RULES QMS

Quality Management System

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Revision Register:

Date	Edit	Rev	Edit for	Issued	Approved
06/10/2014	1	0	First issue Rules	RSG	ADM
01/08/2016	1	1	Transition ISO 9001:2015	RSG	ADM
29/05/2017	1	2	Definitive transition to ISO 17021-1:2015 and 9001:2015	RSG	ADM
14/09/2018	1	3	Cancellation of old edition 2008	RSG	ADM
03/06/2024	1	4	Integration Requirements ISO 9001	RSG	ADM
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1. GENERAL

These Rules define the additional procedures, not as substitute, applied by QS for certification of quality management systems in comparison to what is already defined in the General Rules for the certification of Management Systems.

QS issues the certification in accordance with requirements of standard ISO/IEC 17021-1:2015 to Organizations whose Management System has been recognized in accordance with the requirements of ~~ISO 9001:2008 (that will be definitive withdrawn September 15th 2018) and of the new edition~~ ISO 9001:2015.

In addition; ISO 9001:2015/Amd 1:2024, requires organisations to actively assess and address the implications of climate change in their operations and strategic planning.

In addition, upon request, QS can carry out conformity assessments of a Quality Management System according to other normative documents of reference and, if appropriate, issue the certification (ISO 13485, ISO 3834, EN 14065).

For such cases should also be considered any specific regulations/guidelines of QS.

1.1 Term and definition

Contest: The general environment/area of interest, within which the company is called to carry out its functions, defined by a series of political, legislative, social, cultural and economic conditions and factors (external and internal), which determine the system of risk/opportunities within which the Quality management shall be developed.

Risk: effect (positive or negative) of uncertainty

2. REFERENCE STANDARD/REQUIREMENTS FOR CERTIFICATION

To get certification by QS, a Quality Management System shall meet initially and over time the requirements of ISO 9001 and the additional ones required by Accreditation Bodies.

The Quality Management System is fully operational when, in addition to what is established by General Rules for the Certification of Management Systems, have been undertaken actions that ensure guarantee of regularity in the methods of production and in the quality of products/services provided.

INITIAL CERTIFICATION

In addition to the General Rules for the Certification of Management Systems, the Company must communicate to QS:

- possible elements of the reference standard that does not apply to its organization or that require interpretation or adaptation, indicating clearly the reasons.

Together with the certification request, or at a later stage to it, the Company, in addition to the General Rules for the Certification of Management Systems, will have to make available to QS also a documented information of Quality Management System that includes:

- the description of processes and their interactions;
- field of application and the reasons for the exclusion of any points of the reference standard that are evaluated not applicable, or that require interpretation or adaptation (for ISO 9001:2015 exclusions of requirements are not allowed, only a different degree of application on the same requirements as a function of business reality and work Context of reference. The degree of application of design requirement, as stated by the applicant organization, will be evaluated during Audit by an auditor QS);
- the list of main laws and/or regulations applicable to the product/service provided or necessary for the proper implementation of the quality management system.

The cost of certification activity is proportional to the number of man-days (m/d) necessary to the evaluation of the quality management system of the Organization and the level of com-complexity/criticality of it with reference to document IAF MD 5 in the version in force.

AUDIT STAGE 1

Stage 1 audit can be conducted through a review of the documentation that the applicant must transmit to the of the audit team, at the discretion of the technical direction and taken into account the complexity of the processes and the number of employees in your organization.

The documents must generally contain the information required to demonstrate the conformity of the product/process/service, a description of the means through which the Organization will be able to demonstrate and monitor compliance of your product/service/process (control plan, procedures, instructions, records) compared with the provided requirements of the normative document, the requirements for the certification issued by QS and the Accreditation Bodies, as well in relation to any legal requirements and in accordance with the following paragraph of the General Rules 10.6 QS Quality Services Ltd.

Any inadequacy and gaps in documentation can suspending the process, according to the decision of the audit team, until their resolution. Following the audit, QS transmits to the company a report that identifies any shortcomings, or, in positive case, it suggests the continuation of verification activities. Filled these gaps, the lead auditor of audit team plans the audit on site, communicating to the Organization the audit plan, with details of the sites, processes etc. to be evaluated, as well as the specific programme of assessment of the product/process/service.

In addition to what is established by point 10.6 of QS Quality Services Ltd General Rules for the Certification of Management Systems, during the STAGE 1 audit, will be verified as follows:

a) that the Leadership has defined the Contest, stakeholders involved in their field of application. The field of application shall be documented, defined and updated; the outsourcing process shall be considered and involved in the management systems

b) that the organisation has implemented and maintained the documented information in order to prove that the management system is preserved updated and efficient;

c) that the organisation has all the valid authorisations to carry out its activities;

d) that the Leadership, as a result of the identification of ist activities, processes and interations and has identified and assessed the risks effects, the relationship with requirements and has planned the prevention/risk management actions and the definition of objectives for the improvement Performance (opportunities).

4. INFORMATION FOR TRANSITION PROCESS TO THE NEW STANDARD EDITION ISO 9001: 2015

The new ISO standard 9001:2015 it was released on September 15th, 2015 and for the entry into force of this standard, the IAF (International Accreditation Forum) has established a transition period of 3 years after its publication (ref. IAF ID 9:2015).

According to this document, certification awarded in accordance with ISO 9001:2008, issued after the release of the new standards, will lose their validity automatically after three years from that date.

This means, that the validity of the certificates shall terminate within the time of 15 September 2018, regardless of the effective date of certification. The implementation of the new standard and its verification of the actual implementation of the system should therefore be carried out no later than 3 years after the publication of the standard.

We encourage our customers to make the transition from the old system to the new verification when verifying recertification or surveillance during an annual check as planned.

It will be likely in some cases the necessity to add additional time (from a minimun of half-man day audit) for the assessment of requirements of the new standards.

In any case, for certification in accordance with the new standard, it will required the conclusion of a new contract or upgrade of the existing contract. QS is committed to ensuring that the transition will take place linearly and smoothly; and in particular without that the correct certificate validity, being changed at fault. The cutted months of validity will be considered at the time of issuing the new certificate in accordance with ISO 9001:2015 respecting the natural certification cycle.

At 3 years after the publication of the new edition 2015 of ISO 9001, the certification according the ISO 9001:2008 will cease to be valid, and they will be simultaneously revoked.

QS has obtained the accreditation to ISO 9001:2015 since May 2017.

The organization that has not completed the transition and intends, after the expiration date of September 15th 2018, again access to the certification will have to submit a new application following the normal procedure for initial certification.

QS invites organisations that approach the implementation of their environmental system for the first time, to implement the system directly in accordance with the requirements of the new 9001: 2015 edition.

QS invites the new applicants to apply for the new ISO 9001:2015 certification.

QS declares that will accept only application according the standard ISO 9001 edition 2015 (edition ISO 9001:2008 is obsolete).