


## **LG-01-F-7.4.0**


# **Assessment Methodology applied for EC and National Conformity Verification of Rail Structural Subsystems**

0.0	03/07/17	First Issue	MF Senior Expert	MU Quality Dept.	GM Tecnichal Director
<b>Rev.</b>	<b>Date</b>	<b>Description</b>	<b>Issued</b>	<b>Verified</b>	<b>Approved</b>

 <b>ITALCERTIFER</b> GRUPPO FERROVIE DELLO STATO ITALIANE	<b>GUIDELINE</b>	Rev. 0.0
	<b>LG-01-F-7.4.0</b>	Pag. 2 of 12


## SUMMARY

<b>1</b>	<b>ACRONYMS .....</b>	<b>3</b>
<b>2</b>	<b>FOREWORD .....</b>	<b>4</b>
<b>3</b>	<b>THE ACTIVITIES IN THE DIFFERENT PHASES .....</b>	<b>7</b>
<b>3.1</b>	<b>PROJECT STARTING PHASE .....</b>	<b>7</b>
<b>3.2</b>	<b>DESIGN ASSESSMENT PHASE .....</b>	<b>7</b>
<b>3.3</b>	<b>CONSTRUCTION / INSTALLATION ASSESSMENT PHASE .....</b>	<b>8</b>
<b>3.4</b>	<b>FINAL ASSESSMENT AND CERTIFICATION PHASE .....</b>	<b>8</b>
<b>3.5</b>	<b>OPERATION &amp; MAINTENANCE MONITORING PHASE .....</b>	<b>9</b>
<b>4</b>	<b>THE STANDARD ITALCERTIFER ORGANIZATION .....</b>	<b>9</b>
<b>4.1</b>	<b>PROJECT MANAGER .....</b>	<b>10</b>
<b>4.2</b>	<b>TEAM LEADER .....</b>	<b>11</b>
<b>4.3</b>	<b>TECHNICAL TEAMS .....</b>	<b>11</b>

 <b>ITALCERTIFER</b> GRUPPO FERROVIE DELLO STATO ITALIANE	<b>GUIDELINE</b>	Rev. 0.0
	<b>LG-01-F-7.4.0</b>	Pag. 3 of 12

## 1 ACRONYMS

ACRONYM	MEANING
CCS	Control, Command & Signalling
EC	European Community
INFRA	Infrastructure and Superstructure
I.S.A.	Independent Safety Assessor
No.Bo.	Notified Body
PM	Project Manager
PRM	Person with Reduced Mobility
QMS	Quality Management System
SRT	Safety in Railway Tunnels
TSI	Technical Specifications for Interoperability

 <b>ITALCERTIFER</b> GRUPPO FERROVIE DELLO STATO ITALIANE	<b>GUIDELINE</b>	<b>Rev. 0.0</b>
	<b>LG-01-F-7.4.0</b>	<b>Pag. 4 of 12</b>

## 2 FOREWORD

The Conformity Verification to the applicable European and National rules of a railway component or subsystem consists of a number of well-defined activities, generally identified under the name of “assessment procedure”, aimed to the verification and certification of the compliance to the essential requirements of the “objects” subject to the certification. Such activities mainly consist on:

- the analysis of the documentation provided by the Applicant
- quality audits at the Applicant’s and its main suppliers’ premises and construction/installation sites
- witnessing to the type tests and/or final tests carried out in laboratories and/or on-field

The activities mentioned above are carried out by Italcertifer in the roles of:


- Notified Body (No.Bo., for the demonstration of compliance with the Technical Specifications for Interoperability (TSIs))
- Designated Body (De.Bo., for the demonstration of compliance to the applicable National Rules, when existing and notified to the EU Commission)
- CSM Assessor (As.Bo., for the assessment of the risk analysis carried out by the Applicant, when this process is applicable in conformity to EU Regulation 402/2013)
- Independent Safety Assessor (I.S.A. for the demonstration of compliance with the set of EN 50126, 50128 and 50129 where applicable). Depending on the particular project, Italcertifer may cover one or more of the roles mentioned above.

Following the positive conclusion, utilizing the procedures defined in the applicable Modules (as defined in the EC Decision 713/2010) of the aforementioned activities, Italcertifer provides the issue of the relevant Certificates summarizing the results of the verification process in the attached Technical File.

In accordance with the activities performed as No.Bo., the documentation issued by Italcertifer is an “EC Certificate”, accepted and recognized by all the Member States of the European Union under the “cross acceptance” principle.

In accordance with activities performed as De.Bo., Italcertifer issues a Certificate of Conformity to the applicable National Rules of the specific Member State, where the process that is carried out, is only valid at national level as an integration to the EC rules, in order to cover particular requirements.

At the beginning of the procedure, who requests the certification (the Applicant), that usually is the designer/manufacturer or the final user (i.e. Infrastructure Manager), shall submit a request to start the

 <b>ITALCERTIFER</b> GRUPPO FERROVIE DELLO STATO ITALIANE	<b>GUIDELINE</b>	<b>Rev. 0.0</b>
	<b>LG-01-F-7.4.0</b>	<b>Pag. 5 of 12</b>

process of Authorization to Put in Service (APIS) of a new or renewed/modified structural subsystem (or interoperability constituent).

In order to start the APIS application process the Applicant has to, “inter alia”, nominate a No.Bo. and (when requested) a De.Bo., an I.S.A. and a CSM Assessor and to select the Modules among those allowed by the applicable TSI.

Afterwards, the Applicant has to provide to the Certification Body the complete technical documentation of the object (component(s), subsystem(s)) to be assessed, in such quantity and quality that allow the assessment of the object regarding the applicable TSI and National requirements.

These documents, in relation to the different phases of design, manufacturing and operation, shall be coherent with the reference normative frame defined by the Applicant as applicable to every stage of the process.

Part of the documents are the following:

- Test Reports to be provided in order to demonstrate the fulfilment of the TSI and National requirements. The Interoperability Directive states that tests shall be carried out by Laboratories accredited against ISO 17025 or qualified by the No.Bo.
- Use and Maintenance Manuals
- Quality Manual (including the list of the used procedures), depending on the selected assessment Module.


The assessment procedure may change according to the goals that the certification must reach, which are synthetically listed below:

a) for interoperability components (ICs)

- Design verification;
- Tests of the conformity and/or suitability for use of the component;
- Verification of the quality management system of the manufacturer, if required by the selected Module;

b) for the subsystems

- Design Verification;
- Conformity of the construction/installation (as built) to the design documents
- Tests on the conformity of the subsystem;
- Verification of the technical compatibility and safe integration of the subsystem;

 <b>ITALCERTIFER</b> GRUPPO FERROVIE DELLO STATO ITALIANE	<b>GUIDELINE</b>	<b>Rev. 0.0</b>
	<b>LG-01-F-7.4.0</b>	<b>Pag. 6 of 12</b>

- Verification of the quality management system of the manufacturer, if required by the selected Module.

In order to develop the aforementioned activities, a number of qualified experts are used by Italcertifer as Assessors.

Their skills, competence and independence are the basic requirements and are essential for the correct and complete implementation of the whole certification process. In particular, the Technical Assessors are in charge of the document analysis, the conformity verification and the test witnessing, while the Assessor of Quality Management Systems (QMS) takes into consideration the various factors interacting in the quality assessment process.


Both type of Assessors must have:

- deep knowledge of the procedures, standards and norms to be applied and the related process;
- adequate experience gained in the different involved areas (infrastructure, energy, vehicles, signaling, maintenance and operation etc.).

The staff interested in the assessment activities must guarantee the absence of any conflict of interest and incompatibility to carry out the requested tasks, as requested by the Interoperability Directive for the Notified Bodies.

As far as the implementation of tests static and on track is concerned, two laboratories directly managed by Italcertifer are usually used: the one in Rome for the Infrastructure subsystems (mainly track and signaling) and the one in Florence for the Rolling Stock. Both are properly accredited or qualified for the related sectors and for the kind of tests they carry out.

The first one is provided with particular facilities and equipment, necessary for the control of the infrastructure parameters, installed on-board of a High Speed (HS) Laboratory train that is called Y1.

 <b>ITALCERTIFER</b> GRUPPO FERROVIE DELLO STATO ITALIANE	<b>GUIDELINE</b>	<b>Rev. 0.0</b>
	<b>LG-01-F-7.4.0</b>	<b>Pag. 7 of 12</b>

### 3 THE ACTIVITIES IN THE DIFFERENT PHASES

As already said, the assessment procedures require differentiated activities according to the different goals of the certification (conformity verification and/or safety assessment) as well as according to the different phases of design, production or use of the object to be certified.


Such phases can be identified in detail below:

#### 3.1 PROJECT STARTING PHASE

- a. Definition of the applicable reference regulatory framework concerning the object to be certified following the individuation of one or more of the subsystems concerned and described below: such framework can refer to European rules (TSI and EN standards or to International rules (UIC, AREMA, IEC, ISO, other regulations or standards) or specific standards applied in a Nation, according to what indicated by the Applicant. It is to be underlined that generally, in case of a European regulatory framework, the safety-related verifications are already included in such framework; otherwise, it will be Italcertifer's concern to verify and propose to the Applicant for certification or assessment, which regulations and standards may be possibly applied to the aforementioned verifications.
- b. Issue of one or more Technical Report(s) containing the indication of the selected reference regulatory framework as defined above and "freezing" of the reference regulatory frame work for all the following phases;
- c. Issue of a Quality Audit Report concerning the assessment of the Quality System adopted by each of the parts involved in the project. Such activity is preliminary to the following ones, since it may generate modifications to the procedures that will be used in the subsequent phases concerning design, construction and use of the object to be certified.

#### 3.2 DESIGN ASSESSMENT PHASE

- a. Support of Italcertifer experts to the designers of each of the concerned subsystems, in order to verify, starting from the design phase:
  - which are the requirements stated in the applicable normative frame, for which the compliance has to be demonstrated, with reference standards,
  - which are the steps to demonstrate the correct integration among different subsystems,

 <b>ITALCERTIFER</b> GRUPPO FERROVIE DELLO STATO ITALIANE	<b>GUIDELINE</b>	<b>Rev. 0.0</b>
	<b>LG-01-F-7.4.0</b>	<b>Pag. 8 of 12</b>

- which are the documents to be provided for the above mentioned design assessment phase,
  
- which are the documents to be provided for the demonstration of application of the Quality Assurance System to the design process;

- b. Issue of a Report related to the design phase, including the overall assessment with notes and comments (if present);
- c. Issue an Intermediate Statement of Verification (ISV), if required by the Applicant, according to Directive EU 106/2014.

### **3.3 CONSTRUCTION / INSTALLATION ASSESSMENT PHASE**

- d. Presence on-field of Italcertifer experts during the construction/installation ongoing and final activities of the concerned component(s) and/or subsystem(s), in order to verify the related process, the compliance with the design, the conformity with the standards, the correct performance of the testing activities, etc.


Also in this case, the used procedure depends on the Quality System adopted by the constructor; the use of specific check-lists is still expected;

- e. Issue of a Report related to the construction/ installation (as built) phases, including the overall assessment with notes and comments (if present);
- f. Issue of another Intermediate Statement of Verification (ISV), if required by the Applicant, according to Directive EU 106/2014.

### **3.4 FINAL ASSESSMENT AND CERTIFICATION PHASE**

- a. Support to the definition of the final testing and commissioning activities necessary for each component and/or subsystem, and direct participation of Italcertifer in their carrying out as test witness or testing authority (depending on the applicable rules) and qualification of the laboratories involved to perform them, in the case they are not accredited against ISO 17025;
- b. Support to the definition in particular of the tests for the integration in the railway system of the different subsystems and components either realized during the project to be certified, or external to it or existing before it;



	<b>GUIDELINE</b>	<b>Rev. 0.0</b>
	<b>LG-01-F-7.4.0</b>	<b>Pag. 9 of 12</b>

- c. Issue of one or more final assessment reports of the tests carried out both on each subsystem and on the overall system on the basis of the tests reports issued by the laboratories;
- d. Issue of the Final Report or Technical File and Certificates, according to the applicable regulatory frame.

### **3.5 OPERATION & MAINTENANCE MONITORING PHASE**

Where requested, Italcertifer support may be extended also to the activities following the put in service of the subsystem(s).

They can be monitoring activities of the object certified during the period after its commissioning and during operation and maintenance (O&M).

The duration of such period can be either agreed ~~upon~~ with the applicant or defined by the reference specifications.

Throughout all the agreed period Italcertifer will monitor the O&M activities with respect to limits and procedures to be defined in accordance with the Applicant.

The Applicant itself may have a constant and updated view of the project behavior, potential problems and related solutions, fulfilling of the terms for performance indicators, RAM parameters, etc.

Moreover, Italcertifer may act as “responsible Coordinator” also towards to the other subjects/suppliers that might interact during the different phases and, with such role, take care of the related coordination, through appropriate procedures agreed since the start of the activities.

## **4 THE STANDARD ITALCERTIFER ORGANIZATION**

The organization set up in general by Italcertifer for the assessment activities of a project including different subsystems is shown in the following diagram.

In case of a more limited scope of the assessment (only one subsystem involved, single components, etc.) the organization is subsequently adapted, still keeping though a similar structure.

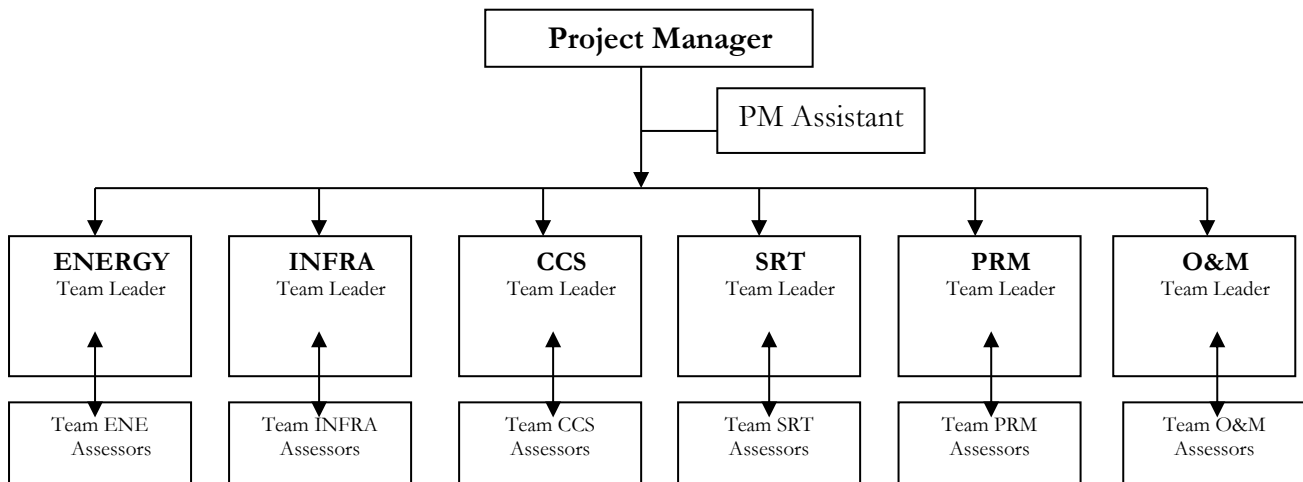


Fig. 1

Main roles and responsibilities in the organization are hereby defined:


#### 4.1 PROJECT MANAGER

The Project Manager (PM) is the expert who coordinates the project activities and represents the main contact point between Italcertifer, the Applicant and the other main “Parts” involved (suppliers, installers, testers,...).

Among the Project Manager’s main responsibilities there are:

- Contract Management;
- Definition and Control of the overall project planning;
- Supervision of the correct implementation of the project (verification of the fulfillment of the terms and of the planned costs as well as the correct detection of the certification activities to be performed);
- Management of the periodic meetings with the Applicant and the subcontractors during the design, construction/installation, final testing and commissioning phases;
- Qualification of the concerned Laboratories, in case of need in accordance with specific agreements with the Team Leaders and the Quality Assurance Department;
- Official delivery of all the documents to be issued;
- In case of complex projects the PM may be supported by a PM Assistant that acts in the Project Manager’s stand in case PM is absent or unavailable.

Both of them are Senior Assessors.

 <b>ITALCERTIFER</b> GRUPPO FERROVIE DELLO STATO ITALIANE	<b>GUIDELINE</b>	<b>Rev. 0.0</b>
	<b>LG-01-F-7.4.0</b>	<b>Pag. 11 of 12</b>

## 4.2 TEAM LEADER

The Team Leader, who operates throughout the overall project duration, is responsible for the planning and carrying out of the activities of his own team, managing and coordinating the related technical resources assigned for the specific subsystem or topic.

Main responsibilities that take part Team Leader's duties are:

- Assignment of the specific assessment tasks to the Team experts;
- Verification of the respect of the time schedule for the specific subsystem assessment process
- Guarantee of the uniformity of the approach, assessment methods and templates inside the Team, in coordination with the other Team Leaders and the project PM;
- Participation in meetings with the Applicant and/or further Parts involved, in order to work out specific problems and rearrange the activities, if necessary, under the PM supervision;
- Information exchange with the other Team Leaders and the project PM regarding the works progress and of potential "common" problems to the different Teams.
- Arrangement and control of the assessment reports issued by his/her Team.

The Team Leader is a Senior Assessor with specific experience in his/her competency field, owning also further knowledge concerning the railway sector in general as well as standards, systems, technologies, components.


## 4.3 TECHNICAL TEAMS

Technical teams, each of them usually operating during the period of time required by the respective activities, are in charge of actually carrying out all the assessment activities expected.

They are normally composed of engineers, specialized in the different areas concerned (infrastructure, energy, control/command & signaling,...)

Many of them are Senior Assessors in the respective areas of expertise and, depending to the project tasks and stages, are helped by Junior Assessors.

The available resources are always estimated by the PM as appropriate for the activities to be carried out.

 <b>ITALCERTIFER</b> GRUPPO FERROVIE DELLO STATO ITALIANE	<b>GUIDELINE</b>	<b>Rev. 0.0</b>
	<b>LG-01-F-7.4.0</b>	<b>Pag. 12 of 12</b>

If and when it is necessary, they can be strengthened with additional staff coming from the main Italcertifer shareholders, represented by four Italian Universities. This possibility allows to integrate the teams' composition with further specialists able to add their own experience and competency from the academic world and to provide special skills for very specialized items.

The Technical Teams are the “core” of the organization and they are organized in order to ensure that all the “areas” present in the project are covered with a specific competence and an appropriate quantity of resources, so that even extra activities not initially planned, can be faced.

All the members of the technical teams are experienced Assessors.

In case of Junior Assessors, they have had a specific registered training and a coaching period of work with a Senior Assessor.

Regarding projects of great importance, the above represented organization may be also “supported” by a Steering Committee, with strategical responsibilities concerning the project goals, the contract management and the solution of potential problems falling outside the Project Managers' competence.