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	Measurement, Analysis and Improvement	Effective Date 09/2002	Revision 01

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

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8 MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 GENERAL

The organization shall plan and implement the monitoring, measurement, analysis and improvement processes needed:

- to demonstrate conformity of the product
- to ensure conformity of the quality management system
- to continually improve the effectiveness of the quality management system.

This shall include determination of applicable methods, including statistical techniques, and the extend of their use.

Deviations become promptly detected by planned monitoring, measurement, analysis and improvement before, while and after the service contribution or the product creation. If necessary corrective actions are arranged. The executed checks should be adapted at the sequence in the work areas. The later the check the more costly the rework. But type and scope of activities of the checks must be economically justifiable. The application of statistical methods is possible only in very limited measure for a ship model basin because performance essentially consists of scientific-technical performances and products in one-off production.

8.2 MONITORING AND MEASUREMENT

8.2.1 Customer Satisfaction

As one of the measurements of the performance of the quality management

system, the organization shall monitor information relating to customer perception as to whether the organization has met customer requirements.

The measurement and monitoring of the customer satisfaction are based on the evaluation of customer's information, which can be collected actively or passively. The methods for obtaining and using this information shall be determined.

8.2.2 Internal Audit

In evaluating the effectiveness of a quality management system, audits are an important element. Audits may be conducted by, or on behalf of, the organization itself (internal quality audit), its customers, or independent bodies.

The standard requires that the organization shall conduct internal audits at planned intervals to determine whether the quality management system

- conformed to the planned arrangements, to the requirements of ISO 9001 and to the quality management system requirements established by the organization, and
- is effectively implemented and maintained.

Procedures for both planning and implementing internal audits should exist and these should cover the following:

- preparing an annual audit program
- the selection of auditors and a team leader if necessary
- planning audits of each type
- conducting the audit

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- recording observations
- determining corrective actions
- reporting audit findings
- implementing corrective actions
- confirming the effectiveness of corrective actions
- the forms on which you plan the audits
- the forms on which you record the observations and corrective actions.

The standard requires that the selection of auditors and the conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work. To ensure their independence, auditors need not be placed in separate organizations. Although it is quite common for quality auditors to reside in a quality department it is by no means essential. There are several solutions:

- Auditors can be from the same department as the activities being audited, provided they are not responsible for the activities being audited.
- Separate independent quality audit departments could be set up, staffed with trained auditors.

The responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining shall be defined in a document procedure.

The audit report should state the results of the audit, what was found compliant as well as what was found noncompliant. The management personnel responsible for the area shall take timely corrective action on deficiencies found during the audit. There are

three actions which the responsible manager should take:

- remedial action to correct the particular nonconformity
- research for other examples of nonconformity and to establish how widespread the problem is
- establish the root cause of the nonconformity and prevent its recurrence.

Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

8.2.3 Monitoring and Measurement of Processes

ISO 9001 requires that the organization apply suitable methods for monitoring and measurement of the quality management processes.

For the evaluation of the effectiveness of the quality management processes may be executed on the internal audit a self-assessment for selected areas of the organization by top management following the standard DIN EN ISO 9004 Appendix A. The evaluation of the requirements and expectations of the interested parties are to be the centre of attention like

- abilities of the organization
- response time to inquiries
- use of technologies
- input-output ratio.

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8.2.4 Monitoring and Measurement of Product

In agreement with the planned regulations in the quality management manual chapter 7.1 "Planning of Product Realization" in suitable phases of the product realization or service provision checks are executed. Recordings of these checks are created in accordance with quality management manual chapter 4.2.4 "Control of records".

Type and scope of the monitoring and measurement of product as well as the competencies for execution and the evaluation of the results are to be determined.

The product monitoring and measurement plans should:

- identify the product to be inspected and tested
- define the specification and acceptance criteria to be used and the issue status which applies
- define the inspection aids and test equipment to be used; standard measuring equipment would not need to be specified as your inspectors and testers should be trained to select the right tools for the job; any special equipment should be identified
- define the environment for the measurements to be made if critical to measurement accuracy
- identify the organization which is to perform the inspections and tests
- make provision for the results of the inspections and test to be recorded.

Final inspection is the last inspection of the product or service. There are two aspects to final inspection. One is checking what has gone

on before and the other one is accepting the product or service.

Final inspection and test checks should detect whether:

- all previous inspections and checks have been performed
- the product (draft, drawing, program etc.) bears the correct identification, part numbers, serial numbers, modification status etc.
- all recorded non conformances have been resolved and remedial action taken and verified
- all concession applications have been approved
- all inspection and test results have been collected
- all documentation to be delivered with the product or service has been produced and conforms to the prescribed standards.

No product shall be dispatched until all the activities specified in the quality plan and/or documented procedures have been satisfactorily completed and the associated data and documentation are available and authorized.

8.3 CONTROL OF NONCONFORMING PRODUCT

A nonconforming product is one that does not conform to the specified requirements. Specified requirements are either requirements prescribed by the customer and agreed by the organization in a contract for products or services, or are requirements prescribed by the organization which are perceived as satisfying a market need.

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The standard ISO 9001 requires that the organization ensures that products which do not conform to product requirements are identified and controlled to prevent their unintended use or delivery.

The top management should empower people in the organization with the authority and responsibility to report nonconformities at any stage of a process in order to ensure timely detection and disposition of nonconformities. Authority for response to nonconformities should be defined to maintain achievement of process and product requirements. The organization should effectively and efficiently control nonconforming product identification, segregation and disposition in order. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a document procedure.

The organization shall deal with nonconforming product by one or more of the following ways

- by taking action to eliminate the detected nonconformity
- by authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer
- by taking action to preclude its original intended use or application

Nonconforming product shall be reviewed in accordance with documented procedures. It may be:

- reworked to meet the specified requirements, or
- accepted with or without repair by concession, or
- regarded for alternative applications, or
- rejected or scrapped.

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained (see 4.2.4).

8.4 ANALYSIS OF DATA

The organization determines, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate.

The analysis of data shall provide information relating to

- customer satisfaction (see 8.2.1)
- conformity to product requirements and service requirements (see 7.2.1)
- characteristics and trends of processes and products including opportunities for preventive action
- evaluation of suppliers
- market-analysis.

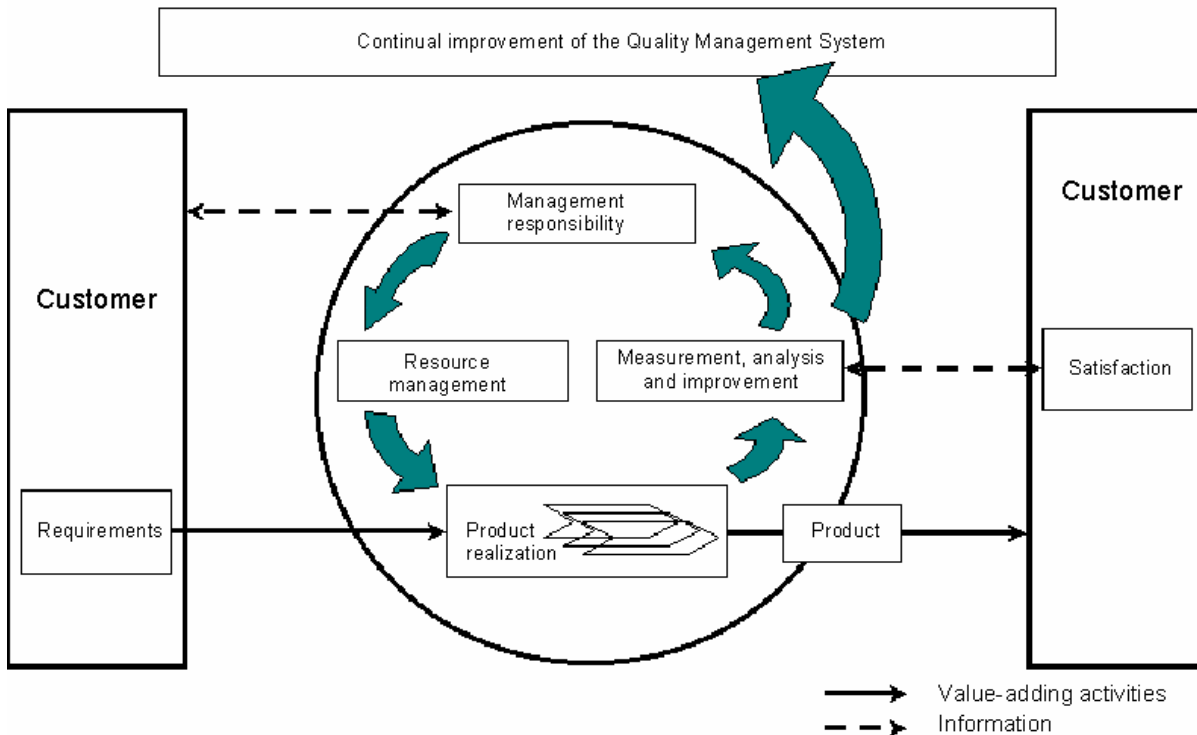
8.5 IMPROVEMENT

8.5.1 Continual Improvement

The organization continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives audit results, analysis of data, corrective and preventive actions and management review.

The requirements for quality improvement can be related to any aspect such as effectiveness, efficiency or traceability.

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Model of a process-based quality management system

8.5.2 Corrective Action

The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. A documented procedure shall be established to define requirements for

- reviewing nonconformities (including customer complaints)
- determining the causes of nonconformities
- evaluating the need for action to ensure that nonconformities do not recur
- determining and implementing action needed
- records of the results of action taken (see 4.2.4)
- reviewing corrective action taken.

Non-conformities are caused by one or more of the following:

- deficiencies in communication
- deficiencies in documentation
- deficiencies in personnel training and motivation
- deficiencies in materials
- deficiencies in tools and equipment
- deficiencies in the operating environment
- deficiencies in calibration of test equipment.

In pursuing corrective actions, the organization identifies sources of information,

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and collects information to define the necessary corrective actions. The defined corrective actions are focused on eliminating causes of nonconformities in order to avoid recurrence. Examples of sources of information for corrective action consideration include:

- customer complaints
- nonconformity reports
- internal audit reports
- outputs from management review
- outputs from data analysis
- outputs from satisfaction measurements.
- relevant quality management system records
- the organization's people
- process measurements
- results of self-assessment.

8.5.3 Preventive Action

The organization shall determine actions to eliminate the causes of potential nonconformities in order to prevent their occurrence. A documented procedure shall be established to define requirements for

- determining potential nonconformities and their causes
- evaluating the need for action to prevent occurrence of nonconformities
- determining and implementing action needed
- records of results of action taken (see 4.2.4)
- reviewing preventive action taken.

Results of the evaluation of the effectiveness and efficiency of the preventive action should be an output from management review, and should be used as an input for the modification of plans and as an input to the improvement processes.

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(possible completion:)

8. 6 RESPONSIBILITY IN GENERAL

Quality Tasks	Responsibility			
	①	②	③	④
Planning of monitoring and measurement	D	I	A	E
Measurement and monitoring of customer satisfaction	A	A	A	A
Planning and conducting of audits	A	A	E	A
Monitoring and measurement of processes	D	E	I	E
Monitoring and measurement of product	D	I	I	E
Control of nonconforming product	D	E	I	E
Analysis of data	D	E	I	E
Corrective and preventive action	D	E	I	E
etc.

① Management
② Commercial department
③ Management representative
④ Engineering department

D → decide
E → execute
A → advise
I → inform