GUIDELINE

(ISO 22163)

International Railway Industry Standard IRIS rev 4

按照ISO 22163（IRIS第4版）进行认证流程指南

IRIS™

Certification

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Inhalt

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1.) VALIDITY

This guide governs the conduct of IRIS management system certifications (all types of audits: certification, surveillance, renewal, post-audit) for IRIS rev 4.

This guideline is a supplement to ISO 22163 and the IRIS Certification® Performance Assessment : 2023 and does not replace them.

1.) 有效性

本指南规范 IRIS 第 4 版管理体系认证的实施（涵盖所有审核类型：认证审核、监督审核、再认证审核和后续审核）。

本指南为 ISO 22163 与《IRIS Certification® Performance Assessment : 2023》的补充文件，并不替代上述文件。

2.) GENERAL

The aim of IRIS is to develop and implement a global system for evaluating companies that supply the railway industry. This is intended to standardize the following: Language, assessment guidelines and mutual acceptance of audits, thus creating a high degree of transparency throughout the supply chain.

The IRIS system defines requirements for the content, procedures and evaluation of audits as well as a requirement profile for certification bodies and auditors.

The IRIS certification system is based on the following building blocks:

2.) GENERAL 总则

IRIS 的目标是建立并实施一套全球统一的评价体系，用于评估铁路行业供应商。该体系旨在统一语言、评估指南及审核结果的互认，从而在整个供应链中实现高度透明。

IRIS 体系规定了审核内容、程序和评价方法的要求，并对认证机构和审核员提出了资质要求。

IRIS 认证体系由以下组成部分构成：

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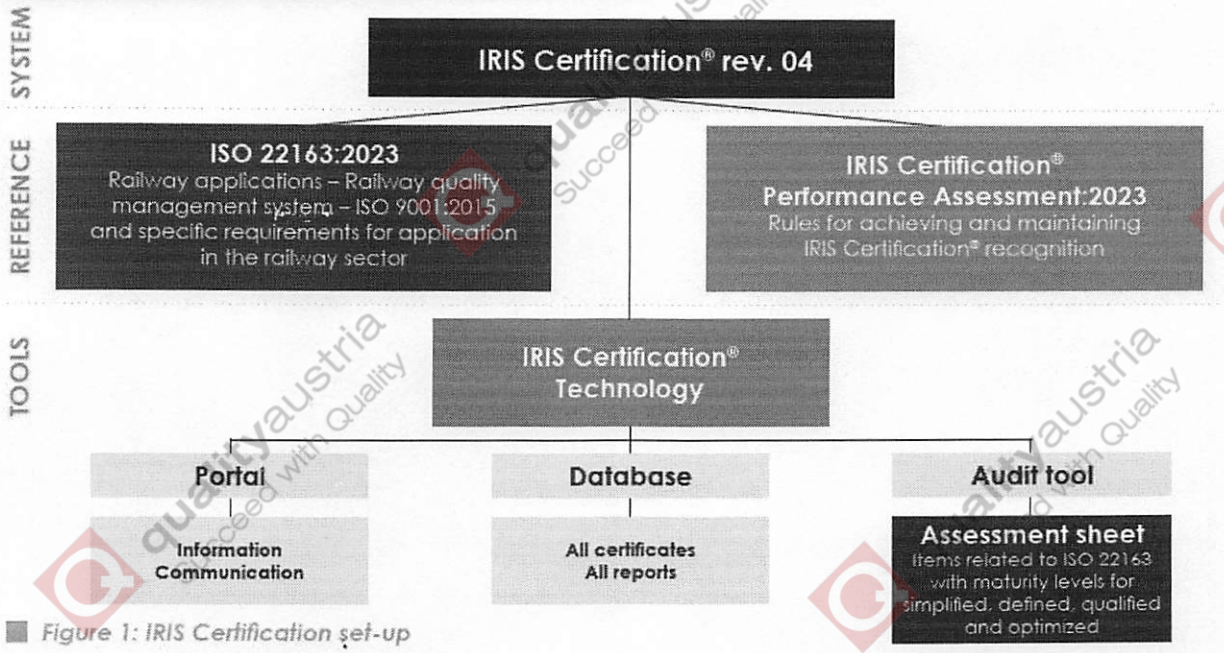

Figure 1: IRIS Certification set-up

(Source: IRIS Certification® Performance assessment:2023; page 5)

The certification according to IRIS can be carried out in combination with a quality, environmental or safety management audit, but can also be implemented independently. The core of ISO 22163 (one of the building blocks of IRIS) is the ISO 9001:2015, which is why companies that have successfully completed an IRIS certification can also apply for and obtain an ISO 9001:2015 certificate

(来源：《IRIS Certification® Performance Assessment: 2023》第 5 页）。

IRIS 认证可与质量、环境或安全管理体系审核结合进行，也可单独实施。ISO 22163（IRIS 组成部分之一）的核心为 ISO 9001:2015，因此顺利通过 IRIS 认证的企业亦可申请并获得 ISO 9001:2015 证书。

2.1 Relevant – applicable – documents 相关 – 适用 – 文件

All regulations to be observed in the course of IRIS certification are defined by the IRIS Management Center in the "IRIS Certification® Performance assessment:2023. These "Rules" are mandatory, and every IRIS auditor is obliged to keep these rules together with the current edition of ISO 22163 during the audits.

The following documents/supplemental information must be taken into account when certifying or submitting offers:

- IRIS Certification® Performance assessment:2023
- IRIS – Audit-tool (online: https://iris-certification.iris-rail.org)
- ISO 22163
- "FO_27_01_247_IRIS Auditplanung Dates" (Excel tool for calculating the minimum times as well es calculation of milestones which are needed to be respected by both: certified company and auditors)
  Note 1: This tool is developed by Quality Austria, is based on IRIS Certification®

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Performance assessment:2023 and will be updated by the IRIS-representative as soon as there are new rules issued by IMC.
Note 2: The minimum-audittime is also mentioned in the diary at the IRIS-portal (www.iris-rail.org)

- IRIS Guidelines → see Quality Austria Intranet → "Informationsplattform" → "IRIS_ISO 22163" The content at this guideline will be updated by the Quality Austria IRIS-product manager.

- RE_27_01_120-1_IRIS-Lessons learned from internal and external audits
(This document includes:
- the basic IRIS-audit-phases,
- the lessons learned from internal/external (witness-)audits; calibration-meetings; audit-report-cross-checks from IMC; internal veto-checks; on any other learning source
- a checklist for the Quality Austria veto-checkers

All terms such as "auditor" are to be understood both male and female.

IRIS 认证过程中需遵守的所有规定均由 IRIS 管理中心在《IRIS Certification® Performance Assessment:2023》中定义。该"规则"具有强制性，每位 IRIS 审核员在审核过程中均有义务携带并遵守这些规则及最新版 ISO 22163 标准。
在进行认证或提交报价时，必须参考以下文件/补充资料：

- 《IRIS Certification® Performance Assessment:2023》
- IRIS – 审核工具（在线链接: https://iris-certification.iris-rail.org）
- ISO 22163
- "FO_27_01_247_IRIS Auditplanung Dates"（用于计算最短审核时间和各个重要时间节点的 Excel 工具，认证企业与审核员均需遵守）
- 备注 1：此工具由 Quality Austria 开发，基于《IRIS Certification® Performance Assessment:2023》，如 IMC 发布新规则，IRIS 代表将进行更新。
- 备注 2：最短审核时间也会在 IRIS 门户网站（www.iris-rail.org）的时间日志中列出。
- IRIS 指南 → 可在 Quality Austria 内部网中查看：
"Informationsplattform" → "IRIS_ISO 22163"
此指南内容由 Quality Austria 的 IRIS 产品经理定期更新。
- RE_27_01_120-1_IRIS 内部与外部审核经验总结文档（该文件包含内容如下）：
  - 基本 IRIS 审核阶段；
  - 来自内部/外部（目击）审核、校准会议、IMC 的审核报告交叉检查、内部否决检查及其他学习来源的经验总结；
  - 供 Quality Austria 否决检查人员使用的检查清单。

所有如"审核员"等术语应理解为包含男性和女性。

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2.2 Quality Austria Certifications 奥地利质量认证

The **quality**austria Certification according to IRIS will basically be performed on site according to a jointly prepared audit plan. The auditors are qualified according to section 4 of this document and hold at least an ISO 9001 Lead Auditor Certificate. The following requirements are taken into account:

- Determination of conformity with the requirements of the IRIS Certification® Performance assessment:2023
- Identification of strengths, weaknesses, opportunities, and risks
- Identification of hidden opportunities and threats
- Maturity assessment based on the assessment checklist

根据 IRIS 的奥地利质量认证（qualityaustria Certification）通常将在现场根据共同制定的审核计划进行。审核员根据本文件第 4 节的规定进行资格认证，且至少持有 ISO 9001 主审核员证书。认证时会考虑以下要求：

- 确认是否符合《IRIS Certification® Performance Assessment:2023》的要求；
- 识别组织的优势、劣势、机会与风险；
- 识别潜在的机遇与威胁；
- 基于评估检查表进行成熟度评估。

2.3 Communication with IMC 与 IRIS 管理中心（IMC）的沟通

The **quality**austria representative (Wolfgang Pölz) attend on the regular meetings organized by IMC (typically two per year). Additionally, he shall contact IMC at least once a year concerning the current and future activity in connection with the Framework Agreement between IMC and **quality**austria.

A deputy for the **quality**austria representative shall be in place. → Mr. Rafael Ziomek

The **quality**austria representative is also responsible for closing and answering CAR's, IAR's and other duties resulting from IMC-witness-audits, office-audits and so on in time.

The **quality**austria IRIS-Representative Certification Body shall inform the IMC about all IRIS related initiatives put in place for communication/marketing/information purpose in media PRIOR to sending the related information to any interested party. The IMC reserves the right to amend such kind of material according to the current version of the System: IRIS Certification® rev.04.

It's within the duty of the **quality**austria representative to inform UNIFE about any major changes in our internal structure within the Certification Process, including, but not limited to, any major changes in the process for the selection of its certification staff (auditors).

On a quarterly basis Quality Austria (IRIS representative) provide to the IMC a yearly forecast for IRIS planning with quarterly updates, whereas the structure of this report is provided by the IMC.

qualityaustria 的代表（Wolfgang Pölz 先生）将定期参加由 IMC 组织的会议（通常每年两次）。此外，他还应每年至少联系一次 IMC，沟通与 IMC 和 qualityaustria 之间的框架协议有关的当前及未来活动。

qualityaustria 需指定一名代表的代理人 → 即 Rafael Ziomek 先生。

该代表还负责及时完成和回复由 IMC 目击审核、办公室审核等所产生的纠正措施报告（CAR）、审核不符合报告（IAR）及其他相关任务。

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qualityaustria 的 IRIS 认证机构代表在将任何与 IRIS 相关的宣传、信息、媒体沟通计划发送给相关方之前，必须提前向 IMC 报备。IMC 保留根据当前《IRIS Certification® rev.04》体系版本修改此类材料的权利。

qualityaustria 的代表还应履行告知义务，向 UNIFE 通报认证流程中内部结构的任何重大变更，包括但不限于其认证人员（审核员）选拔流程的重大变动。

qualityaustria（IRIS 代表）需按季度向 IMC 提供全年 IRIS 规划预测，并每季度更新一次，相关报告结构由 IMC 提供。

3 AKQUISITION 招聘与客户开发

3.1 Target group

In principle, IRIS can be carried out by companies and organisations regardless of their size. Based on chapter 4.1 and 4.2 in IRIS Certification® Performance assessment:2023 the following criteria needs to be met as a minimum:

- Be a legal entity or belong to a corporation,
- Have an autonomous RQMS,
- Have at least three (3) certification activities in the eligible business categories (see the table below),
  Please note: "*Project Management*" and "*Requirements for products and services*" is ALWAYS applicable!
- Be active for one or more of the IRIS Certification product scopes (see below "figure 3"),
- Be located at a single site (or in several sites) with a physical address.

3.1 目标群体

原则上，IRIS 认证适用于各类企业和组织，不受其规模限制。根据《IRIS Certification® Performance Assessment:2023》第 4.1 和 4.2 章节，申请 IRIS 认证的企业必须至少满足以下条件：

- 是一个法人实体，或隶属于某个公司集团；
- 拥有一个自主的铁路质量管理体系（RQMS）；
- 在合格的业务类别中至少具备三（3）项认证活动（见下方表格）；
  请注意："项目管理"以及"产品与服务要求"始终适用！
- 涉及一个或多个 IRIS 认证产品范围（详见下方"图 3"）；
- 设有一个或多个带有实际地址的固定场所。

		Business category						
		Rolling stock	Signaling	Infrastructure	Maintenance	Distributors	Turnkey	Testing and tools
Certification activity	Project management	X	X	X	X	X	X	X
	Requirements for products and services	X	X	X	X	X	X	X
	Design and development for products and services	X	X	X	X		X	X
	Control of externally provided rocesses, products and services	X	X	X	X	X	X	X
	Production and service provision	X	X	X	X			X

(Source: IRIS Certification® Performance assessment:2023; page 9)

Relevant scopes for IRIS-certification:

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		业务类别						
		机车车辆	信令	基础设施维护	经销商	交钥匙工程		测试和工具
认证活动	项目管理	X	X	X	项目管理	X	X	X
	产品和服务的要求	X	X	X	X	X	X	X
	产品和服务的设计和开发	项目管理	项目管理	X	X		X	X
	控制外部提供的流程、产品和服务	项目管理	X	X	项目管理	X	X	X
	生产和提供服务	X	X	X	X			X

资料来源：《IRIS Certification® Performance Assessment:2023》第 9 页)

IRIS 认证相关的适用范围

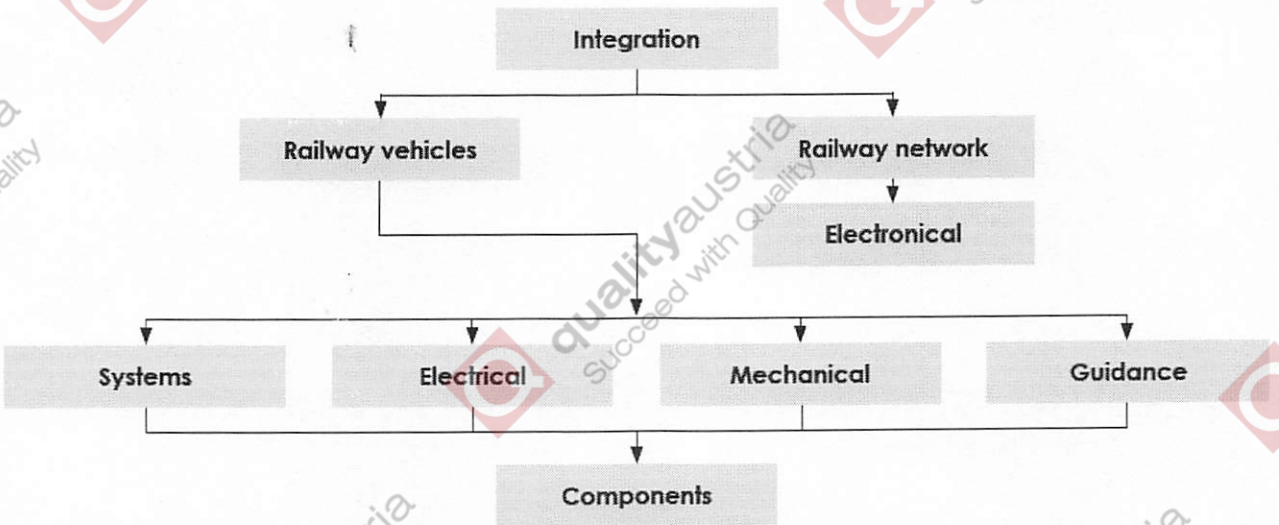

Figure 3: Product scopes for organizations

(Source: IRIS Certification® Performance assessment:2023; page 13)

A detailed overview of related products in the different scopes is shown in TE24EX1_IRIS Rev.04 Product scopes_EN (see also document "C9" in the Quality Austria Intranet → "Informationsplattform" → "IRIS_ISO 22163)

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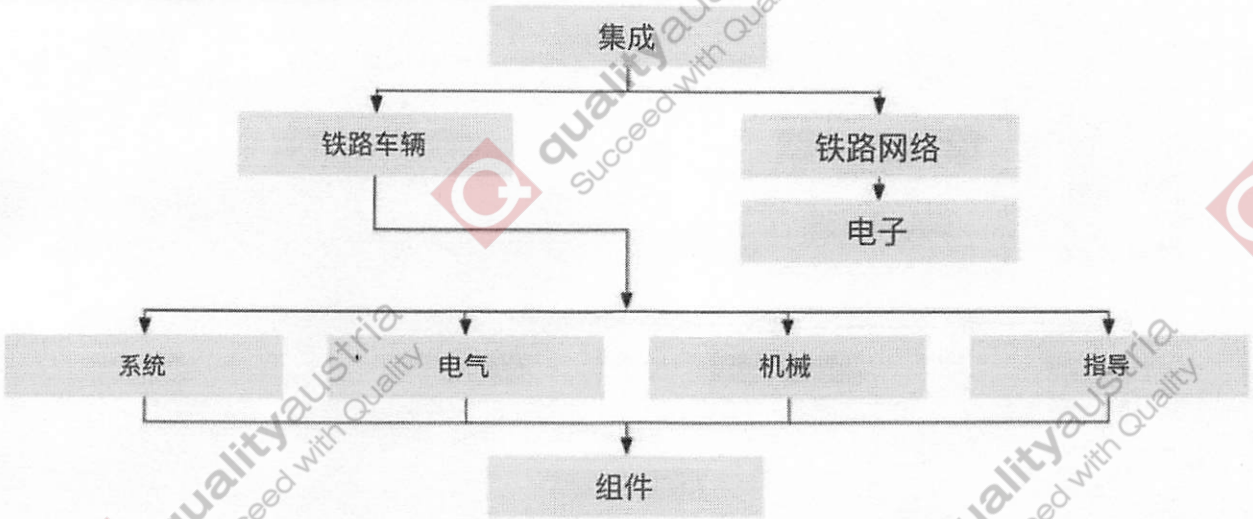

图3：组织的业务范围

资料来源：《IRIS Certification® Performance Assessment:2023》第 13 页)

有关不同认证范围下相关产品的详细概览，请参见 TE24EX1_IRIS Rev.04 Product scopes_EN（也可在 Quality Austria 内部网中查阅"C9"文件：
"Informationsplattform" → "IRIS_ISO 22163"）。

3.2 Contact phase 接洽阶段

3.2.1 Existing **quality**austria customers

In general, the existing Leadauditor is in charge for keeping the contact to the customer. The auditor will be supported by **quality**austria CSC. Whenever topics appear, where IMC needs to be contacted, **quality**austria representative shall be involved.

3.2.1 现有的 qualityaustria 客户

通常由现任的审核组长负责与客户保持联系。审核员将由 qualityaustria 的 CSC（客户服务中心）提供支持。若出现需联系 IRIS 管理中心（IMC）的事项，需有 qualityaustria 代表参与。

3.2.2 New- or customers taken over from other certification bodies

Whenever a new or prospective IRIS-customer is requesting an offer, the **quality**austria representative shall be involved. He is in charge to calculate the offer and to ensure, that the requesting company fulfills at least the minimum criteria (see chapter 3.1 of this guideline). The CSC is supporting the offer-phase and communication with the customers. CSC is responsible to ensure the availability of all needed data.

3.2.2 新客户或从其他认证机构接手的客户

每当有新客户或潜在的 IRIS 客户请求报价时，必须由 qualityaustria 的代表参与。他负责报价的计算，并确保该申请企业至少满足最低准则（参见本指引第 3.1 节）。CSC 负责支持报价阶段并与客户进行沟通，并确保所需的全部数据可用。

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3.3 Offergeneration/Calculation of audittimes 报价生成 / 审核时间的计算

In addition to chapter 5.2 (5.2.1 - 5.2.3) of IRIS Certification® Performance assessment:2023 the excel: "FO_27_01_247_IRIS Auditplanung Dates" is used for the offer-calculation by the **quality**austria representative, which supports the special attention, which has to be given to the minimum audit days defined in the IRIS Certification® Performance assessment although they always can be increased.
For the basic process and involved stakeholders please see: Attachment 5 RE_27_01_120-1_IRIS-Lessons learned from internal and external audits

Note: It is not allowed to invoice the UNIFE fee to the customer 1:1 or to quote it explicitly.

除 IRIS Certification® Performance assessment:2023 第 5.2 节 (5.2.1 - 5.2.3) 外，qualityaustria 代表还需使用 Excel 文件："FO_27_01_247_IRIS Auditplanung Dates" 来进行报价计算，此文件用于支持 IRIS Certification® Performance assessment 中规定的最少审核天数要求（注意：审核天数可以增加，但不能少于最低要求）。
有关基本流程及相关方，请参见附件 5：RE_27_01_120-1_IRIS-Lessons learned from internal and external audits。

注意：不得将 UNIFE 费用 1:1 转嫁给客户，亦不得在报价中明确列出该费用。

3.4 Legal aspects 法律事项

The contractual agreement with the client is based on the General Terms and Conditions of Quality Austria and the submitted offer. By returning the signed offer by the customer, the customer commissions Quality Austria. → see FO_27_01_181e_IRIS Additional Agreement.docx

Attention – International Partners: Quality Austria must always be the contractual partner, due to the fact, that Quality Austria alone is accredited by IRIS Management Center.

与客户签订的合同协议基于 Quality Austria 的《通用条款与条件》以及所提交的报价。当客户签署并返回报价单后，即视为其正式委托 Quality Austria 作为认证机构。
→ 参见文件：FO_27_01_181e_IRIS Additional Agreement.docx

注意 – 国际合作伙伴： 由于仅有 Quality Austria 获得 IRIS 管理中心的认可，因此合同方必须始终为 Quality Austria。

4 AUDITORMANAGEMENT / SCOPE-MANAGEMENT 审核员管理 / 范围管理

4.1 Appointment of IRIS Auditors

Preconditions for IRIS-Auditors are:

- Appointed **quality**austria Lead-auditor at least for ISO 9001 (A1)
- Potential IRIS-Auditors have to have some English skills. Therefore, Quality Austria is going to make interviews in English with the candidates to ensure, they are able to communicate in this language. This is an additional activity to the mandatory English-test mentioned in the Auditor Approval template provided by IMC. An evidence about the oral English competences needs to be archived at the responsible person for auditor appointment at Quality Austria.

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- Potential IRIS-Auditors need profound skills with MS-Teams to be able joining the IRIS-online-Training-modules.

- Auditing experience:
  Candidates shall have participated in at least 4 certification audits as lead auditor or for a minimum of twenty (20) audit days covering all the requirements of ISO 9001 within the last 4 years.

- Work experience:
  Candidates shall have a minimum of 3 years rail experience (operators, system integrators, equipment manufacturer and/or appropriate official rail organization, such as ERA, UNIFE or related national associations) or in similar industries (automotive, aerospace, nuclear, electrotechnic) in the last 15 years and is/was directly involved in engineering, design, purchasing, manufacturing, maintenance, project management, quality, or process control for the respective process scope. Active accredited auditors in QMS schemes of these industries also fulfill the experience.

- These qualification requirements must be documented by the Certification Body and submitted for validation to training participation to the IMC at least thirty (30) calendar days prior to the scheduled training.

- Approvals to join the IRIS-auditor-training-modules are only granted if the potential auditor-candidate has the minimum experience in performing audits as 3rd party auditor. (see F-0010)

- Approval as IRIS-Auditor by IMC
  (Approval-request see **Attachment 1: F-0010 Auditor Approval**)

- To get Leadauditor approval for IRIS the following request shall be used:
  Attachment 2: F-0012 Lead Auditor Request

- Auditors who want to enlarge their field of scopes shall conduct an exam (online at IMC). For requests use: **Attachment 3: F-0011 Scope Extension**

4.1 IRIS 审核员的任命

IRIS 审核员需满足以下前提条件：

- 已被指定为 **Quality Austria** 的审核组长，且至少具备 **ISO 9001（A1）的资格；**

- **具备一定的英语能力。**Quality Austria 将对候选人进行英语面试，以确保其具备基本的口语沟通能力。此要求为 IMC 所提供之《审核员批准模板》中所述英语测试的补充内容。候选人的英语口语能力证据需由 Quality Austria 内部负责审核员任命的人员归档保存。

- **熟练掌握 Microsoft Teams，**以便参加 IRIS 的在线培训模块。

- **审核经验：**候选人在过去四年中需至少参与过 4 次认证审核，并担任审核组长，或累计完成不少于 20 个审核天数，涵盖 ISO 9001 的所有要求。

- **工作经验：**候选人应在过去 15 年中至少具备 3 年铁路行业相关经验（如铁路运营商、系统集成商、设备制造商、或官方铁路组织如 ERA、UNIFE 或相关国家协会），或在类似行业（如汽车、航空、核能、电气工程）中拥有工作经历，且在工程、设计、采购、制造、维护、项目管理、质量或过程控制等相关领域有实际参与。若是这些行业中已获得认可的 QMS 审核员，也视为符合要求。

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- 以上资格要求必须由认证机构记录并在计划培训开始前至少 **30** 个日历日提交至 **IMC** 进行审核与确认。

- 仅当候选审核员具备第三方审核经验时，方可被批准参加 **IRIS** 审核员培训模块。
（参见附件 1：**F-0010** 审核员批准表）

- **IRIS** 审核员的最终批准由 **IMC** 进行。

- 若申请成为 **IRIS** 审核组长，请使用：
附件 2：**F-0012** 审核组长申请表

- 若审核员希望扩展审核领域，需通过 **IMC** 的线上考试。
相关申请请使用：附件 3：**F-0011** 范围扩展申请表

4.2 Ensuring the independence of the auditor 确保审核员的独立性

The independence of the auditor from the organization being audited must be ensured by the auditor. A reference to this is made in the letter of engagement.
The Certification Body hereby guarantees to the IMC that their IRIS auditors have not exercised in the three (3) years prior to the conclusion of this Contract, and shall not exercise during the term hereof, independent advisory or support activities (e.g. consulting services, training, etc., pre-audits and public trainings are excepted and allowed) in IRIS-related areas for or with any Client for whom the Certification Body works within the framework of the Certification Process.
Every IRIS-auditor needs to sign additional conditions for IRIS-auditors (**Attachment 12: RE_05_01_01_06e_Conditons for IRIS auditors / RE_05_01_01_06_Bedingungen für Auditoren IRIS**)

审核员必须确保其与所审核组织之间的独立性。此要求会在委任函中予以明确说明。

认证机构向 IRIS 管理中心（IMC）保证，其 IRIS 审核员在本合同签署前三（3）年内，以及在本合同有效期间内，均未从事也不会从事任何针对其审核客户的 IRIS 相关独立咨询或支持活动（例如：咨询服务、培训等——但预审核和公开培训不在此限制范围内，允许开展）。

每位 IRIS 审核员必须签署 IRIS 审核员附加条件协议.（参见附件 12：
RE_05_01_01_06e_Conditions for IRIS auditors / RE_05_01_01_06_Bedingungen für Auditoren IRIS）

4.3 Auditor-skills 审核员能力

The IRIS auditor approval is valid for three (3) years. Within this period, the IMC is authorized to shorten or cancel the approval status of an IRIS auditor if negative performance of the IRIS-auditor is reported to IMC General Manager.
Each approved IRIS auditor shall carry out at least four (4) IRIS audits per year.

On a yearly basis so called "calibration meetings" shall be held and each IRIS auditor shall attended at least 15 hours of training in 3 years.

Auditors can **develop** through
1) upgrading of qualification (**from auditor to lead auditor**):
if following prerequisites are fulfilled:

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- o 10 IRIS audits performed
- o Audit experience (team leader in 2 schemes),
- o Personal interview, conducted by IMC or its representative

AND, if needed

- o Conditional lead auditor position
- o Witness audit by IMC as validation of capability

IRIS 审核员的批准有效期为三（3）年。在此期间，若 IMC 总经理收到关于某审核员负面表现的报告，IMC 有权缩短其批准期限或撤销其 IRIS 审核员资格。
每位获批的 IRIS 审核员每年必须执行至少四（4）次 IRIS 审核。

每年需举行所谓的"校准会议"（calibration meetings），每位 IRIS 审核员在三年内需至少参与 15 小时的培训。

审核员的能力发展途径：
1）资格升级（从审核员晋升为审核组长）：
需满足以下前提条件：

- 已执行 10 次 IRIS 审核
- 具备审核经验（在两个体系中担任审核组长）
- 通过由 IMC 或其代表进行的面谈

如有需要，

- 先被赋予"条件审核组长"身份
- 通过 IMC 见证审核，以验证其能力

2) **Extension of scopes**. In principle new process scopes can be awarded, if:
扩展审核范围（**Extension of Scopes**）. 原则上，如满足条件，审核员可以被授予新的过程范围。

(Source: IRIS Framework Agreement Amendment 11_2023; page 9)

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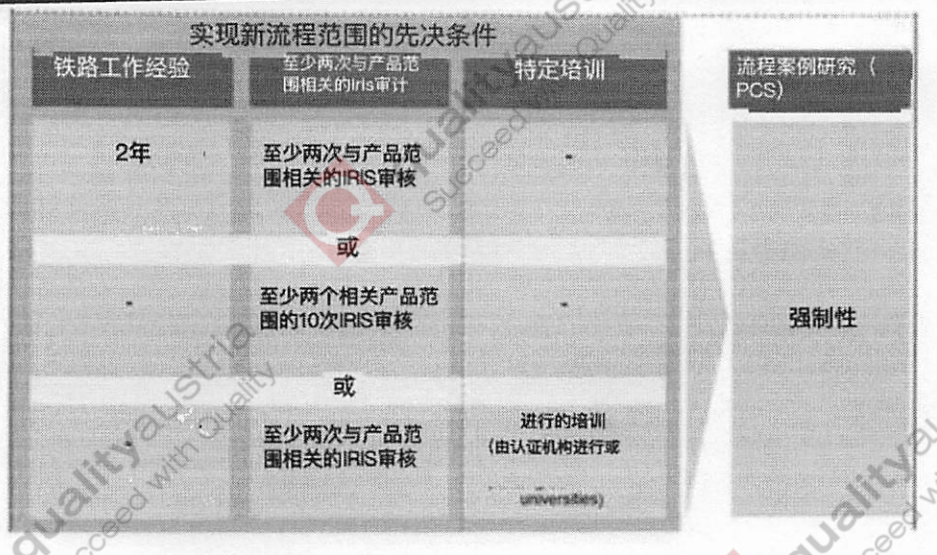

（来源：IRIS 框架协议补充文件 Amendment 11_2023；第 9 页）

4.4 Auditor-toolbox 审核员工具包

Quality Austria supports the IRIS-auditors with the audit-tool-license as well as with the standard (ISO 22163 and the IRIS Certification® Performance assessment:2023).

Quality Austria 为 IRIS 审核员提供审核工具许可证，以及相关标准（ISO 22163 和《IRIS Certification® Performance assessment:2023》）支持。

4.5 Witnessaudits 见证审核

Each IRIS auditor (also for status A2) must be witnessed by another IRIS auditor at least once within 3 years. In general, the Quality Austria - Witness System (documentation in WIS with the respective audit order) - must be used for IRIS audits, too.

Additional witness audits using the checklist "CL 05_01_05_01 Internal witness audits" must be applied by the Product Manager IRIS, if necessary.

Prerequisite for Witness Auditor: Lead Auditor who has been working as IRIS Lead Auditor for at least 3 years

External audits by UNIFE are not counted as internal audits.

The Witness auditor may be part of the audit team.

The CL_05_01_05_01_Witness Audit Auditors must be used.

In addition to the internal witness-audits, IMC will witness each auditor al least once in three years. This can happen during all type of audits, as well as Readiness Reviews, Data reviews, re-audits, performed by Quality Austria at an organizations' site and/or any remote function/site extension, at any time on prior written reasonable notice to the Certification Body (minimum 7 calendar days). We as Certification Body provide assistance and facilitate this. Customers are basically informed about this and agree on that based on a standard-text in the offer.

每位 IRIS 审核员（包括 A2 级别）必须至少每三年接受一次由另一位 IRIS 审核员执行的见证审核。一般情况下，IRIS 审核也必须使用 Quality Austria 的见证审核系统（WIS 系统中与相应审核订单对应的文档记录）。

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如有需要，IRIS 产品经理应使用清单 "CL_05_01_05_01 内部见证审核" 安排额外的见证审核。

见证审核员前提条件：
审核组长，且已作为 IRIS 审核组长工作至少三年。
UNIFE 执行的外部审核不计入内部审核。

见证审核员可作为审核组的一部分参与审核。
必须使用模板：CL_05_01_05_01_Witness Audit Auditors。

除内部见证审核外，IMC 也将在每三年内至少对每位审核员进行一次见证审核。此类见证审核可涵盖所有审核类型，包括现场审核、准备度评审、数据评审、再审核、远程职能或延伸现场审核，均可在提前不少于 7 个日历日书面通知认证机构后执行。我们作为认证机构将协助并配合此项工作。
客户已被明确告知此项要求，并在报价文本中对此达成一致。

4.6 Scopes 审核范围

The IMC is responsible for the evaluation of different professional experience and education, as well as the approval to certain scopes. Depending on the scope approval by IMC, the scope will also be taken over by Quality Austria.

IMC 负责对审核员的专业经验与教育背景进行评估，并批准其审核范围。经 IMC 批准的范围，也将被 Quality Austria 接纳与实施。

4.7 Induction and changes: 审核员引导与变更

For *new IRIS-auditors* an induction in this IRIS-audit-guideline needs to be deployed by the CB-representative. The information about the finalized induction-training needs to be forwarded to the Customer Service Center (i.e. via e-mail).

Whenever *changes concerning IRIS-auditors* happen (i.e.: new/changed scopes; new/changed approval-period; new/changed Auditor-status; and so on), the IRIS-CB-representative shall inform Customer Service Center (i.e. via e-mail).

对新任命的 IRIS 审核员，认证机构代表需对其进行本 IRIS 审核指南的引导培训。培训完成后，需将完成情况通报至客户服务中心（可通过电子邮件）。

每当 IRIS 审核员发生相关变更（如：新增/变更审核范围；新增/变更批准周期；新增/变更审核员状态等），IRIS 认证机构代表需通知客户服务中心（如通过电子邮件）。

4.8 Multi-CB-activities 多认证机构审核活动:

In general Quality Austria do not use Multi-CB-auditors nor do we allow our auditors to work for other CB's. If in exceptional situations such a situation will occur, first the approval of Quality Austria CEO needs to be given. Afterwards the IMC needs to be conducted to get an approval for a specific activity.

通常情况下，Quality Austria 不使用跨认证机构（Multi-CB）审核员，也不允许本机构审核员为其他认证机构工作。如遇特殊情况，需首先获得 Quality Austria 首席执行官（CEO）的批准，随后须联系 IMC 获取对该特定活动的批准。

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4.9 Auditorinformation about changes and news 审核员信息更新与通知

It's the responsibility of the Quality Austria IRIS-representative to keep the IRIS-auditors as well as the IRIS-related colleagues informed. Therefor he shall use the following tools and sources:

Main Sources:

IMC-meetings and newsletters as well as information published at the portal and so on

IRQB-information (Newsletter, Datasheets, and so on) **Audits**:

internal and external Witness-/ office audits **Standards**: i.e

related ISO-standards

Other: every other source, which contains IRIS-audit or -certification related topics

Quality Austria 的 IRIS 代表负责确保所有 IRIS 审核员及相关同事及时获得最新信息。为此，需使用以下信息来源与传播工具：

主要信息来源：

IMC 会议、通讯简报、门户网站发布内容等

IRQB 信息（如：通讯简报、数据表等）

审核相关信息：内部与外部见证审核、办公室审核

标准更新：如相关 ISO 标准

其他涉及 IRIS 审核或认证的所有信息来源

Tools for information:

Mail: Whenever some news (see sources above) occurs, the CB-representative sends an e-mail to alle IRIS-relates colleagues within the Quality Austria network

Calibration meeting: At least once a year, the CB-representative organizes a "calibration-meeting", where all IRIS-auditors (mandatory to join or – if it's not possible for whatever reason – mandatory to walk to the presentation-file) and all other IRIS-related colleagues (voluntarily) participate.

If some non-IRIS-auditor need to join mandatory, it's the CB-representative, who ensures the participation.

Quality Austria knowledge-base: Every (news-)document which has been sent out by mail needs also be uploaded at Quality Austria´s knowledge-base at the Intranet >https://intranet.qualityaustria.com/enabler4BIZ/current/Runtime/Default.aspx?pageid=112< (responsible: CB-representative). At this platform, every IRIS-auditor has access to all IRIS_relevant documents and information.

信息传播工具：

电子邮件：当有上述来源中发布的新信息时，认证机构代表应群发邮件至所有 IRIS 相关同事

校准会议（Calibration Meeting）：认证机构代表应每年至少组织一次 IRIS 校准会议，所有 IRIS 审核员必须参加（若因特殊情况无法参加，则必须查阅演示文档），其他 IRIS 相关同事可自愿参与。

如需强制其他非 IRIS 审核员参与，由认证机构代表负责协调

Quality Austria 知识库（知识共享平台）：所有通过邮件发送的（新）文件也必须上传至 Quality Austria 内部网知识库

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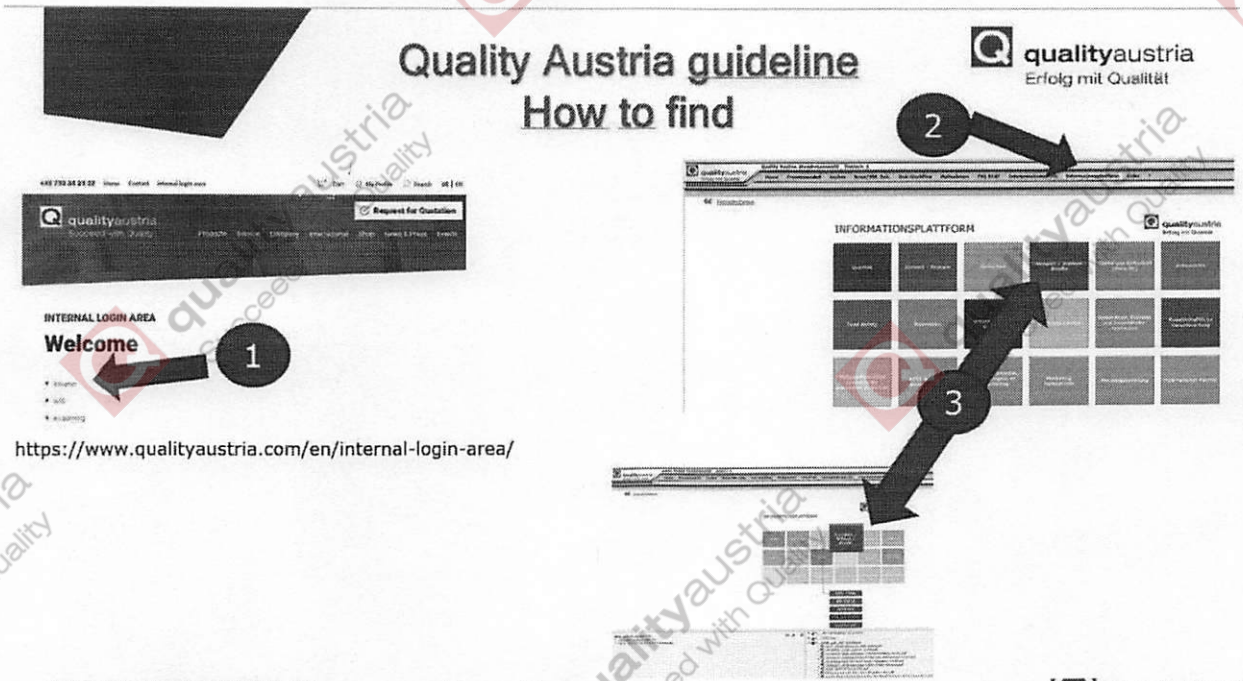
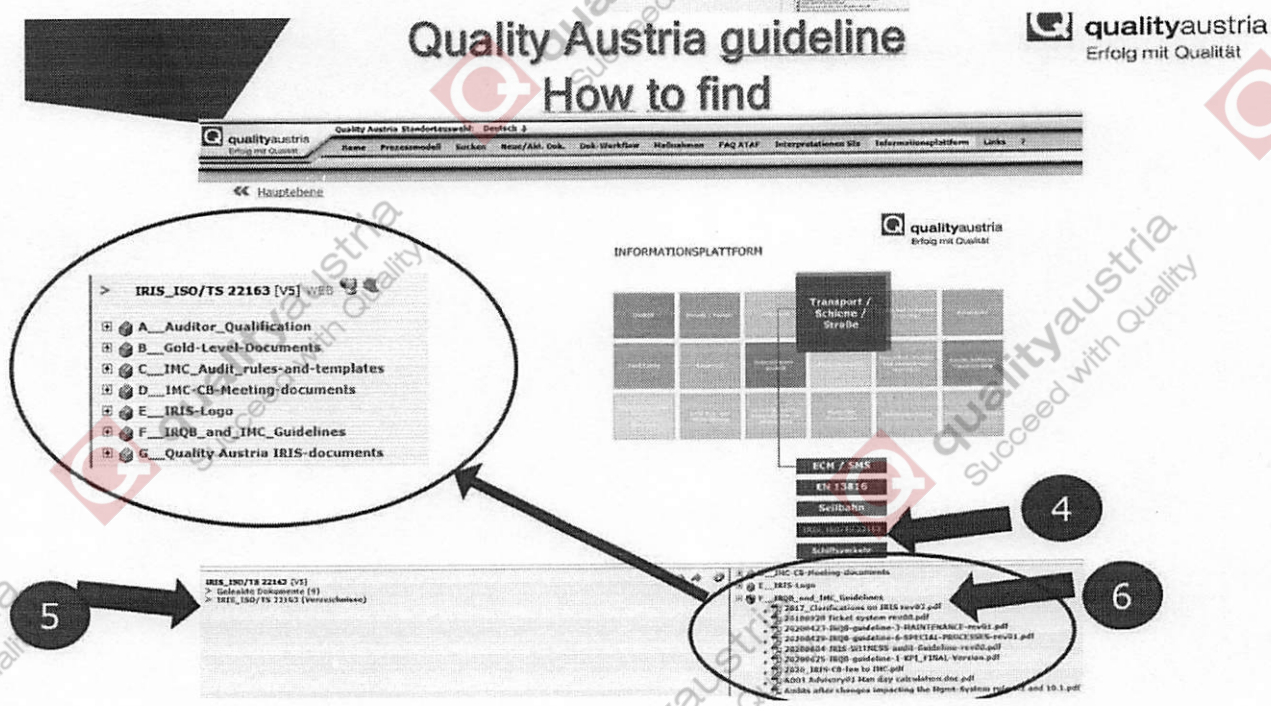
https://intranet.qualityaustria.com/enabler4BIZ/current/Runtime/Default.aspx?pageid=112
（上传责任方：认证机构代表）。所有 IRIS 审核员均可访问此平台获取 IRIS 相关文件与信息。

How to find and structure: "如何查找与组织结构"



https://www.qualityaustria.com/en/internal-login-area/



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5 AUDITPROCESS 审核流程

See: **Attachment 5 RE_27_01_120-1_IRIS-Lessons learned from internal and external audits**

The basic audit-process and necessary steps by the different stakeholders are mentioned in the additional file "RE_27_01_120-1_IRIS-Lessons learned from internal and external audits". This file contains, among other information the steps including relevant tools for the different phases of an IRIS-audit.

参见附件 5：**RE_27_01_120-1_IRIS—来自内部与外部审核的经验教训（Lessons learned）**

基本的审核流程及各相关方需执行的步骤，详见附加文件《RE_27_01_120-1_IRIS—来自内部与外部审核的经验教训》。该文件涵盖了 IRIS 审核各阶段所需步骤及配套使用的相关工具。

5.1 Pre-audit 预审核

It is possible, to perform - on request of our customer - a pre-audit prior to the Readiness Review. A pre-audit is an assessment but it is not part of the IRIS Certification® process.

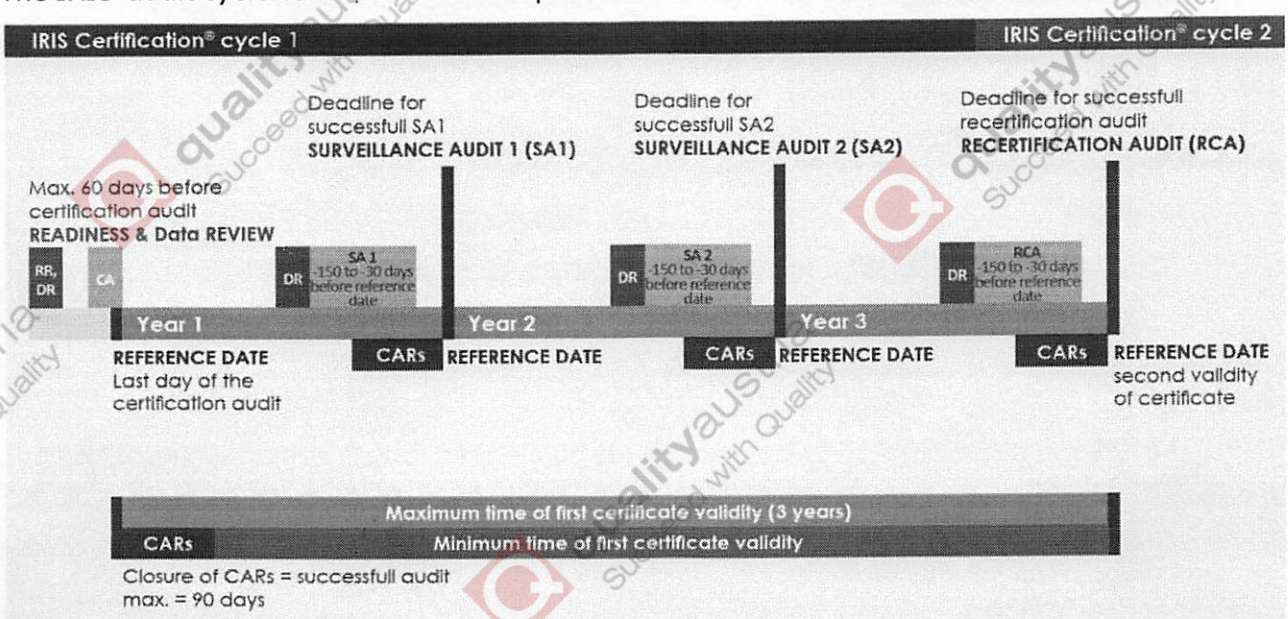
The audit team involved in the pre-audit is not allowed to participate in the readiness review, the certification audit and the first and second surveillance audit. Furthermore, only one pre-audit is allowed.

在客户提出请求的情况下，可以在准备度评审（Readiness Review）之前开展预审核。预审核属于评估性质，但不属于 IRIS Certification® 正式流程的一部分。

参加预审核的审核团队不得参与后续的准备度评审、认证审核以及第一次和第二次监督审核。此外，仅允许执行一次预审核。

5.2 Audit cycle 审核周期

The IRIS-audit cycle contains several important milestones: IRIS 审核周期包含多个关键里程碑



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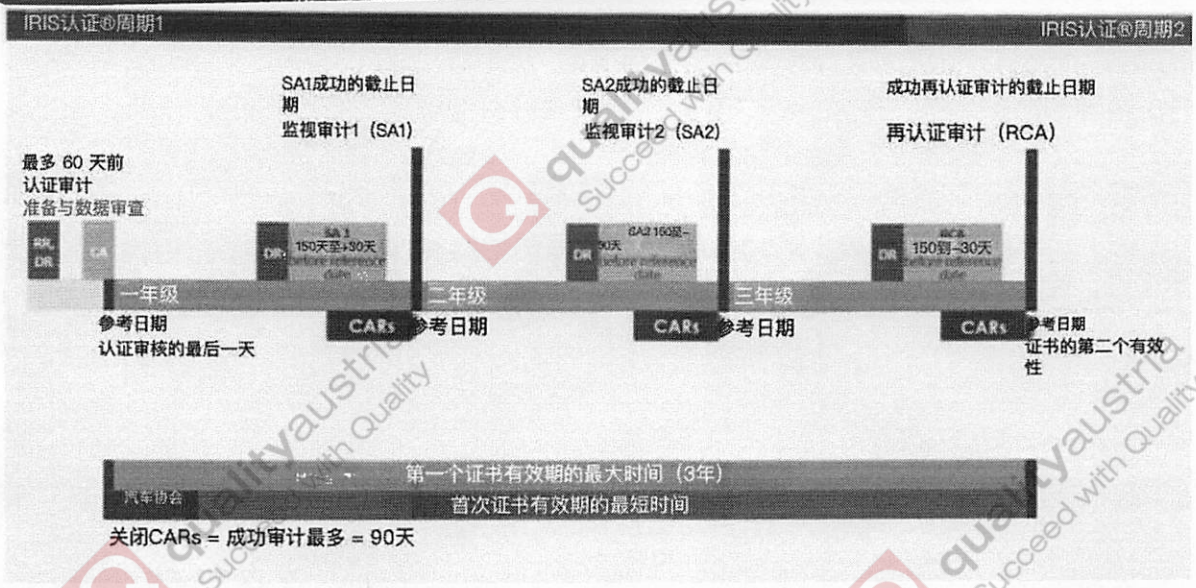

(Source: IRIS Certification® Performance assessment:2023; page 17)

It's important, that the auditdate is scheduled in the IRIS-Portal-diary 60 calender days prior to the audit.
Regarding the processes for company registration and Readiness review, Quality Austria shall not start a Readiness review less than thirty (30) calendar days after the date confirmation in the diary.

The detailed data shall be transferred to the Database within a period of thirty (30) calendar days after the audit was conducted, independent from the audit result (Readiness review, preliminary report).

(来源：《IRIS Certification® Performance assessment:2023》第 17 页)

需特别注意，审核日期必须在审核开始前至少 60 个日历日，提前录入 IRIS 门户系统日历（IRIS-Portal-diary）。
关于企业注册和准备度评审流程，Quality Austria 不得在 IRIS 门户日历中确认日期后的 30 个日历日内启动准备度评审。

无论审核结果如何（包括准备度评审或初步报告），所有详细数据必须在审核结束后 30 个日历日内录入数据库（IRIS Database）。

5.3 Veto-Check 否决审核

The list of veto officers is contained in document "RE_02_01_04_Veto checkers". The Certification Body - Representative (Wolfgang Pölz) must also inform the IMC of the current status or changes.

IRIS-Veto-Checkers need an additional account at the IRIS-portal as well as a training by IMC including a positive exam.

Once the audit is completed, with all activities described in the audit plan carried out, and the audit report has been finalized, the lead auditor shall upload in WIS the following documents and information, as a minimum:

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a) the audit file,
b) the audit report,
c) the annexes to the audit report,
d) the list of CARs/IARs, including eventual comments on the CARs and IARs and information about their follow-up,
e) confirmation of the information provided to the certification body used in the preparation phase.

The target of the documental veto check is to verify the completeness and accuracy of relevant data. Therefor vetocheckers need to use the Veto-Checklist (3rd worksheet in the document RE_27_01_120-1_IRIS-Lessons learned from internal and external audits). It's intended as help during the veto-check, but it's not necessary to be filled in during every check nor is it required to upload it at WIS, but it's necessary and required, that every aspect of this checklist is checked, before you sign the veto at WIS.
Please note, that some helpful information also can be found in worksheet 1 "IRIS-audits". Therefor the CL was integrated in this file.

否决人员名单见文件《RE_02_01_04_Veto checkers》。认证机构代表（Wolfgang Pölz）必须将当前名单或变更情况及时告知 IMC。

IRIS 否决审核员需在 IRIS 门户系统中拥有额外账户，并接受 IMC 提供的培训且通过考试。

一旦审核结束，且审核计划中的所有活动已执行完毕，审核报告也已完成，审核组长必须至少在 WIS 系统中上传以下文件和信息：

a) 审核文件包
b) 审核报告
c) 审核报告的附件
d) 不符合项（CARs/IARs）清单，包括对不符合项的评论及后续处理信息
e) 准备阶段所用的客户信息确认文件

否决审核的目标是验证相关数据的完整性和准确性。因此，否决审核员需参考文件《RE_27_01_120-1_IRIS—来自内部与外部审核的经验教训》第三工作表中的 Veto 审核清单（Veto-Checklist）。该清单用于协助审核过程，不要求每次都填写或上传至 WIS，但在 WIS 上签署否决前，清单中的每一项都必须被逐一核查。

请注意，第一工作表 "IRIS-audits" 中也包含有用信息，因此清单被整合进此文件中。

5.4 Transfer-audit 转移审核

If the audit is a so called "takeover-audit", which means the previous audit has been held by another certification body, the auditteam has to ensure, that the actions from the last audit are also part of the auditplan and the current audit. The previous auditreport and action-list shall be checked.
如果该审核属于所谓的"接手审核"（takeover-audit），即上一次审核是由其他认证机构执行的，审核团队必须确保上次审核中提出的措施被纳入当前的审核计划及审核内容。

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上次的审核报告及整改措施清单必须被审核并验证。

5.5 Remote audits 远程审核

If there is any need for performing a (semi-)remote audit, the chapter 7.2 of "IRIS Certification® Performance assessment:2023" needs to be considered.

如有需要进行（半）远程审核的情况，**必须遵循《IRIS Certification® Performance assessment:2023》第 7.2 节的要求。**

Type of audit	On-site	Semi-remote	Remote	Restriction
Data review	X		X	
Readiness review	X		X	
Certification audit	X	X	Waiver	*
Surveillance audit	X	X	X	**
Recertification audit	X	X	X	**
Re-Audit	X		Waiver	
Transfer audit	X	X	Waiver	*
Changes of the RQMS	X	X	Waiver	*
Remote function	X	X	X	
Site extension	X		Waiver	*
Guiding function	X	X	X	

RESTRICTIONS:

* only remote in exceptional cases (war, pandemic, risk assessment) after formal approval of IMC.

** following clauses shall be audited on-site:

- ISO 22163 clause 7.1.5 monitoring and measuring resources,
- ISO 22163 clause 8.4.2.2 EPPPS verification after release,
- ISO 22163 clause 8.5 Production and service provision,
- ISO 22163 clause 8.6 Release of products and services,
- ISO 22163 clause 8.7 Control of nonconforming outputs,
- ISO 22163 clause 8.9 First article inspection (except EPPPS).

Table 11: Auditing methods

(Source: IRIS Certification® Performance assessment:2023; page 28)

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审计类型	现场	半远程	遥远的	限制
数据审查	X		X	
准备状态审查	X		X	
认证审核	X	X	放弃	*
监督审计	X	X	X	**
再认证审计	X	X	X	**
重新审计	X		放弃	
转账审计	X	X	放弃	*
RQMS的变化	X	X	放弃	*
远程功能	X	X	X	
站点扩展	X		放弃	*
引导功能	X	X	X	

限制条件：

*只有在特殊情况下（战争、流行病、风险评估），经部际委员会正式核准后，方可远程使用。

** 以下条款将在现场进行审计：

· ISO 22163 条款 7.1.5 监测和测量资源，

· ISO 22163 条款 8.4.2.2 发布后 EPPPS 验证，

· ISO 22163 第8.5条 生产和服务提供，

· ISO 22163 条款 8.6 产品和服务的发布

· ISO 22163 条款 8.7 对不合格输出的控制

· ISO 22163 条款 8.9 首件检验（除 EPPPS 外）。

表11：审计方法

(来源：《IRIS Certification® Performance assessment:2023》第 28 页)

5.6 Audits after changes at the company (Certification rules chapter 6.2) 客户发生变更后的审核（参见《认证规则》第 6.2 节）：

To assess the impact of the changes on the business management system, the **template** (Attachment 11: C8_TE24EX1_Changes on RQMS_EN_rev00) **has to be filled in by the organization and evaluated by the lead auditor**, sixty (60) calendar days prior to the audit.

In these three (3) cases,

- change of location (manufacturing, design, maintenance),
- additional IRIS Certification® scope of certification,
- change of main ownership

a readiness review is mandatory and a minimum of three (3) months data and retained documented information shall be available for the related IRIS activities within the scope of certification before this audit can be performed.

The **lead auditor** shall ensure that following information is available on the template:

- geographical constraints,
- transfer of manpower, machines, techniques, processes, etc.,
- any further needed information to ensure a proper audit execution.

In case the total amount of the points assessed in the template (see Appendix 9) is ten (10) or more points, the minimum number of audit days for this type of audit shall be equivalent to a recertification audit

为评估变更对业务管理体系的影响，组织需填写模板（附件 11：C8_TE24EX1_Changes on RQMS_EN_rev00），并由审核组长在审核前至少六十（60）个日历日完成评估。

在以下三（3）种情况下：

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效等级证书（铜、银、金）。
这两份证书均由 IMC 颁发，并通过 IRIS 门户供客户下载。
批准后的证书将以 "xxx.pdf" 的形式由 CSC 发送给客户。
客户如需申请 ISO 9001:2015 证书，可提出请求。在此情况下，需与客户确认并填写独立证书申请表：FO_27_01_010-4_Certificate print order。
IRIS 证书的有效期为三年，需包含以下信息（详见《IRIS Certification® Performance assessment:2023》第 14.1 节）：

- IRIS Certification® 标志
- IRIS 业务类别
- IRIS 产品范围

5.10 Performance Levels 绩效等级

Performance level documents will be issued on a yearly basis by IMC, after successfully passed audit. (see 14.2 IRIS Certification® Performance assessment:2023)

Please take special care of:

a) Customers are the most important stakeholders of the organization
   a. Their needs and expectations
   b. Relevant actions from the organization to scope with
   c. How does the organization deal with feedback from customers?
   d. Relevant customer perception KPI's
b) During the audit projects / orders of at least two main customers shall be selected
c) Strong focus on PI's → "customer satisfaction; customer on time delivery, nonconformities raised by the customer"
d) During the performance-evaluation the focus for the PI's is on the relevance in respect to the stakeholder-needs / -requirements and not on the "easy to calculate"
e) During the readiness review we need to check, if the Customer has bought the IRIS Certification® Performance assessment:2023 as well as the ISO22163(!)
f) The performance-level will be awarded every year - as it is since the beginning of the Performance-level-system. The company to be certified can get every year a different level, which is shown at the IRIS-portal (https://www.iris-rail.org)

IMC 每年将根据成功通过审核的结果，签发绩效等级文件（详见《IRIS Certification® Performance assessment:2023》第 14.2 节）。

请特别注意以下事项：

a) 客户是组织最关键的相关方
   a) 客户的需求与期望
   b) 组织为满足这些需求所采取的行动
   c) 组织如何处理客户反馈
   d) 与客户感知相关的关键绩效指标（KPI）
b) 在审核期间，必须选择至少两位主要客户的项目/订单进行评估
c) 强烈关注 PI（绩效指标）方面，例如：
→ 客户满意度、客户交付准时率、客户提出的不符合项等
d) 在绩效评估中，重点应放在 PI 与利益相关方需求之间的相关性，而非计算是否简单
e) 在准备度评审中，必须确认客户是否已购买《IRIS Certification® Performance

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- 地点变更（包括制造、设计或维护）
- IRIS 认证范围的扩展
- 主要所有权的变更

必须执行准备度评审（Readiness Review），且在进行此次审核之前，须提供至少三（3）个月的数据及保留的文件记录，涵盖 IRIS 认证范围内的相关活动。

审核组长应确保模板中包含以下信息：

- 地理位置限制条件
- 人员、设备、技术、流程等的转移情况
- 确保审核顺利执行所需的其他信息

5.7 Waivers 例外申请

If - for whatever reason - it should be necessary to apply for a waiver at the IMC (e.g. use of an auditor with missing scope), please contact the Certification Body Representative (Wolfgang Pölz). The Certification Body Representative applies for this change to the IMC using Attachment 13: Waiver request form template rev01.

若因任何原因需向 IRIS 管理中心（IMC）申请例外（如使用审核范围不符合要求的审核员），请联系认证机构代表 Wolfgang Pölz。认证机构代表将使用附件 13：Waiver 申请表模板 rev01 向 IMC 提出申请。

5.8 Completion of the audit, billing 审核完成与费用结算

After completion of the audit / on-site assessment, all relevant documents are uploaded into the WIS and the assignment is completed by the auditor.

审核或现场评估完成后，所有相关文件需上传至 WIS 系统，审核员将完成该审核任务。

5.9 Certificate 证书

The customer receives an IRIS certificate and, if the threshold of the relevant maturity-levels are reached, also a Quality Performance Level certificate (bronze - silver - gold) if the result is positive. Both are granted by IMC and made available for download in the IRIS portal for the customer.
The approved certificate is sent to the customer by the CSC as a "xxx.pdf" file.
Customers can also obtain an ISO 9001:2015 certificate upon request. In this case, a separate certificate application (FO_27_01_010-4_Certificate print order) must be agreed with the customer.
An IRIS-certificate is valid for three years and shall contain (see 14.1 IRIS Certification® Performance assessment:2023):

- IRIS Certification® logo
- IRIS business categories
- the IRIS product scopes

若审核结果为正面，客户将获得一份 IRIS 证书，并在达到相应成熟度等级门槛的情况下，同时获得质量绩

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assessment:2023》以及 ISO 22163 标准

f) 绩效等级为 每年颁发一次，与绩效等级制度设立之初一致。被认证企业每年可能获得不同等级，**该等级将显示在 IRIS 门户网站（https://www.iris-rail.org）**。

5.11 Handling and use of the IRIS-portal diary (for audit-planning) IRIS 门户日历（diary）的使用与管理（用于审核计划）

All IRIS-audits needs to be planned within the Quality Austria database as well as in the IRIS-portal – diary. Next you'll find a short description about the handling of the diary. Please note, this is only relevant for those, who are planning audits in the UNIFE-IMC-diary (CB-Representative or his debuty).
所有 IRIS 审核必须同时在 Quality Austria 数据库以及 IRIS 门户系统的日历（IRIS-portal – diary）中进行规划。以下是关于该日历操作的简要说明。请注意：此部分仅适用于在 UNIFE-IMC 日历中进行审核计划的人员（即认证机构代表或其代理人）。

For Planning the following situations are possible 审核计划适用情况如下表:

<table>
<tr><th></th><th>New customer 新客户</th><th>Existing customer 现有客户</th></tr>
<tr><td>Certification
认证审核</td><td>Readiness-Review + "stage 2- audit"
准备度评审 + 第二阶段审核（stage audit）</td><td></td></tr>
<tr><td>Surveillance
监督审核</td><td rowspan="2">Only in case of transfer-audits (see IRIS-certification-rules section 6.1) → Readiness review is mandatory (!)
仅限于转移审核（参见 IRIS 认证规则第 6.1 节）→ 准备度评审为强制要求</td><td>Readiness-Review is only necessary if changes according to IRIS-certification-rules section 6.2 occur)
仅当发生 IRIS 认证规则第 6.2 节所列变更时才需要准备度评审</td></tr>
<tr><td>Renewal
再认证审核</td><td>Readiness-Review is optional.
Leadauditor needs to decide previous to the planning.
准备度评审为可选，是否执行由审核组长在计划前决定</td></tr>
<tr><td>Changes of the plan (update-request)
审核计划变更（更新请求）</td><td colspan="2">Only possible for already planned audits; Reason for change/ cancel needs to be chosen 仅适用于已规划的审核；必须选择更改或取消的理由</td></tr>
</table>

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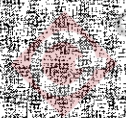
Cancel of an audit
取消审核



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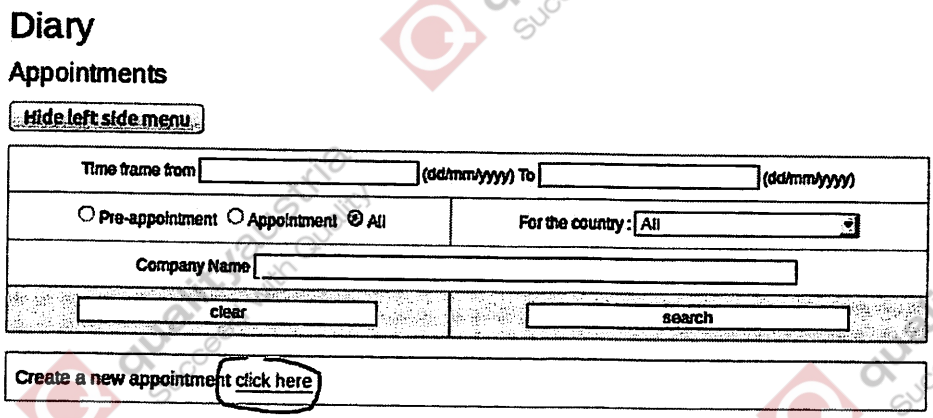
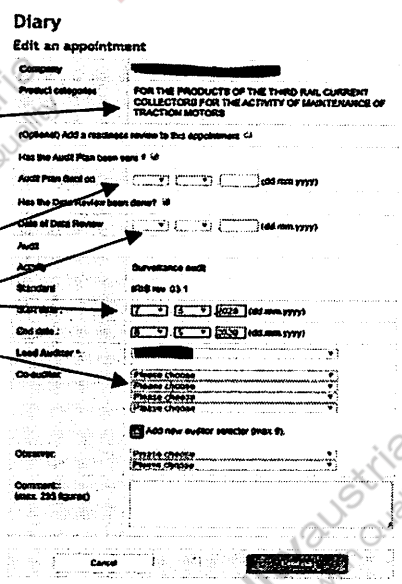
a) Planning an audit for a new customer: → create a new appointment 为新客户安排审核 → 创建新预约



b) Planning of an audit 安排审核

For new customers it must be ensured, that the product-description is entered in the customer data "product categories" in the below shown picture). (see
对于新客户，必须确保客户资料中已填写产品描述（见下图中的"产品类别"字段）

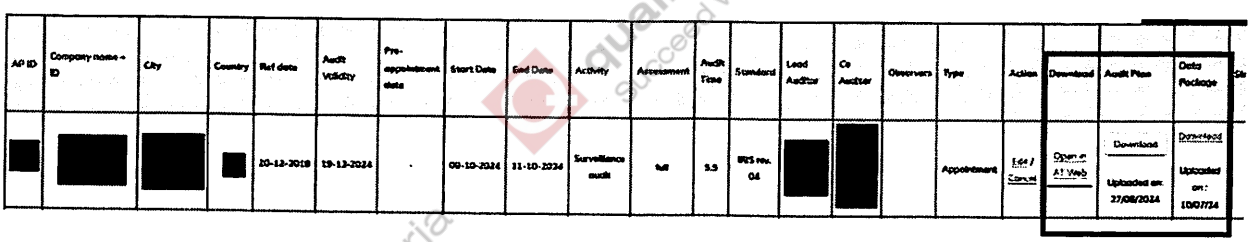


For a new audit - independent from the audittype - the auditdate as well as the auditors need to be entered.
对于一次新的审核 —— 无论审核类型为何 —— 都必须录入审核日期及审核员信息。

The Leadauditor shall inform the planner about the date, when the auditplan will be sent as well as when the data-review will take place / has take place. Both data also needs to be entered.
审核组长应告知计划员以下两项时间点：审核计划的发送日期，数据评审将进行或已进行的时间
这两个时间也必须录入系统。

c) *Auditplan-template and audittool* 审核计划模板与审核工具

After these dates are entered and the company to be audited has checked their master data, it's possible to upload the auditplan-template (FO_27_01_239e Audit Plan-IRIS).
以上信息录入后，且客户已核对其主数据，便可上传审核计划模板：FO_27_01_239e Audit Plan-IRIS



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After the plan was uploaded and the company has checked the masterdata, it's possible and necessary to "click" "open in ATWeb". This will enable the auditor to see the audit in the IRIS audit-tool-web (https://iris-certification.iris-rail.org/#/login)

The detailed process (swimlane) of the whole process-steps and different roles are shown RE_27_01_120-1_IRIS-Lessons learned from internal and external audits

审核计划上传且客户确认主数据后，必须点击 "open in ATWeb"，以便在 IRIS 审核工具网站中查看审核任务：
https://iris-certification.iris-rail.org/#/login

审核的详细流程与各角色任务，请参见：
RE_27_01_120-1_IRIS – 来自内部与外部审核的经验教训（Lessons learned）

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6 ADDITIONAL APPLICABLE DOCUMENTS

- RE_25_03_01_Mindestzeiten Audits
- FO_27_01_181e_IRIS Additional Agreement.docx

The following applicable documents are standard documents of UNIFE. They are available at **quality**austria Intranet – Infoplattform at the following topic:

- Attachment 1 → F-0010 Auditor Approval (Issue: v2021_rev00)
- Attachment 2 → F-0012 Lead Auditor Request (Issue: v2021_rev00)
- Attachment 3 → F-0011 Scope Extension (Issue: v2021_rev00)
- Attachment 4 → deleted
- Attachment 5 → RE_27_01_120-1_IRIS Lessons learned from internal and external audits
- Attachment 6 → deleted
- Attachment 7 → F-0013 CB Change (Issue: v2021_rev00)
- Attachment 8 → deleted
- Attachment 9 → deleted
- Attachment 10: deleted
- Attachment 11: C8_TE24EX1_Changes on RQMS_EN_rev00
- Attachment 12: RE_05_01_01_06e_Conditons for IRIS auditors (English)
- Attachment 12: RE_05_01_01_06_Bedingungen für Auditoren IRIS (German)
- Attachment 13: Waiver request form template rev01
- Attachment 14: auditplan-template FO_27_01_239e Audit Plan-IRIS

6 其他适用文件

- RE_25_03_01 最少审核时间（Mindestzeiten Audits）
- FO_27_01_181e_IRIS Additional Agreement.docx

UNIFE 标准文件（可在 Quality Austria 内部网 Info-Plattform 获取）：

- 附件 1：F-0010 审核员批准表（v2021_rev00）
- 附件 2：F-0012 审核组长申请表（v2021_rev00）
- 附件 3：F-0011 审核范围扩展申请表（v2021_rev00）
- 附件 4：已删除
- 附件 5：RE_27_01_120-1_IRIS 内外部审核经验教训
- 附件 6~10：已删除
- 附件 11：C8_TE24EX1_Changes on RQMS_EN_rev00（变更评估模板）
- 附件 12（英文版）：RE_05_01_01_06e_IRIS 审核员条件
- 附件 12（德文版）：RE_05_01_01_06_Bedingungen für Auditoren IRIS
- 附件 13：Waiver 申请表模板 rev01
- 附件 14：FO_27_01_239e IRIS 审核计划模板

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