GUIDE 28

First edition — 1982-12-15

General rules for a model third-party certification system for products

UDC 006.063

Ref. No. : ISO/IEC GUIDE 28-1982 (E)

Descriptors : certification, rules (instruction).

Foreword

This document was drawn up by the ISO Committee on certification, ISO/CERTICO. It was approved by the IEC Council in June 1982 and by the ISO Council in November 1982.

GUIDE 28-1982 (E)

General rules for a model third-party certification system for products

0 Introduction

These model general rules are valid for the following type of certification system :

A third party certification system of determining conformity with product standards through initial testing and assessment of a factory quality management system and its acceptance followed by surveillance that takes into account the factory quality management system and the testing of samples from the factory and the open market.

NOTE — This model system corresponds to system No. 5 as described in ISO/ITC Publication, *Certification — Principles and practice*. This system was chosen because it was the most comprehensive and could thus offer the best basis for the eventual development of other systems.

The identification of conformity may be in the form of a certificate of conformity or a mark of conformity. (See ISO/IEC Guide 23.)

A certification body operating the system at national level shall as a minimum have a suitable organizational structure[1)] and utilize personnel, equipment, and operating procedures that comply with the criteria given in ISO Guide 24 and ISO/IEC Guide 25 (latest edition).

Any certification scheme under the system requires as a prerequisite a standard that is suitable for certification purposes. (See ISO/IEC Guide 7.)

1 References

ISO Guide 2, *General terms and their definitions concerning standardization and certification.*

ISO/IEC Guide 7, *Requirements for standards suitable for product certification.*

ISO/IEC Guide 23, *Methods of indicating conformity with standards for third-party certification systems.*

ISO Guide 24, *Guidelines for the acceptance of testing and inspection agencies by certification bodies.*

ISO/IEC Guide 25, *General requirements for the technical competence of testing laboratories.*

2 Definitions

The relevant definitions of ISO Guide 2-1980 and its Addendum 1-1981 are applicable.

3 Basic conditions

The basic conditions for obtaining and retaining the licence[2)] to issue a certificate of conformity or to use a mark of conformity are that the applicant/licensee follows these General Rules and the Specific Rules[3)] of the relevant scheme and that he applies the identification of conformity only to products that are within the scope of his licence and are in conformity with the relevant standard(s).

4 Application for licence

The application shall be made on a special form obtainable from the certification body. An example of such a form is given in annex B.

The application relates to the specific product or group of products determined by the certification scheme and specified in the Specific Rules. It should normally cover products coming from one factory only.

---

1) Guidelines on this subject are in preparation within ISO/CERTICO.

2) For the purpose of this document the words "licence" and "licensee" are used although the granting of a licence is only one of several means of indicating that the applicant concerned has been accepted by the certification body.

3) For Specific Rules, see annex A.

A certification body on acceptance of a completed application form and receipt of the deposit, if required, will confirm this to the applicant and provide him with any further information necessary for the processing of the application.

5 Initial inspection of factory and quality management system[1], and initial testing

5.1 General

After confirmation of the acceptance of the application, the certification body shall make the necessary arrangements with the applicant for the initial inspection in accordance with the rules of the scheme.

The certification body is responsible for all actions of certification, from initial testing and inspection, assessment of the factory quality management system through surveillance of the product produced.

The certification body shall inform the applicant of the results of the initial inspection and testing.

If the certification body is not satisfied that all the requirements for licensing are being met, it will inform the applicant of those aspects in which his application has failed.

If the applicant can show that remedial action has been taken by him to meet all the requirements within a specified time limit, the certification body will repeat only the necessary parts of the initial inspection procedure and testing. Otherwise the application will be cancelled.

Where a cost limit is specified by a certification body as part of its application procedure, the filing of a new application or an extension of the cost limit may be required.

Reinspection may not be needed for subsequent submittals of the same product.

5.2 Assessment of factory quality management system

Assessment of the applicant's system of factory quality management forms part of the initial inspection. This may be done according to requirements specified in the Specific Rules of the scheme.

All records produced from implementation of the quality management system related to certification shall be readily available for certification body inspection.

The applicant shall ensure that the question of responsibility to the certification body for the quality management system is clearly defined, e.g. by appointing a designated person who is independent from production management as far as the technical performance of his function is concerned and who is qualified to maintain the contact with the certification body, to ensure that the above provisions have been observed.

5.3 Initial testing[2]

5.3.1 Selection of samples

The selection of samples for tests and examination shall be based on the rules of the scheme.

Samples should be representative of the entire line or group of production to be certified, and be made from production tools and assembled using methods established for the production run.

Where testing is based on prototype samples, confirmation tests or examination, as appropriate, should be made on production samples.

5.3.2 Conduct of initial testing

The initial testing is carried out in accordance with the applicable standard(s) and the Specific Rules of the scheme.

---

1) This term is still under consideration by ISO/TC 176, *Quality assurance*.

2) As used herein, "initial testing" refers to the process by which the certification body before granting or extending a licence, determines that a product complies with the requirements of the applicable standard(s). It is often called "type testing".

5.3.3 Use of test data produced by other than the certification body

Where the certification body chooses to use test data produced by others, the body, or its designated test agency, shall ensure that the party conducting the testing complies with at least the criteria of ISO Guide 24 and ISO/IEC Guide 25.

6 Licensing

The certification body, when complete fulfilment of the requirements has been established, informs the applicant accordingly, submits a licensing agreeement[1)] for his signature (unless already done) and, on conclusion, issues a licence. (An example of such an agreement and a licence is included in annec C.)

7 Extending a licence

A licensee wishing to extend his licence to allow the application of identification of conformity to additional types or models of products, made in the same factory to the same standard as the products for which a licence is already held, shall apply to the certification body, using the usual application form (annex B). The certification body in such cases may decide not to carry out a factory inspection but to require test samples of the additional types of products to determine that they comply with the standard. If the tests are successful, additional licences will be granted.

If the licensee wishes to apply the certification to additional types of products made at the same factory, but to different standards, or if the licensee wishes to apply for certification to be used in an additional factory that is not covered by the earlier license, those parts of the original application procedure which do not cover the new circumstances will have to be carried out.

8 Surveillance

The certification body exercises the surveillance of the products on the basis of the requirements of the relevant standard and of the quality management system on the basis of the Specific Rules of the scheme.[2)]

The certification body may appoint an agent to carry out the surveillance under its authority and responsibility, exercised under agreed conditions. Any agent appointed by the certification body shall have all the facilities and qualified staff necessary for adequate surveillance.

The licensee shall be informed about the results of the surveillance.

The licensee shall inform the certification body about any intended modification in the product, manufacturing process or quality management system which may affect the compliance of the product, and it is up to the certification body to determine whether the announced changes require another initial testing and inspection or other further investigations. In such cases the licensee will not be allowed to release certified products resulting from such changes until the certification body has notified the licensee accordingly.

The licensee should keep a record of all complaints relative to the products covered by the licence and make these available to the certification body on request.

9 Use of a mark of conformity and marking

9.1 Mark of conformity

In cases where the system utilizes a mark of conformity, the principles of ISO/IEC Guide 23 should be followed. Such a mark of conformity shall be distinctive and shall, *inter alia*.

— be proprietary in nature — with legal protection as regards composition, control of use;

— be so coded or otherwise designed as to aid in detection of counterfeiting or other forms of misuse;

---

1) If a certification scheme falls under a law that specifies in detail the scheme in question and if such a scheme is administered by a governmental body or body acting on its behalf, such an agreement may not be necessary.

2) In some cases it may be unnecessary to base surveillance on a repetition of all the elements of initial testing; this could be the case with custom-built products and be applied to cases where the initial testing is very complicated or where the samples are very expensive. In such cases the surveillance may be based on examination only or combined with more simple identification tests which ensure that the product is in conformity with the tested sample. Such identification tests should be described in the Specific Rules of the scheme.

— be non-transferable from one product to another;

— be directly applied to each unit of production except where the physical size of the unit or the type of product does not permit, in which case the mark may be applied to the smallest package in which the unit is marketed.

9.2 Marking

In certain circumstances it may be appropriate to use other marking in association with the mark of conformity, such as :

— name or trademark of certification body where such cannot be determined from the mark of conformity used;

— name of product classification where such is not completely obvious;

— identification of the relevant standard(s).

Such marking shall be in accordance with the Specific Rules of the scheme.

In the event of revision of a standard on which a certification scheme has been based it is important that the marking clearly indicates the appropriate edition of the standard in question or a date code marking where applicable, so that the user is informed correctly of the requirements laid down for the product.

10 Publicity by licensees

A licensee has the right to publish that he has been authorized to issue a certificate of conformity or apply a mark of conformity for products to which the license applies.

In every case the licensee shall take sufficient care of his publications and advertizing that no confusion arises between certified and non-certified products.

If the manufacturer wishes to publish parts of a test report which relates to the certification of his products he shall have a written agreement of the certification body.

The licensee shall not specify function, claim or the like in user information, that could mislead purchasers to believe that performances of the product or its use are covered by the certification when in fact they are not. Instruction books or other user information accompanying the product and related to the certification scheme shall be approved by the certification body if so required by the Specific Rules of the scheme.

11 Confidentiality

The certification body is responsible for ensuring that secrecy is maintained by its employees and those of its agent (see clause 8, second paragraph) concerning all confidential information with which they become acquainted as a result of their contacts with the licensee.

12 Misuse of a certificate or mark of conformity

The certification body shall operate a checking programme as a part of its programme of proper control on the use of its certificates or mark of conformity.

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.

In cases of misuse of certificates or the mark of conformity by licensees corrective action shall be taken.

13 Suspension of a licence for a product

The licence applicable to a specific product may be suspended for a limited period, for example in the following cases :

— if the surveillance shows non-compliance with the requirements of such a nature that immediate withdrawal is not necessary;

— if a case of improper use of the certificate or the mark, e.g. misleading prints or advertisement is not solved by suitable retractions and appropriate remedial measures by the licensee;

— if there has been any other contravention to the rules of the scheme or the procedures of the certification body.

The licensee shall not identify as certified any product that has been produced under a suspended licence applicable to that product.

A licence may be also be suspended after mutual agreement between the certification body and the licensee for a limited period of non-production or for other reasons.

An official suspension of a licence will be confirmed by the certification body in a registered letter to the manufacturer (or by equivalent means).

The certification body shall indicate under which conditions the suspension will be removed, such as for example corrective action taken in accordance with clause 15.

At the end of the suspension period the certification body will investigate if the indicated conditions for reinstituting the licence are fulfilled.

On fulfilment of these conditions the suspension shall be removed by notifying the manufacturer that the licence has been reinstated.

If the conditions are not fulfilled the certification body shall withdraw the licence.

14 Withdrawal/Cancellation

14.1 Apart from the suspension of a licence, a licence may be withdrawn in the following cases :

— if the surveillance shows that the non-compliance is of a serious nature;

— if the licensee fails to comply with the due settlement of his financial obligation;

— if there is any other contravention of the licensing agreement;

— if inadequate measures are taken by the licensee in the case of suspension.

In the above cases the certification body has the right to withdraw the licence by informing the licensee by registered letter (or equivalent means). Concerning specification of time limit, see article 10 of specimen licensing agreement (annex C).

The licensee may give notice of appeal, and the certification body when considering the appeal may or may not — depending on the nature of the case — decide to proceed with its decision to withdraw or cancel the licence.

Prior to withdrawal of a licence the certification body shall decide upon the consequences in relation to products certified under the licence, whether the mark of conformity shall be removed from all products in stock and perhaps even if practicable from products already sold, or whether a clearance of the stock of marked products should be allowed within a short period of time, and if other actions are required.

14.2 Furthermore, the licence may be cancelled in the following cases :

— if the licensee does not wish to prolong the licence;

— if the standard or rules are changed and the licensee either will not or cannot ensure compliance with the new requirements, cf. clause 16;

— if the product is no longer made or the licensee goes out of business;

or on the ground of other provisions certified in the licensing agreement.

14.3 Withdrawal or cancellation of a licence may be published by the certification body.

15 Corrective action

In cases of misuse of a certificate or a mark of conformity corrective action should be taken to safeguard their use.

NOTE — Guidelines on corrective action in case of misuse of a mark of conformity are in preparation.

16 Implementation of modifications of a standard (see also article 11 of annex C)

There are a number of factors that need to be considered when establishing the date on which product requirements in a revised standard will come into force (effective date), where the previous edition of the standard has formed the basis of the certification.

The effective date of modification to a standard must be published by the certification body and all licensees listed under the scheme in question by the certification body are to be notified to provide adequate time for resubmittal.

The factors to be considered when choosing the effective date include, but are not necessarily restricted to

- the urgency of complying with revised health, safety, or environmental requirements;
- the length of time and financial costs for retooling and manufacturing a product complying with the revised requirements;
- the extent of stock on hand and whether it can be reworked to meet the revised requirements;
- avoidance of unintentional commercial advantage given to a particular manufacture or design;
- operational problems of the certification body.

17 Liability

Where questions of product liability are involved, they must be dealt with on the basis of the relevant legal system(s).

18 Dispute

In cases of disputes the appeal procedure of the certification body can be brought into action.

19 Fees

The fees for the operation of a certification scheme are to be decided by the certification body for each scheme.

Annex A

Checklist for basic content of Specific Rules

For each scheme, a set of Specific Rules should be established, taking into account the production methods and the kind of product or group of products to be covered by the scheme (see clause 4). In establishing Specific Rules for a scheme, the following checklist may be utilizated to indicate items which should be considered among others.

a) Full identification of the products and related standard(s) to which the scheme applies.

b) Requirements for initial testing and inspection such as :

- selection of items to be inspected and tested;
- sampling procedure;
- initial product testing and test methods;
- evaluation of the test results;
- initial inspection of the factory[1];
- evaluation of the inspection result;
- evaluation of the factory's quality control system (see appendix 1 to annex B);
- evaluation of competence of staff of the factory;
- evaluation of measuring and testing equipment used by the manufacturer including calibration;
- marking of product (related to mark of conformity);
- checklist for possible instructions (e.g. for mounting or use);
- certificate of conformity (content of the document).

c) Requirements for surveillance procedure such as

- check product testing and check inspection of the factory;
- evaluation of the results of the checks;
- frequency (minimum) of check testing and check inspection.

d) Fee and cost structure of the scheme.

e) Details of the contract to be established between the certification body and the licensee.

f) If applicable, format of test report.

1) Including inspection upon receipt of incoming supplies to verify if they comply with contract requirements and storage and internal transport of raw materials, parts and end products.

Annex B

Specimen of form for
APPLICATION for CONFORMITY CERTIFICATION
BY USE OF CERTIFICATES OR MARK OF CONFORMITY

To be sent to ..... (Certification body)

Address :

Information regarding the applicant :

The applicant's name and address of registered office :	Phone and telex numbers :
	Manufacturing place of the product :
Name and title of person responsible for the quality management system : Business address : Phone and telex numbers :	

Designation of product for which conformity certification is requested :

Description of products : (see first two columns of specimen licence — appendix 1 to annex C)	Relevant standard(s) Number : Title : Date of issue :	Relevant Specific Rules Number : Title : Date of issue :

Statement : * We herewith declare that we will settle the costs related to this application.

Statement : * We herewith declare to be willing, on a positive result of the initial testing and inspection, to conclude within a specified time an agreement related to the certification of the products mentioned above.

Date of application .....

Name and title of person authorized to sign on behalf of the applicant :
.....
(In block letters)

Signature .....

* (Examples)

Appendix 1 to annex B

Specimen[1] for initial questionnaire for factory assessment

Annex to application .....

This questionnaire should be filled in and returned together with the application form. It is intended to provide preliminary information relative to the applicant and his capability to control the quality and continuing conformance of his products to the requirements of relevant specifications.

This document will be used by the certification body's inspection staff during preliminary visits to the factory or factories involved as a part of the initial inspection.

Supplements may be included where it is necessary to expand any statements.

A separate document should be completed for each factory involved, or variations between factories clearly indicated.

The statements should relate to the facilities available as the date of completion of this form.

The information given in this document will be treated in the strictest confidence.

Information on the following subjects will furthermore facilitate the treatment of the application.

Date sample is available for evaluation :

Will this be production or prototype sample?

If protoype, when is production scheduled?

Has product been tested to the standard? (if so please attach report) :

Urgency of application.

INDEX

Section 1 — Factory organization

1.1 Procedures/paperwork

Please give following information on basic system

1.1.1 Do you produce against orders or for stock?

1.1.2 Do you issue a Works Order or equivalent?

1) This specimen was selected from a current national practice; no attempt was made to harmonize the wording with the main part of this Guide. The specimen can be adapted in accordance with the actual situation for a given scheme.

1.1.3 If so does this identify a batch as a separate entity?

1.1.4 Do products and/or containers carry Works Order identification in manufacture?

1.1.5 If not how does system allow for products to be isolated in case of doubtful quality?

1.1.6 Please give any other relevant information on basic system

1.2 Quality control/inspection staff

Please give following information on factory QC staff organization :

1.2.1 Head of Quality Assurance

1.2.2 Reporting to?

1.2.3 Is there a separate QC/Inspection Dept?

1.2.4 If so indicate

1.2.4.1 Chief Inspector if different from 1.2.1

1.2.4.2 If staff are aware of the tests in the relevant standard(s)

1.2.5 Are storeman/production operators responsible for inspection and test on

1.2.5.1 Materials?

1.2.5.2 In process operations?

1.2.5.3 Final product?

1.2.6 If so are they monitored by QC staff?

1.2.7 Are Quality Audit checks carried out and by whom?

1.2.8 Please give any other information on QC staff organization

Section 2 — Materials, components and services

2.1 Purchase specifications/materials quality assurance

Please detail main materials purchased, specification used and major suppliers involved.

Please also give quality assurance methods adopted on receipt of materials, components, or services, indicating action taken on rejects.

Section 3 — Manufacture

3.1 System

Please detail various steps in manufacture — a production schedule and/or supplement in chart form showing stages may be advantageous.

3.2 Maintenance system plant and equipment

What maintenance system is in operation?

Section 4 — Quality control and testing

4.1 System

Please detail Quality Control system, including sampling system followed, with particular reference to the tests in the relevant standard. A QC schedule or supplement cross-referenced to chart required in 3.1 is advantageous.

Please attach any QC manual or instructions on Quality Control issued to staff.

4.2 Test equipment/instruments, gauges and tools

Please detail test equipment used, makers' names and references, and indicate system and frequency of checking and if certificates are available.

Section 5 — Records and documentation

5.1 General

5.1.1 Please indicate form of master specification, i.e. drawings, product/parts schedule, reference sample, etc. Also indicate other general records available.

5.1.2 Please indicate system used to amend design/specification.

5.2 Compliance — Specification

5.2.1 Please indicate level of defectives found in past six months. If tests in accordance with the relevant standard(s) have already been carried out, attach copies of summary of test results if available.

5.2.2 Please indicate the level of claims/complaints made under warranty and/or otherwise and give also as a percentage of total output.

5.2.3 Have independent tests been made on products against the standard? By whom? Please attach copies if available.

Section 6 — Application of indications of conformity

6.1 Mark of conformity

Please attach an illustration if available and indicate method, e.g. special label, embossing, etc., which will be used to show mark of conformity. Please indicate at which stage of manufacture the mark of conformity will be applied.

6.2 Certificate of conformity

Please attach an illustration of the proposed format and indicate at which stage of manufacture or shipment the certificate is issued. A specimen certificate is reproduced in appendix 2 by way of an example.

Appendix 2 to annex B

Specimen of a certificate of conformity

. . . . . .*

Certificate of conformity

Certificate No. . . . . .

The . . . . . hereby certifies that . . . . . .
[name of Certification Body]

(hereinafter called the Firm) has complied with the published General and Specific Rules Number . . . . . in respect of a certification scheme for the manufacture of . . . . . shown in the attached schedule.
(name of product)

These Rules have *inter alia* necessitated the submission of samples of the scheduled product(s) for examination and testing by the Certification Body to the standards referred to in the schedule. Additionally the scheme requires the Firm to

a) permit their factory(ies) situated at . . . . . to be periodically inspected by the Certification Body and

b) allow samples of the scheduled product(s) to be selected from production, or from the market, for independent testing and examination for assurance that continuity of conformity is being maintained.

This certificate is granted with the authority of the Certification Committee of the . . . . . * whose terms of reference are defined in document No. . . . . of . . . . . 19 . . [Date]

The Firm hereby covenants with the Certification Body to duly observe and comply with the requirements of the scheduled standards, the General and Specific Rules and with any Regulations for the scheme which the Certification Body may establish.

Signed for the Certification Body :

. . . . . .
Director

Date . . . . . 19 . .

Signed for the Firm :

. . . . . Date . . . . . 19 . .

* Name of the Certification Body

[NOTE — The rules of a third-party certification system may also specify additional information to be included.]

Annex C

Specimen of a licensing agreement for the use of a certificate or mark of conformity

The ..... Certification Body, having its registered offices at ....., hereinafter referred to as the certification body and represented in this matter by ..... (name), ... (title) ....., hereby grants to ....., having its registered offices at ....., hereinafter referred to as the licensee, licence to certify the products covered by the appended licence, as approved by the certification body for such products specified in the first column of the valid licence which are controlled by the licensee in accordance with the standards referred to in the second column and the Specific Rules referred to in the third column of the valid licence and on the conditions of the following general agreement.

Article 1 : Regulations for certification and inspection

The stipulations of the *General Rules for the certification system* (in question) apply to this agreement as well as the standard(s) and the Specific Rules, specified in the attached licence.

Article 2 : Rights and obligations

2.1 The licensee agrees that the certified products manufactured and supplied by him as specified in the licence based on and attached to this agreement will comply with the requirements stated in the standards and General and Specific Rules specified in the licence. Accordingly, the certification body authorizes the licensee to certify the products covered by the licence, as stated in the Specific Rules of the scheme.

2.2 The licensee agrees that the persons representing the certification body will have unobstructed access without prior notification to the premises of the factory covered by the license during the normal working hours of the factory involved.

2.3 The licensee agrees that the products for which the licence is granted will be produced to the same specifications as the sample that the certification body found by the initial testing to be in compliance with the standard.

Article 3 : Surveillance

3.1 The certification body carries out a continuing surveillance on the licensee's compliance with his obligations, in accordance with the conditions stated in the *General Rules for the certification system* and the Specific Rules for the scheme as specified in the licence.

3.2 This surveillance is carried out by the certification body employees or by employees of agencies on behalf of the certification body.

Article 4 : Information on modifications in production

The licensee shall inform the certification body of any intended modification in the product, the manufacturing process or the quality management system.

Article 5 : Complaints

The licensee shall upon request of the certification body keep records and report to the certification body any complaints regarding those aspects of the products covered by the licence.

Article 6 : Publicity

6.1 The licensee has the right to publish that he has been authorized to certify the products to which the license applies.

6.2 Among other methods the certification body gives publicity to the authorization of certifying compliance with a standard in the public journal ..... and to cancellation of this agreement with the licensee, as appropriate.

Article 7 : Confidentiality

The certification body is responsible for seeing that confidentiality is maintained by its employees concerning all confidential information with which they become acquainted as a result of their contacts with the licensee.

Article 8 : Payment

8.1 The licensee shall pay to the certification body all expenses in relation to the surveillance, including test, inspection and administration costs.

Article 9 : Agreement period

This agreement comes into force on ..., and remains in force until ... unless withdrawn for justified reasons or cancelled by either party upon due notice given to the other party.

Article 10 : Withdrawal/cancellation of licence

If withdrawal/cancellation of the licence comes into question, the necessary time of notice prior to the withdrawal/cancellation will differ due to the situation that causes it.

Depending on the reason for the withdrawal/cancellation the following schedule of notice will be followed :

Situation requiring the dispatch of notice that can lead to withdrawal/cancellation	**Days of notice prior to withdrawal/cancellation**
Manufacturer's wish to cancel :	to be specified by the certification body
The certification body determines that the product is hazardous :	none
Violation of an existing standard, for other reasons than safety :	max. 60 days
Non-payment of charges to certification body :	max. 30 days
Failure to meet other provisions of the licensing agreement :	max. 60 days
Mandatory compliance with new requirements in relation to revision of a standard :	Negotiable

Advice of cancellation shall be sent by registered letter (or equivalent means) to the other party, stating the reasons and the date of termination of the agreement.

Article 11 : Modification of product requirements

11.1 If the requirements applying to the products covered by this agreement are modified, the certification body shall immediately inform the licensee by registered letter (or equivalent means), stating at what date the modified requirements will become effective, and advising him of any need for a supplementary examination of the products which are subject to this agreement.

11.2 Within a specified period of time after receipt of the advice described in paragraph 11.1, the licensee shall inform the certification body by registered letter (or equivalent means) whether he is prepared to accept the modifications. If the licensee gives confirmation within the specified period of his acceptance of the modification and provided the result of any supplementary examination is favourable, a supplementary licence will be issued or other modifications of the certification body's records.

11.3 If the licensee advises the certification body that he is not prepared to accept the modification within the time specified in accordance with 11.2 or if he allows the terms for acceptance to lapse, or if the result of any supplementary examination is not favourable, the licence covering the particular product shall cease to be valid on the date on which the modified specifications become effective to the certification body, unless otherwise decided by the certification body.