SVENSK FÖRENING FÖR MEDICINSK TEKNIK OCH FYSIK
Swedish Society for Medical Engineering and Medical Physics

MIDS
Medicintekniska
Informationsdatasystem

Project

Guidelines for MIDS

Proposals for measures for collaboration between
Biomedical Engineering and IT for improved patient safety

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Preface

The border between Biomedical Engineering and IT is one of the areas that the Swedish Society for Medical Engineering and Physics (MTF) gives priority to because it is very important for the future development of a safe and effective healthcare.

When medical devices and IT systems are interconnected potential safety risks for the patient arise. Clear guidelines on safety for medical devices exist and the biomedical departments guarantee that these are complied with.

Those involved are not always aware of the safety requirements to be met for medical devices, and today in some cases rules and procedures of how interconnected medical systems and IT systems should be handled are missing.

MTF's Board of Directors has appointed a task force on **MIDS** (Medical Information Data Systems) with the task/assignment of working with issues on patient safety in healthcare. This includes guidance on how Biomedical Engineering and IT will work together on the issue of ensuring patient safety. The assignment also includes the preparation of proposals for national competence.

The project "Guidelines for MIDS" started in 01-12-2005 and with this report, issues a proposal for measures.

For the Swedish Society for Medical Engineering and Physics

Per Ask
Former president of MTF

Note: Due to a great interest for this report from biomedical engineers, IT engineers, authorities, companies and other organisations outside Sweden MTF's Board of Directors decided to publish this report also in English. The English version is fully comparable with the Swedish original published September 2007.

For the Swedish Society for Medical Engineering and Physics

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Abstract

Guidelines for **MIDS** describes how to improve patient safety by clarifying the responsibilities of Biomedical Engineering (BME) and IT-departments (IT) when dealing with medical devices and systems.

Medical Information Data Systems, **MIDS**, concerns medical devices/ systems, in conjunction with IT products/systems, where the intended use (according to the medical devices directive, MDD) is diagnosis, monitoring and/or treatment of individuals for medical purposes. Communication takes place via networked server systems, databases and/or other methods of storage.

At present there are problems with, among other things, unclear responsibility, vague roles and limits of liability between the IT departments, BME departments, suppliers and system users.

The project provides suggestions and recommendations on national guidelines for the use and management of MIDS-products/systems thus increasing the possibility for BME, IT, health professionals and suppliers to act jointly on the basis of their roles and responsibilities.

Methods of identification and classification of computer/equipment/network associated with BME and IT are proposed as a national standard.

The "System Integrator", according to standard SS-EN 60601-1, third edition, should be established within the activities.

Introduction

Project Guidelines for MIDS

The aim of the project is to improve patient safety by clarifying the areas of responsibility for BME[1] and IT activities concerning medical devices/systems and IT products/systems.

The goal is to create proposals for national requirements concerning competence and guidelines for collaboration between BME and IT in order to comply with the rules and regulations for medical devices/systems and IT products/systems.

Project Organisation

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[1] BME, Biomedical Engineering

Results

MIDS products and systems

Definition

The Medical Information Data System **MIDS** refers to medical devices/systems interacting with IT products/systems, where the intended use (according to the medical devices directive, MDD) is diagnosis, monitoring and/or the treatment of individuals for medical purposes. Communication takes place via networked server systems, databases and/or other methods of storage.

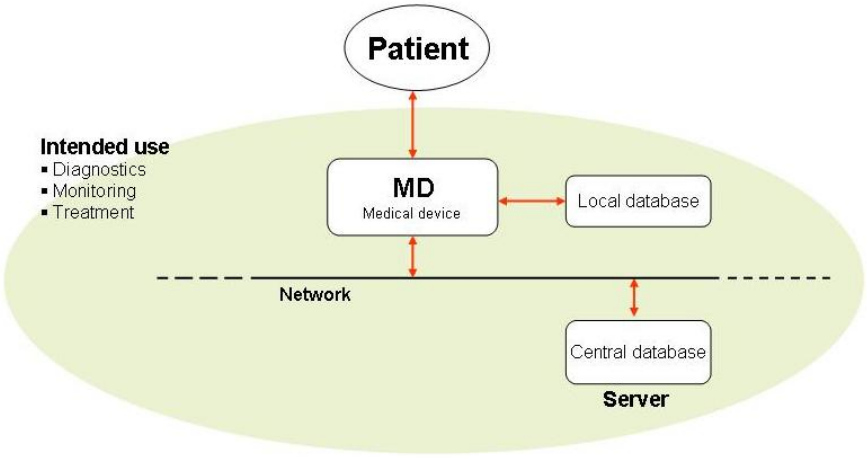

Fig. 1: MIDS medical information data system

MIDS components

The following components can be identified in an MIDS product/system, see below. Each component makes its own demands on maintaining patient safety.

Equipment/modality

A piece of equipment/modality [2] is a medical device (MD). In most cases it consists of a computer with adherent software and can be directly connected to a network.

Client/workstation

A client/work station is often a personal computer with software alternatively a medical device (MD) with built-in computer and adherent software. Occasionally the software, when defined as a medical device, interacts with other software of a more administrative character.

[2] **Modality:** Definition for a group/type of medical imaging systems/entities in Radiology e.g., CT, MR.

Networks

Network-connected MIDS products can be part of a common IT infrastructure or be connected to a separate, isolated network.

In a modern network topology in health and hospital care, segmenting and switches are used to obtain intelligent traffic flow control. This type of communication equipment requires continuous monitoring and recurrent updating.

Server/database

A server distributes information to other computers (acting as clients). The database with stored information is found on the server.

MIDS-products in intensive care and surgery

PDMS system

The Patient Data Management System (PDMS) brings to a head the issue of MIDS. The PDMS system consists of a server/database, care register, patient monitoring, decision support, clients (even patient-related), networks, medical devices, connections to health record systems, to laboratory systems, to the management of quality systems (nonconformities/customer complaints) etc., in complex sets of systems. Here medical engineering and medical informatics are integrated in the IT infrastructure.

The PDMS system is an MIDS system according to the Swedish Medical Products agency (MPA) as well as the Swedish National Board of Health and Welfare's assessment and thereby the rules and regulations for medical devices are applicable. Here some clarification is required concerning the management of equipment as well as of the division of responsibility between caregivers and suppliers. The rules and regulations for drawing a borderline between health record systems and medical devices need to be clarified.

MIDS system	Affected users	Affected suppliers managing the product
PDMS (Patient Data Management System)	Intensive care units, Surgery etc.	IT, BME and manufacturer/supplier
CTG-monitoring	Maternity wards, Women´s clinics	IT, BME and manufacturer/supplier

Table 1: An example of MIDS systems in intensive care, anesthesia and surgery

MIDS products in laboratory medicine

MIDS products involved in laboratory medicine are examples of complex systems where technology is integrated in an advanced chain of processes. The laboratory information system, with belonging peripheral systems in laboratorial medicine, are MIDS products and are included in the EU directives MDD and IVDD. Laboratory work is often accredited by SWEDAC with demands for collaboration between Medical Engineering and IT. The accredited activities are governed by specific rules and regulations.

MIDS system	Affected users	Affected suppliers managing the product
Laboratory information systems	Clinical chemistry, Clinical microbiology, Transfusion medicine, Pathology, Cytology etc.	IT, BME and manufacturer/ supplier
Automation systems with medical devices/ equipment systems	Clinical chemistry lab., Clinical Microbiology lab., Transfusion medicine, Pathology, Cytology lab., etc.	IT, BME and manufacturer/ supplier

Table 2: Examples of MIDS systems in laboratory medicine

Image-generating MIDS-products

Modalities (e.g., CT, MR, angiography, ultrasound, gamma camera, digital fluoroscopy) are connected to a PACS short-term archive which in turn is connected to a PACS long-term archive. There is often a coupling, a "broker" between an RIS system and modalities as well as between RIS and PACS. The protocol DICOM [3] is used for storing and managing images.

MIDS system	Affected users	Affected suppliers
PACS	Radiology departments as well as who scrutinize and use X-rays, medical physics etc.	IT, BME and manufacturer/ supplier
Other X-ray systems not always connected to PACS	Dental specialists, mammography, medical physics etc.	IT, BME and manufacturer/ supplier
Gamma cameras, PET	Medical physics etc.	IT, medical physics and manufacturer/ supplier
Ultrasound with image storage	Radiology departments, Clinical physiology, Medical physics etc.	IT, BME and manufacturer/ supplier
Endoscopy with image storage	Gastro-internal activities, all who generate or inspect endoscopic images	IT, BME and manufacturer/ supplier
Retinal imaging system with image storage	Ophthalmic healthcare	IT, BME and manufacturer/ supplier

Table 3: Examples of image-generating MIDS systems

[3] http//medical.nema.org/

MIDS-products in electro medicine

In electromedicine there are MIDS systems/products that are coupled to digital imaging storage or data storage systems, as well as instrument guiding systems for medical devices and systems.

MIDS system	Affected users	Affected suppliers
ECG	Clinical physiology depts. and all who generate or interpret ECGs	IT, BME and manufacturers/ sup pliers
Ultrasound	Clinical physiology depts., X-ray activities etc.	IT, BME and manufacturers/ sup pliers
EEG/EMG/EP/ EneG/MVC	Neurophysiology wards and all who generate or interpret neuro physiological measurement data	IT, BME and manufacturers/ sup pliers
Patient monitoring	Intensive care units, post-op, surgery, emergency care units	IT, BME and manufacturers/ sup pliers

Table 4: MIDS in electromedicine

MIDS-products in telemedicine and home healthcare

In telemedicine there are a number of systems that permit the transfer of information between different areas of activity/locations, see the examples below:

MIDS system	Affected users	Affected suppliers
Advice in home healthcare (e.g., dialysis in home)	Patient, relatives, treatment clinic, specialist unit, healthcare centre, domestic help service	IT, BME and manufacturers/ sup pliers
Transfer of parameters from the home till to the care unit (e.g., ECG, SAO^2)	Patient, relatives, treatment clinic, specialist unit, healthcare centre, domestic help service	IT, BME and manufacturers/ sup pliers
ECG-monitoring ambulance-hospital	Emergency care, clinical physiol ogy depts., treatment clinic, spe cialist unit	IT, BME and manufacturers/ sup pliers
Image-transfer of X-ray images to staff on call	X-ray depts. and all involved in present X-ray images	IT, BME and manufacturers/ sup pliers
Image-transfer of X-ray images to other caregivers	Clinics responsible for treatment, X-ray clinicians	IT, BME and manufacturers/ sup pliers

Table 5: MIDS in telemedicine and home healthcare.

Telemedicine can be a solution to the shortage of specialists in healthcare. Caregivers can supply a diagnosis to one another irrespective of location.

Rules & regulations/requirements

Medical devices

What constitutes a medical device becomes evident from the definition in the Swedish law on medical devices (SFS 1993:584). Here the fundamental requirements are found: “A medical device must be suitable for its intended use. The product is suitable if it, in normal use for its intended purpose, achieves the performance that the manufacturer has intended and fulfills high demands on safety for life, personal security and health in patients, users and others.”

Medical devices must fulfill the essential requirements according to the Swedish Medical Products Agency (MPA) regulations LV 2003:11.The first requirement is that: “Products must be designed and manufactured in such a way that they do not endanger the patient’s clinical condition or safety, nor the users’, nor where appropriate other individuals’, health and safety, when used under the intended conditions and for its intended purpose. The risks in using the products must be acceptable regarding the benefits to the patient and in accordance with a high health and safety level”.

The responsibility for the use and in-house production of medical devices is clearly stated in the Swedish National Board of Health and Welfare’s regulations SOSFS 2005:12.

In-house production and system integration

The concept “in-house production”, which previously mainly applied to a few devices, nowadays has come to refer to systems of devices. Virus management and security updates, “patching”, of operating systems can lead to a larger MIDS system having to be treated as in-house produced.

The consequences of this are not always easy to grasp. The risk analysis needed can e.g., be difficult to perform if essential parameters are only known to the manufacturers of those components included in the system.

In this situation a sound application of system integration according to SS-EN60601-1 can give guidance toward what is needed to be able to finalise in-house production. The actual production procedure should thereby be possible to regard as the legal finalisation, with the approval of whoever is responsible for the system in clinical use.

Software is included in the MDD directive

The revision of the medical devices directive MDD (Medical Devices Directive, revision 5 April 2005) makes clear that software can be regarded as a medical device in its own right. This clarification aims at providing more secure computer-based products in healthcare.

Demands on competence

In the Swedish National Board of Health and Welfare’s regulations for management systems for quality and patient safety in health and hospital care, SOSFS 2005:12, it is made apparent that there must be a management system which guarantees that there are routines in place which ensure that personnel have the required competence to perform their work tasks and that

there are plans for competence development, based on the needs of the actual area of activity.

Demands from areas within healthcare

Activities in healthcare make demands on increasingly integrated solutions with medical devices that interact with network-connected computers where all applications can be accommodated.

Increased demands for more secure computer networks

Complex MIDS systems make increased demands on more secure computer networks in healthcare as well as more secure integration of medical devices and IT products.

Information security

Stored information must not be corrupted and must only be accessible to those authorized. The demands on information security within healthcare also are important to patient safety (SOSFS 2005:12).

Special demands on management

The management of MIDS products that are connected to communication networks makes special demands on:

- domain management (AD, groups, policies)
- antivirus software with updates
- security updates (patching) of the systems
- software including OTS (off-the-shelf software) from suppliers

The suppliers/manufacturers are responsible for the functionality, validation, updating of MIDS products/systems that are connected to a network, including OTS software. The suppliers/manufacturers are however not responsible for the caregiver's communication network (WAN, LAN, VLAN, WLAN, PAN, BAN etc.).

Here co-operation and collaboration between suppliers and caregivers is a necessity.

Irrespective of its configuration the system must fulfil the security requirements for medical devices and be safe for its intended use.

This can involve:

- Application software and operating system must not be patched/upgraded without the validation and approval of the supplier/manufacturer (of the medical device/s).
- Antivirus software must not be freely installed
- Equipment/modality must not be able to re-start automatically
- The supplier of equipment/modality often supplies all the software included
- Other software and hardware may not be added

- The end user preferably has local administrator's rights for all included client devices
- The equipment/modality is approved and CE marked according to MDD (Medical Devices Directive).

Networks

The requirements in MDD mean that the network must not affect patient safety either in treatment or diagnostics.

This demands that:

- Manufacturers can demand segmented physical networks for certain products
- Stops in network traffic must not affect medical safety
- Firewall functions may be necessary

For especially demanding clients/applications the possibility of creating virtual networks exists. Demands are made that:

- Only clients that fulfil running requirements may be connected to the network
- Network equipment in use must all comply with the same level of standards
- Communication networks must be secure with extremely high accessibility and redundancy

Server/database

The server/database function in an MIDS product is often distinguished by not following the absolute latest developments in server operations and storage.

The supplier can, as a result of the requirements from MDD, demand that:

- The database must reside on a local, dedicated server
- Only verified and validated antivirus software may be used
- Only verified and validated patches may be used
- The manufacturer's specific database format must be used
- A specific operating system must be used
- Complete CE-marked storage solutions as well as separate hardware is used

The county council's IT structure can make other and partly conflicting demands. It is usual that:

- The number of permitted operating systems is limited to a few
- The number of database motors is limited
- Virtualization of databases is used to keep costs down

- Storage takes place in a so-called SAN (Storage Area Network)
- Patching occurs synchronized and automatically for all software in order to maintain a high level of information security.

Competence and education in MIDS

Competence requirements and need for education according to questionnaire

In order to clarify competence and the need for educational input, a questionnaire was sent to personnel in the affected areas at all county councils. A number of interviews have also been carried out.

The answers to the questionnaire show that there is a tendency that BME personnel supplement their knowledge with IT competence and that IT personnel compliment existing IT competence with different courses in medical engineering.

The affected categories express different degrees of needs to supplement their education. BME personnel are more positive to supplementing their knowledge than IT personnel are.

As regards IT personnel this can partly be due to the fact that responsibility is experienced as being outside their own area of activity and partly that there are gaps in their knowledge of what competence is actually needed.

The answers to the questionnaire also show a general need for hospitals to map out competencies in order to subsequently invest in further education.

Formal competence requirements exist for clinically active personnel but the equivalent requirements are missing for BME and IT personnel. A voluntary opportunity does however exist for medical engineers and other engineers organized to obtain certification through MTF. Most of the answers to the questionnaire have identified MIDS products/systems in their activities but only half of the personnel active in healthcare state they have sufficient knowledge to use these products/systems.

This diverges from the legal demands that clearly state that:
“Personnel in healthcare must have sufficient knowledge of equipment, medical conditions and how equipment influences the course of the illness”.

The questionnaire clearly shows that all those who contributed have gaps in their knowledge concerning the MIDS field.

Quality assurance of activities

In interviews with those affected it has emerged that BME, IT and healthcare activities must have quality assurance for each area of activity in order to achieve a minimum level of patient safety when using MIDS. A conceivable first step is to introduce joint risk management for MIDS products/systems with the focus on patient safety and on freeing time for a joint educational study day for healthcare personnel.

What problems are associated with MIDS?

Indistinct division of responsibility

One common problem in national healthcare in Sweden today, according to the surveys conducted by the Swedish National Board of Health and Welfare and the Swedish Work Environment Authority, is that flaws exist in complying with the rules and regulations for medical devices. In particular this applies to issues of responsibility concerning delegation routines for all affected personnel categories in healthcare as well as documentation and established routines for the use and management of MIDS according to SOSFS 2001.12.

This can be due to difficulties in interpreting the regulations, in particular when complex systems have been created.

Legislation on IT in healthcare and welfare

The legislation on IT in healthcare and welfare is to be reviewed according to the "National Strategy for e-Health" where efforts in 1 Area will be aimed at harmonizing laws and regulations due to the increasing use of IT.

Flaws in specification requirements upon procurement

MIDS products/systems are sometimes procured with flaws in the specification requirements on the part of the caregiver. In turn the suppliers sometimes have limited knowledge of the regulations in place concerning the use of the MIDS products/systems they sell.

Examples of problems when purchasing MIDS

An MIDS product/system is purchased to be connected to medical devices as well as to health record systems. As only one supplier is available on the Swedish market, and can show a "Declaration of Conformity" for the product, a contract is drawn up. When the delivery takes place it is revealed that the product is not fully developed. The product can not, for instance, be connected to the current health record system nor keep separate information concerning different patients.

In-house production

With the motivation that the manufacturer's intended use is deviated from, the supplier often disclaims responsibility for the MIDS product that has been purchased by the caregiver. This causes huge problem for healthcare representatives who must then regard the equipment as being in-house produced.

Examples where in-house production can be needed

A supplier of MIDS does not accept the antivirus system standardised by the buyer for use in the buyer's healthcare organisation. The supplier then points to in-house production as a solution where the customer takes over complete responsibility for the product. This can also be resolved with documented maintenance routines for the supplier's divergent antivirus system.

Flaws in risk analysis and documentation

Risk analysis and documentation of MIDS products/systems is often lacking. Those caregivers that have longest experience have documented guidelines for a common method of working where the identification and categorizing of products form the foundation for continuing work.

It is important to identify different parts of BME and IT products in different groupings in order to be able to clarify the BME and IT departments' areas of responsibility as well as to carry out the correct steps for the respective grouping.

Indistinctness in definitions

The scientific field of medical engineering comprises medical informatics as a sub-field, according to the definition of the Swedish Research Society. With this definition as starting point the healthcare sector must get a joint grip on the area. Examples of definitions are to be found in the Appendix.

Recommendations

Measures for the use and management of MIDS

The following measures for the use and management of MIDS are proposed:

- The introduction of common national definitions, policies & nomenclature and guidelines for the use and management of MIDS products/ systems is recommended for.
- Harmonisation with the National Strategy for e-Health must take place.
- Considering the rapid technological developments the division of responsibility between healthcare and suppliers/manufacturers must be clarified by a revision of rules and regulations. This also applies to interpretation of the rules and regulations on in-house production.
- Efforts to increase knowledge of, the use and management of, education about and responsibility for MIDS products in healthcare must be initiated by all those affected.
- Optimal collaboration and co-operation between BME, IT and end users should be aimed at. This can occur e.g., through working out joint process descriptions with structured divisions of responsibility.
- The rules and regulations for IT and MIDS products as well as their practical application need to be harmonised.
- Established methods for risk management should be used by all those involved. The standard ISO 14971:2007 as well as common methods and applications can provide a framework.
- The function of “System Integrator” according to SS-EN 606601-1, edition 3, should be incorporated into the system.
- A classification of computer equipment and the division of responsibility between IT and BME is needed.

Collaboration and co-operation

The establishing and division of areas of responsibility between medical technicians and IT technicians as well as the compiling of common processes and tools is recommended.

Collaboration and co-operation between medical technicians and IT technicians, irrespective of their chosen forms of organisation, is essential for success. An adaptation based on local preconditions and critical mass in the form of personnel is also an important factor.

To organisationally separate BME and IT has taken place for historical reasons while today collaboration is a necessity. The fields of BME and IT merge into one another that should be reflected in joint processes.

The rapid developments in ICT, medical engineering, medical informatics and information technology as well as the political decisions that regulate healthcare will, in the future, demand new, even further developed, interdisciplinary organisations and forms of collaboration in IT and BME.

Quality assurance and certification of IT and BME

Is it plausible from the perspective of medical patient safety to be permitted to have different local medical engineering departments and IT departments in regionally divided healthcare? Is belonging to the same organisational unit a guarantee that collaboration and co-operation works?

One sure thing however is that common and collaborative processes, routines and tools between BME and IT are a decided ingredient for success, irrespective of organisational form. This is achieved appropriately by the activities being quality assured.

Quality assurance and certification of BME and IT organisations is recommended in order to heighten patient safety and information security in management and use of MIDS systems. This can be implemented by means of ISO 9001, ISO 13485, ISO 17025 and ISO 20000 (ITIL), or by a combination of several standards.

Organisations should be quality assured at least to the level of being certifiable.

Administration of MIDS products/systems

To establish product and system administration for the management of different MIDS systems is recommended for BME and IT. In this way the routines, processes, collaboration and areas of responsibility are regulated in a self-evident manner. There are also good preconditions in place to improve patient safety and information security through documented routines and good order.

System Integrator

“System integrator” is a new function that, according to the standard SS-EN 60601-1, edition 3, concerns responsibility for an integrated system. This means that the manufacturer/supplier and those responsible for BME/IT systems establish this new function in order to be able to secure the acquisition and management of MIDS products/systems.

The position of “System integrator” can hardly be upheld by one individual but must be a joint interdisciplinary function.

Local ”areas of use/usability” groups

Local “areas of use/usability” groups should be established for MIDS products/systems. IT units and suppliers must turn to them before upgrades and changes to the IT infrastructure concerned.

These **“**areas of use/usability” groups’ task would be to guarantee that the new function is equal to the local users’ demands and requirements.

The advantage of having local “areas of use/usability” groups is that these are familiar with the needs of the activities concerned and consist of interdisciplinary competencies (finance, technology, medicine).

Procurement of MIDS products and systems

Specification of requirements

Standardised national/regional technical functional requirements/document templates for BME and IT should be prepared. These will be used in the technical specification of requirements which together with the activities' functional requirements documentation is sent to the supplier upon the purchase of MIDS products/systems. In this way it becomes easier for the supplier to comply with the valid rules and regulations.

Information about and guidelines for virus protection, upgrades, changes in versions, patches, concerning MIDS products as well as connection to the caregivers' communication network must be drawn up. The suppliers'/manufacturers' responsibility must also be clearly stated in these document templates.

Competence and education

There is cause to reflect over the costs for education in questions concerning BME and IT. The consequences of wrongful management due to a lack of competence must be contemplated by the different areas of activity.

The requirements of the Swedish National Board of Health and Welfare (SOSFS 2005:12) are valid for all personnel who are active in healthcare. In order to comply with these demands it is necessary that those who work with or around MIDS equipment are responsible for showing great humility when presented with the different areas of competence and the problems we have ahead of us.

Complementary education for involved personnel

Medical engineers with a background from university or a corresponding institution need to complement their knowledge by education in IT standards, network technology, risk analysis, IT security and quality systems for IT.

Information technicians with a background from university or a corresponding institution need to complement their knowledge in medical engineering safety, risk analysis with the focus on patient safety as well as the rules and regulations for medical devices.

System administrators today are most often university-educated healthcare personnel with specialist knowledge of system applications. They need to complement their knowledge in IT security, network technology, risk analysis, IT-standards, medical engineering safety, as well as the regulations in place for medical devices.

Academic studies

Presumptive university-educated engineers with a medical engineering orientation are recommended to, apart from network technology, receive education on the standards and quality systems for IT as well as supplementing their education with those questions arising around MIDS.

MTF courses and certification of competence

The project group recommends that MTF works towards providing education in the MIDS field (e.g., risk management and system integration).

Furthermore it is recommended that MTF's certification committee investigates if a new category of "MIDS-engineers" need to be certified.

Proposals for a classification model

A type-classification of computer/PC, thin client, PDA, work station, server:

TYPE

W IT computer (standard configuration)

WM IT computer with medical device application(s)

M Medical device computer for instruments/systems (configured according to current regulations, MDD)

Classification with regard to the computer's location

In the table below the equipment is classed in relation to the patient environment. Group 0 has the lowest level of demands and group 2 the highest level of demands.

	Group 0 Outside patient environment	Group 1 In patient environment with demands acc. to SS-EN 60601-1	Group 2 In patient environment with demands acc. to SS-EN 60601-1 and EN 60529
TYP W IT computer (standard configuration)	**W0**	**W1**	**W2**
TYP WM IT computer with medical device application(s)	**WM0**	**WM1**	**WM2**
TYP M Medical device computer for instruments/systems (configured according to current regulations, MDD)	**M0**	**M1**	**M2**

Table 6: Classification of computers in relation to their location in the patient environment. Group 2 also fulfils the demands for cleansing routines and protection against the intrusion of liquids according to standard SS-EN 60529 Encapsulating classes for electrical materiel (IP-suite). Equipment types where BME and IT interact are marked in grey.

The division of responsibility

In class W, IT is responsible for group 0 and collaborates with BME in groups 1 & 2. In class WM, IT and BME collaborate in group 0 after which the responsibility is transferred to BME in classes 1 & 2. Class M is in BME's area of responsibility in all groups, 0, 1 & 2.

Grey zones and hard to define "hybrids" are defined in ordinary collaboratory meetings between IT and BME.

Marking computers/equipment/signal paths

A national system for marking all IT computers/equipment/signal paths and MIDS products/computers/equipment/signal paths should be introduced. This would mean being able to more easily identify MIDS products/systems.

For example, “green” for MIDS products and their signal paths/networks and “white” for IT systems. This marking is coupled to the above described classification of computers for BME and IT.

Reflections

The project has highlighted problems that can occur in the management of medical devices interacting with IT systems. The focus has been on establishing collaboration between BME and IT in order to increase understanding of MIDS and the importance for patient safety.

The project group is of the opinion that even other professional categories should be involved, e.g., end-users in the areas affected.

In connection with the charting of this project the definition of MIDS has been changed, as the field has proven to be considerably more extensive than the project found initially.

The ongoing work should even be directed towards further efforts to encourage a deepening collaboration between the parties concerned. The incorporation of the proposed classification and marking can facilitate this.

Competence in ordering and purchasing are areas that can be developed in collaboration with suppliers. Better acquisition can be achieved through using common templates for purchasing.

University colleges, universities and other course providers, as well as affected professional organisations/societies, should draw up plans for adaptable educational training in the MIDS field e.g., purchasing, risk analysis and product security.

A description of functions for system integrators should be drawn up and adapted to the dimensions of the activities.

Appendix

Definitions

Medical engineering

According to the Swedish Research Council, medical engineering consists of the following sub-areas:

Image-generating technology, bio-material and artificial organs, biosensor technology, bio-optics, biomedical mechanics, physiological measurement techniques and modelling, medical image and signal treatment, medical informatics, medical radiology physics, elocution and audiologist techniques, therapeutic techniques, aids for the disabled and ultrasound technology.

Internationally Biomedical Engineering (BME) is divided into sub-groups Clinical Engineering (CE), Medical Informatics (MI), Medical Imaging etc. Clinical Engineering is the group that is usually associated with medical engineering departments in hospitals (Bronzino,1995, p.viii).

BME integrates physics, mathematics and bioscience with engineering skills with the aim of partly studying biology, medicine, healthcare and welfare systems and partly to improve our health and quality of life. Medical engineering provides knowledge at all levels from molecular to organ system level. It develops materials, products, aids, systems, informatics, technology administration methods, strategies for the assessment and evaluation of technology, methods for the prevention, diagnosis and treatment of illnesses as well as procedures for the instrumentation of healthcare, patient care and rehabilitation (Lindahl et al., 2007).

Medical Informatics

Medical Informatics comprises the development and application of IT-based methods for the collection, representation, processing, presentation, communication and all kinds of data management, information and knowledge in health and hospital care (Koch, 2005).

Medical informatics has been defined according to certain well-established sources, on the one hand as general informatics which refers to information-science and technology used within healthcare systems but is not specifically intended for the healthcare sector e.g., salary systems for healthcare personnel. On the other hand, there does exist information-science and technology that is used in healthcare systems and which is specifically intended for this field. Information-science and technology specifically intended for healthcare systems and their direct activities can thereby be defined as medical informatics (de Dobal, 1996, p.4-5).

Health Informatics

The expression health informatics (Healthcare Informatics) is used when there is a need to express a more general, strategic term which embraces every possible aspect of information-science and technology used within the healthcare systems (de Dobal, 1996, p. 4).

Informatics

Informatics is a social science that studies the use and development of information technology in areas of activity.

Information technology

Information technology is the technology used to support the collection, processing, distribution and use of information. Modern information technology consists of hardware, software, data and communication technology. (Beynon-Davies, 2002).

Information and communication technologies

Information and communication technologies (ICT) is an area within information technology focused upon communication between users in society in order to more efficiently make the most of and exploit information. Today it is more common to speak of IT (information technology) instead of the previously used ADB.

Medical devices

In the law (SFS 1993:584) a medical device is a product which, according to the manufacturer's information, is to be used separately or in combination with others, in order to only in humans or mainly:

- Indicate, prevent, monitor, treat or alleviate an illness
- Indicate, monitor, treat, alleviate or compensate an injury or a disability
- Examine, change or replace anatomical or a physiological process, or Control fertilisation

If a device achieves its primarily intended effect with the help of pharmaceuticals, immunological or metabolic methods, then it is not a medical device according to the above law.

In-house production of medical devices

By in-house produced medical devices is meant only those devices that are designed and manufactured by a caregiver and which exclusively will be used in own activities (SOSFS 2001:12). The caregiver is regarded as the manufacturer and defines the equipment's intended use.

A CE-marked product, according to the Medical Devices Directive MDD, is regarded as in-house produced if it is used outside of the product manufacturer's intended use. Even systems assembled of CE-marked products are regarded as in-house produced if the products' original manufacturer has not intended them to be active together in systems of this kind. Systems that contain non-CE-marked, or for the purpose not approved products, are regarded as in-house produced. An in-house produced system must be just as patient safe as the equivalent CE-marked system. The caregiver has the overall responsibility for patient safety in this case.

Proposals for technical solutions concerning MIDS clients, server management and databases

The project group has discussed different proposals for technological solutions when connecting MIDS products/systems to networks and databases.

Common domain

MIDS clients and servers are managed in the existing common domain, for example MS Windows Active Directory domain (AD domain).

In the common domain MIDS products/systems can be distinguished by placing them in a “MIDS OU” (Organisational Unit in an AD environment), alternatively by using attributes that distinguish them from other products/systems.

The IT functionary administrates, by order of the caregiver, the overall IT environment for MIDS products/systems.

Medical engineering makes demands on, as well as supervising, the scope of policies and group affiliation.

MIDS domain

MIDS clients and servers can be managed in a separate MIDS domain.

IT administrates the overall hospital IT infrastructure with the existing domain.

IT co-operates with Biomedical Engineering that makes demands on, as well as supervising, the extent of policies and group affiliations within MIDS domains.

Segmented and separate networks

In order to improve patient safety and information security, network traffic can be identified and regulated by using firewalls and segmented networks to protect MIDS products/systems and other systems.

Antivirus software and network- connected MIDS

Antivirus software with updates must be used for network-connected MIDS and the function verified/validated in consultation with the end user and supplier/manufacturer. It is recommended that a form of comprehensive antivirus administration is used with participants from IT and BME where requirements for MIDS, according to the valid rules and regulations, are incorporated and applied.

Conditions and consequences for different classes of equipment (examples)

Classification	W/WP	WM	M/MP	M/MP
Name given	W	W	M	M
Separate Organisational unit (OU) in AD		BME/WM	BME/M	N/A
Error reporting to	IT	IT	BME	BME
Support label for error reporting	-	White label	Green label	Green label
Connected to county councils network	Yes	Yes	Yes	No
Registered in AD	Yes	Yes	Yes, if equipment connected to domain BME	No
Scripting of changes & operative system	Yes	Yes	No	No
Local administrator´s rights for BME	No	Yes	Yes	Yes
Start package on installation	IT	IT	M	OS only
Security patches of OS	Yes	Yes	See policy, IT supervises BME responsible	No
Virus protection	Yes	Yes	IT supervises BME responsible	No
Remote control of computer by BME	No	Yes	Yes	-
Personnel other than IT/BME can be local admin.	No	No	Normally no – conditional	Normally no – conditional
Remote control	Yes	Yes	Conditional	No
Policies in AD	Yes	Yes	Separate M-policy, normally blocked	No
”IT-software”	Yes	Yes	According to list	No
”BME-software”	Free clients only, normally only for reference	Yes, according to list	Yes	Yes
Forms a BME-product	No	Yes	Yes	Yes
Documentation according to list	No	Yes for actions involving BME software No for packaged re-installation	Yes	Yes
Medical diagnosis with aid of system	No	Yes	Yes	Yes

Abbreviations

ICT
Information and Communication Technology

PDMS
Patient Data Management System

WAN
Wide Area Network

LAN
Local Area Network

VLAN
Virtual Local Area Network

WLAN
Wireless Local Area Network

PAN
Patient Area Network

BAN
Body Area Network

FDA
Food and Drug Administration

RIS
Radiology Information System

PACS
Picture Archive Communication System

Annex 1

Project Description ”Guidelines for MIDS”

Background

The development of medical devices and IT makes possible new technological solutions within telemedicine, image diagnostics and medical information systems connected to medical devices. In the past few years medical devices have become increasingly integrated with IT. In turn, they are often components in networks of varying sizes and breadth.

The combination of products and applications from different technological fields makes increasing demands on the right competence and forms of collaboration between Biomedical Engineering (BME) and IT-departments.

Today, management, development and responsibility in these areas demands an increase in the exchange of experiences, collaboration and development of competence between engineers and technicians from BME and IT, in order to secure patient safety and comply with rules and regulations.

The Medical Information Data System **MIDS** concerns medical devices/systems in collaboration with IT products/systems, where the intended use (according to the medical devices directive, MDD) is diagnosis, monitoring and/or treatment of individuals for medical purposes. Communication takes place there via networks between server systems, databases and/or other methods of storage.

These products/systems, together with their software, intended for medical engineering applications, are embraced by the Swedish Medical Products Agency’s (MPA) regulation LVFS 2003:11 on medical devices, as well as the Swedish National Board of Health and Welfare’s regulations SOSFS 2005:12 on the use and in-house production of medical devices in health and hospital care and SOSFS 2005:12 concerned with management systems for quality and patient safety in health and hospital care.

Aim

The aim is to improve patient safety by clarifying the areas of responsibility for BME and IT activities regarding medical devices/systems and IT products/systems.

Goal

To create proposals for national requirements on competence and guidelines for collaboration between BME and IT, in order to comply with the regulations and rules for medical devices/systems and IT products/systems.

Intermediate goals

- To create a MDS forum for the exchange of experiences at a national level between representatives of BME and IT.
- To chart the use and management of “MIDS products”.
- To chart demands on competence and the need for education.

- To chart the rules and regulations concerning MIDS.
- To plan/arrange/execute seminars.
- To participate in different conferences/debates.
- To establish proposals for guidelines for the use and management of MIDS.

Impacting goals

That healthcare shall receive improved and more efficient use and management of MIDS products.

- Improved patient safety
- Clarification of professional roles and responsibility
- Guidance in order to comply with current laws and regulations.

Delimitations

The products/systems that are embraced by MIDS in accordance with the above definition are included in the assignment.

Project organisation

Assigner:	MTF, Swedish Society for Medical Engineering and Medical Physics
Steering group:	MTF board
Project leader:	Salvatore Capizzello MT Norrbotten County Council, Luleå
Project members:	Per Ackeberg MTF
	Mats Almgren MTA Stockholm South General Hospital, Stockholm
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	Nils-Erik Pettersson LfMT, Örebro
	Helene Richardsson SKL, Stockholm
	Heikki Teriö MTA Karolinska University Hospital, Stockholm

Time plan

The project starts 01-12-2005 and is planned to end on 30-11-2006 and be handed over to the MTF board for further administration. Information will be submitted recurrently at the MTF board meetings.

Resources

Costs incurred within the project will be financed partly by MTF according to the society's economical policy and partly via own activities.

Methods and ways of working

The work involved in producing the "Guidelines for MIDS" has been carried out in the form of a project.

The project group has written a final report drawn partly from the intermediate reports that have been written by smaller working groups and partly by means of joint discussions between the project group and the reference group.

Facts have been drawn from the experience of the project members, interviews with those affected, a questionnaire, reading the literature, surveillance of the outside world and discussions within the working groups.

The project group has also acquired information via discussions with participants during seminars as well as via viewpoints received from different interested parties within the sphere of activities concerned.

A special portal "MIDS portal" via MTF's home page was set up in order to spread information from the project (www.mtf.nu).

The reference group has contributed recurrently with points of view during the project work.

Annex 2

Charting the use and management of MIDS products/systems

Annex 3

Charting the rules and regulations for MIDS

Annex 4

Charting the demands on competence and need for education

Annexes 2-3-4 are to be found on MTF's home page www.mtf.nu - MIDS portal