Rule for the certification of Quality Management Systems in the aerospace sector according to EN9100

Effective from 01/01/2017

RINA
Via Corsica 12
16128 Genova - Italia

tel +39 010 53851
fax +39 010 5351000
web site : www.rina.org

Technical rules

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

Section 1:
Rule for the certification of Quality Management Systems according to EN9100 series 2016 standards.

Section 2:
Rule for the certification of Quality Management Systems according to EN9100 series 2009 standards.

Section 3:
Transition of certification from EN9100 series 2009 to series 2016 standards

CONTENTS

SECTION 1: CERTIFICATION OF QUALITY MANAGEMENT SYSTEMS ACCORDING TO EN9100 SERIES 2016 STANDARDS

CHAPTER 1
GENERAL

1.1

These Rules define the additional and/or substitutive procedures applied by RINA for the certification of Automotive 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.

For any issues not covered in this document, reference should be made to:

- General contract conditions governing system, product and staff
- EN9104-001:2013
- AS 9101 F
- Resolution issued by IAQG and available on www.sae.org
- RT-18 ACCREDIA

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:

EN 9100 series 2016.

The above certificates can be issued both independently and as supplements to ISO 9001:2015 certificates.

If an organisation that is already certified to ISO 9001 requests certification according to the EN 9100 scheme, all the processes must be fully audited on site from an airworthiness point of view. It is therefore not permitted for just the additional requirements with respect to ISO 9001 to be audited.

1.3

Certification is open to all organisations working in the aerospace, space and defence sectors and does not depend on whether they belong to an association or group but just on the type of activity they perform.

The "aerospace sector" (pursuant to the EN 9104 series of Standards) means the entire supply chain concerning the design, development, production, distribution, installation, maintenance and servicing of

products used in aerospace and/or space and/or defence applications. In particular, the reference standards for certification according to the EN 9100 scheme are as follows:

- EN 9100 – Quality Management Systems – Model for quality assurance in design, development, production, installation and servicing: standard applicable to organisations which design, develop and produce any type of system/component for the aerospace sector, including installation and servicing (i.e.: design and construction of aircraft, helicopters and any of their components/parts/systems)
- EN 9110 – Quality Management Systems – Model for quality assurance applicable to maintenance organisations: standard applicable to organisations which undertake maintenance in the aerospace sector (i.e.: maintenance of aircraft and their parts, helicopters and their parts, etc.)
- EN 9120 – Quality Management Systems – Requirements for stockist distributors: standard applicable to organisations which distribute/sell parts, components, materials to clients in the aerospace sector.

1.6

The body guaranteeing the certificates issued by RINA (Accreditation Body) may require its observers to take part in the audits performed by RINA in order to ascertain whether the auditing methods applied by RINA comply with the relative standards. As well as the presence of these observers, the organisation must also allow representatives of the civil and military authorities and/or of the client and/or of the ASD Aerospace and Defence Industries Association) /AIAD (Italian Industries Association for Aerospace, Systems and Defence) / CBMC (Certification Bodies Management Committee) to company RINA personnel during the audits. The participation of these observers is agreed in advance between RINA and the organisation. If the organisation refuses to accept the above, RINA will implement the certificate withdrawal process.

1.7

The terminology used in these Rules is the one indicated in the ISO 9000 UNI CEI EN ISO/IEC 17000 and EN9104-001:2013 standards.

CHAPTER 2
REFERENCE STANDARD / CERTIFICATION REQUIREMENTS

2.1

To obtain RINA certification, a Quality Management System, as far as applicable in relation to the type of product or service in question, must satisfy, both initially and in the long run, the requirements of the reference scheme and those indicated in the following points of the present chapter, as well as the following requirements:

- RT-18 ACCREDIA – Requirements for the accreditation of bodies undertaking certification of Quality Management Systems of companies in the aerospace, security and defence sectors;
- EN 9104 – Aerospace series: Process requirements for aerospace quality management system certification/registration programmes;
- any specific requirements requested by the client

During its accreditation activities, in fact, RINA must abide by certain reference documents issued by the accreditation bodies. These documents can be obtained from RINA or directly from the accreditation bodies (consulting their Internet sites, for example).

2.2

In particular, in order to obtain Quality Management System certification in accordance to aerospace scheme, the organisation must:

2.2.1 Have established a Quality Management System and kept it active in total compliance with the requirements of the EN 9100 certification scheme. A Quality Management System is considered as being fully operative when:

- the internal audit system has been fully implemented and its effectiveness can be demonstrated;
- at least one complete management review of the management system has been carried out and documented,
- the objectives and processes required to obtain results in agreement with client requirements and company policy have been defined,
- these processes have been developed,
- monitoring activities and measurements of the processes and products with respect to the policy, the product objectives and requirements have been performed and registered for at least 12 months,
- actions have been implemented to promote continual process improvement and guarantee constancy in production methods and in the quality of the products or services supplied,
- an analysis has been made of the critical nature of the product and the job, as well as of the relative processes, activities and/or production processes that can affect the full conformity of the product (these preventive risk assessments should at least follow the method proposed by EN 9134). This approach makes it possible to identify the possible dangers deriving from anomalies and define the most appropriate control system, on the basis of the potential effect of these anomalies on safety, reliability and airworthiness requirements, and of the potential or measured frequency of occurrence. The relative operative controls, including audit activities, technical and instrumental checks, as well as the relative registrations, required to manage risk factors must be defined on the basis of this analysis.

2.3

Conformity of the Management System with the reference standard is verified by means of an audit programme comprising.

- an initial audit in two stages,
- a surveillance audit in the first year
- a surveillance audit in the second year
- a certification renewal audit in the third year.

In particular, for the entire certification process and for subsequent surveillance and recertification audits, RINA will use lead auditors (AEA) and auditors (AA) qualified according to the EN 9104-3 standard.

CHAPTER 3
INITIAL CERTIFICATION

3.5

The initial audit comprises two stages:

- Stage 1 audit – performed at the organisation's site
- Stage 2 audit – performed at the organisation's site

During the initial audit, the organisation must demonstrate that the Management System has been fully operational and that it effectively applies the system.

If any significant changes which would impact the management system occur, RINA can consider the need to repeat all or part of stage 1. In this case, RINA inform the Organisation if the results of stage 1 may lead to postponement or cancellation of stage 2.

3.6

In addition to what is stated in section 3.5 of the General Rules for the Certification of Management Systems, the certification process is suspended if major or minor non conformities are found. If at least one or more major and/or minor non-conformities are found, a supplementary audit just be performed within three months in order to check that the proposed corrective action has been applied correctly and effectively; if this audit is successful the certification process is renewed.

Depending on the seriousness and number of findings, RINA may decide to perform a supplementary audit at organisation's site or conduct a documents review of the corrective action taken by the organisation.

If the supplementary audit for checking the proposed corrective action is not performed within three months from the stage 2 audit, RINA reserves the right to terminate the certification procedure and charge the time and money spent up until that moment. In such a case, if the Organisation wishes to proceed with RINA certification, it must submit a new application and repeat the certification procedure.

CHAPTER 4
MANTAINING VALIDITY OF THE CERTIFICATE

4.6

In addition to what is stated in section 4.6 of the General Rules for the Certification of Management Systems, If any non-conformities are found during the surveillance audits, RINA evaluates the management of these non-conformities as follows:

- if major non-conformities are found, the organisation is subjected to a supplementary audit within the deadline established by RINA, depending on the importance of the non-conformities, but always within three months from the surveillance audit;
- if minor non-conformities are found, the organisation may be subjected to a supplementary audit at the auditor's discretion and within the deadline established by RINA. The organisation must always send RINA written evidence to show it has effectively implemented the proposed corrective action and within 60 days from notification of the non-conformities.

Depending on the seriousness and number of findings, RINA may decide to perform a supplementary audit at the organisation's site or conduct a documents review of the corrective action taken by the organisation. If the non-conformities are not eliminated within the established times or if they do not assure the supplied products/services satisfy customer requirements and applicable law, RINA may suspend certification until these non-conformities have been eliminated and, in any case, as specified in point 11.1.

All costs relative to any supplementary audits deriving from shortcomings in the Quality System will be charged to the organisation.

CHAPTER 5
RICERTIFICATION

5.4

In addition to what is stated in section 5.4 of the General Rules for the Certification of Management Systems, if at least one or more major and/or minor non-conformities are found, within a maximum of three months and in any case before the date of expiry of the certificate of conformity, a supplementary audit must be performed in order to ascertain the correct and effective application of the proposed corrective action.

Depending on the seriousness and number of findings, RINA may decide to perform a supplementary audit at the organisation's site or conduct a documents review of the corrective action taken by the organisation.

The established times within which the organisation must perform the supplementary audit are communicated to the organisation in the recertification audit report.

All costs relative to any supplementary audits deriving from shortcomings in the Quality System will be charged to the organisation.

CHAPTER 9
SPECIAL REQUIREMENTS FOR MULTI-SITE ORGANISATIONS (MULTIPLE SITE, CAMPUS, COMPLEX, SEVERAL SITE)

9.1

This paragraph defines the different types of organisational structure when an organisation operates through more than one operational site and in particular:

- Multiple site organisations: an organisation can be defined as multiple site when it minimally meets the requirements of the IAF MD 1 document.
- Campus organisations: an organisation is defined as campus which has identified a central function here specific activities (detailed in annex B of EN9104 standard) are planned, controlled and managed and whose production process of the product/service is decentralised, sequential and linked. In the production process, the output elements of one site are the input elements of another site and the final result is the product/service. Dissimilar processes or activities can be developed in different sites or combination of sites; however, all the sites depend on the same quality management system. A campus can produce one or more products, guaranteeing that these products belong to the same family (>80% similar) and are produced using the same methods and procedures.

- Organizzazioni Several Site: E' definita Several Site, un'Organizzazione che ha identificato una funzione centrale dove specifiche attività (dettagliate in allegato B alla norma EN9104-1) sono pianificate, controllate e gestite ed è composta da una rete di siti dove i processi di ogni sito non sono sostanzialmente simili (<80% simili); i siti possono operare seguendo o non seguendo le stesse procedure e metodologie che devono essere comunque controllate attraverso un unico sistema di gestione per la qualità. I siti realizzano diversi prodotti/servizi.
- Several site organisations: an organisation is defined as several site which has identified a central function where specific activities (detailed in annex B of EN9104 standard) are planned, controlled and managed and which consists of a network of sites in which the processes of each site are not substantially similar (<80% similar); the sites can operate following or not following the same procedures and methods which must, in any case, be controlled through one common quality management system. The sites produce different products/services.
- Complex organisations: an organisation is defined as complex which has identified a central function where specific activities (detailed in annex B of EN9104 standard) are planned, controlled and managed and which can consist of a combination of multiple site, campus and/or several site organisations.

During the contractual assessment stage, through the information sent by the organisation applying for certification, RINA must identify the type of structure and on the basis of this, define case by case how the certification activities are to be carried out, which will be confirmed during the stage 1 audit.

9.2

In the case of certification, regardless of the type of organisational structure, all the sites subject to certification, the head office, all the production sites and any remote sites (e.g.: commercial sites, design centres, etc.) must undergo the stage 2 audit and be audited against the complete and applicable requirements of the quality management standards of the aerospace sector.

Moreover, the stage 1 audit must be performed at the site identified as the headquarters and at a significant number of sites, including the sites which differ in terms of both technology and activities.

In the case of surveillance, if the organisational structure is multiple site, all the sites subject to certification must be audited at least once during the surveillance cycle:

- during the first year of the three-year certification cycle, the head office and 50% of the production sites subject to certification must be audited;
- during the second year of surveillance, the head office and the remaining 50% of the production sites subject to certification must be audited.

In the case of campus, complex or several site organisational structures, on the other hand, all the sites subject to certification must be audited at each surveillance audit.

In recertification, regardless of the type of organisational structure, the head office and all the sites (including the remote sites) subject to certification must be audited against the complete and applicable requirements of the quality management standards of the aerospace sector.

CHAPTER 10
TRANSFER OF ACCREDITATED CERTIFICATES

10.1

In addition to what is stated in section 10.1, transfer of certification always occurs after an audit of the organisation's site as follows:

- if the certificate is to be transferred in the 12 months before its expiry, a complete audit (Stage 1 and Stage 2) is to be carried out;
- if the certificate is to be transferred during the first two years of the certification cycle, an AEA will have to carry out an audit of the organisation's site to confirm validity of the certificate being transferred.

CAPITOLO 11
SOSPENSION, REINSTATEMENT AND WITHDRAWAL OF CERTIFICATION

11.1

The validity of the Certificate of Conformity may be suspended as indicated in the "GENERAL CONTRACT CONDITIONS GOVERNING SYSTEM, PRODUCT AND PERSONNEL CERTIFICATION" and in the following specific cases:

- if the organisation does not allow surveillance or recertification audits to be performed at the requested frequencies;
- if non-conformities are found in the Quality Management System which have not been corrected within the time limits established by RINA and, in any case, not later than 60 days from the date of the audit;
- if the organisation does not observe the deadlines established for the communication of corrective actions, following non-conformities/observations indicated in the audit report;
- if the organisation has made far-reaching changes to its site/s or moves to another site without informing RINA of such changes;
- if the organisation has made significant modifications to its Quality Management System which have not been accepted by RINA;
- the organisation has undergone important re-structuring and has not reported this to RINA;
- if it refuses or obstructs the participation in audits of the observers of the accreditation body and of AIAD-CBMC;
- for evidence that the Quality Management System does not guarantee compliance with the laws and regulations applicable to the activity and/or the site/s;
- notification to the organisation of inadequately managed complaints made by aerospace manufacturer clients;
- payment arrears;
- if the organisation does not define and does not update the data related to the OASIS Administrator throughout the period of validity of the certificate;
- if justified and serious complaints received by RINA are confirmed.

The organisation may also make a justified request to suspend certification, normally for not more than six months and in no case after the date of expiry of the certificate. The recertification audit is to be performed 3 months before the certificate expires.

The suspension will be notified to the organisation in writing, stating the conditions for reinstating certification and the date by which the new conditions are to be complied with.

CHAPTER 13
CONTRACTUAL CONDITION

In addition to the contents of chapters 20 and 21 of the above document concerning the use of the certification logos, organisations certified according to the EN 9100 scheme can use the SCSA-AIAD (Aerospace Sector Certification Scheme) logo on their letterhead and other company documents, such as invoices and brochures, with the following limits:

- il logo è protetto da Copyright e può essere utilizzato solo per indicare il possesso della certificazione EN 9100 / EN 9110 / EN 9120 da parte dell'Organizzazione
- the logo is protected by copyright and can only be used to indicate the organisation's possession of EN 9100, EN 9110, EN 9120 certification;
- minimum dimensions: sufficient to ensure the wording in the logo remains legible;
- maximum dimensions: no particular requirements;
- Colours: only the original ones.

In addition to the contents of chapter 6.2 of the contractual conditions, access to and consultation of the documents concerning certification/ validation and verification are restricted to the functions involved in the certification/validation and verification procedure and to the organisation in question, as well as to the representatives of Accreditation and Control Bodies such as ACCREDIA, ASD, AIAD, JAA and NAA.

Organisations which apply to RINA for certification authorise the latter to make the information related to the certification, surveillance and recertification process available in the OASIS database; this information is divided into TIER 1 (information related to issue of the certificate) or TIER 2 (information related to audit results, non-conformities, corrective actions, suspensions, etc.).

Should an organisation lose certification according to the EN 9100 scheme, it must immediately inform its clients in the aerospace sector.

SECTION 2: RULE FOR THE CERTIFICATION OF QUALITY MANAGEMENT SYSTEMS ACCORDING TO EN9100 SERIES 2009 STANDARDS

Until June 15, 2017 will be able to carry out audits in accordance with the EN9100 series of 2009 standards. For the already certified organizations, who decide to make the surveillance audit / recertification according to the old edition of the 9100 scheme standards, or to the Organization who decide to get certified according to those rules, the contents in section 1 of this Regulation for certification are valid.

SECTION 3: TRANSITION OF CERTIFICATION FROM EN9100 SERIES 2009 TO SERIES 2016 STANDARDS

A.0 - GENERAL

This section applies when an Organization certified in compliance with EN9100 series 2009 standards asks for transition to the new edition of the EN9100 series 2016 standards, following defined as "transition".

To obtain RINA certification in accordance with the new edition of the standards, a Quality Management System must first and henceforth satisfy the requirements of EN9100 series 2016 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 (withcon i tempi di audit calcolati secondo i criteri adottati per l'effettuazione della transizione in concomitanza di un audit di sorveglianza)

As provided by the SR-003 of 12th October, 2016 is not possible perform a transition audit in conjunction with a transfer audit; if the Organization request for it, RINA will carry out the transfer of the certification audit with the issuance of the certificate of conformity and subsequently perform the transition audit.

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

Upon receiving an application for transition, RINA sends to the Organisation document QMS SELF ASSESSMENT QUESTIONNAIRE FOR TRANSITION that must be filled in all its parts, enclosing any necessary documents.

According to the information written in document QMS SELF ASSESSMENT QUESTIONNAIRE FOR TRANSITION, RINA decides whether it is possible to proceed with transition and, i n the presence of an audit time increase, prepares a specific economic offer for the transition audit.

A.2 – PERFORMANCE OF AUDITS

Transition audit is composed by:

- documental review of the elements of change, based on the "SELF ASSESSMENT QUESTIONNAIRE FOR TRANSITION" and on documented information required by EN9100 series 2016 standards
- on-site audit to assess the fulfilment of new requirements of EN9100 series 2016 standards

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 EN9100 series 2016 standards 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 EN9100 series 2009 standards.

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 EN9100 SERIES 2016 STANDARDS

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 previous certification/recertification decision date.

A.4 – VALIDITY OF THE CERTIFICATES IN CONFORMITY WITH EN9100 SERIES 2009 STANDARDS

EN9100 series 2009 certificates will expire on 14th September 2018. After the expiry date of its certificate, an Organization that needs to obtain an EN9100 series 2016 certification, must submit a new application for certification following the requirements of the initial certification.

Publication: RC/C 34
English Edition

RINA
Via Corsica 12
16128 Genova - Italia

tel +39 010 53851
fax +39 010 5351000
web site : www.rina.org

Technical rules