# EU Notified Body conformity assessment process

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## Contents

# 1. Definitions

1.1

The in this document mentioned terms are defined in the RD.004 (GNG TIC list of terms and conditions).

1.2

Where this document is used for Conformity Assessment under the GNG TIC NANDO scope, the term ‘Conformity Assessment scheme’ shall mean to also include the applicable rules stemming from the NANDO scope related to the Conformity Assessment that is being performed. ‘Certification’ and/or ‘Inspection’ scheme shall also be meant when ‘Conformity Assessment scheme’ is said.

1.3

Where the work being performed under this document is done against ISO 17065:2012. Conformity Assessment shall mean to include certification.

1.4

Where the work being performed under this document is done against ISO 17020:2012. Conformity Assessment shall mean to include inspection.

# 2. Purpose

2.1

This document regulates how GNG TIC assesses conformity of products/processes/services as far as it relates to its Notified Body status (NANDO 2832) or other scopes that follow from work performed under ISO/IEC 17065 or ISO 17020.

2.2

GNG TIC shall confine its requirements, evaluation, review, decision, and surveillance (if any) to those matters specifically related to the scope of Conformity Assessment.

2.3

The GNG TIC will use this Conformity Assessment process for the Conformity Assessment of:

- Products requiring Conformity Assessment as specified in the GNG TIC NANDO scope 2832.
- Products requiring Conformity Assessment under the “Regeling lozen buiten inrichtingen”.
- Other products/processes/services such to the discretion of GNG TIC.

# 3. Conformity Assessment process

3.1

Each Conformity Assessment issued by GNG TIC must have followed one or multiple Conformity Assessment processes. Conformity Assessment, as defined in Article 2.3, must be carried out against ISO 17065:2012 or ISO 17020:2021, in case of unclarity the applicable ISO 17000 standard prevails.

3.2

A Conformity Assessment process is the culmination of the individual (sub) processes laid out in this document. A Conformity Assessment process can consist of the following:

- Application
- Application review
- Conformity Assessment advice
- Conformity Assessment plan
- Conformity Assessment file
- Evaluation
- Conformity Assessment decision
- Certificate
- Complaint
- Ongoing obligations

The above-mentioned terms are explained in this document.

3.3

If the Conformity Assessment process is successful, it must contain all (except complaints) the above (sub) processes/ documents.

3.4

A Conformity Assessment process results in:

- If applicable, a product being certified against a norm for which GNG TIC is appointed to certify against.
- If applicable, a product receiving an inspection report against a norm for which GNG TIC is appointed to provide inspections against.
- The extension/modification of an existing Conformity Assessment
- The transferring of a Conformity Assessment from a different notified body to GNG TIC.

3.5

If the client has requested the extension, modification, or upgrade/downgrade of an existing Conformity Assessment, GNG TIC starts a new Conformity Assessment process. It will determine during the application review phase the applicable norm elements and required work.

3.6

GNG TIC may also invite external observers with or without consultation of the client. These observers will be given the right to view all documents relating the Conformity Assessment process. The GNG TIC supervising bodies and the appointing government(s) are always external observers.

3.7

GNG TIC office operations is not authorized to meddle with the content-based/norm-specific matters of the Conformity Assessment process. If the person described in 9.1 is also part of office operations for a product, they may only signal problems for which the assigned lead auditor must make a decision. In case of deadlock, the HCA prevails.

3.8

A product must meet the Conformity Assessment requirements and those set by any related norms, directives, and other set requirements.

3.9

At the end of the Conformity Assessment process, no matter the outcome/result, GNG TIC asks for feedback from each at the time of completion of the Conformity Assessment activities. It will do so using SurveyMonkey, Wufoo (in accordance with RD.002 (Quality manual)), or face-to-face. The quality officer has permanent access to all filled-in forms and must respond to negative reviews.

3.10

GNG TIC shall inform it's notifying authority of the following:

- Any refusal, restriction, suspension or withdrawal of certificates
- Any circumstances affecting the scope of and conditions for notification
- Any request for information on conformity assessment activities performed which they have received from market surveillance authorities
- On request, conformity assessment activities performed within the scope of their notification and, any other activity performed, including, cross-border activities and subcontracting

3.11

GNG TIC shall provide the other bodies notified under the same community harmonization legislation (or other forms of legislation) carrying out similar conformity assessment activities and covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

3.12

GNG TIC will store all Conformity Assessment documents in accordance with PD.007.

3.13

Internal approval for documents can be achieved through email or phone-based communications. Legally binding approval (i.e. of the contract by the client) must always be done through SOP.003.

3.14

In the event of any unclarity or interpretation issue arising from the Conformity Assessment process, GNG TIC retains the right to seek advice from an advisory mechanism of its choosing and to integrate this advice into the resolution of the above. Should GNG TIC wish to invoke this right, the Conformity Assessment process will be on hold until the matter is decided. GNG TIC will involve relevant human resources, including the lead auditor, in this decision. The decision GNG TIC takes to resolve the above will be binding.

# 4. Application

4.1

Each product that GNG TIC certifies must have a valid application

4.2

An application must contain at least:

- The product information
- The client information including company registration and contact details
- Information required to determine what norm is required for Conformity Assessment

4.3

For CE Conformity Assessment the list of documents that a client must have in their possession for Conformity Assessment is specified in the legal act against which Conformity Assessment will be provided. This is the legal act as also referred to in the GNG TIC NANDO scope. The client agrees to these requirements through the signing of the contract. The client also agrees not to have submitted an application with another Notified Body.

# 5. Application review

5.1

Each application received by GNG TIC is subject to a review process.

5.2

GNG TIC is free to deny any application. However,

- Access to the Conformity Assessment process shall not be conditional upon the size of the client or membership of any association or group, nor shall Conformity Assessment be conditional upon the number of Conformity Assessments already issued. There shall not be undue financial or other conditions.
- GNG TIC Conformity Assessment should be open to all clients and products if they fall within the scope of Conformity Assessment that GNG TIC operates.
- GNG TIC is free to refuse a client or product if there has been evidence of non-compliance with GNG TIC rules, national or international legislation or (suspected) participation in criminal activities.

5.3

GNG TIC will communicate the denial to the client. The client is allowed then to alter the application and start the Conformity Assessment process in accordance with Article 4 to be processed accordingly or file a complaint.

5.4

Each review must yield a Conformity Assessment advice as internal verification of the viability of the project in accordance with ISO 17065:2012 article 7.3 or ISO 17020:2012 article 7.

5.5

GNG TIC must determine at the application review process whether it is able to carry out the Conformity Assessment process requested by the client. This includes but is not limited to ensuring required testing equipment is available and the intellectual, experience and audit capacity/capability exists (by assigning qualified persons) within GNG TIC to certify against the desired norm and whether sufficient technical information is present or obtainable. If GNG TIC cannot executed a Conformity Assessment activity it shall document this and be reported to the quality officer.

5.6

GNG TIC and the lead auditor must be able to select the applicable norm(s) for this product from the norm cache. GNG TIC may only proceed with the Conformity Assessment if the Conformity Assessment requirements are contained in specified standards and/or other normative documents as stored in the normative cache. If the norm is not found it must either be added, or the Conformity Assessment request cannot go ahead. If applicable the appropriate authority, government, committee or accrediting body will be consulted.

5.7

The lead auditor and office operations must sign off on the Conformity Assessment advice to ensure that GNG TIC has the competence and abilities to carry out the desired Conformity Assessment activities.

# 6. Conformity Assessment advice

6.1

In accordance with Article 5.3 a review of an application for Conformity Assessment will always yield a Conformity Assessment advice. A Conformity Assessment advice is an internal document designed for verify GNG TIC is able to start and carry out the Conformity Assessment.

6.2

A Conformity Assessment advice must contain:

- Whether GNG TIC is capable of performing the actions requested in the application
- What norm the product in the application will be certified against
- What audit team will be responsible for the Conformity Assessment
- In case of audits within a cycle the planning for the cycle and the required audit moments.

6.3

Once a Conformity Assessment advice is issued GNG TIC will set up a draft Conformity Assessment agreement in accordance with TD.001.

6.4

A Conformity Assessment advice must appoint a lead auditor who will be responsible for evaluating the product. Office operations may only appoint a lead auditor whom has been appointed with the appropriate competency code in accordance with RD.005 (QUALIFICATION PROFILES) for this evaluation.

6.5

The Conformity Assessment advice must be accepted and approved by the lead auditor.

6.6

A Conformity Assessment advice must contain a Conformity Assessment plan as described in article 7.

6.7

At the client's request the lead auditor will give explanation on how the Conformity Assessment process will proceed and what evaluations will be carried out as well as answering any other questions the client may have.

# 7. Conformity Assessment plan

7.1

Each Conformity Assessment advice will contain a Conformity Assessment plan.

7.2

A Conformity Assessment plan will contain the expected dates for Conformity Assessment and the essential procedures required for Conformity Assessment. It must contain:

- Expected start and end date of Conformity Assessment
- Expected submittal date to HCA
- For Module D1 it must contain:
    - All details relating to the conformity assessment scope including dates of surveillance audits and re-conformity assessment audits.

7.3

The Conformity Assessment plan is open to modification if additional evaluation activities are required which were not evident at the start of the Conformity Assessment process.

# 8. Conformity Assessment file

8.1

GNG TIC is responsible, through the legally enforceable commitment made in TD.001 (Conformity Assessment agreement), for the management of all information obtained or created during the performance of Conformity Assessment activities and the execution of PD.001 (Conformity Assessment process).

8.2

Every certified, currently being certified, or certified in the past product must have a corresponding Conformity Assessment file. The Conformity Assessment file will contain all information, documents, evidence, correspondence etc. related to the Conformity Assessment of the product.

8.3

The Conformity Assessment file will contain at least:

8.3.1 Always:

- Identification of the client.
- An application for Conformity Assessment & identification of the product
- The product technical information.

8.3.2. If Conformity Assessment advice was accepted:

- The Conformity Assessment agreement signed by GNG TIC and the client
- The Conformity Assessment plan

8.3.3. If Conformity Assessment was successful:

- As mentioned under 8.3.2 and additionally:
    - The standard(s) and other normative document(s) to which conformity has been established and if applicable certified
    - The evaluation audit report(s)
    - The Conformity Assessment decision
    - The certificate and/or inspection report if applicable

8.3.4

The Conformity Assessment file must contain records to demonstrate that all Conformity Assessment process requirements are fulfilled. The documents as mentioned in 8.3.3 must demonstrate that all process requirements have been effectively fulfilled. Any relevant communication with the client may also be included.

8.4

The Conformity Assessment file is stored according to PD.007 (Document management) using CETOOL.

8.5

Documents may be stored in different locations if relevant to the process of Conformity Assessment and they must be retrievable by unique project number

# 9. Conformity Assessment decision

9.1

After finalizing of all required evaluations without non-conformities a Conformity Assessment decision must be created.

9.1.1

Before the Conformity Assessment decision is created, GNG TIC may ask a second qualified lead auditor to perform a remote inspection of the Conformity Assessment file.

9.1.2

If applicable, after approval from the supervising lead auditor the Conformity Assessment decision will be set up in accordance with article 9.2.

9.2

The Conformity Assessment decision is issued by the head of Conformity Assessment upon receiving the recommendation of a Conformity Assessment file by the lead auditor and performing a review of that file. The Conformity Assessment decision must be based on TD.003.

9.3

The Conformity Assessment decision can lead to:

- Acceptance:
    - This can only be done if the Conformity Assessment file is completed, including the presence of a technical file meeting all requirements.
- Denial:
    - In which case the product is denied. The client must then resubmit an application.
- Improvement required:
    - The client/lead auditor will be given an unspecified or X amount of days, at the discretion of the head of Conformity Assessment, to comply. Failure to do this will lead to automatic denial.

9.4

In case of acceptance, the board of GNG TIC retains the right to deny the Conformity Assessment on non-content-based grounds. If it does not exercise this, the product will be certified.

9.5

GNG TIC must inform the client of all Conformity Assessment decisions regardless of status and provide explanation hereto.

9.6

In case of acceptance, formal Conformity Assessment documentation shall only be issued after, or concurrent with, the following:

- The decision to grant or extend the scope of Conformity Assessment has been made (to be documented in a Conformity Assessment decision).
- Conformity Assessment requirements have been fulfilled (to be documented in evaluation report(s))
- The Conformity Assessment agreement has been completed/signed (to be placed in the Conformity Assessment file)

9.7

The GNG TIC board must sign all issued certificates through SOP.003.

# 10. Certificate & Conformity Assessment documentation

10.1

A by the board of GNG TIC approved Conformity Assessment decision will always lead to the issuing of a certificate.

10.2

The certificate will be issued for the specific standard/norm/directive/law determined during the review phase and for the specific product submitted during the application phase.

10.3

Usage of the certificate and all issued marks, are subject to PD.004 (Rules for the use of marks and certificates).

10.4

Every certificate issued by GNG TIC can be revoked and suspended as described in PD.001 (Conformity Assessment process).

10.5

GNG TIC will keep a public register of certificates, regardless of status, as described in Article 20.

10.6

Each certificate will have a unique identification number which must be visible in any distribution variant of the certificate. If the product Conformity Assessment norm/directive/standard/law defines a number format GNG TIC will follow this, in all other cases the following format will be followed:

- [type-Conformity Assessment]-[product name]-[issue date]-[expiry-date]-[unique alphanumeric sequence]

Additionally, GNG TIC certificates contain at least the following:

- Name of the product
- Applied norm
- Period of validity
- Date of issuing
- Any comments left by GNG TIC. These will be binding.
- The GNG TIC Conformity Assessment number issued by the notifying authority body (NANDO number).
- The signature of the board

10.7

Certificates are solely signed by the board.

# 11. Lead Auditor

11.1

GNG TIC will appoint a lead auditor for each Conformity Assessment process. It may also appoint an audit team where needed (ie Module D1). In that case 1 team member will be the team lead and be fully responsible. This team lead also fulfills the lead auditor roles specified in PD.001.

11.2

The lead auditor must meet the lead auditor competency profile described in RD.005 (Qualification profiles).

11.3

The lead auditor will be responsible for guiding the audit process, ensuring that the product up for Conformity Assessment meets the applicable standards in the norm(s), creating a recommendation for the Conformity Assessment decision and performing evaluations to support their claims.

11.4

The lead auditor must only be tasked with evaluating the product against the standards in the norm and may only recommend the Conformity Assessment file to the head of Conformity Assessment if the product conforms to the standards in the norm(s).

11.5

The lead auditor is responsible for submitting the Conformity Assessment file for review to the head of Conformity Assessment. The lead auditor is not involved in the decision of granting the Conformity Assessment of the product.

11.6

The lead auditor shall have an agreement and sign PD.006 (Code of conduct).

11.7

The lead auditor must determine the evaluation results without burden and consultation of GNG TIC, unless a request hereto is made by the lead auditor. The lead auditor is independently authorized to determine the advice for the Conformity Assessment decision. In case of unclarity in the requirements for Conformity Assessment article 3.14 applies.

11.8

The human resources involved in conformity assessment activities shall not be remunerated in a way that influences the results of the conformity assessment activities.

# 12. Head of Conformity Assessment

12.1

The head of Conformity Assessment (HCA; former: Head Certification Department (HCD))is responsible for providing the Conformity Assessment decision and the review (the head also specifically fulfills the role as described in ISO 17065:2012 article 7.5 when this standard applies) of the Conformity Assessment file in the Conformity Assessment process.

12.2

The task of the head of Conformity Assessment is to ensure:

- The correct protocol was followed when certifying a product.
- The management system performed effectively and if not, report to the quality officer and the board.
- Identifying (potential) nonconformities and if detected, report to the quality officer and the board
- Identifying (potential) impartiality issues and if detected, report to the quality officer, board and impartiality committee

Hereto the head of Conformity Assessment has the obligation to sign off for the above-mentioned points on all Conformity Assessments performed by GNG TIC.

12.3

The head of Conformity Assessment must meet the head of Conformity Assessment competency profile as described in RD.005 (Qualification profiles).

12.4

The head of Conformity Assessment shall have an agreement with GNG TIC and must sign PD.006 (Code of conduct).

12.5

The head of Conformity Assessment must make the Conformity Assessment decision without burden and consultation of GNG TIC, unless a request hereto is made by the head of Conformity Assessment.

12.6

The head of Conformity Assessment is independently authorized to create the Conformity Assessment decision.

# 13. Evaluation and audits

13.1

As part of the Conformity Assessment process, GNG TIC may have to conduct one or multiple evaluations of the product against the relevant norm/standards/directive/law determined in the review process.

13.2

All evaluations must be carried out by the lead auditor assigned to the corresponding Conformity Assessment process, or delegated by the lead auditor to a team member under their responsibility.

13.3

All evaluations must be planned and accepted by both GNG TIC and the client.

13.4

All evaluations will be concluded with an audit report. This audit report will be placed in the Conformity Assessment file.

13.5

The lead auditor is responsible for creating the audit report. The audit report will be shared with the client.

13.6

The audit report will contain:

- Results of all evaluation activities both that were found during the evaluation and audit
- Clarification of non-conformities

13.7

If one or more nonconformities have arisen, and if the client expresses interest in continuing the Conformity Assessment process, the Conformity Assessment body shall provide information regarding the additional evaluation tasks needed to verify that nonconformities have been corrected.

13.8

If the client agrees to completion of the additional evaluation tasks that require site visits, the process specified in article 13 shall be repeated to complete the additional evaluation tasks. The additional evaluation shall be documented in the Conformity Assessment file.

13.9

If GNG TIC omits activities through the reliance on Conformity Assessments

- it has already granted to the client,
- that the client already possesses,
- or has already been granted to other clients,

it will reference these Conformity Assessments in the technical file. If requested by the client, GNG TIC shall provide justification for the omission of activities.

13.10

GNG TIC shall only rely on evaluation results related to Conformity Assessment completed prior to the application for Conformity Assessment, where it takes responsibility for the results and satisfies itself that the body that performed the evaluation fulfils the requirements contained in PD.001 (Conformity Assessment process, article 17) and those specified by the Conformity Assessment scheme.

13.11

GNG TIC shall carry out the evaluation activities that it undertakes with its internal resources and shall manage outsourced resources in accordance with the Conformity Assessment plan. The products shall be evaluated against the requirements covered by the scope of Conformity Assessment and other requirements specified in the Conformity Assessment scheme.

13.12

At the discretion of the lead auditor, if not all required technical files/documentation is present the evaluation will be postponed or cancelled.

# 14. Norm cache

14.1

GNG TIC will retain a cache of normative documents for as far as they relate to the (potential) Conformity Assessment activities that GNG TIC will carry out. These can be documents such as CE Module descriptions, relevant ISO norms etc.

14.2

The norm cache and its contents are stored according to the PD.007 (Document management).

14.3

The norm cache is a non-public document folder that may only be accessed by employees and GNG TIC appointed organizations.

14.4

Changes to the normative cache must be logged according to PD.007 (Document management) or by a relevant authority.

# 15. Normative changes

15.1

In the lifespan of GNG TIC, norms that GNG TIC has, will, or may certify / inspect against can change.

15.2

GNG TIC will check regularly (unless it is otherwise informed) whether changes have occurred to documents in the norm cache or whether the contents of the norm cache require addition/deletion. The quality officer or board will carry out these changes.

15.3

While checking for required change the quality officer must also check for announced changes and act accordingly.

15.4

Normative changes may lead to changes in the Conformity of products. PD.001 (Conformity Assessment process) and the scheme must be consulted to see how changes in Conformity Assessment norms that lead to non-conformity should be addressed.

15.5

15.5.1

When the Conformity Assessment scheme introduces new or revised requirements that affect the client, GNG TIC shall ensure these changes are communicated to all clients via email.

15.5.2

The client is requested to show proof of the implementation of the changes.

15.5.3

A GNG TIC appointed lead auditor shall verify the implementation of the changes by its clients and shall take actions required by the scheme.

15.6

GNG TIC shall consider other changes affecting Conformity Assessment, including changes initiated by the client, and shall decide upon the appropriate action.

15.7

The actions to implement changes affecting Conformity Assessment shall include, if required, the following:

- Evaluation
- Review
- Decision
- Issuance of revised formal Conformity Assessment documentation to extend or reduce the scope of Conformity Assessment
- Issuance of Conformity Assessment documentation of revised surveillance activities (if surveillance is part of the Conformity Assessment scheme)

And shall be done according to PD.001 (Conformity Assessment process)

# 16. No use of harmonized standards

16.1

A client may request to have non-harmonized standards used in their audit if allowed by the certification scheme.

16.2

GNG TIC will appoint a lead auditor to review these standards and advice GNG TIC on whether this standard is allowed. Additional information may be asked of the client.

16.3

GNG TIC will add these standards to the normative cache if they are applicable and where required.

16.4

The use of non-harmonized standards may be combined with additional costs for the review and application.

16.5

GNG TIC may choose for formally accept certain standards without review or based on past reviews, if so it must document this in a board decision or SOP.

# 17. Resource management

17.1. Evaluation activities via internal resources or other resources under our direct control

17.1.1.

When GNG TIC performs evaluation activities, either:

- with its internal resources, or
- with other resources under our direct control,

GNG TIC shall ensure to meet the applicable requirements stemming from

- GNG TIC's NANDO scope, and
- the relevant International Standards:

- For product Conformity Assessment:
  - It shall meet the applicable requirements of ISO/IEC 17065
  - In addition: if the product is to be certified under an EU legal instrument as listed in the GNG TIC NANDO scope, it must meet the applicable requirements of this directive
- For product Conformity Assessment evaluations:
  - The resource must always be ISO/IEC 17065 accredited, or part of an ISO/IEC 17065 accredited organization, or appointed against the applicable standard by an EEA member state.
  - In addition: if the product Conformity Assessment evaluation is performed under an EU legal instrument as listed in the GNG TIC NANDO scope, the resource must also be appointed hereto.
- For testing or product Conformity Assessment where testing is performed:
  - it shall meet the applicable requirements of ISO/IEC 17025
  - if evaluated by another resource under our direct control, it must be under ISO/IEC 17025 accreditation in accordance with the scope of the required work assignment or test.
- For inspection or product Conformity Assessment where inspection is performed:
  - it shall meet the applicable requirements of ISO/IEC 17020
- For management system auditing:
  - it shall meet the applicable requirements of ISO/IEC 17021

17.1.2.

GNG TIC excludes:

- management system auditing according to ISO/IEC 17021

17.1.3.

GNG TIC reserves the right to request permission from the Notifying Authority for deviations on the before mentioned principles.

17.1.4.

Any deviation from these requirements must be documented in a board decision.

17.1.5.

The impartiality requirements of evaluation personnel must always meet ISO/IEC 17065:2012 requirements.

17.2 Outsourcing of evaluation activities

17.2.1

When GNG TIC outsources evaluation activities, it shall only be to bodies that meet the applicable requirements of the requirements stemming from

- GNG TIC's NANDO scope, and
- the relevant International Standards:

- For product Conformity Assessment:
  - It shall meet the applicable requirements of ISO/IEC 17065
  - In addition: if the product is to be certified under an EU legal instrument as documented in the GNG TIC NANDO scope, it must meet the applicable requirements of this instrument.
- For product Conformity Assessment evaluations:
  - The resource must always be ISO/IEC 17065 accredited, or part of an ISO/IEC 17065 accredited organization or appointed against the applicable standard by an EEA member state.
  - In addition: if the product Conformity Assessment evaluation is performed under an EU legal instrument as documented in the GNG TIC NANDO scope the resource must also be appointed hereto.
- For testing or product Conformity Assessment where testing is performed:
  - it shall meet the applicable requirements of ISO/IEC 17025
  - if evaluated by another resource, it must be under ISO/IEC 17025 accreditation in accordance with the scope of the required work assignment or test.
- For inspection or product Conformity Assessment where inspection is performed:
  - it shall meet the applicable requirements of ISO/IEC 17020
- For management system auditing:
  - it shall meet the applicable requirements of ISO/IEC 17021

17.2.2.

GNG TIC excludes:

- management system auditing according to ISO/IEC 17021

17.2.3.

GNG TIC reserves the right to request permission from the Notifying Authority for deviations on the before mentioned principles.

17.2.4.
Any deviation from these requirements must be documented in a board decision.
17.2.5.
The impartiality requirements of evaluation personnel must always meet ISO/IEC 17065:2012 requirements.
17.2.6.
If evaluation activities are outsourced to non-independent bodies (e.g. client laboratories), GNG TIC shall ensure that the evaluation activities are managed in a manner which provides confidence in the results, and that records are available to justify the confidence. The lead auditor assures that the evaluation is executed in a verifiable manner and stores the proof in the Conformity Assessment file. When work is performed under the GNG TIC NANDO scope for FPR, this article is overruled by SOP.006.
17.2.7.
Where GNG TIC subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in EU decision 768/2008, article R17, and shall inform our notifying authority accordingly.
17.2.8.
Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client. The client agrees through signing of the TD.001 agreement to subcontracting of any and all GNG TIC contracted subcontractors at the date of signing the agreement. The client is free to raise an objection to this and then the board must decide.
17.2.9
Lead auditors under contract with GNG TIC which have signed the code of conduct and Conformity Assessment agreement are not considered outsourced parties.
17.3
GNG TIC ensures that required testing equipment is available. If non-available internal or external resources are required for Conformity Assessment a determination must be made during the application review stage and a request must be submitted to the board.
17.4
GNG TIC will keep a list of testing equipment (ID.005).

17.5
If testing equipment is required for a Conformity Assessment and this is not in ownership, or already leased by GNG TIC, the costs will be charged to the client.
17.6
GNG TIC may charge an administration fee to the client for the finding and renting of equipment.
17.7
If the client has testing equipment available GNG TIC may use that equipment to avoid costs. GNG TIC ensures this equipment is qualified according to PD.001 (Conformity Assessment process), in order to avoid any breach of impartiality and to ensure the integrity of the Conformity Assessment process.
17.8
Testing equipment may be explicitly used by the lead auditor or a by the lead auditor appointed person.
17.9
GNG TIC ensures testing equipment is correctly calibrated before use.
17.10
Equipment thought not be required by article 17.3 but required at a later stage may be rented if the proper request is made to the board.

# 18. Monitoring

18.1

18.1.1

Where required by the applicable standard/norm/directive/regulation GNG TIC will continuously monitor the quality of certified products if this is a type certified product.

18.1.2

If no other maintenance requirements exist: Once a year the client may be hold to deliver a legal binding statement which declares that all products are built in accordance with the applicable norms and requirements, if allowed by the certification scheme.

18.1.3

GNG TIC clients must, without delay, inform GNG TIC of changes to the product and the client's ability to conform to the Conformity Assessment requirements.

18.1.4

If changes are reported GNG TIC will appoint a lead auditor to evaluate the changes and see if they violate the standards set by the applied norms/directives/standards/laws.

18.1.5

If the changes violate the standards set by the applied norms GNG TIC will create a Conformity Assessment advice that contain the required changes.

18.1.6

The client must accept this advice, or the Conformity Assessment will be revoked.

18.2

18.2.1

As part of the monitoring process the client must setup a register of complaints regarding the product in any way. The client must provide GNG TIC with access to this register and the supporting documentation of how each complaint has been dealt with. If this is denied, or this information is not available, GNG TIC is authorized to revoke the Conformity Assessment.

18.2.2
GNG TIC will keep a publicly accessible complaints system of its own in which the product end users can leave complaint, for as far as they relate to the compliance with the norm/standard/law/directive. GNG TIC will process these complaints and appoint a lead auditor to investigate. These complaints are to be handled according to PD.002 (Complaint procedure).
18.2.3
If a complaint is filed, the client must inform GNG TIC within 10 working days or the client is in violation TD.001 (Conformity Assessment agreement)
18.3
GNG TIC may, at any time and if for good reason, perform a (partial) re-Conformity Assessment and corresponding evaluation. If the client does not consent to this, GNG TIC has the right to suspend the Conformity Assessment.
18.4
GNG TIC will periodically monitor the usage of certificates, marks and company public material.
18.5
In the event of a change, to a certified product or its production, that violates the norm, any applicable regulation, applied standard or Conformity Assessment requirment the corresponding Conformity Assessment is automatically invalid.
18.6
Where period audits are required to maintain the conformity assessment, or conformity assessment is part of a certification cycle, audits are planned according to a relevant SOP and documented in the conformity advice.

# 19. Non-conformity, Suspension and Revocation

19.1

Every certificate, and corresponding Conformity Assessment can be revoked, suspended or changed by GNG TIC.

19.2

The client is always allowed to request revocation of the certificate for any possible grounds.

19.3

GNG TIC may decide to continue the Conformity Assessment under pre-conditions if a minor non-conformity was determined and this is allowed by the norm. What these conditions are and what is considered a minor non-conformity is up to the individual lead auditor. This continuation must be agreed upon with GNG TIC's appointing body.

19.4

19.4.1

If Conformity Assessment is suspended, GNG TIC shall assign a lead auditor to formulate and communicate the following to the client:

- Actions needed to end suspension and restore Conformity Assessment for the product(s) in accordance with the Conformity Assessment scheme
- A defined timeframe to resolve the issues
- Any other actions required by the Conformity Assessment scheme

19.4.2

These persons shall be competent in their knowledge and understanding of all aspects of the handling of suspended Conformity Assessments.

19.4.3

If successful, the Conformity Assessment will be reactivated.

19.4.4

If the client does not correct the non-conformities within the aforementioned timeframe, GNG TIC will revoke the Conformity Assessment.

19.5

If Conformity Assessment is suspended, GNG TIC shall a lead auditor to formulate and communicate the following to the client:

- Actions needed to end suspension and restore Conformity Assessment for the product(s) in accordance with the Conformity Assessment scheme;
- Any other actions required by the Conformity Assessment scheme.

19.6

If the client wants to reactivate the Conformity Assessment after a suspension (resolve the suspension) a new Conformity Assessment process will be started according to PD.001 (Conformity Assessment process).

19.7

If Conformity Assessment is reinstated after suspension, GNG TIC shall make all necessary modifications to formal Conformity Assessment documents, public information, authorizations for use of marks, etc., in order to ensure all appropriate indications, exist that the product continues to be certified. If a decision to reduce the scope of Conformity Assessment is made as a condition of reinstatement, GNG TIC shall make all necessary modifications to formal Conformity Assessment documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of Conformity Assessment is clearly communicated to the client and clearly specified in Conformity Assessment documentation and public information.

19.8

Once a Conformity Assessment is revoked it cannot be renewed. To achieve the same/comparable Conformity Assessment status a new Conformity Assessment application must be submitted.

19.9

19.9.1

If Conformity Assessment is terminated (by request of the client), suspended or revoked, GNG TIC shall take actions specified by the Conformity Assessment scheme and shall make all necessary modifications to formal Conformity Assessment documents, public information, authorizations for use of marks, etc., in order to ensure it provides no indication that the product continues to be certified.

19.9.2

If a scope of Conformity Assessment is reduced, the Conformity Assessment body shall take actions specified by the Conformity Assessment scheme and shall make all necessary modifications to formal Conformity Assessment documents, public information, authorizations for use of marks, etc., in order to ensure the reduced scope of Conformity Assessment is clearly communicated to the client and clearly specified in Conformity Assessment documentation and public information.

19.9.3

Any change in the Conformity Assessment status must be reflected in the public register.

19.10.

Unless otherwise required by a conformity assessment scheme or a SOP document the GNG TIC lead auditor is responsible for determining how long a client has to resolve non-conformities.

# 20. Public register

20.1

GNG TIC will maintain a register of certified products and the norm(s) under which they are certified.

20.2

The register is available on request for the verification of certificates.

20.3

The public register will contain:

- The unique certificate numbers
- The product names
- The applied norm(s) and standard(s)
- The status of the Conformity Assessment

20.4

The register must be searchable by the unique certificate number.

# 21. Complaints

21.1.

It is possible to make complaints against GNG TIC. Complaints will be handled according to PD.002 (Complaints procedure).

# 22. Standard operating procedures

22.1

GNG TIC maintains several SOP documents. SOP's are procedures GNG TIC uses when certifying a product and for using tools.

22.2

The allowed SOP's for the Conformity Assessment procedure described in this document are:

- SOP.001
- SOP.002
- SOP.003
- SOP.004
- SOP.006
- SOP.007
- SOP.008

These are considered as inserted and binding.

22.3

SOP's are used by default and always applicable. If GNG TIC decides not to use an SOP it must describe this in the Conformity Assessment advice in accordance with Article 6. This may only be allowed if that SOP is not required by PD.001

22.4

In the case of 22.3 an alternative procedure must be described and documented.