White paper:

Implementation of ANSI/AAMI/IEC 62304 Medical Device Software Lifecycle Processes

This paper reviews the implementation of the ANSI/AAMI/IEC 62304 Medical Device Software - Software Life Cycle Processes standard. This paper aims to provide an overview of the dynamic utilization of ANSI/AAMI/IEC 62304 with regards to key concepts and activities.

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Prerequisites

The list below provides prerequisites for the users of the Technical Paper:

- Availability of ANSI/AAMI/IEC 62304

- Familiarity with ANSI/AAMI/IEC 62304

- General Knowledge of project management, systems development processes and system life cycle models.

Scope of the ANSI/AAMI/IEC 62304

ANSI/AAMI/IEC 62304 Standard applies to the development and maintenance of medical device software where the software itself is a medical device or when the software is an embedded or integral part of the final medical device.

The standard does not cover testing, validation and final release of the medical device, even when the device consists entirely of software.

This paper does not detail the maintenance activities of the medical devices because the activities and processes are similar to the software development concept.

Context of the ANSI/AAMI/IEC 62304

An organization needs to be able to conduct business and perform operations. Standards facilitate businesses by providing a common framework for establishing agreements between systems acquirers and suppliers with respect to developing, using and managing a system within the defined life cycle of that system.

The ANSI/AAMI/IEC 62304 standard is applicable to organizations, enterprises and projects whether they act as the acquirer or the supplier of a system.

The standard defines the life cycle requirements for medical device software. It defines conceptual structure spanning the life of the software from the definition of its requirements to manufacturing, which:

- Identifies the Processes, Activities and Tasks involved in development of a Software

- Describes the sequence of the dependency between activities and tasks, and

- Identifies the milestones at which the completeness of specified deliverables is verified.

The software development process is divided into a set of activities, with most activities further divided into a set of tasks. These activities are listed below:

- Software Development Planning

- Software Requirement Analysis

- Software Architectural Design

- Software Detailed Design

- Software Unit Implementation &Verification

- Software Integration and Integration testing

- Software System Testing

- Software Release.

The maintenance process activities are considered to be as important as the software development process activities. These activities include:

- Generate Software Maintenance Plan

- Problem and Modification Analysis

ANSI/AAMI/IEC 62304 refers to the risk management process described in International Standard ISO 14971 for identifying and managing risks during development and maintenance of the software.

It is imperative to note that ANSI/AAMI/IEC 62304 recognizes two additional processes considered essential for developing safe medical software. They are the software configuration management process and software problem resolution process.

Compliance with the standard is accomplished by implementing all of the processes, activities and tasks identified in the standard in accordance with the software safety class.

Software Safety Classification

ANSI/AAMI/IEC 62304 identifies three classes of medical device software in accordance with the possible effects on patient, operator, or any other people affected by software-related hazards.

The medical device software should be classified based on severity as follows:

- Class A: No injury or damage to health is possible

- Class B: Non-Serious injury is possible

- Class C: Death or Serious injury is possible.

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The figure below illustrates the activities associated with each of three different classes of the software.

Class A

Software Development Plan

Software Requirement Analysis

Software Unit Implementation and Verification

Class B

Software Development Plan

Software Requirement Analysis

Software Architectural Design

Software Detailed Design

Software Unit Implementation and Verification

Software Intergration and Intergration Testing

Software System Testing

Software Release

Class C

Software Development Plan

Software Requirement Analysis

Software Architectural Design

Software Detailed Design

Software Unit Implementation and Verification

Software Intergration and Intergration Testing
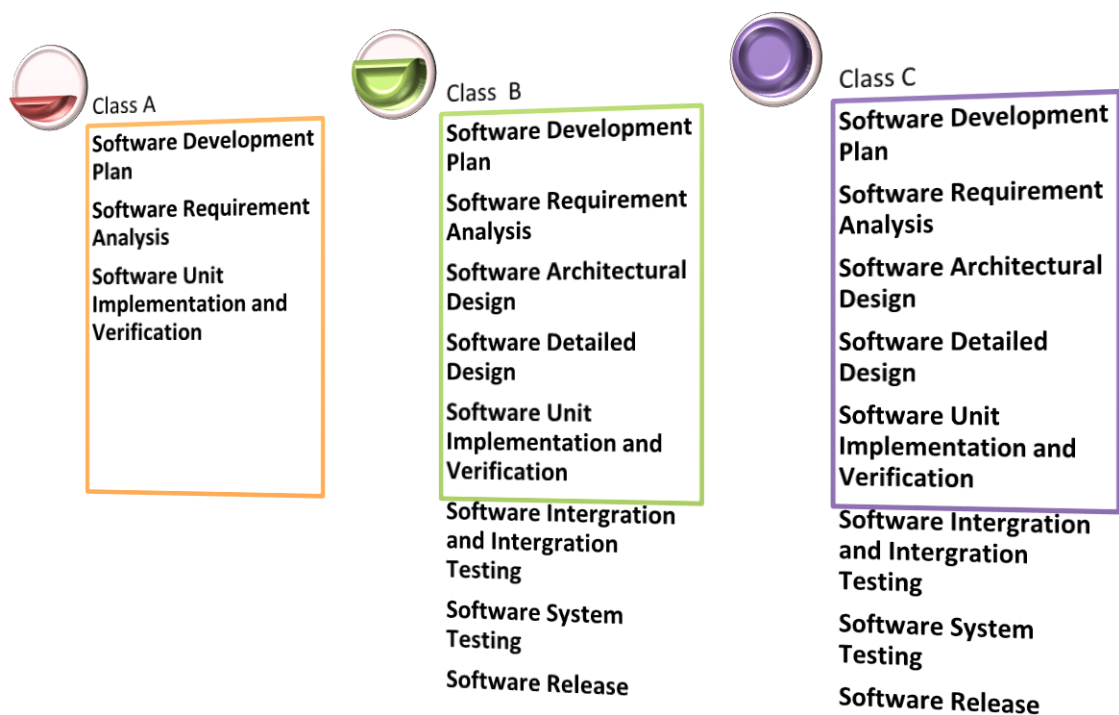
Software System Testing

Software Release

Figure 1 Classification of software and related activities

Use of the Standard

Overview

- A specific project can use the standard for developing and supporting a medical device software.

- An organization can use the standard for managing one or more of the medical device software's life cycle stages.

- An organization can use the standard for developing the Quality Management System.

Concept of use

An organization is driven by the nature of its business, corporate responsibilities and its business strategy.

To help achieve the overall business and quality goals and exploit opportunities, an organization should establish policies and procedures to guide control and monitor the performance of projects and function groups.

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To create these policies and procedures, and define the resources needed by the organization, the ANSI/AAMI/IEC 62304 standard can be utilized to provide specific standardized processes for use within one or more software development life cycles.
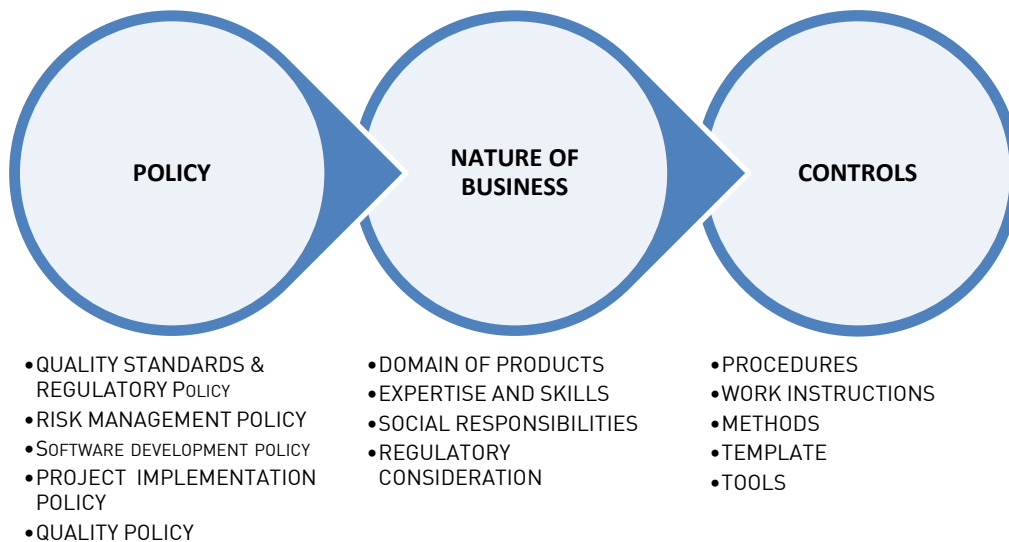

POLICY

- QUALITY STANDARDS & REGULATORY POLICY
- RISK MANAGEMENT POLICY
- SOFTWARE DEVELOPMENT POLICY
- PROJECT IMPLEMENTATION POLICY
- QUALITY POLICY

NATURE OF BUSINESS

- DOMAIN OF PRODUCTS
- EXPERTISE AND SKILLS
- SOCIAL RESPONSIBILITIES
- REGULATORY CONSIDERATION

CONTROLS

- PROCEDURES
- WORK INSTRUCTIONS
- METHODS
- TEMPLATE
- TOOLS

Figure 2 Overview of concept of use

The overall relationships between the various organizational activities are portrayed in Figure 2. The aim of the Quality Standard Policy is to define the standards and industry regulations that the organization adapts in order to achieve its organizational objectives which is reliant on the nature of business. The above figure also illustrates the factors that influence the nature of business.

Similarly, the Risk Management, Project Implementation and Quality policies are used to ensure that adequate assessment planning and control activities are utilized to create support and monitor projects.

At the initiation phases of the project to satisfy the stakeholder's requirements, assessment should be conducted to identify if the current policies and procedures are sufficient.

If the procedures and policies are not adequate, new ones are created or existing modified based on the current standard in accordance with the scope, size and funding of the work to be done.

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How Does Standard-Driven Development Work

- Management defines expectations for how software is written and tested.

- Developers are trained on how the expectations relate to the business objectives.

- An automation infrastructure sits in the background of the development environment to automatically monitor compliance according to defined expectations. For example, a policy may require all code to follow a designated set of secure development practices, undergo peer review, and be verified by test cases.

- When requirements are implemented, the automation infrastructure unobtrusively identifies policy violations.

- If policy violations are identified, the infrastructure alerts the responsible developer that policy violations need to be addressed immediately.

- The ability to passively and unobtrusively monitor developers' work is paramount to policy-driven development. If it is done properly, it will improve quality and increase productivity.

Consideration for Use

The ANSI/AAMI/IEC 62304 standard can be considered for a specific project with a set duration or for a continuous work effort conducted by an organization.

The following are examples of items to consider while planning use of the ANSI/AAMI/IEC 62304 standard.

The scope of the work effort, such as:

- A single project or multiple projects within the organization.

- Concentration on some key processes or a single process where there is expected to be some gain for the organization.

- Concentration on a single life cycle stage to carry out the operation of that stage.

Identification and listing of stakeholders, such as:

- Intended users or customers of the medical device software.

- Other interested parties who have an interest or stake in the products.

- Sources of requirements and constraints.

Desired outcomes, such as:

- Work products (software configuration item, or procedure document).

- Services or capabilities to be delivered or demonstrated at the end of the project and at specific milestones.

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Special considerations, such as:

- Medical Device Software technologies that focus on hardware or humans.

- Medical Device Software classification including single use, repeated use and continuous use.

- Medical Device Software builds such as one-of-a-kind, replicated or mass-produced.

Goals and objectives of the project, such as:

- Specific objectives identified by milestones.

- Long-term utilization goals related to the use of the medical device software.

- Project strategy, such as:

- How the project will be carried out, including any agreement considerations.

- How work packages will be planned, assessed and controlled.

- How work products will be planned, evaluated and controlled.

- How work and changes will be authorized.

- Major milestone decision or event points (e.g. management reviews, meetings, pilot tests, deployments and deliveries) with milestone entry or exit criteria.

Requirements and constraints, such as:

- Specific functional and performance requirements for, capabilities of or data from a Medical Device Software, including special quality attributes and usability expectations or safety concerns.

- Policies, priorities and constraints such as risks, personnel, facilities, sites and critical resources that will affect meeting the requirements and objectives of the project.

- Core organizational technologies that will affect medical device software requirements or other work product requirements and constraints; applicable organizational processes, standards and specifications (including source and availability); product implementation risks; and how information (including different product versions) will be captured, stored and controlled.

- Applicable medical device software life cycle stage activities (for example development, pilot testing, full production) and expected outputs (for example. deliverables, work products and management reviews).

- Relevant stage entry or exit criteria, including expected level of medical device software maturity, level of acceptable risks and management review concerns.

- Project start-up and end dates, including milestone dates associated with approval and progress reviews and pilot tests, as applicable.

- Management structure, including participants and their roles.

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- Exclusions of organizations or persons (if applicable), including when the exclusion is or is not valid.

- Level of security classification and other security considerations, if applicable.

- Expected deliverables at milestones, at end of project/work and during project/work performance.

- Environment, recycling and reuse issues.

Amending

When the ANSI/AAMI/IEC 62304 is used by an organization to form a set of policies and procedures governing project work, amending the existing Quality Management System may be done to appropriately reduce or extend the scope of the ANSI/AAMI/IEC 62304 standard implementation.

Thus, it is expected that the requirements of the ANSI/AAMI/IEC 62304 will be tailored to the characteristics of a particular project, life cycle stage, or agreement.

Revising should be given careful consideration so that critical factors of the ANSI/AAMI/IEC 62304 are not excluded, and that factors that do not add value to the process or Medical Device Software element are not added.

When adapting out factors from the ANSI/AAMI/IEC 62304, care should be taken that the appropriate balance between timely delivery, cost and satisfaction of requirements is achieved.

When amending is done, it may be important to ensure that applicable compliance requirements of ANSI/AAMI/IEC 62304 are met.

Amending considerations

The objectives and requirements of an agreement should define the context of application of the Standard.

To assist in defining the level of detail and effort required for execution of some processes, the following should be considered when implementing the standard.

- The life cycle stage and the applicable exit criteria.

- The mission profiles, operational scenarios and operational concepts for each major functional requirement of the Medical Device Software.

- The set of measures of effectiveness, with relative importance, by which the acquirer typically determines satisfaction of the requirements.

- Empirical data that describes the constraints and risks that could affect the project and organization, including budget, resources, competition and schedule.

- The technology base and any limitations on the use of technologies.

Amending guidance

Either the organizational unit responsible for forming policies and procedures, or the project team or individual assigned to plan the project can be responsible for completing appropriate modification.

To aid changing, the following factors affecting the project effort should be helpful:

- Project requirements such as the required work, schedule, funding and technical requirements based on the classification (for example functional requirements, performance requirements and interface requirements) can drive stage timing and the definition of the Medical Device Software under consideration.

- Applicable processes should be used, only the processes of the ANSI/AAMI/IEC 62304 Standard that apply to the domain, business of the organization and type of organization (for example supplier, user, acquirer, or other stakeholder) should be included in project plans. Other processes that are not in the ANSI/AAMI/IEC 62304 Standard can be required by an agreement, or they can be required by the nature of the project, the applicable Medical Device Software or the type of organization. These processes may be added, complete with their purpose, outcomes and activities.

- Activities for each applicable process and the expected outcomes of each activity should be selected.

- Software development models and tools required for activity completion should be determined. The applicable Software development models and tools are not mandated in the ANSI/IEC 62304 standard.

- Reporting and technical review requirements applicable to the life cycle stage or stipulated in the governing agreement or in organizational policies and procedures should be considered.

- Project measurement requirement provisions should be included for the collection and reporting of key measures by which project progress will be evaluated.

- Requirements related to activities and tasks involving specialty engineering and functional disciplines may be integrated in appropriate processes. These processes include requirements (special requirements or critical project and Medical Device Software requirements) and life cycle stage entry or exit criteria (for example safety, security, design, software development, production and test). Specialty and functional plans that are needed to ensure completion of project work may be included in work definition.

- Applicable standards, policies and procedures, regulations and laws can be the source of additional process and activity requirements to add to the work definition, even though not included in the ANSI/IEC 62304 Standard process requirements.

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Depending on the size and scope of the project, the type of organization and whether the Medical Device Software is the object of the project, one or more of the ANSI/IEC 62304 Standard activities for a process could possibly be applied to develop the quality management system.

Likewise, outcomes and activities may be added to a process when needed to meet agreement requirements or to meet unique requirements for a Medical Device Software.

Get Started with Standard-Driven Development

Policies must be formed around any aspect of the development process, but to be effective they must be definable, enforceable, measureable, and auditable.

There are various types of policies that align with different goals as shown in figure 2.

Process Policies drive overarching sets of tasks through to completion and usually establish quality gates associated with the completion of a release cycle.

Examples include policies that oversee:

- Compliance with industry standards & regulations or recommendations
- Software development models
- Software lifecycle processes
- Project Implementation
- Risk Management.

People (or human) policies can be designed based on role, responsibility, skill-level, etc. They oversee processes related to human interactions, for example:

- Task estimation
- Specification & documentation review
- Training

Quality policies promote business objectives that are defined as non-functional requirements.

They are measured by process monitors that deliver unprecedented visibility into the software.

Examples include policies that cover:

- Application development (monitored by static code analysis)
- Code reliability (monitored by coverage analysis)
- Change impact (monitored by regression testing).

Adopting a combination of these policy types leads to a number of benefits that fundamentally improve the development process.

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Summary

The most important factor controlling the ability to produce defect-free software is the inability to conceive policies and procedures to oversee its development.

At the same time, creating defect-free software requires discipline, which is burdensome and time-consuming.

Creating policies and procedures from standards and guidelines before the need arises does not come naturally, so the confrontation to policy-driven development is understandable. The confrontation though, is misguided by the prejudices engrained by traditional software development strategies.

This confrontation will fade as organizations begin to realize that elevating guidelines to definable, enforceable, measureable, and auditable policies will drastically improve how they develop software.

It not only helps organizations accurately measure application quality and development productivity, but also improve it by preventing errors and eliminating waste.

Adopting a policy-driven development process is key for achieving the following goals:

- Ensuring that developers do not make trade-offs that potentially compromise reliability, performance and safety.
- Preventing defects that could result in costly recalls, litigation, or a damaged market position.
- Accurately and consistently applying quality processes.
- Gaining the traceability and auditability required to ensure continued policy compliance.

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Terms	Definitions
Activity	A set of one or more interrelated or interacting tasks.
Anomaly	Any condition that deviates from the expected based on requirements specifications, design documents, standards, etc. or from someone's perceptions or experience.
Architecture	Organizational structure of a system or component.
Change request	A documented specification of a change to be made to a software product.
Configuration item	Entity that can be uniquely identified at a given reference point.
Deliverable	Required result or output (includes documentation) of an Activity or Task.
Evaluation	A Systematic determination of the extent to which an entity meets its specified criteria.
Harm	Physical injury, damage, or both to the health of people or damage to property of the environment.
Hazard	Potential source of harm.
Medical Device	Any instrument, apparatus, implements, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more specific purpose(S) of diagnosis, prevention, monitoring, treatment or alleviation of disease, compensation for an injury, investigation, replacement, modification, or support of the anatomy or of a physiological process.
Medical Device Software	Software system that has been developed for the purpose of being incorporated into the Medical Device being developed or that is intended for a use as a Medical Device in its own right.
Problem Report	A record of actual or potential behavior of a software product that a user or other interested person believes to be unsafe, inappropriate for the intended use or contrary to specification.
Process	A set of interrelated or interacting activities that transform inputs to outputs.
Regression Testing	The testing required to determine that a change to a system component has not adversely affected functionality, reliability or performance and has not introduced new defects.
Risk	Combination of the probability of occurrence of harm and severity of that harm.

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Risk Control	Process in which decisions are made and risks are reduced to, or maintained within, specified levels.
Risk Management	Systematic application of management policies, procedures, and practices to the tasks of analyzing evaluating, and controlling risk.
Risk Management File	Set of records and other documents, not necessary contiguous, that are produced by a risk management process.
Safety	Freedom from unacceptable risk.
Security	Protection of information and data so that unauthorized or systems cannot read or modify them and so that authorized persons or system are not denied access to them.
Serious Injury	Injury or illness that directly or indirectly: Is life threatening, Results in permanent impairment of a body function or permanent damage to a body structure, or Necessitates medical or surgical intervention to prevent permanent impairment of a body function or permanent damage to a body structure.
Software development life cycle model	Conceptual structure spanning the life of the software from definition of its requirements to its release for manufacturing, which; Identifies the PROCESS, ACTIVITIES and TASKS involved in development of a SOFTWARE product, Describes the sequence of and dependency between ACTIVITIES and TASKS, and Identifies the milestones at which the completeness of specified deliverables is verified.
Software Item	Any identifiable part of a computer program.
Software Product	Set of computer programs, procedures, and possibly associated documentation and data.
Software System	Integrated collection of Software items organized to accomplish a specific function or set of functions.
Software unit	Software unit that is not subdivided into other units.
SOUP	Software Of Unknown Provenance (acronym). Software item that is already developed and generally available and that has not been developed for the purpose of being incorporated into the medical device (also known as "off-the-shelf software") or software previously developed for which adequate records of the development Processes are not available.

System	Integrated composite consisting of one more of the processes, hardware, software, facilities, and people, that provides a capability to satisfy a stated need or objective.
Task	A single piece of work that needs to be done.
Traceability	Degree to which a relationship can be established between two or more products of the development process.
Verification	Confirmation through provision of objective evidence that specified requirements have been fulfilled.
Version	Identified instance of a configuration item.

Sources

Links used within this document are prone to change. Please refer to the appropriate source for the most recent information. We endeavour to keep an up-to-date record of information at www.pharmout.net

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