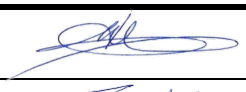
**INFRABEL NV**

**TECHNICAL SPECIFICATION**

# QA
# Supplier Quality Requirements

**Description of the relationship between Infrabel and its suppliers in terms of quality in the context of public procurement legislation**

| | Name | Date | Signature |
|---|---|---|---|
| **Proposal** | W. Luyckx | 12.09.2024 |  |
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# Table of amendments

| Edition | Key changes |
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| **09/2024** | 1.5 Terminology: reviewed<br>1.6 Reference documents: reviewed<br>2.4 Confidentiality: reviewed<br>4.1.3.2 Quality and control plan content: control plan content in more detail<br>4.2.2.1 Controlling measurements & measuring devices - measurements: requirements for rules and regulations specified<br>4.2.5 Statistical process control: detailed<br>Annex 5 Quick Reference Card added |
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# Table of contents

# 1 Introduction

## 1.1 Preface

The nature of Infrabel's activities, as well as the legal framework within which they must take place, require strict control of procurement processes. The suppliers with whom Infrabel places orders and the quality of the products they supply make a significant contribution to Infrabel's priorities, listed below:

- Safety First
- Trains on time, to achieve together with all stakeholders
- Redefining the rail network
- Catalyst for Mobility as a Service
- Sustainable business
- Making informed economic choices

## 1.2 Document content

The document describes the relationship between Infrabel and its suppliers in terms of quality, more specifically Infrabel's expectations and requirements regarding the quality of the products delivered, in the context of public procurement legislation.

The document provides guidance on the quality assurance process of products delivered to Infrabel. For specific aspects, mentioned in the contract as appropriate, it refers to:

- the technical provision(s) applicable to the product
- the administrative provision Y15 on qualification of suppliers

## 1.3 Application

The provisions of this document, if mentioned in the contract documents, apply to all deliveries of products to Infrabel. It supplements the general provisions regarding deliveries, by clarifying the quality assurance level expected from the supplier and describes the interventions of Infrabel Inspections (or any body mandated by Infrabel Inspections) regarding the supervision of quality assurance by means of inspections and audits.

## 1.4 General principles

The supplier is responsible for delivering a "total quality performance" and is bound to comply with all provisions stated in the order documents, as well as all legal requirements applicable in addition to these. For this purpose, the supplier must provide an organisation, methods and means, and keep these updated and take all necessary measures to meet Infrabel's requirements and expectations.

Infrabel Inspections performs appropriate actions to verify the supplier's ability to consistently deliver products that meet all conditions.
These actions are in the following areas:

- Monitoring in the context of a qualification: carrying out an evaluation of the production site
- Monitoring in the context of provisional acceptance of products: performing inspections and audits

## 1.5 Terminology

**Appeal:** request to Infrabel by the supplier of the inspected object, to review the decision taken at the time of inspection.

**Certificate of Conformity**: written declaration by the supplier declaring the products to be in conformity with the requirements of the order documents.

**Control documents**: all quality system documents to be presented during an inspection or audit as agreed on the basis of the control plan.

**Control plan**: plan describing how inspections and tests are carried out for a product or product group produced in series after product validation.

**Infrabel Inspections:** department within Infrabel responsible for carrying out inspections and audits. Named in the Infrabel organisation chart as 'Product Quality Assurance'

**Inspection:** inspection by the contracting authority as to whether the contractual conditions have been met with respect to the products to be processed, the works carried out, and the supplies to be delivered or already delivered.

**Inspection request**: Infrabel B678 'Request for inspection' form

**Complaint**: expression of dissatisfaction, other than appeal, raised by a supplier with Infrabel, in relation to Infrabel's activities and for which a response is expected.

**Qualification:** procedure for evaluating the suitability of a potential supplier and the conformity of a product/service, enabling Infrabel to ensure that:

- ✓ a product or a service
- ✓ supplied by a specific supplier
- ✓ from a defined production site (in case of products)

meets Infrabel's specific requirements described in the relevant technical and administrative provisions.

**Quality plan**: plan detailing the processes that ensure quality assurance.

**Acceptance:** determination by the contracting authority that the works or supplies delivered in full or partially by the contractor comply with the rules of good workmanship as well as the terms and conditions of the contract.

**Production site**: effective production site or a site accepted by Infrabel Inspections, chosen by the supplier (with which Infrabel has concluded the purchase agreement), where both the review of the internal control documents and the performance of the inspection tests provided for in the technical provision can take place.

**Series tests**: series tests are carried out by the supplier on each lot produced to control quality and demonstrate conformity with set requirements.

**Technical conditions**: collection of all technical documents related to a purchase file such as standards, technical provisions, drawings.

**Total quality performance**: this means not only delivering a compliant product, but also paying due attention to aspects such as meeting delivery deadlines, controlling the design, controlling suppliers, logistics, technical-commercial contacts, after-sales service, guarantee, and sustainable development requirements to the extent specified in the applicable legislation, the specifications, the order and the documents to which they refer.

**Type tests**: tests carried out before starting series production of a new product (or during a qualification process) to demonstrate conformity with specified requirements as well as the suitability of the product for its intended purpose.

### 1.6 Reference documents

- General specifications for public works contracts, public supply contracts and public service contracts (07/2013 edition)
- Royal Decree of 14 January 2013: Royal Decree determining the general implementing rules for public works contracts and public works concessions
- NBN-EN-ISO-9001: Standard for Quality management system - Requirements
- NBN EN 10204 - Metallic products - Types of inspection documents.
- NBN EN ISO/IEC 17050 - Conformity assessment - Supplier's declaration of conformity
- NBN-EN-ISO-17020: Conformity assessment - Requirements for the operation of various types of bodies performing inspection
- Y15: administrative provision 'qualification of suppliers'

## 2 General aspects

### 2.1 Communication

The supplier must establish a communication matrix of all departments involved in the design, production, inspection and delivery of the offered products. This list must include names and contact details of contact persons. It must be provided to the person designated by Infrabel before the first delivery is made. Specifically, the supplier must designate a staff member to serve as a point of contact for Infrabel Inspections, in terms of quality assurance. All documents prepared by the supplier for the benefit of Infrabel Inspections, such as the quality and control plan, control certificates, must be drawn up in Dutch, French or English.

### 2.2 Access

The supplier must give Infrabel's representatives, experts mandated by Infrabel as well as auditor experts from BELAC (Belgian accreditation body) free access (under supervision) to the workshops, warehouses, testing rooms where the products (or parts thereof) to be delivered to Infrabel are produced, tested or stored.

Infrabel Inspections' inspector must be able to attend the performance of the inspections, measurements and tests by the supplier and any subcontractors. The presence/intervention of Infrabel's representative in no way relieves the supplier of its responsibility for the 'total quality performance'.

### 2.3 Safety

During each visit, the supplier shall inform Infrabel's representatives of the potential dangers and of the safety regulations in force at the production site and shall make the necessary personal protective equipment available to Infrabel's representatives. If the Infrabel representative considers that despite all this, their personal protection is not sufficiently guaranteed, they can independently decide to stop the inspection at any time.

## 2.4 Confidentiality

Infrabel undertakes to treat all knowledge acquired during an inspection or audit concerning trade and/or production secrets as strictly confidential and not to disclose such knowledge to third parties unless required by law. If information is disclosed to third parties, the data subject will be informed of the information provided, unless prohibited by law.

## 2.5 Support

The supplier must support Infrabel in carrying out the quality interventions by providing free of charge all necessary resources such as: manpower, premises, records, machines, lifting equipment, testing and measuring equipment, means of communication, personal protective equipment.

## 2.6 Costs borne by the supplier

The costs incurred by the supplier in support of the inspection (see section 4.3), including the value of all products destroyed during the inspection, as well as the costs incurred by the supplier in preparation for the inspection, shall always be borne by the supplier.
In the following cases:

- If it is mandatory for the inspection to take place outside the European Union
- If the personnel in charge of the inspection travel in vain (the product was refused, or the inspection could not take place for a reason attributable to the supplier)
- For qualification visits according to administrative provision Y15 (where appropriate, for details see administrative provision Y15)

the following costs shall also be borne by the supplier and shall be invoiced on the basis of the tariffs below (ex. VAT):

Personnel costs: these costs include the travel and accommodation costs (meals and accommodation) and remuneration of the personnel in charge of the inspection/qualification and are calculated on the basis of the total number of hours worked by Infrabel Inspections' inspector(s). A flat hourly rate of €102 is used as a basis ("transport" and "work" are charged per 4-hour period; the "rest" period is not charged, for definitions see below par. 2.7). A maximum of 2 inspectors from Infrabel Inspections can be charged as above.

Travel costs:

- travel by train: price of a 2nd class ticket
- travel by air: price of air ticket in economy class

## 2.7 Inspections: deadlines and duration

After receiving the inspection request (see chapter 1.5), Infrabel Inspections has the following legal deadlines for making a decision on the outcome of the inspection:

- thirty days for an inspection without laboratory tests
- sixty days if laboratory tests are to be carried out.

The date of inspection of the products is:

- either the date of receipt of the inspection request, if this is later than the date on which the products are available for inspection.
- or the date on which the products are available for inspection, if this is later than the date of receipt of the inspection request.

The supplier must organise itself in such a way that the duration of inspection at the production site (see par. 1.5) including travel (checking internal control documents and witnessing tests on samples) is a maximum of 60 h, respecting the following limits:

- Maximum 12 hours of uninterrupted transport (all transport to and from and waiting times included)
- Maximum 12 hours of continuous work (including breaks for meals and transport to and from)
- Minimum 12 hours of uninterrupted rest (sleep, eat, rest, etc., during which no transport or meeting); this is increased by 1 hour if 3 or more time zones are travelled and by 2 hours if 5 or more time zones are travelled.

If the transport is immediately followed by work: maximum 12 hours combined duration. Each block of transport, work or combination of both is always followed by a block of uninterrupted rest.

# 3 Qualification

## 3.1 General

A qualification was introduced by Infrabel for a number of products, these products can only be supplied by suppliers previously qualified by Infrabel. All existing qualification systems were published in the Bulletin of Public Tenders at www.publicprocurement.be and in the Public Journal of the European Union (OPOCE): https://ted.europa.eu.

Infrabel's Qualifications service can be contacted by sending an e-mail to:
kwalificaties@infrabel.be

## 3.2 Procedure

If a qualification was introduced for the relevant product, the qualification must be carried out in accordance with the requirements of Administrative Provision Y15 and the relevant technical provision. The qualification can consist of up to five steps:

- approval of an administrative file
- approval of a technical dossier
- conducting an evaluation of the production site (quality audit)
- delivering a trial order
- conducting an in-service trial

If an evaluation of the production site needs to be carried out, Infrabel Inspections will contact the supplier about this in advance and make an appointment to carry out the evaluation. A schedule will be drawn up for the course of this evaluation. The evaluation aims to establish technical capability and the quality management system.

During this evaluation, the following topics are generally covered:

1. Procurement and inspection of raw and semi-finished materials and control of suppliers;
2. Identification and traceability of the manufactured product;
3. Process control;
4. Description of inspections and tests carried out;
5. Storage, post-treatment, packaging, transport and delivery;
6. Measurement systems, verifications and calibrations;
7. Management of non-conforming products;
8. Corrective and preventive measures;
9. Quality system organisation and responsibilities;
10. Contract management;

11. Management of documents and data;
12. Managing new projects

After the evaluation, the supplier is formally informed of the non-conformities, action points and points for improvement identified and asked to submit an action plan. Depending on the findings during the evaluation and the underlying action plan, Infrabel Inspections will issue a qualification release for the 'quality audit' aspect.

Upon completion of the qualification procedure, the decision will be communicated to the applicant in writing.
A qualification is awarded for a period of five years. After this period, Infrabel will decide whether the qualification can be extended and, if so, what steps should be taken by the supplier. The supplier will be notified in writing. Infrabel Inspections may decide to carry out a new evaluation of the production site. A qualification is always linked to a product and a production site.

## 3.3 Monitoring of qualified suppliers

Infrabel Inspections is entitled to periodically evaluate qualified suppliers, in addition to monitoring in the framework of provisional acceptance of products, by any means it deems necessary in order to determine whether quality assurance continues to meet Infrabel's requirements.

# 4 Series production

## 4.1 Quality assurance

### 4.1.1 Quality Management system

Infrabel requires a quality management system in accordance with the NBN-EN-ISO-9001 standard, or equivalent.
The scope of the quality management system will include at least all activities that may affect the quality of products intended for Infrabel.

### 4.1.2 Supplier classification

For each product, Infrabel suppliers are divided into 2 classes:

- **Level A suppliers:** suppliers who have a quality and control plan evaluated and approved by Infrabel Inspections for the relevant product (see chapter 4.1.3). These can be products for which a qualification system is provided, as well as other products.

- **Level B suppliers:** all other suppliers.

### 4.1.3 Quality and control plan

#### 4.1.3.1 General

The means used by the supplier to achieve and control the quality of the products to be delivered to Infrabel must be described by creating a quality and control plan. The quality and control plan refers to the supplier's quality system and is a complement to it providing additional information concerning the product delivered and the requirements imposed on it by Infrabel. A quality and control plan is required for all framework contracts and regular orders with a value greater than €100,000 and all regular orders or the (technical) documents included therein that mention it.

Infrabel Inspections advises its suppliers to create a quality and control plan, to the extent possible, for the products to be delivered.

Infrabel Inspections may require a quality and control plan to be drawn up by the subcontractor for certain subcontracting and/or subcontracted activities.

Infrabel Inspections reserves the right to evaluate the supplier's quality and control plan at any time through audits or other evaluation techniques.

#### 4.1.3.2 Content of the quality and control plan

Before starting series production, the supplier must create a quality and control plan (in accordance with NBN-EN-ISO-9001 or equivalent) and submit it to Infrabel Inspections for approval.

The supplier must report any relevant change in its organisation; if this change affects the content of the quality and control plan, the latter must be adapted and a new version submitted to Infrabel Inspections for approval. Infrabel Inspections may decide to evaluate the changes on site.

Approval of the quality and control plan does not relieve the supplier of the responsibility to deliver products in conformity with the requirements of the specifications and/or the order and all other documents made applicable therein.

The quality plan should include the following points:

1. The scope
2. Quality system organisation and responsibilities
3. Contract management
4. Document and data control
5. Purchase and inspection of raw materials and semi-finished products and control of sub-suppliers
6. Identification and traceability of the manufactured product
7. Process control: a flow chart of the production process including a control plan (see below)
8. Steering the methods of control, measurement and testing
9. Management of non-compliant products
10. Corrective and preventive measures
11. Handling, storage, packaging, preservation and delivery

The quality plan may refer to the relevant quality system documents for this purpose.

The control plan must include the inspections carried out during the main process steps of the relevant processes in the production of the relevant product(s), covering at least the following:

- the supply process: process that describes how purchased raw materials, semi-finished products, parts, etc. are checked and released before they can be used in production;
- preparation process: process that describes how parts, components, etc. are checked and released during preparation for production before they can be used in production;
- the production process that describes how the products concerned are inspected during production
- the final control and release process: process describing how the manufactured products are finally inspected and released.

The control plan must be unambiguously identified (relevant products, version number, date, prepared by, approved by, technical provisions, standards, etc.). It describes at least the following points for each process step for which one or more inspections take place:

- In-process control points (place where an in-process control is carried out): an unambiguous link to the process step as mentioned in the flow chart must be made here;
- The inspected characteristics (of process and/or product): which characteristic is being inspected;
- Monitoring frequency: the frequency of taking samples;
- Sampling size: the number of items checked each time;
- The control method: the procedure that describes how the control takes place;
- The acceptance criteria: the document stating the acceptable values for the inspected characteristic;
- Where the responsibility lies (person or department) for the control;
- Recording of control results: how and where the measurement is recorded;
- Dealing with deviations - reaction plan: what happens when measurement results do not meet acceptance criteria (including use of control limits and rejection limits).

The results of these inspections must be recorded and kept available for Infrabel Inspections. They should at least mention, in addition to the control results and their interpretation:
Identification of the lot concerned, the date of production, identification of the production machinery, control and testing equipment used and person carrying out the inspections.

In case of discussion between Infrabel Inspections and the supplier about the possible absence of in-process control points for certain process steps, the supplier must be able to justify this by means of a risk analysis. If this risk analysis cannot be submitted or is inadequate, additional in-process control points should be introduced.

A control plan can also be created for a prototype. Where appropriate, it is referred to as a Pre Launch Control Plan.

If a supplier does not have their own template for a control plan, the Infrabel template can be used (see annex 1)

## 4.2 Other quality requirements

### 4.2.1 Subcontracting and deliveries

As part of its 'total quality performance', the supplier is responsible for the quality of the raw materials they supply and the tasks they subcontract.

The supplier will pay particular attention to:
- the evaluation and selection of suppliers and subcontractors
- controlling purchase data

checking the products purchased
In case one or more tasks are subcontracted, the supplier must inform Infrabel Inspections. The supplier must transmit its up-to-date list of subcontractors to Infrabel Inspections if requested. The supplier must demonstrate that the quality of the products delivered as well as the level of quality assurance by the subcontractor meet Infrabel's contractual requirements. To this end, Infrabel Inspections may require subcontractors to draw up a quality and control plan (see chapter 4.1.3.2).

The supplier's supervision of its subcontractors must be documented and made available to Infrabel Inspections. Infrabel Inspections may decide to audit this. If deemed necessary, Infrabel Inspections may require the supplier to request an intervention/evaluation of one or more subcontractors. In this case, Infrabel Inspections has the right to be present. However, the intervention/evaluation shall always be carried out in cooperation with and under the responsibility of the supplier.

### 4.2.2 Controlling measurements & measuring devices

#### 4.2.2.1 Measurements

The supplier must ensure the conformity of the product with the contractual requirements through measurements/inspections/tests.
The measurement/inspection/testing process must be evaluated by the supplier in order to ensure the integrity of the results obtained (which demonstrate compliance with the contractual requirements) and to identify the influence of measurement errors on the results.

The evaluation steps include:

- correctly selecting and adopting the measurements/inspections/tests to be carried out
- estimating necessary measuring tools (nature, number, precision, calibration, etc.)
- estimating the need for procedures and instructions to support the measurement/inspection/testing process
- estimating the required competences of operators: achieving and maintaining them
- estimating possible interactions on the measurements
- calculating measurement uncertainties of individual measuring instruments as well as of measuring systems

Depending on the product and the product/process parameter measured, Infrabel Inspections may require the supplier to statistically measure its variation for the measurement systems used, either once or periodically, thus demonstrating the integrity of the measurement system (e.g. via a Gage R&R study).

If a Gage R&R study is used to demonstrate the integrity of the measurement system, the following rules apply:

When the total R&R is greater than 30%, the measurement system will not be accepted and the measurement system may not be used. Action must be taken to reduce the total variation before the measurement system can be used in the production process.

When the total R&R is greater than 10% but less than 30%, the measurement system is accepted and the measurement system may be used, but a plan must be submitted within an agreed timeframe and implemented to reduce the total variation.

The aim is to achieve a measurement system with total R&R below 10%.

Where appropriate, these measurement results must be made available to Infrabel Inspections free of charge and in electronic form.

#### 4.2.2.2 Measuring instruments/Measurement systems

All measuring instruments/measurement systems used to provide evidence of conformity of the product to the requirements shall be periodically verified and/or calibrated. To this end, the supplier will develop and maintain a documented system. Evidence should be recorded and archived.

The crucial measuring equipment or installations used during the final inspections of the product must be calibrated in a way that links the measurements to national and international standards. If significant modifications (hardware or software) are made to the measuring system used for final inspections of the product, Infrabel Inspections must be informed in advance and give its approval before use of the system for Infrabel products.

Proof that the calibrations are performed must be made available to Infrabel Inspections free of charge.

#### 4.2.2.3 Measurement outsourcing

The supplier can outsource certain measurements included in the control plan to an external body. In this case, the supplier must demonstrate to Infrabel that these measurements also meet the requirements set out in sections 4.2.2.1 and 4.2.2.2, and must make proof of this available to Infrabel free of charge.

### 4.2.3 Prototypes

If provided for in the specifications, the supplier must have a prototype approved prior to series production
Where appropriate, conditions should be determined with regard to:

- how many prototypes need to be produced
- where these are kept
- how they are maintained
- how to adjust them in case of product changes on the series product
- who is financially responsible
- how long they should be kept

Where appropriate, Infrabel may ask the supplier:

- to create a control plan for the relevant prototype, hereinafter referred to as 'Pre Launch Control Plan'.
- to make a limited pre-series in serial conditions

The evaluation and approval thereof is a task to be carried out by Infrabel's responsible technical department, where appropriate in collaboration with Infrabel Inspections. Once accepted, the prototypes are identified as such.
The approved prototypes must be kept by the supplier, protected against damage and degeneration unless decided otherwise in joint agreement in writing with Infrabel.

The prototypes should be available to Infrabel at all times. All subsequent deliveries of the product must be of at least equal quality to the prototype in all areas, any deviation from the prototype may result in rejection of the proposed products.

Any modification to a product compared to the approved prototype requires the prior written agreement of Infrabel or written notification to Infrabel, depending on the type of modification (see chapter 4.5). Infrabel reserves the right to demand a new prototype; new tests may also be demanded to confirm its conformity.

#### 4.2.4 Process FMEA

If provided for in the specifications, the supplier must carry out an FMEA process (in accordance with VDA4), based on the Pre Launch Control Plan (see chapter 4.1.3.2), and make the results available to Infrabel.

The identified failure modes should allow the manufacturer to take prior process measures to prevent this possible failure, reduce the probability or reduce the impact, with the end goal of obtaining a robust production process and production control plan (serial production control plan).

#### 4.2.5 Statistical process control

If provided for in the order documents, the supplier must apply statistical techniques for measuring, meeting and possible adjustment of critical process and/or product parameters. The desired performance for these process and/or product parameters are defined in a Cpk parameter (adjusted short-term performance index).

Where appropriate, the supplier must make these performance data available free of charge and in electronic form in the context of product inspections. If the supplier cannot meet the desired performance (exceeding or irregular behaviour), Infrabel Inspections reserves the right not to accept the products and the supplier must create an action plan to bring the obtained performance back in line with the desired performance.

For each **process and product parameter** to be measured according to the relevant technical provision, the supplier must provide a graphical representation and statistically interpret the progress of the measured values, at least for the duration of the entire contract. In case of significant and/or statistically relevant changes in measurements, the supplier must investigate this and, if necessary, create and implement an action plan to remedy the causes.

The supplier shall share the figures relating to the **internal rejection** of its production with Infrabel Inspections. The supplier must also interpret these figures and, if necessary, create and implement an appropriate action plan to reduce internal rejection. The relevant technical provision may impose additional requirements regarding internal rejection and the necessary actions if they are not respected.

#### 4.2.6 Maintenance plan

Depending on the product, Infrabel Inspections may require the supplier to create and implement a maintenance plan, and make it available to Infrabel. This maintenance plan must demonstrate that for the instruments/equipment/machines included in the control plan for the relevant product, the necessary periodic inspections have been carried out and that any necessary corrective and preventive actions have been taken to ensure their proper functioning at any time.

### 4.3 Inspection of products

#### 4.3.1 General

The supplier must provide objective proof of the conformity of all products delivered to Infrabel. Each delivery must be accompanied by a certificate of conformity 3.1. according to EN 10204 or EN 17050-1 or equivalent. The supplier shall be obliged to carry out all contractually provided tests and to submit proof of their performance. The supplier undertakes to carry out all contractually provided series tests

on each production lot, the records of these tests shall be made available to Infrabel Inspections before provisional acceptance (see section 4.3.2).

The results of the inspections, measurements and tests carried out by the supplier shall be recorded and archived by the supplier, these records shall be made available to Infrabel Inspections free of charge and in electronic form upon request.

Sampling (size, distribution, frequency) is the subject of a prior agreement between the supplier and Infrabel. The essential characteristics of the delivered products must be inspected by the supplier at his expense. The essential characteristics are: dimensions, composition of the materials used, physical, electrical or other characteristics necessary and sufficient to define the product to be delivered. The inspections, measurements and tests carried out should be related to the expected functionality of the unit.
The supplier must define the nature of the records, their retention period and the retention method. The minimum retention period for quality data records must be 10 years.

During provisional acceptance, Infrabel Inspections may request the supplier to repeat some or all of the series tests, without owing any additional fees to the supplier. Any documents destroyed for this purpose shall be borne by the supplier.

If the relevant technical provision specifies specific inspection conditions, these take precedence over the general inspection conditions described below.
In the absence of a technical provision, the current rules of the art of relevance to the sector must be respected.

### 4.3.2 Procedure

Depending on the product to be delivered, the order shall always state if an inspection is planned and, if so, the type of inspection (single or double inspection):
- Double provisional acceptance: partial provisional acceptance at production site, with mandatory release by Infrabel before shipment of products and full provisional acceptance at acceptance site
- Full acceptance at place of delivery: full provisional acceptance at acceptance site without partial provisional acceptance at production site

#### 4.3.2.1 'Double provisional acceptance' products

The interventions by Infrabel Inspections regarding the inspection (provisional acceptance) of purchased products are laid down in, and in accordance with, the law on public works contracts.

Taking into account the scheduled delivery time, the supplier sends an inspection request (form B-678 available on the Internet www.infrabel.be) by e-mail to keuringen@infrabel.be,. This signed inspection requests states the following details: supplier identification, order number / framework agreement number (if applicable), location where the inspection is to be carried out, date from which the inspection can be carried out, name list number, order line number and position number, description of the product offered, number of products offered for inspection, date on which the inspection application was drawn up, purpose of the products. A Quick Reference Card for completing Form B678 can be found in Annex 5.

The inspection request (form B-678) must be accompanied by the certificates of conformity and control documents (see chapter 4.3.3). In the case of an on-site inspection carried out at the supplier's

production site, the certificates of conformity and control reports shall be available at the latest at the time of inspection.

The nature and content of these are defined for each product. If a quality and control plan is drawn up for the product, the nature and content are laid down in it.

The delivery date is the date on which the products, after approval and release, should arrive at Infrabel's warehouse. The supplier must take inspection deadlines into account when scheduling production. The products must be submitted for inspection, taking into account a maximum inspection period as provided for in the law on public works contracts.

Products can only be delivered upon receipt of a shipment authorisation signed by Infrabel Inspections. The delivery must always be accompanied by a copy of the shipment authorisation signed by Infrabel Inspections.

**Granting a free-pass**
Level A suppliers whose quality level required for the product has been reached (confirmed) during successive deliveries and/or an evaluation visit may be exempted from the above-mentioned release obligation for this specific product. A free-pass is only ever granted for a specific product.

The documents to be transmitted to Infrabel Inspections will be determined on a case-by-case basis by mutual agreement. Only Infrabel Inspections decides for which products this method is applied and judges whether these simplified inspection methods apply for a supplier. For each free-pass granted, the supplier will receive a written confirmation clarifying the details of the simplified inspection specifications.

In case deficiencies are identified, Infrabel Inspections has the right to temporarily or permanently suspend the free-pass at any time.

4.3.2.2 Products 'Full acceptance at delivery site':

For the delivery of these products, the supplier is not required to submit an inspection request. After production, inspection and internal approval, the products are shipped to the delivery address specified in the order within the scheduled delivery time. Infrabel carries out the inspection at the delivery site. Each delivery must be accompanied by a certificate of conformity. At Infrabel's request, the records should also be sent.

### 4.3.3 Implementation

4.3.3.1 'Double provisional acceptance' products

For deliveries of 'Double Acceptance' products, Infrabel Inspections may decide to carry out the provisional partial acceptance:

- by inspecting products and verifying quality records at the production site
- On the basis of the control documents provided with the inspection request: verification of completeness, correctness, plausibility, etc.

The frequency of interventions by Infrabel Inspections at the supplier's production site is determined by:

- the strategic importance for Infrabel of the product to be delivered
- the value of the order, the scope and duration of the contract

- the supplier's technical capabilities and experience in delivering the product to Infrabel
- whether or not an approved quality and control plan for the product is available
- the level of quality assurance by the supplier, determined during an evaluation visit
- the analysis of the delivered control certificates
- quantities delivered since the last provisional partial acceptance with production site visit
- any deficiencies identified during previous inspections or with respect to delivered products

Infrabel Inspections will inform the supplier, case by case, if a provisional partial acceptance will or will not take place at the production site. If Infrabel Inspections decides that no physical inspection of the products is necessary, after evaluating the submitted control certificates, the inspection request shall be returned to the supplier signed for acceptance and release.

If Infrabel Inspections carries out an inspection at the supplier's site, on approval of the products, the supplier will receive the inspection request signed by Infrabel, this will constitute release and authorisation to dispatch the products.

If the decision to approve cannot be taken on site, immediately after the inspection has been carried out, or if laboratory tests have to be carried out, the supplier will be formally informed of the decision afterwards.

#### 4.3.3.2 'Full acceptance at place of delivery' products

After delivery of the products, the provisional full acceptance will be carried out at the delivery site by Infrabel Inspections. The supplier will only be informed if the products are rejected or if important remarks need to be made regarding the delivered products.

### 4.3.4 Rejected products

If it is found during the inspection that the products do not meet the contractual requirements, they must be improved or replaced and presented again for inspection. Under no circumstances may the supplier supply rejected products to Infrabel. Rejected parts or raw materials may not be used in productions for Infrabel.

If products do not meet the contractual requirements (established during the inspection or subsequently after delivery), the supplier will propose in writing to Infrabel Inspections, in addition to immediate actions, corrective measures to prevent that the same problem occurs in the future.

## 4.4 Audit

Infrabel may decide at any time to evaluate the quality and control plan through an audit, and formally inform the supplier of the result. In case non-conformities or action points are identified, the supplier shall draw up a detailed action plan and deliver it to Infrabel Inspections, within the requested deadline, for the purpose of further evaluation. This deadline is determined by Infrabel Inspections according to the problems identified.

These deadlines are standard:

- Within 2 working days: in case blocking issues were identified, regarding deliveries
- Within 7 working days: in case no blocking issues were identified

A blocking issue is considered to be any deficiency that may result in dangerous or unsafe conditions or that has a major adverse effect with regard to the performance/durability/interchangeability/reliability/maintenance/effective use or operation of the product.

If deemed necessary, Infrabel Inspections may request an 8-D report to deal with a particular non-conformity. The action plan describes in detail the status of the planned actions, the planned deadlines and the person responsible for each action.

These audits may be related to:

- The produced design (Design Verification Audit)
- The supplier's supplier management process (SQA Audit)
- Subcontractor audit (audit at supplier’s subcontractor)
- Quality management system audit (QMS Audit)
- Product audit
- Other

## 4.5 Product changes

If the supplier wants to change a validated product, Infrabel distinguishes between a 'Major change' and a 'Minor change'. Each contract requires a written agreement between the supplier and Infrabel on what constitutes a 'Major change' and a 'Minor change' and to which products/components this applies.

Major change: any product change that may result in hazardous or unsafe conditions or adversely affect performance, durability, interchangeability, reliability, maintainability in the effective use or operation of the product.

Minor change: all other product changes.

In the case of a 'Major change', Infrabel must formally approve the product change in advance (via 'Request for Change'). This 'Request for Change' should be sent to the responsible inspector of Infrabel

Inspections, to the functional mailbox 'keuringen@infrabel.be' and to the technical manager of the responsible technical department. The latter is responsible for validation of this 'Request for Change'.

In the case of a 'Minor change', only a formal notification of the product change (via 'Change Notification') needs to be sent to Infrabel prior to its introduction. This 'Change Notification' should be sent to the responsible inspector of Infrabel Inspections, to the functional mailbox 'keuringen@infrabel.be' and to the technical manager of the responsible technical department.

If the supplier does not have an appropriate form for 'Request for Change' and 'Change Notification', the Infrabel form can be used (see Annex 3).

## 4.6 Request for one-off acceptance of a different product

If the supplier is of the opinion that a product with a deviation of the ‘as is’ condition or after correction can be accepted on a one-off basis, it can submit a 'Request for one-off acceptance of a deviating product' to Infrabel Inspections in writing. This request must contain all elements to enable Infrabel's responsible Technical Manager to make a decision regarding the acceptability of the request. The company will be informed in writing of the decision taken by Infrabel. Pending Infrabel's decision, products with deviations may not be delivered under any circumstances. If the supplier does not have an appropriate form, the Infrabel form can be used (see Annex 4).

## 4.7 Supplier complaints

In case Infrabel Inspections reports a complaint to the supplier in writing, identified during the inspection process or afterwards, the supplier will propose an action plan to Infrabel in writing, within the timeframe requested by Infrabel Inspections.

This deadline is determined according to the problem identified by Infrabel Inspections.
For handling complaints, Infrabel prefers the 8-D methodology.

The 8-D methodology consists of the successive process steps:

- D1: Select a multidisciplinary team to gather all existing knowledge and expertise and appoint this team.
- D2: Describe the problem as objectively and unambiguously as possible.
- D3: Establish a plan to temporarily solve the problem. Sometimes it is necessary to solve a problem very quickly. Finding the best solution is then of later concern.
- D4: Trace the cause. Before implementing a final solution, it is necessary to know the cause of the problem. Several methodologies can be used for this purpose. e.g.: Is-Is Not methodology, Ishikawa or fishbone diagram, 5-why,...)
- D5: Define the corrective actions: Find the solution. Once the cause of the problem is known, then the best solution can be targeted.
- D6: Apply corrective actions: Implement the solution. Once the final solution is known, its implementation will follow in this phase.
- D7: Preventive actions: Prevent the problem. Additional measures are usually needed to prevent that similar problems occur in the future.
- D8: Reward the team.

If the supplier does not have an appropriate form, the Infrabel form can be used (see Annex 2).

## 4.8 Complaints and appeals

### 4.8.1 Record-keeping

Every complaint or appeal reported to Infrabel Inspections is recorded in order to create an individual file. All documents related to the treatment are kept in this file. In case of an appeal, it will be verified whether the appeal was filed within 15 working days from the date of the decision or measure, if not, the appeal will be rejected. Infrabel Inspections will confirm receipt to the submitting party and whether or not inspection activities are involved.

### 4.8.2 Treatment and Handling

An investigation will be launched into the reason (cause). If the complaint/appeal proves well-founded, after thorough analysis of the cause, appropriate corrective and/or preventive measures will be defined and implemented. In all cases, a justification in writing is sent to the submitting party after which the complaint/appeal is considered settled. The decisions formulated in the answer are taken or reviewed and approved by a person or group of persons who have not been involved in the relevant inspection activities. The examination of and decision on appeals will not result in discriminatory actions.

## 4.9 Supplier assessment

Supplier assessments are vital to ensure the quality of services and purchased products and to control risks. It is therefore a mandatory component within the ISO 9001 standard and is in line with Infrabel's code of conduct for suppliers and contractors. Therefore, selected suppliers will be assessed annually by the Procurement Department.

The result will be used to determine where improvement is possible or needed.

In case of a poor evaluation, this will be communicated in writing and the supplier will be asked to provide an action plan. The supplier will be reassessed the following year to evaluate the efficiency of the actions taken.

Annex 1

| | | | | | |
|---|---|---|---|---|---|
| Document ID.: | | Company name: | | Applicable standards: | |
| Version number: | | Product: | | Applicable technical provisions: | |
| Date: | | | | | |
| Prepared by: | | | | | |
| Approved by: | | | | Customer approval: | |

| Theme | (Process) checkpoint | Controlled characteristic | Frequency | Size of sampling | Control method | Acceptance criteria | Responsible for controlling | Registration document | Treatment of abnormali-ties |
|---|---|---|---|---|---|---|---|---|---|
| Supply process | Entrance control | Physicochemical properties | | | | Doc. XX | M. XX | Doc. YY | Doc. ZZ |
| | | Evaluation certificate | Any certificate | | Analysis certificate | Doc. XX' | M. XX' | Doc. YY' | Doc. ZZ' |
| Preparation process | | | | | | | | | |
| | Raw materials | | | | | | | | |
| | | | | | | | | | |
| | Machine park | | | | | | | | |
| Production and control process | | | | | | | | | |
| | | | | | | | | | |
| Finishing process | | | | | | | | | |
| | | | | | | | | | |
| Final inspection process | | Dimensions | | | | | | | |
| | | Aspect | | | | | | | |
| | | Physicochemical properties | | | | | | | |

**Annex 2: 8-D report**

# 8D REPORT

| | | | |
|---|---|---|---|
| Title: | | Date Opened: | Last Updated: |
| Product/Process Information: | Organisation Information: | | |
| DØ Symptom(s): | | | |
| DØ Emergency Response Action(s): | | % Effective: | Date Implemented: |
| verification: 100% IO | | | |
| D1 Team (Name, Dept., Phone)<br>Champion:<br>Team Leader:<br>Team Members: | D2 Problem<br>Problem Statement: | | |
| | Problem Description: | | |
| D3 Interim Containment Action(s): | | % Effective: | Date Implemented: |
| Verification: | | | |
| D4 Root Cause(s) and Escape Point(s): | | | % Contribution: |
| Verification: | | | |
| D5 Chosen Permanent Corrective Action(s): | | | % Effective: |
| D6 Implemented Permanent Corrective Action(s): | | | Date Implemented: |
| Validation: | | | |
| D7 Prevent Actions (poka yoke): | | | Date Implemented: |
| D7 Systemic Prevent Recommendations: | | | Responsibility: |
| *P-FMEA update needed ?* Yes ☐ No ☐ | | | |
| D8 Team and Individual Recognition: | | Date Closed: | Reported by: |

**Annex 3**

Request for Change (RFC) / Change Notification (CN)

| | |
|---|---|
| Date of issue | |
| Version | |
| Author | |
| Supplier | |
| Identification NN Infrabel | |
| Identification NN Supplier | |
| Technical specification Infrabel<br>➢ type + version | |

| | |
|---|---|
| Change title | |
| Description | |
| Classification | ☐ Request for Change – supplier name - ……<br>➢ Infrabel approval necessary<br>☐ Change Notification – supplier name - …… |

Reason for product change:

Way of change:

| | |
|---|---|
| Impact-analysis | |
| - on product | |
| - on | |
| - on specification | |
| - on safety | |
| - on cost | |
| - on lead-time | |

Schedule of modification:

| Attachments | | |
|---|---|---|
| nr. | filename | description |
| | | |
| | | |
| | | |

| Infrabel approval | | | |
|---|---|---|---|
| Name | department | date | signature |

**Annex 4**

| **Request for one-time acceptance of a deviating product** | **Serial number adm. office:** |
|---|---|
| | **Serial number inspector:** |

| **1. File references** | Material number(s) and description(s) |
|---|---|
| Inspection request number: | |
| Order number: | |
| Company: | |

| **2. Description of the identified non-conformity** | | |
|---|---|---|
| | | |
| Annexes: | | |
| Name: | Date: | Initial: |

| **3. Advice from research department** | | |
|---|---|---|
| **o Acceptable** | | |
| **o Acceptable under conditions** | | |
| Conditions: | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| Advice given by: | Date: | Signature: |

**Annex 5 Quick Reference Card B678**

1. For products for which the order states a 'double provisional acceptance' (see QA §4.3.2.1), the supplier must submit an inspection request. For this purpose, form B678 must be completed (available via the internet: www.infrabel.be) and sent by e-mail to keuringen@infrabel.be

2. How to complete form B678 correctly? On the next page you will find which fields you need to complete.

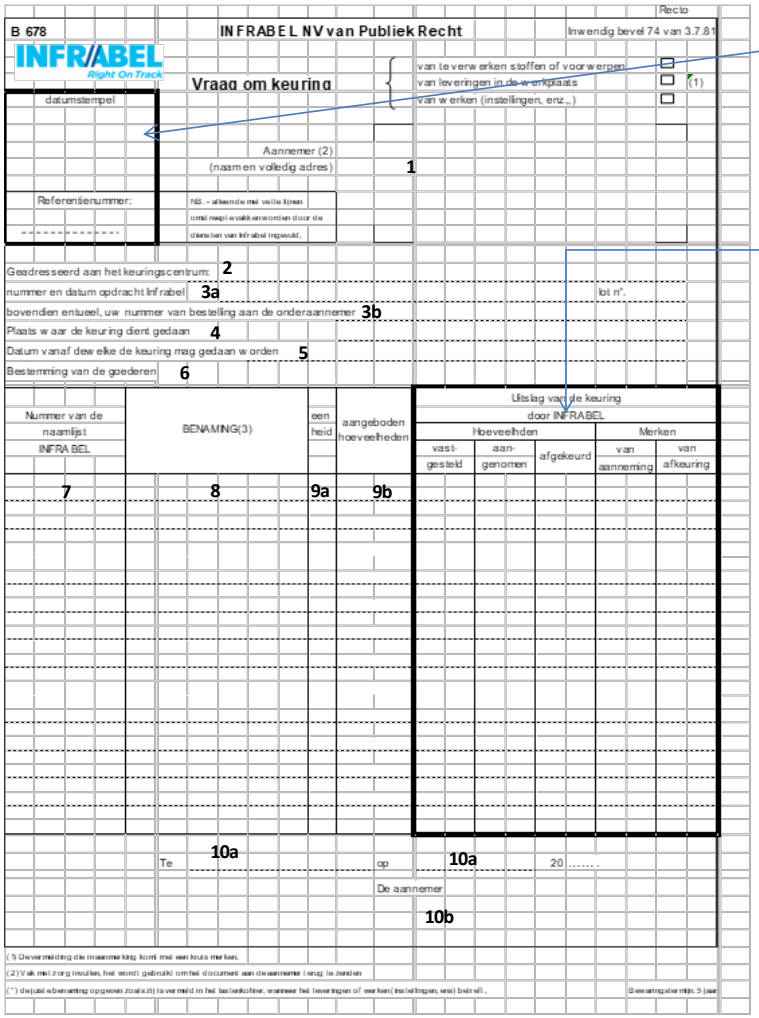
3. After receiving the inspection request, a confirmation email will be sent after verification of the data.
   Infrabel has the following legal deadlines (see QA §2.7) for making a decision on the result of an inspection:
   - Thirty days for an inspection without laboratory tests
   - Sixty days if laboratory tests need to be carried out

4. The responsible inspector of Infrabel Inspections can decide on the basis of the submitted inspection request:
   - To carry out the inspection of the products and inspection of the quality registrations at the place of production
   - To carry out the inspection on the basis of the inspection documents supplied with the inspection request

5. If the inspector decides to carry out the inspection of the products at the place of production, he will contact the supplier's contact person as indicated on the inspection request to determine the date of inspection.

6. After the inspection has been carried out and the goods have been approved, the supplier will receive a 'shipment authorisation' via e-mail. A copy of this must be placed with the goods to be shipped. Without this 'shipment authorisation', the goods will be refused at the place of delivery.

## How to fill out Document B678 Request for inspection




### Rules of thumb

- All information in the bold squared areas is reserved for Infrabel
- B678 is per PO and preferably also per delivery (the same form can be used for a delivery made by multiple trucks on the same day)

Tip !!! Use the Infrabel purchase order to fill in this form

### Supplier mandatory fields

1. Supplier company name and address (as mentioned in PO)
2. Infrabel department that will do the inspection: Infrabel Inspections
3a. Infrabel order reference (PO) starting with 450…. And if applicable the contract number starting with 460…
3b. If applicable, the order reference number of the subcontractor (if production is not done by your company)
4. The location and address where the inspection should take place, this is preferably the production site.
5. The date when the parts are ready for inspection (ready means passed final control and packaged).
6. The location of delivery (see purchase order)
7. Part number of Infrabel you want to present for inspection
8. Part description of the part number mentioned on the left
9a. Unit of quantity, usually pieces (pcs) or length (m, km), see PO!
9b. Quantity of parts you want to present during the inspection
10a. Location and date of submission of the form
10b. Name and signature of the submitter