

# **Quality Management System**

## **Sisoft Healthcare Information System**

*This document describes the ISO/IEC 15504 processes used by Sisoft Health Information Systems during product development life cycle and mapping of these processes with ISO 9001: 2015 Quality management system.*

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Author :	Serkan SERT

## Index

<b>Introduction</b>	<b>4</b>
<b>1. ORGANIZATION</b>	<b>4</b>
1.1. Institutional Management Process	4
1.1.1 Definition Of Management Infrastructure	5
1.1.2 Provision of Management Infrastructure	5
1.1.3 Selection and Implementation Of Software Management Applications	5
1.1.4 Performing Selected Management Applications	5
1.2. Quality	5
1.2.1 Creation and Publication of Quality Policy	6
1.2.2 Creation of Quality Targets	6
1.2.3 Scope and Management of Project Quality Assurance Activities	6
1.2.4 Scope and Management of Operational Quality Assurance Activities	7
1.2.5 Internal Audit Process	7
1.2.6 Verification Process	7
1.2.7 Test Process	7
<b>2. DEVELOPMENT</b>	<b>8</b>
2.1 Requirements Management	8
2.1.1 Acquisition of Requirements	8
2.1.2 Entering Requirements Into the System	8
2.1.3 Monitoring Requirements	9
2.2 Design Process	9
2.2.1 Description of Software Architecture	9
2.2.2 Development Of Detailed Software Design	10
2.2.3 Software Design Analysis	10
2.2.4 Verification of Design	10
<b>3. TEST</b>	<b>11</b>
3.1 Planning Testing Procedures	11
3.2 Conduct of Test	12
3.3 Test Types	13
3.4 Test Plan Creation	13
3.5 Establishment Of Test Environment	14

3.6 Conduct Of Test and Reporting Of Test Results	14
3.7 Traceability	14
<b>4. IMPLEMENTATION</b>	<b>15</b>
4.1 Definition of the Released Products	15
4.2 Preparation of Product For Distribution	15
4.3 Product Version Classification and Numbering Plan Preparation	15
4.4 Production Activities and Work Environment	15
4.5 Manufacture Of Product From Designed Parts	16
4.6 Notification of Type, Level, and Duration of Product Support Before Last Version	16
4.7 Selection Of Distribution Environment Used in Version	16
4.8 Definition Of Packaging Structure Of Product Which To Be Released	16
4.10 Obtainment of Approval For Version Before Releasing Product In Market	17
4.11 Distribution Of Product To Relevant Customers	17
<b>5. MAINTENANCE</b>	<b>17</b>
5.1 Problem Solving Strategy	18
5.2 Recording Of Problem	18
5.3 Classification Of Problems	18
5.4 Investigation Of Problem's Source	19
5.5 Assessment of Impact of Problem	19
5.6 Solution Of Urgent Problems	19
5.7 Warning Mechanism	20
5.8 Problem Solution and Initiation Of Change Requests	20
5.9 Monitoring Problem Status	20
6.1 Measurement	20
6.1.1 Institutional Commitments Establishment for Measurement	21
6.1.2 Development of Measurement Strategy	21
6.1.3 Identification Of Measurement Information Needs	21
6.1.4 Collection and Storage of Measurement Data	22
6.1.5 Measurement Data Analysis	22
6.2 Process Assessment	22
<b>7. Mapping Table</b>	<b>24</b>

# Introduction

This document describes Sisoft Health Information Systems Product Development Life Cycle's ISO/IEC 15504 processes and maps these processes with ISO 9001: 2015 Quality management system.

## 1. ORGANIZATION

### 1.1. Institutional Management Process

The purpose of the institutional management process is to realize and establish the software management practices required to provide services and software products that are consistent with the organization's business objectives.

#### 1.1.1 Definition Of Management Infrastructure

The management infrastructure has been defined to implement software applications that are consistent with the organization's business objectives. Institutional roles and responsibilities are defined separately in the job description folder under the heading of integrated management system in the quality management system. Management hierarchy is detailed in organization chart. The distribution of the documents is made by creating a distribution list on the quality management system.

Processes established by the organization are recorded as process-based performance indicators. The desired measurement frequency is determined and the overall status is monitored from the process performance measurement dashboard screen.

The business objectives of the Agency are determined at the Annual Meetings of the Management Agenda (OGG) meetings and are recorded in the meeting minutes.

#### 1.1.2 Provision of Management Infrastructure

The defined management infrastructure is established throughout the organization. This stage is supported by the automation of Sisofis.

#### 1.1.3 Selection and Implementation Of Software Management Applications

The software management applications to be used within the organization are determined by the top management with the team leaders and software architects. The selected applications are put into practice with the approval of the top management. The decision-making stage takes place during meetings. These meetings are recorded on the meeting definition screen. Decisions taken are also recorded on this screen.

#### **1.1.4 Performing Selected Management Applications**

The management applications determined by the top management are carried out by the top management with the equipment established in accordance with the infrastructure process.

### **1.2. Quality**

A quality management system that ensures creation, control and improvement of processes, procedures and related documents is established.

#### **1.2.1 Creation and Publication of Quality Policy**

An appropriate and relevant quality policy has been established by SISOFT senior management. This policy is included both in Integrated Management System Handbook and Quality Guarantee Process. The Quality Policy was transmitted electronically to all employees and hung in a place that could be seen by all departments. The Quality Policy is reviewed at the management oversight meetings and revised when necessary.

#### **1.2.2 Creation of Quality Targets**

Quality objectives are determined annually in administrative supervision meetings attended by senior management. In the target plan, specific goals are included (PEK-04.PL-01). Quality objectives are defined in the created processes. In order to measure the performance of the operations, a follow-up plan was prepared. In addition, the method of monitoring fulfillment of goals is mentioned in processes.

In order to control operations; internal audit procedures, verification, joint compliance, testing and problem-solving processes were established. Process performances are viewed on performance indicator tab at standard process definition screen; performance indicators of project-based processes are viewed on processes tab located at performance indicator heading. Performance of processes is sent to senior management during management oversight meetings.

#### **1.2.3 Scope and Management of Project Quality Assurance Activities**

Project specific processes, which are defined on project management screen of Sisofis, are applied in projects. The scope and steps of application are explained in all processes.

If there is a customization specific to project for project operations, this information is stated

during the process under the heading of the adaptation manual. The project management plan is prepared by the project manager in the beginning of the project. All plans generated in the project must be consistent with the project management plan. The project manager describes business operations in the project plan.

Quality assurance and control activities such as internal audit, product validation, joint and administrative review, testing, problem solving, the collection and analysis of measurements are performed in project.

The life cycle processes applied in the projects are;

- Project Management Process
- Risk Management Process
- Configuration Management Process
- Problem Management Process
- Requirement Management Process
- Design Process
- Test Process
- Verification Process
- Process of Releasing Product To The Market

#### **1.2.4 Scope and Management of Operational Quality Assurance Activities**

In the software, processes are defined for operational activities that are outside of the software life cycle. The internal audit plan is prepared annually by the Quality System Personnel and the departments are audited according to the relevant processes.

#### **1.2.5 Internal Audit Process**

Internal audits are conducted in a planned manner to determine whether the SISOFT Quality Management System complies with TS-EN-ISO 9001 and ISO / IEC 15504 standards, internal quality management requirements and whether the system has been implemented. The internal audit plan is prepared annually by the Quality System Engineer. Plans are prepared by taking into consideration the situation of the departments to be audited and processes. Audit criteria, their implementation, records and reporting are described in the internal audit procedure. How the internal audit will be implemented is explained in detail in the audit process.

#### **1.2.6 Verification Process**

- The Management Representative and / or Quality System Engineer examine the documents if they are prepared in accordance with the procedure and endorses if it is so.
- Requirements, Design, Codes, User Guides, verification of tests are described in the verification process.

### **1.2.7 Test Process**

The steps and applications are described in the testing process.

## **2. DEVELOPMENT**

### **2.1 Requirements Management**

#### **2.1.1 Acquisition of Requirements**

If customer requirements are indicated alongside with the terms of reference; the terms of reference is examined for identification of requirements and expectations, then the requirements are carried out in a planned manner with the approval of the manager. Customer requirements can also be obtained through examination of the targeted operating environment and the hardware environment. In addition, if needed, customer requirements and their applicability are discussed with the customer. This stage is carried out by business analysts. When a consensus is reached, the minutes of the meeting will be prepared and ratified by attendants. If the terms of reference has not been prepared yet, subsequent to the meetings with customer, business analysts will understand the customer's requirements. Requirements are planned afterwards.

Needs that emerge in the company or requirements for a new project are determined after the research is done by the relevant person. Requirement manager should ensure that both requirements of the client and the supplier understand each requirement in the same way.

#### **2.1.2 Entering Requirements Into the System**

The requirements for a new project are recorded on the project management screen as an unscheduled requirement. These requirements are classified according to their status as new, delayed, invalid and valid. Creating an unscheduled requirement record is described in detail in the instructions for creating an unscheduled requirement. This stage is performed by business analysts. Validated requirements are planned and transferred to the list of planned requirements by the requirements manager. How the planned requirements are to be created is explained in the planned requirement creation instructions in detail. Intra-system discussions can be created to clarify requirements. Creation of the discussion is explained by the instructions for information sharing platform. A baseline is created by business analysts for those who have mutual agreement with the customer from the requirements on the list of planned requirements. The created baseline is printed out and signed by customer.

Requirements having a baseline can not be changed. If a change will be made, a new copy of the baseline is created and recorded. Creation of a baseline is explained step-by-step in the instructions for creating the baseline. Comparisons can be made for created baselines. As a result of the comparisons, difference between the baselines can be displayed. Comparison is performed by the comparison requirement manager or business analyst by selecting baseline comparison from the baseline tab on the project management screen. Comparison of baselines is described in the baseline creation instructions. When the status of the

requirement is changed as Approved on the project management screen, the checklist is opened. Unless all the questions on the checklist are answered as yes, it can't be proceeded to the next step.

All these stages can be performed by the requirements manager or business analyst. Approval of the requirements is made only by the requirement manager.

### **2.1.3 Monitoring Requirements**

In order to monitor the state of the requirements of each project, the client is authorized to follow from the project management screen in the system.

Traceability is provided through the company's internal Sisofis and IBM ClearQuest programs. At the end of the project, with the assistance of traceability, requirements manager checks if there is no remaining standard item. The tool that will be used for traceability and the related versioning system is described in the project documentation.

## **2.2 Design Process**

### **2.2.1 Description of Software Architecture**

The software architecture may vary depending on the work environment, security and performance of the product to be developed. Therefore, these details are taken into consideration when designing the architecture. Evaluation criteria are determined before system architectures are established. These criteria are usually specified by the design manager as:

- Performance
- Safety
- Ease of Maintenance
- Sustainability
- Expandability

System architectures are selected in the framework of these criteria. Along with alternative system architectures, the most suitable architect is chosen. Activity and Usecase diagrams are created by the designer as a result of analysis of error and change requests made by clients. Software Requirements (SR), which are identified by taking client requests into account, are also created as well. They are configured (by the designer) by relating them to the SR or request on the Sisofis project management screen. The way to perform this is illustrated in the Design Guide in detail with screenshots.

### **2.2.2 Development Of Detailed Software Design**

Designer explains the decisions made during the requirements analysis phase, which coincides with creation of software architecture design, in detail. The priority at this stage is to meet the requirements. Therefore, the requirements will be met by taking into account the below mentioned standards:

- Best performance
- User friendly



- Easy-to-understand user alerts (Alert messages)
- The criteria that can be improved

After these criteria are taken into consideration, the programming language will be selected. During the elaboration of relevant requirements, it is also benefited from the SRs.

### **2.2.3 Software Design Analysis**

The determined design must be very flexible due to the possibility that the requirements may change constantly or that new requirements may occur. The design manager reviews the risks that may be caused by feedback and new requirements, while compliance with system architecture is checked as well. If there is a change related to the requirement or to the SR, this change will be reflected on the attached architecture.

### **2.2.4 Verification of Design**

Selected system and software design are reviewed by design manager and designers. At this stage it is checked whether the requirements can be met or not. Following factors are also checked;

- User friendly
- Reliable
- Easy to maintain
- Best performance
- Free from security vulnerability

If the control leads to conclusion that there is a failure, it is reviewed again with joint review meetings that will be organized under the leadership of design manager. It is also controlled by Sisofis with a specific approval mechanism during the verification and supervision phase.

## **3. TEST**

The test is performed to ensure that the developed product meets the customer needs and to find errors. The test process is interwoven with the validation process.

As a result of this process,

- The product has been tested with regard to the requirements,
- It is ensured that the software works properly in a user-friendly environment to meet customer expectations, thus ensuring compatibility with software requirements,

- Test scenarios in which the Software Requirements (SR) have been established,
- It is verified that errors are corrected,
- Errors are recorded,
- The test of the the relevant changes is made according to the regression strategy of integrated software.

When the test process is successfully applied, number of errors identified during usage would be few, each test cases; each component of the application would have been tested, and it would be easy to identify test cases that are affected when there is change in product and that are required to be added.

### **3.1 Planning Testing Procedures**

Tasks to be performed during the testing phase, assignments, types of testing to be applied and the testing process are determined by project manager and related personnel during the project planning stage. This phase is carried out during the project planning stage before the preparation of the test plan.

### **3.2 Conduct of Test**

- After generation of the version, the new version is loaded to the server by the test manager.
- Server is accessed through the company's Web address.
- Each test manager has its own "User Code" and "Password" (given by the System Administrator).
- Besides the test manager, some training support personnel may perform the test after obtaining approval and authorization for the testing process and after analyzing the system requirements.
- Through Sisoft Office, web interface project management screen is opened. Build is selected, build management is selected via buildin.
- The version is selected. Edit tab is clicked. The status of the build to be tested is first changed as "being tested". The activities of the relevant slides are then assigned to the test experts by the test manager.
- During the assignment process, the test scenario of the activity is added. These scenarios are created by the test manager.
- Test scenarios, each of which consists of at least 10 steps (and more if required), are prepared for each test.
- Scenarios must be accurate, understandable and must reach to conclusion.
- There must be at least one verification scenario per test (the test scenarios must include validation and approval steps).
- Scenarios, as written, are tested with the closed box method (only the input and output values are known when testing the software. The algorithms are tested in the program, how it works, how to encrypt it, the design details and the icon remain unknown) step by step, and the final score is recorded as successful / unsuccessful on the Sisoft Office program.

- In Sisoft Office web interface, each test user has its own "User Code" and "Password" (these codes and passwords are assigned by the management).
- Sisoft Office is accessed only by particular security-related IP addresses for high security reasons. For this reason, when the environment is changed or when the user is not authorized, the administrator informs the system administrator about the external IP address of the user environment, verbally or in writing, and obtains the connection authority.
- The test users are obliged to report their IP changes within the working hours of that day in case of media changes and to obtain their authority.
- The connection to the Sisoft Office program is made through [www.sisoft.com/cozumhbys](http://www.sisoft.com/cozumhbys).
- During the test procedure, the test program is opened on one page and Sisoft Office program on another page. Test is performed on the former page and test scenario results are recorded on the latter.
- Test scenario is initiated at the moment when the task is given.
- The end of test scenario corresponds to the starting time of next business day.
- Regarding these test scenarios, which are performed on the web environment without space and time constraints, the user can initiate and complete the task at any time during the day.
- All requirements related to the software and all test scenarios related to these requirements are checked by the test manager.

### 3.3 Test Types

**Unit Test:** These are the tests written by the software developer for the smallest unit of the system. It is expected that by making certain entries in the system correct values would be produced. In this way, the code blocks are tested.

**Functional Test:** Performed according to the created test plan. A functional test is performed for each activity identified in the test plan according to the test scenario. Functional test is a test made on screens according to the activities in the build.

**Regression Test:** It's a repeated test. If one of the tests in one version is faulty, the same test is repeated in the other version.

**Load Test:** The system is tested to find out how it operates under intense transaction volume and large amounts of data entry. The system is put under extraordinary pressure to test whether it can operate with more users and higher amounts of data than expected.

**Acceptance Test:** The acceptance test is the test conducted by the client. It tests whether the end-user or client meets the client's expectations of the software product.

### 3.4 Test Plan Creation

At this stage, the test strategies to be followed in the project, the features to be tested and not to be tested, the criteria for success and failure, the types of test to be applied, roles and responsibilities, and the reporting and error reporting mechanisms are identified. Depending

on the life cycle of the program to be used, the test plan can be prepared once or repeatedly for each version.

Test cases are prepared by testers or developers by covering relevant requirements and scenarios. Inputs for test cases appear when the analysis model is created. Test cases can be created by updating them from the analysis phase to the end of the integration phase. According to the program life cycle used, the starting time of test cases are specified in the project management plan or test plan. The test cases prepared for the functional and the closed box tests are presented to the client after the requirements are met. Customer creates acceptance criteria by accepting test cases.

### **3.5 Establishment Of Test Environment**

The tools required for the conduct and management of the test in the project are set up before the tests begin.

### **3.6 Conduct Of Test and Reporting Of Test Results**

Both successful and unsuccessful test cases are logged when test cases are performed. Test results that feature errors are recorded. It is sent to the related programmer. The test is repeated until the error is corrected.

In Sisofis Automation, the test details can be displayed on the test scenarios section of Project Manager screen. Test results are also displayed on the Test Management screen of the Project Management module.

### **3.7 Traceability**

Traceability is provided by controlling and saving which requirements are tested, which activities are proved to be successful, which steps are followed. The project tracking mechanism is explained in the project's CMP and tracked by Sisofis. From the Project Management screen, details of all tests can be displayed on the "test run" tab.

## **4. IMPLEMENTATION**

The objective of this process is to ensure that the version is distributed without problems after approval by the Test Manager.

### **4.1 Definition of the Released Products**

Subjects such as software development environment, software development language, frequency of version release, etc. which will be used based on the platform of developed product and improvability status software are defined in the project management plan of the product.

## **4.2 Preparation of Product For Distribution**

The product is released at the intervals specified in the Update Plan section of the Product Project Management Plan Document. After the testing process is completed, the version is ready to use. The version that passed the testing stages successfully is activated by the Test Manager to create the release version. As a result, the version becomes ready for distribution.

## **4.3 Product Version Classification and Numbering Plan Preparation**

The product is released at the intervals specified in the Update Plan section of the Product Project Management Plan Document. If this interval is four times a month or more, a four-phase version number system (1.2.3.456) can be used.

If this interval is quarterly, a two-stage version number system (v.1.2) is used. In addition to this, the version system to be created for the product may include numeric string characters. The version system can start with "v". If the product is newly developed (the product that is not for sale yet and in R&D stage), the version names can be string expressions such as "alpha" or "beta". Versions with the same name for the same product are not allowed.

## **4.4 Production Activities and Work Environment**

Project-based planned version calendar is created. Customer requests, error records entered into the system and program changes are included in the version release plan. The changes to be made are assigned to the personnel in the Software Development Department. After the development is completed, the test is performed by the Test Unit. If the work is approved by the Test Manager, a downloadable version is produced. The release version is installed on Sisoft servers. The distribution may vary according to each project. However, in all projects, customer can update release version from the Web Version Management screen.

## **4.5 Manufacture Of Product From Designed Parts**

During the creation of the version, the modules designed on the current program are modified. Other parts won't be created again. Other classes remain the same while the class that will be modified is prepared. The version is created. The release version is installed on Sisoft servers. The web version is accessed from the Administration tab.

## **4.6 Notification of Type, Level, and Duration of Product Support Before Last Version**

The product support is identified in the project plan. The changes that will be performed on the project and version are identified. The person who will perform the development and time given for the development are determined. When the version is released on pre-determined dates, changes in the version are included in release notes.

## **4.7 Selection Of Distribution Environment Used in Version**

Up-to-date versions and template update files are accessed through Web Version Management screen. The update can vary across mobile applications. The version released for Android apps are uploaded on the Google Play store, and iOS are uploaded on the App Store. However, up-to-date versions of mobile projects can be accessed from the Web Version Management screen.

## **4.8 Definition Of Packaging Structure Of Product Which To Be Released**

Platform on which the product that will be developed, language and ide variables used in its coding may differ according to packaging type of project. Update file can be created in desired format (exe, zip, apk, ipk, etc.). Access to the screen where template file is displayed is not encrypted since the access is subject to authorization. Only authorized users can display it.

## **4.9 Definition And Preparation of Release Guide of Software Product**

Product update file is obtained from the system. The storage of the update files is described in the article of control and storage of records. The client logs into the webofis system by using username and password. The process is completed by client's downloading of files into his or her system. Client can also view logs of changes made in the version from the system.

## **4.10 Obtainment of Approval For Version Before Releasing Product In Market**

The build is created after arrangements are made on product. The created build is tested by the Test Department. After the testing process results in success, the Release version is created if the Test Manager approves the build. Only Release versions are launched to the market.

## **4.11 Distribution Of Product To Relevant Customers**

Customers can download the current version from the Web Version Management screen. Information of client's download of version is displayed in the 'Downloaded Institutions' field which is opened when this directory is followed: Project Management> Build> Build Management> Downloaded Organizations button. Performance of this process conducted through internal audits and operational outputs. Following cases indicate that process performance can be improved: system failure during update processes, long-lasting of errors related to update, low customer satisfaction, long problem cycle times, and inability to access to system performance reports.

## 5. MAINTENANCE

The aim of this process is to address problems occurred in products created or developed in the shortest time, to record and track these notifications. At the end of this process, problems are logged and tracked.

As a result of the successful implementation of the problem management process:

- A problem management strategy is developed,
- Problem is recorded, identified and classified,
- Problems are analyzed and evaluated to determine acceptable solutions,
- Problem solving implemented,
- Followed to address problems,
- Status of problem reports explained.

### 5.1 Problem Solving Strategy

In case of encounter with any problem during project development process, a problem solving strategy is determined by implementing steps mentioned in headings below.

### 5.2 Recording Of Problem

The notification of problem can be made by the client or during the project development stage. Firstly, login is made on Web Office. The Project Management screen is opened. From the New Orders tab, "new" button is clicked. "The Project Request Recording" screen is displayed. Problem notification is made by recording it in this screen.

When a problem is reported, this information is entered by the person or organization who make problem notification:

- The person or organization making the notification
- Related project
- Detailed problem description (the areas affected by the problem can be specified in this section)
- Notification type
- If any, image related to the error.

If problems are reported via telephone, e-mail or fax; registration of problems is made by the employees on Project Request Registration screen.

### 5.3 Classification Of Problems

Problems are classified according to their importance. After evaluating the reported problem, clients may be also consulted before classification of problems. The problems are classified

as Error Notification, New Request, Change.

The client, who makes the notification, clicks the Control Panel button.

The program request is made by clicking on the "request" button on the Program Requests screen and filling following fields on this screen: Notification Type, Section, Date, Version, E-mail, Fields.

If there is a screenshot of program request, "Add Picture" button is used to upload this image so that software developers can view this image.

The root cause of the error is designated as "Error in Code," "Design Error," "Property Error," "Connection Error," "Unknown" on the Project Request Registration screen. It is also possible to specify type of correction with the proposed correction field.

## **5.4 Investigation Of Problem's Source**

After the notification of the problem, a task is assigned to Test Expert or Test Manager for his or her examination of the problem. "Project Request Form" is used by Expert or Test Manager to understand the problem or to control code structure of the problem.

If changes will be made with regard to problem, the Information Sharing Platform is used to ask opinions of clients.

After identifying the cause of the problem, a task is assigned to a software developer who will make related changes and customizations. Software developer will address the problem by making necessary changes and customizations.

In case, problem's cause is not identified, Test Expert or Test Manager may contact the person or institution, who makes the notification of the problem, via e-mail or phone.

## **5.5 Assessment of Impact of Problem**

In order to measure the effect of the reported problem, the definition of the problem entered on Project Request Registration form is taken into account. The person or institution who makes the notification has to mention impact of the problem on them. These effects can be defined as the Architectural Effect, Impact of User Experience, Test Impact, Development Impact, and Technical Publication Impact. Project Manager makes assignments according to affected cases when he or she examines the problem. Tasks to be assigned are categorized as follows;

- Urgent
- Very Urgent
- Normal task



- Mission to be Completed Immediately

## **5.6 Solution Of Urgent Problems**

During notification of urgent programs, quick solution is found for cases which constitute problem for running of program or which contradicts legal regulations and in which penal measures are taken after time limit in contracts. The problem is resolved quickly. When the operation is urgent the test manager assigns the task to the related software developer. Urgent requests are categorized as "critical" in the system. By this way, software developer schedules his or her tasks according to the priority of requests. After software developer meets such urgent requests, the 'class' featuring changes of the developer will be sent to client without waiting for release of new version.

In mobile projects, the users who experienced problems are sent ".ipa" for iOS and ".apk" for Android. User sends these ".ipa" and ".apk" into their applications via computer.

## **5.7 Warning Mechanism**

The problem is assigned to employees through Web Office program used in the company. Personnel are notified with an e-mail one Web Office application and email is sent to the individual mail account. A text message may also be sent to mobile phone according to urgency.

## **5.8 Problem Solution and Initiation Of Change Requests**

After identifying the problem, solution method is determined by the project manager and the project team member assigned to the task. If a change is needed, the change request will be initiated with the problem registration number. The change request is initiated with the task assigned to the user. After the solution is developed, the relevant test team will test and approve the concerned activity. Unapproved cases are notified again with problem registration form to project responsible.

## **5.9 Monitoring Problem Status**

After notification of the problem, all authorized personnel, including individuals who open the notification record, can view the status of the problem. At the same time, through the information exchange platform, the client may also be included in the program for him or her to participate the discussion. It is displayed in the dependencies field where the developer describes the problem. Test Expert controls by entering explanation in dependencies field. If the test is successful, the request is closed. Closed requests are sent to as e-mail to clients.

## **6. MEASUREMENT, PROCESS EVALUATION**

### **6.1 Measurement**

This process is performed for analyzing data related to the projects being developed and processes being implemented by the institution. In addition, it is aimed at supporting an effective process management and displaying of products' quality impartially.

In scope of this process;

- An institutional measurement process is implemented.
- Measurement data needs are determined.
- Measurement activities are identified and implemented
- Necessary data are collected, analyzed and results are interpreted.

#### **6.1.1 Institutional Commitments Establishment for Measurement**

The responsibility of the management is to select personnel who will make measurement and enable a sustainable process. For this purpose, personnels (data entry responsible) who will make measurements will be identified. Firstly, data entry responsible is selected from "Performance Indicator" tab on "Standard Process Definition" screen. Measurements are conducted by this personnel but the role of general responsible (indicator responsible) is assumed by Quality System Engineer. Indicator responsible is selected from the same screen.

#### **6.1.2 Development of Measurement Strategy**

Measurement and outcome activities are determined according to the institution and project requirements, and appropriate strategies are identified for their achievement. The measurements for each project are developed on the basis of certain criteria and are stored for review meetings. From the standard process definition screen for measurements, special performance indicators are defined for each process. These performance indicators should be redefined for projects.

#### **6.1.3 Identification Of Measurement Information Needs**

Appropriate measurements are carried out in line with the needs of the institutional and management processes. These needs are required for healthy progression of the project with regard to the needs and requirements. In this context, the measurement

data is the quantitative evaluation of the project for the Project Manager. It enables making of process evaluation for each process included in general processes. The way in which the specified targets are to be recorded in the Sisofis is described in detail in the performance indication record instructions.

#### **6.1.4 Collection and Storage of Measurement Data**

If the measured data is received automatically from the system, the measurement result is automatically recorded by the system under the performance indicators within the specified period.

If the result of the performance indication in the automatically recorded data is not within the target range, related mail will be sent to the indicator responsible person. If there is data to be entered manually, it is saved in the system by the data entry authority. A reminder e-mail will be sent automatically 1 week before, 2 days before and 1 day before the measurement date. How to record performance measures is described in detail in the performance measurement entry instructions. When the performance indicators are opened by clicking on the performance indicators tab of the standard process definition screen, under the heading of the data collection method, it is explained how the person performing the measurement will perform the measurement and how to enter the measurement result in the field. The person can view all the information related to measurement from here.

#### **6.1.5 Measurement Data Analysis**

Instant viewing can be performed on the process performance measurement dashboard screen within the range of maximum and minimum target values determined for the analysis of collected measurement data.

At the top left of the screen, the last state of the entire process can be displayed as a pie chart. On the lower left side, previous period status and daily status can be monitored. On the right side of the screen, process measurement status can be monitored. The evaluation of measurement data is explained in detail in instructions for interpretation the process performance measurement dashboard.

### **6.2 Process Assessment**

Monitoring, measuring and analyzing with the aim of observing productivity, positive or negative effects, cost, objectives and improvement (if needed) of all established process groups (Basic Life Cycle Processes, Institutional Life Cycle Processes, Support Life Cycle Processes).

- A. Evaluation objectives are defined according to the process objectives of the institution. The targets for the processes to be evaluated are recorded on the process

evaluation screen via Sisofis. How to register the process information to the process evaluation screen and how to identify the targets, is described in detail in Process Evaluation Process Registration and Goal Registration Instructions. All these stages are carried out by the Quality System Engineer.

- B. An evaluation plan is created by the quality system engineer to evaluate the performance and follow-up of processes in order to continually improve processes, depending on the business objectives of the organization. With the meeting tab, when the meeting will be evaluated, who will be attending the evaluation meeting and the topics will be determined and recorded. How to register to the meeting definition screen is described in detail in the Meeting Registration Instruction.
- C. An evaluation meeting will be held with the planned persons on the previously scheduled date for evaluation purposes. Assessment data are collected and evaluations are carried out within the framework of evaluation objectives.
- D. The evaluation results are recorded from the process evaluation screen via the Sisofis, by creating a new record under the heading of the evaluation results. Entry of how to registry is explained step-by-step on Evaluation Result Registration Instructions.
- E. Evaluation results are reported by clicking the print tab on the process evaluation screen. The reported evaluation results are approved by the Assistant General Manager of the R & D Unit.
- F. In line of the evaluation results, improvement record can be created if necessary. From the process evaluation screen, process improvement screen can be accessed by clicking the improvement tab on the relevant process.
- G. If, after evaluation, there is a situation that needs to be urgently corrected, a corrective preventive activity record is created in accordance with the corrective preventive action procedure. While this record is being created, the type of task on the evaluation measurement screen is selected urgently or very urgently and the person is notified.

## 7. Mapping Table

Article	ISO 9001:2015 Quality Processes	Sisoft Processes
1	Scope	
<b>4-Structure of Organization</b>		
4.1	Understanding organization and structure	1.1.1
4.2	Understanding the needs and expectations of interested parties	
4.3	Determination of the scope of the Quality Management System	1.2.3
4.4	Quality management system and processes	
<b>5-Leadership</b>		
5.1	Leadership and commitment	
5.1.1	General	
5.1.2	Customer Focus	
5.2	Policy	
5.2.1	Creating Quality Policy	1.2.1
5.2.2	Delivery of Quality Policy	1.2.2
5.3	Organizational Roles, Responsibilities and Authorizations	
<b>6-Planning</b>		
6.1	Actions addressing risks and opportunities	1.1.1
6.2	Planning for achievement of quality goals and objectives	1.1.3
6.3	Planning for changes	1.1.3
<b>7-Support</b>		
7.1	Sources	
7.1.1	General	
7.1.2	Human	
7.1.3	Infrastructure	
7.1.4	Environment in which processes are run	

7.1.5	Monitoring and measurement of resources	
7.1.5.1	General	
7.1.5.2	Measurement Traceability	
7.1.6	Organizational Knowledge	
7.2	Competency	
7.3	Awareness	
7.4	Communication	
7.5	Documented Information	
7.5.1	General	
7.5.2	Creation and update	
7.5.3	Control of Documented Information	
<b>8-Operation</b>		
8.1	Operational Planning and Control	2.1.1
8.2	Product and service terms	2.1.1
8.2.1	Communication with customer	2.1.1 / 2.1.3
8.2.2	Determination of product and service terms	2.1.2
8.2.3	Review of product and service terms	2.1.2
8.2.4	Changes in product and service terms	2.1.2
8.3	Product and service design and development	2.1.2
8.3.1	General	
8.3.2	Design and development planning	2.2
8.3.3	Design and development inputs	2.2.1
8.3.4	Design and development control	2.2.4
8.3.5	Design and development outputs	2.2.1
8.3.6	Design and development changes	2.2.3
8.4	Control of externally supplied processes, products and services	
8.4.1	General	
8.4.2	Types and limits of control	
8.4.3	External provider's information	
8.5	Production and service presentation	4.1/4.2
8.5.1	Control of production and service delivery	4.3

8.5.2	Identification and traceability	4.4
8.5.3	Ownership of the customer or external provider	4.6
8.5.4	Protection	4.8
8.5.5	Post-delivery activities	4.11
8.5.6	Control of changes	4.9
8.6	Release of product and service	4.11
8.7	Inappropriate output control	4.11
<b>9-Performance Evaluation</b>		
9.1	Monitoring, Measurement, Analysis and Evaluation	
9.1.1	General	
9.1.2	Customer Satisfaction	
9.1.3	Analysis and Evaluation	6.5
9.2	Internal Audit	1.2.5
9.3	Management review	1.2.1
9.3.1	General	
9.3.2	Management review inputs	1.2.2
9.3.3	Management review outputs	1.2.2
<b>10-Improvement</b>		
10.1	Inappropriateness and corrective action	6.2
10.2	Continuous improvement	6.2