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**SUMMARY**

<<Summarize the content of the Quality plan and its most essential parts for accomplishing the desired quality level by outlining the foundation for the organisational confidence that the requirements will be met. >>

# Scope

<<Describe the purpose of the quality plan and what is in general expected from applying it on the project. Describe specific aspects of this particular project and any limitations or delimitations. If there are certain conditions that affects the validity of the Quality plan; this could be concrete aspects such as dimensions or temperature, resources or management system status. >>

# Input to this quality plan

<<List any referred input to this quality plan that users’ needs to know in order to understand the quality plan. Also refer to the input documents that must be checked for consistency during the maintenance of the Quality Plan. Refer as well to the documents that upon revision could initiate an update of the quality plan. >>

# Quality goals

<<State the quality objectives, and present them in measurable terms for the specific project and in general elaborate how they will be achieved. Quality objectives may be, but are not limited to:

* Specific quality characteristics for the project
* Matters that is especially important to the customer or other interested parties.
* How working methods can be improved >>

# management responsibilities within this quality plan

<<Specify the person or persons within your organisation that for this specific project are responsible for:

* Nominate the Person Responsible for the Quality Plan
* Ensuring that the required activities/processes defined in the Quality Plan are being planned, implemented, controlled and monitored.
* Decide how these activities/processes relates and connect to each other.
* Mediate requirements on to concerned departments and functions, sub-suppliers and customers and deal with problems that might arise in the interfaces between these.
* Review results of any audits
* Authorize deviations from the management system or from the quality plan
* Steer and control application of corrective and preventive actions >>

# documentation and storage of data

<<Describe how documents and data for this Quality Plan will be identified. Describe who will review and approve documents and data for this Quality Plan. Describe to whom the documents are distributed and how concerned personnel can access the required documents or data. >>

# Control of records within this QUality plan

<<Specify all records that are generated during this project, where they are archived and on what media and their retention period. (i.e please see the below table)

|  |  |  |
| --- | --- | --- |
| Record No | Place for archive | Retention period |
| Doc. No1 Design review protocols | Digital Document management system/ CD rom | 15 yrs / life cycle of equipment |

If there are certain contractual or regulatory requirements on the records; describe how these are satisfied. Describe how records are made available, how this is ensured safely and how disposal of records are being done. Describe which records that are supplied to customer and if applicable; the language these are written in. >>

# Resources

<<Describe types of resources in general (materials, human resources, infrastructure and work environment) needed for the successful execution of the project. In the case of any potential conflict in terms of material needs and availability elaborate on the solution for the smooth execution of the Quality Plan. >>

## Materials

<<Describe all material resources needed for the project. In case of specific characteristics for the required materials outline the standard to which materials have to conform in order to complete the project as per the Quality Plan. >>

## Human resources

<<Describe all human resources that are needed to complete the project. This includes specific competence for each role and the number of required staffing. Specify if new personnel is required for the project, and the required training for new and existing staff. >>

## Infrastructure and work environment

<<Describe infrastructure and the work environment that are needed to complete the project as per Quality Plan, this includes manufacturing and service facilities, workspaces, tools, equipment, technology for communication and information distribution etc. If there are certain work environment aspects that has a direct effect on the product quality specify the particular environmental characteristics (electrostatic sensitive device protection, biological hazard protection, ambient light and ventilation). >>

# Requirements

<<List and describe the requirements specific for this project and outline if there are conflicts within the requirements. Specify when, how and by whom the requirements will be reviewed and conflicts within requirements resolved. Describe how the results of the review will be recorded. >>

# Customer communication

<<Specify by name and title who is responsible for communication with customer in particular cases and how communication is done. Describe the process to be followed for the customer feedback and describe which records are kept of customer communication. >>

# Design and development Process

<<Refer to the plan(s) for design and development and summarize how this is proceeding in the quality plan. Also refer to:

* Relevant standards, codes, specifications, quality characteristics and regulatory requirements.
* Guidelines or methods used for design and development process (i.e. ISO 9004)
* Criteria’s for approving design and development inputs and outputs.
* How, by whom and when outputs of design and development must be reviewed, verified and validated. >>

## Control of Design and Development changes

<<Describe:

* How request for change to the design is steered
* Who is authorized to request a change in design
* How request for changes are reviewed
* Who is authorized to approve or reject changes
* How approved changes are implemented and verified

Note, that even if the project does not involve any Design and Development process, control of changes can still be required (for instance on existing designs). >>

# Purchasing

<<Specify which services will be outsourced. Describe which products will be purchased and their critical characteristics that can affect the quality of the products or services. Describe how these requirements are communicated to the suppliers in order for them to control critical characteristics. Describe the methods, which will be used to evaluate, select and control suppliers. Describe requirements for Supplier quality plans or any other plans if appropriate. Specify which methods will be used to satisfy relevant requirements for quality assurance and regulatory requirements. Describe how verification of purchased products conformity towards specified requirements will be performed. >>

# Production and service provision

<<Describe the complete processes for Production and service provision and how these relate to each other, specifically for this project, either in text or in process maps. Specify their inputs, realization activities and outputs. Specify how production processes are controlled in order to ensure that they are capable of delivering required output and to verify the results (controls, process validation, monitoring and measurements). For the applicable areas, describe:

* All process steps
* Refer to all the applicable standard operating procedures and work instructions
* Tools, equipment, techniques and methods that will be used to achieve the specified results. This includes information about required certification of materials, products and processes.
* Required controlled conditions to meet planned results and how compliance is determined, for instance process controls methods.
* Details about specific qualification or certification of involved staff, other regulatory requirements and industry practices >>

## Installation and post-delivery activities

<<Describe if applicable, how the product will be installed and how this will be verified and validated.

If the project includes further post-delivery activities such as support or maintenance, describe how this will be performed and how to assure conformance to applicable regulatory requirements and industry practices. If certain competence, training or technical support is required specify this. >>

# Identification and traceability

<<If identification of products is applicable, describe methods, product scope and level of detail. The methods should include how requirements in agreements and regulatory constitutions are identified and established. Describe how this is traceable in related product documentation and how documentation is controlled. Specify how product test status is identifiable and traceable. >>

# Customer property

<<Describe how customer property is identified within your organisation and how it is controlled. Seen as an input, describe how it is verified that the provided customer property fulfils the stated requirements before use, and if they are not; how these nonconformities are handled. Specify how lost or damaged property of customer is handled. >>

# Preservation of product

<<State all requirements for handling, storage, packaging and delivery of product and how those will be fulfilled. If your organisation is responsible for delivery, the same aspects must be considered and fulfilled securing delivery of product with requested characteristics. >>

# Control of nonconforming product

<<Describe how nonconforming products or components are handled. Nonconforming products must be isolated and controlled in order to prevent misuse until concession, rework or disposal has been completed. State what degree of rework or repair that is allowed, and how rework and concessions are approved and made traceable. >>

# Monitoring and measurement

<<If specific inspection, control or test plans are available, please refer to these.

In order to provide objective evidence of conformity define:

* Monitoring and measurements activities of processes and product that will be applied and specify in which stages.
* Which characteristics will be measured and monitored in different stages
* Routines and criteria for acceptance of measurements
* Any applied method of statistical analysis
* Inspections or tests required to be performed or witnessed by an external part or regulatory authorities (such as type testing, site acceptance test, product verification or validation).
* Third parties inspections or tests
* Criteria for product release
* The control measures used in order to ensure that equipment for monitoring and measurement are controlled and calibrated. This includes records of calibration/verification and information about equipment status >>

# Audits

Describe all types of audits that will be done related to this project and their purpose, such as:

* Monitor the establishment and implementation of the quality plan(s)
* Monitor and verify the conformity to requirements
* Monitor supplier performance
* Objectively assess the compliance to customers and stakeholders needs.

Describe when audits will be performed and how they are carried out. Specify who is responsible for carrying out audits and authorized to approve actions based on the results.

# Implementation and revision of the quality plan

## Review and acceptance of the quality plan

<<Describe from what aspects the quality plan is being reviewed and which designated role or group of representatives of adequate parts of the organisation that has reviewed it and formally approved it. Also describe which persons and roles that are authorized to review and approve changes to the quality plan. Specify if the quality plan according to agreements is to be reviewed and accepted by ESS Lund before approval. >>

## Implementation of the quality plan

<<Describe how you inform and distribute the quality plan among concerned parts and how you separate controlled copies which are being used and updated accordingly and copies that are distributed as information only. Describe how it is ensured that everyone concerned of the quality plan knows how to use it and if there are any training sessions for non-regular Quality Plan users. Describe how you internally monitor and control that the quality plan is being followed (for instance; audits, milestones, reviews). Specify how monitoring of Quality Plan conformity will be done in collaboration with ESS Lund (organisational commitment assessment, practical implementation of the Quality plan, risk analyses, corrective and preventive actions, improvement opportunities). >>

## Revision of the quality plan

<<Describe which sources have the authority and in which format they can initiate a revision (i.e. changes and improvements) of the quality plan. Describe how revisions in the quality plan are made known to everyone using the plan. Describe how it is ensured that all documents affected by revisions in the quality plan are changed. Describe how ESS Lund will be informed and involved in the Quality Plan revisions (communication, application of revision). >>

## Authorized deviations to this quality plan

<<Specify who is authorized to approve or reject these deviations. >>

# Glossary

| Term | Definition |
| --- | --- |
| <<Sample term>>  | <<Sample explanation >> |
|  |  |
|  |  |

# references

1. <<Sample reference to internal/external document: Document (document Number)>>

Document Revision history

| Revision | Reason for and description of change | Author | Date |
| --- | --- | --- | --- |
| 1 | First issue | <<Name>> | <<YYYY-MM-DD>> |
|  | <<Keep only full number revisions when approving document>> |  |  |
|  |  |  |  |