

IRIS BECOMES ISO/TS 22163 – DEKRA RESPONDS TO FREQUENTLY ASKED QUESTIONS

The successor to IRIS, ISO/TS 22163, was published in May 2017. This involves a number of new challenges, which you should deal with in good time, if you don't want to put your ticket to the railroad business in jeopardy. In the following we have compiled a list of what we consider to be the most important questions, and the answers to them.

Should you have any further questions after reading this and would be interested in more detailed information on this subject in the form of a webinar, then please email us at the following address:

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1. By when do I have to make the transition to ISO/TS 22163?

The transition to ISO/TS 22163 must be successfully completed by no later than 14 September 2018. Existing IRIS certificates will expire on this date. This also applies to certificates that have a later expiration date, because, notably, the basis of this procedure, ISO 9001:2008, shall no longer be valid.

Audits carried out after 14 September 2018 must be performed as a first-time certification audit, without a reduction for an existing IRIS certificate. In this case, please also note the expiry dates of your ISO 9001: 2008 certificate.

2. UNIFE has presented two options for the transition strategy. What does this mean for my company?

Option 1 is based on the next upcoming audit being conducted as a transition audit (to the new standard), regardless of whether it is a recertification audit or a monitoring audit. The reference date shall be maintained in this option.

Option 2 is based on the next audit not being carried out within the time window of the reference date. Your company will then be given a new reference date, and in this case the new reference date will be the last day of your transition audit. In future, this date will be date for your company's audit planning. With this option, there may be a period where your company does not have a valid certificate, but, if this is the case, we will be happy to provide you with a letter of confirmation, stating that you are undergoing the certification procedure.

The significant date for audit planning will be the reference date. The reference date is the last day of the first-time certification to IRIS and can be found on the first page of your IRIS audit report.

If you have decided on **Option 1**, UNIFE recommends that you plan the audit 90 days before the reference date. This will give you sufficient time

for deviation management, in the event of any deviations.

With both options, a 20% bonus will be deducted from the cost of a first-time certification audit for the existing IRIS certificate. (Only applicable for companies with more than 46 employees)

3. What effects will transition to the new ISO/TS 22163 have?

The start of the transition audit will start a new certificate cycle, i.e., your certificate will be valid for 3 years and there will be two monitoring audits during this time.

4. The UNIFE website is still showing IRIS Certification. Why is that?

In May 2017 the IRIS 2.1 standard for the management system in the railroad industry was transposed into an internationally recognised standard, ISO/TS 22163. Your management system shall now be audited on the basis of ISO/TS 22163:2017.

The certification process shall continue to be called IRIS Certification TM and UNIFE shall retain sovereignty over the specifications as to how the audit process is to be conducted. The tried-and-tested assessment sheet and assessment procedure will therefore remain unchanged.

5. How much work will be involved in changing over my system? Is it something I can do on the side?

The management system helps you to do the correct things correctly. To this end, you should ideally break it down into the requirements for your organisation.

As the revision of ISO/TS 22163 is inextricably linked to the revision of ISO 9001, the transition is not something that can be accomplished on the side, in our opinion..

How great of an effort is actually involved, however, will depend on the complexity, the performance of your system and the results of the gap analysis (IRIS vs. ISO/TS 22163). Filling out the assessment sheet will help you with this, if you have updated your audit tool for internal audits.

In order to sustainably integrate your system into your organisation in accordance with ISO/TS 22163, please use **Option 2** presented under Question 2 for audit planning. This will give you the necessary scope for implementation. If you already agreed a date with your audit team at the last audit, you should communicate any postponements early on.

6. Is there already a German version of ISO/TS 22163 and where can I order a copy?

The translation of ISO/TS 22163 into German is currently underway; an exact publication date is not known at this time. You can enquire with Beuth Verlag or you can pre-order a copy there.

7. Do I require the certification rules?

Once the German version of ISO/TS 22163 is published, the certification rules will also be available in German from Beuth Verlag.

We recommend that you obtain a copy of these rules. You will find useful information for audit planning and preparation in the appendices. They will definitely help you to better understand some of the requirements of the auditors.

8. What are the biggest and most important changes?

ISO/TS 22163 contains ISO 9001:2015 and has therefore also assumed the high-level structure. There are no longer any required procedures, but only required processes.

In addition, there is much more emphasis on the concept of risk-based thinking and action, and on the process-oriented approach. The focus on processes is further supported by the requirement for key performance indicators (KPIs) to be regularly evaluated, to regulate processes, i.e., in the event of deviations from targets, corrective measures are to be initiated.

Detailed requirements for the definition of KPIs are set forth in section 9.1.1.1. For example, there must be a clear assignment to the process, or an explanation of how a KPI is calculated. Other requirements for KPIs include:

- setting achievable targets,
- stating to whom must this KPI be reported

- stating who is responsible for the corrective measures

Important key indicators to be determined are customer satisfaction, adherence to delivery dates agreed with the customer, as well as internal errors, for example.

Another new requirement is regular process reviews. A process review is a review of the calculated indicators, in order to derive additional measures from them. You should be able to produce this at the transition audit.

9. Will my quality management officer(s)/internal auditors require further training?

In order for the system to meet the requirements, it needs to be further developed accordingly. The relevant process owners therefore need to know the requirements. In any case, ISO/TS 22163 has now also stipulated binding requirements for internal auditors.

10. Can I also train my existing consultant in ISO/TS 22163?

Certainly, if you feel he/she is competent enough. Consultants do not guarantee protection against deviations, however.

11. What effort (audit duration) is involved in the transition to ISO/TS 22163?

The audit day table has been revised and now specifies the on-site time of the audit team. The time taken for audit preparation and follow-up work is also specified. The duration of audit preparation for companies with 86 or more employees was determined as 1 day in addition, and 0.5 days in addition for companies with 85 employees or less.

The time required for reporting for certification/recertification audits was determined as max. 1 day, and 0.5 days for a monitoring audit.

We will be happy to draw up a quotation for you, which will give you a price that includes audit preparation and follow-up work, as well as certificate creation. We will account for data fees separately.

12. Do I have to audit the entire company for ISO/TS 22163?

No, there is the option, where employees work exclusively for the railroad industry, to use these as the basis for calculating the audit days. However, we also have to take the other employees, who have no involvement in railway-specific processes, into consideration in the ISO 9001 procedure. This will add a small surcharge.

We will be happy to help you to identify your rail-specific employees.

13. Will there be any changes in the running of the audit procedure?

Yes. For the auditors, in particular, there will be more work involved in preparing for the audit. At least 60 days before the audit begins you must provide the lead auditor with information on the 5 required processes, as well as the results on customer perception and satisfaction.

14. What happens if I am not able to provide the auditor with all the documentation for audit preparation 60 days before the audit date?

First of all, it is important that you plan your audits in good time. The best thing to do is to plan the next audit at the final meeting.

If you don't manage to provide the auditor with the documents on time for audit preparation, then the on-site audit time will increase by 0.5 days.

This time cannot be offset against the audit preparation time, because the auditor will require the additional time to conduct the entire audit.

15. What information does a DEKRA auditor expect from our company to prepare for an audit?

You will receive a checklist from our assigned auditor, to help you prepare for the audit. This checklist will require the following information from you:

- Proof of key performance indicators and process turtle diagrams (please keep this to around 2 pages) relating to the following 5 processes (standards section):
 - 8.1.3 Project management
 - 8.2 Product and service requirements
 - 8.3 Development of products and services
 - 8.4 Control of externally prepared processes, products and services
 - 8.5 Production and service provision

Notes on turtle diagrams can also be found in the certification rules in Appendix 5.

Another important part of audit preparation is stakeholder analysis and customer perception. Possible information (see Appendix 4 of the certification rules) to be submitted to the auditor includes:

- Stakeholder analysis:
 - e.g. market analyses and railroad industry strategy
 - sales trends
 - criticality of supply

- product safety or other social aspects
- Customer perception:
 - e.g. results of customer supplier evaluations,
 - results of supplier performance (ppm, adherence to delivery deadlines),
 - Complaints statistics or warranty costs.

Some of this information is available from the supplier portals. In any case, the following documents must be provided to the auditor before every audit: Status of customer complaints

- Statistics on warranty services
- Management review report
- KPIs for product and service quality and supplier performance
- If applicable, KPIs for product safety aspects

16. What must I take into consideration if we have excluded section 8.3 at our company?

In this case, you obviously don't have to define a process for section 8.3; therefore, only information on the other 4 processes needs to be verified.

17. What do I need to bear in mind if we have combined the two standard sections into one process?

Please inform your auditor accordingly on the checklist for audit preparation.

18. Why do I have to provide the auditor with the documentation so early?

Firstly, this is a stipulation of the certification rules. The documents provide the auditor with a more comprehensive picture of the current status of the efficiency of your processes and of your management system and its further development. The information provided also constitutes an important part of audit planning.

19. How is the performance level determined (i.e. Bronze, Silver or Gold rating)?

The evaluation in the assessment sheet plays a large part in this. In addition, the results of the performance data for your 5 (4) service processes are highly significant, as well as the results of the customer perception section in the assessment sheet.

This data is combined into one factor and culminates in this classification. What is important for you here is that the efficiency of your defined processes gains in significance.

20. What criteria does UNIFE require for the process definition?

UNIFE's requirements are as follows:

- Process owner
- Internal/external process customer
- Internal/external process supplier
- Interfaces or other dependencies (input/output)
- Work content/Process instructions
- Material resources
- Human resources
- Key performance indicators
- Primary risks and opportunities

21. What content will be included in the ISO/TS 22163 certificate?

The content of the certificate will be the same as before. Company data forms an important part, including the extended workbenches and/or remote locations, if applicable.

What is important is the information on IRIS activities (design and development, manufacture and maintenance), the scope of your company, as well as the description of your products for the railroad industry.

22. Can I also get an ISO 9001:2015 certificate?

Yes, if DEKRA has been assigned to do so. Or discuss this matter directly with the audit team.

23. What is an extended workbench and how can I integrate this into the certification procedure?

An extended workbench is not a legally autonomous production facility. It is monitored and controlled by and is spatially separate from the location to be certified.

An extended workbench does not have its own management system and is an integral part of the production processes of the audited production location. Maintenance work on the manufactured products can also be carried out in an extended workbench.

An extended workbench can be incorporated into the certification procedure. If you wish to add an extended workbench to the certification procedure, please consult your regional sales representative. We will be happy to prepare a follow-up quotation for you and will amend the contracts upon assignment. As a general rule, the only costs you will incur will be the cost of reissuing your certificates.

24. What is a remote location?

A remote location performs activities of your management system that are not carried out at the location to be certified.

The distance between the location and the remote location is of no significance – a remote location can therefore be on the other side of the street or a longer distance away.

The employees at the remote location are integrated in the procedure. If this remote location has already been audited by DEKRA or another certification company, the results of this audit will be taken into consideration and shown on the certificate accordingly.

Remote support functions must not describe any production activities, but, rather, must support the management system, e.g., in purchasing, product development or distribution.

Remote locations can be legally autonomous, but will not be awarded their own, separate certificate, and will therefore only be shown on the second page of the certificate.

25. Will a EUR 500 database fee continue to be payable in future?

UNIFE will invoice DEKRA the database fees and we will bill you for this amount with no additional charges. In future, we will show the EUR 500 separately, to increase the transparency of our quotations.