The Medical Products Agency’s Working Group on Medical Information Systems

Project summary

Proposal for guidelines regarding classification of software based information systems used in health care

This is an unconfirmed translation from Swedish of the report

“Läkemedelsverkets arbetsgrupp om Medicinska informationssystem
Projektredovisning
Förslag till vägledning för klassificering av vårdens mjukvarubaserade informationssystem”,
dated 2 June 2009

The revision dated 18 January consists of two translation corrections:

- The word “not” was missing on page 8, 4th paragraph.

- The term “Medical Device Directive” is changed to “Medical Device directives” in all places where all three directives are addressed.
# Content

1. Introduction ......................................................................................................................... 4
2. Abstract ................................................................................................................................. 4
3. Background ............................................................................................................................ 6
4. The Task .................................................................................................................................. 6
   4.1 Aim and objective .................................................................................................................. 6
   4.2 Method and structure .......................................................................................................... 6
   4.3 The Working group ............................................................................................................ 7
5. Definitions, terms, evaluation tools and principles ............................................................... 7
6. Applicable regulations ............................................................................................................ 9
   6.1 Regulations connected to device safety ................................................................................ 9
   6.2 Regulation regarding handling and use ............................................................................... 9
7. Classification .......................................................................................................................... 10
   7.1 About classification in general ........................................................................................... 10
   7.2 Characteristics that determines the classification of a medical information system ......... 10
   7.3 Choice of verification method in the regulation ................................................................. 12
8. Monographs .......................................................................................................................... 12
   8.1 Introduction, summary ....................................................................................................... 12
   8.2 Comments on the system descriptions .............................................................................. 13
9. Clinical evaluation of medical information systems ............................................................. 17
   9.1 Clinical evaluation does not necessarily mean clinical investigation ................................. 17
   9.2 Product and method is not the same thing ....................................................................... 17
10. Installation and maintenance of medical information systems in networks ...................... 20
   10.1 Infrastructure systems/Buildings ..................................................................................... 20
   10.2 Medical information systems communicates with other systems ................................ 20
   10.3 Managing residual risks, verification of installation ......................................................... 20
   10.4 Verification after changed prerequisites in the installation environment ......................... 21
11. Consequences for different stakeholders on the Swedish market ........................................ 22
   11.1 National consequences ........................................................................................................ 22
   11.2 Consequences for the health care providers ................................................................. 22
   11.3 Consequences for the manufacturers ............................................................................. 25
   11.4 Consequences for Medical Product Agency’s market surveillance ............................... 26
   11.5 Consequences for notified bodies .................................................................................... 27
12. Standardisation project ........................................................................................................ 27
   12.1 Useful standards are available .......................................................................................... 27
   12.2 Application of risk management for IT-networks incorporating medical devices (ISO/IEC 80001) ........................................................................................................................................ 27
   12.3 Medical device software – Life cycle processes (ISO/IEC 62304) ............................... 29
   12.4 Medical device software – Guidance on the application of ISO 14971 to medical device software (ISO/TR 80002) .............................................................................................................................. 29
   12.5 Mandate 403, eHealth-INTEROP ..................................................................................... 29
   12.6 Health informatics - Application of clinical risk management to the manufacture of health software (CEN ISO/TS 29321) and Health informatics - Guidance on risk evaluation and management in the deployment and use of health software (CEN ISO/TR 29322) ......... 30
   12.7 Communicating with medical devices in direct patient care – “Point-of-Care Diagnostics” .................................................................................................................................................. 30
13. Discussion ................................................................................................................................ 31
   13.1 Medical device or not ......................................................................................................... 31
   13.2 Administrative systems for the health care sector .......................................................... 31
   13.3 Requirements and statements at procurement .................................................................. 32
References ..................................................................................................................................... 34
Appendix ........................................................................................................................................ 36
Appendix 1 Constitution of the Working group ......................................................................... 36
Appendix 2 Monographs ............................................................................................................. 36
Appendix 3 Regulation on health care providers’ responsibility managing information systems .......................................................... 36
Appendix 4 Information from the Medical Products Agency’s web platform .......................... 36
1. Introduction
On 12 May 2008 the Medical Products Agency invited different stakeholders for a discussion on how programmable systems for processing patient information are affected by the Medical Device directives. The outcome of this discussion resulted in the Medical Products Agency initiating a working group, represented by different parties, with the task to assess and to provide information to be used as guidelines in classification matters.

Presented in this report is the outcome from the Working group. It must be pointed out that this document presents issues and suggestions that reflects the opinion in the Working group and that the decision making process to legally enforce valid guidelines is a responsibility of the authorities.

The Working group believes that the Swedish actors have a coherent view in this matter and that they share the conclusions in this report in general. While preparing the report, however, several comments were forwarded regarding the future work implementing appropriate routines and appointing positions in the health care organisations to meet the proposed device classifications. One of the project goals was that the expected outcome should serve as guidance for health care providers as well as a prerequisite for ensuring that the safety requirements for Medical Information Systems will have the intended effect. For future success, it is especially important that these components are accepted at all management levels in the health care organisation. A deeper analyse of the health care providers’ processes is not within the framework of this project.

2. Abstract
A general opinion of the health care providers represented in this Working group is that from a patient safety point of view, it is desirable that stand alone software and systems intended to, directly or indirectly, affect diagnosis, health care and treatment of an individual patient shall be regulated under a Product Safety Regulation. The Working group has not been able to define any other appropriate regulation than the Medical Device directives when it comes to the definition of such systems. Adherence to the Medical Device directives is important so that manufacturers and clients can work with the same intentions. This project report serves as one step towards the clarification regarding which conditions that shall apply.

The Working group believes that software intended for a medical purpose must be regarded as a "device" and expressions such as "project", "service" and similar must be avoided describing a Medical Information System. This approach has advantages since a product safety regulation, such as the Medical Device directives, can be applied and the product will have:

- a defined intended use
- defined and documented specifications
- a manufacturer with a clear responsibility until the delivery is accepted
- a controlled “Post Market” surveillance
Furthermore, the Working group believes:

- that the Medical Device directives shall be applicable for software and systems that fulfils the definition of a medical device
- that the manufacturer of the intended systems shall follow the appropriate validation method in the Medical Device directives
- that the level of risk shall be assessed, motivated and control the classification and verification method
- that applicable standards shall be followed for design, verification and validation regarding software and information systems that are medical devices
- that there is no legal requirement that manufacturers of devices in the lowest device classes must have certification for their operational processes to fulfil the Medical Device directives. The Medical Products Agency has in these cases no mandate to formally demand certification, such as for instance ISO 13485. 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 the prerequisite for a successful and fair application of the regulation assumes that health care providers demands that such systems shall be CE-marked and be regarded as medical devices
- that a controlled and standardised verification method when performing installation work 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 using the device.

The Working group has developed device descriptions, so-called monographs, for a number of Medical Information Systems. The descriptions are made with a specific terminology and the intention of the monographs is to function as classification guidance also for similar and future systems.

In general, the Working group has identified the need to improve the clarification of the intended use for a device. It is the responsibility of the manufacturer to describe the intended use in various ways, and this will hopefully be more refined than it has been up until today. Next step is for the users to implement the software in their own environment according to the intended use. The Working group experiences that there is a big need to develop and improve the relation between manufacturer and client in this respect, to ensure that devices are being used in the proper way as described by the manufacturer. Working with specifications, procurement, configuration and education are important tasks and must therefore be managed properly.

If a manufacturer claims that the offered information system intended to be used in health care is not classified as a medical device, then the medical expertise at management level should consider if that system is appropriate and safe for patients and users.
3. Background

Various health care providers and actors are uncertain of which rules that shall apply when it comes to information systems that are used in health care. The Medical Products Agency often gets questions about whether various software, intended to be used in health care organisations, should be defined as medical devices and if so, how they shall be classified. Furthermore, an increasing number of incidents have been noted with the involvement of computerized information systems. On some occasions patients have suffered severe consequences. In most of these cases the Medical Device directives has not been applied, either by manufacturers or by health care providers. This means that the assessment of safety issues has become unclear since the manufacturer’s responsibility is not clear.

Many systems are, without any doubt, to be considered as medical devices according to the Medical Device directives, and therefore also apply to the Swedish Medical Devices Act (1993:584). Still, others are borderline cases.

In the preamble of the amending directive 2007/47/EC, that changes the MDD 93/42, EU clearly points out the following

“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”.

4. The Task

4.1 Aim and objective
The task of the Working group has been to assist the Medical Products Agency in formulating a guideline for classification of medical information systems used in health care, based on the Medical Device directives and applicable standards. Implicitly, the classification system shall also describe the role for the notified bodies, and when they shall be consulted.

The mapping and proposed guidelines shall also be helpful for other authorities, manufacturers, distributors, procurement officials and users within health care organisations to follow the Medical Device directives.

This will encourage the fulfilment of a high level of patient safety.

4.2 Method and structure
The Medical Products Agency has been the convenor.

The tasks in the Working group have been to:

- identify relevant systems and assess why they are relevant
- identify what rules that may be applied
• identify what standards that may be applied
• discuss how to interpret the definition of medical devices according to the Swedish law and what the definition involves
• discuss the interpretation of classification rules that may be applied in order to classify devices in accordance with the classification rules
• discuss terms and nomenclature that can be useful at, for instance, procurement of systems
• suggest possible need for follow up and handling of systems where safety is of importance although the device is not regarded to be a medical device.

4.3 The Working group

5. Definitions, terms, evaluation tools and principles
The Working group has used a systematic approach and a set of terms appropriate to describe a programmable system in a way that supports a decision whether the system shall be handled as a medical device or not.

The Swedish law for medical devices is based on EU Directives. The devices covered are described in the definition of medical devices as expressed in the Swedish Medical Devices Act (SFS 1993:584)

2§ According to the law, 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:

1. diagnosis, prevention, monitoring, treatment or alleviation of disease
2. diagnosis, monitoring, treatment, alleviation of compensation for an injury or handicap,

The wording in the Medical Device directives definition of a medical device have caused some problems. If interpreted word-by-word it involves a great number of devices that has never been intended to be covered by the Medical Device directives. Due to this reason, EU has documented more or less well defined agreements which exclude some types of devices, even though they in a literal sense fulfil the definition. Such agreements can be found in the European Commission’s guidance document on Medical Devices referred to as MEDDEV. These documents are available at the website of the European commission¹. It has occurred that some actors have stated that specific software, for different reasons, should not be covered by the Medical Device directives even though they fulfil the definition of a medical device, with reference to an older version of MEDDEV.
Due to this reason, preventing the Working group from starting up with a discussion regarding exclusions etc, the first issue instead focused on **whether a specific device is considered to fulfil the definition of a medical device in the Medical Device directives in a broader perspective**, based on an interpretation word-by-word. The interpretation is based on the manufacturer’s expressed intention for a device.

A **device can be part of diagnosis and treatment**, directly or indirectly. In that respect the arguments do not differ from those used for traditional medical devices. Software can directly control radiotherapy treatment for instance. Most medical devices used for diagnosis, including in-vitro diagnostic 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.

Even though it is not clearly described in the legal framework, the interpretation of the Working group is that the Medical Device definition should **not apply** to devices intended for diagnosis, treatment, etc., **intended for a population** such as statistics, quality registries, etc.

The Medical Device directives 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. The next issue aims to focus on, if **a specific device is suitable to be regulated according to a product safety regulation**. The Working group has chosen to exclude items that cannot be regarded as devices in this context such as literature, forms or services.

The Working group agreed on 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**:

1. Device complexity
2. Responsibility user/manufacturer
3. Risk for maltreatment / injury
4. Feedback

**Point 1 and 2**: These parameters are used in the description to clarify that the manufacturer must take more responsibility for the proper function of a system where a user has little possibility to control and avoid hazardous situations. Many functions are often hidden for a user. The intention is to describe the difference between, for instance, older paper based patient records and systems for new electronic patient records.

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

**Point 3 and 4**: These parameters give basic information for conducting a 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 tool for risk classification.

6. Applicable regulations

6.1 Regulations connected to device safety

The Working group has assessed which Swedish regulations that would be appropriate for medical information systems and the use of such.

Requirements for manufacturers, integrated risk management, validation and product follow up, is stipulated in the European regulation on device safety, based on a concept called 'The new approach'. The Medical Device directives is such type of regulation, and it appears that many information systems fits into the definition of a medical device.

Medical devices are divided into three European directives 'Active Implantable Medical Devices (AIMDD)', 'In-Vitro Diagnostic Medical Devices (IVDD)' and 'other Medical Devices (MDD)', see definitions in the reference list at the back of this document. Devices belonging to MDD and IVDD have additionally been classified according to its level of risk, indicating how harmful it could be for a patient.

The classification of programmable systems (first sorted as MD, IVD or AIMD and then as risk classes) should not cause greater problems than it does already for other medical devices. It might be a problem concerning which verification route that is most appropriate within MDD or IVDD. Some routes imply only product quality assurance (MDD annex VI) or production quality assurance (MDD annex V) which is often an insufficient method for complex software. This problem is a known fact which is being discussed between the EU member states.

6.2 Regulation regarding handling and use

All providers within health care and dental services must have a management system for quality and patient safety implemented in their operation. The management system shall contain a basic set of routines which are the same for all types of operations. In the same way, all health care providers must also have routines for information management, record keeping and how to handle medical devices in their operations. The management system is then provided with additional routines depending on the type of operation.

The health care providers must consider three important fundamental regulations regarding quality, safety, information management, record keeping and medical devices. Additional fundamental regulations, with requirements on supplementary routines within some areas, are to be expected.

The regulation on quality and patient safety (SOSFS 2005:12), legally enforced in 2005, includes specific requirements on the management system of a health care provider when it comes to working with quality and safety. The quality system covers all parts of the operation and clarifies the responsibility between health care provider, operational manager and staff. The management system shall include routines for several critical areas such as, cooperation and collaboration as well as delivery of services, devices and technology. Two regulations, enforced in 2008, include more comprehensive requirements on the health care providers. The regulations partly cover information
management and record keeping (SOSFS 2008:14) and partly the use of medical devices, including information system, (SOSFS 2008:1). These regulations also contain norms regarding supplementary routines in the management system.

The new regulations have several points of interest; amongst other things it specifies the provisions for information systems. In the regulations on information management and record keeping it states that the information system shall have possibilities of tracking the actions for a user. The regulation on the use of medical devices contains provisions for information systems that are connected to medical devices.

The requirements for health care providers managing information systems, as well as those classified as medical devices or connected to such, are specified in Swedish National Board for Health and Welfare’s regulation, SOSFS 2005:12, for “Quality systems”, supplemented by the regulation SOSFS 2008:1 for “Handling medical devices” and the regulation SOSFS 2008:14 for “Information management and record keeping for health care providers”. The last-mentioned regulation requires that the health care provider must have an information security policy as well as one or more appointed staff responsible for handling information security.

Information on the regulation on transfer of personal data to a third country (non EU or EEA country) can be found on The Swedish Inspection Board’s website: http://www.datainspektionen.se/in-english/in-focus-transfer-of-personal-data/

Further information on Swedish regulations can be found in appendix 3 “Norms for health care providers’ responsibility managing information systems”.

7. Classification

7.1 About classification in general

It is important to point out, regardless of the choice of classification and applicable annex in the regulation that the manufacturer must verify that his product fulfils the essential requirements. Only thereafter, the annexes are useful for advising on how the manufacturer should verify that the products manufactured and delivered conform to the type that has been designed. The requirement to demonstrate that a product fulfils the essential requirements applies regardless of what annex is chosen.

7.2 Characteristics that determines the classification of a medical information system

In the Medical Product Agency’s regulation on medical devices in the Swedish implementation of MDD, LVFS 2003:11 annex 9 regarding classification criteria, the following can found and be of interest for software:

Standalone medical device software is active medical devices. This means that rule 9, 10 and 12 in annex 9 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.

Software intended to control a device that administers or exchanges energy is in Class Ila 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 no stand alone 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 product 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 evaluated on/inside the device itself, e.g. ECG measurements, where 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 or monitor such devices, or which directly influence their performance, are in Class IIb. Stand alone software such as for instance software intended for image enhancement in X-ray equipment, is considered to directly influence its performance and automatically 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 Working group will most likely belong to this class.

Devices or systems that are accessories to **active implants** shall be handled as active implants (AIMD).

Devices or systems belonging to in-vitro diagnostic devices are IVD devices and shall be regulated according to the IVD directive.

Devices that are handling **information generated by an IVD device** are medical devices (MD) according to the MD directive and belong to Class I according to rule 12.

Some helpful examples can be found in the MEDDEV 2.4/1 – rev. 8: Guidelines for the classification of medical devices. However, the document may be used keeping in mind it is of an older date. The document is from 2001, and since then the development of medical device software has moved rapidly.
7.3 Choice of verification method in the regulation

The annexes in each regulation describe different routes to verification. The chosen verification route must be based on the level of system risk – what undesired consequences a system can generate – and what acceptable evidence that must be demonstrated to verify that a finished product is safe enough.

It is expected that a manufacturer with software in the lowest risk class will follow the verification method for CE-marking, ensuring that the manufactured devices fulfil the essential requirements, but without the requirement on a formal quality system and without consulting a notified body.

It is also to be expected that manufacturers with software in the highest risk class of MD/IVD and AIMD shall follow the verification method which requires the implementation of a full quality assurance system. At the same time, it is reasonable that a manufacturer with software in a risk class somewhere in-between the highest and the lowest can demonstrate that the chosen verification method provides a sufficient level of safety.

For software with a risk level above the lowest, it is reasonable to expect that the appropriate, or possibly the only, verification route will be to implement a full quality assurance system according to for instance Annex 2 in MDD or Annex 4 in IVDD.

8. Monographs
8.1 Introduction, summary

In the so-called monographs, attached to this report, the Working group has described some different systems that are commonly used in the Swedish health care sector which are more or less software based and according to its intended use could be seen as to fulfil the definition of a medical device in the Medical Device directives. Each product is described with a short monograph, justifying if and in what way the Medical Device directives is applicable. Slightly more than twenty monographs have been developed, which means that not all systems on the market are covered. The monographs 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. In the same way as for the law, it is based on the definition of a medical device in the Medical Device directives.

The monographs also include risk analysis, which means an assessment on how the product will affect the safety for its intended use. The Working group points out that several information products, even though they are not classified as medical devices, in reality are being used as such and in a medical environment, like for instance diagnosis, care and treatment and that they are affecting safety in a crucial way.

These systems can roughly be divided into different groups, as described below.
8.2 Comments on the system descriptions

8.2.1 Communication and network

a) Internal networks

The health care sector uses communication systems to transfer electronic messages. Different types of messages are transferred such as prescriptions, referrals, images, patient records, etc.

Internal networks can be divided into different components:

- General networks that only transfer data like administrative information.
- Secured networks for interconnection of a medical system in some way.

In Sweden we have usually designated networks that transfer both medical and non-medical data, but in a way that the networks are logically separated. Such general networks are built on software intended for general purposes; they are OTS (off-the-shelf) products.

General networks are often not regarded as medical devices but instead as general supply systems\(^1\) such as described in the Swedish National Board of Health and Welfare’s regulation on quality management systems in health care, SOSFS 2005:12. There also exists regulation on open networks in the “2\(^{nd}\) chapter on Responsibility for Information Security” in the National Board for Health and Welfare’s regulation 2008:14 for Information management and record keeping in health and hospital care.

b) External networks

External networks allows for transferring both medical and non-medical data. Examples of external networks are the Internet and Sjunet (Swedish Health Care Network). It may not be clear how to manage the potential redundancy which depends on the physical wiring of the network. External networks shall be regarded as general supply systems.

c) Telecommunication

Telecom systems can be used for paging, e.g. doctors that are on call, or other staff that has to be contacted in emergency situations. Within health care it is also possible to use telecom systems to transfer medical data such as from a mobile patient to the health care unit that is responsible for the medical decision. The last-mentioned situation requires that it is determined what the system shall be used for; does it include life supporting functions or shall it just collect data that has no vital impact. Even here, the trend is moving towards IP telecom systems sharing the same network as other IT systems, and for this reason also susceptible to the same type of interference. Telecom systems shall be handled as general supply systems.

\(^{1}\) General supply system is a term used by the Swedish National Board on Health and Welfare’s regulation on quality management systems in health care, SOSFS 2005:12.

Supply of services, products and technology

7 § The management system shall guarantee that there are routines for purchasing services, products, general supply systems (e.g. water and gas supply) and information systems (e.g. phones and computers) from vendors that have been evaluated, approved, and are safe for the use and handling of products, distribution and information systems.
d) Internet

Nowadays, various applications are using the Internet as a data carrier. Naturally, a risk assessment taking into account the Internet’s ability to perform in a given situation should be carried out.

e) Radio communication

Radio communication solutions can be evaluated in the same manner as for telecommunication solutions, and should be handled as general supply systems.

f) Embedded software systems in networks

Embedded systems in networks are software with functions like filters for removing network traffic, functions given priority to certain network traffic as well as all types of security software in firewalls etc. The embedded systems often work autonomously and it could be difficult for a user to verify its function, other than the awareness that it exists. As for other software, the classification as a medical device depends on the manufacturer’s statements and intended use. Without this commitment the software must be regarded as a “regular product” without the validation of important factors for patient safety. The responsibility for these types of products that are to be used in health care lies with the health care provider, who is expected to conduct a systematic risk analysis before a product is taken into clinical use, and which may affect system availability and thereby patient safety.

8.2.2 Medical Imaging Systems

Medical Imaging Systems, e.g. PACS/RIS systems and Retinal Imaging Systems, shall naturally be regarded as medical devices since they have a purpose that conforms to the definition of a medical device and directly affects diagnosis and consequently the patient safety. Image acquisition and processing, as well as transmission and storage of image information together with the electronic patient record system, are also functions that conform to the definition of a medical device. The classification of PACS has been prepared and specified in the Manual on borderline and classification in the community regulatory framework for medical devices. (06-05-2008).²

8.2.3 Electronic patient records

Electronic patient record systems are more than an archive for just documents, they also have features for compiling and transferring information to be used for decision making. Patient records are the basis for documentation and planning of diagnosis, therapy and follow-up, especially when it comes to drug prescriptions and recommendations. It is becoming more common that electronic patient record systems and other systems are interconnected, for instance imaging systems or laboratory systems. It is obvious that such systems should not be regarded as “purely administrative”; instead they have the characteristic features that are typical for medical devices. They sort, compile and present information on patients’ treatments and should therefore be regarded as medical devices in accordance to the definition.

² A consensus document prepared by “the Working Group on Borderline and Classification for Consultation”. The group is supervised by the Commission and consists of representatives from the member states and other stakeholders. http://ec.europa.eu/enterprise/medical_devices/index_en.htm
Since the electronic patient record system often replaces/constitutes the user interface of “traditional” medical device systems, the call for 100% accuracy of the presented information is increased.

Patient record systems have crucial impact on patient safety, and this has been proven to be the case after a series of incidents that has been reported to the Swedish National Board of Health and Welfare.

### 8.2.4 Portals and patient summaries

Several health care organisations and other actors use portals. The portals contain many different types of health care information. There could be information about medical care advice, waiting lists, addresses to health care providers, health care contact persons and so on. Portals or parts of a portal that only contain one-way general information shall not be regarded as medical devices.

However, it is becoming more frequent that these portals also have components that could be subjected to the Medical Device Directive. There is for example a new trend in making it possible for the patient to access parts of its own patient record on the Internet. Other functions that are becoming available are to gather patient information by using different functions in the portal, like for instance making the patient enter information directly into the electronic patient record himself. If this information is intended for diagnosis, treatment or monitoring of a patient, then those parts should be handled as medical devices.

Health care is strongly moving in the direction of developing local, regional and national patient summaries. This type of guidance gathers and presents medical and individual patient information from several different systems and health care providers. The software has a large number of complex functions that controls in which way the information is presented and synchronised between different systems. This type of patient summaries are intended to be used as tools for diagnosis, treatment and monitoring, and should thereby be handled as medical devices.

### 8.2.5 Decision support systems

Decision support systems are already implemented in various places within health care to facilitate for the medical staff to take measures. One common example is the system for automatic ECG interpretation, which often gives a better interpretation than the average physician would do. At the rear end of the scale we find systems for radiotherapy dosage planning, how to calculate the dosage of cytostatic treatment and at which intervals they should be administrated, etc. If something goes wrong the effects could be immense. The intended purpose as expressed by the manufacturer is the guidance for the classification. However, the Working group believes that it would be difficult for a manufacturer to specify a functional decision support system in other ways than it would be defined as a medical device.
8.2.6 Information sources

Within the Working group there has been a thorough discussion regarding databases containing raw data. Please see chapter 13 below on the discussion on boundaries. “Passive” data sources such as databases providing stored information, and that does not sort out personal patient data, should usually not be regarded as medical devices. Even though errors can cause great problems it is doubtful if the regulatory definition applies when the system does not perform any function and the information is not linked to any specific patient.

Information sources with the intended function to provide information for an individual patient, as in the case of a decision support system, with critical functions that directly affects the evaluation or treatment of a patient, should be regarded as a medical device. This is since its function can have an impact on safety and the effectiveness of treatment for a patient.

The transformation on how a database is being used, including its patient data, may eventually change the situation so that the use is more matching a product according to the definition of a medical device.

8.2.7 ePrescriptions

ePrescriptions can be regarded as “a system” with the purpose to ensure the information chain all the way from the health care provider’s prescription to the pharmacy that hands out the medication. The “system” includes several sub systems such as an electronic patient record system, electronic transfer and network services as well as the pharmacy’s dispatch system.

There have been several severe incidents (even deaths) in Sweden caused by mistakes with medications and prescriptions governed by electronic systems where patients have been given the wrong medication due to the prescriber mixing the patients. Previously the control was made when the patient had their prescription handed to him and could check for himself that the medication was correct. Since the introduction of ePrescription this manual control mechanism has more or less disappeared. A way to prevent such mistakes would be to give the patient a printout of the prescription list. A prerequisite is then that the prescription list is correct or otherwise it may lead to unwanted extra work or may even confuse the patient. The Working group has come to the conclusion that systems for ePrescriptions fit the definition of a medical device.

8.2.8 Web systems for monitoring medical devices

A web system for the monitoring of medical devices is a software based database that is being used in various medical clinics to store, analyse and communicate information from patients’ medical devices. The information is sent over the Internet, regular phone or mobile network from an external transmitter that communicates with the medical device. The information can also be sent from a clinic that has followed up a patient and wants to have complete information about the patient’s treatment.
The system normally contains information on patient identification, diagnostic information or operational data from the medical device. The information in the system can also be forwarded to other electronic patient record systems through regular interfaces.

Different manufacturers of such systems have assessed the systems differently. The opinion of the Working group is that the systems’ specifications are such that they should be handled as medical devices.

9. Clinical evaluation of medical information systems

9.1 Clinical evaluation does not necessarily mean clinical investigation

The Working group has experienced that manufacturers have some doubts on how to address the issue of clinical trials if the medical information systems are classified as medical devices. This in particular due to the stricter wording as stated in the amending directive 2007/47/EC.

All medical devices, regardless of classification, must undergo a clinical evaluation. The clinical evaluation shall verify the clinical capabilities that are being claimed for a medical device. The clinical evaluation must be preceded by one or more questions that shall be answered by the evaluation. These questions are normally, and most appropriately, identified in the manufacturer’s risk analysis and usability analysis (Usability Engineering Process according to IEC 62366).

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 products that can be considered to be valid for the actual product. If such relevant documentation is missing, the manufacturer must initiate a clinical investigation to create substantial clinical data, so that the regulatory statements in the Essential requirements can be answered and fulfilled. In reality this means that the specific questions in the risk analysis must be answered and hopefully the issues are 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 analysis and usability analysis, based on the Essential requirements, determines which questions that must be answered.

9.2 Product and method is not the same thing

Medical devices are normally used in situations as a method where good patient care has been established according to “scientific relevance and proven experience”. A typical issue that has been discussed in the Working group is that medical information systems often controls the methods used in health care. 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 product and who shall be responsible for the method. Most of the reported adverse events are due to misunderstandings and vague roles of responsibility. 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:
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 analysis 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 product in a normal way, according to the manufacturers instructions for use. This could be 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 is also misuse that could not have been foreseen or where the manufacturer has small chances to be prepared for, so called abnormal use. By this we refer to anticipated risks, taking shortcuts, using the product for the wrong purpose and so on (not in accordance with the intended use). The liability then rests fully on the user but does not automatically free the manufacturer from updating the risk analysis, monitoring and minimising the consequences for possible misuse if it is reasonable.

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

This is often where it goes wrong. The health care provider uses the system in their operations, either without regard to the specification from the manufacturer or although specifications are missing. A manufacturer that resists regarding his system as a product with defined specifications has limited capabilities to treat and assess any specific requirement a health care provider may have for local adaptation. 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, 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 user friendly system.

**Explanation in figure:**

The manufacturer of medical information systems can use several different standards, which are useful tools, to be able to meet the essential requirements in the Medical Device directives. ISO 14971 is the general risk management standard for medical devices. IEC/TR 80002 will be a guidance document for how the standard ISO 14971 shall be applied when designing medical device software.

IEC 60601 is a general safety standard for active medical devices, and annex H includes overall guidance for PEMS Programmable Electrical Medical System, a description of structure, the 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 future standard IEC 80001, Application of risk management for IT-networks incorporating medical devices.
IEC 62366 describes the process of usability engineering which must be considered in the design phase to assure that medical devices are easy-to-use. It is also relevant for the user to have some insights in this process.

10. Installation and maintenance of medical information systems in networks

10.1 Infrastructure systems/Buildings
It is important that systems for infrastructure and support functions are as robust as it can 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 assessment, 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 increasingly 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. The requirements for support and infrastructure systems in health care are described in the Swedish National Board for Health and Welfare’s regulation, SOSFS 2005:12, on management systems for quality and patient safety in health care, including dental care.

10.2 Medical information systems communicates 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 manufacture to understand the total picture. It is therefore an obligation of an individual manufacturer to design a system which is as robust as possible, by applying any existing knowledge. In the risk analysis 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.

10.3 Managing residual risks, verification of installation
The validation of a system and how the products will be used is of significance for the function. The manufacturer shall perform the validation in a controlled environment, as far as possible similar to the hypothetical environment of the user. Any residual risks that the manufacturer cannot control and where the result is depending 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 carried through in a structured way and that the information about any residual risks that have been expressed have been taken into account.

2 June 2009 revised 18 January 2010
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 conduct a risk analysis in order to be able to perform a validation based on the proper information about the device, including the intended environment where it is often linked to other products 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 more predictive 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 that any additional installation or configurations in the network shall 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 legislation.

10.4 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, and the approval of the 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 may not be aware of any ongoing changes in the network or if, for example, more systems have been added or deleted.

The Working group believes that there are appropriate guidelines and terminology for verifying changes in the installation environment, as described in the ongoing standardisation project IEC 80001 Application of risk management for IT-networks incorporating medical devices. Furthermore, we have noted that there is a consistency between the proposed guidelines and the Swedish National Board of Health and Welfare’s regulation on information management and record keeping in health care; SOSFS 2008:14. The description of the roles of responsibility for different actors is especially interesting.

The Swedish National Board for Health and Welfare requires that all health care providers and dental services must have a management system for quality and patient safety implemented in their operation. The management system shall contain a basic set of routines which are the same for all types of operations.

Please see the following guideline which might be useful to consider³:

³ The text contains several different terms that originate from 62A/635/CD proposal to IEC 80001 (in progress) and SS-EN 60 601-1 Annex H.6. The Swedish translation is not yet settled.
To be able to identify and manage risks systematically in networks where changes occur, the health care provider (responsible organisation) must set up some kind of responsibility agreement with the stakeholders such as manufacturers, IT department at the health care provider, biomedical/clinical engineering department, network operators, facility owners and other possible system owners. The health care provider needs to implement a controlled process for change management in their management system to guarantee that the agreement is established and will be maintained. Potential risks for related changes must be handled within the framework of the organisation’s risk management process. The outcome from risk management may lead to necessary renewal of the verification before any additional changes can be implemented. There must be documented routines for monitoring, like being prepared to assess and monitor risks that have been accepted as residual risks before, and other new risks that might be introduced and that have not been identified before.

The health care provider (the responsible organisation) must within the organisation appoint responsible staff for risk management (a risk manager) and for system integration (a system integrator).

An unclear leadership will be avoided since it is the responsibility of the health care provider to identify and appoint members of top management. In Sweden it would most likely mean that top management would be a County Council Director, Regional Director or CEO in a health care organisation.

11. Consequences for different stakeholders on the Swedish market

11.1 National consequences

The Swedish National IT-strategy requires that stand alone systems and networks are sufficiently safe and robust. A regulation of the medical information systems according to this new approach will be a prerequisite to implement the National IT-strategy successfully.

11.2 Consequences for the health care providers

11.2.1 General

The situation is described without any scientific data; instead it is based on the general experience within the Working group. However, it seems like the health care providers nowadays have a similar approach for their biomedical/clinical engineering departments regarding e.g. clinical use, maintenance, safety issues whether they are operated by the County Council, the Municipality or private companies. One of the reasons for this is that the regulations for medical devices and how they shall be used by health care providers, as described partly in this report, are quite clear and properly described. However, one unclear issue is how to handle contracts and operational management between the County Councils and other actors. This issue has also influenced our work.

The Swedish National Board for Health and Welfare’s regulation on the use of medical devices SOSFS 2008:1, shows that information systems that are connected to medical devices are included in the area of application. This together with those information systems not connected to medical devices (for instance electronic patient record systems) also should be included in the framework of
application, will have consequences for health care providers and their biomedical/clinical engineering and IT departments.

11.2.2 The situation today

Quality issues within health care are managed in different ways and a uniform organisational structure has not been developed. Medical device and IT issues for health care are handled in different quality processes. Biomedical/clinical engineering departments are often operated according to a clear regulation while different health care providers apply different levels of risk management for their actual IT systems. The requirements are in general nowadays the same for how medical devices and IT systems shall be controlled with quality assurance.

For issues regarding applications and risk management these are often discussed between the health care providers and vendors. There is no specific method ensuring the application in any other way than specifying the requirements of routines and documentation in the contract. Upgrades and security patching in the operational situation shall be handled according to descriptions in the local service agreements (e.g. SLA Service Level Agreement which is a contract between the client and vendor to ensure a certain level of service and support) (ITIL, ISO 20000). Even here the responsibility issue is not solved. We believe that there is a need to work with quality in a more professional and controlled way.

11.2.3 Responsibility, organisation and regulation

According to the regulation on health care and welfare, the services must be operated in line with a management system that is properly defined and documented. Biomedical/clinical engineering and IT departments in health care have more and more similar and overlapping areas of responsibility. It is therefore of great importance that the health care provider establishes controlling documents that are clear and descriptive about the areas of responsibility and tasks to facilitate the increasing need for close cooperation between Biomedical/clinical engineering and IT departments that will become necessary. This also applies to the collaboration between the departments, management and other services, and involves all phases in the life cycle of a product or system (i.e. from procurement, purchase, installation, management, maintenance, user support to phasing out).

A clear role needs to be defined to ensure that the regulation can be fulfilled and that top management is always updated with relevant decision documents in any given situation. This role shall be appointed to a person with direct access to decision makers on the highest level possible.

The draft standard 62A/635/CD (planned IEC 80001) contains a comprehensive description of problems associated with the increasing amount of medical devices, the linking between applications and the information transfer that takes place between them, and the problematic task to follow up and sustain quality issues. Management issues are especially emphasised. It seems obvious that a role like risk manager must be implemented, fully staffed and operational, for each health care
provider’s area of responsibility. Collaboration with other services such as ITIL, ISO 20000\(^4\) is also very clear and descriptive in the text.

The process map below illustrates how it could be seen from a Swedish perspective.

The documented processes shall be included in the management and quality system at both management level and department level, and shall regularly be followed up and revised. It has been successfully achieved when patients, clinics, management and other stakeholders do not notice the seamless line between different services. Issues and problems must be forwarded directly, without any delays or unclear ownership between departments, to an assigned person with the correct competence to take measures. Issue and deficiency reports shall not end up between departments where nobody is responsible, or the other way around, at several departments causing inefficient work.

\(^4\) IT Infrastructure Library is a compilation (a framework) of “Best practices” (good examples) that have been achieved for several years in cooperation with companies worldwide. ITIL describes, on a basic level, how to structure the workflow and organisation to deliver IT services in a stable and cost-effective way by adapting a controlled method to deal with faults, measures and changes as well as preventing disasters by working in sustainable way.
11.2.3.1 Competence and training

Clinical management and health care top management have the responsibility to identify and allocate resources for necessary competence. Successful integration between Biomedical/Clinical engineering and IT departments is a clear requirement which must be considered according to the new and more thorough approach for medical devices and IT systems. To meet this requirement it will become necessary for Biomedical/Clinical engineering departments to gain supplementary training in IT applications, which also applies in the opposite direction.

Another consequence is that it might become necessary to have staff with dual competence within both Biomedical/Clinical engineering as well as IT. A likely scenario is that the departments will need to hire staff with custom made master degrees to meet the complex environment that medical devices and information systems share.

11.2.3.2 Conclusion

An increasing number of incidents reported to the Swedish National Board for Health and Welfare and to the Medical Products Agency shows that it is needed to implement a risk and quality method for both health care providers and vendors as well as for manufacturers of medical IT systems. From a patient safety point of view, the existing regulations for evaluation and classification need to be clarified and implemented.

A strategic position as Medical IT-Risk Manager needs to be appointed and coordinated with the Chief Medical Information Officer at top management level (County council or similar) to ensure that management can fulfil its responsibility. Issues should be able to be synchronised in this manner, through shared and clear processes as illustrated above.

The requirement in the Swedish National Board for Health and Welfare’s regulation on quality management responsibility for health care, states that the management and organisation of these issues is a responsibility of the top management and medical management. Patient safety highly depends on management commitment, competence within the area and awareness of the consequences of potential deficiencies. This responsibility can therefore not be delegated without considering the consequences and that authority must be included in the delegation.

11.3 Consequences for the manufacturers

The conclusion of the Working group shows that the clarification that has been added in the amending directive 2007/47/EC means in general that medical software systems offered by the manufacturers shall be regarded as medical devices, probably according to risk class I, with the subsequent requirement on CE-marking.

To fulfil the requirements on CE-marking the manufacturers will have to follow a few standards that they are not currently using. This will involve more work for the companies if they should adapt to these standards. The most significant standard to follow is the harmonised standard for quality management systems, EN ISO 13485. This standard also means that other standards have to be followed such as the standard for risk management. The amending Medical Device Directive also requires an evaluation of the usability.
Clinical investigations will most likely only be required on rare occasion to assess the clinical need for a product. Necessary specification on device performance, safety and clinical effectiveness can most likely be obtained from tests done by the manufacturer and from clinical data gathered from relevant scientific literature and/or clinical investigations.

The manufacturers for those products must implement a system for reporting incidents and accidents (vigilance system). Today, many of those manufacturers lack routines for reporting accidents and near-accidents.

Stricter requirements to monitor experiences for devices already placed on the market (post market surveillance) means that most manufacturers will need to develop a plan for how to fulfil this, or they will have to update any existing plans.

Language requirements, according to the implementation of Medical Device Directive 93/42/EEC, for labelling and instructions for use, should be presented in the national language and that applies to device labels, user manuals and device interfaces.

Medical devices shall bear the CE-mark. Appropriate routines for how labelling should be realized will be necessary to implement. Possibly labelling can be included in the software’s “information about the software”.

Until today there have been some doubts about how the essential requirements shall be fulfilled for software. The manufacturers believe that proper guidelines must be developed for this purpose.

Manufacturers wish a continuous contact with the Medical Products Agency until clear guidelines for CE-marking of software is available, and for solving possible unclear issues.

11.4 Consequences for Medical Product Agency’s market surveillance

Since the change in the amending Medical Device Directive 2007/47/EC, stating that stand alone software can be considered to be a medical device if the definition is fulfilled, only is a clarification, any transition period has not been considered for the interpretation. When the Medical Product Agency obtains information about a product that should be CE-marked, the same rules generally apply as for any other product. The expectations on the manufacturer are based on a risk analysis and are in general that the manufacturer shall:

- stop marketing the product until it is CE-marked
- present a time table of the CE-marking process for the Medical Product Agency
- inform existing users of the product
- introduce existing products into their post-market system and vigilance system
- inform existing product users about corrective actions regarding safety measures applicable for the product

After the CE-marking procedure the manufacturer shall deal with already delivered systems in the same manner as the ones that are CE-marked, and when necessary, update them to the same level of safety. The manufacturer must inform existing users about the limitations that follows when the
product is regarded as a medical device, i.e. the manufacturer’s responsibility for safety and function will be limited to the purpose of a product as expressed as the intended use by the manufacturer. In principle, this does not apply for products that are no longer marketed because the rules only apply for products that are being placed on the market. The Working group has identified that upgraded software is a problem but without providing a solution.

11.5 Consequences for notified bodies
The impact on Notified Bodies seems rather limited in this respect. Notified bodies already deal with medical devices that are stand alone software. One expected outcome is that more manufacturers will be aware of that their products are subjected to the Medical Device directives. Depending on the classification of a product it might become necessary to consult a notified body for the conformity process. This may increase the workload for the notified bodies to some extent. Since the existing procedures for conformity can be used without any changes, the working methods and processes at the notified bodies can remain unchanged. Notified bodies that are not already dealing with software may need to develop their competence in this area if they are aiming to deal with these types of products in the future.

12. Standardisation project

12.1 Useful standards are available
Several useful standards for software systems are available (see the reference list). These include requirements on design method, risk management, verification and validation methods and documentation. Some standards demonstrate possibilities of dividing the system into more or less critical modules, which can be handled accordingly. If the system is planned to be used in combination with other systems then this must be defined, verified and validated. The standards also provide guidance for risk classification.

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 product that is requested. The Swedish Act on Public procurement emphasises that technical specifications (if available) must be included in the request for proposal if the procurement exceeds a threshold value.

12.2 Application of risk management for IT-networks incorporating medical devices (ISO/IEC 80001)
This standard (in progress) is a proposal aimed at primarily hospitals to be a help when connecting medical electrical equipment with software in the hospital’s network. The document especially covers the administration of the hospital’s computer network and is intended to be used as a quality standard for the organisation using the network, for management system and management functions.
ISO/IEC 80001 is a sufficient supplementary to IEC 60601-1 for medical electrical equipment, which has very strict requirements on how software shall be developed and how it can communicate in a network. IEC 60601-1 contains a descriptive section on risk classification and much information that describes the responsible organisation’s way to communicate the hospital specifications in computer networks. It also contains a checklist on the suggested requirements that a device manufacturer must fulfil.

The standard describes risk analysis for interconnection with new equipment and includes a checklist with suggested possible hazards that can help the reader to conduct a complete risk analysis. The risk analysis references to ISO14971 in a very clear way. The standard defines what a medical network is, which also is makes it easier for understanding as well as defining the area of application.

Simply by looking at the content list it is easy to understand the message in the standard

- Roles and responsibilities
- Responsible organization
- Top management
- Medical IT-network risk manager
- Medical IT-network maintainer
- Medical device manufacturer(s)
- Other providers of information technology
- Risk management team
- Life cycle risk management in medical IT-networks
- Policy for risk management for incorporating medical devices
- Risk management process
- Project planning and documentation
- Risk analysis
- Risk evaluation
- Risk control
- Residual risk evaluation
- Reporting and approval
- Change management
- Monitoring
- Document control
- Document control procedure
- Medical IT-network risk management file

Finally;
Hospitals that are going to apply the standard, and who communicate with vendors that are aware of the content, can provide a safer network when the hazards are identified. Applying this standard for medical devices with software connected to a network allows for the intended use to be fulfilled in a safer way.

12.3 Medical device software – Life cycle processes (ISO/IEC 62304)
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.

12.4 Medical device software – Guidance on the application of ISO 14971 to medical device software (ISO/TR 80002)
This Technical Report is aimed at risk management practitioners who need to know how to do risk management when software is included in the medical device or system, and at software engineering practitioners who need to understand how to fulfil the requirements for risk management addressed in ISO 14971:2007 Medical devices — Application of risk management to medical devices, combined with the standard IEC 62304 Medical device software - Software Life cycle process. The report gives a good description of how a software designer of medical devices shall adopt a proactive approach instead of reactive work method to mitigate problems.

12.5 Mandate 403, eHealth-INTEROP
Mandate 403, eHealth-INTEROP is the European Commission mandate to try to prioritise and coordinate the development of standards in the field of e-Health. The European Standards Organisation (CEN, CENELEC and ETSI) has been given the task to prepare a proposal and the project started in the beginning of 2008. e-Health is an expression used for remote health care and support, in other words it is information and communication tools used for preventive actions, diagnosis, treatment and for monitoring and controlling of health. The idea is that European standards shall be a tool for ensuring availability and correct health care information, when in electronic format. Patients shall be able to have a free choice of where to receive health care and at the same time feel secure that the correct information is available when needed.

The first phase of the project assessed all working methods and documents for all standards used within the area e-Health, both for international organisations and for industrial consortiums. An analysis of the needs and recommendations of the possible development of specific standards was also conducted. The report was prepared during 2008 and includes a work plan for Phase 2, for continuing the work with priorities and coordination of the development of standards within the area of e-Health. The starting point is patient safety and quality where the goal is to create interoperable systems within Europe.

The project has high priority for the Swedish technical committee in Health informatics. The Swedish expert group has forwarded many ideas to influence the European ongoing development within e-Health. Vendors with know-how in designing IT-structure will gain several benefits if the informatics systems are built on standards. This ensures components to be interoperable if they are replaced or...
need to be developed, or when information is transmitted between health care providers and patients or next of kin.

For primary health care centres in Sweden the documentation is electronic to 100% while at hospitals it is electronic to 88%. Eight out of ten prescriptions are in an electronic format and the electronic transfer method is in use at all pharmacies within the country.

Phase 2 will be implemented within the next two years. Then the project will be evaluated during the fourth year.

One scenario is that a new EU directive will be developed, which will be a supplement to the service and device directives when it comes to treatment of patients or other citizens. This will facilitate the development and structure of the standards since the areas of distinctions will become clearer than they are today, for those standards that cannot be connected to the Medical Device directives. In addition, it would instantly affect the market so that the conditions for product design would become more stable.

12.6 Health informatics - Application of clinical risk management to the manufacture of health software (CEN ISO/TS 29321) and Health informatics - Guidance on risk evaluation and management in the deployment and use of health software (CEN ISO/TR 29322)

These two documents have raised many questions. Basically because they mention the Medical Device directives and declare that the technical report should cover systems that are not subjected to the MDD. They mention examples that should not be applicable to MDD, due to national differences, even though it is defined as “Health software”. These examples and the term “Health Software” are indeed controversial.

It can be pointed out that neither of the documents was approved by the member states in the international committee for Health informatics within ISO when they were going to be accepted as a technical specification and a technical report. During the autumn in 2008 the documents were sent for voting in the European committee on Health informatics. In Europe the report was approved but not the specification. European standards will automatically become Swedish standards. This is not an automatic procedure for technical reports and specifications and neither for the documents mentioned here.

12.7 Communicating with medical devices in direct patient care – “Point-of-Care Diagnostics”

ISO and CEN are presently preparing the standards "Point-of-Care Diagnostics" which is a set of standards focusing on the connection between all medical devices and central systems and databases. This also includes standards for ECG, curve forms in general and chemical analysis products. One interesting area is the “Personal Health Systems” which is supposed to take care of the expected increase of chronic diseases and where IT is a tool for the patients to get more involved in their own rehabilitation. This is by monitoring and by using health programs to assist older people to become healthier and to feel better and at the same time use fewer resources within health care.
13. Discussion

13.1 Medical device or not

A particular problem that the Working group has focused on is how to demonstrate appropriate and useful methods for the distinctions towards systems and products which certainly are used for diagnosis or treatment of patients, and therefore possibly could be in the medical devices definition in a broader sense, but still for other reasons should not be defined as medical devices.

Typical examples of systems that have been discussed are databases containing raw data:

- Supply databases of medical devices, for instance at vendors
- Compilation of medical data for a specific method such as quality registries stored in databases
- HSA, the Swedish list of addresses within health care (authenticity)
- Electronic library, such as Eira, Effective Information Retrieval and Acquisition

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.

Without drawing to many parallels, similar arguments can be found in one of the European Commission guidance document for the Medical Device Directive MEDDEV 2.1/1, Definition of "medical devices", Definition of "accessory", Definition of "manufacturer", under the section “aids for handicapped persons”:

In the case of equipment intended for alleviation of or compensation for a handicap, there must be a direct link between the corrective function and the person concerned.

Therefore the following equipments are not medical devices:
- acoustic signals at traffic lights,
- special water taps, toilet equipment for handicapped

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

13.2 Administrative systems for the health care sector

Systems with a purely administrative function like staff scheduling systems, payroll systems, inventory systems, financial systems, and invoicing systems for health care providers, etc. should not be subjected to the Medical Device directives. Even though they are used to improve functions for the health care provider they cannot be seen in general to have a purpose that fits the definition of a medical device.
However, there are administrative systems for the health care sector where the manufacturer has not defined his product as a medical device, but still it could affect the safety for patients under certain conditions. Health care providers shall in these instances consider if those products should be handled with the same awareness of safety as if it had been a medical device.

More unsophisticated “information products” such as paper forms and paper patient records not used as active digital information have been decided to be “inappropriate” according to the definition of a medical device even though it could be appropriate in the broader perspective. The reasons for this could be discussed, but the Working group does not believe that they are “devices” where a product safety regulation should be applied, neither could they gain anything from such regulation.

Software intended for administrative work such as applications for word processing, registration and calculation software, like Microsoft Office, cannot be regarded as medical devices, even though they are used in the process to document clinical findings, diagnosis or other patient information. However, if someone develops an application and it is claimed that it is according to the definition of a medical device with the help of these programs, then the application might be subjected to the definition of a medical device.

General administrative software like word processors or operating systems may be part of a medical device and as OTS Software (Off-The-Shelf). It will be the responsibility of the medical device manufacturer to decide if the OTS software’s specifications or safety is sufficient enough to fulfil the expressed intended use.

Previously the so-called Patient Administrative Systems (PAS) has not mainly been regarded as medical devices. The system typically has functions for booking medical appointments, admission or managing waiting lists. Those are all medical decisions based on the priority of the clinical need. It is not unusual that modern systems have many complex additional functions, apart from the traditional ones, and with an intended function that fulfils the criteria of a medical device. Their capability to affect patient safety increases significantly. There are several systems of this type and the classification as a medical device is most likely not controversial for the manufacturer.

13.3 Requirements and statements at procurement
The Medical Devices Directives states 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 directive. However, a manufacturer can for some reasons avoid mentioning this, even though it is obvious that the product will be used for a purpose in accordance with the definition. The product will then not be under the supervision by the Medical Product Agency and no requirements for medical devices will be applicable. This situation can be improved if the market, i.e. the health care providers, demands in the procurement process that only systems classified as medical devices will be procured.

In the procurement situation a vendor can claim in the tender for an information system, e.g. an electronic patient record that it is not classified as a medical device. Medical management must then consider if a system with such reservations will be appropriate for the intended purpose, and if it can
be trusted and fulfil the requirement of a safe system. This responsibility lies with the procurement office and the clinic where it shall be used.
References

The Medical Device Directives

Medical Devices are divided into three areas.

- Active implantable Medical Devices - AIMD
- Medical Device Directive - MDD
- In Vitro Medical Devices - IVD

There are three European directives for regulation of how to place medical devices on the market and how to put them into clinical use:

  - EGT L 189/ 20.7.1990, p 17
  - EGT L 169/ 12.7.1993 p 1
  - EGT L 331/ 7.12.1998 p 1

EC regulation


Applicable Swedish legislation

Laws

Swedish Medical Devices Act (1993:584)
Law on health care (1982:763), 2, 2a, 2e, 28, 29 and 31 §§
Law (1998:531) on occupational work within health care, Chap 2 1 and 5 §§
Patient data law (2008:355)

Ordinance

Medical Devices Ordinance (1993:876)

Medical Product Agency regulations

(LVFS 2003:11) on medical devices (changed through LVFS 2004:1 and 2007:3)
(LVFS 2001:5) on active implantable medical devices (changed through LVFS 2007:1)
(LVFS 2001:7) on in vitro diagnostic medical devices
On manufacturers' obligation to report accidents and near-accidents with medical devices

National Board of Health and Welfare’s provisions
(SOSFS 2005:12) on quality management systems and patient safety in health care
(SOSFS 2008:1) on the use of medical devices in health care
(SOSFS 2008:14) on information management and record keeping in health care

Standards for software systems (International reference numbers)

- EN 1041:2007 Information supplied by the manufacturer with medical devices,
- EN ISO 14155 Clinical investigation of medical devices for human subjects
- ISO 14971 Medical Devices – Application of Risk Management to Medical Devices – 2007
- CEN/TS 15260:2006 Health informatics: Classification of safety risks from health informatics products,
- ISO/IEC 20000-series Information technology -- Service management (ITIL-related set of standards)
- ISO/IEC 27000-series, LIS Information security management systems
- 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. Proposal
- CEN/TR 15640 CEN Health informatics – Measures for ensuring the patient safety of health software
- CEN/TS 15260 CEN Health informatics – Classification of safety risks from health informatics products
- CEN/TR 27809 CEN Health informatics – Measures for ensuring the patient safety of health software
- CEN/TS 25238 CEN Health informatics – Classification of safety risks from health informatics products
Appendix

Appendix 1 Constitution of the Working group

Appendix 2 Monographs

Appendix 3 Regulation on health care providers’ responsibility managing information systems

Appendix 4 Information from the Medial Products Agency's web platform
Annex 1

Working group members

– Medical Products Agency
  Mats Ohlson, (chair),
  Per Gillblom

– National Board for Health and Welfare,
  Lars Asteborg
  Maria Jacobsson

– Swedish Medtech,
  Erik Öhman
  Sandra Sjöäker

– Swedish Association of,
  Local Authorities and Regions
  Håkan Nordgren, SKL
  Björn Erik Erlandsson, SLL
  Stefan Olsson, Lfmt
  Ronnie Lundström, Lfmt
  Karl Gemfeldt, SLIT
  Stig Brinck, SLIT

– Swedish standardisation
  Git Eliasson, SIS

– Notified Bodies
  Hans Ericsson, Intertek
The Medical Products Agency’s Working Group
on Medical Information Systems
Appendix 2

Monographs
Descriptions of various software based information systems in health care
1. Electronic Patient Record System ................................................................. 6
2. Anaesthetic Record System ........................................................................ 8
4. CTG Central Station .................................................................................. 10
5. Pre-hospital ECG ..................................................................................... 11
6. ECG Storage System ................................................................................ 12
7. Retinal Imaging System ........................................................................... 13
8. Picture Archive Communication System (PACS) ...................................... 14
9. Radiological Information System (RIS) .................................................... 16
10. Web Based Patient Questionnaires ............................................................ 18
11. Portal of National Patient Summaries (NPÖ) ........................................... 19
12. National Prescription Information (NOD/PASCAL) .................................. 20
13. Basic Services for Information Supply, BIF ............................................. 21
14. Quality Registries .................................................................................... 23
15. Quality Indicators ................................................................................... 25
16. Communication Systems ........................................................................ 27
17. Advanced Decision Support Systems ..................................................... 28
18. Telemedicine Systems ............................................................................ 30
19. Web Systems for Monitoring of Medical Devices .................................... 33
20. In-vitro diagnostic (IVD) software: LIS & WAM ....................................... 35
21. Medication Module .................................................................................. 36
22. ePrescriptions ......................................................................................... 39
Monographs
The Working group has described a number of different systems used within the health care sector and presented them as so-called monographs. These systems include software in some extent that could be seen to fulfil the regulation for medical devices. Each device is described with a short monograph, justifying if and in what way the Medical Device Directive is applicable. Slightly more than twenty monographs have been developed, which means that not all systems on the market are covered. The monographs 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. In the same way as for the law, the basic principle is according to the definition of a medical device in the Medical Device Directive.

The monographs also include risk analysis, which means an assessment on how the device will affect the safety for its intended use. The Working group points out that several information products, embedded or not, and even though they are not classified as medical devices, in reality are being used as such and in a medical environment, like for instance diagnosis, care and treatment and that they are affecting safety in a crucial way.

Questions used in the descriptions
The Working group has used a systematic approach and a set of terms appropriate to describe a programmable system in a way that supports a decision whether the system shall be handled as a medical device or not.

The Swedish law for medical devices is based on the EU Medical Devices Directives. The devices covered are described in the definition of medical devices as expressed in the Swedish Medical Devices Act (SFS 1993:584)

2§ According to the law, 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:
1. diagnosis, prevention, monitoring, treatment or alleviation of disease
2. diagnosis, monitoring, treatment, alleviation of compensation for an injury or handicap,

The wording in the MDD definition of a medical device have caused some problems. If interpreted word-by-word it involves a great number of devices that has never been intended to be covered by the Medical Device Directive. Due to this reason, EU has documented more or less well defined agreements which exclude some types of devices, even though they in a literal sense fulfil the definition. Such agreements can be found in the European Commission’s guidance document on Medical Devices referred to as MEDDEV. These documents are available at the website of the European commission. It has occurred that some actors have stated that specific software, for different reasons, should not be covered by the Medical Device Directive even though they fulfil the definition of a medical device, with reference to an older version of MEDDEV.

Due to this reason, preventing the Working group from starting up with a discussion regarding exclusions etc, the first issue instead focused on whether a specific device is considered to fulfil the definition of a medical device in the Medical Device Directive in a broader perspective, based on an interpretation word-by-word. The interpretation is based on the manufacturer’s expressed intention for a device.
A device can be part of diagnosis and treatment, directly or indirectly. In that respect the arguments do not differ from those used for traditional medical devices. Software can directly control radiotherapy treatment for instance. Most medical devices used for diagnosis, including in-vitro diagnostic 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.

Even though it is not clearly described in the legal framework, the interpretation of the Working group is that it should apply to devices intended for diagnosis, treatment, etc., intended for a population such as statistics, quality registries, etc.

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. The next issue aims to focus on, if a specific device is suitable to be regulated according to a product safety regulation. The Working group has chosen to exclude items that cannot be regarded as devices in this context such as literature, forms or services.

The Working group agreed on 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:

1. Device complexity
2. Responsibility user/manufacturer
3. Risk for maltreatment / injury
4. Feedback

Point 1 and 2: These parameters are used in the description to clarify that the manufacturer must take more responsibility for the proper function of a system where a user has little possibility to control and avoid hazardous situations. Many functions are often hidden for a user. The intention is to describe the difference between, for instance, older paper based patient records and systems for new electronic patient records.

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

Point 3 and 4: These parameters give basic information for conducting a 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 tool for risk classification.
Each monograph includes a graphic model that the Working group used to discuss how to manage the number of different variables, so it would be possible to discuss in a consistent way. It shall be noted that this is not a formal classification. The texts inside the boxes shall be seen as examples to illustrate different levels.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment or injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is too late</td>
</tr>
</tbody>
</table>
1. **Electronic Patient Record System**

Electronic patient record systems are tools for managing patient information associated with care and treatment within the health care sector. Together with health care staff opinions, measures and decisions they are thereby devices that fulfill the definition of a medical device.

Electronic patient record systems are involved in diagnosis and treatment since all 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 which are vital to the patient’s treatment. Decisions on drug prescriptions are being stored in a medication module which is often an integrated part of an electronic patient record system.

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. The medication modules contain interaction registries with functions to make alerts for inappropriate combinations. Evaluations can be delayed due to access problems in the system, which could be critical for some patients.

At drug prescription different support functions are used such as interaction registries which can be seen as form of decision tool. Some systems also include specific functions for decision support which means that they give recommendations or suggestions to doctors or health care staff. If decision support is implemented, there are usually only two options. It is either hard coded in the system which means that the vendor is responsible for the decision support functioning according to the relevant system specifications. For the option where the decision support has a flexible construction and based on rules defined by the client (health care staff) the full responsibility for any operational specifications lies with the health care staff.

Electronic patient record systems are from a technical and commercial point of view “products” managed according to the vendor’s operations and design processes.

Electronic patient record systems are especially complex products that normally require extensive configuration work. The system often includes several functions and the amount of code is extensive. The product is part of a very complex environment that is affected by many external factors, e.g. upgrades on the operating system where the software is installed. The client is responsible that the environment meets the necessary requirements for the product 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 requires that specific products are connected to the electronic patient record system.

The electronic patient record system presents facts entered by the user or from imported data, e.g. laboratory test results. Responsibility for the evaluation of the presented data lies with health care staff. The evaluation is based on the information about which integrity is guaranteed by the system. Meaning, the system guarantees accurate data if the data itself has been entered correctly. If the electronic patient record system functions insufficiently, and not according to the intended use, then there are obvious risks for maltreatment. If the information presented to the health care staff is not correct then there would be a risk of taking the wrong measures.
A regulation of electronic patient record systems is highly recommended. Since there are no other known suitable product regulations, electronic patient record systems should be classified as medical devices. The complex design of the product includes many hidden automatic functions that a user can not be accountable for. There are obvious risks for maltreatment if the system fails. Depending on what is expressed by the manufacturer, the system shall be classified not lower than risk class I in MDD.
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 identification, 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

The anaesthetic record systems that are available on the market can be configured in different ways, depending on when it was developed and in what extent it is interfaced with medical devices. A modern anaesthetic record system incorporating functions as described above fulfils the criteria to be classified as a medical device. It is intended to be used for the planning of a patient’s diagnosis and treatment. As such it can be seen as a device for decision support. Depending on system complexity various functions are either built-in or integrated through an interface. The interacted information presented to the user is complex and critical. The user has small possibilities of checking whether the system presents accurate information. If the system fails the risk for maltreatment is obvious.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**

A regulation of anaesthetic record systems is highly recommended. Since there are no other known suitable product regulations, anaesthetic record systems should be classified as medical devices. The complex design of the product includes many hidden automatic functions that a user can not be accountable for. There is a risk for maltreatment if the system fails. Depending on what is expressed by the manufacturer, the system shall be classified not lower than risk class I in MDD.
3. Clinical Information Systems – CIS / Patient Data Management Systems - PDMS

A CIS/PDMS is a software based system primarily intended for intensive care units to store, manage and transfer patient information generated in association with the patient’s intensive care treatment. 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
- Report generator
- Support for quality review and statistical data
- Interface (usually HL7) towards other systems

Those CIS/PDMS available on the market can be configured in different ways, depending on when it was developed and in what extent it is interfaced with medical devices. A modern CIS/PDMS incorporating functions as described above fulfils the criteria to be classified as a medical device. It is intended to be used for the planning of a patient’s diagnosis and treatment. As such it can be seen as a device for decision support. Depending on system complexity various functions are either built-in or integrated through an interface. The interacted information presented to the user is complex and critical. The user has small possibilities of checking whether the system presents accurate information. If the system fails the risk for maltreatment is obvious.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>Clinical Information Systems – CIS / Patient Data Management Systems - PDMS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
</tr>
</tbody>
</table>

Conclusion of the Working group:

The CIS/PDMS on the market are already classified as medical devices. The product presents automatic summaries and has some kind of monitoring function. There is a risk for maltreatment if the system fails. The systems are classified as risk class I in MDD, but depending on the manufacturer’s information on system functions it may be considered that such systems shall be classified in IIa since monitoring of vital parameters are included.
4. 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 fetus and mother in connection to childbirth. Usually the system contains information about patient identification, 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 central stations available on the market can be configured in different ways, depending on when it was developed and in what extent it is interfaced with medical devices. A CTG central station incorporating functions as described above fulfils the criteria to be classified as a medical device. It is intended to be used for the planning of a patient’s diagnosis and treatment. As such it can be seen as a device for decision support. Depending on system complexity various functions are either built-in or integrated through an interface. The interacted information presented to the user is complex and critical. The user has small possibilities of checking whether the system presents accurate information. If the system fails the risk for maltreatment is obvious.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**

A regulation of CTG central stations is highly recommended. Since there are no other known suitable product regulations, CTG central stations should be classified as medical devices. The complex design of the product includes many hidden automatic functions that a user can not be accountable for. There is a risk for maltreatment if the system fails. Depending on what is expressed by the manufacturer, the system shall be classified not lower than risk class I in MDD.
5. **Pre-hospital ECG**

A system for managing pre-hospital ECG is a software-based system 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 identification, 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 while it is being transported.

A system for pre-hospital ECG’s normally supports the following functions:

- Patient registration
- Patient identification
- Scanning of relevant documents
- 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. A system for managing pre-hospital ECG incorporating functions as described above fulfils the criteria to be classified as a medical device. It is intended to be used for the planning of a patient’s diagnosis and treatment. As such, it can be seen as a device for decision support. Depending on system complexity, various functions are either built-in or integrated through an interface. The interacted information presented to the user is complex and critical. The user has small possibilities of checking whether the system presents accurate information. If the system fails, the risk for maltreatment is obvious.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible, like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is too late</td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**

Systems for pre-hospital ECG’s on the market are already classified as medical devices. The complex design of the product includes many hidden automatic functions that a user cannot be accountable for. There is a risk for maltreatment if the system fails. The systems are classified as risk class ILa according to MDD, but depending on the manufacturer’s information, it may be considered that such systems shall be classified in IIb since monitoring of vital parameters are included.
6. **ECG Storage System**

A system for storing ECG’s is a software based system 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 and finally approved by a doctor.

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
- 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 a similar way. An ECG storage system incorporating features as described above fulfils the criteria to be classified as a medical device. It is intended to be used for the planning of a patient’s diagnosis and treatment. As such it can be seen as a device for decision support. Depending on system complexity various functions are either built-in or integrated through an interface. The interacted information presented to the user is complex and critical. The user has small possibilities of checking whether the system presents accurate information. If the system fails the risk for maltreatment is obvious. No other product safety regulation than the MDD has been identified.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**

Most ECG storage systems available on the market are usually classified as medical devices already. The complex design of the product includes many hidden automatic functions that a user can not be accountable for. There is a risk for maltreatment if the system fails. The system may be a class I device according to MDD, but depending on how much involvement the system has in the review process according to the manufacturer, it may be that the device should belong to class IIa if no other review possibilities for diagnosis of ECG is possible.
7. Retinal Imaging System

A retinal imaging system is a software based system used by eye clinics to store, manage and transfer information about patients who has photographed the eye ground. 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 a similar way. A system retinal imaging incorporating functions as described above definitely fulfils the criteria to be classified as medical devices. It is intended to be used for the planning of a patient’s diagnosis and treatment. As such it can be seen as a device for decision support. 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. The interacted information presented to the user is complex and critical. The user has small possibilities of checking whether the system presents accurate information. If the system fails the risk for maltreatment is obvious.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible - Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>

Conclusion of the Working group:

A regulation of retinal imaging systems is highly recommended and the systems on the market are normally classified as medical devices already. The complex design of the product includes many hidden automatic functions that a user can not be accountable for. There is a risk for maltreatment if the system fails. Depending on what is expressed by the manufacturer, the system shall be classified not lower than risk class I in MDD.
8. Picture Archive Communication System (PACS)

Background

Basically, a PACS, Picture Archiving and Communication System, 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 hospital information systems. It does not contain controls for 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 site remotely from imaging systems and is configured to provide limited or extensive capabilities to further process, manipulate and/or view patient images and information collected from diagnostic imaging systems. The manufacturer of the PACS states that the system does not influence the radiation of the X-ray machine.

Generally speaking there are various types of PACS:

- (a) PACS used for viewing, archiving and transmitting images
- (b) PACS where the post-processing of the image for diagnostic purposes are 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

The conclusion formulated by the EU commission in the Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices, version 1.1 (06-05-2008)

In cases where the PACS falls under the definition of a medical device, i.e. 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 is 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 annex 9 2.3 which classifies them as 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 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.
<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>broader sense</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>
9. Radiological Information System (RIS)

A Radiological Information System (RIS) is a software-based database 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

Furthermore, RIS also often supports:

- Scheduling of appointments
- Creating customised reports
- Interface to PACS
- Invoicing
- Procedures

A RIS can be configured in many different ways. In its simplest form, such as how systems designed 5-20 years ago, it was used as an administrative tool and it was a borderline case whether to be classified as a medical device or not. A modern RIS is however intended to be used for the planning of a patient’s diagnosis and treatment. As such, it can be seen as a device for decision support. Depending on system complexity, various functions are either built-in or integrated through an interface. The interacted information presented to the user is complex and critical. The user has small possibilities of checking whether the system presents accurate information. If the system fails, the risk for maltreatment is obvious.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible, like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrides human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for malreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is too late</td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**
A regulation of Radiological Information Systems is highly recommended. Modern systems incorporating functions as described above and available on the market are usually classified as medical devices already. The complex design of the product includes many hidden automatic
functions and interactions with other systems, like PACS, that a user can not be accountable for. There is a risk for maltreatment if the system fails. Depending on what is expressed by the manufacturer, the system shall be classified not lower than risk class I in MDD.
10. Web Based Patient Questionnaires

This is a Java application installed in the patient’s mobile phone. 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 mobile phone (since the mobile is usually on and located near the patient) 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 see them for follow up. When the patient has responded, the answers are sent to the database.

The database is used for compiling the information from the patient’s answers from the mobile phone.

This web application is intended for doctors or nurses to view the answers from the patients. The results are presented as graphics.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>broader sense</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible, Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
<tr>
<td></td>
<td>be detected</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**

Web based patient questionnaires *could be classified as medical devices depending on what the manufacturer has expressed about the system.* The complex design of the product includes some hidden automatic functions that a user can not be accountable for. There are small risks for maltreatment if the system fails. It could be considered to define the system as class I according to MDD.
11. Portal of National Patient Summaries (NPÖ)

This web based service, irrespective of time or location, can offer personal access from one spot, to a customised interface where it is possible to present information internally and externally.

Several health care organisations and other actors use portals. The portals contain many different types of health care information. There could be information about medical care advice, waiting lists, addresses to health care providers, health care contact persons and so on. However, it is becoming more frequent that these portals also have components that could be subjected to the Medical Device Directive, such as the National Patient Summaries NPÖ. There is for example a new trend in making it possible for the patient to access parts of its own patient record on the Internet. Other functions that are becoming available are to gather patient information by using different functions in the portal, like for instance making the patient enter information directly into the electronic patient record himself. If this information is intended for diagnosis, treatment or monitoring of a patient, then those parts should be handled as medical devices.

Health care is clearly moving in the direction of developing local, regional and national patient summaries. This type of guidance gathers and presents medical and individual patient information from several different systems and health care providers. The software has a large number of complex functions that controls in which way the information is presented and synchronised between different systems. This type of patient summaries are intended to be used as tools for diagnosis, treatment and monitoring, and should thereby be handled as medical devices.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**

A regulation of the National Patient Summaries NPÖ is highly recommended. The Swedish portal of National Patient Summaries contains patient specific information intended to be used for diagnosis and treatment and should thereby be seen as a medical device. The complex design of the product includes some hidden automatic functions that a user cannot be accountable for. There is a risk for maltreatment if the system fails. The system should be classified not lower than risk class I.

The purpose of a national prescription information system is to improve quality and cost effectiveness for drug prescriptions. This will be offered with the help of a Swedish prescription database providing relevant actors (mainly health care providers, patients and pharmacies) access to accurate information on the patient’s drug prescriptions.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>National Prescription Information (NOD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>1: No</td>
</tr>
<tr>
<td>Device complexity</td>
<td>1: Everything is visible. Like manual mode</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>1: Only presents basic data</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>1: No risk or little risk that always can be detected</td>
</tr>
</tbody>
</table>

Conclusion of the Working group:

PASCAL is an ongoing project in Sweden where the system’s interface towards other systems needs to be monitored including what functionality to be considered when complying with the definition of a medical device. However, the ambition of the project seems to match the definition of a medical device.
13. Basic Services for Information Supply, BIF

To ensure that the right patients have access to accurate patient information, it is a vital part that needs to be considered to successfully manage the national IT strategy for the health care sector. To achieve the goal where health care professionals in a simple and effective way can get access to the complete information about a patient on the local, regional and national level requires a joint-security infrastructure. The shared infrastructure is called BIF, Basic Services for Information Supply. BIF is based on nine services.

1) **Verification**: The Verification Service checks that the health care staff can identify themselves in two different ways with the help of PIN code and safe cards, referred to as SITHS cards. SITHS is a national security solution (Security for IT and health care) based on public health care staff having personal electronic ID card with an electronic PKI certificate.

2) **Access control**: The Access Control Service matches the user properties with the health care information properties and with the help of a set of rules the service decides which health care information that will be accessed.

3) **Care relation**: This service keeps track on the relations between the health care staff and patients.

4) **Permission**: The service for permissions assists the access control system by registering and keeping track on permissions. It is anticipated that the patient has a positive attitude towards making his health care information available for health care staff that might need the information to be used in other health care situations. The patient must be given the chance to refuse this availability. The result is that nobody shall be able to retrieve any information until the patient gives his permission.

5) **Secure Patient Context**: The service for Secure Patient Context controls when a user simultaneously works in several applications. If the patient is changed in one application then the patient is changed in all other applications as well. This is a safety measure to make sure that patients can never be mixed up.

6) **Exposure**: The service organises information so that it can be communicated to a different health care provider after checking that it does not negatively affect the patient.

7) **Notification**: The Notification Service manages messages so that they can be sent between users or systems in a secured way by using for instance signatures and receipts.

8+9) **Logging and log analysis**: The service for logging and log analysis is available to ensure that the health care information is provided in a correct way and that the patient’s integrity can be maintained. All IT systems connected to BIF can use these services to check that logging and log analysis is conducted in a safe manner.
Conclusion of the Working group:

Basic Services for Information Supply is an ongoing project where the system's interface towards other systems needs to be monitored including what functionality to be considered when complying with the definition of a medical device. *A regulation of some kind is considered to be recommended.*
14. Quality Registries

Definition of National Quality registries

A National Quality Registry contains individual patient information on problems, clinical measures and results within the health care sector. The registry is reviewed and evaluated on a yearly basis and has been approved for funding from the Decision group on National Quality Registries in Sweden.

General

There are at present (2008) 64 “National Quality Registries” operating in Sweden and that are jointly funded through the health care providers and the Swedish government. A few more registries are planned or under construction. Three competence centres are presently available for supporting start-up, operation and use of National Quality Registries. Support for development of registries and administration of the applications are provided by the registration office at the Swedish Association of Local Authorities and Regions.

All National Quality Registries contain patient specific information on problems, diagnosis, treatment and results. When the 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.

The quality registries are tools for continual education and development and are essential components in a modern health care system.

The registries are created by professionals to be used by professionals in their daily work. Management of the registries is handled by several clinics in the country. Swedish Association of Local Authorities and Regions are collaborating with the National Board for 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. At the turn of the year 2006/2007 the administrative work with funding applications etc. for the registries was transferred from the National Board of Health and Welfare to the Swedish Association of Local Authorities and Regions.

Clinical use of quality registries

The following strategic goals demonstrate which areas of development that are prioritised to fulfill the vision as mentioned above in due course.

The National Quality Registries provide 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, etc).

The National Quality Registries are actively involved in measurement based and patient focused work for continual improvements.

The National Quality Registries follow the patient’s path through health care and overcome organisational and professional boundaries.
Established National Quality Registries contribute by presenting their results in a transparent way and by making them accessible and adapted for medical profession, society and health care management.

From an IT perspective the National Quality Registries are integrated with the electronic patient record systems.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>Quality Registries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfill the definition of a medical device in a broader sense</td>
<td>No</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
</tr>
</tbody>
</table>

* The patient record where quality registry information is located can be used for other purposes such as decision support.

**Conclusion of the Working group:**

Since Quality Registries are not intended to be used for individual patients, even though the overall goal is to improve health care, they are not considered to be applicable for the Medical Device Directive. Quality registries are already controlled by other types of strict regulation.
15. Quality Indicators

A quality indicator is a measure that reflects the quality and which can be used to provide basic data concerning operational development and for a transparent demonstration of the quality within a health care organisation.

How to use quality indicators

Monitoring and reporting of quality is important to meet the different stakeholders’ needs and expectations about information on quality. This means that information must be aggregated at various levels to be useful for the various stakeholders. This puts demands on how data acquisition and data source accessibility are managed.

However, it is rather unusual that information from the National Quality Registries is used for activity reporting describing the quality in an organisation and to demonstrate the results of dedicated work with improvements.

The quality indicators are intended to be used for all types of stakeholders. Depending on the stakeholder, quality indicators are mainly used for:

- Learning
- Quality improvement
- Operational improvement
- Reporting or following up at different levels
- Control
- Provide information for contracts and reimbursements
- Information on the choice of health care provider

Quality indicators used for development, control, follow-up and improvement in health care is dependent on several factors, such for instance:

- Commitment of stakeholders to participate in the process of developing quality indicators (early involvement in development process will provide for more firmly established measures when they are ready to be used)
- That the quality indicators are used for promoting continual improvements at operational level.
- Availability of appropriate systems or tools for regular reporting of quality indicators in the daily work (web based organised health care documentation by using templates) for customised databases and quality registries.
- Easily accessible systems or tools for continuous feedback or compilation of the indicators that are offered to different stakeholders.
- Existing competence for analysing or interpretation of the indicators.
- Active promotion of quality indicators in the contract and follow-up work and in the dialogue between public contract providers and private health care givers.
### Quality Indicators

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**

Since quality indicators are not intended to be used for individual patients, even though the overall goal is to improve health care, they are *not considered to be applicable for the Medical Device Directive.*
16. Communication Systems

The health care sector uses communication systems to transfer electronic messages. Different types of messages are being sent such as prescriptions, referrals, images, patient records, etc. Most of the communication systems handle other types of messages other than medical information. They are also designed by software that are intended for general purposes, and that is used for both medical and non-medical transfer of messages within the health care sector.

Communication systems normally support the following functions:

- Transfer of electronic messages
- Control and monitoring of message flow
- Functions for alarms and trouble shooting
- Logging and archiving of transfer information

They are often integrated with a number of different software used in health care and can send different types of electronic messages, such as electronic patient record systems and pharmaceutical systems.

Communications systems are of a very complex nature. Often they manage the transfer of messages automatically and independently without any possibilities for the user to control. The risk for maltreatment and injuries is mainly apparent if a message does not reach the intended receiver, the information is distorted or has been mixed up.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / Injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is too late</td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**

Communication systems, as mentioned above, are already covered by several strict regulations. They are normally based on software for general purposes, and are not used for the purposes that are stated in the definition of a medical device. For this reason **they are not considered to be included in the definition of a medical device.**
17. Advanced Decision Support Systems

A decision support system is here referred to as a computer based tool 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 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 consist of plain 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 include functions for e.g. processing information on different patient results to 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.

Decision support systems that only provide information on a population level should mainly be compared to quality registries, see monograph no 14. Those decision support systems that are used as decision support for individual patients indeed fulfill the definition of a medical device when they are intended to be used as guidance for diagnosis, planning and treatment. 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.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is too late</td>
</tr>
</tbody>
</table>

Decision support for a population, specifically designed for health care
### Decision support for a population, basic software not specifically designed for health care even though it is used in health care

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>

### Decision support for individual patients

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>

### Conclusion of the Working group:

A regulation of electronic decision support systems intended to be used in health care for individual patients is highly recommended. Since there are no other known suitable product regulations, electronic decision support systems should be classified as medical devices. The complex design of the product includes many hidden automatic functions that a user can not be accountable for. There are obvious risks for maltreatment if the system fails. Depending on what is expressed by the manufacturer, the system shall be classified not lower than risk class I in MDD.
18. Telemedicine Systems

Telemedicine is a promising area of technology that will lead to dramatic changes within health care development. Several technical breakthroughs have been achieved in digital imaging processing, mobile communication and sensors which has enabled an accelerated development of telemedicine applications. Even though a number of applications are already mature technologies many still have a long way to go before they can be implemented in the daily clinical environment.

Telemedicine applications allows for:

- Availability of remote specialist competence
- Monitoring of patients’ health conditions remotely, and allowing for faster interventions
- Avoiding or postponing patients to be admitted to hospital treatment
- Effective use of health care staff
- Raising the competence for health care staff
- Reduced transportation costs for both patients and staffs
- Patient empowerment by allowing patients to be more actively involved in their own health
- Utilisation of foreign and external expertise

To mention a few different types of telemedicine applications:

**Telesurgery**

Telesurgery take help of telecommunication and IT-solutions to conduct a surgical intervention from a remote location. With the help of VR 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. Most likely it will need another 10 year 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 types of telepathology applications: statistics, real time and virtual. Statistics, or store and forward telepathology, use a digital camera connected to a microscope and transfers the image from a sample.

In real time pathology applications the pathologists control the microscope.

VR telepathology uses micro array technology to create a three dimensional image of the total sample to be reviewed from a remote location.

**Home care monitoring, wired or mobile**

These systems use IT and mobile telecommunication to monitor the patient’s health remotely and are used to check that the patient gets sufficient help. The patient recieves equipment for measuring
e.g. blood pressure, oxygen saturation, pulse, weight, etc, and the values are transferred to the clinic for evaluation.

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 be used for patients typically 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 is used already and especially within psychiatry.

Teleradiology
Teleradiology is used to review radiological information from a remote location by a radiology expert. Such systems are already in clinical 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 attend the clinic (unless an interventional technique is required).

The matrix used for describing complexity, severity and risk for harm in case of malfunction is rather difficult to generally apply to telemedicine applications since they are of such diverse nature.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>broader sense</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible.</td>
<td>Hidden automatic</td>
<td>Many hidden functions</td>
</tr>
<tr>
<td></td>
<td>manual mode</td>
<td>function</td>
<td>and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic</td>
<td>Presents calculations</td>
<td>Provides suggestions</td>
</tr>
<tr>
<td></td>
<td>data</td>
<td></td>
<td>and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk</td>
<td>Risk is possible to</td>
<td>Risk can not be</td>
</tr>
<tr>
<td></td>
<td>that always can be</td>
<td>detect to some extent</td>
<td>detected until it is</td>
</tr>
<tr>
<td></td>
<td>detected</td>
<td></td>
<td>is late</td>
</tr>
</tbody>
</table>

Conclusion of the Working group:
A regulation of telemedicine systems can be recommended depending on its application area. Based on the manufacturer’s specification it could be applicable to classify these as medical devices. The
complexity of the devices varies. Reproduction of data can on some occasions be critical and it is a possible risk of maltreatment if the system fails. Depending on what is expressed by the manufacturer, the systems shall be classified not lower than risk class I in MDD.
19. Web Systems for Monitoring of Medical Devices

Web system for monitoring of active implants

A Web system for monitoring of implants (pacemakers or ICDs (Intra cardiac defibrillators)), is a software-based database used at cardiology clinics to store, analyse and transfer cardiac information from the patients’ pacemakers or ICDs. Cardiac information is sent over the Internet/phone/mobile 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. See figure 1-3 below for examples of transmitter/receiver that can communicate with a pacemaker/ICD patient.

The patient’s cardiac information is only accessible for professionals at the clinic responsible for the patient’s treatment.

The system normally contains information on patient identification and cardiac information from patients’ pacemakers or ICDs. The information in the system can also be forwarded to other electronic patient record systems through regular interfaces.

Figure 1. Medtronic’s CareLink Monitor

Figure 2. St Jude Medical’s Merlin@home and Merlin.net
Figure 3. Biotronik’s CardioMessenger II

**Web systems for monitoring in vitro diagnosis devices**

For monitoring of diabetes patients, a software based database is available to be used by endocrinologists to store, analyse and transfer information from patients’ insulin pumps or blood sugar counters. The information is transferred in the same manner as for cardiac implants. The acquired information is also being sent directly from the clinic that has followed up a diabetes patient and wants to have complete information about the patient’s treatment.

The patient’s information is only accessible for professionals at the clinic responsible for the patient’s treatment.

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

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**

A regulation of web systems for monitoring a medical device is highly recommended. *Available systems on the market are classified as medical devices by some manufacturers.* Reproduction of data can on some occasions be critical and it is a possible risk of maltreatment if the system fails. Depending on the manufacturers’ specifications of system functions it is likely that the device shall be classified in higher risk classes, IIa or IIb, considering that vital parameters are being registered or monitored.
20. In-vitro diagnostic (IVD) 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, where different types of validation, quality control and various interconnections with analytical instruments are possible. 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 be interfaced with Hospital Information Systems (HIS), Electronic Patient Record Systems, Infectious control databases etc.

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**

A regulation of In-vitro diagnostic software not connected to analytical instruments is highly recommended. LIS and WAM fulfill the criteria for medical devices since their purpose is to diagnose, prevent and monitor diseases, amongst other things.

An important distinction is that such integrated, specific software for controlling an analytical instrument, independently of which instrument LIS or WAM is connected to, is included in the IVD Directive and therefore not covered in the Medical Device Directive.

In most cases this concerns complex systems which to a large extent overrule the human responsibility. However, evaluation and final decision shall always be made by the user. It is difficult for the user to decide if the presented information is correct, which means a risk for maltreatment and harm if a failure occur due to missing information.
21. Medication Module

Medication modules raise many expectations of increased patient safety, improvements in logistics and follow-up as well as cost control. It is a strategic, complex and wide area and the examples presented below are only a few of many. The medication module can be seen as a process support in a chain of activities between different providers where information transfer and security is vital to patient safety.

Altogether the medication module contains many different components where single or several components make up the functionality, and often from different vendors or stakeholders. Previous manual systems in cardex (prescriptions) and paper-based documentation and prescription management have been extremely difficult to evaluate for follow up and quality control – the handwriting and the interpretation of people’s handwriting has also contributed to challenges for nurses and pharmacies in the daily work.

In Sweden there have been a number of documented severe incidents (even deaths) due to the malfunction of medication modules. The state-owned pharmacy company, Apoteket, has reported problems in the e-prescriptions chain where patients have been given the wrong medication. Databases and sources for medication modules have been known to have various quality and has sometimes provided contradictory advice and recommendations. The Swedish Drug Information Database has focused on quality assurance in this area.

Much of the source information is non-standardised (information wise) and text based (not codified) which has caused difficulties and obstacles. Furthermore, uncertainties about the conditions for responsibility and the regulatory framework for pharmaceuticals have not contributed to an easy transition to use the sources in the medication modules.

The absence of a substance database and standardised expressions and terms within the area has caused additional problems, which creates risks for the patient safety in the medication modules. Efforts have been made for parts of areas to solve the problems, and especially within the area of ePrescriptions.

The medication modules often interact with other modules in an electronic patient record, especially with documentation and laboratory modules. The warning module has traditionally been a part of the medication module since the connection to severe hypersensitive reactions has been so evident. A proposal for a new regulation has been prepared, where the warning information will instead be a specialised documentation module which will require other types of interaction. For specific patient groups with required 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.

Attempts have been made to assist the prescribers with interaction checks, generic controls and information that are based on previous diagnosis (e.g. renal failure) and specific laboratory results (e.g. renal function values).

A medication module can consist of:

- Medication list with a compilation of all ongoing medication for a patient (including history)
- Warnings and hypersensitivity
  - Prescription module (prescriptions)
    o Personal aid prescription
    o Foods for specific purposes
    o ePrescription functionality (electronic communication with pharmacies)
- Different types of information sources
  o FASS – Physicians’s desk reference on pharmaceutical specialities in Sweden
o Recommended drugs
o Pharmacy drug supply list
o Interaction information (e.g. Sfinx drug-drug interaction database)
o The Swedish Drug Information Database
o Commercial information sources (e.g. First Databank)
- Prescription support based on the sources mentioned above, etc.
o Template management system (standardised prescriptions)
o Specialised modules for cytostatic drugs, waran, intravenous nutrition etc
- Prescription module (for prescribers)
o Blood products
o Delegation management system (e.g. delegation for nurses to prescribe drugs)
- Drug dispensation module (for nurses, according to prescription)
- Pharmacy module (ordering of drugs)
- Pharmacist module (require a process implemented with the pharmacist that is involved in prescription)
- Quality system, quality registry
- Special handling of extemopore, and pharmaceuticals for research
- APO-dosage module prescription of drug dosage packages to individual patients
- Reports on side-effects
- NOD Swedish National Prescription Information (ongoing project)
- NPÖ Portal of Swedish National Summaries includes pharmaceutical information
- epSOS European Patient Summaries includes pharmaceutical information
- epSOS European ePrescription system
- National databases (Swedish National Board for Health and Welfare)
- Systems for clinical trials on pharmaceuticals
- The pharmacies internal system
  o Dispatch systems
  o Discount systems
  o Databases (prescriptions)

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>

**Conclusion of the Working group:**

A regulation of the various types of medication modules is highly recommended. **It would be possible to classify medication modules as medical devices depending on how the system manufacturer has defined the system.** The complex design of the products includes many hidden automatic functions that a user can not be accountable for. There is a big risk for maltreatment if the system fails.
Depending on what is expressed by the manufacturer, the system shall be classified not lower than risk class I in MDD.
22. ePrescriptions

ePrescription 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 is rearranged) before the prescriptions are transferred to the pharmacy to their server for further distribution to the local pharmacies or to the national electronic mailbox. Finally the dispatch system at the pharmacy checks the prescription before the medication is handed out. In addition, there are also often software for encrypting and signing to ensure secure data transfer in the networks. The information is transmitted in both directions, for instance for confirmation of received data or error messages. An important part in the ePrescription chain is the data transfer in the different secured or public networks, whether the services are internally operated or provided by an external operator. The situation for ePrescription services is that software from different vendors is being used by different organisations at many different levels. The description below only mentions what is typical for ePrescriptions, other information can be found under the medication module.

In Sweden the state-owned pharmacy company, Apoteket, has in addition been able to offer two types of prescriptions for outpatients, traditional and APO-dos (customised dosage packages of drugs by using a particular web interface).

A number of different national projects are initiated in Sweden to improve the security and quality of the function of ePrescriptions. A prescription requires mutual responsibility, shared between the prescriber and the dispatching pharmacy. Prescriptions shall be checked for reasonability before it is handed out, and if in doubt the prescriber must be contacted.

ePrescription services can consist of:

- Prescription module (for components included see the medication module)
  - Personal aid prescription
  - Foods for specific purposes
  - ePrescription functionality (electronic communication with pharmacies)
- APO-dosage module prescription of drug dosage packages to individual patients
- epSOS European ePrescription system (ongoing project)
- The pharmacies internal system
  - Dispatch system
  - Discount system
  - Databases (prescriptions)

<table>
<thead>
<tr>
<th>Factor / Severity</th>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fulfils the definition of a medical device in a broader sense</td>
<td>No</td>
<td>Possibly</td>
<td>Yes</td>
</tr>
<tr>
<td>Device complexity</td>
<td>Everything is visible. Like manual mode</td>
<td>Hidden automatic function</td>
<td>Many hidden functions and processes</td>
</tr>
<tr>
<td>Device overrules human responsibility</td>
<td>Only presents basic data</td>
<td>Presents calculations</td>
<td>Provides suggestions and conclusions</td>
</tr>
<tr>
<td>Risk for maltreatment / injury</td>
<td>No risk or little risk that always can be detected</td>
<td>Risk is possible to detect to some extent</td>
<td>Risk can not be detected until it is to late</td>
</tr>
</tbody>
</table>
**Conclusion of the Working group:**

A regulation of systems for ePrescriptions is highly recommended. As for the *medication modules* these systems would be possible to classify as medical devices depending on how the system manufacturer has defined the system. The complex design of the products includes many hidden automatic functions that a user can not be accountable for. There is a risk for maltreatment if the system fails. Depending on what is expressed by the manufacturer, the system shall be classified not lower than risk class I in MDD.
Regulation of health care providers’ responsibility managing information systems

According to the Swedish Health and Medical Service Act (HSL) good health and equal access to health services for the population is the goal for the Swedish health care system. The goal for the dental care system is according to the National Dental Service Act (1985:125) good dental health and equal access to dental services for the population in Sweden. The health care system shall according to 2 a § in the Swedish Health and Medical Service Act be conducted in a way that the requirements for good health care can be met. In particular this means that it must be of good quality and be able to meet the patient’s need for security in care and treatment, be based on respect for the patient’s right for the self determination and privacy and meet the patient’s need for safe health care. The Swedish National Dental Service Act includes corresponding quality requirements. Where health and medical services are conducted, there shall be present staff, facilities and equipment necessary in order for the provision of good care to be possible (2 e § Swedish Health and Medical Services Act).

The top management of health and medical services shall be organised in such a way as to provide a high level of safety for patients and good quality of care, as well as promoting cost efficiency (§ 28 in the Swedish Health and Medical Services Act). The quality of activities in health care and dental services shall be systematically and continuously developed and secured (§ 31 in the Swedish Health and Medical Service Act).

The health care provider must, according to the Swedish National Board of Health and Welfare’s regulation (SOSFS 2005:12) on “Quality management systems in health care” take responsibility for providing instructions and ensure that the management system is appropriate for each operational unit. The management system shall, amongst other things, ensure the provision of routines for the secure use of information systems. The management system shall ensure that there are routines for purchasing services, products, general supply systems and information systems from distributors that have been evaluated and approved (chapter 4, §7 in SOSFS 2005:12). The operational manager or the equivalent is responsible for, within the framework of the management system, establishing and documenting the routines for the organisation. The health care and medical staff shall be familiar with the applicable legislation, the National Board of
Health and Welfare's regulation as well as the routines established by the operational manager.

The area of application in the National Board of Health and Welfare's regulation (SOSFS 2008:1) on “The use of medical devices” covers information systems that are connected to medical devices. The health care provider shall give instructions and ensure the availability of organisational routines of each operational unit to allow for the safe use of medical devices (chap. 3, §4 in SOSFS 2008:1). The operational manager shall be responsible for making sure that only safe medical devices are used on patients, etc. (chap. 3, §5 in SOSFS 2008:1). The health care and medical staff shall, amongst other things, have the sufficient knowledge of the proper handling and associated risks when using medical devices (chap. 3, §8 in SOSFS 2008:1).

If, in connection with medical or health care, a patient suffers or is exposed to the risk of suffering serious injury or illness then the health care provider is obliged to, according to chapter 6, §4 in the legislation LYHS on “Occupational work within health care”, report the incident to the National Board of Health and Welfare without delay. The National Board of Health and Welfare's legal provision (SOSFS 2005:28) stipulates the reporting duty according to the “Lex Maria” rule. Incorrect use or maintenance of medical devices and information systems should be reported.

The Swedish Patient Data Law (PDL) shall be applied for health care providers handling patients’ personal data within health care. The information management within health care shall be organised in such a way it fulfils patient safety and good quality as well as promote cost efficiency. Personal data shall be documented and managed in a way that the patient’s and personal data of other people is handled with respect for individual integrity. Documented personal data may not be disclosed for unauthorised use (chap. 1, §2 in PDL). A health care provider shall according to chapter 4, §2 in PDL define the requirements for access rights of patient data that is processed in an electronic format. The health care provider shall ensure that there are documented access rights (logged) and that it is available for inspection. The health care provider shall systematically and regularly make inspections to prevent information from being disclosed for unauthorised use (chap. 4, §3 in PDL).

According to chapter 2, §1 in SOSFS 2008:14 the health care provider is obliged to implement an information security policy. The information security policy is a top level document setting out goals and ambitions and controls the task to protect information. This information security policy is the foundation for the operational unit’s common platform when working with information security. The policy shall ensure that the patient data is
available and useful for authorised users that the data is correct and protected from unauthorised use (chapter 2, §2 in SOSFS 2008:14). The provisions clearly describe the health care provider’s responsibility for information processing and record keeping, as set out in the rules for using open networks, for control of access rights, for access of patient data, for control of access and for safety-backups, etc.

**Do the rules apply irrespective of whether patient data is documented in an electronic format or not?**

The rules in chapter 2, §2, 4 and 4–17 as well as in chapter 4, §2, 5 and 6 in the National Board of Health and Welfare’s regulation (SOSFS 2008:14) on “Information management and record keeping in health and hospital care” shall be applied by health care providers that use automatic or semi-automatic systems for processing patients’ personal data (patient information).

Other rules shall be applied irrespectively of which ways patient data is documented. The Patient Data Law and the National Board of Health and Welfare’s regulation (SOSFS: 2008.14) on “Information management and record keeping in health and hospital care” is also applicable for operational units that are using paper based patient record systems.

**What is a patient record?**

A patient record consists of one or several medical records concerning one individual patient. The term patient record is defined in chapter 1, § 3 in the Patient Data Law as the presentation of information, text or image, and a recording which can be read, listened to or by any other means be interpreted with a technical aid and that is created or delivered in association with health care for one patient and that contains information about a patient’s health condition or other personal conditions or if a health measure has been conducted or is planned. In other words, the patient record consists of all information about a patient that is relevant to his or her health care situation.

A patient record must be maintained when providing health care (chapter 3, §1 in the Patient Data Law). This means that the health care provider is obliged to ensure that patient records are maintained for each patient. Chapter 1, 3§ Patient Data Law regulates the intention of the Health and Medical Service Act.

A patient record shall according to chapter 3, §1 in the Patient Data Law, be maintained for each patient and may not be shared with several patients. This however, does not restrict the possibility of having several patient
records per patient at one health care provider. Different clinics at the health care provider can maintain their own patient record concerning the same patient.

A patient record shall contain the information needed to provide good and safe health care (chapter 3, §6 in PDL).

For what purposes may patient data be used?

The Patient Data Law applies to the health care providers that handle personal data within health care. The basic provision of the legal requirements when processing patient data within health care is stipulated in chapter 2, §4 in the Patient Data Law. Personal data may, according to this provision, be processed within health care if it is necessary to fulfil the obligation of record keeping and create other documentation necessary for providing health care for patients, for administrative purposes associated to patients' and where the purpose is to provide health care for individual patients or otherwise the need to provide health care for individual patients, to create other documentation that is legally compulsory, ordinance or other provision, as for in a systematic and continual way develop and secure quality within the operational unit, administration, planning, following-up, evaluation and surveillance of the operational unit, or for creating statistical data to be used within health care.
Safety requirements for medical information systems

Programmable systems and software have obtained an increasing and direct critical significance for the care and treatment of the individual patient. Depending on the intended application, these systems and programs can be covered by the legal requirements for medical devices. Against this background, the Medical Products Agency and the National Board of Health and Welfare are of the opinion that the safety of medical information systems and data management require a more explicit assignment of responsibility from both the manufacturer and the health care provider.

Thus, the Medical Products Agency (MPA) intends to develop the market surveillance practices as well as to inform the manufacturers and suppliers on the Swedish market that the medical device legislation shall be applied to those parts of an information system or a software that fulfil the definition of a medical device.

The National Board of Health and Welfare intends to issue regulations to support and help health care providers in their ambition to improve the patient safety by a more systematic approach to implementation, management, maintenance and upgrading of software systems in clinical use.

Boundaries between IT and medical devices are disappearing

Medical devices have received an all more and direct critical significance in the diagnosis and treatment and an increasing role in healthcare. In some cases, the devices have a life-supporting function. Access to good and safe devices is an essential prerequisite for today’s health care.

The traditional view of a medical device is a stand-alone-product, that is, a product and its software designed to a certain aim and without any purpose to be combined or to interact with other products. Defibrillators and mechanical heart valves are examples of stand-alone-products.

However it is an obvious trend that an increasing number of medical devices can be integrated with other products in the care giver’s administrative patient management system. An electrocardiograph or digital X-ray equipment can transfer data directly to a patient monitoring system or other administrative patient management systems. The boundaries between information technology (IT) and medical devices are disappearing.
Another trend is that information management in the health care sector is increasingly integrated with the clinical procedures. The market offers software and system solutions with patient monitoring and decision support features for the care and treatment of individual patients. It is particularly important that these products manage the information in accordance with what the user is promised and has the reason to expect. The products therefore have to be designed for the intended use.

The MPA’s and the National Board of Health and Welfare’s starting point for both equipment and software designed for clinical use in the health care sector is that the responsibility is shared between the manufacturer and health care provider.

The manufacturer shoulders the responsibility for the safe design before placing the product on the market. The health care provider is liable for the systematic implementation, integration and management of medical devices, software products and systems within the framework of the management system, which also includes demands for risk analyses, testing and documentation.

Patients are exposed to risks when responsibility is unclear between manufacturer and caregiver

Software and system solutions are not always validated for the intended use. The consequence is that they are then passed on to the caregiver with undefined regulatory references, i.e. it is not clear the legislative sphere for the product and which legal (regulatory) requirements that should apply and that the caregiver should expect the product to fulfil. The caregiver is left with the user responsibility for a system with inadequate basic information and for which the user has insufficient knowledge. The system is impossible to follow up and greatly limits the possibility of carrying out a risk assessment.

The terminology in the existing legislation does not provide good guidance as the product sector has developed substantially since the laws were formulated. There are safety requirements in the European directives for those products that are covered by the definition of medical devices. The legislation for medical devices is directed towards manufacturers and the MPA is the competent authority in Sweden. The national legislation for all medical information systems within health care are formulated in general terms in the National Board of Health and Welfare’s provisions and are directed towards the users.

In spite the fact that there is a definition of medical devices in the medical device legislation, it is still often unclear when a certain medical information system should or should not be regarded as medical devices. Manufacturers are conservative when defining their systems. We have observed manufacturers that issue a “declaration of non conformity” (to the medical devices directive) The motive behind that kind of statements is probably that the manufacturers wish to avoid the costs associated with the specific procedure described in the national medical devices legislation that in the end is aimed to protect the patient. By declaring that a system is not a medical device the manufacturer also shirks responsibility of that the product is safe for its intended use.
The consequence is that the responsibility is juggled between the manufacturer and the care giver and patients are exposed to risks.

Many important programs and information systems are involved

It is important to avoid being locked into the existing nomenclature as this leads to a far too narrow vantage point for viewing the problem. Such terms can be:

- Programmable electro medical systems (PEMS)
- “Journal system”
- Patient administrative systems (PAS)
- Decision support systems
- Medical IT system
- Medical information system
- Medical information management system
- Medical instrument data system (MIDS)

In turn this means many important programs and information used for patient diagnoses and treatments are involved.

- Software integrated in a specific, physical medical device such as in a computer tomograph or an infusion pump.
- Software performing a medical device function such as medical imaging
- Software for storing data such as PACS (Picture Archiving and Communication System)
- Software for storing patient information such as RIS (Radiological Information System)
- Software used for decision support and planning such as dose planning
- Software communicating with medical devices
- Software that handle test results for clinical laboratories

Software must be regarded as a "product”

The MPA and Swedish National Board of Health and Welfare consider that satisfying safety can only be achieved if the software is regarded as a “product” with specifications for a defined, intended use and with a responsible manufacturer that gives the basis for a clear delivery with a regulated product follow up. Such product follow ups of products released to the market, the Post Market Surveillance, include the manufacturers’ handling of product experiences, vigilance reports, corrective actions and recalls.

The necessary requirements, including risk management, software validation and product follow ups, are put down in European product safety legislation based on the so-called 'New
Approach’. The medical device legislation is based on the New Approach and many medical information systems seem to be covered by the definition of a medical device.

Medical devices are classified according to three European Directives ‘Active Implantable Devices (AIMDD), ‘In Vitro Diagnostic Devices (IVDD)’ and other Medical Devices (MDD),” see the definitions in the references at the end of this document. Products within MDD and IVDD are classified further with reference to the level of risk, in other words, the risks the patient is exposed to when the product is used. The classification of programmable systems (as MD, IVD or AIMD in their respective risk classes) should probably not be more of a problem than for other medical devices. Possibly it can be uncertainty about the appropriate verification procedure to follow within MDD or IVDD. Some of the available verification methods involving quality assured final product control or quality assured production are, for example, often totally inadequate methods for complex software. This is a well-known problem that is discussed among the EU member states. The Swedish authorities should work to solve this in future modifications of the Directives.

The choice of the verification procedure must be based on the system’s risk level – what the system itself can cause – and what can be offered as acceptable proof that the final product is sufficiently safe. It is logical that a manufacturer of a software of the lowest MDD/IVDD risk class can follow the verification method for CE marking that ensures that the manufactured products fulfil the essential requirements but without the requirements for a formal quality management system and without the involvement of a notified body. It is also logical that manufacturers of software in the highest MDD/IVDD risk classes and AIMDD shall follow the verification methods with the requirements for a complete quality management system. At the same time, it is reasonable that the software manufacturer of other risk classes in-between can show that they chose a verification method that gives an adequate safety level. For software with a risk level above the lowest class, it is reasonable to assume that the only appropriate verification method is via a complete quality management system, such as MDD annex II or IVDD annex IV.

Useful standards are available

There are a number of useful standards available for software systems (see the reference list). These include requirements for development models, risk management, verification and validation methods as well as documentation. Certain standards show the possibilities for dividing the system in more or less critical modules which thereby can be handled more or less exhaustive.

If the system is intended to be used together with other systems, the combination shall be defined, verified and validated. The standards also give guidelines to risk classification. The standards thereby give support to fulfil most of the regulatory requirements.
Clarification of the requirements

The MPA will develop practices in the authority’s market surveillance as well as inform the manufacturers and suppliers on the Swedish market that:

- Medical device regulations shall be applied to those parts of the products that are covered by the definition of a medical device
- The manufacturer of the system concerned shall follow the appropriate verification methods in the medical device legislation
- The system's risk level shall be evaluated, motivated and be the guide for the classification and verification method
- The software is to be divided into medical device and non-medical device if possible
- It can be appropriate to consider dividing the system into modules with different risk levels
- The appropriate standards for development, verification and validation of software and information systems for clinical use should be complied with.

At the same time, the National Board of Health and Welfare concretizes the requirements that the health care providers should state during purchasing and putting in use of programmable systems, based on the general requirements in the National Board of Health and Welfare’s provision, such as, e.g., SOSFS 2005:12 and SOSFS 2001:12:

- The manufacturer shall ensure that the product is specified and ready-made prior to clinical use
- There is a manufacturer that takes the manufacturer’s responsibility
- The manufacturer shall be required to include a system for follow up of products released to the market (just as the Post Market Clinical Follow up for medical devices)
- The system may only be used for the intended use and shall not be combined or extended beyond that which has been validated or approved without a decision on further product design development being taken
- Software updates must be regarded as a new software product and be formalized with orders, delivery, acceptance check and training

The National Board of Health and Welfare further clarifies the stipulations for systems under development in the new regulations with requirements for management systems for information security and patient safety in the healthcare sector’s management of information, such as:

- A product where the user takes part in the development to some extent shall not be used in clinical routine procedures before it is completed and approved and a manufacturer has assumed the manufacturer’s responsibility
- A product under development shall only be used in specially regulated, limited and controlled conditions similar to a clinical trial
• New systems, regardless of being medical devices or not introduced into a new environment shall be used under special supervision to identify the risks that have not been foreseen.
• The new SOSFS 2008:1 on the management of medical devices clarifies the caregiver’s responsibility for medical devices and the accompanying information systems.

The MPA and the National Board of Health and Welfare together will clarify the requirements for systems that will be integrated or communicate with other systems.
• The interface shall be defined either through a standardized format or by the manufacturer specifying other compatible products.
• The system shall be continuously protected from data virus without the manufacturers’ product validation being nullified.
• The actual system shall not interfere with operation of other systems.
• If the communication channels and links are not parts or accessories of the actual system but rather for example the existing local network, the Internet, telenet, cables etc. more or less uncontrolled by the manufacturer of the system, these should be viewed as general supply systems.

The manufacturer must take the inadequacies of those links into consideration in a risk assessment of such links and determine the consequences of a breakdown and, when needed, find measures to compensate for the lost communication

**Future work with revisions necessary**

It is important that the question is clarified in the European Directives for medical devices. The MPA will work actively in the EU groups participating to ensure that regulations more clearly indicate that it includes some software and system solutions for clinical use.

The National Board of Health and Welfare will in connection with the drawing up of the provisions for a management system for information security and patient safety for the health care sector and infectious disease information management “build in” a SDLF (System Development Life Cycle) that includes medical devices, including those based on ITL (Information Technology Infrastructure Library) and CobiT (Control Objectives for Information and Related Technology).

**References**

**Medical Device Directives**

Medical devices are divided into three different product groups:

• Active Implantable Medical Devices - AIMD
• Medical Devices - MD
• In Vitro Diagnostic Medical Devices - IVD
Three European Directives regulate the manner in which medical devices may be released to the market and put into operation:

- Active Implantable Medical Devices Directive (AIMDD)
  Directive 90/385/EEC - OJ L189/ 20.7.90,
- Medical Devices Directive (MDD)
  Directive 93/42/EEC - OJ 169/ 12.7.93
- In Vitro Diagnostic Medical Devices Directive (IVDD)

See the link in the right margin for more information.

**Useful standards for software systems**

- IEC 62304, Ed. 1: Medical device software – Software life cycle processes,
- IEC 60601-1:2005, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance,
- CEN/TS 15260:2006 Health informatics: Classification of safety risks from health informatics products,
- EN 1041:1998 Information supplied by the manufacturer with medical devices,
- EN ISO 14155 Clinical investigation of medical devices for human subjects.

---

1 *General supply system* is a term that is used by the National Board of Health and Welfare in the regulations on quality management systems in health care SOSFS 2005:12: