

**INDEX**

1. SCOPE AND PURPOSE.....	2
2. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER.....	2
3. REQUIREMENTS WITH RESPECT TO WHICH ASSESSMENT IS REQUIRED.....	3
4. BINDING REQUIREMENTS AND LEGALITY CONTROL LIMITS.....	3
5. DEFINITIONS.....	3
6. CERTIFICATION REQUIREMENTS.....	4
7. PROVISION OF THE CERTIFICATION SERVICE.....	5
8. SCORING AND EVALUATION METHOD.....	10
9. AUDIT DOCUMENTATION.....	12
10. IRIS CERTIFICATION™ PERFORMANCE LEVEL.....	12
11. NON-CONFORMITY MANAGEMENT.....	13
12. DECISION ON THE CERTIFICATION.....	14
13. PUBLICATION OF DATA.....	14
14. COMPLAINT MANAGEMENT.....	14
15. WITHDRAWAL OF THE CERTIFICATION.....	15
16. COMPLAINTS, APPEALS AND DISPUTES.....	15
17. USE OF THE MARK AND OF THE CERTIFICATE OF CONFORMITY.....	16
18. COMMITMENTS OF THE ORGANISATION.....	17
19. CHANGES OF THE CERTIFICATION SCHEME.....	18
20. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT.....	18

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## 1. SCOPE AND PURPOSE

This Regulation defines the rights and duties, as well as the operational methodology that governs the relationships between Kiwa Cermet Italia S.p.A. (hereinafter referred to as Kiwa Cermet) and the Customer Organisations, in the provision of the IRIS Certification™ services.

The requirements stated in this regulation are an integral part of the agreement stipulated with Kiwa Cermet (quotation, *the Kiwa Regulation for Certification and General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* – hereinafter *General Terms and Conditions*). These requirements refer solely to the aspects specifically connected with the scope of the requested certification.

The agreement expressly excludes any form of consultancy to the Customer that could jeopardise the independence of the assessments carried out.

This Regulation is also available on the Kiwa Cermet website ([www.kiwa.it](http://www.kiwa.it)).

## 2. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER

In its certification activity, as well as the General Terms and Conditions, Kiwa Cermet applies the following principles:

- a) Absence of discrimination: access to certification services is allowed to any Organization requesting them, in accordance with this Regulation, without any discrimination of commercial or financial nature or regarding membership of particular associations.
- b) Impartiality and independence: ensured through the following measures:
  - Certification activities are assigned to personnel with no interest in the Organisation subject to certification, bound to observe the rules of conduct and independence set by Kiwa Cermet; regarding this aspect Kiwa Cermet undertakes to accept any justified concerns of the Customer concerning the existence of incompatibility of the duty assigned, which could compromise the impartiality or independence of judgement. Impartiality is also ensured thanks to the involvement of special bodies that control the modalities in which Kiwa Cermet renders its services;
  - Precise application of formalised rules and procedures used by all the personnel of certification services and periodic consultation with suitable certification stakeholders;
  - Clear separation between the personnel carrying out the audit activity and the personnel responsible for the certification decision;
  - Total absence of any kind of assistance in defining and applying the requirements for obtaining the Certification.
- c) Prompt management of complaints, appeals and disputes, as defined in § 16 of this Regulation.
- d) Confidentiality: As well as set out in the *General Terms and Conditions and in the Kiwa Regulation for Certification*, Kiwa Cermet requires all its personnel, including Auditors, to sign a confidentiality agreement as well as a document in which personnel commit to treat any information that comes into their possession in accordance with the provisions of the Privacy Act.
- e) Accreditation: Kiwa Cermet undertakes to inform the Customer of any waiver, suspension or withdrawal of accreditation, as well as to support the Customer during the transition to another Certification Body; in such cases Kiwa Cermet is in no way responsible for any damages caused to the Customer by the renunciation, suspension or withdrawal of the accreditation; in the above cases, the Customer has the right to renounce the contractual relationship with Kiwa Cermet, without prior notification and without any additional cost.

Kiwa Cermet operates as an IRIS Certification™ certification body, in accordance with the signing of a collaboration agreement between Kiwa Cermet and UNIFE; if the aforementioned agreement were to be interrupted before the conclusion of the certification process, the customer is not authorised to request the release of the IRIS Certification™ from IMC/UNIFE.

It shall be the responsibility of Kiwa Cermet to assist customers with regard to all necessary actions required to transfer to another registered certification body.

### 3. REQUIREMENTS WITH RESPECT TO WHICH ASSESSMENT IS REQUIRED

- IRIS CERTIFICATION Conformity Assessment in force (of which this Regulation is an excerpt and to which reference should be made for additional details);
- ISO/TS 22163 Standard, current Revision;
- ISO 9001 requirements as complementary norms to the ISO/TS 22163 Standard, contained in it.

### 4. BINDING REQUIREMENTS AND LEGALITY CONTROL LIMITS

The legal conformity to which the certification refers shall be considered by Kiwa Cermet an essential pre-requirement for issuing the certification.

The certification issued by Kiwa Cermet does however only regard the conformity to the reference standard(s), and so it does not constitute a guarantee of compliance with the mandatory requirements. Such compliance is the specific competence of the Customer Organization, which retains responsibility, towards itself and towards others, for the legal obligations involved in the activities object to certification.

In this regard, the audit activities of Kiwa Cermet shall not be considered as a form of waiver of responsibility with regard to possible assessments carried out by the Competent Authorities.

### 5. DEFINITIONS

The definitions referred to in the ISO/TS 22163 standard apply:

**Non detailed data:** the data made public on the IRIS Database consisting of:

- General customer information (name, address, contact person, etc.)
- The approval status;
- The last day of the audit;
- The validity status of the IRIS certification;
- The scope of the IRIS certification.

**Detailed data:** data that does not fall under the definition of "Non detailed data" and includes information necessary for the preparation of the audit, the audit results, the audit plan, the audit report and its annexes, the score obtained and the relative corrective and/or improvement actions.

The detailed data is strictly confidential in nature and shall be stored by Kiwa Cermet in an area of the database with limited access, to which initially only the customer, Kiwa Cermet and the database administrator (hereinafter referred to as the "database administrator") shall have access. The customer shall decide whether to grant further access rights to the detailed data, for example, if the detailed data in question can be made available to third parties, including UNIFE members, through the database.

The database administrator is an individual employed by UNIFE which shall be responsible for maintaining the database. For clarification purposes, the database administrator shall not have the right to share detailed data that has been collected with other individuals, except with other UNIFE employees, with the customer to whom the detailed data belongs and with the respective Certification Body that collected the detailed data.

For clarification purposes, the purpose of the assessment process is not to obtain sensitive information, such as financial information or data that contains references to specific prices or tariffs, offers or demand indicating the business undertakings or information on the performance of specific market participants, etc., unless such information is deemed necessary for verifying requirements associated with key performance indicators. Moreover, detailed and non detailed data shall only be obtained following the execution of the evaluation process.

**Remote functions:** Remote functions are support functions carried out at remote sites (e.g. design, sales, logistics, purchasing and warehouse activities). They must be audited but they cannot obtain their own IRIS certification.

**Site extensions:** a site extension is applicable if:

- The site may not have an independent IRIS certification;
- The site carries out production or maintenance activities belonging to the connected certified site;
- It is included in the certification scope of the connected certified site;
- Carries out only production or maintenance activities;
- It is included in the planning of the audits.

**Autonomous business management system:** Business management system in which the organisation maintains its processes without control activities carried out by senior managers or shareholders of external organisations.

**Key Performance Indicator (KPI):** indicator used to measure the performance of a process.

**Site:** An organisation carrying out design and development activities and/or production activities and/or maintenance activities (fleet maintenance, restructuring or inspection of components) and/or repair activities within the scope of the defined IRIS purposes at a single site.

**IRIS Certification Quality Performance Levels:** (Levels of qualitative performance): are three levels classified as "Bronze", "Silver" and "Gold" that are assigned by IMC following the results of each audit and are published on the IRIS portal.

**UNIFE:** Association of the European Rail Industry.

**IRIS Management Center (IMC):** Entity created by UNIFE for developing and implementing the IRIS Certification™ certification scheme.

## 6. CERTIFICATION REQUIREMENTS

Before starting the Certification process with Kiwa Cermet, the Organization must meet the following requirements:

- Be an autonomous legal entity or belong to an organisation;
- Have an autonomous Business Management System that meets the ISO 9001 and ISO/TS 22163 requirements and the applicable of IRIS CERTIFICATION™ Conformity Assessment Rules at the time of application for certification;
- Carry out at least one IRIS Certification™ activity: design or production or maintenance;
- Be eligible for at least one scope of the IRIS Certification™ process, among those listed in Annex 1 of the IRIS Certification Rules, to be agreed upon with the Certification Body;
- Consist of a single site;
- Register on the IRIS Certification™ portal for:
  - Obtaining detailed information on the IRIS Certification process™;
  - Being able to purchase the audit tool;
  - Selecting the Certification Body via the IRIS Certification™ portal;
  - Preparing itself to start the IRIS Certification™ process;
- Complete the self-assessment questionnaire aimed at understanding the level of compliance, of your management system, with respect to the requirements of ISO/TS 22163 on the IRIS portal paying particular attention to the questions of Knock-Out (KO), mandatory processes for performance assessments and customer perception.
- Maintain the relevant data updated on the IRIS Certification™ portal (number of employees);
- Fully implement the said system;
- Accept the conditions set out in this Regulation;
- Ensure collaboration with the Kiwa Cermet Audit Team during all Audit activities;
- Authorise access to premises, plants, areas and information (detailed or otherwise) necessary to carry out the Audit;
- Designate a Representative as the main contact of the Audit Team;

- Be responsible for applying the requirements prescribed by the laws in force on matters of safety in the workplace. In the absence of binding provisions, the Organisation agrees to provide Kiwa Cermet with complete and detailed information regarding the specific risks existing at the facilities where Kiwa Cermet personnel is expected to operate and PPE necessary for carrying out the appointment, informing Kiwa Cermet personnel concerning their correct use. In this regard, the Organisation has to provide appointed Kiwa Cermet personnel the Company documentation concerning the workplace safety (D.V.R., safety plan, procedures, etc.), limited to aspects of specific interest. If for such omissions, injuries occur or illnesses are contracted, no charges may be made, for any reason against Kiwa Cermet.
- Accept, without additional costs, the possible presence of auditors from the accreditation body or from UNIFE/IMC, which shall be communicated by Kiwa Cermet with a clear illustration of their roles. Their presence has the aim of assessing that the evaluation methods used by Kiwa Cermet are compliant with the requirements for accreditation.

## 7. PROVISION OF THE CERTIFICATION SERVICE

### 7.1 START-UP OF THE CERTIFICATION PROCESS

Based on the information provided by the Organisation, Kiwa Cermet prepares an Offer for Certification, indicating the reference Standard/s and the scope of the Certification reported by the Customer Organisation.

The return of the Certification Offer to Kiwa Cermet, signed by the Organisation, constitutes the formal request for the Certification activities, as well as the acceptance of the contractual and economic conditions (defined in the Offer), of the conditions contained in the present Regulation, in the *Kiwa Regulation for Certification* and in the *General Terms and Conditions* (also available on the [www.kiwacermet.it](http://www.kiwacermet.it) website), of which a copy is attached and sent with the Offer.

Upon receipt of the aforementioned documents, Kiwa Cermet shall examine the data provided, verifying that:

- The requirements for the provision of the requested service have been clearly defined, documented and understood by both parties;
- There is capacity for Kiwa Cermet to perform the required activities;
- The data and documents required have been provided in full, including the field of application required, the certification structure and processes required by the Organisation;
- There are no differences with respect to the data provided at Request for Proposal time and to the data registered on the IRIS Certification™ portal.

Upon successful completion of the previous examination, Kiwa Cermet assigns an order number to the Customer. In the event of a negative outcome, Kiwa Cermet is entitled to request any necessary additions or changes before the formal start of the procedure, or communicate the impossibility for said start, providing the Customer with reasons.

After the process here described starts, in cases where during provision of the service changes are ascertained, with respect to the conditions stated by the Customer (and under which the offer and the agreement was signed), Kiwa Cermet reserves the right to amend the agreement terms and conditions, the Customer is entitled not to accept the new conditions, but pay Kiwa Cermet the fee for the activities carried out up to that point.

Kiwa Cermet notifies the Organisation in advance of the members of the Audit Team; if there are any conflicts of interest, the Organisation can request substitutions, within 3 working days, by submitting a formal and substantiated request.

Kiwa Cermet shall notify the Customer of any subsequent modifications to the contractual documents; it is the Customer's responsibility to always have an updated version of these documents, downloading them from the [www.kiwacermet.it](http://www.kiwacermet.it) website.

### 7.2 AUDIT CYCLES

The first three-year audit cycle includes:

- 1 initial audit consisting of: A Readiness review and a Site audit (Certification audit);
- 2 Surveillance audits;
- 1 Recertification audit.

The first cycle begins on the last day of the initial phase (Certification Audit), which shall be registered in the IRIS portal and shall be recognised as the *Reference Date* for the planning of subsequent activities.

Subsequent three-year cycles begin from the last day of the Recertification audit and include:

- n. 2 surveillance audits, which shall be completed within 12 months of the reference date respectively in the case of first surveillance and within 24 months of the reference date in the case of second surveillance.;
- 1 Recertification audit to be completed within 36 months of the reference date;

Surveillance audits are conducted annually and are scheduled at least 90 days in advance of the *reference date*. This is to avoid the risk of suspension of the certification due to potential non-conformities.

Before the expiry of the IRIS Certification™, the customer must be recertified through a recertification audit conducted on site based on a similar procedure to the certification audit.

The relationships between the audits and the validity of the certification are outlined in Annex 2 of the Rules IRIS CERTIFICATION Conformity Assessment.

### 7.3 AUDIT

Each audit includes an initial meeting, in which the following are shared: the objectives, methods of conducting the activity, the classification criteria of non-conformity with treatment and corrective actions and the consequent confidentiality constraint to which Kiwa Cermet staff are bound; and a closing meeting, communicating the outcome of the audit and in which clarifications on the formal results documented in the report are provided.

When the audit is being carried out, if significant deviations are found between the company situation and what has been communicated by the Organisation, the Audit Team shall notify Kiwa Cermet immediately of this deviation in order to decide upon any contractual modifications with consequent updates of the duration of the audit<sup>1</sup>.

### 7.4 PRE-AUDIT

On request, one pre-audit can be conducted before the readiness review; the pre-audit is an evaluation activity, but is not part of the IRIS Certification™ process.

The audit team conducting the pre-audit shall not participate in the readiness review, in the certification audit and/or in the first two surveillance audits.

### 7.5 READINESS REVIEW

#### 7.5.1 Prerequisites

Before the start of the readiness review the Organisation shall provide to the Lead Auditor the following documentation:

- Customer perception (stakeholder analysis, key customers and related KPIs);
- Customer feedback;
- Customer complaints and warranties;
- "Turtle diagram" for the 5 mandatory processes in order to assess their performance:
  - Project Management, ISO/TS 22163 §8.1.3;
  - Requirements for products and services, ISO/TS 22163 §8.2;
  - Control of externally provided processes, products and services, ISO/TS 22163 §8.4;
  - Design and development of products and services, ISO/TS 22163 §8.3;
  - Production and service provision, ISO/TS 22163 §8.5.1.1.1) for performance evaluation purposes;
- Definition of KPIs with connection to internal/external processes;
- KPIs for the audit period;
- List of the Organisation's processes and their interactions.

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<sup>1</sup>"Significant differences" shall mean a difference involving changes to the duration of the audit.

The sending of the above-mentioned documents must be registered by the customer on the IRIS Confirmation Statement form on the IRIS portal.

The above documents and the form completed by the company must be sent to the RGA in charge at the latest 60 calendar days before the start of the audit.

If the submission of such documents does not take place in sufficient time to allow effective audit planning, the review of the documents shall be carried out on-site before the start of the audit, adding an audit time of half a day compared to the offer. The additional time will be invoiced according to the conditions set out in the offer.

### **7.5.2 Readiness Review**

The objective of the readiness review is to verify the level of organisational compliance to the IRIS Certification™ prerequisites.

The readiness review is carried out at the customer's site before the certification audit or in case of a change of the certification body, a maximum of 60 calendar days prior to the start of the certification audit.

The readiness review aims to verify:

- The cross-check between mandatory processes and KPIs;
- The customer's perception;
- A preliminary verification of KO (Knock Out) questions;
- An assessment of the conditions of the client's site and applicable remote locations;
- Verification of the agreed upon certification scope;
- Allocation of resources for the certification audit;
- The planning of the certification audit.

Non-conformities are not identified during the readiness review, however, the review must be repeated if failed.

### **7.6 CERTIFICATION AUDIT**

The certification audit shall be conducted on-site and shall be aimed at evaluating the implementation, including the effectiveness, of the business management system.

Certification audits must be conducted on-site; at least 6 months of data and records relating to the activities covered by the IRIS Certification™ must be made available.

The audit includes the verification of the following elements:

- Mandatory KO requirements;
- Mandatory processes and related KPIs;
- Applicable ISO/TS 22163 requirements;
- Evaluation via the evaluation grids based on the ISO/TS 22163 requirements;
- Customer perception;
- Process performance through the evaluation of performance.

If the audit fails, the organisation shall repeat a new audit within 90 calendar days or close the non-conformities by documentary means.

At the end of the audit and following any eventual re-audits or closure of non-conformities (successful audit), the certification and the qualitative performance level (score), which is always the Bronze one in these specific cases, can be issued.

### **7.7 SURVEILLANCE AUDIT**

For the continued validity of a certification, a surveillance audit is required.

The surveillance audit must be conducted on site and is intended to assess compliance with specific requirements of the business management system.

The audit must be conducted with success or performed and any non-conformities closed with adequate support documentation or through a re-audit.

The decision on the processes to be assessed during the Monitoring Audit will be based on an analysis of the data submitted prior to the audit which was found to be weaker and should include the verification of the following elements:

- Mandatory KO requirements;
- Customer perception;
- Mandatory processes and related KPIs;
- Project management with a focus on interfaces, especially in the case of a corporation;
- Management review;
- Change and configuration management;
- ISO 9001 requirements agreed upon with Kiwa Cermet for surveillance audits;
- Specific areas where non-conformities were identified, if not already the subject of the audit;
- Specific areas with regard to which improvement actions have been agreed to;
- Specific areas requested by the customer to improve the quality performance level.

### **7.8 RECERTIFICATION AUDIT**

Before the expiry of the certification the company must be recertified.

The scope of the recertification audit is identical to that of the certification audit.

### **7.9 SUPPORT SITES**

Examples of management of support activities are described to Annex 3 of the IRIS Certification™ Rules

#### **7.9.1 Remote functions**

Remote functions are considered as such only if there is no autonomous business management system.

Remote functions must be controlled, but cannot request their own IRIS Certification® certificate.

In the event that the audit and the certification relate to two sites, where one serves a remote function of the other, that which carries out the complete process shall be audited first. All results marked in the IRIS assessment sheet shall be taken into account for auditing activity during the second venue audit.

In the event that a remote function supports more than one site, this shall be audited along with the first site.

In certification and recertification audits, remote functions shall be audited before the production sites, unless they fall at the end of the business or production process (e.g. warehouses); in this case, they may be audited after the production and/or design sites.

Remote functions shall always be audited during the certification and re-certification audits and at least one other time during the certification life cycle.

Please also refer to Annex 3 of the Rules for examples of audit planning, including remote functions and site extensions.

#### **Design and development**

If the design and development function is a remote function, on-site or remote, the same must be included in all surveillance audits.

It is considered remote only if it is not associated with an autonomous Business Management System.

The audit of remote functions can be excluded if:

- All evidence and information are available on-site during the audit;
- The size of the remote function permits to do so;
- The management team of the remote function participate in the audit directly or through appropriate communication tools.

In the event of changes in scope, activities or sites of the Organisation following the certification audit, all remote functions which the changes impact shall have to be audited before the first useful surveillance audit.

In the event of remote functions that support multiple sites and these sites are audited by different certification bodies, Kiwa Cermet may accept the audit findings conducted by other certification bodies subject to the following conditions:

- The audit conducted by the other certification body must completely cover the certification scope of these functions;
- The Organisation must provide Kiwa Cermet with a copy of the audit plan, audit report, all findings, corrective actions and the verification actions of the other certification body;
- The information must be in the language agreed upon between the Organisation and the other certification body;
- The information must confirm that the interfaces between the remote function and the site were adequately audited by the other certification body;
- Copies of all surveillance and recertification audits of remote function audited by the other certification body shall have to be provided by the Organisation to Kiwa Cermet;
- The other certification body shall ensure that corrective actions have been applied; copies of all site audits shall be provided by the Organisation to Kiwa Cermet.

The certification shall also include the remote functions; in the event that the remote function supports multiple sites, it shall appear on all certificates.

### **7.9.2 Site extensions**

Site extensions shall be audited for each audit but may not be issued their own certificate.

A site extension is defined as such if:

- It cannot obtain an independent IRIS Certification™, and;
  - The site carries out production or maintenance activities belonging to the connected certified site, and;
  - It is included in the certification scope of the connected certified site, and;
  - It carries out only production or maintenance processes, and;
  - It is included in the audit plan (at least in the certification and recertification audits) of the audit at the connected certified site.
- The site is not autonomous in terms of objectives and the definition of processes (quality objectives, KPI targets, definition of processes in the process landscape). The processes and objectives are defined by the certified organisation;
  - The percentage of people working for production/maintenance activities (in the case of organisations certified in these fields) is higher than 75% of the total number of employees of the site extension.

In the event that the site extension carries out only maintenance tasks, the audit may be excluded if:

- All evidence and information are available on-site during the audit;
- The size of the remote function permits to do so;
- The management team of the remote function participate in the audit directly or through appropriate communication tools.

The certification shall include all site extensions.

## **7.10 OTHER TYPES OF AUDITS**

### **7.10.1 Transfer audits**

A transfer audit occurs when an organisation certified with the IRIS Certification™ decides to change the approved certification body.

A transfer audit can be conducted at any point of the certification validity cycle. It is mandatory to conduct a readiness review and at least three (3) months of data and documented information must be made available.

At least three (3) years must pass between one transfer audit and another.

Prior to the transfer audit, the following activities shall be conducted:

- Verification of the validity of the current IRIS Certification™;

- The Organisation must request the certification body change via the IRIS Certification™ portal;
- Following approval of the request by the IRIS Management Center (IMC), Kiwa Cermet shall be able to access the customer's data and documents relating to the last audit;
- Kiwa Cermet may carry out a review of the documentation in order to begin the transfer audit planning process;
- Kiwa Cermet shall ensure that no member of the audit team has previously conducted audits for the customer.

Following the transfer of the certification body, the reference date does not change and a quality performance level document will be issued.

### 7.10.2 Change of site or certification scope

An organisation can evolve during the certification validity cycle, with the impact on their business system for example:

- Change of site or purpose IRIS Certification™;
- Addition of IRIS scope;
- Change in ownership structure.

In this case, it is mandatory to conduct a readiness review and at least three (3) months of data and documented information must be made available.

In order to assess the impact of the changes, the organization must complete the Changes impacting the management system form available on the IRIS portal and send it to the RGA 60 days before the start of the audit.

Kiwa Cermet will verify the presence of the following information within the form sent:

- geographical constraints;
- transfer of labour, machinery, techniques, processes, etc.;
- any further information necessary to ensure proper performance of the audit.

If after review of the documentation sent the score obtained, depending on the impact that the change has on the Management System of the organization, more than 10 the audit time for the next audit will be equivalent to that of a recertification.

## 8. SCORING AND EVALUATION METHOD

To promote continuous improvement, a score is assigned representative of the organisation's compliance level, based on the evaluation of these three elements:

- a) Evaluation of enabling factors through an evaluation matrix based on the ISO/TS 22163 requirements
- b) Customer perception
- c) Process performance through the evaluation of performance.

A global score is given based on these assessments.

### a) Evaluation of enabling factors through an evaluation matrix based on the ISO/TS 22163 requirements

The audit is conducted using the Audit Tool released by UNIFE, which supports the evaluation process.

This requires the assignment of a level of maturity for each criterion set up in the Audi Tool, based on evidence gathered during the audit:

- The maturity level can be assigned only if all of the criteria for this level of maturity and those below are met;
- The maturity level can be assigned when there is evidence that the criterion is applied consistently in all applicable stages and projects;
- The lead auditor can decide if a specific criterion is not applicable and consider it N/A.

The Audit Tool includes three types of criteria:

- Knock-Out items:

Are evaluated as YES/NO; their evaluation is mandatory and their satisfaction is a prerequisite for certification.

Can be declared not applicable and shall be verified for each audit, including their applicability.

In the event of non-fulfilment of a KO (Knock Out) requirement during the readiness review, the latter must be repeated.

If non-conformity is identified during an audit concerning a KO requirement, it shall be classified as a major non-conformity and shall require a re-audit to verify the effective resolution of the same.

Details Concerning Knock Out requirements can be found in Annex 7 of the Rules.

- Closed items:

They are criteria without progressive scores with two possible outcomes:

- The answer is "YES", the requirement is satisfied = 2 points
- The answer is "NO", the requirement is not satisfied = 0 points

- Opened items:

Applying the scoring principle, each requirement must be progressively classified according to the following general criteria:

- "Optimised" level: the requirement is exceeded and continuously improved = 4 points
- "Qualified" level: the requirement is exceeded = 3 points
- "Defined" level: the requirement is fully met = 2 points
- "Poor" level: the requirement is partly satisfied = 1 point
- The ISO/TS 22163 requirement is not met in all aspects;
- The requirement is not applied in all projects;
- No impact on product quality or on the customer's requirements
- A corrective action is required in relation to a minor non-conformity.
- "Insufficient" level: the requirement is not met = 0 points
- The ISO/TS 22163 requirement is not met;
- A corrective action is required in relation to a major non-conformity.

The following table summarises the assignment of maturity levels and the related required actions:

Compliance	Maturity level	Points	Required actions	
			Opened items	Closed items
Compliant	Optimised	4	No action required	
	Qualified	3	Improvement action could be recommended	
	Defined	2	Improvement action based on the auditor's request	No action required
Non-compliant	Poor	1	<b>Mandatory corrective action</b> To close within 90 days	
	Insufficient	0	<b>Mandatory corrective action</b> To verify with a re-audit within 90 days	<b>Mandatory corrective action</b> To verify with a re-audit within 90 days

## b) Customer perception

The evaluation of the Organisation shall focus on the customer related requirements according to the following criteria:

- Interested parties' needs and expectations;
- Customer orientation

- Customer satisfaction
- Review activities.

These requirements shall be assessed during each audit as described in Annex 4 of the Rules

### **c) Process performance through the evaluation of performance.**

During each audit, the performance of 5 mandatory processes shall be evaluated:

- Project Management, ISO/TS 22163 §8.1.3;
- Requirements for products and services, ISO/TS 22163 §8.2;
- Control of externally provided processes, products and services, ISO/TS 22163 §8.4;
- Design and development of products and services, ISO/TS 22163 §8.3;
- Production and service provision, ISO/TS 22163 §8.5.1.1.1.

Consistent with the IRIS Certification™ activities, one of the mandatory processes can be defined as not applicable.

Additional details are provided in Annex 6 of the Rules.

## **9. AUDIT DOCUMENTATION**

The findings of each audit shall be recorded in an audit report prepared using the IRIS Certification™ Audit Tool, preliminary and final.

The audit report shall be drafted in the language agreed upon for the audit and in English.

The structure of the audit report is defined by the Audi Tool and includes:

- All the required audit summary data;
- Evaluation of the stakeholder analysis and of the customer's perception;
- "Turtle diagrams" of the performance evaluation of mandatory processes;
- The scope of the audit in terms of identification of the Organisation and/or functional units and/or audited processes;
- Identification of the audit team and of the customer representatives;
- The dates and sites where the audit took place;
- Results, conclusions (CAR, IAR, etc.), strengths and areas for improvement;
- The score and whether the Organisation has successfully passed the audit;
- A declaration for Kiwa Cermet to issue the IRIS Certification™, after an audit has been successfully concluded.

The audit report shall be signed by the Lead Auditor and the customer may receive a hard copy, if requested.

After carrying out a thorough Veto Check of the required documentation, a full electronic copy of the audit report will be uploaded to the IRIS Certification™ portal, to which the customer shall have access.

## **10. IRIS CERTIFICATION™ QUALITY PERFORMANCE LEVEL**

Following the evaluation of the three elements described in paragraph 7.9, the Organisation shall receive a specific evaluation issued directly by the IMC:

- Bronze level: this is the base level and is the result of the relation between the enabling factors applicable and the minimum score (2 points);
- Silver level: implies, on top of the Bronze level requirements, a transparency on performance and is achieved if the company management system has been implemented and is effective according to ISO requirements / TS 22163, including a performance management system. High transparency in stakeholder analysis, customer feedback, performance assessment and Kpis shall be provided during an audit.

To get the Silver level, the following minimum scores need to be achieved for the three (3) pillars:

- enabler evaluation (assessment sheet based on ISO/TS 22163 requirements): seventy percent (70%) of the maximum score,
- customer perception: seventy five percent (75%) of the maximum score,
- process performance through performance evaluation: eighty percent (80%) of the maximum score.

- Gold level: this is the highest level and can be reached if there is clear evidence of the optimisation of the customer's perception of the organisation's performance.

Based on the high level of transparency of quality performance, it is clear that the controlled organization continuously meets the requirements of the customer and has a highly developed business management system.

To get the Gold level, the following minimum scores need to be achieved for the three (3) pillars:

- enabler evaluation (assessment sheet based on ISO/TS 22163 requirements): eighty percent (80%) of the maximum score,
- customer perception: eighty five percent (85%) of the maximum score plus positive direct feedback from customer (see Appendix 4 clause A4),
- process performance through performance evaluation: ninety percent (90%) of the maximum score.

At the certification audit, the level of quality performance that is awarded is bronze.

The organization may request the Silver and Gold level during the Audit of surveillance or recertification.

For the achievement of Silver and Gold quality levels, it is mandatory that documents and data for the preparation of the audit are available to the RGA with sixty (60) calendar days in advance (see clause 10).

If the sending of the above documents does not take place in time to allow an effective evaluation of the documents and subsequent planning of the audit, the levels Silver and Gold will not be recognized, but only the level of Bronze quality performance can be recognized.

The IRIS quality performance level Certification® is defined after the audit is finalised (and is the result of the audit as directly related to the audit score). A declaration of the IRIS quality performance level Certification® will be generated and uploaded to the IRIS portal and is valid for one (1) year.

The performance level is updated with each audit and can vary over the years, but the certification is still valid provided that the audits have been conducted successfully within the reference dates.

## 11. NON-CONFORMITY MANAGEMENT

For each non-conformity identified during the audit a Corrective Action Request (CAR) shall be opened and recorded in the audit report, together with the relative performance level.

Each CAR must be closed within 90 days from the last day of the audit, respecting the reference dates.

A CAR requested based on requirements deemed as "Insufficient" must be closed with an on-site audit; in the event of requirements considered as "Poor", it shall be the responsibility of the Lead Auditor to decide on the need for a re-audit or other methods to verify the effectiveness of the corrective actions applied.

In the event that a CAR that has already been closed during the previous audit is reopened (certification or monitoring), it shall be required to verify the effectiveness of the actions through a re-audit.

Once CARs have been closed, the performance level shall be adjusted accordingly and recorded in the audit report.

In order to manage the resolution of non-conformities, the Organization shall:

- Analyse the root cause of the non-conformity;
- Define and implement corrective actions;
- Verify the effectiveness of the corrective actions;
- Inform the Lead Auditor of their resolution within 90 days;
- Arrange to the re-audit with the Lead Auditor within 90 days.

### Improvement actions

An Improvement Action Request (IAR) can be agreed upon to achieve a higher level of maturity and shall be subject to verification during normal audit scheduling.

The application of an improvement plan within the next audit is recommended, but longer periods may be accepted, if justified.

The identification of IARs does not preclude the completion of the audit report and the issue of the IRIS Certification™ certification.

If an improvement plan is not applied within the agreed upon period, a non-conformity shall be issued with regard to the continuous improvement process.

## 12. DECISION ON THE CERTIFICATION

The certification decision (granted or not) shall be communicated by the Lead Auditor during the closing meeting of the audit.

In order to guarantee its completeness and consistency, following the audit the audit documentation shall be subjected to a thorough Veto Check activity, before being uploaded to the IRIS Certification™ Portal.

After the audit was successfully completed and the results were validated by the Veto Check, the IRIS certification can be issued.

The IRIS Certification™ is issued in English and indicates the scope of the certification and related activities: design and/or production and/or maintenance.

Any remote functions or site extensions shall be listed on the second page of the certificate.

Is it also possible to obtain the certificate in other languages.

The certification shall have a validity of three (3) years from the reference date, if the criteria are satisfied.

Any changes deemed necessary to the IRIS Certification™ may be introduced only after an audit has been carried out.

An ISO 9001 certification can be issued in parallel even if the conditions for issuing the IRIS Certification™ are not met.

The evaluation activity conducted with reference to the ISO/TS 22163 standard, if requested by the Organisation, is used by Kiwa Cermet with the same scope of application even for the granting and maintenance of the applicable ISO 9001 certification.

For this certification, the rules set out in the PSC 05 A document ("Regulation for the certification of management systems") shall apply.

### Corporation-level letter of compliance

After an IRIS Certification™ has been issued for all sites belonging to a corporation, IMC may issue, upon request, a letter of compliance.

## 13. PUBLICATION OF DATA

Within 14 days after the conclusion of an audit, the audit report and all related documentation shall be published on the IRIS Certification™ portal, regardless of the outcome of the audit.

The customer irrevocably authorises Kiwa Cermet to communicate this data to IMC, regardless of the outcome.

IMC shall publish Non Detailed Data on the Database present on the IRIS Certification™ portal.

The client irrevocably authorises IMC to publish and make available Non Detailed Data on the database.

The customer shall be able to decide who can access Detailed Data by granting access to it using the features available on the IRIS Certification™ portal.

## 14. COMPLAINT MANAGEMENT

In the event that any obvious and repetitive issues exist, customers in the railway sector may report complaints.

The complaint handling process can be initiated for:

- Direct complaints made by the customer to IMC
- Customer complaints or audit information directed at Kiwa Cermet.

IMC shall analyse these reports and communicate them to the competent certification body (based on documentation or on-site).

If the complaint proves to be unjustified Kiwa Cermet shall confirm the IRIS Certification™.

If the complaint proves to be justified, Kiwa Cermet shall request appropriate corrective actions, whose closure shall be managed in close engagement with IMC.

If the evaluation of corrective actions is positive, the IRIS Certification™ shall be confirmed, with the level of performance accordingly updated, which may be lowered while always remaining above the minimum threshold.

If the evaluation of corrective actions is negative the IRIS Certification™ is withdrawn; the withdrawal of the IRIS Certification™ does not necessarily imply the withdrawal of an eventual associated ISO 9001 certification.

The IRIS Complaints Management Center will notify the complainant of the results of the analysis of the complaint after a maximum of ten (10) calendar days from the resolution.

The above process applies to justifiable complaints regarding the Business Management System and not concerning non-compliant products.

A detailed procedure for handling complaints is available on the IRIS Certification™ portal at [www.iris-rail.org](http://www.iris-rail.org).

## 15. WITHDRAWAL OF THE CERTIFICATION

If any situation occurs such as to indicate that the initial conditions of the IRIS Certification™ are no longer satisfied, Kiwa Cermet shall have the option to initiate the certification withdrawal process. The initial conditions to start this process include:

- a. Kiwa Cermet receives a complaint regarding the performance of the Customer from IMC or any customer in the railway sector;
- b. Non-conformity issued by the Kiwa Cermet audit team at the end of the surveillance and recertification audits;
- c. Corrective actions not reported in accordance with the timelines established as a result of non-compliance/comments reported on the audit report;
- d. Significant changes in the Customer ownership structure or discontinuation of the product production which fell under applicability for the certification;
- e. Surveillance audit not conducted according to the schedule and permitted intervals;
- f. Reasons outlined in the *Kiwa Regulation for Certification*.

In view of the start of the withdrawal process, Kiwa Cermet shall perform an analysis of the situation and shall decide within 20 days from the process start date, whether to revoke the certification process or not. In the case of non-conformities this analysis should include the review of the root causes identified by the customer and its methodology, analysis, results and implemented correction.

If the start of the withdrawal process is linked to major non-conformities or surveillance audits not performed within the required timeframes, Kiwa Cermet must compulsorily decide to revoke the certification.

The withdrawal of the certification determines the automatic resolution pursuant to Article 1456 of the Italian Civil Code of the agreement to which this Regulation applies, except, in any case, the compensation of any damages suffered by Kiwa Cermet.

## 16. COMPLAINTS, APPEALS AND DISPUTES

### 16.1 Complaints

The Organisation may present documented complaint regarding its dealings with the certification activities provided by Kiwa Cermet.

The complaint may arise from problems encountered during the certification process, such as for example, delays in completing the various phases and/or incorrect conduct by the Certification Body Auditor.

Kiwa Cermet proceeds to register the complaints, analyse them and inform the complainant about the actions taken. Kiwa Cermet shall establish with the complainant whether and to what extent the content of the complaint and its resolution should be made public.

## 16.2 Appeals

If the complainant is not satisfied with the response received, or intends to appeal against Kiwa Cermet's decision, the latter can present an appeal in writing.

The complainant must state the grounds for their appeal and, in cases where the appeal refers to a decision made by Kiwa Cermet (e.g. reference to a Major non-conformity), it must be presented to Kiwa Cermet within 10 calendar days of the decision being communicated.

Kiwa Cermet shall provide the complainant with a written reply and shall give notice of any actions to be taken within 30 days of the date of receiving the appeal.

A detailed description of the process for presenting complaints and appeals is available on the [www.kiwacermet.it](http://www.kiwacermet.it) website.

## 16.3 Disputes

If the result of the appeal is not accepted by the complainant, any dispute between the Customer and the Contracted Party shall be managed in compliance with Article 18 paragraph 1 of the *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders*.

## 17. USE OF THE MARK AND OF THE CERTIFICATE OF CONFORMITY

Customers in possession of a quality management system certified with the IRIS Certification™ by Kiwa Cermet can use the Kiwa Cermet certification Mark (registered trademark) shown in figure 1.

Using the certification mark the Customer has to fulfil all the applicable rules set out in the *Kiwa Regulation for Certification* as well as the following rules.



Fig. 1

Kiwa Cermet certification mark:

- a) Must be shown together with the mark and/or name of the certified Organisation;
- b) Must be shown together with the applicable standard, cited with the year of issue. The Customer can use the Kiwa Cermet trademark in reference to one or more standards simultaneously, provided that the Customer management system is certified by Kiwa Cermet with respect to all the above standards;
- c) Must be used on a white or transparent background;
- d) Must be used with the colours shown in fig.1 including in the negative version (white, black and grey with 50% black); as an alternative to black the colour "Kiwa blue" can be used (Pantone 2945);
- e) Must be used in such a way as to ensure the Management System certification cannot be attributed to requirements other than those for which it was issued; for example the Management System certification must not be used in such a way that it could be mistaken for a product certification, and therefore the mark cannot be used on products or on their packaging. Any statement affixed to the product packaging<sup>2</sup> or inside the<sup>3</sup> accompanying product information, regarding to the fact that the Customer has a certified management

<sup>2</sup>Product packaging is considered as that which can be removed without the product being broken apart or damaged.

<sup>3</sup> Accompanying information is considered as that which is separately available or easily detachable. Type labels or identification plates are considered as part of the product.

system, should not be used in such a way that the management system certification can be confused with a product certification. Any statement affixed on the packaging or accompanying the product, relating to the possession of the management system certification by the Customer, must contain the following references:

- Identification (e.g. brand or name) of the certified Customer;
- Kiwa Cermet Italia identification;
- Type of management system (e.g. quality, environment) and the applicable standard;

e.g. *"The XXXX Organisation has a Quality Management System Certified by Kiwa Cermet Italia S.p.A. in accordance with the ISO/TS 22163 standard: XXXX"*.

- f) Must be used only with reference to the products/sites subject of the certification granted (listed on the certificate);
- g) Can be enlarged or reduced ensuring the proportions in fig. 1 while always ensuring that the words and numbers inscribed in the trademark are legible;
- h) Can be applied on the shipping/handling systems of the products provided that they are matched to the certified Organisation's logo/name;

To publicise the certification the customer can, ensuring compliance with the above, and avoiding to provide information that can cause confusion or lead to misunderstandings on the part of its customers and end users, use wording such as: *"Organisation with Quality Management System Certified by Kiwa Cermet in accordance with the ISO/TS 22163 standard: rev. XXX"* (or similar). This wording can also be used on products and their packaging.

These requirements also apply in the case where transferable trademarks are used (e.g. adhesives).

The Customer must inform personnel who can make use of the mark of the above requirements.

Reproduction is permitted (including in colour) of the certificates of conformity issued by Kiwa Cermet, provided that the original is reproduced in full.

The IRIS Certification™ logo can be downloaded from the IRIS portal after accepting the conditions for use.

## 18. COMMITMENTS OF THE ORGANISATION

The Customer undertakes to:

- Not refuse any witness audits performed by IMC with regards to Kiwa Cermet and any internal witness audits carried out by Kiwa Cermet (this does not require any additional burden on the Customer and does not in any way alter the performance of the audit);
- Not refuse access to UNIFE representatives or their delegates;
- Evaluate the work of Kiwa Cermet and its auditors through the features available on the IRIS Certification™ portal;
- The Customer, including its employees, directors, agents and other representatives, as well as its shareholders and other companies or members of its Group, undertake to only use the rules and the original IRIS certification software and to refrain from using any document or copy of the software that may infringe on UNIFE's intellectual property rights.
- Irrevocably authorise Kiwa Cermet to transmit audit data to IMC through the IRIS Certification™ portal;
- Irrevocably authorises IMC to publish and make available "Non Detailed Data" on the database present on the IRIS Certification™ portal.
- Promptly inform Kiwa Cermet and in writing, of any significant change in their quality management system or other changes that may affect compliance, including:
  - Interruption of their business;
  - Changes in the application request for certification (including the site/s, scope, documentation, significant changes in products/processes and/or the number of personnel involved);
  - Changes of ownership, legal, commercial and Organisational status;

In response to these changes, Kiwa Cermet shall assess the consequent actions to be taken (such as: the need to carry out a supplementary Audit, if necessary accompanied by a revision of the certification, or to initiate a new certification process).

- Promptly inform Kiwa Cermet of exceptional events, judicial and/or administrative procedures, accidents, emergencies which occurred, or legislative non-conformities;
- In the event of withdrawal of the certification, send a notification to customers requesting the certification, informing them that they are no longer certified with the IRIS Certification™ and requesting the return the certificate to Kiwa Cermet.

If a change is not communicated to Kiwa Cermet, this can lead to the issuance of a major non-conformity and/or to the withdrawal of the certification granted to the Customer.

The customer is perfectly aware of the fact that any proprietary and/or confidential information, know-how or other intellectual property belonging to IMC/UNIFE, whether registered or unregistered, shall remain the exclusive property of UNIFE, that all intellectual property rights on the System shall remain the exclusive property of UNIFE, and that no clause of the agreement between Kiwa Cermet and the Customer must give rise or can be considered as a cause for the assignment, transfer or licensing of UNIFE's intellectual property rights.

The Customer acknowledges and accepts that UNIFE and its representatives and employees cannot be held responsible for any direct or indirect damages suffered by the Customer in relation to the IRIS Certification™ certification process.

This limitation of liability shall only apply to the extent permitted by applicable mandatory law.

This exclusion of liability shall not apply in cases in which an exclusion of liability is prohibited by applicable mandatory law.

## 19. CHANGES OF THE CERTIFICATION SCHEME

Changes may include the following: the reference Standard, the IRIS Certification Rules or the Kiwa Cermet contractual documents (including this Regulation).

These changes shall be managed in accordance with the procedures set out in the *Kiwa Regulation for Certification*.

## 20. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

Kiwa Cermet may freely withdraw from the Agreement with the Customer Organisation by giving written communication to the Customer Organisation with a notice of six months from the effective date of withdrawal. The withdrawal by Kiwa Cermet determines the withdrawal of the issued certification. The Organisation is in any case obliged to pay Kiwa Cermet the amounts due for the services received during the notice period, as established in the last valid quotation.

In case the Organisation wishes to terminate the Agreement, the unilateral withdrawal during the period of Certification validity requires the respect of notice times established in the *General Terms and Conditions of Kiwa Cermet Italia for the performance of orders* and in the *Kiwa Regulation for Certification*.

In particular, for notice of less than three months and more than two weeks from the scheduled Audit, the Customer must pay 50% of the amount relative to the cost foreseen for the subsequent activity as agreed upon in the Agreement. For periods of notice of less than two weeks, the conditions specified in the *General Terms and Conditions* shall apply.

In case of termination of the Agreement, Kiwa Cermet will issue an invoice for the expenses of closing the certification file, in accordance with the last valid quotation.