REGULATION FOR THE CERTIFICATION OF IRIS CERTIFICATION™ MANAGEMENT SYSTEM

Kiwa Cermet Italia S.p.A. – Single-member company subject to management and coordination by Kiwa Italia Holding S.r.l.
Headquarters: Via Cadriano 23, 40057 - Granarolo dell'Emilia (BO), Italy – Registered at the Chamber of Commerce of Bologna with registration number and Fiscal code: 03502820370, REA: BO-295316, VAT n. 00627711203 - Share capital: € 1.000.000,00 paid-up
Tel. +39.051.4593.111 - Fax +39.051.763.382 – it.info@kiwa.com - PEC: kiwa@pec.kiwaitalia.com - www.kiwa.it

INDEX

Rev. No.	SUMMARY OF CHANGES	DATE
1	Elimination of the requirements on the use of trademarks and inclusion in a specific Regulation	2025-11-19
0	Reissue due to significant changes after implementing IRIS CERTIFICATION® Performance Assessment: 2023.	2024-03-15

Verified by:

Compliance Manager Dr. Diego De Rosa

Approved by:

Compliance and Legal Affairs Director Eng. Maria Anzilotta

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 Italia or Kiwa) 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 Italia (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 Italia website (www.kiwa.it).

2. GENERAL PRINCIPLES AND GUARANTEES FOR THE CUSTOMER

In its certification activity, as well as the General Terms and Conditions, Kiwa Italia 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 formalized rules and controls, including:

- 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 Italia; regarding this aspect Kiwa Italia 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 Italia 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 and appeals, 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 Italia 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 Italia 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 Italia 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 Italia, without prior notification and without any additional cost.

Kiwa Italia operates as an IRIS Certification™ certification body, in accordance with the signing of a collaboration agreement between Kiwa Italia 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 Italia to assist customers with regard to all necessary actions required to transfer to another registered certification body.

3. REQUIREMENTS FOR WHICH THE ASSESSMENT IS REQUIRED

- IRIS Certification™ Performance Assessment:2023;
- ISO 22163 Standard - current revision;
- ISO 9001 requirements as additional standards to ISO 22163 Standard, contained in it.

In the revisions in force.

4. BINDING REQUIREMENTS AND LEGALITY CONTROL LIMITS

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

The certification issued by Kiwa Italia 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 subject to certification.

In this regard, the audit activities of Kiwa Italia 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 ISO 22163 standard and IRIS Certification™ Performance Assessment:2023 apply:

Non-detailed data: data made public in the IRIS Database consisting of:

- Customer's general information (name, address, contact person, etc.)
- Approval status;
- Last day of the audit;
- Validity of the IRIS Certification™;
- Scope of the IRIS Certification™.

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

Remote functions: they are supporting 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: production and maintenance activities performed at another site but connected to a certified site.

A site extension is applicable if:

- The site cannot 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;
- The site only carries out production or maintenance activities;
- It is included in the planning of audits.

Guiding function: group of processes that guide various sites remotely.

Autonomous business management system: Business management system in which the Organisation manages its processes without any control activities from senior managers or shareholders of external Organisations.

Performance Indicator (PI): indicator used to measure the performance and the effective and/or efficient control of a process, but it is not limited to processes [ISO 22163:2023, 3.1.4.7].

Key Performance Indicator (KPI): a Performance Indicator chosen by the top management to assess the performance of the RQMS and its business objectives; it is pivotal to ensure a long-lasting success of an Organization [ISO 22163:2023, 3.1.4.6].

Site: An Organisation carrying out design and development activities and/or production and/or maintenance activities (fleet maintenance, renovation or inspection of components) and/or repair activities at a single site within the defined scope of the IRIS Certification™.

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

UNIFE: Association of the European Rail Industry.

IRIS Management Center (IMC): Body created by UNIFE to develop and implement the IRIS Certification™ scheme.

Veto check: upon completion of the audit, when all activities described in the audit plan are performed and the audit report is drwan up, the audit documents are reviewed to verify that data is complete and accurate.

6. CERTIFICATION REQUIREMENTS

6.1. General requirements

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

- Be an autonomous legal entity or belong to an Organisation;
- Have an autonomous Rail Business Management System that meets ISO 9001 and ISO 22163 requirements and the Rules of IRIS Certification™ Performance Assessment:2023 applicable at the time of the certification application;
- Carry out at least three certifiable activities among those provided for in the allowed business categories (see Table 1 in IRIS Certification™ Performance Assessment:2023);
- Be eligible for at least one certification scope among those indicated in Pic. 3 in the IRIS Certification™ Performance Assessment:2023, to be agreed upon during the audit;
- Consist of a single site.

The Organization shall register in the IRIS portal http://www.iris-rail.org to:

- Update its data or keep it updated: number of total employees and employees assigned to rail activities, turnover, sites, business category, certification scope/s, project management type applied by the Organization (see Pic. 2 IRIS Certification™, full or simplified IRIS Certification™ type);
- Purchase the IRIS Certification™ Performance Assessment:2023 which is mandatory to start the certification process;
- Gather detailed information about the IRIS Certification™;
- Purchase the IRIS Certification™ audit tool;
- Be ready to start the IRIS Certification™ process;

After registering in the IRIS portal, IMC examines and approves the registration in due time. After paying the due registration fee to UNIFE, the Organization is activated in the IRIS portal and an e-mail is automatically sent to Kiwa Italia.

Toward Kiwa Italia the Organization shall:

- Accept the conditions set out in this Regulation;
- Ensure collaboration with Kiwa Italia Audit Team during all audit activities;
- Make an internet connection available to the Audit Team;
- Authorise access to premises, facilities, areas and (detailed or non-detailed) information necessary to carry out the Audit;
- Appoint its Representative as the main contact for 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 Italia with complete and detailed

information regarding the specific risks existing at the facilities where Kiwa Italia personnel is expected to operate and PPE necessary for carrying out the appointment, informing Kiwa Italia personnel concerning their correct use. In this regard, the Organisation has to provide appointed Kiwa Italia personnel with 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 Italia;

- Accept, without additional costs, any auditors from UNIFE/IMC or Accredia, which shall be communicated by Kiwa Italia with a clear illustration of their roles. Their presence aims at assessing that the evaluation methods used by Kiwa Italia comply with the requirements for accreditation.

6.2. Simplified IRIS CERTIFICATION™

Small Organizations that meet the requirements in Table 2 in IRIS Certification™ may choose a full or a simplified IRIS Certification™.

The choice is shown in the Organization's general information in the IRIS portal; when an Organization choses a simplified scope of the IRIS Certification™, it shall confirms it in the IRIS portal.

Small Organizations belonging to a bigger Organization cannot apply the simplified approach.

The Organizations that choose a simplified IRIS Certification™ obtain a "simplified" certificate (indication in the certificate) and cannot obtain a QPL.

A simplified IRIS Certification™ can only be upgraded to a full IRIS Certification™ after a certification cycle and during a re-certification audit.

A simplified certification cannot be chosen if the Organization is already certified with a full IRIS Certification™ scheme.

6.3. Use of detailed data

It is strictly confidential data and Kiwa Italia saves it in a database area with limited access, which only the Customer, Kiwa Italia and the database administrator (hereinafter referred to as "database administrator") access initially. The Customer can choose whether to grant more access to detailed data, for instance whether such data may be available to third parties, including UNIFE members, through the database.

The database administrator is employed by UNIFE, who is responsible for the database maintenance. To avoid doubts the database administrator is not entitled to share acquired detailed data with no one but other UNIFE employees, the Customer to whom the data belongs, and the relevant certification body that has acquired the detailed data.

To avoid doubts the assessment process does not aim at acquiring sensitive information, such as financial information or data containing specific prices or rates, supply or demand referring to businesses or information on the performance of specific market stakeholders, etc., unless such information is necessary to verify the requirements of the main performance indicators. Instead, only the detailed and non-detailed data are obtained after the assessment process.

7. SUPPLY OF THE CERTIFICATION SERVICE

7.1. Starting the certification process

Based on the information provided by the Organisation, Kiwa Italia prepares a Quotation for Certification, indicating the reference Standard/s and the scope of the Certification reported by the Customer Organisation.

The quotation specifies the site/s subject to certification, the agreed certification scope, the expected audits during the certification cycle and their relevant days, including off-site days for planning and reporting.

The return of the Certification Quotation to Kiwa Italia, 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 Quotation), 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 website), of which a copy is attached and sent with the Quotation.

Upon receipt of the aforementioned documents, Kiwa Italia shall examine the data provided and verifies that:

- The requirements for the provision of the requested service have been clearly defined, documented and understood by both parties;
- Kiwa Italia can perform the required activities;

- The required data and documents have been provided in full, including the required scope, the chosen certification type and the Organization's processes;
- There are no differences with the data provided upon request of the quotation and the data registered in the IRIS Certification™ portal.

Upon successful completion of the previous examination, Kiwa Italia assigns an order number to the Customer. In the event of a negative outcome, Kiwa Italia 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 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 quotation was issued and the agreement signed), Kiwa Italia reserves the right to amend the contractual terms and conditions, the Customer is entitled not to accept the new conditions, but shall pay the activities carried out up to that point to Kiwa Italia.

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

Kiwa Italia shall notify the Customer of any subsequent changes to the contractual documents; it is the Customer's responsibility to always have an updated version of these documents, downloading them from the website www.kiwa.it.

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 Re-certification audit.

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

The reference date is also the expiry date of the certificate.

To confirm the certificate validity the audit shall be carried out, the non-conformities be successfully closed and the audit be registered in the IRIS portal each year, by the reference date.

Audits shall be planned within a timeframe between 150 and 30 calendar days before the reference date.

Data shall be reviewed before each audit.

The initial audit cycle includes a mandatory Readiness review of the company combined with a certification audit and two (2) surveillance audits.

Within such audit cycle the last day of the certification audit is called reference date. The reference date is registered in the IRIS portal and is regarded as a distinctive reference for the subsequent audits.

To maintain the certificate validity two surveillance audits are required to be planned and carried out within a timeframe between 150 and 30 calendar days before the reference date to avoid losing the certificate due to potential non-conformities.

The date of the first surveillance audit shall not exceed eleven (11) months from the last day of the certification audit.

The date of the second surveillance audit shall not exceed twenty-three (23) months from the last day of the certification audit.

The date of the re-certification audit shall not exceed thirty-five (35) months from the last day of the certification audit.

Before the expiry of the IRIS Certification™, the Customer shall be re-certified through an on-site re-certification audit based on similar procedures to the certification audit.

The relationship between the audits and the certificate validity is outlined in Pic. 4 in the IRIS Certification™ Performance Assessment:2023.

7.3. Audit pre-requisites

The Organization shall confirm its general information (e.g. personnel, company categories, certification activities, supporting functions, type of project management, etc.) in the IRIS portal 90 days before the audit.

Kiwa Italia shall confirm the data during the planning phase. To review the data in detail the following documents with detailed information in them shall be uploaded by the Organization in the planner of the IRIS portal not later than sixty (60) calendar days before the starting of the confirmed audit:

- Report of the management review,
- List of the Organization's processes and interactions,
- Status of Customer's complaints,
- Statistic of warranty complaints,
- Mandatory Performance Indicators (PIs), including their definitions and values for the audit period,
- Turtle diagrams or similar diagrams for no more than five (5) key processes,
- Process PIs, including their definitions and values for the audit period for no more than five (5) key processes;
- Eligibility for a simplified approach, if indicated in the Organization's general information,
- To obtain the gold level: the direct feedback by Customers (see clause 11.3).

NOTE: Any delayed upload of all preliminary data prevents the Organization from obtaining an IRIS Certification® - silver or gold Quality Performance Levels (QPL).

The data necessary to review documents with detailed information shall be uploaded by the Organization in the planner of the IRIS portal not later than sixty (60) calendar days before the audit.

Thirty (30) days after the reference date all actions regarding the last audit shall be closed and no more changes can be done.

All uploads will be deleted.

7.4. Audits

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 Italia 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.

If during the audit significant deviations are found between the company situation (sites, number of employees, company processes) and what has been communicated by the Organisation, the Audit Team shall notify Kiwa Italia immediately of this deviation in order to decide upon any contractual modifications with consequent updates of the duration of the audit[1].

7.5. Pre-audits

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

The audit team conducting the pre-audit cannot participate in the readiness review, the certification audit and the first two surveillance audits.

7.6. Readiness review

The readiness review (if applicable) shall be performed together with the data review remotely or on site, but not before sixty (60) days before the audit.

The readiness review aims at verifying the level of the Organization's compliance with the IRIS Certification™ prerequisites.

Non-conformities are not reported in the readiness review report. The readiness review is documented in the IRIS audit and its result is positive or negative. Upon passing the readiness review the Audit team shall review the audit plan based on the information collected during the readiness review, if necessary.

The readiness review is carried out before the re-certification audit or in case of a change of the Audit team within the same certification body. The readiness review aims at verifying:

[1] "Significant differences" shall mean a difference involving changes to the duration of the audit.

- The crosscheck between mandatory processes and KPIs;
- The customer's perception;
- A preliminary verification of KO questions;
- An assessment of the conditions of the customer's site and any remote locations;
- A verification of the agreed certification scope;
- Allocation of resources for the certification audit;
- The planning of the certification audit.

To verify the Organization's readiness for the audit the following data shall be examined:

- Quality policy;
- Organizational charts;
- Company's category/categories;
- Certification activities;
- Crosscheck with the processes and the relevant mandatory PIs for IRIS Certification™;
- Customer's perception performance;
- Detailed pre-assessment of the requirements linked to KO items;
- Assessment of the Organization's location and the specific conditions of the site (e.g. supporting functions);
- Assessment of the product scope (or scopes) agreed upon for the certification;
- Allocation of resources for the audit and agreement of the details with the Organization;
- Audit planning.

KO items of the IRIS Certification™ are essential requirements to be met by an Organization in the railway sector, and their positive assessment is necessary to pass the readiness review.

If the readiness review has a negative result, it shall be repeated.

Considering the information collected during the readiness review, if all abovementioned data is met, the auditor decides that the Organization is ready to proceed with the planned audit.

7.7. Certification audit

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

At least six (6) months of data and records relating to the relevant IRIS Certification™ activities within the certification shall be available before the certification audit starts.

The audit includes the verification of the following elements:

- Mandatory KO requirements;
- Customer perception;
- Performance of mandatory processes and related KPIs;
- Applicable ISO 22163 requirements;

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 any re-audits or closure of non-conformities (successful audit), the certificate can be issued.

7.8. Surveillance audit

The surveillance audit shall be conducted on site and aims at assessing the compliance with specific requirements of the business management system. Any non-conformities shall be closed with adequate support documentation or through a direct review before the reference date.

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

- Mandatory KO requirements;
- Customer perception;
- Performance of mandatory processes and related KPIs;
- Applicable ISO 22163 requirements to be verified again in the two surveillance audits;
- Corrective and improvement actions from the previous audit.

All processes shall be verified at least once during the two surveillance audits.

If a surveillance audit is not carried out, the IRIS Certification™ is not valid anymore and cannot be used for any scope, as defined in paragraph 7.2.

7.9. Recertification audit

Before the expiry of the certificate the company shall be recertified.

The aim of the recertification audit is the same as the aim of the certification audit and includes:

- Mandatory KO requirements;
- Customer perception;
- Performance of mandatory processes and related KPIs;
- Applicable ISO 22163 requirements;
- Corrective and improvement actions from the previous audit.

At the end of the audit and the closure of any non-conformities (successful audit), the new certificate can be issued.

7.10. 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.

A transfer audit can only be carried out if at least three years have passed from any previous transfer audit.

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

- The Organisation shall request the certification body change through the IRIS portal;
- Verification of the validity of the current IRIS Certification™ by Kiwa Italia;
- After the approval of the request by the IRIS Management Center (IMC), Kiwa Italia can access the Customer's data and documents relating to the last audit;
- Kiwa Italia may carry out a review of the documentation to start planning the transfer audit;
- Kiwa Italia shall ensure that no member of the audit team has previously conducted audits for the Customer in the previous two years.

Following the transfer a new certificate is issued which reports the same reference date.

7.11. Change of site or certification scope

An Organisation can be subjected to changes during the certification validity cycle, with an impact on its business system, for instance:

- Change of site;
- Change of business category;

- Change of verifiable activity[2];
- Change of the IRIS Certification™ scope;
- Change in the ownership structure;
- Change from a simplified IRIS Certification™ to a full IRIS Certification™.

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 shall fill in the form *Changes impacting the management system* available on the IRIS portal and send it to Kiwa Italia 60 days before the start of the audit.

Kiwa Italia shall verify the presence of the following information in the sent form:

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

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

7.12. Re-audits

A re-audit may be required to ensure the closure of non-conformities:

- The requests of Corrective Actions defined as “poor” shall be assessed during ta new on-site audit;
- If the requirements are defined as "poor" (levels assigned in the checklist which are equivalent to major or minor NCs), the Lead Auditor may decide to carry out another audit or choose other suitable methods to assess the effectiveness of corrective actions.

7.13. Support sites

The criteria applicable to the supporting functions are described in Table 3 of the IRIS Certification™ rules. The supporting functions are audited every year.

8. EVALUATION METHOD AND SCORING

To promote continuous improvement a representative score of the Organisation’s compliance level is assigned, based on the evaluation of the following three elements which are assessed in any type of audits:

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 performances.

A global score is given based on these assessments.

8.1. Evaluation of enabling factors through an evaluation matrix based on ISO 22163 requirements

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

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

- The maturity level can only be assigned if all specified criteria for this maturity level 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 (LA) can decide whether a specific criterion is not applicable and consider it N/A (non-applicable);

[2] A change means an addition or a removal.

- Mandatory PIs and applicable KO items cannot be considered N/A (compare Table 10 in IRIS Certification® Performance Assessment:2023).

8.2. Customer perception

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

- Needs and expectations of the interested parties;
- Customer orientation;
- Customer satisfaction;
- Review activities.

Such requirements shall be assessed in each audit according to Chapter 11 in IRIS Certification® Performance Assessment:2023.

8.3. Process performance through the evaluation of performances

The performance of 5 mandatory processes shall be evaluated during each audit:

- Project Management, ISO 22163 §8.1.3;
- Requirements for products and services, ISO 22163 §8.2;
- Control of externally provided processes, products and services, ISO 22163 §8.4;
- Design and development of products and services, ISO 22163 §8.3;
- Production and service provision, ISO 22163 §8.5.

Consistently with IRIS Certification™ activities two of the mandatory processes can be defined as non-applicable; Project Management and Requirements for products and services area always applicable.

More details are provided in Chapter 10 in IRIS Certification® Performance Assessment:2023.

9. AUDIT DOCUMENTATION

The findings of each audit shall be recorded in a preliminary and final audit report and its annexes drawn up by using the IRIS Certification™ Audit Tool.

The audit report shall be drawn up in the language agreed upon for the audit and in English, and be approved by the LA.

The electronic copy of the audit report and its annexes shall be given to the Organization.

The structure of the audit report is defined by the Audit Tool.

The structure of the annex to the audit report is defined by the Audit Tool.

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

By 30 days from the closing of the CA and after carrying out a document Veto Check a complete electronic copy of the audit report is uploaded to the IRIS Certification™ portal, to which the customer shall have access. The Organization is entitled to decide whether other organizations may view it partially or totally.

10. MANAGEMENT OF NON-CONFORMITIES

If a non-conformity is identified during an audit, a Corrective Action Request (CAR) shall be opened and the non-conformity shall be recorded in a preliminary audit report.

The current score shall also be recorded in the report.

Each CAR shall be closed not later than 90 days (all types of audits) and before the recurrence of the reference date (surveillance and recertification).

If an auditor reopens a CAR that was closed after the previous audit, a new audit is required to verify the effectiveness of the new corrective action.

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

- Analyse the root cause of the non-conformity;
- Define and implement a corrective action;
- Verify the effectiveness of the corrective action;
- Inform the Lead Auditor (LA) of the resolution of the non-conformity before the reference date;
- Reschedule the audit with the LA (if applicable) before the reference date.

The audited Organization shall implement improvement actions (Improvement Action Request IAR) that enable it to reach a higher maturity level of the Rail Management System in the future.

The improvement areas or the improvement actions as requested by the auditor shall be re-assessed by an auditor within the common audit cycle.

An IAR does not prevent the audit report to be completed or the IRIS Certification™ to be issued.

Depending on how many IARs are identified, the audited Organization may undertake to close a specific number of IARs until the next audit (at least one).

If an agreed IAR is not closed within an agreed timeframe, it is considered a non-conformity against a continuous improvement and the relevant item in the assessment checklist. Such IAR becomes a CAR.

11. IRIS CERTIFICATION™

11.1. General Requirements

After the audit the documents are subject to a document activity of Veto Check before they are uploaded in the IRIS Portal to ensure their thoroughness and consistency.

After the IRIS Certification™ audit is successful and the documentary control of the Veto Check is approved, an IRIS Certification™ is issued which specifies the category of IRIS Certification™ activities, the certification activities and the product group to which the products belong (refer to Pict. 3 in IRIS rules).

The current supporting functions are reported on the second page of the IRIS Certification™.

The IRIS Certification™ has a maximum validity of three (3) years minus one (1) calendar day from the reference date.

The IRIS Certification™ is issued in English. Upon request other languages are available.

If any changes to the IRIS Certification™ are necessary, they can only be implemented after an IRIS Certification™ audit (certification, first and second surveillance, recertification audit) and not later than thirty (30) days from the issue date of the certificate.

An ISO 9001 certificate can be issued simultaneously provided that all its requirements have been met, even though the conditions to issue an IRIS Certification™ are not met.

The assessment activity carried out according to ISO 22163, if requested by the Organization, is used by Kiwa Italia with the same scope, even for the issue and maintenance of the applicable ISO 9001 certification. The rules in the document PSC 05 A “Regulation for the Certification of Management Systems” shall apply for such certification.

The Customer is entitled to use the Certification Mark and/or enter the market as an Organization certified by Kiwa Italia according the Scheme, only after the IRIS Certification™ is issued and except when the certificate is withdrawn.

11.2. Qualitative performance level IRIS CERTIFICATION™

Following the evaluation of the three elements described in paragraph 7.9, the Organisation shall receive a specific evaluation of its qualitative performance level (QPL) issued directly by the IMC.

The QPL document is issued by IMC yearly not later than thirty (30) days after the reference date and after successful audits based on the performance results.

The annual QPL of an Organization is available in the IRIS portal. The QPL document is drawn up in English.

Criteria and thresholds to reach the various QPLs are described in paragraph 14.2.

12. PUBLICATION OF DATA

Within 30 days after the conclusion of an audit, the audit report and all related documentation shall be uploaded in the IRIS portal regardless of the outcome of the audit.

The Customer irrevocably authorises Kiwa Italia to communicate such data to IMC, regardless of the outcome.

IMC publishes the Non-Detailed Data in the Database which is in the IRIS Certification™ portal.

The Customer irrevocably authorises IMC to publish and make the Non-Detailed Data available in the database.

The Customer decides who can access the Detailed Data by granting access to it through the features of the IRIS Certification™ portal.

13. COMPLAINT MANAGEMENT FROM CUSTOMERS OF CERTIFIED ORGANIZATIONS

Complaints reported by customers of certified organizations can be sent:

- to IMC;

- to Kiwa Italia, which may also receive audit-related reports.

Complaints sent to IMC will be reviewed by IMC and forwarded to Kiwa Italia.

If the complaint is assessed as unfounded, Kiwa Italia shall confirm the IRIS Certification™.

If the complaint is assessed as well-founded, Kiwa Italia shall request appropriate corrective actions, whose closure shall be closely managed with IMC during the subsequent conformity assessment.

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

If the evaluation of corrective actions is negative, Kiwa Italia starts the withdrawal process for the IRIS Certification™ (ref. subsequent paragraph); the withdrawal process of the IRIS Certification™ does not necessarily imply the withdrawal of any associated ISO 9001 certification.

The complaint analysis process to determine its validity lasts one month from the date of reporting. The complaint management and resolution process cannot exceed three months. The Management Center of IRIS Certification™ Complaints shall notify the complainant of the results of the complaint analysis after a maximum of ten (10) calendar days from the resolution of the compliant. Overall, the complaint management and closure process takes a maximum of 3 months and 10 days.

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

A detailed procedure to manage complaints is available in the IRIS Certification™ portal at www.iris-rail.org.

Certified organizations can in turn submit a complaint (or appeal) to Kiwa Italia; this process is described in § 15 below.

14. WITHDRAWAL OF THE CERTIFICATION

If any situation occurs so that the initial conditions to grant the IRIS Certification™ are no longer met, Kiwa Italia is entitled to start the certification withdrawal process. The initial conditions to start it include:

a. Kiwa Italia receives a complaint regarding the performance of the Customer from IMC or any customer in the railway sector;

b. Non-conformities issued by the Kiwa Italia audit team after the surveillance and recertification audits;

c. Corrective actions that are not reported in accordance with the established timelines as a result of non-conformities/comments reported in 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. A surveillance audit not conducted according to the schedule and allowed intervals;

f. Reasons outlined in the *Kiwa Regulation for Certification;*

g. Any breach of contract with reference to the expected requirements for the certification or the contract with Kiwa Italia.

In view of the start of the withdrawal process, Kiwa Italia shall analyse the situation and decide whether to withdraw the certification or not within 20 days from the process starting date. In the event non-conformities this analysis shall 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 due to major non-conformities or the non-performance of surveillance audits within the required timeframes, Kiwa Italia is forced to withdraw the certification.

The withdrawal of the certification results in the automatic termination of the contract pursuant to Article 1456 of the Italian Civil Code to which this Regulation applies, except, in any case, the compensation of any damages suffered by Kiwa Italia.

15. COMPLAINTS AND APPEALS

15.1. Complaints

The Organisation may file a documented complaint regarding its relationships with the certification activities provided by Kiwa Italia.

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

Kiwa Italia records the complaints, analyses them and informs the complainant of the adopted actions within thirty days from the date on which the complaint is received.

To ensure impartiality all complaints are managed by personnel who are not involved in the activities subject to the complaint.

Kiwa Italia shall establish with the complainant whether and to what extent the content of the complaint and its resolution should be made public.

15.2. Appeals

If the complainant is not satisfied with the response, or intends to appeal against Kiwa Italia's decision, he/she may lodge an appeal in writing.

The complainant shall provide explanations for his/her appeal and, in the event that the appeal refers to a decision made by Kiwa Italia, the appeal shall be lodged to Kiwa Italia within 10 calendar days from the date on which the decision is communicated.

Kiwa Italia shall provide the complainant with a written reply and give notice of any actions to be taken within 30 working days from the date on which the appeal is received.

Appeals are managed by functions which are not involved in the activities subject to the appeal.

A detailed description of the process to file complaints and appeals is available on the website www.kiwa.it.

16. USE OF THE CERTIFICATION MARK

Customers with a Management System certified by Kiwa Italia can choose whether or not to use the certification mark granted by Kiwa Italia.

If using the certification mark, the customer must comply with all applicable rules set forth in the Kiwa Certification Regulations and the Regulations for Use of the Mark, to which reference is made (www.kiwa.it).

Customers with a certified Management System can also use the IRIS Certification® logo, which can be downloaded from the IRIS portal after signing the terms of use.

17. COMMITMENTS OF THE ORGANISATION

The Customer undertakes to:

- Not refuse any witness audits performed by IMC towards Kiwa Italia and any internal witness audits carried out by Kiwa Italia (this does not imply any additional cost for 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 Italia and its auditors through the features available in the IRIS portal.

The Customer, including its employees, managers, agents and other representatives, as well as its shareholders and other companies or members of its Group, undertake to

- only use the original rules and software of the IRIS Certification™ and refrain from using any document or copy of the software that may infringe UNIFE's intellectual property rights;
- Irrevocably authorise Kiwa Italia to transmit the audit data to IMC through the IRIS portal;
- Irrevocably authorise IMC to publish and make Non-Detailed Data available in the database in the IRIS portal;
- Promptly inform Kiwa Italia 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 data reported in the application for certification (including the site/s, scope, documentation, significant changes in products/processes and/or the number of the involved personnel);
- Changes of ownership, legal, commercial and organisational status;

In response to these changes, Kiwa Italia 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 start a new certification process).

- Promptly inform Kiwa Italia of exceptional events, judicial and/or administrative proceedings, accidents, emergencies or legislative non-conformities;
- In the event of a withdrawal: send a notification to customers requesting the certification, informing them that the Organization is no longer certified with the IRIS Certification™ and return the certificate to Kiwa Italia.

If a change is not communicated to Kiwa Italia, it 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 Italia and the Customer shall give rise or can be considered 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 damage suffered by the Customer in relation to the IRIS Certification™.

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.

18. CHANGES OF THE CERTIFICATION SCHEME

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

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

19. RIGHT OF UNILATERAL WITHDRAWAL FROM THE CONTRACT

Kiwa Italia may freely withdraw from this agreement by giving written communication to the Customer Organisation with a notice of six months from the effective date of withdrawal. The withdrawal by Kiwa Italia determines the

withdrawal of the issued certification. The Organisation shall in any case pay to Kiwa Italia the amounts due for the services received during the notice period, as established in the last valid quotation.

If the Organisation desires 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 *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 Italia will issue an invoice for the expenses of closing the certification file, in accordance with the last valid quotation.

20. UNILATERAL AMENDMENT OF THE CONTRACT

Kiwa Italia reserves the right to amend this regulation at any time. Any new clauses/amendments shall become effective from their written notification to the Customer.

If the Organisation does not accept the amendments, it may terminate the contract by giving written notice by registered letter with return receipt or certified e-mail within 30 calendar days, under penalty of forfeiture, from the day after the communication to Kiwa Italia.

The termination shall become effective from the last working day of the month in which the Customer’s notice is received.