

a) PACS used for reviewing, archiving and transmitting images
b) PACS used for post-processing images for diagnostic purposes such as:
    - image processing functions which alter the image data (e.g. filtering, multiplanar reconstruction, 3D reconstruction)
    - complex quantitative functions (e.g. artery stenosis evaluation, ventricular volume calculation, calcium scoring, automatic indication (detection) of potential lesions
c) PACS used for image enhancement by controlling image acquisition.

In cases where the PACS fall under the definition of a medical device, i.e. is specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the medical device definition, the following situations can be foreseen:

In relation to PACS a) intended by its manufacturer to be used for viewing, archiving and transmitting images, it is considered that applying rule 12 could be appropriate, and accordingly this type of PACS is generally classified as Class I medical devices. However, PACS that are only intended for archiving or storage of data may not fall within the definition of a medical device provided that data is not manipulated.

Those types of PACS b) which drive a device or influence the use of a source device fall automatically in the same class in accordance with rule 2.3. Accordingly they should be Class IIa or IIb.

If this type of PACS b) does not drive or influence the use of the source device, this type of PACS can be classified under rule 10 if such PACS are intended to allow direct diagnosis, classifying them as Class IIa.

PACS c) falls under the same class as the source device. This is based upon firstly implementing rule 2.3 ”Software, which drives a device or influences the use of a device falls automatically in the same class” and the last paragraph of MEDDEV 2.4/1 rev 8 section 3.2 stating that “Standalone software, e.g. software which is used for image enhancement is regarded as driving or influencing the use of a medical device and so falls automatically into the same class. Other standalone software, which is not regarded as driving or influencing the use of a device, is classified in its own rights.” Applying this classification rule and the interpretation from MEDDEV allows this type of PACS c) to be classified as Class IIa or IIb medical devices according to the classification of the device itself.

10. Radiological Information System (RIS)

A RIS (Radiological Information System) is a software based system used at radiology departments to store, process or transfer radiological images and patient information. The system normally includes functions for patient identity, scheduling, examination results and imaging identification details.

Radiological Information Systems normally support the following functions:

- Patient registration
- Scanning of referrals and documents
- Entering results
- Reports
- Sending clinical reports by using for instance fax and e-mail
- Patient identification
- Interactive documents
- Scheduling of appointments
- Creating customised reports
- Interface to PACS
- Invoicing
- Procedures.

Depending on system complexity, various functions are either built-in or integrated through an interface.

Qualification

A RIS can be configured in many different ways. In its simplest form, such as how systems where designed 5-20 years ago, it was used only as an administrative tool and therefore made a borderline case whether to be classified as medical devices or not. A modern RIS is however intended to be used for the planning of a patient's diagnosis and treatment.

Those RIS that are available on the market are normally intended to support diagnosis and treatment of disease or injury of a patient, and have therefore such functions and medical purpose that fall under the medical device directive. Systems with such medical purpose, as expressed by the manufacturer, shall be considered to qualify as medical devices and shall be CE marked.

The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Associated risks

RIS are highly advanced products that normally require extensive configuration work. The product is part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed. The information presented to the user is complex and critical. The user has limited possibilities for checking whether the system presents accurate information.

If a RIS functions insufficiently, and not according to the intended use, then there are obvious risks for maltreatment. If incorrect information is presented to health care staff then the wrong measures could be taken. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

Classification

A Radiological Information System (RIS) that is a medical device is an active diagnostic device and should fall under Class I according to rule 12.

11. Telemedicine System

Telemedicine is a technology that can lead to dramatic changes within health care development. Technologies such as digital imaging processing, mobile communication and sensors have enabled the development of telemedicine applications. Even though a number of applications already are mature technologies, many still have a long way to go before they can be implemented in the daily clinical environment.

Telemedicine applications allows for:

- Monitoring of patients' health conditions remotely, and allowing for faster interventions
- Reducing the need for patients to come to the hospital for treatments
- Effective use of health care staff
- Raising the competence for health care staff
- Reducing transportation costs for both patients and staffs
- Utilising foreign and national clinical expertise
- Giving patients better possibilities to be more actively involved in their own health, "patient empowerment".

To mention a few different types of telemedicine applications

Interactive behavioural development

Individuals with various health problems, e.g. obesity, diabetics, rehab after physical injury, change in life style, are connected to an interactive cell phone app where entered data, as well as the lack of entered data, is communicated with the patient interactively.

Preventive care – individuals at risk for stroke or who had a minor stroke

By online monitoring via mobile broadband the patient can be risk assessed and a stroke could be prevented by medication.

Long-term ECG – 24, 48 or 72 hours

To view arrhythmias and events that occur infrequently for patients with early heart problems to prevent more severe disorders.

Combined data, weight, physical activity, body temperature, pulse/oxygen and ECG with HRV analysis

By applying a multi-use-sensor on the body with mobile communication, the caregiver could be provided with comprehensive data of the most common parameters.

Telesurgery

Telesurgery uses telecommunication and IT solutions to conduct a surgical intervention from a remote location. With the help of virtual technology and telerobots a surgeon placed on a remote location can conduct surgery by moving the hands while the manoeuvre is transferred to a surgical robot.

This technology is still young and not fully developed, but it exists in military applications. It will most likely take at least ten years before the application is widely spread and available.

Telepathology

In telepathology applications the pathologists uses a telemedicine solution to view and evaluate a pathological sample from a remote location.

There are three different types of telepathology – static, real time and virtual telepathology.

At static, or "store and forward" telepathology, a digital camera is used connected to a microscope which transfers the image from a sample.

Real time pathology is when the pathologists control the microscope.

At virtual telepathology, micro array technology is used to create a three dimensional image of the total sample to be reviewed from a remote location.

Home care monitoring, wired or mobile

A system for home care monitoring uses IT and mobile telecommunication to monitor the patient's health remotely to check that the patient receives sufficient help. The patient is given equipment to measure e.g. blood pressure, oxygen saturation, pulse, weight, etc, and the results are transferred to the clinic for evaluation. See the product example described in chapter 16 Web system for monitoring medical devices.

Retinal imaging

Telemedicine is used for transferring retinal images to utilise remote competence to diagnose diseases of the retina, mainly for diabetic related retinopathy. The DICOM standard is used for transferring image information.

Remote ECG monitoring

Telecardiology means that the ECG is transferred to a specialist for review by using the telecommunication system or IT network. This technology can, for instance, be used for patients with pacemakers or implanted defibrillators (ICD).

Teledermatology

Teledermatology is a technique used to evaluate skin disorders by a remote expert.

Video appointments

Video conference systems are used for remote consultations between clinics and patients. This technology has recently been used especially within psychiatry.

Teleradiology

Teleradiology is used to review radiological information from a remote location by a radiology expert. Systems are already in use. Today these are also frequently used for radiologists that are on call, where they can stay at home or elsewhere without the need to physically attend the clinic (unless an interventional technique is required).

Qualification

Telemedicine applications are normally intended to support diagnosis and treatment of disease or injury of a patient, and have therefore such functions and medical purpose that fall under the medical device directive. Systems with such medical purpose, as stated by the manufacturer, shall be considered to qualify as medical devices and shall be CE marked. The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Associated risks

Telemedicine applications are very complex products that normally require extensive configuration work. The product is part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed.

If a telemedicine application functions insufficiently, and not according to the intended use, then there are obvious risks for maltreatment. If incorrect information is presented to health care staff then the wrong measures could be taken. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

Classification

A telemedicine application that is a medical device is normally an active *diagnostic device* and should fall under Class I according to rule 12.

12. Applications for cell phones and tablets

Applications for cell phones and tablets, or "cell phone apps" are typically small applications which run as a sub function in a larger and more complex digital environment, usually on a cell phone, e-reader, tablet PC or Laptop, but also in a computer or as part of a larger system in a server environment or as a web based function.

It could also be an application that is installed in a cell phone or a tablet that is part of a medical device combination, belonging to health care staff or the patient.

Examples of components in a combination:

- Web Based Patient Questionnaires. The service makes it simple for the patient to answer any questions that the doctor or nurse requires on different occasions. The patient will answer the cell phone (since the patient's cell phone usually is nearby) and does not need to login at a computer for responding. Neither does the patient need to own a computer. The patient does not have to send questionnaires by ordinary mail. The doctor and nurse can work more efficiently since they do not have to call every patient to book new appointments or perhaps meet them for follow up. When the patient has responded, the answers are sent to the database.
- The database is used for compiling the information after the patient has answered the questions in the cell phone.
- This web application is intended for doctors or nurses to view the answers from the patients. The results are presented as graphics.

What characterises a cell phone app is that it receives or acquires data in real time mode for immediate processing and distribution and thereafter displays data, often as a change from the previous state. The distribution can be that the result is displayed on the device screen and/or sent to a new environment via some kind of communication interface, such as mobile broadband or Internet. Several parallel environments may exist for reviewing the result from an app.

Cell phone apps are usually interactive in such way that an occurrence in the app, or non-occurrence, generates a message or an alert to someone about something.

Qualification

Cell phone apps may be intended to support diagnosis and treatment of disease or injury of a patient, and have therefore such functions and medical purpose that fall under the medical device directive. Cell phone apps with such medical purpose, as expressed by the manufacturer, shall be considered to qualify as medical devices and shall be CE marked.

Examples of cell phone apps that shall be CE marked are those intended to transfer data from the human body, such as body temperature, weight, pulse, pulse/oxygen in combination, various types of ECG, irrespectively if data has been entered via a sensor with body contact or implanted, or if data has been entered manually. If the purpose is to collect data for diagnosis to influence the health of the individual who sends the information, then the cell phone app has a medical purpose and shall be CE marked.

A cell phone or "smartphone" that the software is run on, or through, however, is not a medical device unless it is converted for an explicit medical purpose.

The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Associated risks

The most common risk with apps in cell phones, or other mobile digital communication devices, is the sudden loss of energy leading to data transfer interruption. To avoid this problem the user is usually prompted by an alert, however, this cannot always be guaranteed. Another common risk is that the communication gets interrupted due to external problems.

Cell phone apps are often part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed. The manufacturer must choose a design where this complex nature can be managed by the system itself, and where the user only needs to follow logical instructions and options displayed on the screen of the mobile device.

If the cell phone app functions insufficiently, and not according to the intended use, then there are obvious risks for maltreatment. If incorrect information is presented to patients or health care staff then the wrong measures could be taken. It is therefore necessary for the developer to manage patient identification so that the information can always be allocated to the right patient.

Evaluations can be delayed due to access problems in the system, which could be critical for some patients. Cell phone apps should for that reason never be used on patients who have diseases where time is critical. The design must also guarantee that the information transfer causes no delay in order to provide proper diagnostic support.

Classification

A cell phone app that is a medical device is normally an *active diagnostic device* and should fall under Class I according to rule 12 or Class IIa according to rule 10.

13. Advanced Decision Support System, Expert System

Medical decision support systems is a general term for a large number of various systems and means in this context computer based tools for providing health care professionals with guidance for diagnosis, prognostics, monitoring and treatment of individual patients or groups of patients. Decision support systems use some form of a medical knowledge database such as e.g. best practises, and combine this data with acquired information about one or more patients.

Decision support systems normally support the following functions:

- Acquisition and storage of information
- Processing of information at individual and/or population level
- Presentation of customised information
- Integration at different levels towards other systems, such as e.g. electronic patient record systems.

Some types of decision support systems also support processing and presentation of decision support for a specific patient which is based on the patient's own medical information.

There are often interfaces available for integration with electronic patient record systems and web applications.

At a basic level, a decision support can for instance consist of simple information presentation or that a patient's diagnosis is included in the software that provides health care professionals with recommendations on treatment methods. More complicated systems, expert systems, can on the other hand include functions for e.g. processing information on different patient results and calculate medication doses based on this information. Other systems process information from a large number of individuals and parameters to provide support for e.g. monitoring diabetes patients at a clinic, at both individual level and as a group.

Qualification

Decision support system that only provides support and information about a population is best compared with quality registers, refer to that product example.

However, systems intended to be used as a decision support system for individual patients can meet the definition of a medical device. A decision support system, that is intended to support diagnosis and treatment of disease and injury of a patient, have the functions and medical purpose that fall under the medical device directive. Systems with such medical purpose, as stated by the manufacturer, shall be considered to qualify as medical devices and shall be CE marked.

The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Associated risks

Medical decision support systems are very complex products that normally require extensive configuration work. The product is part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed.

If the medical decision support system functions insufficiently, and not according to the intended use, then there are obvious risks for maltreatment. If incorrect information is presented to health care staff then the wrong measures could be taken. These systems take over the responsibility of the human to a various extent based on the complexity of the system. However, evaluation and final decision is usually made by the user. A user might find it difficult to evaluate the accuracy of the presented information, which is a risk for maltreatment and harm if a failure occurs due to incorrect or missing information. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

Classification

Medical decision support system that is a medical device is an *active diagnostic device* and should fall under Class I according to rule 12.

14. *In vitro* diagnostic software – LIS & WAM

Laboratory Information Systems (LIS) and Work Area Managers (WAM) mean in this context systems that support the IVD process. Typically they have pre-analytical functions for ordering, sorting and distribution of test samples. The main task is the analytical process. It is possible to do different types of validation, quality control and be interconnected to various analytical instruments. Finally the post analytical process takes care of communication of laboratory results, statistics and optional reporting to external databases (e.g. to the Swedish Institute of Infections Disease Control).

The software normally supports the following functions:

- Ordering of laboratory tests, samples with labels and sorting
- Analysis, technical and clinical validation, connection to analytic instruments
- Laboratory results and reports on paper, fax or electronic records that can be directly returned to e.g. the ordering clinic's patient record.
- Analytical instruments can in some cases be interfaced with Hospital Information Systems (HIS), Electronic Patient Record Systems, Infectious control databases etc.

Associated risks

Laboratory Information Systems (LIS) and Work Area Managers (WAM) are especially complex products that usually require extensive configuration. The product is part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed.

There are obvious risks for maltreatment if Laboratory Information Systems (LIS) and Work Area Managers (WAM) do not function satisfactorily and in accordance with their intended use. If incorrect information is presented to health care staff then the wrong measures could be taken. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

Qualification

Laboratory Information Systems (LIS) and Work Area Managers (WAM) are usually intended to support diagnosis and treatment of disease or injury of a patient, and have therefore such functions and medical purpose that fall under the medical device directives. Systems with such medical purpose as stated by the manufacturer shall be considered to qualify as medical devices or IVD medical devices and shall be CE marked. See section 4.2.

The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Laboratory Information Systems (LIS) and Work Area Managers (WAM) that are IVD medical devices should be considered to be an IVD medical device other than those covered by Annex II and devices for performance evaluation.

15. Transfusion Medicine Blood Data System

Blood data systems are used to manage information on patients, blood donors and blood components for transfusion medicine.

The system has a large number of built-in security checks and control barriers. These are used for staff to verify that patients receive the correct blood component at blood transfusion and that the blood donor is giving blood in accordance with the appropriate rules. It is possible to register waiting periods or block blood donors in the system. The system then keeps track on donors that have waiting periods or have been prohibited to leave blood by the blood donor centre.

Security checks are typically used:

- To ensure that blood tests correspond to the right patient or blood donor and that the lab result comply with previous test data
- Generate alerts if lab results deviate from previous test data and prevent automatic registration of deviated results
- For some test methods, lab results are used to automatically block the use of other test methods.
- For dispatch of blood components to patients. If the features of the blood component are noncompliant with the applicable patient requirements, the system blocks the dispatch of a blood component to that patient.
- To ensure that blood components comply with the requirements when selling blood to the pharmaceutical industry
- To verify that patient data matches blood donor data when booking blood components for transfusion. The system blocks certain combinations of patient/blood donor data to safeguard patients from potentially life threatening blood transfusions.

By utilising registered patient data and blood donor data the system can suggest appropriate blood components at blood transfusion for patients.

The system supports the staff to choose the correct type of blood components to a patient.

The blood data system is integrated with different analytical instruments for automatic transfer of analytical results for patients and blood donors. The integration often works in both directions. The analytical instrument communicates with the blood donor system concerning what analysis should be carried out on blood tests from patients or blood donors. Based on previous data on a patient, the blood data system can be configured to make decision on analyse method. For instance, when ordering blood grouping of a patient, if the patient is unknown to the system, the blood data system will request forward grouping (Typing red cells for A and B antigen) and reverse grouping (Screening serum or plasma for the presence of anti-A and anti-B isoagglutinins). If the system already contains information of previous blood grouping data on the patient the system can request forward grouping only". At blood grouping of blood donors, the blood group from the blood donation is checked against the previous blood group of a donor when giving blood. If the blood groups don't match, the system automatically blocks all blood components from the blood donation to prevent booking of patients or distribution of blood.

The blood data system is integrated with other lab systems for transfer of lab results from different laboratory disciplines, such as from clinical chemistry and virology analysis. The system automatically blocks all blood components from the blood donation to prevent booking of patients or distribution of blood if lab virology results are positive.

Associated risks

A blood data system is a very complex IT system that requires accurate configuration to meet a satisfying safety level.

A blood data system functions both as a decision support system and an expert system. Evaluations and decisions that are critical to a patient's treatment cause delays if the access to the system is interrupted. Some types of analysis cannot be conducted, and recommendations for blood components to a patient cannot be managed if the system has limited access.

If the electronic blood data system functions insufficiently, offers limited access, or is not used according to the intended use, then there are obvious risks for maltreatment. If the wrong information is displayed for health care professionals or the system is configured with the wrong security functions, then this could lead to incorrect measures and life threatening situations.

Qualification

A blood data system, as stated by the manufacturer, is intended to be used as a decision support system or expert system for measures of medicine for transfusion in respect to diagnosis and treatment of disease or injury. A blood data system can therefore be considered to have a medical purpose according to the definition of a medical device.

Classification

A blood data system that is a medical device is an active diagnostic device and could fall under Class I according to rule 12.

(Blood data system can also be intended to control the use of blood components according to rule 8 and can therefore be an accessory of such.)

16. Web System for Monitoring Medical Devices

Web system for monitoring of active implants

A Web system for monitoring of active implants (e.g. pacemakers or implantable cardioverter defibrillators [ICD]), is one or several applications and databases used at cardiology clinics to store, analyse and transfer cardiac information from the patients' implants. Cardiac information is sent over the Internet, phone or cell phone from an external transmitter, which also can function as a receiver, in the patient's home or from a mobile transmitter communicating with the implant through an inductive communication link or through a radio communication link. The information can also be sent from the clinic that has reviewed a pacemaker patient by using a programmable device.

The patient's cardiac information is only available to the health care professionals at the clinic where the patient belongs to.

The system normally contains information on patient identity and cardiac information from patients' implants. The information in the system can be forwarded to other electronic patient record systems through regular interfaces.

Web systems for monitoring of IVD medical devices

For monitoring of e.g. diabetes patients, there are applications to be used by endocrinologists to store, analyse and transfer information from a patient's insulin pump or blood sugar counter. The information is transferred in the same manner as for cardiac implants, as mentioned above. The information can also be acquired and sent directly from the clinic that has followed up a diabetic and who need comprehensive information about the patient's treatment.

The patient's information is only available to the health care professionals at the clinic where the patient belongs to.

Usually the system includes information about patient identity, diagnostic information from the patient's blood sugar counter and operational status from the insulin pump. The information in the system can also be forwarded to other electronic patient record systems through regular interfaces.

Qualification

Web systems for monitoring of medical devices are normally intended to support diagnosis and treatment of disease or injury of a patient, and have therefore such functions and medical purpose that fall under the medical device directive. Systems with such medical purpose, as stated by the manufacturer, shall be considered to qualify as medical devices and shall be CE marked as AIMD medical devices, accessories for IVD medical devices or general medical devices.

The manufacturer can choose to divide the system into modules with or without a medical purpose and only CE mark those modules that have a medical purpose.

Associated risks

Web systems for monitoring of medical devices are especially complex products that normally require extensive configuration work. The products are part of a very complex environment that is affected by many external factors, e.g. upgrades of the operating system where the software is installed.

If a Web system for monitoring of medical devices functions insufficiently, and not according to the intended use, then there are obvious risks for maltreatment. If incorrect information is presented to health care staff then the wrong measures could be taken. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

Classification

Web systems for monitoring medical devices that are general medical devices are active diagnostic devices and could fall under Class I according to rule 12.

17. Quality Registries

The national quality registries acquire individual data about diagnosis, measures and treatment outcomes. The quality registers have been developed to be used as tools to improve the quality in health care by ongoing analysis of data. They also play an important role for transparent comparisons and research within health care.

The national quality registries are a set of quality tools that gives unique possibilities to develop the quality within the health care sector. They have been developed mainly with limited financial resources and with little governmental control. The registries have been developed by professionals and the registries are often managed by different clinics in Sweden. The different registries are allocated to health care organisations with the authority and responsibility to manage personal data.

When a registry is fully developed it can be used to follow up the effectiveness in health care for all patients in a clinical area and on a national basis. It is also possible to follow up the effectiveness on regional, hospital or clinic level.

There are at present (in 2012) 78 national quality registries operating in Sweden which are jointly funded through the health care providers and the Swedish government. Additional registries are planned or under construction, and during 2012, 27 new registries will get funding.

The quality registries are tools for continual education and development and they are essential components in a modern health care system. Swedish Association of Local Authorities and Regions are collaborating with the National Board of Health and Welfare at strategic level and provides funding and support for the development of the registries. Each year the registries have to apply for new funds, and at the same time feedback is given on suggestions for development and improvement of the registry. This feedback is an important part for quality assurance of the National Quality Registries.

The Swedish Society of Medicine and the Swedish Society of Nursing are also participating on a national level. Administration of the registries funding is managed by The National Board of Health and Welfare.

Future use of the quality registries

The following strategic goals demonstrate which areas of development that are prioritised to further improve the use of the registries.

The national quality registries:

- Provides a multilayer view of the quality in the health care sector: medical quality (survival, complications, drugs, etc.) functional quality (if the patient can walk, get dressed, go shopping, etc.) and quality experienced by the patient (the patient's evaluation of the clinical result, presence of pain, how the patient has been treated on a personal level, etc.)
- Are actively involved in measurement based and patient focused work for continual improvements
- Follows the patient's path through health care and overcome organisational and professional boundaries
- Contributes by presenting their results in a transparent way and by making them accessible and adapted for medical profession, society and health care management
- Are integrated with the electronic patient record systems.

Qualification

Quality registries are in fact intended to improve health care but since they are rather aimed for a population than a specific patient they don't qualify as medical devices. However, there are software that extracts, processes and compiles information from the registries to match criteria for a specific patient, to be used as a decision support for that patient. Such software can, depending on how the manufacturer has described the purpose of the software, be determined to be medical devices.

18. Quality Indicators

A quality indicator is a measure that can be used to reflect the quality and effectiveness of social services and health care. Quality indicators can be useful tools to develop an organisation.

Different types of indicators

Indicators are traditionally divided into the following three groups:

- *Structural measures* demonstrate the fundamentals for good health care
- *Process measures* demonstrate actual activities within health care; when, where and how
- *Result measures* demonstrate health care results and outcomes of patients' health and wellbeing.

The National Board of Health and Welfare has introduced a set of criteria to be used for guidance when defining an indicator and to distinguish them from other key performance indicators and background information.

Applicable requirements for definition of indicators

- The indicator shall indicate quality or effectiveness in some area of the organisation that is being assessed
- The purpose of the indicator is to show areas of importance to achieve sustained/improved quality or effectiveness
- The indicator's concept, populations and measurement period shall be defined (i.e. the indicator should be reliable)
- The indicator shall be valid, i.e. it shall measure what it is intended to be measured or indicate what is intended to be indicated. It shall be based on profound knowledge, e.g. scientific relevance or proven experience
- The indicator shall indicate the direction, i.e. high/low values are used for good/poor quality and effectiveness
- The health care provider or organisation shall be able to influence the result.

Other requirements for indicators

- The indicator should be able to be measured with existing data
- The indicator should have a goal level, when possible
- The indicator should be applicable on a national level and possible to divide into sub divisions. Effort should be made to include municipalities, counties and units for comparisons, applying for both public and private organisations and NGO's within the public sector that operates with governmental funds
- The indicator should be based on different data compilations generated from different participators within the area.

Qualification

Quality indicators are in fact intended to improve health care but since they are rather aimed for a population than a specific patient they don't qualify as medical devices.

19. National System

The term medical information system also includes different software systems that are used within the health care sector on a national basis, and which is part of the national eHealth strategy.

One of the goals of the Swedish eHealth strategy is to make the patient information more easily accessible and to offer patients in Sweden better health care. Several systems that are included in the project, see below, are medical devices or depending on that medical device software work satisfactorily.

In general, the following areas are typically of interest:

- Systems for ePrescription
- The National Prescription Database, referred to as NOD
- The dose prescription support system, referred to as Pascal
- Data bases with medicine lists and codes, SIL, FASS etc.
- National Patient Summary (NPÖ)
- Different patient registries, quality registries.

At present there is a discussion whether it is possible, and how, to apply the regulatory requirements for such systems. The question is relevant also for those systems that are used by the pharmacy operators for ePrescriptions, so called prescription handling systems.

Pharmacy, ePrescriptions and prescription information

It has been discussed whether the systems that are part in the prescription chain are medical devices or not. The prescription module in the electronic patient record system has already been described in a separate section in this guideline. Even though systems such as National Prescription Database (NOD/Pascal) match the description of a system with a medical purpose, it has limited market potential since it is used in Sweden only, and therefore makes it questionable to CE mark. Internationally it is unlikely, if at all interesting, to come to a mutual understanding since each country has its own prerequisites for structure and operation of such systems.

In respect to the pharmacies prescription handling systems, the Swedish regulation contains general requirements and gives little guidance to aid pharmacies and inspectors from the Medical Products Agency.

However, the authorities have assessed that the requirements for software that are medical devices are appropriate in general, which could be a reason for the Medical Products Agency to use them as interpretation in respect to the requirements of a prescription handling system.

Data bases and registries

Various decision support systems, e.g. electronic patient record systems, interact and acquire a lot of information from data bases, drug lists and other registries. The requirements on the manufacturers are explicit but the systems can still cause maltreatment of patients if the acquired data in the registries is incorrect. It is therefore important that the administration of the registries have a security level that matches the requirements put on manufacturers of the decision support systems.

Collaborations and projects

Collaboration with other organisations and authorities has proven to be of importance since the national information systems have several inputs from several participators, and proper use requires that all parties share the same opinion on the systems functional status and limitations. A well defined partnership between different authorities (Medical Products Agency, National Board of Health and Welfare, Swedish Civil Contingencies Agency etc.) is essential to synchronise, develop and monitor the fulfilment of regulatory requirements.

Tryck: Åtta 45. 2013-01-31.

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

approvals • authorisation • clinical trials • communication • competence • cosmetics • dialogue • directives • efficacy • environment • evaluation • guidelines • harmonisation • health economics • herbals • homeopathics • information • inspection laboratory analysis • market surveillance • medicinal products • medical devices • narcotics • public health • quality • registration • regulations • reliability • risk/benefit • safety • scientific • standardisation • transparency • vigilance • approvals • authorisation • clinical trials •

Adress: Läkemedelsverket, Box 26, 751 03 Uppsala
Besöksadress: Dag Hammarskjölds väg 42
Telefon: 018-17 46 00 Fax: 018-54 85 66
E-post: registrator@mpa.se
Internet: www.lakemedelsverket.se