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TC S371 Product Certification and Laboratory Accreditation Practices (Free Courseware)

香港公開大學
THE OPEN UNIVERSITY OF HONG KONG

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Chapter 1 Product certification

1.1 Introduction

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Welcome to this free courseware topic, 'Product certification'!

This topic is taken from *Unit 1* of one of our OUHK distance learning courses, *TC S371 Product Certification and Laboratory Accreditation Practices*. *TC S371* is one of the core courses of the BSc/Bsc (Hons) in Product Design, Testing and Certification programme and is recommended to students who want to learn about product certification, practices for laboratory accreditation and the ISO/IEC 17025 laboratory management system. It is a higher-level, 5-credit course and takes one semester to complete.

Units in OUHK courses normally contain various elements to enhance the content, such as activities, self-tests, figures and assigned readings. You can find most of these elements in the courseware here so that you can have a taste of what an OUHK course is like. In addition to this introductory topic on product certification, the original unit also goes into more detail on product certification systems and guidance for the drafting of product certification schemes.

TC S371, like most OUHK courses, is presented in the distance learning mode using print-based materials. The materials for this free courseware have been specially adapted to make them more suitable for studying online.

In this module, we will introduce the most important conformity assessment activity in the field of testing and certification — *product certification*. Product certification is an activity by which a third party (not the supplier, not the buyer, but an i*ndependent certification body*) gives written assurance that a product (or a process or a service) fulfills specified requirements. The value of certification is the degree of confidence and trust that is established by an impartial and competent evaluation by a third-party. We will look into the concepts of conformity assessment activities and quality management systems (QMS). QMS and other conformity assessment activities such as testing and inspection are core elements in the determination stage of product certification. After we've studied these elements, we will then give a brief introduction to product certification. The procedure of product certification and the use of conformity marks will be covered.

The module should take around **4 hours** to complete, including time spent on activities and self-tests.

1.2 Overview of conformity assessment activities and system certification

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Before we start to delve into the concept of product certification, let's take a moment to think about why it exists in the first place. In the Activity 1 (Page 2), you'll watch a short online video that discusses the promise of product certification.

After watching the video (https://www.youtube.com/watch?v=ZA-Tky2HLFI), you should have a basic idea of the importance of product certification. Next, we need to understand what kinds of activities are involved in product certification. These are called *conformity assessment activities*.

1.2.1 Activity 1

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Watch the following short video clip from Youtube: 'Buyer Be Fair: The Promise of Product Certification (http://www.youtube.com/watch?v=ZA-Tky2HLFI) '.

The video lasts around three minutes.

What is the promise that the video refers to regarding product certification?

1.2.1.1 Activity 1 feedback

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The video emphasizes one aspect of product certification: the fact that buyers of products bearing certain logos can be sure that what they are buying has been manufactured under fair trade principles. This is just one way in which product certification can reassure or promise customers of the quality of the product they are purchasing.

1.2.2 Conformity assessment activities

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In product certification, conformity assessment activities are used to demonstrate whether an object (which can be material, installation, process (A set of interrelated or interacting activities which transforms inputs into outputs (ISO 9000:2005 clause 3.4.1).), system, person, body or **product** is fulfilling specified requirements.

Product

Product — The result of a process. There are four generic product categories are noted in ISO9000:2005 defined, namely service (e.g. transport), software (e.g. computer program, dictionary), hardware (e.g. engine, mechanical part) and processed materials (e.g. lubricant). Many products comprise elements belonging to different generic product categories. Whether the product is then called service, software, hardware or processed materials depends on the dominant elements (ISO/IEC 17000:2004, clause 3.3).

The three major activities used for conformity assessment are defined below:

- **Testing**
  Testing is the determination of one or more characteristics of an object of conformity assessment (The particular material, product (including services), installation, process, system, person or body to which conformity assessment is applied (ISO/IEC 17000:2004, clause 2.1).), according to a procedure. Testing can be applied to materials, products or processes.

  Example: Determining the total lead content in a plastic toy material according to the test method CPSC-CH-E1002-08.1 (you are not required to know the details of this test method), to see whether the material fulfills the lead content requirement of the US Consumer Product Safety Improvement Act (CPSIA).
- **Inspection**
  Inspection is the examination of a product design, product, process or installation and determination of its conformity with specific requirements, or, on the basis of professional judgement, with general requirements.

  Example: Examining the net weights of shampoo liquid in bottles (i.e. total weight – weight of bottle) from the same production batch to see whether they all contain 700 ml ± 20 ml of shampoo.
- **Certification**
  Certification is the issuance of a conformance statement by a third party (usually a certification body (The third-part conformity assessment body operating certification schemes.)) that a product, process, system or person has demonstrated the fulfillment of specified requirements.

  Example: An independent certification body conducted an audit on Company A and has concluded that the quality management system (QMS) of Company A fulfilled the requirements of ISO 9001.

Conformity assessment activities like testing and inspection can be conducted by first, second or third parties in a certification process. It is important to note that certification can *only* be conducted by a third party.

First party in a certification process

First party conformity assessment activities are performed by the person or organization that provides the object (i.e. object manufacturer or supplier). A typical example for first party conformity assessment activity is an internal quality control laboratory in a manufacturing plant which tests the product samples to see whether they pass the manufacturing specifications.

Second party in a certification process

Second party may refer to a person or organization which would like to purchase or use the object, or as a customer or the representative of a customer who shows interest in the object. Examples such as buyer's inspection audit to a manufacturer or colour test to an applicant's eyes during an employment interview are second party conformity assessment activities.

Third party in a certification process

Third party conformity assessment activities are performed by a person or body that is independent from either first or second parties. An independent laboratory which is owned by neither the toy manufacturer nor the buyer, conducting heavy metal testing for a sample produced by the toy manufacturer, can be classified as third party conformity assessment activity.

Table 1.1 provides an overview of different conformity assessment activities.

Conformity assessment system or scheme	Management system	Party performing conformity assessment			Surveillance (when needed)	Result
		First party	Second party	Third party		
Certification of products	ISO/IEC Guide 65	×	×	o	o	Certificate
Certification of management systems	ISO/IEC 17021	×	×	o	o	Certificate
Certification of persons	ISO/IEC 17024	×	×	o	o	Certificate
Inspection	ISO/IEC 17020	o	o	o	×	Report

Table 1.1: Different conformity assessment activities

Conformity assessment system or scheme	Management system	Party performing conformity assessment			Surveillance (when needed)	Result
Testing (for non-medical laboratory)	ISO/IEC 17025	o	o	o	×	Report

Table 1.1: Different conformity assessment activities

Can you identify any more examples of first, second, and third party conformity assessment activities?

Having discussed the conformity assessment activities, let's take a closer look at the quality management system (QMS) certification — which is the core of many product certification and laboratory accreditation practices.

1.2.3 Quality management system (QMS) certification

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It is known that managing an organization in a systematic and transparent manner is the way to lead and operate the organization successfully. An effective QMS should be designed for continually improving performance and addressing the needs of all parties. Managing an organization encompasses quality management amongst other management disciplines, where a quality management system can assist organizations in enhancing customer satisfaction.

Generally speaking, an effective QMS encourages organizations to:

- analyse customer requirements;
- define the processes that contribute to the achievement of a product which is acceptable to the customer; and
- keep these processes under control.

A QMS provides the framework for continual improvement and aims to enhance satisfaction from customers and other interested parties. As we have discussed in the previous section, certification of the quality management system (which also applies to product certification) by a third party certification body provides confidence to the organization and its customers that it is able to provide products that consistently fulfill requirements.

The ISO 9000 series (http://en.wikipedia.org/wiki/ISO_) 9000 (including ISO 9001) for quality management systems is one of the ISO's (International Organization for Standardization (http://www.iso.org/iso/home.html)) most well known standards ever. The series helps organizations to implement quality management systems. There are quite a lot of companies and organizations in Hong Kong that hold ISO 9001 certification. Can you identify some local companies that are ISO 9001 certified?

There are eight fundamental quality management principles in the ISO 9000 series that can be used by top management in order to lead the organization towards improved performance. They are:

1. **Customer focus**
   The success of all organizations depends very much on whether they understand their customers' current/future needs/requirements and whether they are willing to strive to exceed customer expectations. Customers' needs and expectations are usually reflected in product specifications and collectively referred to as customer requirements. Customer requirements may also be specified contractually by the customer or may be determined by the organization itself. Eventually, customers are the parties that ultimately determine the acceptability of the product. However, we should bear in mind that customer needs and expectations are not static; they are dynamic and change with time. Sometimes they change slowly, sometimes they change fast. Major reasons for the changes include competitive pressures and technical advances, and the organizations are driven to continually improve their products and processes. For example, a three mega-pixel digital camera was considered to be the state-of-the-art technology ten years ago. In 2011, an entry level digital camera can deliver photographs with ten mega pixels.

   Monitoring customer perceptions can include obtaining input from sources such as customer satisfaction surveys, customer data on delivered product quality, user opinion surveys, lost business analysis, compliments, warranty claims and dealer reports.
2. **Leadership**
   Leaders take total control of resources and the direction of the organization. One of their major duties is to develop and maintain an internal environment in which all employees within the organization are fully involved in achieving the organization's objectives.
3. **Involvement of people**
   Employees are the asset and essence of all organizations. With the support from leaders, employees are expected to have full involvement (i.e. to put their abilities to use) for the organization's benefit. This can be achieved by effective internal communication within the organization and providing necessary training to employees.
4. **Process approach**
   Every organization is made up of a series of interacting processes. A process can be considered as a set of activities that uses resources (materials, manpower, machines, etc.) to transform inputs into outputs. The process approach emphasizes the interaction between different processes, and the inputs and outputs that link these processes together. The output of one process becomes the input of another.

   To illustrate the process approach, you can think of the example of making a cake, which involves the following processes:
   - purchasing of ingredients at specified grade
   - measuring the weight of each ingredient

- mixing the ingredients homogeneously
- baking the mixed ingredients in an oven.

The product (e.g. the cake in our example) is the result of processes, and the ISO 9001 Standard is designed to manage and improve those processes. The key steps can be summarized as follows:

1. Identify your key processes.
2. Define quality standards for those processes.
3. Decide how process quality will be measured.
4. Document the approach to achieving the desired quality, as determined by your measurements.
5. Evaluate the quality and continuously improve.

It can be seen from the above example that the effectiveness of the entire system depends very much on the effectiveness of individual processes.

5. **System approach to management**
   Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives. The system approach can be summarized into the steps below:
   a. Determining the needs and expectations of customers and other interested parties (refer to the earlier section on 'Customer focus' for details).
   b. Establishing the quality policy and quality objectives of the organization. The quality policy and quality objectives can provide a focus to the organization, which also determine the desired results in order to satisfy the customers. The quality policy shall:
      - be established and maintained by the top management. The top management shall provide necessary resources and commit to comply with both regulatory and other requirements.
      - provide a framework for establishing and reviewing quality objectives.
      - be promoted throughout the organization to increase awareness, motivation and involvement.
      - be reviewed periodically for suitability during management reviews and undergo continual improvement.

      The quality objectives need to be consistent with the quality policy and commitment to continue improvement, and their achievement needs to be measurable.

Examples of quality objectives

Examples of some quality objectives are:

- product — reduction in defect rates to 50 ppm (defective parts per million)
- process — increase in the output rate to 10k per day by reducing the waste and cycle time of the processes
- customers — reduction in the number of complaints per month
- suppliers — rejection percentage of defective materials less than 5%
- resources — reduction in the number of incidents per year

c. Determining the processes and responsibilities necessary to attain the quality objectives. (Refer to the earlier section on the process approach for details of process determination.)

d. Establishing and implementing methods to measure the effectiveness and efficiency of each process.
Monitoring and measuring equipment (thermometer for temperature, timer for timing, etc.) shall be used. The equipment shall be calibrated or verified at specified intervals before use. Equipment shall be identifiable with the calibration/verification status, and shall be protected from damage and deterioration during handling, maintenance and storage.

e. Determining the means of preventing non-conformities and eliminating their causes. This can be achieved by monitoring customer satisfaction, internal audit, monitoring and measurement of processes and product. The product shall not be released to the customer until all the product requirements have been satisfactorily met.

f. Establishing and applying a process for continual improvement of the quality management system. The effectiveness of the quality management system can be evaluated through the use of the quality policy, quality objectives, internal and external audit results, analysis of production data, corrective and preventive actions and management review.

6. **Continual improvement**
When planned process outcomes are being achieved and requirements fulfilled, the organization should focus its efforts on actions to improve process performance to higher levels on a continual basis. The following short description on continual improvement is extracted from SCI S319 Unit 5.

In a total quality management organization, internal and external customers define quality. With quality defined, the organization must then become obsessed with meeting or exceeding this definition. This means all personnel at all levels approach all aspects of the job from the perspective of 'how can we do this better?' When an organization is obsessed with quality, good enough is never good enough. There must be a continual striving to improve all business and production processes. Quality improvement projects, such as on-time delivery, order entry efficiency, billing error rate, customer satisfaction, scrap reduction and supplier management are good places to begin. Continuous quality improvement helps management to review and

improve the quality of the company's products continuously by gradual changes as in below.

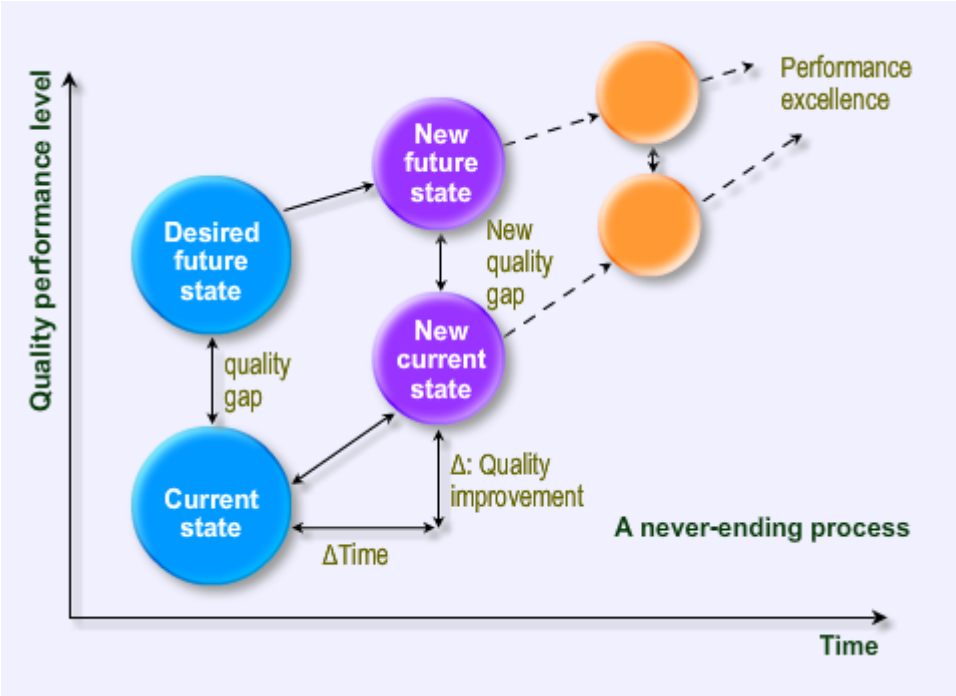

Fig. 1.1: The never-ending process of continuous improvement

Examples of improvements include: process simplification, enhancement of efficiency, improvement of effectiveness, reduction of process cycle time). Verify the effectiveness of the improvement using statistical methods.

7. **Factual approach to decision making**
   Results from accurate data and information analysis form the basis of effective decisions. Statistical methods are commonly used to quantify process performance and assist in decision making.
8. **Mutually beneficial supplier relationships**
   A manufacturer (or an organization) and its suppliers are interdependent. A mutually beneficial relationship (or win-win situation) enhances the ability of both to create value. A manufacturer (or an organization) requires its suppliers to provide quality materials in order to produce quality goods. On the other hand, the suppliers of a quality manufacturer can also enhance its reputation and increase the business opportunities.

Having read the eight fundamental quality management principles, try the Activity 2 (Page 10).

We have discussed different conformity assessment activities and certification of QMS. Conformity assessment of products can be carried out in many ways (i.e. testing, certification and inspection) and by many different parties (i.e. first, second and third). Certification of QMS is one of the most popular approaches to provide products that consistently fulfill requirements and to enhance customer satisfaction. The International Standards ISO 9000 (http://en.wikipedia.org/wiki/ISO_9000) family describes the fundamentals of QMS for organizations. The requirements for QMS specified in ISO 9001 are generic and applicable to organizations in any industry or economic sector regardless of the offered product category. However, ISO 9001 itself

does not establish requirements of products. Product certification was introduced to incorporate the requirements of a product or type of products into a certification scheme. A product certification scheme (The certification system related to specified products, to which the same specified requirements, specific rules and procedures applied (ISO/IEC 17000:2004 clause 2.8).) may also employ other different conformity assessment activities such as testing and inspection. We will discuss product certification in the next section of this module.

Before we discuss the product certification basics, have a go at the following activity, in which you will watch an eight-minute video from the International Organization for Standardization on ISO 9001.

We now move on to look at the process of product certification

1.2.4 Activity 2

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Do you remember our example of baking a cake? We divided this process into the following steps:

1. Purchase the ingredients at the specified grade.
2. Measure the weight of each ingredient.
3. Mix the ingredients homogeneously.
4. Bake the mixed ingredients in an oven.

Based on the process approach, determine what parameters you should measure in steps 2 and 4 of the baking a cake example to monitor the process quality.

1.2.4.1 Activity 2 feedback

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For step 2 of the cake-making process, you could monitor the quality by measuring the mass of each ingredient in grams. For step 4, you could measure the temperature of the oven in °C and the time for baking in minutes.

1.2.5 Activity 3

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Watch the short Youtube video 'The ISO 9001 Family — Global Management Standards' (http://www.youtube.com/watch?feature=player_embedded&v=oq1Zi_V4KyE).

This is a useful video that explains the background, benefits and applications of ISO 9001 in different organizations and sectors.

According to the video, what percentage of ISO 9001 users are in the service sector?

1.2.5.1 Activity 3 feedback

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Over 30% of ISO 9001 users are in the service sector, and so it's worth remembering that product certification applies not only to physical products but also to services.

1.3 The purpose and process of product certification

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Product certification is a means of providing assurance that a product complies with specified requirements in standards and other normative documents. It would be expected to apply mainly to those societal concerns whose significance calls for the involvement of an independent body. The use of product certification bears out this observation as it is generally applied only to significant concerns. Concerns can involve such product attributes as safety, health or environmental (SHE) impacts, durability, compatibility and suitability for intended purposes or for stated conditions. Product certification may also be used by manufacturers and retailers to improve the acceptability of their products by the market, especially when the certified products can bear a mark of conformity. In this module, we are mainly focusing on certification of tangible products (toys, electronic products, construction materials, etc.). In fact, product certification can also be applied to non-tangible products (software, service, etc.) and to process certification.

Three fundamental purposes of product certification become evident:

1. Product certification should address the concerns of consumers, users and more generally, all interested parties by instilling confidence regarding fulfillment of requirements.
2. Product certification may be used by suppliers to show to the market the third-party involvement.
3. Product certification should not require excessive resources that result in product costs beyond what society in general is willing to bear.

In general, product certification should instill confidence in those with an interest in fulfillment of requirements, and product certification should provide sufficient value so that suppliers can effectively market products. Product certification is most successful when it delivers the required confidence while utilizing the fewest possible resources; i.e. maximizing value.

Product certification is used in various ways. For example, governments may impose certification requirements in connection with such matters as communications, food and drugs. Local governmental authorities rely on certification of products to assure that such technical areas as electrical wiring and construction products are suitable for use in building construction. Retailers of consumer goods rely on certification as evidence that aspects such as the safety of electrical appliances have been addressed by a third party, thus giving confidence that products they place on their shelves for

sale to the public are not likely to bring harm to their customers. Manufacturers may require certification of parts/components provided by suppliers in order to assure the quality of the finished products.

While these examples illustrate important distinctions in the way product certification is used, these brief overviews neither serve to fully explain the details of certification in the respective cases, nor constitute the entire universe of ways in which certification is used.

Product certification as a technique to address concerns related to the design, production, distribution, use and disposal of products has been in use for over 100 years. Many effective forms of product certification can be found all over the world. While all forms of product certification can be highly effective, the specific concerns to be resolved by product certification and the conditions (both voluntary and regulatory) under which product certification will operate will quickly narrow the choices for the optimum set of elements for a specific product certification system.

1.3.1 Activity 4

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List some product certification marks you have come across in your daily life.

Hint: You might look at the transformers of your laptop computer or PC monitor, some food products (fair trade, organic, halal and kosher, etc.), vehicle windscreens, etc.

1.3.1.1 Activity 4 feedback

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Here are some examples of product certification marks you may have found:

Electrical and electronic products:

- UL certification by Underwriters Laboratories Inc. (http://www.ul.com/global/eng/pages)
- China Compulsory Certification (CCC or 3C) of the Certification and Accreditation Administration (CNCA) of People's Republic of China (http://www.cnca.gov.cn/cnca/rdht/qzxcprz/cprzbz/4759.shtml)
- Energy Star Certification Program of the US Environmental Protection Agency (EPA) (http://www.energystar.gov/)

Food:

- Fairtrade certification mark (http://www.fairtrade.net/)
- Halal Monitoring Committee (HMC) certification for Islamic food (http://www.halalhmc.org/)
- OK certification for kosher food (http://www.ok.org/consumers)

1.3.2 Procedures for certification of products

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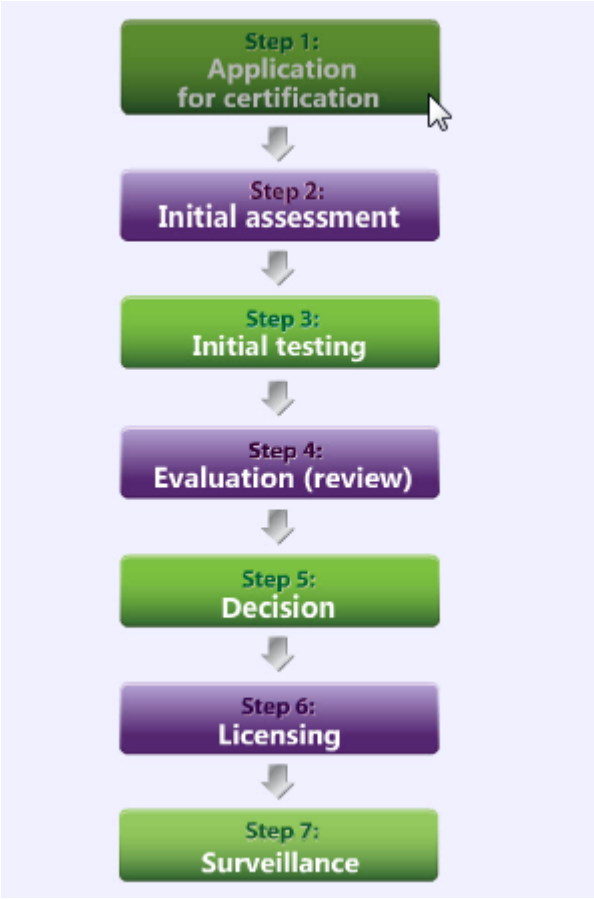
An organization that is interested in certifying its products should first contact the product certification scheme owner (The person or organization that is responsible for developing and maintaining a specific certification scheme.) or the appointed certification body to obtain a copy of the corresponding scheme. Before submitting an application to the certification body to apply for the product certification on its products, the organization should determine whether its products, production processes, management system, etc. can fulfill the requirements as set in the product certification scheme. The organization should also read and agree to all the terms and conditions for the application of the product certification scheme (including the rule for using the certification mark).

In general, a certification body that operates product certification should comply with the requirements of ISO/IEC Guide 65. Accreditation of the certification bodies to demonstrate their competence in certification of corresponding product certification schemes shall also follow this International Standard. According to the ISO/IEC Guide 65, the procedure for product certification can be summarized in the steps on the following screen.



Click this link to watch the video:
http://www.opentextbooks.org.hk/system/files/resource/10/10432/10446/media/Steps%20towards%20product%

20certification%20%28click%20on%20the%20steps%20to%20listen%20to%20the%20audio%20explanation%29.mp4

1.3.3 Use of marks of conformity

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The use of marks on products and/or their packaging and other materials to demonstrate the conformity to the requirements in relevant product certification schemes is widespread. The conformity marks can enhance the confidence of stakeholders, including governments, regulators, customers and industry to the products which have fulfilled certain regulatory requirements and/or industrial practices. This can increase the business opportunities and reputation of the product manufacturers.

In general, the marks of conformity can be either licensed by the owners of the product certification schemes or the certification bodies providing certification service for those schemes (i.e. conformity mark licenser). A license or an agreement is used to assure the certified manufacturer (i.e. licensee) follows the rules of the scheme, and to control the use of the mark of conformity.

The design of the mark can allow modification from the licenser's own corporate logo, but should avoid confusion with other certification systems (e.g. QMS). In order to let the stakeholders understand the meaning of the marks of conformity, a legend containing the information of the schemes and a short indication of the aspects covered (e.g. safety) may be used. Furthermore, a unique identity for the certified product is also suggested to indicate the traceability.

The conformity mark licenser shall have documented procedures for the use of its marks, with the details for measures to be adopted in case of misuse, including false claims as to certification and false use of certification body marks. Incorrect references to the certification system or misleading use of certificates or the mark found in advertisements, catalogues, etc., should be dealt with by suitable actions, which could include legal or corrective action or publication of the transgression.

The marks of conformity shall primarily be placed on the products, except where the physical size of the product does not permit this or when the application is not appropriate for the type of product. In case it is not feasible to place the mark onto the product, the mark may then be applied on the packaging or other accompanying information. Depending on the rules of the product certification scheme, the marks may also be used in advertising materials (e.g. catalogues and websites), where there must be a clear association between the marks and the certified products, to avoid misleading stakeholders about the conformity to the schemes of other products which have not been certified.

Where certification has been suspended for any reason (when a critical non-conformity has been found, or the certification subscription fee has not been paid, etc.), the certification body shall require that, during the period of suspension, the supplier make no misleading claims and should advise relevant existing and potential buyers of the products regarding the status of certification, and cease to use the

certification mark on the products manufactured since the date of notification of suspension.

At this point, try to complete the following short Self-test 1 (Page 15) to see how well you have understood this section.

1.3.4 Self-test 1

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Select the most appropriate answers to the questions.

1. Is surveillance required for all product certification systems?
    a. Yes, surveillance is required for all product certification systems to monitor whether the products continue to fulfill the requirements.
    b. Yes, surveillance is required for all product certification systems and should cover all the locations where the designing, testing and inspection of products take place.
    c. No, surveillance is required only when there is a modification of the production process.
    d. No, surveillance is required only when the product certification scheme is specified.
2. Which of the following logo(s) can be used as conformity marks of a product certification scheme?
    i. the company logo of the certification body with a legend of the scheme information indicated below
    ii. the corporate logo of the product certification owner alone without any information attached
    iii. a newly designed logo specified for the use in the designated product certification scheme, with the identification number of the product manufacturer.
        a. i and ii
        b. i and iii
        c. none of the above
        d. all of the above

1.3.4.1 Feedback to Self-test 1

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1. d
2. b

1.4 Conclusion

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This module has presented a brief introduction to the concept of product certification. We first covered the fundamentals of various conformity assessment activities, including testing, inspection and certification of quality management systems, which are commonly employed in a product certification system.

We then discussed the general purposes of using product certification and outlined the certification procedure and the use of marks of conformity after certification is granted. You should now be familiar with the basics of product certification, one of the most important conformity assessment activities in the field of testing and certification.