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# Tailoring Software Process Capability/Maturity Models for Telemedicine Systems

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## ABSTRACT

Developing high-quality asynchronous store-and-forward telemedicine systems (ASFTSs) remains a challenge. However, there is no accepted understanding as to what are the important quality characteristics for this type of software system and/or what defines a mature software process for producing high-quality ASFTSs. Through adopting a multi-step research methodology, we define a quality model for ASFTSs indicating relevant quality characteristics and their priority for this specific type of software system based upon ISO/IEC 25010. We, then, propose an extended software process capability/maturity model based on ISO/IEC 15504 and ISO/IEC 12207 to meet these particular quality requirements. The resulting model can be used to both guide the development and the evaluation of such systems. We expect that the availability of such a customized model will facilitate the development of high-quality ASFTSs, reducing related risks and improving the quality of telemedicine services.

## Keywords

Software Process Capability/Maturity Models, Asynchronous Store-and-Forward Telemedicine Systems, ISO/IEC 15504, Software Quality, CMMI.

## INTRODUCTION

Telemedicine systems and services cover a broad spectrum of capabilities including acquisition, storage, presentation, and management of patient information (represented in different digital media such as video, audio, or data), and communication of this information between care facilities with the use of communications links (ISO, 2004). Although, telemedicine has the potential to solve diverse problems in modern health care (Bashshur, 1997) (U.S. Congress, 1995), their quality remains a challenge considering their potential impact on human health (LeRouge, 2004), highlighting concern over the safety, reliability, privacy, security, efficiency and effectiveness of telemedicine technology. For instance, does a radiologist at a central medical center, receive images with the proper resolution to effectively provide a correct examination result? Are the patient's data and information protected against access of non-authorized persons? Will there be no erroneous mix ups of examination results to patients?

Given these concerns, there exists a legitimate interest in protecting the public from unsafe and untested telemedicine technologies. However, so far, there is no official telemedicine standard (ISO, 2004). So, commonly the telemedicine industry uses high-level health care guidelines and technical standards developed for various technology sectors including

multimedia conferencing, information technology, data communications, and security. In this context, basically, three types of guidelines can be identified: clinical, operational and technical (Loane and Wootton, 2002). Clinical guidelines address specific medical specialties, e.g., teleradiology or tele dermatology. Operational guidelines focus on providing guidance on email communication, Internet access and videoconferencing, whereas technical guidelines cover specific aspects, such as interoperability, security, privacy, etc. Well-known examples, include DICOM (Digital Imaging and Communications in Medicine), a standard for the transfer of radiologic images and other medical information and HL7, a standard for the electronic interchange of clinical, financial and administrative information among independent health care oriented computer systems. All these initiatives demonstrate the need for tailoring quality guidelines to the specific characteristics and needs in the telemedicine context. However, the existing guidelines and standards are still not comprehensive for the development of routine telemedicine products or services (Loane and Wootton, 2002). Especially software process capability/maturity models, which guide the assessment and improvement of a maturing software process for the development and maintenance of telemedicine systems and services are, basically, non-existent. And, although, there are various well-accepted generic Software Process Capability/Maturity Models (SPCMMs), including the CMMI framework (CMMI Product Team, 2010), ISO/IEC 12207 (ISO/IEC, 2008), ISO/IEC 15504 (ISO/IEC, 2003), or ITIL (ITIL, 2011), their application in practice often requires a customization to the specific context to be effective (Beecham, Hall and Rainer, 2005). Therefore, a current trend is the customization of those generic process models for specific domains, including e.g., adaptations for space software SPICE4SPACE (Cass et al. 2004) or the automobile sector (Spice User Group, 2012). Yet, model customizations for the health care sector are basically non-existent (Wangenheim, Hauck, Salviano, Wangenheim, 2010), with the exception of the Medi SPICE initiative (McCaffery and Dorling, 2010), which is working on a customization of ISO/IEC 15504 for the development of medical devices (McCaffery and Richardson, 2007). Two main challenges that face the medical device software industry are 1) how can companies find a complete repository detailing all the processes and practices that would be required to develop safe medical device software, and 2) how can medical device manufacturers and regulatory authorities select competent software suppliers that will not put the medical device manufacturer at risk as they (as the owner of the complete system i.e. manufactured device including software) will retain overall responsibility for the safety of the device. Medi SPICE is currently being developed to satisfy both these challenges and likewise there is a need to create such a customized model for the telemedicine domain.

In this context, the research objective of this work is to develop a customized SPCMM for the development and maintenance of telemedicine software systems based on existing standards, such as, ISO/IEC 12207 and ISO/IEC 15504. We further focus our research in this broad field of telemedicine applications on asynchronous store-and-forward telemedicine systems for diagnostic purposes, which are implemented as web-based systems. Such systems enable the consultation of one (or more) distant health care professional(s) by a locally present health care professional concerning a patient's diagnosis and treatment, through using a web-based telemedicine system to bridge the spatial distance between the two (or more) participants. A tailored SPCMM for this specific context is expected to facilitate software process assessment & improvement in this specific domain as well as to contribute positively to the quality of the systems and services being developed.

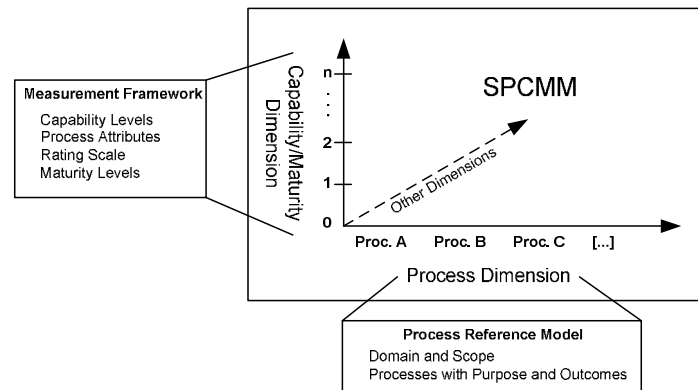
## **SOFTWARE PROCESS CAPABILITY/MATURITY MODELS**

Based on the basic premise that the quality of a software product and project performance is largely determined by the quality of the software process used to build it (Paulk, 2009), organizations implement software process improvement initiatives assuming that a higher process capability will result in better project performance and product quality (Jung and Goldenson, 2009; Fuggetta, 2000).

Software process improvement and assessment guided by a maturity level or a process capability profile based on a capability/maturity model is now well established in practice as a successful means for improving the software process. In this context, software process capability/maturity models (SPCMMs) are defined as models describing best practices for software life cycle processes, based on good engineering and process management principles, and a set of process attributes comprising capability/maturity aspects, suitable for the purpose of assessing and/or improving processes (Salviano and Figueiredo, 2008). A SPCMM consists of a sequence of capability/maturity levels for a class of objects. It represents a targeted evolution path of these objects in the form of discrete phases (or stages). Typically, these objects are organizations, processes or people. The lowest phase represents an initial state characterizing an organization having little capabilities in the domain under consideration. In contrast, the highest phase represents a conception of total capability/maturity. Advancing on the evolution path between the two extremes involves a continuous progression regarding the object's capabilities or maturity (Becker, Knackstedt and Pöppelbuß, 2009).

These models are used as an evaluative and comparative basis for process improvement and/or assessment implicitly assuming that higher process capability or organizational maturity is associated with a process or organization that is in a stronger position to achieve its objectives. SPCMMs are the basis for the definition of measures used to collect evidences in

order to evaluate if a certain object reaches a specific capability/maturity level. Based on such a determination, then, improvement paths are recommended based on the successive, discrete levels of capability and/or maturity of the SPCMM. Typically, SPCMMs are represented by a two-dimensional structure: a process dimension describing “what is done” and a capability/maturity dimension, indicating “how well a process is done” (Figure 1).



**Figure 1. Dimensions of SPCMMs** Error! Reference source not found.(adapted from (ISO/IEC, 2003))

The capability/maturity dimension sets the criteria that (based on an assessment framework) indicate the ability that a process or an organization has to achieve its business objectives, in relation to the service to process attributes associated with processes of each maturity level (ISO/IEC, 2003). While capability refers to the specific characteristics of individual processes, maturity establishes levels of organizational evolution, characterizing stages of improvement of process implementation in the organization (CMMI Product Team, 2010).

The process dimension defines a set of processes that an organization may perform to acquire, supply, develop, operate, evolve and support software, grouped into categories of related activities. The process dimension may be provided as in ISO/IEC 15504 by an external Process Reference Model (PRM), comprising definitions of processes in a life cycle described in terms of process purpose and outcomes, together with an architecture describing the relationships between the processes for a specific domain, e.g., through ISO/IEC 12207 for the software life cycle. To represent a set of best practices in the given software domain, SPCMMs are tailored to include relevant processes and practices that contribute to meeting the relevant requirements of quality and performance in the specific domain.

## QUALITY CHARACTERISTICS FOR ASYNCHRONOUS STORE-AND-FORWARD TELEMEDICINE SYSTEMS

Aiming at the improvement of the quality of ASFTSs, a first step is to clearly define relevant quality characteristics for this kind of system. In order to systematically elicit these characteristics, we adopted a multi-step research methodology based on the DUMOD process (Villalba, Fernandez-Sanz, Martinez, 2010), including the following steps:

- Context analysis of ASFTSs in terms of the service workflow, stakeholders and their conceptual representation. The analysis is based on literature and our experiences in developing and running a large-scale ASFTS - the Santa Catarina State Integrated Telemedicine and Telehealth System (STT/SC) (<http://telessaude.sc.gov.br>), a public telemedicine and telehealth infrastructure that is a joint initiative of the Telemedicine Laboratory of the Federal University of Santa Catarina – UFSC and the Santa Catarina State Government Health Office (Wallauer et al., 2008) ( von Wangenheim et al., 2009).
- Analysis of the state of the art regarding software quality models for ASFTSs through a systematic literature review searching for peer-reviewed articles in English published between 1990-2011 on software quality models for ASFTSs. The systematic search is complemented by ad-hoc searches amplifying the scope to quality models related to any kind of telemedicine system.
- Identification of relevant quality characteristics (preliminary model). Based on the previous steps, principally on the definition as given by ISO/IEC 25000, we decompose the abstract quality concept of ASFTSs into characteristics and sub-characteristics. This is done based on our experiences in defining quality models as well as on the development and running an ASFTS. In addition, we realized unstructured interviews with representative of diverse stakeholder classes in order to elicit their quality needs and expectations. In this step, the elicitation is limited to stakeholders involved in the Santa Catarina Telemedicine Project due to practical reasons.
- Prioritization and validation of the quality model. The identified quality requirements are validated and prioritized by their importance through an expert panel. The expert panel has been conducted online using a questionnaire with questions to identify the importance of each of the quality (sub-)characteristics on a 4-point ordinal scale (essential,

important, desirable, not relevant) with an additional option (don't know). We invited about 400 persons world-wide involved in telemedicine, identifying them by tracking publications and/or participation in conferences, working groups, networks and suggestions of contacted experts. The survey has been run in October/November 2011 with a response rate of about 10%.

The resulting software quality model focusing on quality in use and system quality indicates relevant quality characteristics for ASFTSs and their priority as presented in Table 1 (Wangenheim and Wangenheim, 2011).

| Perspective                                | Characteristic  | Sub-characteristic(s)             |
|--|---|-----------------------------------|
| <b>Essential characteristics</b>           |   |                                   |
| Quality in Use                             | <b>Freedom from risk:</b> degree to which a product or system mitigates the potential risk to economic status, human life, health, or the environment   | Health and safety risk mitigation |
| System Quality                             | <b>Reliability:</b> degree to which a system, product or component performs specified functions under specified conditions for a specified period of time.  | Maturity                          |
|  |   | Availability                      |
|  |   | Fault tolerance                   |
|  |   | Recoverability                    |
| System Quality                             | <b>Security:</b> degree to which a product or system protects information and data so that persons or other products or systems have the degree of data access appropriate to their types and levels of authorization.                      | Confidentiality                   |
|  |   | Integrity                         |
|  |   | Non-repudiation                   |
|  |   | Accountability                    |
|  |   | Authenticity                      |
| <b>Essential-Important characteristics</b> |   |                                   |
| System Quality                             | <b>Functional suitability:</b> degree to which a product or system provides functions that meet stated and implied needs when used under specified conditions.  | Functional completeness           |
|  |   | Functional correctness            |
|  |   | Functional appropriateness        |
| Quality in Use                             | <b>Satisfaction:</b> degree to which user needs are satisfied when a product or system is used in a specified context of use.   | Usefulness                        |
|  |   | Trust                             |
|  |   | Pleasure                          |
|  |   | Comfort                           |
| System Quality                             | <b>Usability:</b> degree to which a product or system can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.  | Appropriateness recognizability   |
|  |   | Learnability                      |
|  |   | Operability                       |
|  |   | User error protection             |
|  |   | User interface aesthetics         |
| <b>Important characteristics</b>           |   |                                   |
| Quality in Use                             | <b>Context coverage:</b> degree to which a product or system can be used with effectiveness, efficiency, freedom from risk and satisfaction in both specified contexts of use and in contexts beyond those initially explicitly identified. | Context completeness              |
|  |   | Flexibility                       |
| System Quality                             | <b>Performance efficiency:</b> performance relative to the amount of resources used under stated conditions.  | Time behavior                     |
|  |   | Resource utilization              |
|  |   | Capacity                          |
| System Quality                             | <b>Compatibility:</b> degree to which a product, system or component can exchange information with other products, systems or components, and/or perform its required functions, while sharing the same hardware or software environment.   | Co-existence                      |
|  |   | Interoperability                  |
| <b>Important-Desirable characteristics</b> |   |                                   |
| System Quality                             | <b>Maintainability:</b> degree of effectiveness and efficiency with which a product or system can be modified by the intended Maintainers.  | Modularity                        |
|  |   | Reusability                       |
|  |   | Analysability                     |
|  |   | Modifiability                     |
|  |   | Testability                       |
| System Quality                             | <b>Portability:</b> degree of effectiveness and efficiency with which a system, product or component can be transferred from one hardware, software or other operational or usage environment to another.                                   | Adaptability                      |
|  |   | Installability                    |
|  |   | Replaceability                    |

**Table 1. Relevant quality characteristics ranked by importance**

The created quality model confirms that high quality requirements are required in ASFTSs by requiring all quality aspects as proposed by ISO/IEC 25010, with most considered either essential or important. Especially the characteristics relating to safety (freedom from risk), reliability, security and functional suitability are considered essential. This indicates the importance of assuring these qualities in the development of high-quality ASFTSs to reduce related risks and contribute positively to the quality of telemedicine services. The principal contribution of the created quality model is the prioritization of quality characteristics by their importance within the specific context of ASFTSs, as within the generic standard ISO/IEC 25010 all characteristics are considered equally important.

**PROPOSING A TAILORED SOFTWARE PROCESS CAPABILITY/MATURITY MODEL**

Considering that the quality of a software system is largely determined by the quality of the software process used to build it, we propose a tailored SPCMM for the assessment and improvement of the software development and maintenance of ASFTSs (SPCMM-ASFTS) by customizing a generic SPCMM focusing on the achievement of qualities as defined by the specific quality model presented in the previous section.

The model is systematically tailored through following the TRIM method (Hauck et al., 2011) and the LEGO Maturity & Capability Model Approach (Buglione et al., 2011), including the following steps:

- Step 1 - Knowledge Identification: During this step, we characterized the specific context of ASFTSs and identified relevant product qualities (as presented in the previous section); and
- Step 2 - Knowledge Specification: During this central step, we propose an initial version of the customized model based on appropriate source model(s), including structure and content specification of the model.

The basis for the SPCMM-ASFTS is given by ISO/IEC 15504 (ISO/IEC, 2003), which provides a commonly accepted generic framework for the assessment of processes. The International Standard ISO/IEC 15504 also defines capability/maturity levels and specifies minimal requirements for appropriate process reference models. Accordingly, we adopt the two-dimensional structure of the ISO/IEC 15504, including the capability/maturity and the process dimension.

**Capability/Maturity Dimension**

The measurement framework of SPCMM-ASFTSs is based on a continuous representation following ISO/IEC 15504-2, therefore defining capability levels and in the case of a staged representation based on ISO/IEC 15504-7 defining maturity levels.

*Capability Levels*

Based on ISO/IEC 15504-2, process capability is defined on a six point ordinal scale that enables capability to be assessed from the bottom of the scale “Incomplete” through to the top end of the scale “Optimizing”. The scale represents increasing capability of the implemented process, from not achieving the process purpose through to meeting current and projected business goals.

Within this measurement framework, the measure of capability is based upon a set of Process Attributes (PA). Each attribute defines a particular aspect of process capability. The extent of process attribute achievement is characterized on a defined rating scale. The combination of process attribute achievement and a defined grouping of process attributes together determine the process capability level (Table 2).

| Capability Level              | Definition  | Process Attribute(s)  |
|-------------------------------|---|---|
| <b>0. Incomplete process</b>  | The process is not implemented, or fails to achieve its process purpose.  | --  |
| <b>1. Performed process</b>   | The implemented process achieves its process purpose.   | PA 1.1 Process performance attribute  |
| <b>2. Managed process</b>     | The Performed process is now implemented in a managed fashion (planned, monitored and adjusted) and its work products are appropriately established, controlled and maintained. | PA 2.1 Performance management attribute<br>PA 2.2 Work product management attribute |
| <b>3. Established process</b> | The Managed process is now implemented using a defined process is capable of achieving its process outcomes   | PA 3.1 Process definition attribute<br>PA 3.2 Process deployment attribute          |
| <b>4. Predictable process</b> | The Established process now operates within defined limits to achieve its process outcomes.   | PA 4.1 Process measurement attribute<br>PA 4.2 Process control attribute            |
| <b>5. Optimizing process</b>  | The Predictable process is continuously improved to meet relevant current and projected business goals.   | PA 5.1 Process innovation attribute<br>PA 5.2 Process optimization attribute        |

**Table 2. Definition of capability levels (ISO/IEC, 2003)**

Here, we adopt the definition of capability levels from ISO/IEC 15504-2 “as is”, as the process capability is not expected to change in the context of ASFTSs.

### Organizational Maturity Levels

As defined ISO/IEC 15504-7, Organizational Maturity is an expression of the extent to which an organization consistently implements processes within a defined scope that contributes to the achievement of its business goals (current or projected).

Organizational maturity is defined on a six point ordinal scale that enables maturity to be assessed from the bottom of the scale “Level 0 Organization - the Immature Organization”, through to the top end of the scale “Level 5 Organization - the Innovating Organization”. The scale represents the extent to which the organization has explicitly and consistently performed, managed and established its processes with predictable performance and demonstrated the ability to change and adapt the performance of the processes fundamental to achieving the organization’s business goals.

| Organization Maturity Level | Definition   |
|-----------------------------|--|
| <b>0. Immature</b>          | The organization does not demonstrate effective implementation of its processes that are fundamental to support the organization’s business.   |
| <b>1. Basic</b>             | The organization demonstrates achievement of the purpose of the processes that are fundamental to support the organization’s business.   |
| <b>2. Managed</b>           | The organization demonstrates management of the processes that are fundamental to support the organization’s business.   |
| <b>3. Established</b>       | The organization demonstrates effective definition and deployment of the processes that are fundamental to support the organization’s business.  |
| <b>4. Predictable</b>       | The organization demonstrates a quantitative understanding of relevant processes that are fundamental to support the organization’s business goals, in order to establish consistent and predictable performance.    |
| <b>5. Innovating</b>        | The organization demonstrates the ability to change and adapt the performance of the processes that are fundamental to support the organization’s business goals in a systematically planned and predictable manner. |

**Table 3. Definition of organization maturity levels (ISO/IEC, 2003)**

Following ISO/IEC 15504-7, processes can be categorized into 5 sets based on their contributions to the business goals of the organization. The set of fundamental processes that support the business is called the basic process set. Each organizational maturity level beyond level 1 maturity is characterized by the implementation, at an appropriate level of process capability, through a further set of processes that drive the achievement of the capabilities relevant to each maturity level. These are called extended process sets. As a starting point, we draw the definition of the basic and extended process sets from Appendix A of ISO/IEC 15504-7, which defines an exemplar organizational maturity model designed for organizations in the software industry. Based on the identified quality model (as presented in the previous section), further processes (not covered by the organizational maturity model as defined in 15504-7) are added to the sets in relation to their identified priority:

- Safety and security related processes are added to the basic process set;
- Usability related processes are added to the extended process set related to Maturity Level 1; and
- Portability related processes are added to the extended process set related to Maturity Level 3.

### Process Dimension

Defining a process dimension for the SPCMM-ASFTS implies identifying relevant processes that contain best practices for the development and maintenance of ASFTSs with the required quality characteristics as defined in the previous section. Yet, as ISO/IEC 15504 only defines requirements for a process reference model, a concrete PRM is external to 15504. We, therefore, base the process dimension on the software process as defined by ISO/IEC 12207:2008 as a starting point. Considering the context of this work, the international standard ISO/IEC 12207 provides an adequate base for defining a process reference model as ISO/IEC 12207:2008 Systems and software engineering -- Software life cycle processes is an international standard that provides a generic comprehensive set of life cycle processes, activities and tasks for software that are part of a larger system, and for stand-alone software products and services (Figure 2). The set of life cycle processes that is defined through ISO/IEC 12207 is directed to the development and maintenance of software systems meeting several of the quality characteristics considered relevant in the context of ASFTSs, such as, reliability, functional suitability, performance efficiency, etc. All processes as defined by ISO/IEC 12207 are selected as relevant for the SPCMM-ASFTS satisfying relevant quality characteristics.

However, some of the quality characteristics identified as essential or important (security, safety, usability and portability) are not completely covered by ISO/IEC 12207. Therefore, we need to tailor the International Standard to comprehensively satisfy the specific quality requirements for ASFTSs (similar to what has occurred in Medi SPICE, Automotive SPICE and SPICE4SPACE). Tailoring typically involves the selection of relevant processes and/or the addition of relevant processes not covered by the baseline, in this case ISO/IEC 12207. In order to attend specific quality needs of ASFTSs, we have extended the process reference model given through ISO/IEC 12207 through several additional processes from other sources (Figure 2).

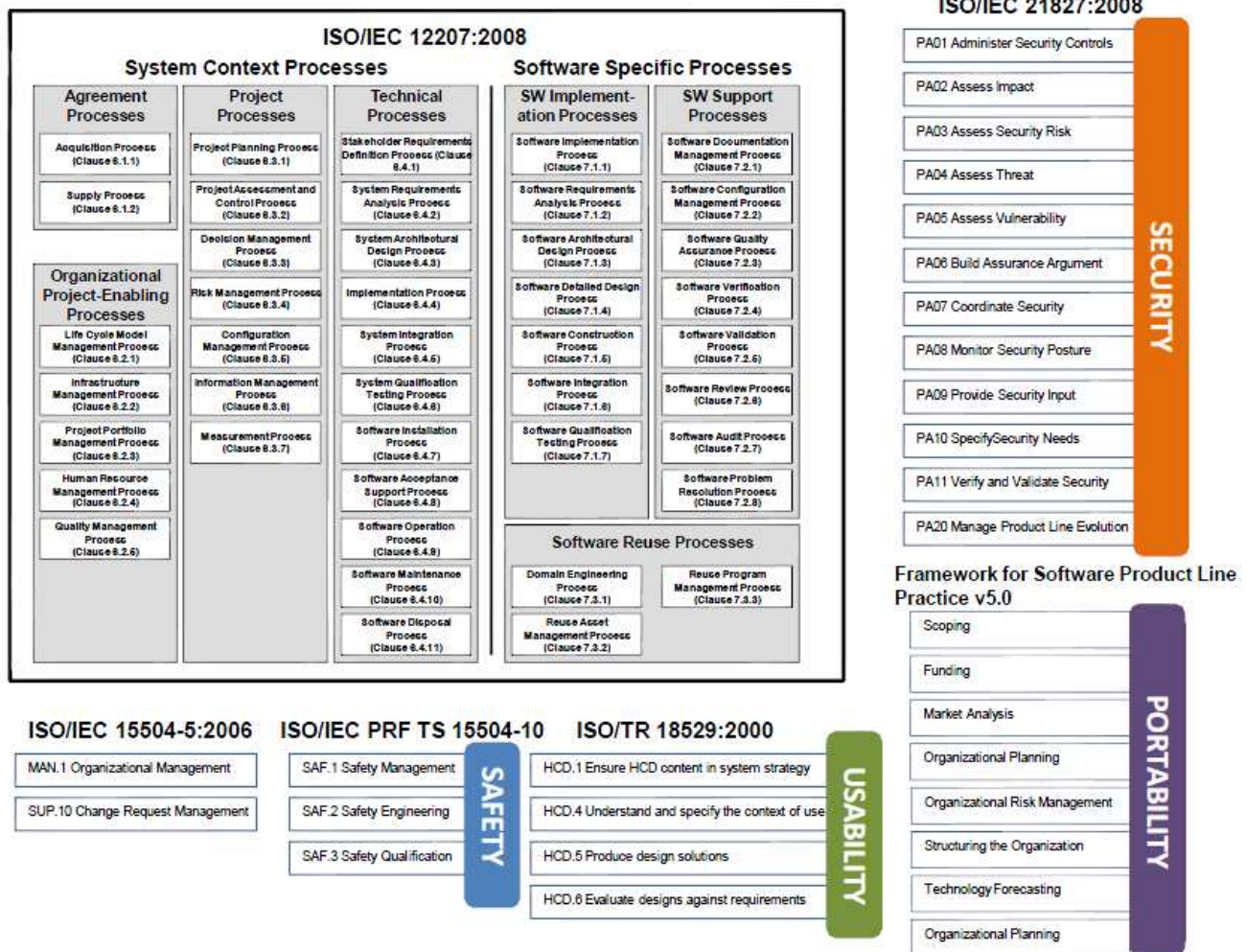


Figure 2. Tailored process dimension

Meeting the specific safety requirements related to the freedom of risk of ASFTSs, the process reference model is extended by processes defined by ISO/IEC PRF TS 15504-10 Information technology -- Process assessment -- Part 10: Safety extension. Security requirements are covered through an extension based on ISO/IEC 21827:2008 Systems Security Engineering Capability Maturity Model (SSE-CMM) (ISO/IEC, 2008). Furthermore, principally when considering the current trend of digital conversion also in the field of telemedicine porting applications to different kind of devices (such as cell phone, tablets etc.), we also added processes related to the Framework for Software Product Line Practice (v5.0) (Northrop and Clements, 2007). This addition emphasizes the need to organize the development of a set of different versions of such systems for different types of devices using product lines to enable effective and efficient management, in order to reduce cost by preventing rework. In this context, also the usability of such systems gains in importance and therefore, processes from ISO/TR 18529:2000 Ergonomics -- Ergonomics of human-system interaction (ISO, 2000) -- Human-centered lifecycle process descriptions have been added in order to satisfy this important quality characteristic. Completing system and software life cycle processes, two processes as defined by the exemplar process reference model in ISO/IEC15504-5:2006 are added, which are not covered directly by ISO/IEC 12207.

**CONCLUSIONS**

Based on identified quality characteristics and their degree of importance for ASFTS, we propose a software process capability/maturity model for the development and maintenance of ASFTSs. The SPCMM-ASFTS is based on ISO/IEC 15504 and its process dimension is developed by extending ISO/IEC 12207 through several processes related to quality characteristics considered essential and/or important in the context of ASFTSs. Our next steps are to validate the proposed SPCMM through an international expert panel and to accompany its application in practice. As such, this innovative SPCMM



for this kind of software system has the potential to guide the development and evaluation of high-quality ASFTSs by indicating and prioritizing relevant non-functional requirements as well as indicating processes relevant to mature the development of ASFTSs. This work is a step forward to provide a better understanding of the development of ASFTSs potentially contributing to the improvement of the quality of such systems as a basis for an improvement of telemedicine services.

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