INTERNATIONAL RAIL QUALITY BOARD

IRIS Guideline 2: First Article Inspection (FAI)

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English

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1. Introduction

The aim of this guideline is to provide guidance to all organizations during the implementation and maintenance of an IRIS certified Business Management System (BMS) concerning planning, preparation, execution (covering inspection and verification activities) and documentation of the First Article Inspection (FAI) necessary to comply with the requirements of ISO/TS 22163.

FAI applies to internal and external products to release serial production, the validation of production equipment and the production processes. FAIs may also be contractually agreed milestones with suppliers or with customers, e. g. on prototypes, pre-series, or technical specifications.

The main purpose of the FAI is to give objective and documented evidence that all engineering, design, and specification requirements are correctly understood, accounted for, verified, and recorded, as well as to validate the production operations (including manufacturing gauges, tools, jigs, and fixtures) of a new product (or major upgrade of an existing one) and can be considered as a binding requirement to be met prior to release the series production.

Simultaneously, the FAI validates the manufacturing equipment used to produce the products.

2. Terms and definitions, Abbreviations

For the purposes of this guideline, the terms, definitions, and abbreviations given in ISO 9000 and ISO/TS 22163 apply.

The ISO/TS 22163 defines the FAI as:

Set of inspection and verification activities in order to validate a production process.

Please note following application aspects (see IRIS Certification® Conformity Assessment: 2020):

- If the product is one-off, FAI is meant as validation.
- FAI is not applicable for organizations having activities in design, only.
- If the product is software only, FAI is meant as validation according to applicable IEC standards (e.g., EN 50128 / EN: 50657)
- FAI is a key milestone of the organization's production process.

The terms "inspection", "verification" and "documentation" hereinabove specified, are to be understood as a complete, independent, and documented physical and functional inspection process to verify that prescribed production methods to produce an acceptable item as specified by engineering drawings, planning, purchase order, engineering specifications, and (or) other applicable design documents (extract from the EN 9102).

2.1 Terms and definitions

Additional terms used in this guideline:

Corrective Action Request (CAR):	non-compliance found during the FAI process, to be recorded in the FAI Report and to be closed by the responsible party within the agreed time frame.
First Mounting Inspection:	inspection performed, upon positive result of the FAI, on the product installed at the expected final destination (e.g.: system or rail vehicle), to review interfaces or any other additional detail or both not verifiable during the FAI process.

KO:	Knock out requirement according to IRIS Certification Conformity Assessment APPENDIX 7 of IRIS Certification® Conformity Assessment: 2020
Product Manufacturing and Inspection Plan (MIP):	document planning controls, inspections and tests foreseen during the manufacturing process of a product, specifying (directly or through specific references) the operational mode, the applicable technical documentation (e.g., technical specifications, procedures, drawings, work instructions) and the relevant acceptance criteria. Development of any manufacturing step and relevant inspection result (wherever applicable) may be recorded in the appropriate area of the MIP.
Quality plan (QP):	Specification of the procedures and associated resources to be applied when and by whom to a specific object. [ISO 9000]
System:	aggregation of hardware and software components, arranged to achieve specific functions or features. The term "system" also consists of subsystems, equipment and all other components requested or recommended or both to achieve the required functions.
Type test:	single (series) of test(s) through which technical compliance of the system to the project, statutory and regulatory requirements is proven.

3. Requirements and responsibilities

3.1 ISO/TS 22163 FAI requirements

The requirements on the FAI are covered in ISO/TS 22163 chapter 8.9.

The implementation of a documented process for FAI is assessed through the verification of a KO question (IRIS assessment sheet item 8.9-1), which can also be put as not applicable if no manufacturing or maintenance activity is part of the scope.

In addition, ISO/TS 22163 chapter 8.9 requires a process to be established, implemented, and maintained within the organization's BMS to ensure proper outcome of the FAI. These requirements also apply to external providers to release serial production.

Customer specific FAI requirements need to be taken into account. In case a customer FAI is contractually required, this will be supplemental to the BMS control and consequently, the organization may still perform an internal FAI to check if all requirements are met.

3.2 Responsibility

According to ISO/TS 22163 requirements, a process owner is appointed for the FAI process (ISO/TS 22163 chapter 5.3.1).

The turtle approach (or similar means) will allocate responsibilities through the different organization's departments on the FAI's management. Duties and commitments of the different individuals appointed for the corresponding activities will be stated therein, regarding the main activities to be carried out to plan, execute and document a FAI.

4. Process of the FAI

4.1 FAI management

To manage the FAI process properly and punctually, the organization can address the following main questions:

- **WHEN:** To define, plan and manage when and under which condition a FAI could be conducted;
- **WHAT:** To decide and specify what product or component could be subject to the FAI, what inspections (verifications) could be conducted on these products or components, and which associated processes to be validated, what data to be recorded as output of the FAI process;
- **HOW:** To specify how an FAI could be performed and how the results could be documented and recorded; define criteria for: release, conditional release, and rejection;
- **WHO:** To state different responsibilities through the organization, concerning the overall FAI process management (who is responsible for what?);
- **WHERE:** To determine whether the FAIs could be performed internally or at external provider's (tier to be defined), primarily depending on the processes developed by the organization.

The FAI process is defined by the organization (e.g., through a turtle diagram) by addressing the following elements:

- process owner;
- internal/external process customers;
- internal/external process suppliers;
- interfaces and dependencies (input/output);
- work content / process operation;
- material resources;
- personal resources;
- performance indicators;
- main risks & opportunities.

4.2 Applicability – When

The FAI is performed on a representative item from the first series production run of new products, by using defined methods intended to validate the normal production process (series production), or in case of major upgrade of an existing product.
Significant changes of existing products can include:

- major design changes (such as changes relating to performance, reliability, availability, maintainability, safety, or other important features);
- major production process changes (such as process methods, test methods, production or measuring equipment, location or other changes);
- transfer from one factory to another;
- restart of production if process conditions have changed;
- change that could affect the conformity of the product;
- change of an external provider or external provider site change.

Whether the FAI is a compulsory condition, this requirement is included in the QP and MIP, as a mandatory step to release series production of the product.
Table 1 gives an overview about different types of FAIs.

Table 1: Types of FAI

FAI process apply to	Conditions	Required by whom	Who	What	Output
Products made by **suppliers/ outsourcing** of organization	first production at new supplier	Organization	Supplier and Organization	• inspection of product. • inspection of production documents of critical processes and special processes • verification of quality inspection and results. • verification of fixture/ tools of critical & special processes. • verification of parameters of production machines (critical processes). • considering requirements of customer's FAI. • a standard checklist should be used for FAI. See sample below.	• FAI report with clear result. See ISO TS 22163 clause 8.9 d). • released production including new fixtures/ new tools in case of condition release/ release. • corrective actions in case of condition release/ rejection.
	new product for existing supplier	Organization	Supplier & organization or supplier		
	new production line for existing product/ new machine/ new fixtures…				
	new location of existing supplier				
	re-starting after long time break of existing product				
	major technical change				
Products made by **organization self**	new product	Organization	Organization		
	major technical change				
	new production line/ technology / new machine / new fixtures				
	new location of existing production line/ products				
Required by **customer**	defined by customer	Customer	Customer and organization	• customer requirements. • preparation according to customer requirement.	• Decision by customer. • Actions when required.

4.3 Arrangement and planning - What and Who

A typical “List of products and components to be subject to the FAI” may be defined by the organization and included in the FAI process.

In case an FAI is developed by an external provider of the organization on a determined product or component, specific requirements may be defined and included into the contract (purchase order) issued by the organization, to manage and rule such activity with the external provider.

Standardized FAI checklist/template may be defined and used during FAI and examples are provided in chapter 5.1.

FAI program: Can be defined by the organization for each project and may include the “List of products and components to be subject to the FAI”, the relevant responsibility (internal or external provider), and all the relevant data to properly schedule and manage the FAI activities (e.g., product part number, purchase order number, FAI expected date, FAI effective date, presence of open items).

Specific responsibilities may be assigned within the organization, to monitor and to keep the project’s FAI program updated.

FAI team: Depending on the product to be subject to the FAI, on the overall design & development responsibilities and whether the inspection could be performed at organization’s or at external providers premises, a “typical” list of participants (with relevant individual responsibility) may be defined by the organization and included as a template in the FAI process.

The FAI team has to be able and responsible to execute, complete and report the outcome of the following tasks like:

- review all the documentation pertaining to the manufacturing process (e.g. MIP & QP, manufacturing work instructions) to make sure that the foreseen operations included therein are carried out as planned;
- review all applicable documents supporting the FAI for completeness and updating (e.g. QP, MIP, inspection and test data, acceptance, and routine test procedures);
- review material certifications for updating, completeness and conformance to the stated requirements (e.g. non-metallic materials fire and smoke test reports, raw materials test certificates, …);
- verify that performed special processes during manufacturing are qualified, validated and approved as required by contractual or internal or both requirements (including authorized personnel and external sources, if any);
- verify that applicable defined key characteristics of product and process are fully achieved;
- verify that all specific gauges, tools, jigs, and fixtures designed and used during manufacturing are validated, qualified and traceable, as applicable;
- verify that statutory and regulatory requirements applicable to the product are met,
- verify product configuration and its correlation to the applicable and updated project documentation and drawings;
- verify that traceability requirements are met, as applicable;
- report and record any possible discrepancy or non-conformity or both, in term of the product and/or process, the statutory and regulatory, contractual, and internal requirements;

- determine the result of the FAI and authorize the starting of the serial production (in case of approved or conditionally approved) or to repeat the FAI (in case of rejection);
- fill and distribute the FAI report including list of open items (if any), with addressing responsibilities, and defining the expected closing date for each item;
- follow-up and close all open items raised during the FAI (if any), gathering required information by the interested parties, and reviewing them for completeness and conformity to the stated requirements.

4.4 Execution – How and Where

Pre-conditions to perform an FAI are to be evaluated by related FAI team of the organization prior to beginning the FAI, by reviewing the availability of a list of approved documents, drawings, certifications and plans, applicable to the product or to the component to be subject to the FAI (e.g., final design review report, list of applicable drawings, QP, MIP, fire and smoke test reports).

In case of a complete system, the positive result of the type tests (or comparable positive results on a similar application) may be also considered as a pre-condition to perform the FAI.

In case of some specific type test, where the outcomes could be made available after the FAI (e.g., endurance tests results), any possible impact on the system's configuration can be evaluated for product's modifications and repetition of FAI.

When all the stated pre-conditions are fulfilled, the organization may begin the FAI (either internal, customer required or at external providers premises).

The organization may also define whether a "First Mounting Inspection" will be necessary to settle the FAI process (e.g., in case of interior fittings) and finally release the series production.

In exceptional cases it may also be possible to perform an FAI remotely. In this case a well-organized preparation is necessary to ensure the technical feasibility of the execution.

4.5 Non-conformance management

The FAI has to be considered incomplete (therefore series production cannot be released) until all the non-conformities, the open items and/or the CARs affecting the product subject to the FAI are closed and the corrective actions are implemented by the responsible parties.

According to the requirements of ISO/TS 22163, the organization defines criteria and conditions for releasing or not releasing the serial production, regarding the following possibilities:

- Approved: FAI successful
- Conditionally Approved: no blocking open items
- Rejected: FAI failed because of blocking open items

In case of a conditional approval, a concession, or a deviation permit by customer (if applicable) is needed and the serial production can start, providing those materials under concession are identified and the open items are closed within the agreed time and documented.

In case of unsuccessful evaluation of FAI's pre-condition, non-conformance FAI, the organization may inform the customer in writing timely.

5. Bibliography

5.1 Forms & templates

It is strongly recommended that the FAI process includes specific forms and templates, to assure punctual and complete gathering of the FAI results and to allow easy sharing and updating of the different information through the organization and the stakeholders and to report FAI output data, results, and outcomes.

Such forms and templates can be designed to allow a simple, clear, and quick management of the information through the organization, the stakeholders and during the FAI planning, execution, and data review.

However, the FAI documentation records retention, based on customer or regulatory or both requirements (if any), can be foreseen and included in the FAI process.

A “FAI Checklist Template”, which may be used by the organization during the FAI process, is enclosed with the present Guidance as “Annex 1”.

The IRIS Guideline 09: Small and medium enterprises also offers an editable FAI report template that may be used.

First Article Inspection

Document Nr.	

FAI Typ		Product 1
		Product 2
		Product 3

FAI Reason		New Supplier		Change production sequence
		New or Changed Part		Production Interruption
		Repeated Inspection		Changed Design
		New Manufacturing faci		Other

Participants	NAME	SIGNATURE	NAME	SIIGNATURE

Serial Production		Released
		Released with condition
		Blocked

Confirmation

We declare that:	1. The shown samples were produces with serial tools and under serial conditions
	2. The FAI and description in this report were made correctly in all conscience, deviations were registered and

	Date	Name	Signature
Responsible 1			
Responsible 2			
Responsible 3			
Responsible 4			

Reviewed material / system / component

Article Number	ID	Drawing and description	Revision	Quantity	Serialnumber	Manufacturingdate
...						
...						

Co-applicable Documens

Identification Nr.	Document	Drawing	Date	Comments

FAI Performed by	
Date	
Signature	

Created by	
Checked by	
Approved by	
Revision	
Date	

Distribution list	

Figure 1: Example FAI report

ANNEX 1

First Article Inspection (FAI) Checklist

Project:
Component:
Type of FAI:
Contact person/function:

#	Section	Question	Answer	Details/Evidence	Action	Who	Due-date	Blocking?	Closure date	Remarks to status of action	Remark to question
1	Purchase order	Is the status of the purchase order correct? (number, date and issue level)									
2	Purchase order	Is the order confirmation available?									
3	Scope of supply	Is the documentation updated as per latest purchase order and relevant open items: - external providers supplier drawing / BOM / wiring lists -drawing detail / issue -supplier part numbers -modification level									
4	Type testing / Routine testing	Is the routine testing status of first article consistent with the Inspection Test Plan? (Remark: All procedures and reports shall be available for review)									
5	Type testing / Routine testing	Is the type testing status of first article consistent with the Qualification and Test Plan (QTP)? (Remark: All procedures and reports shall be available for review)									Not relevant to all components/ systems
6	Identification/ Configuration	Have the identification/configuration of the parts been inspected?									Configuration matrix with serial numbers of sub-components

7	Documentation	Is the content/layout of the certificate of conformity (e.g. CoC 3.1 according to EN10204) consistent with customers requirements?									
8	Inspection of component	Is all the required labelling available & positioned correctly (e.g. identification plate)?									
9	Inspection of component	Has the first article used for the FAI been produced using the final series production processes & equipment (i.e. prototype not acceptable)									First article to be produced using the final series production processes & equipment
10	Inspection of component	Do workmanship and aesthetics meet customer requirements?									Undertake a visual inspection against drawings, glass case standards and other relevant agreement focusing on workmanship and aesthetics.
11	Inspection of component	Are all routine test reports compliant with test procedures? (Witness routine test as specified, cross reference the FAI component serial number, and review test reports)									
12	Inspection of component	Is the routine test equipment calibrated? (Request copies of supporting documentation)									
13	Inspection of component	Do the critical parameters (e.g. dimensions, electronic values) and interfaces match the latest specifications or model on all parts? (Review dimensional reports for all the FAI component parts, and understand how dimensions have been recorded, e.g. using a measuring machine or by hand, ...)									
14	Inspection of component	Is the correct version of software (and of software patches if applicable) installed? (Record and check with Engineer)									

15	Installation instruction and training	If applicable: Have the installation instruction and the documents for installation training at the customer been forwarded to the relevant persons?									
16	Packaging	Do the packaging, delivery method, delivery documentation, and component identification meet export, customs and customer requirements?									
17	Concessions	Has the status of any applicable concession been documented?									
18	Concessions	If rework has taken place on the component, was an agreed & approved rework procedure followed and did the supplier obtain approval prior to reworking this specific item?									
19	SWQA: Part number	Is a part number given for each software and hard ware component of the system?									SWQA: Software Quality Assurance
20	SWQA: Documentation	Have all documents required been accepted by Software Quality Assurance?									If applicable, refer to SWQA checklist
21	SWQA: Validation	Is the Software validated and has the Validation report been approved?									If applicable, refer to SWQA checklist
22	Safety	Does the product match all the safety requirements?									
23	Special processes	Are special processes carried out during manufacturing qualified, validated and approved as required by contractual or internal or both requirements (including authorized personnel and external sources, if any)?									

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