Certification of
Quality Management Systems
Based on the
ISO 9001:2008 requirements

RD_054, Issue 05

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Revision record sheet

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Contents

1 INTRODUCTION ......................................................... 4
  1.1 ABOUT TELEFICATION ........................................... 4
  1.2 ABOUT THIS DOCUMENT ........................................ 4

2 BENEFITS OF ISO 9000 CERTIFICATION .......................... 5

3 ISO 9000 FAMILY ....................................................... 5
  3.1 ISO 9000:2000 FUNDAMENTALS AND VOCABULARY ............. 5
  3.2 ISO 9001:2000 THE REQUIREMENTS ................................ 6
  3.3 ISO 9004:2000 GUIDELINES FOR PERFORMANCE IMPROVEMENT . 6

4 ASSESSMENT PHILOSOPHY ............................................. 6

5 CERTIFICATION PROCESS ............................................. 7
  5.1 APPLICATION AND ORDERING FOR QUALITY SYSTEM CERTIFICATION . 7
  5.2 PRE-AUDIT OPTION .................................................. 7
  5.3 DOCUMENTATION REVIEW ........................................ 7
  5.4 ON-SITE REGISTRATION AUDIT (COMPLIANCE AUDIT) ............. 7
  5.5 ASSESSMENT RECOMMENDATION ................................... 7/8
  5.6 ASSESSMENT REPORT ............................................... 8
  5.7 ISSUANCE OF CERTIFICATE AND CONTRACT OF CERTIFICATION . 8
  5.8 SURVEILLANCE VISITS ............................................. 8

6 CONDITIONS AND FEES ............................................... 8

7 MODIFICATIONS TO THE QUALITY SYSTEM ......................... 9

8 EXPIRATION, SUSPENSION AND WITHDRAWAL OF QUALITY SYSTEM CERTIFICATES . 9

ANNEX A REFERENCES & FORMS ......................................... 10

ANNEX B ADDITIONAL INFORMATION .................................. 111
1 Introduction

1.1 About Telefication

Telefication, formally known as KTL Arnhem and KTL Certification, is a third party test laboratory and a third party certification and inspection body. The Dutch Council for Accreditation (Raad voor Accreditatie: RvA) has accredited Telefication to ISO/IEC 17025 (laboratory) and ISO/IEC 17065 (product certification). This procedure is not under the scope of these accreditations.

Specialising in the area of information technology and telecommunications equipment and systems (IT&T), the activities of Telefication cover product and quality system certification as well as product inspection.

Furthermore, Telefication offers a Liaison for approval service for national approval application in various countries.

More information about Telefication is available in RD_560, About Telefication.

1.2 About this document

This document is intended as a guide for clients who want to be certified for certification services based on the ISO 9001:2008 series.
2 Benefits of ISO 9001 Certification

Management system certification stimulates a climate of confidence in the procedures and practices businesses apply in support of their products and services.

- It reinforces a company's management system
- Provides a framework for controlling and improving business activities
- Adds value to products and services
- Adds to competitiveness
- Increase in profitability
- Provides a marketing edge
- Reducing costs

In today's marketplace, various manufacturing, industrial, commercial and service organizations gain many benefits from ISO 9001 certification.

3 ISO 9000 family

The ISO 9000 family consists of a core of three International Standards plus many associate standards, technical reports and guides, two of which are included here as having very close ties with the family.

There family consists of:

- ISO 9000:2008
  Quality Management systems – Fundamentals and vocabulary
- ISO 9001:2008
  Quality Management system – Requirements
- ISO 9004:2008
  Guidelines for performance improvement

Associated with the above are:

ISO 10012 Quality assurance requirements for measuring equipment – Metrological confirmation system for measuring equipment; and
ISO 19011 Auditing quality and environmental management systems

3.1 ISO 9000:2008 Fundamentals and vocabulary

The fundamentals of quality management systems present a good general approach to the subject and provide, in plain language, a description of the 'system' approach, the 'process' approach and many of the features dealt with in the other standards, illustrating why the requirements are necessary. It also contains the quality management principles, which were derived from earlier editions and used as a basis for developing the requirements and guidance provided in the current family of standards. An appreciation of these principles is vital to the interpretation of the requirements and guidelines contained in ISO 9001 and ISO 9004.
3.2 ISO 9001:2008 the requirements

This is the key standard of the family. The requirements for quality management systems are contained in ISO 9001. The 2000-year edition of the standard covers all the previous levels of the ISO 9001, ISO 9002 and ISO 9003.

The quality assurance standard lays down the requirements that a quality system should meet, but does not dictate how they should be achieved.

The original so called twenty elements in the standard have been replaced by five clauses. The clauses are:

4. Quality Management system
5. Management responsibility
6. Resource management
7. Product realization
8. Measurement analysis and improvement

There are 250 individual requirements in ISO 9001 that can be condensed into five key statements:

- Determine the needs and expectations of customers and other interested parties
- Establish policies, objectives and a work environment necessary to motivate the organization to satisfy the needs
- Design, resource and manage a system of interconnected processes necessary to implement the policy and attain the objectives
- Measure and analyze the adequacy, efficiency and effectiveness of each process in fulfilling its purpose and objectives and
- Pursue the continual improvement of the system from an objective evaluation of its Performance

The requirements are applicable to any kind of organization: profit, or non-profit, manufacturing, hardware or software, service, commercial or government.

3.3 ISO 9004:2008 Guidelines for performance improvement

This standard replaces ISO 9004:1994 and was written to be consistent with ISO 9001 but is not a guide to implementing the requirements of ISO 9001. The addition of the requirement clauses from ISO 9001 placed in boxes followed by guidance dealing with the same subject give the impression that the guidance is ‘how to’ meet the requirements whereas it is meant to show how to improve on the minimum requirements given in ISO 9001.

4 Assessment Philosophy

Telefication philosophy is to build a practical and professional working relationship with clients, which includes close customer care that maximizes the benefits of management system certification. Telefication satisfies the criteria relating to proficiency, independence, and impartiality. In this connection, European standards EN45012 and guidelines on management systems for auditing quality systems ISO 19011:2002 are particularly important and followed.
5 Certification Process

5.1 Application and ordering for quality system certification

- The first step towards registration is to complete a questionnaire called: *Questionnaire for quality system approval* (RF_300) the client provides Telefication with some basic information of his quality system. With this information the activities needed for assessment and certification of the quality system are determined and a quotation is prepared. If necessary, Telefication will contact the applicant to request for further information. This inquiry is without any obligation: detailed planning and assessments will begin after the applicant has accepted the quotation and returned the signed order for assessment to Telefication.

- In case clients are already certified, but want to continue the service by Telefication, Telefication is able to accept the certificate, in case a certification body has performed the previous certification assessment, accredited in accordance 45012 and or 17065.

5.2 Pre-Audit option

Telefication will, if required, carry out optional pre-audits, which are separate from the registration audit and have the assessment process explained in detail. This pre-audit can be a tool to determine the readiness of your quality system for the registration audit. The pre-audit includes a documentation review, an on-site audit and a report.

5.3 Documentation review

In case an initial visit can not be carried out, Telefication will perform a documentation examination. Preceding an audit, the client will be informed of determined non-compliances.

5.4 On-Site registration Audit (compliance audit)

The Lead Assessor shall forward the assessment agenda and plan to the client for agreement. The client will be requested to sign the agenda and return a copy to the Lead Assessor as conformation. Depending on the scope of registration, the required days on-site will be determined. The purpose of the assessment is to verify the effectiveness and application of the documented procedures in practice. The on-site registration audit will be performed after a documentation review. On completion of the assessment, the auditor presents his findings to the company, in a closing meeting.

5.5 Assessment recommendation

During the closing meeting, the company is informed whether or not the auditor intends to make a recommendation for registration. An assessment report form is presented to the company, detailing the report summary, non-conformities and the recommendation.

The typical recommendations that can be made are as follows:

- If significant numbers of major non-compliances are found, then the recommendation should be; re-assessment.
If subjective major non-compliances are found, then the recommendation should be certification after the submission and acceptance of a corrective action plan and evidence of the closure of major non-compliances. The non-compliances will be re-assessed at the next surveillance.

If only minor non-compliances are found, recommendation should be certification subject to the submission and acceptance of a corrective action plan. The non-compliances will be re-assessed at the next surveillance.

If no non-compliances are identified then, then recommendation should be certification.

5.6 Assessment Report

After performing the audit, the assessment report will be circulated around the assessment team and the final report will be authorized by the Lead Assessor and then forwarded to the Director of Telefication for final authorization. The signature of the Director signifies that the Governing Board has accepted the recommendations. If registration is not recommended, a re-assessment date should be arranged. A signed copy will be supplied to the client.

5.7 Issuance of Certificate and Contract of Certification

The Director of Telefication shall ensure that all relevant actions are concluded, and documentation is complete prior to issuing any certification certificate. Prior to the issue of the certificate a Contract for certification will be sent to the client detailing conditions of the certification. The client is required to return a signed copy before certification will be officially granted. In addition, once the certificate is issued the surveillance will be scheduled. The certification will continue for a period of three years at which point a renewal assessment will be performed.

5.8 Surveillance Visits

Telefication is responsible for ensuring all surveillance and renewal assessments are conducted prior to the certificate expiration date. At least annually, the quality system is subject to a re-examination, to verify that the requirements of the appropriate standard continue to be met. For continuity, Telefication endeavors to ensure that the auditors who carried out the first assessment also conduct the initial surveillance visits.

6 Conditions and fees

The General conditions of Telefication are applicable for all services. Telefication will charge fees for audits. These fees may be broken down in several categories. Costs are usually retrospective (based on fixed hourly rates), plus travel and accommodation expenses and where applicable the fees charged for technical experts.

An estimation of the fees will be included in the quotation for quality system approval upon request. Clients may be required to make an advance payment to cover expenses to be incurred.
7 Modifications to the quality system

Modifications to the quality system are handled as an addition to an original application. The client can request a modification by using the form *Questionnaire for quality system approval* (RF_300).

Telefication will perform an additional assessment. The scope will depend on the nature of the modification(s) and existing experience from the previous surveillance audits performed.

8 Expiration, suspension and withdrawal of quality system certificates

The quality system certificate expires when:
- the certificate is replaced by another certificate, or;
- the contract for quality system approval is terminated, or;
- the certificate is withdrawn by Telefication.

A quality system certificate may be suspended or withdrawn by Telefication immediately when:
- quality system surveillance audits reveal non-compliances. In the event of minor non-conformities, the manufacturer gets the opportunity to take corrective actions, or;
- markings are abused by the certificate holder, or;
- complaints are received, from e.g. the purchasers, regarding marketed products and these complaints are substantiated by supplementary examinations that reveal non-compliances, or;
- it was granted on the basis of false or misleading data or documentation provided, or;
- withdrawal is requested by the national authorities, which have the power to supervise and enforce the relevant certification scheme (when applicable);
- the certificate holder does not pay the certification fees due.

The manufacturer is informed of suspension or withdrawal in writing. In case of suspension the conditions for reinstatement are included. If a quality system certificate is suspended or withdrawn, the manufacturer may no longer apply related markings to any product involved. Withdrawal may result in the manufacturer being obliged to recall the products from the market (in case the certification scheme has a legal background).
### Annex A

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<td>ISO/IEC 17065</td>
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<td>General requirements for bodies operating assessment and registration systems</td>
</tr>
<tr>
<td>ISO 19011:2002</td>
<td>Guidelines on auditing management systems</td>
</tr>
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<td>Questionnaire for quality system approval</td>
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<td>Quality management systems - fundamentals and vocabulary</td>
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Annex B  

Additional information

For more information on quality system certification, please contact us:

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