

[English translation]

TISI-R-PC-01

[Logo of Thai Industrial Standards Institute (TISI)]

Thai Industrial Standards Institute (TISI),
Ministry of Industry

Criteria for Product Certification

[Royal Garuda Emblem]

Proclamation of Thai Industrial Standards Institute

Re: Criteria for Product Certification

It is appropriate to revise the criteria for product certification to ensure that the TISI's product certification is conducted appropriately, clearly, transparently and fairly, complying with the international certification system and developing the industrial sector so that it has capacity to compete. The Industrial Product Standards Council (IPSC) passed a resolution to agree to revise the criteria for product certification at a 557-1/2552 meeting on 21 January 2009.

The TISI, therefore, cancelled the TISI's proclamations concerning the criteria for product certification dated 4 March 2008 and 26 January 2009 and announced new criteria for product certification as per the details appended to this proclamation.

These new criteria are to be enforced from now on.

Announced on 4 March 2009.

(Mrs Rattanaporn Jungsanguansit)

Secretary General for the Thai Industrial Standards Institute

Criteria for Product Certification

1. Scope

This document specifies definitions, objectives, principles, inspections for granting permission, monitoring after a licence is granted, and conditions that must be followed by licensees for the certification of both voluntary products and compulsory products.

2. Definitions

- 2.1 “Standards” means industrial product standards specified and proclaimed by the Minister of Industry.
- 2.2 “Voluntary products” means industrial products which have specified and proclaimed standards.
- 2.3 “Compulsory products” means industrial products which have specified and proclaimed standards and have a Royal Decree determining that they have to comply with the standards.
- 2.4 “Sor Mor Or.” means Thai Industrial Standards Institute (TISI).
- 2.5 “Officials” means officials according to the Industrial Standards Act, B.E. 2511 (1968) and its amendments.
- 2.6 “Applicants” means persons wishing to apply for a licence showing the voluntary product standards symbol or persons wishing to apply for a licence to produce or import compulsory products.
- 2.7 “Licensees” means persons granted a licence in accordance with Section 16, Section 20 and Section 21 of the Industrial Standards Act, B.E. 2511 (1968) and its amendments.

3. Objectives

These Criteria for Product Certification have been specified with the following objectives:

- 3.1 To conduct the certification in an appropriate, clear, transparent and fair manner.
- 3.2 To comply with the international certification system and to develop the industrial sector so that it has capacity to compete.
- 3.3 To comply with the Ministry of Industry’s policy to increase the potential of the industrial sector.

4. Principles

Consideration of granting a licence for displaying, producing or importing products is based on the following principles:

- 4.1 Product quality complies with the specified standards.
- 4.2 Product quality control systems must be adequate for maintaining consistent product quality in compliance with the standards.

5. Inspections for Granting Permission

5.1 Inspections before a licence is granted will be conducted as follows:

- 5.1.1 Inspection of product manufacturing
- 5.1.2 Inspection of products

5.2 Inspection of product manufacturing

The TISI will conduct the inspection as follows:

- 5.2.1 Inspect the production of products by manufacturers both in the country and abroad by assessing the product quality control systems of factories that follow the activity requirements of Appendix Khor (B).

5.3 Inspection of products

The TISI will conduct inspections as follows:

- 5.3.1 Products will be inspected according to specific criteria in the certification of related products by officials collecting samples for inspection.
- 5.3.2 Products will be assessed according to the requirements in the standards by giving appropriate consideration to test results as follows:
 - (1) Test results from designated testing laboratories.
 - (2) Test results from testing laboratories approved by the TISI according to criteria specified by the TISI.

6. Monitoring after a Licence is Granted

To ensure that licensees consistently maintain product quality in compliance with standards, the TISI will monitor after licences are granted *by inspecting product manufacturing by licensees and inspecting products* as follows:

6.1 Inspecting product manufacturing by licensees

The TISI will conduct inspections as follows:

6.1.1 Where permission is given to show the standard symbol with the products or to produce industrial products

- (1) Inspect product manufacturing by manufacturers by assessing the product control systems according to the activity requirements in Appendix Gor. (A) of these criteria for product certification and collecting samples from licensees for inspection.
- (2) Consider the acceptance of factory assessment results instead of product manufacturing inspections (1) in the case of manufacturers who have been assessed by an organisation accepted by the TISI in compliance with standards specified by the TISI.

In general, the TISI will conduct inspections of manufacturing and inspect the products of each licensee once a year. If inspection results show that the licensee can consistently and continuously maintain product quality in compliance with standards, the TISI may consider adjusting and reducing the number of manufacturing inspections and product inspections. If, on the other hand, inspection results provide reason to believe that the licensee cannot consistently and continuously maintain product quality in compliance with standards, the TISI may consider adjusting and increasing the number of manufacturing inspections and product inspections as appropriate.

6.1.2 In cases where permission is given to import industrial products

- (1) Unless otherwise specified, the TISI will once a year inspect the production of products by manufacturers abroad by assessing the product quality control systems according to the activity requirements in Appendix Gor. (A) or by inspecting the product quality control systems of importers according to the activity requirements in Appendix Khor. (B) of these criteria for product certification, depending on the case.

- (2) Consider the acceptance of factory assessment results instead of product manufacturing inspections (1) in cases where manufacturers abroad have been assessed by an organisation accepted by the TISI in accordance with standards specified by the TISI.
- (3) Unless otherwise specified, the TISI will collect product samples from licensees at each time of import to send for inspection. If there is reason to believe that imported products do not comply with standards, products will be inspected and released only when inspection results comply with standards.

6.2 The TISI will inspect and monitor licensed products by purchasing samples from distribution points as appropriate, and will inform licensees. The cost of the inspections must be paid in line with advertised rates.

7. Conditions that Must be Followed by Licensees

7.1 Licensees must comply with methods of industrial product quality control in order to comply with the standards.

Licensees must be monitored after a licence has been granted as specified in (6) above, and must arrange for factories specified in the licence to have the following product quality controls:

- (1) There must be methods of quality control in compliance with activity requirements in the product quality control systems as per Appendix Gor. (A) or Appendix Khor. (B).
- (2) There must be controls/ inspections/ testing on all listed items in compliance with the standards specified. Inspection of each listed item may be carried out by the licensee or others who have been given authorisation.
- (3) For the inspection of product manufacturing by manufacturers both in the country and abroad, factories must as a minimum have testing tools for listed items in compliance with the requirements under specific criteria for certifying relevant products, and must conduct regular tests at the factories.
- (4) For the inspection and assessment of the product quality control systems of importers, there must be item testing as specified in the specific criteria for certifying relevant products by the following means:
 - (4.1) Importers must have item testing tools in compliance with requirements under specific criteria for certifying products, and must conduct regular tests at the licensees' locations, or

- (4.2) Importers must send licensed products for item testing in compliance with the requirements under specific criteria for certifying relevant products at testing laboratories approved by the TISI.
- (5) The TISI must be informed every time information is changed from that given to the TISI where there might be an impact on the quality of the licensed product.
- (6) The TISI must be informed of the quantity of licensed product manufacturing. Every half calendar year, information must be given within 30 days of the date due.
In the case of imports, licensees must in each case inform the TISI of the products imported and the product quantity prior to import.
- (7) Complaints concerning product quality must be recorded and kept. Amendments must also be recorded and copies sent to the TISI on request.

7.2 In cases where licensees display standards symbols on industrial products and voluntary products:

Licensees must display standards symbols on licensed products within 30 days of the date notice is received from the TISI.

7.3 Licensees must pay the cost of product inspections within 15 days of receipt of a payment notice.

Appendix Gor. (A)

Activity requirements in the product quality control systems of manufacturers

Licence applicants must arrange for factories for which they are applying to have product quality control systems in compliance with activity requirements in the following product quality control systems:

Activity requirements in the product quality control systems of manufacturers
1. Control of raw materials
2. Control during production
3. Control of ready-made products
4. Control of products which do not conform with the requirements
5. Identification and traceability
6. Product preservation and storage
7. Machinery used in manufacturing and maintenance
8. Control of inspection, measuring and testing equipment
9. Training (skills, knowledge and capabilities)
10. Control of quality records

Detailed requirements in the product quality control systems of manufacturers

1. Control of raw materials

Licence applicants must arrange for factories for which they are applying for a licence to have controls/ inspection/ testing to ensure that raw materials (meaning raw materials, components, packaging, work produced by sub-contractors and raw materials which are assets of customers) used for manufacturing have good quality and comply with the specified quality criteria by:

- (1) Setting out random sampling plans, quality criteria and ways of checking each listed item of raw materials on receipt and/or methods of checking raw materials on receipt.
- (2) Conducting inspections and/or checking raw materials on receipt in compliance with specified plans.
- (3) Recording inspections/ test results and keeping records as evidence.

2. Controls during production

2.1 Production process planning

Licence applicants must arrange for factories for which they are applying for a licence to create a chart showing the steps of production and product quality controls, which must specify the following, as appropriate:

- (1) The production process.
- (2) Control of conditions during the production process; inspection and testing during production. Criteria specifying results from this planning must be on appropriate forms used in organisations.

2.2 Production process controls

Licence applicants must arrange for factories for which they are applying for a licence to control production according to the production process under inspection and control conditions, which include:

- (1) Information that specifies requirements or the product specifications required.
- (2) Work practices, as necessary for people working on the production process.
- (3) Usage of appropriate tools, machinery and equipment.
- (4) Usage of tools for measuring and monitoring.
- (5) Conducting the measuring and monitoring.
- (6) Conducting product release, delivery and post-delivery activities.
- (7) Necessary records as evidence that the production process and products received comply with requirements.

2.3 Permission to use the production process where products cannot be inspected directly (if applicable)

Licence applicants must arrange for factories for which they are applying for a licence to prove that the production process is validated, and give permission to use the production process in cases where products cannot be inspected directly; for example, inspection, measuring including any processes in which product faults might appear after products have been used or after delivery.

Proof of validation of the production process must show that the capability of the production process for the products complies with requirements.

3. Control of ready-made products

Licence applicants must arrange for factories for which they are applying for a licence to show details or methods, frequencies, quantities and ways of inspections/ testing to ensure that quality of ready-made products complies with the specification in the standards (inspection/ testing of each listed item may be performed during any stage of production process but it must be ensured that later steps do not affect a change in quality, OR may be performed by the licensee or others who have been given authorisation.). Also, inspection/ testing results must be recorded and the results must be kept as evidence.

4. Control of products which do not conform to the requirements

Licence applicants must arrange for factories for which they are applying for a licence to create working methods and practices to ensure that products which do not comply with requirements are specified and controlled in order to prevent unintentional usage and to eliminate non-compliance, which may be carried out by:

- (1) Re-manufacturing or repairing products in order to comply with to the criteria specified.
- (2) Changing the quality level.
- (3) Giving permission for use by persons with authorisation or releasing the products.
- (4) Destroying them.

Non-compliance, including actions taken on the products, must be recorded and records must be kept as evidence.

Notes

- 1. Products that do not comply with requirements include raw materials, work in process, ready-made products and faulty products returned by customers.*
- 2. Products that have been re-manufactured and/or repaired must be reinspected according to the details specified in product inspection plans.*
- 3. Where there have been changes to quality levels (lower than allowed in the licence) or permission has been given to use products that do not comply with the requirements, the standards symbol cannot be displayed on the products.*
- 4. Factories that are applying for a licence should analyse information concerning non-compliance with product requirements to determine methods of improvement.*

5. Identification and traceability

Licence applicants must arrange for factories for which they are applying for a licence to:

- (1) Identify products with appropriate materials throughout production.
For identification of ready-made products, information must be given at least in accordance with industrial product standards.
- (2) Identify product status with appropriate materials.
If there are traceability requirements, product identification must be controlled and recorded in compliance with requirements.

6. Product storage

Licence applicants must arrange for factories for which they are applying for a licence to store products, including raw materials, work in process, and ready-made products in compliance with requirements until delivery. This storage must include identification, transfer, packaging, storage and prevention of deterioration.

7. Machinery used in manufacturing and maintenance

Licence applicants must arrange for factories for which they are applying for a licence to have appropriate manufacturing tools, machinery and equipment and have adequate capacity to produce products in compliance with the standard, including preventative maintenance of important machinery, tools and equipment as appropriate to ensure that capacity in producing products in compliance with the standards is maintained consistently.

8. Control of inspection, measuring and testing equipment

Licence applicants must arrange for factories for which they are applying for a licence to have as a minimum inspection, measuring and testing of equipment as specified in the specific criteria for product certification of each product to test regularly at factories, including control and calibration of inspection, measuring and testing equipment that affects the measurement of quality in order to be confident in the inspection, measuring and testing results by:

- (1) Calibration or verification in the period specified or prior to usage in comparison with measuring standards which can be verified up to national or international levels. (In cases where no standards are specified, basic methods used for calibration or verified status must be recorded.)
- (2) Showing calibration status.
- (3) Prevention of customisation, both deliberate and unintentional.
- (4) Prevention of damage and deterioration during transfer, maintenance and storage.

If the inspection, measuring and testing equipment are found not to comply with requirements, factories must have appropriate methods of action to deal with inspection, measuring and testing equipment, and the affected products, and keep records of the results of calibration and verification.

Software used for inspection, measuring and testing must be confirmed for accuracy prior to usage, and reconfirmed for accuracy when necessary.

9. Training (skills, knowledge and capabilities)

Licence applicants must arrange for factories for which they are applying for a licence to have personnel who affect product quality with sufficient knowledge and capabilities to perform the tasks, as follows:

- (1) Specifying necessary capabilities required for personnel who affect product quality.
- (2) Organising training or other action methods in order to have specified capabilities.
- (3) Accessing results of organised training or other action methods.

Producing and keeping appropriate records of educational background, training, skills and experience.

10. **Control of quality records**

Licence applicants must arrange for factories for which they are applying for a licence to:

- (1) Specify methods of identification, storage, care, usage, duration of storage and destruction of the records.
- (2) Establish and keep records to show compliance with the requirements.
- (3) The records must be clear, easy to read and kept in a way that can be used easily in appropriate conditions to prevent damage, deterioration or loss.
- (4) The period of keeping records must as a minimum cover the TISI's follow-up inspection cycle.

Notes: Records can be kept in any form; for example, paper or electronic form.

Appendix Khor. (B)

Activity requirements in the product quality control systems of importers

Licence applicants must have product quality control systems in place in compliance with activity requirements in the following product quality control systems:

Activity requirements in the product quality control systems of importers
1. Purchasing
2. Control of products which do not comply with the requirements
3. Identification and traceability
4. Product preservation and storage
5. Control of inspection, measuring and testing equipment
6. Training (skills, knowledge and capabilities)
7. Control of quality records

Detailed requirements in the product quality control systems of importers

1. Purchasing

Import licence applicants must specify and maintain methods in writing to ensure that products for which import permission is requested comply with specified standards.

(Gor) Assessing product manufacturers

Licence applicants must:

- (Gor. 1) Assess and select product manufacturers based on their capacity to meet requirements for purchasing or sub-contracting including quality systems and requirements for quality assurance.
- (Gor. 2) Specify selection criteria, assessment and reassessment after purchase.
- (Gor. 3) Create and maintain quality records concerning the results of assessing product manufacturers and the results of any actions arising from the assessment.

(Khor) Purchasing information

Products purchased must have specifications according to the standards (TIS); purchasing documents must as a minimum contain the following information:

- (Khor. 1) Design, class, type or other clear specifications.
- (Khor.2) Names or specifications, and detail requirements with document issuing code, specifications, designs, process requirements and other relevant technical information, including requirements for certification of product quality, methods, process, machinery and personnel.
- (Khor.3) Names, numbers and document issuing code for the quality systems that will be used.

(Kor) Verification of purchased products

- (Kor 1) Licence applicants must verify purchased products to ensure that purchased products comply with purchasing requirements (TIS)
- (Kor 2) Licence applicants must show details or methods, frequencies, quantities and ways of inspection to ensure that quality of ready-made products complies with the specifications specified in the standards prior to delivery/ sale in the market. The product testing list must not be less than the testing list specified for the manufacturer's factories to test regularly at factories specified in the specific criteria

for product certification. Inspection/ testing results must be recorded and records must be kept as evidence.

2. Control of products which do not comply with the requirements

- (1) Licence applicants must specify and maintain the methods which ensure prevention of both deliberate and unintentional delivery/ sale of products which do not comply with requirements. The stated control must have clear identification by separating, amending and improving (where applicable) in order to comply with standards (TIS).
- (2) Licence applicants must recall products from all markets in which they have been delivered/ sold in the market in cases where it is later found that these products do not comply with standards.

3. Identification and traceability

Licence applicants must identify products as appropriate and specify the date of import in so that it can be verified with appropriate materials.

4. Product storage

Licence applicants must maintain products in compliance with standards (TIS) until delivery. This storage must include identification, transfer, packaging, storage and prevention of deterioration.

5. Control of inspection, measuring and testing equipment

Licence applicants must arrange as a minimum to have measuring and testing of equipment as specified in the specific criteria for product certification of each product to test regularly, including control and calibration of inspection, measuring and testing equipment that affects the measurement of quality in order to be confident in the inspection, measuring and testing results by:

- (1) Calibration or verification in the period specified or prior to usage in comparison with measuring standards which can be verified up to national or international levels. (In cases where no standards are specified, methods used for calibration or verified status must be recorded.)
- (2) Showing calibration status.
- (3) Prevention of customisation, both deliberate and unintentional.
- (4) Prevention of damage and deterioration during transfer, maintenance and storage.

If the inspection, measuring and testing equipment are found not to comply with requirements, factories must have appropriate methods of action to deal with inspection,

measuring and testing equipment, and the affected products, and keep records of the results of calibration and verification.

Software used for inspection, measuring and testing must be confirmed for accuracy prior to usage, and reconfirmed for accuracy when necessary.

6. Training (skills, knowledge and capabilities)

Licence applicants must arrange personnel who affect product quality to have sufficient knowledge and capabilities to perform the tasks and keep appropriate records of training as evidence.

7. Control of quality records

Licence applicants must keep records of product quality to show compliance with the standards (TIS). All records must be clear, easy to read and kept in a way that can be accessed easily in appropriate conditions to prevent damage, deterioration or loss, and the appropriate period for keeping the records must be specified: The above records of quality may be in any form, such as paper or electronic format. These quality records must be ready to deliver when requested by the TISI.