# GUIDE 53

## An approach to the utilization of a supplier's quality system in third party product certification

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## Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) together form a system for worldwide standardization as a whole. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

This Guide was drawn up by the ISO Committee on conformity assessment, ISO/CASCO. It was approved by the IEC Council in August 1988 and by the ISO Council in September 1988.

The documents produced by CASCO are issued as Guides and follow the general rules for development and promulgation of ISO and IEC standards except that they are the result of a consensus reached within a Council committee, endorsed by the ISO Council and the IEC Council.

The work of ISO/CASCO in preparing Guides relating to certification, assessment and testing, uses as a basis the principles established in ISO/IEC Guide 16, *Code of principles on third party certification systems and related standards*.

Guide 16 recognizes that third party certification systems should, to the extent possible, be based on internationally agreed standards and procedures. While recognizing the major role of manufacturers' declaration of conformity through normal manufacturer/customer relationship, Council resolutions have emphasized the preparation of guidance documents on third party certification and assessment procedures in order that national systems may be compatible with one another so as to facilitate bilateral and multilateral agreements.

Whilst these documents are intended to provide guidance, it is hoped that any changes from the documents made in introducing systems nationally would be minimal. In recognizing that some countries may choose to adopt the Guides directly, they are written to enable this to be done by including words such as "shall" to indicate those aspects which desirably would be mandatory. The overriding basis that the document is intended to provide guidance holds good.

While this emphasis on creating the infrastructure for mutual recognition covers most of the work of ISO/CASCO, notice has to be taken that a further objective is to create the basis for an international certification system in due course, if found to be required. Some ISO/CASCO documents relate to the development of rules for such a system.

It is recognized that there are already well established certification systems, e.g. in the electrotechnical field, which have been developed with the aim of facilitating trade and which are functioning satisfactorily in the spirit of relevant ISO/IEC Guides.

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## Introduction

Certification programmes[1] utilizing elements of a supplier's quality assurance system can be very effective for both the supplier and the certification body in achieving certification in a timely and cost-effective manner and in assuring that products continuously conform to standards.

The process involves close collaboration between a third party certification body and suppliers in the industry sector for whose products the programme was developed. This collaboration involves using prescribed elements of the supplier's quality assurance system under a qualification and certifier audit procedure to fulfil some needs of the certification programme, with all remaining needs being provided by the third party certification body. The quality system elements selected may be drawn from one or more standards which detail differing levels of quality systems.

Certification programmes can take many forms, including some that do not utilize a supplier's quality assurance capability. There is no inference in this Guide that one form of certification programme is superior to another. Further, when a certification body has several forms of certification programmes available for a class of product, the supplier must have the right to choose the form of programme under which he wishes to apply for certification.

This Guide is based on the understanding that persons using it to develop certification programmes are familiar with the principles and practices covered by the ISO 9000 series of International Standards and/or other appropriate standards on quality systems. The elements selected from these standards should be tailored to meet the specific needs of the certification programme. It is also understood that persons using this Guide will be familiar with and utilize, in addition to the programme aspects described herein, the specific product standard(s) involved and the more general certification and follow-up provisions such as those contained in ISO/IEC Guide 28.

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1) The term "certification programme" is used here to cover the same concept as "certification scheme" (ISO/IEC Guide 2, definition 14.2).

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# An approach to the utilization of a supplier's quality system in third party product certification

## 1 Scope

**1.1** This Guide outlines a general approach by which certification bodies wishing to do so can develop and apply product certification programmes utilizing elements of suppliers' quality systems.

**1.2** The forms of programmes espoused by this Guide are for conformity certification of products only and in all cases involve the following as principles :

a) assessment of a supplier's capability to manufacture consistently a product conforming to the relevant standard(s);

b) testing or comparable evaluation of the product to the satisfaction of the certification body to determine compliance with the requirements of the standard;

c) application of a suitable follow-up service to assure ongoing conformity of products manufactured by the supplier;

d) control of the mark and/or name of the certification body.

**1.3** Within certification programmes it is possible for third party certification bodies to develop a variety of certification procedures to meet the needs of suppliers having a wide range of quality assurance capabilities. Those suppliers with the least demonstrated capabilities in this regard could be involved in certification procedures where the greatest number of steps in the total certification programme would be carried out by the certification body. Those suppliers with highly developed quality systems could process a large number of the steps required by the certification programme under a system of ongoing auditing by the certification body. Whatever the form of programme that is developed, the certification body reserves the authority to certify or not to certify any product manufactured by the supplier. A certification body may at its discretion specify programme criteria in addition to those described herein.

## 2 References

ISO/IEC Guide 2 : 1986, *General terms and their definitions concerning standardization and related activities.*

ISO/IEC Guide 28 : 1982, *General rules for a model third-party certification system for products.*

ISO 9000 : 1987, *Quality management and quality assurance standards — Guidelines for selection and use.*

ISO 9001 : 1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

ISO 9002 : 1987, *Quality systems — Model for quality assurance in production and installation.*

ISO 9003 : 1987, *Quality systems — Model for quality assurance in final inspection and test.*

ISO 9004 : 1987, *Quality management and quality system elements — Guidelines.*

## 3 Definitions

The relevant definitions of ISO/IEC Guide 2 apply. In addition, for the purposes of this Guide, the following definition applies.

**supplier** : The party that is responsible for the product, process or service and is able to ensure that quality assurance is exercised. The definition may apply to manufacturers, distributors, importers, assemblers, service organizations, etc.

## 4 Steps in developing a programme

### 4.1 Deciding on the form of programme

The programme is developed by the certification body to meet the needs of individual suppliers, a certain sector of industry or several industry sectors which have reached an acceptable level in their knowledge and application of quality assurance practices.

The elements of the quality system practices commonly employed within the industry sector are examined and those elements which can be applied to achieve the needed certification programme are incorporated into the programme criteria.

NOTE — Information on the elements of quality systems can be found in the ISO 9000 series or in similar national documents of some countries.

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### 4.2 The three phases in the implementation of a certification programme

All forms of product certification programmes within the scope of this Guide consist of the following three phases :

a) qualification;

b) certification;

c) follow-up.

## 5 The qualification phase

**5.1** In this phase the supplier is assessed to see if he qualifies in meeting all parts of the certification process which he is required to fulfil under the particular certification programme.

**5.2** To facilitate the assessment, a programme data form is developed which contains pertinent information needed to be acquired from the applicant. Two examples of such forms, one fairly simple and one more complex, with regard to the number of quality system elements involved in the programme, are shown in annexes A and B.

**5.3** Depending upon the nature of the programme being developed and the degree to which the programme will utilize a supplier's quality system, the certification body may require a supplier to have a minimum level of successfully demonstrated experience with the certification body in the production of conforming products before the supplier is permitted to apply for product certification under the programme.

**5.4** An applicant completes the form and returns it to the certification body. An evaluation of the responses provides an excellent indication of whether or not the applicant is likely to qualify as a programme participant. Clarifications required by either party are obtained by the quickest available form of communication.

**5.5** Following clarifications, a date is arranged for a visit to the applicant's plant. The certification body's assessement team should contain persons knowledgeable in

a) the applicable product standard(s);

b) appropriate laboratory procedures and techniques;

c) assessment procedures;

d) the quality system elements included in the programme.

**5.6** The matters to be investigated by the assessment team at the supplier's plant will vary widely depending upon the degree to which the supplier is to be involved in the certification process. Normally, however, the assessment team shall take the following actions :

a) in general, ascertain that all information provided in the programme data form is correct;

b) check to ensure that the supplier has the necessary equipment, staff and facilities for carrying out the tasks assigned to him for his participation in the certification programme;

c) have the supplier demonstrate his capability to test samples so as to assure conformity with the specific product standard(s) used in the programme; this may involve verification of test results by the certification body;

d) ensure that those quality elements that must be carried out by the supplier as part of the certification programme are being properly performed; also, that the necessary safeguards to ensure that they will continue to be properly performed are in place.

**5.7** Following the visit to the factory by the certification body's assessment team, a report on the team's findings is prepared and submitted together with the completed application to the responsible persons or group in the certification body to determine whether and under what conditions the applicant may be qualified. If the information is found to be complete and acceptable, the applicant is so informed in writing.

**5.8** A supplier can be qualified for additional product categories only after another assessment specifically directed to the new product category has been successfully completed.

**5.9** All the facilities involved in the process of developing a product covered under a certification programme, whether part of the supplier's organization or not, must be evaluated by representatives of the certification body.

## 6 The certification phase

**6.1** The action to be taken for certification will depend upon the type of programme developed. Following the qualification phase, the supplier may, for example, need to apply for certification each time he desires a new product to be certified. The certification process will then be implemented as described in the programme and the prescribed elements of the supplier's quality system will be included in that process. See also clause 7c).

**6.2** As a first example, a simple procedure may be based only upon acceptance of test data generated by the supplier's laboratory, i.e. only those elements required for assessment of the supplier's testing facilities and practices are involved in the qualification (see annex A). In such a case, after its qualification the laboratory would be visited by a representative of the certification body to

a) witness all types of tests; or

b) witness some types of tests; or

c) review the supplier's test results;

and if found to be in order, to accept them.

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**6.3** As a second example (see annex B), following a qualification phase which involves assessment of a large number of the elements of a supplier's quality system and of all the other requirements of the certification programme, the supplier is permitted to apply the certification body's mark to certain categories of products under an ongoing follow-up phase.

**6.4** The examples given in annexes A and B are illustrative of programmes which utilize (A) very few elements, and (B) many elements of the supplier's quality system. In addition to these examples, there are many different combinations of elements possible which a certification body may decide to employ in order to meet different needs.

## 7 The follow-up phase

This phase is designed to provide a means for assuring those who rely on the certification mark that products, once certified, and for the subsequent period of time that the supplier applies the certification body's mark to the products, continue to meet the requirements of the applicable product standards. Involved in this phase is an ongoing, in plant, working relationship between staff of the certification body and staff of the supplier. Details of the follow-up inspection will vary with the needs of the type of programme being developed. However the following general principles always apply.

a) In carrying out follow-up inspection at the supplier's plant, a representative of the certification body ensures that all quality system elements prescribed in the programme are being adhered to and, in general, satisfies himself that the product covered by the programme continues to conform to the product standard. Normally this would also include witnessing some selected tests, examination of quality assurance records and examination of products to determine compliance with requirements.

b) During a follow-up inspection, discussion shall take place concerning the test programme as it relates to new products within the authorized product category to be evaluated prior to the next inspection visit. When such discussion pertains to authorization to apply the mark or other evidence of certification of the certifcation body to new or revised products, the inspection team shall be composed of individuals who normally make such decisions within the certification body.

c) Labels or other evidence of certification shall not be applied to a design or construction which, in the opinion of the inspection team, could produce non-conformance until the evidence of compliance has been accepted by the certification body.

d) The minimum frequency of follow-up visits is prescribed in the programme. Follow-up will take place at all locations covered by the programme. For example, if products are manufactured at a different location from that at which the products are designed, tested and evaluated, and all these elements are part of the programme, follow-up will cover all relevant locations.

e) Records shall be kept by the certification body of all models of products certified.

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# Annex A

## Example of a programme data form in a case involving very few elements of a supplier's quality system

**Introductory note** (not part of the programme data form)

This is an example of a certification body's programme data form for a supplier who requests certification under a programme which has been developed to make use of the supplier's testing laboratory for generating some or all of the test data required to indicate compliance with the tests called for by the applicable standard(s).

The supplier's quality system elements to be assessed by the certification body under this programme are

— measuring and testing equipment;

— product testing and measurement.

The assessment by the certification body of the supplier's quality system involves such items as

— the Quality Manual for the laboratory operations;

— limits of accuracy of all measuring and test equipment involved;

— the environment in which the calibrations are performed;

— the environment in which the testing is performed;

— the methods of measurement and test;

— the availability of appropriate instrumentation and testing equipment;

— adequacy of energy supplies to perform required testing;

— the supplier's equipment calibration programme;

— demonstration of ability to conduct tests in accordance with prescribed standards and the practices of the certification body.

During the qualification phase, other matters of concern to the certification body include

a) establishing the designated person and deputy to be responsible for all dealings with the certification body;

b) ascertaining the supplier's knowledge of the applicable standards and how this knowledge is maintained on an ongoing basis;

c) the experience and qualification of all personnel testing products, including their capability to perform tests in accordance with the techniques and procedures prescribed and/or used by the certification body.

Information pertaining to all of the above items is sought via the programme data form (see example on the following page).

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# Programme data form
(Specimen)

## 1 Introduction and instructions

**1.1** This form is intended to provide the certification body with information about

a) the supplier's programme for assuring that all the products which bear the certification body's mark are in conformity with the applicable requirements;

b) the qualifications and responsibilities of the supplier's staff responsible for implementing the programme.

**1.2** For each of the following questions the certification body requires documentation to confirm the answer wherever appropriate. A copy of the documentation will be kept on file by the certification body.

**1.3** This form is to be completed by the supplier and returned to the certification body with supporting documentation prior to a visit to the facility by representatives of the certification body to review the implementation of the compliance control programme. A form shall be completed for each new or additional facility location.

**1.4** The completed form, documentation, and the supplier's laboratory compliance control programme will be used as the basis of the assessment.

**1.5** In order to retain certification under this programme, the supplier shall advise the certification body promptly in writing of any changes in organization, personnel, information or other detail reported in this form. The information contained in this form will be reviewed periodically by the certification body's personnel during subsequent visits to the facility to determine and record any changes that may have occurred.

**1.6** Where there is not enough space on the form for the information requested a note should be made in the appropriate space : e.g. "See Appendix ..., dated ...". The required material should be identified, dated and attached.

**1.7** When completed, this form and its contents become confidential and will be handled as such by the certification body.

**Location and responsible persons**

**1.8 Test facility (address in full)**

.....
.....
.....
.....
.....

a) Person at test facility with responsibility for handling matters pertaining to products evaluated under this programme, including responsibility for checking product compliance with all relevant standards.

Name : .....
Position : .....

**File :** .....
**Supplier :** .....
**Location :** .....
.....

Telephone : .....
Telex : .....
Telefax : .....

This person must have the written authority to represent the supplier, enforce the certification body's requirements and make necessary changes in production test facilities and procedures when required by the certification body's standards and related documents.

| | Yes | No |
|---|---|---|
| Does this authority exist? | ☐ | ☐ |

To whom does this person report? (name and position)

.....
.....
.....

b) Name of alternate : .....
.....

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### 1.9 Manufacturing (supply) facility

Name (in full) : .....
.....
Address (in full) : .....
.....
.....
.....
.....

Person at manufacturing (supply) facility with responsibility for manufacturing products evaluated under this programme

Name : .....
Position : .....
Telephone : .....
Telex : .....
Telefax : .....

## 2 Personnel

Append job descriptions and indicate the experience of all personnel responsible for testing products to the certification body's requirements and for writing product reports.

## 3 Measuring and testing equipment

**3.1 criteria** : A calibration control system which detects deficiencies and provides timely and positive corrective action shall be established for all measuring and testing equipment used to verify the conformity of products to requirements of the certification body.

Measuring and testing equipment shall be calibrated to applicable reference standards which in turn are certified as being traceable to internationally or nationally recognized standards.

**3.2** What measuring and test equipment is used to carry out tests to the certification body's requirements? List with serial numbers, make and model as applicable and provide accuracies for each item.

**3.3** How frequently are measuring and test devices calibrated? List for each item.

**3.4** How is the calibration status of measuring and test equipment identified?

**3.5** Are permanent calibration records maintained for each relevant measuring and test device? Yes ☐ No ☐

If yes, in what form?
Provide relevant examples.

**3.6** What standard instruments and devices are used for calibration?

**3.7** Are written calibration procedures available? ☐ ☐

Who assumes responsibility for issue?

**3.8** Describe how the standard instruments and devices are traced to international or national metrological standards.

## 4 Test procedures

**4.1** Do written procedures exist for all prototype testing required by the relevant standards and bulletins of the certification body? ☐ ☐

Who assumes responsibility for issue?

**4.2** Are the procedures available to all test personnel? ☐ ☐

**4.3** Are the personnel competent to understand the procedure and to perform all required testing? ☐ ☐

List names of relevant personnel who are competent to conduct the tests.

**4.4** Is there a written programme for revising test methods in accordance with revisions to the certification body's requirements? ☐ ☐

Provide details.

**4.5** Are the records available of the results of tests and investigations of products evaluated under this programme? ☐ ☐

If not, why? Provide details.

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# Annex B

## Example of a programme data form in a case involving many elements of a supplier's quality system

**Introductory note** (not part of the programme data form)

This is an example of a certification body's programme data form for a supplier (electrical supplier in this case) who requests certification under a programme which has been developed to make use of a large number of the elements of a supplier's quality system. The elements involved in this programme include the following : measuring and testing equipment, quality records, nonconformances, customer-supplied items, inspection and test, document control, identification and traceability, purchasing, manufacturing and construction, corrective action, design assurance.

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# Programme data form
(Specimen)

**File :** .....
**Supplier :** .....
**Location :** .....

## 1 Introduction and instructions

**1.1** This form is intended to provide the certification body with information about

a) the supplier's programme for assuring that the products which bear the certification body's mark are in conformity with the applicable requirements;

b) the qualifications and responsibilities of the supplier's staff responsible for implementing the programme.

**1.2** For each of the following questions the certification body requires documentation such as procedures, charts, drawings, test data, job descriptions, etc., as proof of capability to implement the programme. A copy of this documentation will be kept on file by the certification body.

**1.3** This form is to be completed by the supplier and returned to the certification body with supporting documentation as required by the certification body prior to a visit to the facility by the certification body to review the implementation of the compliance control programme. A form shall be completed for each new or additional facility location.

**1.4** The completed form, documentation, and the supplier's compliance control programme will be used as the basis of the assessment.

**1.5** In order to retain certification under this programme, the supplier shall advise the certification body promptly in writing of any changes in organization, personnel, information or other detail reported in this form. The information contained in this form will be reviewed periodically by the certification body's personnel during subsequent visits to the facility to evaluate their acceptability and determine and record any changes that may have occurred.

**1.6** Where there is not enough space on the form for the information requested, a note should be made in the appropriate space; e.g. "See Appendix ..., dated ...". The required material should be identified, dated, signed and attached.

**1.7** When completed, this form and its contents become confidential and will be handled as such by the certification body.

**1.8** The supplier must agree to establish procedures that control the design of products to ensure that the certification body's requirements are translated correctly into specifications, drawings, procedures and instructions for purchasing, testing, manufacturing and construction.

## 2 Organizing for the programme

**2.1** At least two persons shall be appointed to be responsible for the operation of this programme implemented at a manufacturing facility, i.e. a person with primary responsibility and at least one alternate person to act in his absence. Only these persons may authorize the application of the certification body's mark.

**2.1.1** Person at the manufacturing (supply) facility responsible for handling matters pertaining to products under this programme

Name : .....
Telephone : .....
Physically located at : .....
.....
Position in organization : .....
.....
To whom does this person report? .....
.....

**2.1.2** Alternate person responsible

Name : .....
Telephone : .....
Physically located at : .....
.....
Position in organization : .....
.....
To whom does this person report? : .....
.....

**2.1.3** Provide an organization chart showing the relationship of these persons to the organization.

NOTE — If this application is for a facility depending on another location within the supplier's organization for design and prototype verification control, provide the information required in 2.1 for location of control.

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## 2.2 Independence and authority

The individuals identified in 2.1 shall be independent of management directly responsible for production and have written responsibility and authority to take the following actions.

a) require correction of deviations from the requirements before the application of the certification mark.

| | Yes | No |
|---|---|---|
| Do they have this authority? | ☐ | ☐ |
| Do they exercise this authority? | ☐ | ☐ |

b) require changes pertaining to the certifier's requirements in design, drawings, procurement, etc.

| | | |
|---|---|---|
| Do they have this authority? | ☐ | ☐ |

c) arrange for and verify the removal of the certification mark from products which do not comply with the certifier's requirements or from products which have not been covered by the programme.

| | | |
|---|---|---|
| Do they have this authority? | ☐ | ☐ |
| Do they exercise this authority? | ☐ | ☐ |

## 2.3 Criteria concerning experience and/or training and responsibility

The individuals identified in 2.1 shall be experienced and/or have been trained for performing their duties. What experience and related on-the-job formal training do they have?

**2.4** The individuals identified in 2.1 shall have the authority and responsibility for ensuring that

a) the certification mark is applied only to those products for which authorization has been given by the certification body in writing.

| | | |
|---|---|---|
| Do they have this authority and responsibility? | ☐ | ☐ |

b) the latest documents of the certification body pertaining to the applicable requirements are available at the facility and are being worked to.

| | | |
|---|---|---|
| Do they have this authority and responsibility? | ☐ | ☐ |

c) the products which bear the certification mark comply with the applicable requirements before shipment.

| | | |
|---|---|---|
| Do they have this authority and responsibility? | ☐ | ☐ |

d) the applicable requirements of the following sections are implemented and being followed at the facility.

| | | |
|---|---|---|
| Do they have this authority and responsibility? | ☐ | ☐ |

Provide position descriptions, signed by a responsible executive, in which the authority and responsibility of 2.2 and 2.4 are given.

## 2.5 Compliance management

A compliance management programme shall be in existence and operating at the facility.

| | Yes | No |
|---|---|---|
| **2.5.1** Is there a compliance management programme? | ☐ | ☐ |

**2.5.2** How is the compliance management programme documented?

Provide a copy of the compliance management procedures as applicable.

| | | |
|---|---|---|
| **2.5.3** Are the documents that describe the compliance management procedures approved by management? | ☐ | ☐ |
| **2.5.4** Are these documents periodically reviewed and updated? | ☐ | ☐ |

By whom? .....
Position : .....
At what intervals? .....

**2.5.5** The compliance management documents shall contain

a) organization, structure and assignment of responsibilities within the compliance management programme;

b) inspection and test plans;

c) procedures for each element.

| | | |
|---|---|---|
| Do the compliance management documents provide this information? | ☐ | ☐ |

# 3 Design control and prototype verification

**3.1** The supplier shall establish procedures that control the design of products to ensure that the certification body's requirements are translated correctly into specifications, drawings and procedures.

| | | |
|---|---|---|
| Have such procedures been developed? | ☐ | ☐ |

Describe these procedures briefly in general terms and attach applicable supporting documents.

| | | |
|---|---|---|
| **3.2** Is a design review made by personnel who are fully conversant with the certification body's requirements? | ☐ | ☐ |

What are their names?

.....
.....
.....
.....

NOTE — If these persons are the same as those identified in 2.1, state the fact above and go to 3.3.

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What qualifications, experience and related on-the-job or formal training do these persons have?

**3.3** Inspections and tests shall be performed by the supplier on representative samples of each prototype product and whenever an engineering change is made to a product to verify conformance to the certification body's requirements.

| | Yes | No |
|---|---|---|
| Are such inspections and tests performed? | ☐ | ☐ |
| Are records kept of these inspections and tests? | ☐ | ☐ |

**3.4** Give the names of the persons who have the responsibility for carrying out these tests and inspections.

Names :

.....

.....

.....

.....

What qualifications, experience and related on-the-job or formal training do each of these persons have?

**3.5** Provide an organization chart showing the relationship of these persons to other executive, administrative and supervisory positions.

**3.6** The persons responsible for the management of the certification programme at the manufacturing location shall have the authority to participate in design review and to review and approve all engineering changes.

Do they have this authority? ☐ ☐

**3.7** Where is the design control and product verification carried out?

**3.8** There shall be evidence that prototype products comply with all relevant requirements of the certification body before they are released for production. There shall be a statement on file at the manufacturing location which is available to the certification body.

Do the procedures at the facilities provide for this evidence? ☐ ☐

**3.8.1** A detailed record of all tests and test results shall be on file at the location of design control and prototype verification. This shall be accessible by personnel at the manufacturing (supply) location.

Do the procedures at the facilities provide for this evidence? ☐ ☐

## 4 Measuring and testing equipment

**4.1 Criteria.** A calibration control system which detects deficiencies and provides timely and positive corrective action shall be established for all measuring and testing equipment used to verify the conformance of products to requirements of the certification body.

Measuring and testing equipment shall be calibrated to applicable reference standards which in turn are certified as being traceable to internationally or nationally recognized standards.

**4.2** What measuring and test equipment is used? List each relevant type by full description, i.e. make, model and serial numbers.

**4.3** At what intervals is each critical measuring and test device calibrated?

| | Yes | No |
|---|---|---|
| **4.4** Are written calibration procedures available for each type of measuring and testing equipment? | ☐ | ☐ |

**4.5** How is the calibration status of critical measuring and test equipment identified?

**4.6** Are permanent calibration records maintained for each measuring and test device? ☐ ☐

**4.7** Is each measuring instrument marked to show when it was last calibrated? ☐ ☐

**4.8** What standard instruments and devices are used for calibration?

Itemize by make, model and serial number; indicate when last calibrated and when next due for calibration.

**4.9** Describe how the standard instruments and devices are traced to international or national standards.

**4.10** Describe how required environmental conditions that are specified for testing are produced and controlled.

## 5 Production inspection and test plan

**5.1 Criteria.** A written inspection and test plan shall be developed which describes all of the production inspections and tests necessary to ensure that each product under this certification programme complies with the requirements of the certification body before shipment. This plan shall include details of its implementation as follows.

a) Details of inspection controls as applied to incoming materials and components, production lines, final inspection and packaging.

If non-certified components are used, the above information shall include a description of the procedure followed to ensure that shipments received are the same as the original component evaluated and found to be in compliance with the requirements of the certification body.

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b) Details of instrumentation, calibration facilities and records of calibration dates.

c) A system for recording the results of production-line tests as required by the certification body.

d) Details of the methods used for segregation and disposition of nonconforming products.

e) Details of all required factory production tests as provided by the certification body in writing.

| | Yes | No |
|---|---|---|
| Has such an inspection and test plan been developed? | ☐ | ☐ |
| Has such an inspection and test plan been implemented? | ☐ | ☐ |
| Does this plan include details of the certification body's required factory tests? | ☐ | ☐ |

Provide the certification body with a copy of this plan.

**5.2** A list of the characteristics to be inspected and/or tested and the related acceptance criteria shall be available at each location where an inspection and/or tests are performed to verify conformance requirements of the certification body.

Is such information available at these locations? ☐ ☐

## 6 Corrective action

**6.1 Criteria.** A system for controlling components and final products which do not comply with the requirements of the certification body shall be developed to ensure that such components and final products are not released for use before appropriate corrective action has been taken.

Has such a system been developed? ☐ ☐

Has such a system been implemented? ☐ ☐

Provide a copy of the document describing the system.

**6.2** Components and final products that have been reworked or repaired to comply with the certification body's requirements shall be reinspected and/or retested.

Is this done? ☐ ☐

**6.3** Products which bear the certification body's certification mark and which do not comply with the certification body's requirements or have not been covered by the certification programme shall have the certification mark removed before they are shipped from the factory.

Is this done? ☐ ☐

**6.4** All nonconformances shall be investigated to determine the cause.

| | Yes | No |
|---|---|---|
| Is this done? | ☐ | ☐ |

**6.5** After the cause of a nonconformance has been determined, appropriate action shall be taken to prevent repetition.

Is this done? ☐ ☐

Provide an example of documentation.

## 7 Purchasing

**7.1 Criteria.** The supplier shall ensure that purchased components (for his products) under the certification programme comply with the applicable requirements of the certification body and that only certified components are used when required by the certification body.

Has this practice been implemented? ☐ ☐

Describe the procedure used to identify incoming components that are required to be certified and to ensure they are certified.

**7.2** Non-certified components such as switches, circuit-breakers, transformers, motors, etc., may be used. If a non-certified component is used, however, it shall be evaluated and tested to determine compliance with relevant requirements of the certification body.

Describe the procedure used to identify incoming components evaluated in the above manner that ensures they comply fully with relevant requirements of the certification body.

**7.2.1** The examination and testing of representative samples of non-certified components may be carried out either by the certification body or by the supplier. Suppliers may carry out the examination and testing only if they have personnel thoroughly familiar with the latest testing practices and with requirements of the standards relevant to the components and are properly equipped to carry out required testing, and only if specifically authorized by the certification body.

Who is the person responsible for ensuring that all non-certified components are in compliance with requirements of the certification body?

Name : .....

Does this person have the requisite qualifications? ☐ ☐

Provide an organization chart showing the relationship of this person to other executive, administrative and supervisory positions.

**7.2.2** A record of all certified components containing the following information shall be maintained :

a) a description of the component, e.g. switch, relay, etc.;

b) the name of the supplier;

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c) the catalogue or model designation sufficient to provide specific identification;

d) the electrical rating;

e) a record of the standards, bulletins, notices and other requirements of the certification body used to determine compliance;

f) whether the prototype examination and testing was carried out by the certification body or the supplier of the end product;

g) the results of the tests.

| | Yes | No |
|---|---|---|
| Is this record maintained? | ☐ | ☐ |

In what form? .....

For how long? .....

Where is it available? .....

## 8 Programme and product records

### 8.1 Criteria concerning programme records

Production line inspection and test records that demonstrate the conformance of the final product to the certification body's requirements shall include as a minimum

- identification of the product;
- inspection and tests performed;
- inspection and test results;
- basis of acceptance;
- nonconformances;
- corrective action taken;
- measures taken to prevent recurrence;
- date of inspection and/or test;
- inspector's identification.

| | | |
|---|---|---|
| Are such records kept? | ☐ | ☐ |
| Do they contain the information described? | ☐ | ☐ |

Where are they kept? .....

### 8.2 Criteria concerning product records

The following records shall be kept for each product under this certification programme :

a) a copy of the nameplate, nameplate drawing or marker which shows the certification mark, identification number of the product and the electrical rating;

b) environmental conditions and results of inspections and tests performed on the prototype product to verify conformance to the requirements of the certification body;

c) photographs showing external and internal views of the product and its components along with sufficient description, such as drawings and/or text, to provide a record of the initially evaluated designs found to comply with the applicable product standard;

d) schematic drawings of primary and secondary circuits;

e) list of primary circuit components and whether or not they are certified; if they are not certified, a description or drawing of the component and relevant test data to demonstrate conformance to the applicable requirements of the certification body;

f) list of secondary circuit components that are

- in safety circuits; or
- not in Class 2 circuits; or
- in critical circuits (such as interlock circuits, patient circuits in electro-medical equipment, etc.).

| | Yes | No |
|---|---|---|
| Are such records kept? | ☐ | ☐ |
| Do they contain the information described? | ☐ | ☐ |

Who has the authority and responsibility to maintain these records?

Name : .....

Where are they located? .....

### 8.3 Criteria concerning filing and storage of programme and product records

Programme and product records shall be filed for easy retrieval and availability to the certification body's representative. Also, they shall be stored in a proper environment to minimize deterioration or damage and to prevent loss. The product records referred to in 8.2 shall be kept as long as the product is in use. The "period of use" will be mutually agreed upon by the certification body and the supplier, with due consideration to requirements under applicable warranties and laws.

| | | |
|---|---|---|
| Agreed? | ☐ | ☐ |

## 9 Summary of general details

**9.1** File : .....
Date : .....

**9.2** Supplier's name (in full) : .....
.....

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