

Spanish ICOP Certification Scheme. Guide for the Self-Assessment of certifiable Scopes as per the Series EN9100 Standards

Procedure- Guide for the Self-
assessment of certifiable Scopes as
per series EN9100 standards

TEDAE QC 9104-006
Edition 05
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Summary

This document:

- Contains a Self-Assessment Guide that offers guidelines for analysis with the purpose of determining whether the corporate purpose of a company fulfills the requirements to request and obtain a certification as per the series EN9100 standard family.
- Does not contain additional requirements for the certification, but rather, reference criteria to be used in determining the applicability of a certification under TEDAE's aerospace and defense scheme to a specific activity.
- Will not be referenced in the scheme certificates issued by the Certification Bodies.

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Distribution Index

- TEDAE RMS Members.
- TEDAE RMS Delegate.
- Certification Body Representatives.

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1. Introduction

The TEDAE RMS (Regional Management Structure) is the body that manages the ICOP certification scheme of the IAQG in Spain, and is responsible for ensuring the scheme's compliance with the series 9104 standards. As part of its responsibilities in relation to the application of the scheme, and given the breadth of activities and services provided by the Aerospace and Defense industries, the Spanish RMS has considered it necessary to issue this Guide for the Self-Evaluation of Certifiable Scopes as per the series EN9100 standards (EN9100, EN9110, EN9115 and EN9120), with the purpose making the certification activity more orderly.

The prologue of the certification standard itself specifies that the series EN9100 standards may also be highly useful for companies in sectors of the industry other than the aerospace sector which require the application of requirements that supplement those of the ISO9001 standard. However, it is necessary to establish and comprehend the differences that exist between the "use" of the standard as a reference for an organization and the specific Aerospace or Defense certification that results in being added to the OASIS database.

This Guide expressly refers to the applicability or eligibility for inclusion in OASIS, since it is over this scope that the RMS exercises its oversight functions.

A body or company will be considered to be certifiable as per the ICOP scheme when, its specific corporate purpose being related to the aerospace industry or the defense material industry, it requires the application of the additional requirements outlined in the series EN9100 standards. Conceptually, this situation takes place when the company engages in the specific design, production or maintenance of a product that is ultimately certified (aircraft, aero engine, space systems or defense armament systems), thereby being partly responsible –with its own certifications– for the ultimate compliance of the overall product.

2. Purpose

The purpose of this Self-Assessment Guide is to offer assessment guidelines to determine whether the activity or corporate purpose of the company meets the necessary requirements to request and obtain a certification as per the series EN9100 standard family.

This series of standards establishes the requirements related to the Aviation, Space and Defense industry Organization Quality System.

As a general rule, an organization must request to get certified within the scope of these standards when its activity includes some significant, instrumental process related to the Design Quality, Production or Maintenance of aeronautical, space or defense products.

Since these scopes can be easily generalized, it is necessary to specify their applicability with the purpose of determining whether the activity is specific for the aerospace or defense industry, and if it is instrumental in the quality of the aviation, space or defense products or systems, determining whether applying the requirements established by the series EN9100 family is required, in addition to those contained in the ISO9001 standard referenced as a basis. If that is the case, it could be positively said that the activity will contribute in some way to the ultimate compliance of the product or service, and that the certifications issued by a quality management system certified as per the series EN9100 standards will offer the added value of objectively guaranteeing the compliance of the design, production and maintenance performed on an aircraft, space system or defense system, whether aerial, naval or land-based.

Notwithstanding the foregoing, the organizations that do not have Aviation, Space or Defense products or services within the scope of their documented management systems may request

to be, and get, certified, in one or more AQMS standards (9100/9110/9115/9120) provided that they operate within the scope of application of the corresponding AQMS standard and when fulfilling all the applicable provisions of the ICOP scheme.

In its disclaimer, the RMS may refuse to address requests filed by those companies whose activity it does not consider to be certifiable in light of the criteria set forth herein, also refusing to include them in OASIS.

Neither the RMS, nor TEDAE, will act as intermediaries between clients and suppliers in possible conflicts related to the applicability of the ICOP certification requirement – they will limit themselves to issue memos or explanatory notes when deemed convenient.

3. Target audience of this Guide

Through TEDAE (Asociación Española de Empresas Tecnológicas de Defensa, Aeronáutica y Espacio), the RMS offers this guide to any natural or legal person wishing to apply for certification under any of the items referenced in series 9100.

The company itself will be required to perform the analysis by carrying out a self-assessment. It is recommended for the assessment to be performed by the persons in charge of Quality within the organization. In case any assistance or clarification is required, you may contact the Certification Body that is assisting you.

It will also be of interest to the purchase and contracting organizations of already-certified companies, with the purpose of determining whether the compliance with EN9100, EN9110, EN9115 and EN9120 is required for their suppliers in their corresponding agreements or purchase orders.

Likewise, it may also be useful for Certification Bodies in the assessment of the scopes of the certification requests that they receive.

4. Assessment Method

There are three possible assessment alternatives based on the type of interested party:

- a) Direct self-assessment performed by the company. Neither TEDAE nor the RMS provide consulting services; however, they will clarify any concern that might emerge and maintain an active oversight over the scopes to be certified so as to ensure the integrity of the scheme. The activity of the company itself will be analyzed as part of the assessment, in order to determine whether it is specifically certifiable and if additional requirements apply. This analysis is independent from the activities of its clients or providers – the scope of the provider or client company may be certifiable, while that of the company itself may not be.
- b) Assessment performed by the company's purchase technicians, with the purpose of evaluating in advance whether its suppliers are required to get certified.
- c) Assessment performed by technicians of the accredited Certification Body, in order to evaluate the acceptance, or otherwise, of a certification request by a potential client.

Following the self-assessment guide is simple, self-explanatory and, based on its guidelines, you will be able to determine whether it is required to submit a request for certification under the series EN9100 standards to an accredited Certification Body, whether the requirement applies to a procurement agreement, or if a certification file is to be accepted for processing.

5. When to perform an Assessment

It is recommended to perform this self-assessment as soon as possible and, as a general rule, before initiating the certification process with the selected accredited Certification Body.

6. Scope

This guide is of limited application within the scope of processes for certification under the series EN9100 standard of the ICOP scheme of the IAQG. Its scope is also limited to the certification processes performed by the Certification Bodies accredited by the ENAC and under the oversight of the TEDAE RMS, both for companies that are located within and outside of Spain.

7. Definitions.

Even though the definitions of the applicable, general terms can be found in the ISO 9000 standard and the International Dictionary of the IAQG –which can be found in its website– for the purposes of this standard, the definitions in use are as follows:

RMS

Regional Management Structure of the Aerospace and Defense certification scheme. Within the scope of this guide, this term refers to TEDAE RMS—the organization within the European EAQG OPMT that is responsible for the compliance with the ICOP scheme as per the series 9104 standards in Spain and in certified locations under the supervision and oversight of TEDAE’s scheme.

Design and development

Set of processes that transform the requirements into specified characteristics or into a product, process or system specification.

Company (Organization)

Any legal entity, or a defined part of a legal entity, with a Quality Management System that is subject to an ICOP audit and its associated certification process.

ENAC

Spanish National Accreditation Body, approved by the European Sector of the IAQG, whose main responsibility is to accredit Certification Bodies to issue certifications in relation to the Aerospace Quality Management System Standards.

IAQG

International Aerospace Quality Group (IAQG). Body integrated by the main Original Equipment Manufacturers of the aviation, space and defense industry, created with the purpose of developing quality requirements and guidelines for use in the industry to which they belong.

ICOP (Industry Controlled Other Party)

Aerospace Quality Management System Standard certification scheme under the direction of the IAQG and the industry, for the evaluation and certification by other parties of the Quality Management System of organizations, as per the requirements set forth in the series 9104 standards.

Maintenance

Performance of activities required to ensure the continued airworthiness of an aircraft or aircraft component, including any combination of inspection, replacement or defect remediation activities and the performance of a modification or repair.

OASIS (Online Aerospace Supplier Information System)

Online Aerospace Supplier Information System (OASIS) database. Network-based computer application of the IAQG that contains information on the various participants of the ICOP Scheme, National Aerospace Industry Associations (NAIAs), Accreditation Bodies, Training Providers, Training Provider Approval Bodies, auditor Authentication Bodies, Aerospace Auditors, Certification Bodies, certified companies and audit results that are approved and recognized by the corresponding SMS (Sector Management Structure) through the ICOP process.

8. Exceptions.

8.1) The following are cases for which, by performing the self-assessment, one can conclude that the activity being evaluated can be certified as per the series EN9100 standards. However, other circumstances may come into play which would make getting certified unnecessary (although possible).

- a) One acceptable exception is when a specific certification already exists for the activity being evaluated, as is the case of testing or calibration laboratories, for example.
- b) Standard consumables: Manufacturers of fluids or other consumables such as fuels, lubricants, etc.
- c) Raw Material Manufacturers (Titanium, Aluminum, Carbon, Fibers, etc.). While generally the production of these raw materials does require certification, there may be exceptions that are to be evaluated by the OEM or the Tier 1 supplier hiring the services, based on the relevance of the component or process in the ultimate quality of the product or service that is being provided.

d) Manufacturers of “Vendor, Catalog or Commercially available Off-The-Shelf items”: these are generally considered to require certification, but there may be exceptions if the item has been determined to have no impact in the quality (retaining threads in internal parts) or if there is a specific certification for the product and company (fluorescent tube).

8.2) Exceptionally, an organization whose activity holds no direct relation with the Aviation, Space and Defense sectors may request to have its management system certified as per an AQMS standard (EN9100, EN9110, EN9115, EN9120), under the following conditions:

a) that it operates within the scope of any certifiable AQMS standard,

and,

b) it must comply with all the applicable provisions of the ICOP (*Industry Controlled Other Party*) scheme as outlined in the series EN9104 standards (EN9104-001, EN9104-002, EN9104-003), and specifically with the following:

- The certified organizations must allow their Certification Body to enter the information in their certificate into the OASIS Database, as public domain (Level 1 Data).
- The certified organizations must allow their Certification Body to enter information regarding audit results, nonconformities, corrective actions, suspensions, etc., into the OASIS database, as private domain (Level 2 Data).
- The certified organizations must provide the Level 2 data to their clients and regulatory agencies upon request, unless justification against it can be provided.
- If the organization loses its certification in any of the AQMS standards, it must immediately notify this fact to its clients.
- The organization must appoint an OASIS database administrator and ensure to notify its Certification Body of any significant changes within the organization.
- The organization must allow the *AB Assessors*, *OP Assessors*, Clients and Regulatory agencies to accompany a Certification body auditor with the purpose of making on-site supervisions or to confirm the efficacy of the Certification Body’s auditing process.

Non-compliance with these provisions by a certified organization will be grounds for its withdrawal from the ICOP scheme and the OASIS database lists.

9. Examples

Below you will find a few examples or typical case of activities and scopes that may or may not be certifiable.

Certification Required:

- The design, production, assembly or processing of parts, etc., as per the requirements outlined in standard EN9100.
EN9115 Supplement: offers a specific clarification of the software requirements associated with products and processes that support the design, development and implementation of deliverable software for Aviation, Space and Defense.
- The maintenance performed on an already-deployed product as per the EN9110 standard
- Distribution with responsibility over testing, lot splitting and certification, adhesives, sealants, raw materials, etc., as per the EN9120 standard.

Certification Not Required:

- In general, the transportation of items for the aviation, space and defense sectors. There may be exceptions (in rare cases) where the transportation is considered to be a special process due to its criticality on the product's compliance and the requirement for maintenance and recording of parameters during the transport.
- In general, manufacturers and suppliers of auxiliary and cutting tools used in the manufacturing processes, assembly or repair of items of the aviation, space and defense sectors.
- Manufacturers and providers of Hardware or Software that is not embedded in the deliverable element.
- Companies that provide specialized labor, dedicated to the manufacturing, assembly or repair of elements of the aviation, space and defense sectors, provided that they are limited to the provision of services involving processes for which certificates are not required. In such cases, the Quality system used to guarantee the activity, and which does require certification, is that of the hiring company to which the services are provided.

SELF-ASSESSMENT GUIDE		
	YES	NO
1) Is the activity that you intend to certify performed by a registered company: which has a registration No., corporate purpose, registered name, etc.?		
1.1. Is the company a legal person (not a natural person)?		
1.2. With full capacity to enter into and be bound by any contract?		
1.3. Incorporated as per the specific, applicable law?		
1.4. Duly registered with the corresponding Company Register?		
<i>Note: The activity of sole proprietors who provide services, regardless of their activity, is not considered to be certifiable. In general, UTEs (Spanish Temporary Joint Ventures), AIEs (Spanish Economic Interest Groups) and community property regimes are not certifiable either, but other types of legal companies, such as Sociedades Anónimas, Sociedades Limitadas, Sociedades Laborales and Cooperatives are certifiable.</i>		
Section 1. If the answer to any of the foregoing questions is NO, do not continue filling out the questionnaire. You are not certifiable.		
2) The corporate purpose of the company must be either partially or fully within the scope of the series EN9100 standards: Design, Production, Maintenance or distribution of aeronautical products, space products or defense weapon systems (including on-board and land-based).		
2.1 Does the company design, develop and/or produce aviation, space or defense products and/or does it offer post-delivery support, including the provision of maintenance, parts or materials, as per EN9100?		
2.1.1 Does the company design, develop and implement deliverable software for Aviation, Space and Defense, as per EN9115?		
2.2 Does the company provide maintenance and repair services for commercial and military aviation products, space or weapon systems, autonomously engaging for this purpose in maintenance, repair and overhaul operations that are independent from the primary product manufacturing operations, as per EN9110?		
2.3 Does the company obtain parts, materials and assemblies that are resold to clients of the aviation, space or defense industry, whether dividing them or not into smaller quantities for resale and certifying their quality and compliance, as per EN9120?		
Section 2. If all answers to the foregoing questions are NO, do not continue filling out the questionnaire. You are not certifiable.		
3) Has the company, either partially or fully, undertaken contractual obligations with its clients in relation to the manufactured product or scope of the maintenance or distribution services rendered?		
4) Does the company certify the design, manufacturing process, final product or rendered service, declaring its compliance with applicable technical specifications (engineering applicable data), with these certifications contributing to... (if the answer is YES to at least one of the following questions, the global answer to question 4 will be YES).		
- the type certification?		
- the airworthiness certification?		
- system space rating?		

SELF-ASSESSMENT GUIDE		
	YES	NO
- weapon system rating (on-board, land-based)?		
Sections 3 and 4. If the answer to the two previous questions is NO, do not continue filling out the questionnaire. You are not certifiable.		
5) The <i>additional requirements</i> outlined in the reference series EN9100 standard (EN9100, EN9110, EN9115, EN9120) must apply to the activity to be certified.		
5.1. In the manufacturing of its product or performance of its service, in addition to the contractual requirements of the client, does the company need to take into account aviation, airworthiness or defense legal and regulatory requirements? (EASA Part 21, EASA Part 145, PECAL)		
5.2. Does the company generate, and is it required to maintain, records that can be used and requested to demonstrate the compliance of a design or product, or their suitability for use in-flight or for defense purposes?		
5.3. Can or could the company's activities have a direct effect on the reliability, availability and maintainability of the aerospace product or weapon system?		
5.4. Do the company's activities in any way configure the product as per any of the following states: <i>as designed, as planned, as built</i> ?		
5.5. Do the company's activities involve relevant risk factors related to the compliance of requirements applicable to aerospace products or defense weapon systems, therefore having the responsibility for ensuring, controlling and managing the variability of any of the key product or process characteristics?		
5.6. Does the company have the responsibility of managing possible work assignments (between providers, outsourcing, etc.)?		
5.7. Does the company have a responsibility in relation to the definition and release a product's design in a way that involves the total or partial specification of its Critical Components and Key Characteristics, specifying the actions to be undertaken?		
5.8. Is the company responsible (directly or indirectly) for the management and performance of tests to verify and validate the product design and development?		
5.9. Do the company's activities include the management of material purchases, processes or components, reception and compliance assessment, lot splitting (or otherwise), and the certification of their compliance and quality before delivery to the client? (including the case of products purchased from sources specified by the Client).		
5.10. As part of the company's activities, does it perform (either directly or delegating the responsibility and execution) the evaluation and selection of providers, the approval and maintenance of its records and approval status, certification of special processes and risk management associated with the selection and use of providers? (In all cases, this refers to the management of providers with certifiable scopes as per the Series EN9100 standards)		
5.11. Does the company's specific corporate purpose require the development and implementation of proprietary procedures for the prevention, detection, elimination and certification related to foreign objects that might affect the product's performance?		
5.12. As part of its activities, does the company perform (either directly or delegating the responsibility and execution) the evaluation and approval of the Process/Production System/First Article Inspection?		

SELF-ASSESSMENT GUIDE		
	YES	NO
5.13. Do the company's activities involve the implementation of configuration changes in the design or product, changes in its state of approval or identification, or product lifespan control?		
5.14. Does the company have a direct or delegated responsibility over the control and maintenance of tracking, measuring and testing equipment involved in validating or verifying the design/product, while managing the associated records?		
5.15. Does the company deliver and certify, either directly or by delegating its responsibility, applicable engineering information or aircraft parts/components or space systems or defense weapon systems?		
<i>If you have answered YES to any of the questions in section 5, the scope is certifiable.</i>		
<i>If the answer to all of the questions of section 5 is NO, the scope is not certifiable.</i>		