



Rules for the certification of Quality Management Systems

Effective from September 15th, 2015

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Technical rules



This rule is divided into 3 sections depending on the requested certification service:

Section 1:

Certification of Quality Management Systems in conformity with ISO 9001:2015

Section 2:

Certification of Quality Management Systems in conformity with ISO 9001:2008

Section 3:

Transition of certification from ISO 9001:2008 to ISO 9001:2015



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SECTION 1: CERTIFICATION OF QUALITY MANAGEMENT SYSTEMS IN CONFORMITY WITH ISO9001:2015

CHAPTER 1 GENERAL

1.1

These Rules define the additional and/or substitutive procedures applied by RINA for the certification of Quality Management Systems in relation to what is already defined in the

General Rules for the Certification of Management Systems

The paragraphs of these Rules refer to (and maintain the same numbering of) the corresponding paragraphs of the General Rules for the Certification of Management Systems for which changes and/or additions have been made.

1.2

RINA issues certification in accordance with the requirements of the ISO/IEC 17021:2011 Standard to organizations whose Management System has been recognized as fully conforming to all the requirements of the

ISO 9001:2015 standard

Moreover, RINA may audit compliance of a Quality Management System with other reference regulatory documents (ISO13485, EN 9100, EN 9110, EN 9120, ISO 3834, ISO TS 16949, Metrologic Compliance Confirmation), on request, and, if appropriate, issue the relative certificate.

Any specific RINA rules/guides must also be considered in these cases.

CHAPTER 2 REFERENCE STANDARD / CERTIFICATION REQUIREMENTS

2.1

According to what is stated in the General Rules for the Certification of Management Systems, to obtain RINA certification a Quality Management System must first and henceforth satisfy the requirements of ISO 9001 and the additional requirements of accreditation bodies (e.g.: ACCREDIA documents RT 04, RT 05, RT 21,...).



CHAPTER 3

INITIAL CERTIFICATION

3.1

According to what is stated in the General Rules for the Certification of Management Systems, together with or following the certification request, the Organization is to make the following documents available to RINA:

- description of QMS scope including all products and services covered by it,
- justification of any requirements of the standard deemed to be not applicable to the management system scope

RINA examines the above documents for conformity with the reference standard and with the requirements of these Rules.

SECTION 2: CERTIFICATION OF QUALITY MANAGEMENT SYSTEMS IN CONFORMITY WITH ISO 9001:2008

CHAPTER 1 GENERAL

1.1

These Rules define the additional and/or substitutive procedures applied by RINA for the certification of Quality Management Systems in relation to what is already defined in the

General Rules for the Certification of Management Systems

The paragraphs of these Rules refer to (and maintain the same numbering of) the corresponding paragraphs of the General Rules for the Certification of Management Systems for which changes and/or additions have been made.

1.2

RINA issues certification in accordance with the requirements of the UNI CEI EN ISO/IEC 17021:2011 Standard to organizations whose Management System has been recognized as fully conforming to all the requirements of the

ISO 9001:2008 standard

Moreover, RINA may audit compliance of a Quality Management System with other reference regulatory documents (ISO13485, EN 9100, EN 9110, EN 9120, ISO 3834, ISO TS 16949, Metrologic Compliance Confirmation), on request, and, if appropriate, issue the relative certificate.

Any specific RINA rules/guides must also be considered in these cases.

ISO9001:2008 certifications can be issued within the end of the transition period.

Certificates issued in conformity with ISO9001:2008 will expire on 15th September 2018, date of the end of the transition period.

To maintain the quality management system certification, an Organization that is certified in accordance with ISO9001:2008 must perform transition to the new edition of ISO9001:2015 according to Section 3 of this RINA rule, within 15th September 2018.

CHAPTER 2

REFERENCE STANDARD / CERTIFICATION REQUIREMENTS

2.1

In addition to what is stated in the General Rules for the Certification of Management Systems, to obtain RINA certification a Quality Management System must first and henceforth satisfy the requirements of ISO 9001 and the additional requirements of accreditation bodies (e.g.: ACCREDIA documents RT 04, RT 05, RT 21,...).

2.2

A Quality Management System is considered fully operational when, as well as what is stated in the General Rules for the Certification of Management Systems:

- actions have been implemented which guarantee constancy in production methods and in the quality of the products or services supplied.

2.2.2.

A manual is available which:

- defines the goal/scope of the management system, describes the main system processes and elements and their interactions and contains or refers to the relative documented procedures. The description of the processes and their interactions must be extended to all those developed by the organisation (also to outsourced processes) required to manufacture/provide a determined product/service that are fundamental as regards the capacity of the product/service to satisfy the applicable requirements. This can be done in various ways:
 - descriptions;
 - flow charts or logograms;
 - tables or matrices;
 - other;
- takes into consideration the requirements of the standard and provides a description, not necessarily detailed, of the resources and procedures used to ensure compliance with these requirements;
- contains a suitable description of the company organisation.

CHAPTER 3

INITIAL CERTIFICATION

3.1

In addition to what is stated in the General Rules for the Certification of Management Systems, the Organization must inform RINA of:

- any elements of the reference standard that it deems not applicable to its Organization or that must be interpreted or changed, specifying the reasons.

3.2

Together with or following the certification request, the Organisation, in addition to what it stated in the General Rules for the Certification of Management Systems, must provide RINA with a Quality Management System Manual including:

- a description of processes and their interactions;
- the reasons for the exclusion of any elements of the reference standard that it deems to be not applicable or that must be interpreted or changed;
- a list of the main laws and/or rules applicable to the supplied product/service or necessary for the correct application of the Quality Management System.

3.3

During the initial audit, the organisation must demonstrate that the Management System is fully operational and that it effectively applies the system and relative documented procedures.

3.4

Together with or following the certification request, the Organisation must make the following documents available to RINA:

- the organisation's management manual (last valid revision) describing the policy, objectives and programmes for the Management System;
- list of internal procedures concerning the management system

3.5

During the initial audit, the organisation must demonstrate that the Management System is fully operational and that it effectively applies the system and relative documented procedures.

CHAPTER 6

PERFORMANCE OF AUDIT

The stage 2 audit is performed by qualified RINA surveyors, on the basis of the stage 1 audit and the following updated documents prepared by the organisation:

- Management System policy;
- Management System manual;
- informative questionnaire filled in by the organisation;
- list of internal procedures;
- management procedures and other Management System documents;
- other specific documents for the correct and effective implementation of the Management System.

CHAPTER 7

MANAGEMENT OF CERTIFICATES OF CONFORMITY

7.1

ISO9001:2008 certificates will expire on 15th September 2018, the date of the end of the transition period.

CHAPTER 10

TRANSFER OF ACCREDITED CERTIFICATES

10.1

If it accepts the economic offer, the organisation must send RINA the "Certification request" together with the following documents:

- copy of the management system manual and the list of procedures

SECTION 3: TRANSITION OF CERTIFICATION FROM ISO 9001:2008 TO ISO 9001:2015

A.0 GENERAL

This section applies when an Organization certified in compliance with ISO9001:2008 asks for transition to the new edition of the standard ISO9001:2015.

To obtain RINA ISO9001:2015 certification a Quality Management System must first and henceforth satisfy the requirements of ISO 9001:2015 and the additional requirements of accreditation bodies.

The Organization must demonstrate to have correctly implemented and acted the elements of change, for example it must demonstrate:

- to have considered its context defining the scope of quality management system and planning the management system based on its risks and opportunities

A.1 TRANSITION APPLICATION

During the transition period, the certified Organization can decide to perform transition to the new standard:

1. during a surveillance audit (with possible audit time increase)
2. during a recertification audit
3. between two scheduled audits

An authorized representative of the applicant organization has to submit a transition request to RINA.

Only in case of an increase of audit time, RINA prepares a suitable offer limited to the transition audit.

On receipt of the application for transition, RINA sends to the Organization the document "SELF ASSESSMENT QUESTIONNAIRE FOR TRANSITION" that has to be properly filled in, including any necessary documentation.

A.2 PERFORMANCE OF AUDITS

Transition audit is divided into two steps:

Section 3:
Transition of certification from ISO9001:2008 to ISO9001:2015

- documental review of the elements of change, based on the "SELF ASSESSMENT QUESTIONNAIRE FOR TRANSITION" and on documented information required by ISO 9001:2015
- on-site audit to assess the fulfilment of new requirements of ISO 9001:2015

With regard to the execution of the audits what is stated in the General Rules for the Certification of Management Systems applies.

During the transition period, if any major non conformities are raised as per ISO 9001:2015 and not closed within the terms foreseen by the General Rules for the certification of Management Systems, these non conformities will not negatively affect maintenance of current certification provided that it is obviously verified that the quality management system is always compliant with ISO 9001:2008.

The dates and the extension of the following audits for maintenance of the certification remain the same as per three-year surveillance programme.

A.3 ISSUE OF THE CERTIFICATE IN CONFORMITY WITH ISO9001:2015

Following the successful outcome of the transition audit and the approval by RINA, a certificate of conformity with new edition of the standard is issued; the validity will be calculated based on the Organization's three-year audit cycle.

A.4 VALIDITY OF THE CERTIFICATES IN CONFORMITY WITH ISO9001:2015

ISO9001:2008 certificates will expire on 15th September 2018.

After the expiry date of its ISO9001:2008 certificate, an Organization that needs to obtain an ISO9001:2015 certification, must submit a new application for certification following the requirements of the initial certification.



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