GUIDE 53

Conformity assessment — Guidance on the use of an organization's quality management system in product certification

Second edition 2005

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Contents

Page

Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. 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. In the field of conformity assessment, the ISO Committee on conformity assessment (CASCO) is responsible for the development of International Standards and Guides.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

Draft Guides adopted by the responsible Committee or Group are circulated to the member bodies for voting. Publication as a Guide requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/IEC Guide 53 was prepared by the ISO *Committee on conformity assessment* (CASCO). It was circulated for voting to the national bodies of both ISO and IEC, and was approved by both organizations.

This second edition cancels and replaces the first edition (ISO/IEC Guide 53:1988), which has been technically revised.

Introduction

Product certification schemes incorporating an organization's quality management system can be beneficial for both the organization and the certification body in determining the conformity of products to specified requirements and in assuring that products continue to conform to those requirements.

In these types of schemes, product certification is based on both the assessment of conformity of an organization's quality management system to specified requirements, and the assessment of conformity of the product to specified product requirements. Certification bodies can conduct both types of assessment for product certification schemes that are covered by this Guide.

Product certification schemes can take many forms, including those that do not utilize an organization's quality management system. There is no inference in this Guide that one form of product certification scheme is superior to another. Furthermore, when a certification body has several forms of product certification schemes available for a class of product, the organization has the right to choose the scheme under which it wishes to apply for certification.

NOTE In some countries, technical regulations predetermine the available type(s) of product certification scheme to be used.

This Guide is based on the understanding that interested parties using it to develop product certification schemes are familiar with

— the principles and practices covered by the ISO 9000 family of International Standards,

— the more general certification and surveillance provisions established for product certification systems in ISO/IEC Guide 67, and

— the specific product requirements.

Conformity assessment — Guidance on the use of an organization's quality management system in product certification

1 Scope

1.1 This Guide outlines a general approach by which certification bodies can develop and apply product certification schemes utilizing requirements of an organization's quality management system. The provisions given in this Guide are not requirements for the accreditation of a product certification body and do not substitute the requirements of ISO/IEC Guide 65.

1.2 The schemes contained in this Guide are for product certification only and in all cases involve the following principles:

a) assessment of an organization’s quality management system and its capability to consistently supply products conforming to specified requirements;

b) testing, inspection or comparable verification of the product's conformity to scheme criteria and specified requirements;

c) application of a suitable surveillance scheme to ensure continual conformity to specified requirements of products supplied by the organization;

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

1.3 Within product certification schemes, it is possible for certification bodies to verify conformity with the specified requirements through a variety of ways, including the assessment of an applicant's quality management system. Whatever the form of scheme that is developed, the certification body retains the authority to certify or not. A certification body can at its discretion specify scheme criteria in addition to those described in this Guide.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2000, *Quality management systems — Fundamentals and vocabulary*

ISO/IEC 17000:2004, *Conformity assessment — Vocabulary and general principles*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC 17000 and the following apply.

3.1
assessor
〈certification〉 competent person assigned by a product certification body to perform, alone or as part of an assessment team, an assessment of an organization

4 Steps in the scheme

4.1 Deciding on the scheme

In order to achieve the needed assurance within the product certification scheme, the scheme criteria should incorporate quality management system requirements, as established in ISO 9001 or a similar quality management system standard.

NOTE The quality management system requirements can be based on ISO 9001, one of its sector applications (e.g. ISO/TS 16949 and ISO/TS 29001), or a similar quality management system standard.

The product certification body should give consideration to the risks and cost involved in the application of a product certification scheme when it decides the extent of the requirements of the quality management system to be incorporated into the scheme criteria.

If the level of risks is high, the certification body should consider incorporating a greater number of quality management system requirements into the scheme criteria.

4.2 Functions in the implementation of a product certification scheme

All forms of product certification schemes within the scope of this Guide include the following functions:

a) selection;

b) determination;

c) review and attestation;

d) surveillance.

NOTE These functions are consistent with the requirements established in ISO/IEC Guide 65. The product certification schemes that certification bodies develop by using this Guide are given in ISO/IEC Guide 67. A description of the functions described above appears in ISO/IEC 17000.

Clauses 5 to 8 describe activities, for each of the above functions, related to utilizing an organization's quality management system as part of the product certification scheme.

5 Selection

5.1 During this function, the certification body should gather information to determine the extent of conformity with requirements (see Clause 6).

5.2 When the organization has implemented a quality management system, the certification body should conduct a document review in order to establish the readiness and capability of the organization, and the degree to which the system has been established.

5.3 To facilitate the assessment, the applicant may need to provide pertinent information in a scheme data form. Two examples of such forms, one fairly simple and one more complex with regard to the number of quality management system requirements involved in the scheme, are shown in Annexes A and B.

5.4 Depending on the nature of the scheme and the degree to which the scheme utilizes an organization's quality management system, the certification body should ensure that the organization has a minimum level of experience in the application of its quality management system before the organization submits an application for product certification.

5.5 The certification body may take into account the organization's current quality management system certification provided that the certification covers

a) the scope of products being considered, and

b) the sites where the activities take place.

NOTE Consideration could also be given to the extent that the quality management certification is mutually recognised, through it originating from a certification body that is accredited and/or peer assessed in accordance with relevant International Standards (e.g. ISO/IEC 17021 and/or ISO/IEC 17040).

5.6 The certification body should evaluate the information provided, request additional information as needed, and determine whether the application can proceed to the determination function.

5.7 The certification body should arrange a date for a visit to the applicant's organization and should form an assessment team that includes persons competent in

a) the applicable product requirements,

b) appropriate test and/or inspection procedures and techniques,

c) conformity assessment procedures,

d) the quality management system requirements included in the scheme, and

e) audit methodologies as recommended in ISO 19011.

NOTE For additional information on audit activities and personal attributes, and knowledge and skills of auditors, reference can be made to ISO 19011.

6 Determination

6.1 The matters to be investigated by the assessment team at the organization's facilities will vary widely depending upon the specific quality management system requirements that have been included within the relevant product certification scheme. Normally, however, the assessment team should take the following actions:

a) determine that all information provided in the application is correct and complete;

b) check to ensure that the organization has the necessary equipment, staff and facilities for carrying out the tasks assigned to it for its participation in the product certification scheme;

c) ask the organization to demonstrate its capability to monitor and measure the product so as to assure conformity with the specific product requirements used in the scheme; this may involve verification of test results or inspection reports by the certification body;

d) ensure that the organization performs those quality management system processes that are to be carried out by the organization as part of the product certification scheme, and that the organization has the necessary planned arrangements to ensure that the quality management system processes will continue to be effectively implemented and maintained.

6.2 Following the assessment of the quality management system by the certification body's assessment team, a report on the team's observations should be prepared. This report should be submitted, together with

the completed application, to the responsible persons or group in the certification body who will decide whether and under what conditions the applicant may be approved. Such conditions may relate to establishing confidence that the applicant's quality management system can result in products being consistently produced or supplied to specified requirements.

6.3 An organization should only be approved for additional product categories when the certification body has confirmed that the product complies with specified requirements and when it has completed another assessment of the quality management systems directed to the new product category(s), as applicable.

6.4 If required by the relevant product certification scheme, all the organization's facilities involved in the product design process, whether part of the organization or not, should be covered in the determination function by the certification body.

6.5 The certification body should give consideration to the amount of assessment time when the organization's quality management system is certified by an accredited or peer assessed quality management system certification body.

NOTE Consideration could also be given to the extent to which the quality management certification is mutually recognised. This can be through it originating from a certification body that is accredited and/or peer assessed in accordance with relevant International Standards (e.g. ISO/IEC 17021 and/or ISO 17040).

7 Review and attestation

7.1 The specific way in which the accepted quality management system is utilized will depend upon the specific requirements in the relevant product certification scheme.

The certification process should be completed as described in the scheme and the acceptability of the organization's quality management system at all sites covered by the product certification should be included in the certification documents.

7.2 As a first example, a simple procedure may be based only upon acceptance of test data generated by the organization's laboratory; i.e. only those requirements related to the organization's testing facilities and practices are involved in the assessment (see Annex A). In such a case, an assessor of the certification body should visit the laboratory in order

a) to witness all types of tests or inspections, including sampling, or

b) to witness some types of tests or inspections, or

c) to review the organization's test results or inspection reports and, if found to be in order, to accept them.

NOTE For testing and calibration laboratories, ISO/IEC 17025 contains both management systems requirements and the requirements for technical competence. In operating a product certification scheme in accordance with this Guide, it is only the assessment of the quality management system requirements that are relevant. ISO/IEC 17025 is not intended to be used as the basis for certification of quality management of laboratories.

7.3 As a second example (see Annex B), following a determination function which involves assessment of a large number of processes of an organization's quality management system and of all other requirements of the product certification scheme, the organization is permitted to apply the certification body's mark to certain categories of products under an ongoing surveillance function.

7.4 The examples given in Annexes A and B are illustrative of schemes that utilize very few requirements (Annex A) and many requirements (Annex B) of a quality management system. In addition to these examples, there are many different combinations of possible requirements that a certification body may decide to employ in order to meet different needs.

NOTE Providing a product certification within a product certification scheme that is based on this Guide does not mean that the relevant quality management system is also certified.

8 Surveillance

This function is to provide assurance that a certified product continues to meet specified requirements for an ongoing period of time.

Details of the surveillance may vary depending on the needs of the type of scheme. However, the following general principles always apply.

a) In carrying out surveillance at the organization's facility, an assessor of the certification body should ensure that all quality management system requirements prescribed in the scheme are being fulfilled, and that the product covered by the scheme continues to comply with the specified requirements. Normally this should also include witnessing some selected tests or inspections, verification of records and examination of products to determine conformity with requirements.

b) During surveillance, consideration should be given to the scheme criteria as they relate to new or modified products within the approved product category. When it has been determined that changes have occurred that could affect the application of the mark to new or modified products, the assessor should refer to the person or group of persons who have overall responsibility for the certification decision at the certification body.

c) The minimum frequency of surveillance visits should be stated in the scheme. Surveillance should take place at all locations covered by the scheme. For example, if products are manufactured at or supplied from different locations from that at which the products are designed, tested and inspected, and all these activities are part of the scheme, surveillance should cover all relevant locations (see also 6.4).

9 Mark of conformity

Requirements for the issuing and use of third-party marks of conformity are contained in ISO/IEC 17030. Further guidance can be found in ISO/IEC Guide 23 and ISO Guide 27.

Annex A
(informative)

Example of a data form for a product certification scheme that uses very few requirements of a quality management system

A.1 Introductory note (not part of the scheme data form)

This is an example of a certification body's scheme data form for an organization which requests certification under a scheme that has been developed to use the organization's testing laboratory for generating some or all of the test data required to indicate conformity with the applicable requirements. The example is based on the requirements of ISO 9001.

In the example, the organization's quality management system requirements to be assessed by the certification body under this scheme are related to

— control of monitoring and measuring devices (e.g. ISO 9001:2000, 7.6), and

— monitoring and measurement of the product (e.g. ISO 9001:2000, 8.2.4).

The organization's quality management system assessment involves such items as

— the laboratory operational procedures or instructions,

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

— the environmental conditions under which the calibrations are performed,

— the environmental conditions under which the testing is performed,

— the methods of measurement and test,

— the availability of appropriate measurement and testing devices,

— the adequacy of energy supplies to perform the required testing,

— the organization's equipment calibration programme, and

— demonstration of the ability to conduct tests in accordance with specified requirements of the certification body.

During the selection function, the certification body may consider

a) confirming with the organization who their designated representative and deputy will be, for all dealings with the certification body;

b) evaluating the organization's knowledge of the applicable requirements and how this knowledge is to be continually maintained;

c) checking the competence of all personnel who test products, including their skills to perform tests in accordance with the requirements.

Information pertaining to all of the above items is sought via the scheme data form (see Example A.2).

A.2 Scheme data form (specimen)

File:
Organization:

Introduction and instructions

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

a) the organization's quality management system for assuring that all the products which bear the certification body's mark are in conformity with the applicable requirements, and

b) the competence and responsibilities of the organization's staff responsible for implementing the scheme.

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.

This form is to be completed by the organization. It should be returned to the certification body with supporting documentation prior to a visit to the organization by certification body assessors. A form should be completed for each new or additional facility location.

The completed form, the documentation and the organization's conformity assessment programme will be used as the basis of the assessment.

In order to retain certification under this scheme, the organization should inform the certification body promptly in writing of any changes in organization, personnel, information or other details reported in this form. The certification body's personnel will periodically review the information contained in this form during subsequent visits to the facility to determine and record any changes that may have occurred.

If 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.

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

1 Location and responsible persons
Test or inspection facility (address in full):
a) Person in this facility with responsibility for handling matters related to assessing products under this scheme:
Name:
Position:
Location:
Telephone:
E-mail:
Fax:

This person should have the written authority to represent the organization, 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.
Does this authority exist? Yes □ No □
To whom does this person report? (name and position)
b) Name of alternative person with the same responsibilities as under 1 a):
2 Production (or supply) facility
Name (in full):
Address (in full):
Person at production (or supply) facility with responsibility for product realization evaluated under this scheme:
Name:
Position:
Telephone:
E-mail:
Fax:
3 Quality management system
3.1 Has the organization implemented a quality management system in accordance with the requirements of ISO 9001 or an equivalent quality management system standard? Yes □ No □ Where applicable, specify the equivalent quality management system standard.
3.2 Is the quality management system certified by an accredited certification body? Yes □ No □
3.3 Does the scope of the quality management system certification cover the production (or supply) processes in the category of product for which product certification is requested? Yes □ No □
3.4 Are all the sites in charge of production (or supply) of the product covered by the quality management system certificate(s)?Yes □ No If yes, please attach a copy of the current certificate(s) and, if available, a copy of the last audit report.
4 Personnel Append the quality management system documentation that specifies the responsibility and authority of all personnel responsible for testing or inspecting products for conformity to requirements, and for writing product monitoring and measurement records. Append the documentation of the required competence for these personnel and the records of their education, training, experience and skills.

5 Control of monitoring and measuring devices Criteria: The quality management system shall be effective in controlling the monitoring and measurement devices used to verify the conformity of the product, in accordance with either 7.6 of ISO 9001:2000, or an equivalent quality management system standard (which should be identified).
5.1 What measuring and test equipment is used to carry out tests? List with serial numbers and the measured quantity, as applicable, and provide accuracies for each item.
5.2 How frequently are measuring and test devices calibrated? List each item.
5.3 How is the calibration status of measuring and test equipment identified?
5.4 Which standard devices are used for calibration?
5.5 Are permanent calibration records maintained for each relevant measuring and test device? Yes □ No □
5.6 Are written calibration procedures available? Yes □ No □
5.7 Who assumes responsibility for issue?
5.8 Describe how the standard devices are traced to international or national standards.
6 Test procedures
6.1 Do documented procedures exist for all products tested? Yes □ No □
6.2 Who assumes responsibility for issuance?
6.3 Are the procedures available to all test personnel? Yes □ No □
6.4 Are the personnel competent to understand the procedure and to perform all required testing? Yes □ No □ List names of relevant personnel who are competent to conduct the tests.
6.5 Is there a documented procedure for control including the review and approval of test methods in accordance with changes in the relevant requirements? Yes □ No □ Provide details.
6.6 Are the records available of the results of test or inspection of product assessed under this scheme? Yes □ No □ If not, why not? Provide details.

Annex B
(informative)

Example of a data form for a product certification scheme that uses many requirements of a quality management system

B.1 Introductory note (not part of the scheme data form)

This is an example of a certification body's scheme data form for an organization (electrical organization in this case) that requests certification under a scheme that has been developed to make use of a large number of quality management system requirements. The requirements involved in this scheme include the following: planning of product realization, customer-related processes, design and development, purchasing, production and service provision, monitoring and measurement of product, control of monitoring and measuring devices, control of nonconforming product, corrective action, preventive action, document control and record control.

The example is based on the requirements of ISO 9001.

B.2 Scheme data form (specimen)

File:
Organization:

Introduction and instructions

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

a) the organization's quality management system for assuring that the products which bear the certification body's mark are in conformity with the applicable requirements, and

b) the competence and responsibilities of the organization's staff responsible for implementing the scheme.

For each of the following questions, the certification body requires documentation or records, such as procedures, charts, drawings, test records and inspection reports, as proof of capability to implement the scheme. A copy of this documentation will be kept on file by the certification body.

This form should be completed by the organization. It should be returned to the certification body with supporting documentation prior to a visit to the organization by certification body assessors. A form should be completed for each new or additional facility location.

The completed form, the documentation and the organization's conformity control scheme will be used as the basis of the assessment.

In order to retain certification under this scheme, the organization should inform the certification body promptly in writing of any changes in organization, personnel, information or other detail reported in this form. The certification body's personnel will periodically review the information contained in this form during subsequent visits to the facility to evaluate their acceptability and determine and record any changes that may have occurred.

If 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.

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

The organization should agree to establish the documents required in this data form to ensure that the product requirements are fulfilled.

At least two persons should be appointed to be responsible for the operation of this scheme implemented by the organization; i.e. a person with primary responsibility and at least one alternative person to act in his/her absence. Only these persons may authorize the application of the certification body's mark.

1 Location and responsible persons
1.1 Supply facility (address in full):
1.2 Person at supply facility with responsibility for handling matters pertaining to products assessed under this scheme:
Name:
Position:
Location:
Telephone:
E-mail:
Fax:
To whom does this person report? (name and position)
1.3 Alternative responsible person:
Name:
Position:
Location:
Telephone:
E-mail:
Fax:
To whom does this person report? (name and position)
1.4 Provide an organization chart showing the relationship of these persons to the organization. If this application is for a facility depending on another location within the organization for planning the product realization and/or design and development, provide the information required in 1.2 and 1.3 for the location of control.

2 Responsibility and authority

2.1 The individuals identified in 1.2 and 1.3 should have documented responsibility and authority to take the following actions.

a) Require correction of nonconformities before the application of the certification mark.

Do they have this authority? Yes □ No □

Do they exercise this authority? Yes □ No □

b) Require changes pertaining to the requirements in the specifications, drawings, procurement, etc.

Do they have this authority? Yes □ No □

Do they exercise this authority? Yes □ No □

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

Do they have this authority? Yes □ No □

Do they exercise this authority? Yes □ No □

2.2 Criteria concerning competence.

The individuals identified in 1.2 and 1.3 shall be competent to perform their duties. What experience and related on-the-job formal training do they have?

2.3 The individuals identified in 1.2 and 1.3 should have the authority and responsibility for ensuring the following.

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? Yes □ No □

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? Yes □ No □

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

Do they have this authority and responsibility? Yes □ No □

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

Do they have this authority and responsibility? Yes □ No □

Provide the documentation, signed by a responsible executive, in which the authority and responsibility are given.

3 Quality management system

3.1 Has the organization implemented a quality management system in accordance with the requirements of ISO 9001, or an equivalent quality management system standard? Yes □ No □

Where applicable, specify the equivalent quality management system standard.

If yes, please provide a copy of the quality manual and/or quality management system documentation.

3.2 Is the quality management system certified by an accredited certification body? Yes □ No □

3.3 Does the scope of the certification cover the activities of production and/or supply of the category of product for which certification is requested? Yes □ No □

3.4 Are all the sites in charge of production and/or supply of the product covered by the certificate(s)? Yes □ No □ If yes, please attach a copy of the current certificate(s) and, if available, a copy of the last audit report.
3.5 The quality management system documentation should contain details of a) organization structure, responsibility and authority, b) inspection and test plans, c) documented procedures, d) required external documents (e.g. technical standards and statutory and regulatory requirements applicable to the product), e) specific documents established by the organization (e.g. specifications, drawings, work instructions, and forms necessary for effective implementation of the quality management system and the control of production or supply and conformity assessment of the product), and f) records. Does the quality management system documentation provide this information? Yes □ No □
4 Personnel Append the documentation of the quality management system that specifies the responsibility and authority of all personnel responsible for product design, calibration of measuring devices, verification of incoming products, testing or inspecting products to requirements and for writing product monitoring and measurement records. Please attach the documentation of the required competence for these personnel and the records of their education, training, experience and skills.
5 Planning of product realization Criteria: The quality management system shall comply with the requirements of 7.1 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified).
5.1 Is the result of planning of product realization documented? Yes □ No □
5.2 Are there exclusions from the requirements within 7.3, 7.4, 7.5.2 and 7.5.4 of ISO 9001:2000 in the quality management system? Yes □ No □ If yes, describe the exclusion and its justification.
6 Customer-related processes Criteria: The quality management system shall comply with the requirements of 7.2 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified).
6.1 Is a review conducted prior to the organization's commitment to supply a product to the customer to ensure that — product requirements are defined, — contract or order requirements differing from those previously expressed are resolved, and — the organization has the ability to meet the defined requirements? Yes □ No □
6.2 Are records of this review maintained? Yes □ No □
6.3 Are records of customers' complaints maintained? Yes □ No □

7 Design and development

(Only for organizations responsible for product design and development)

Criteria: The quality management system shall comply with the requirements of 7.3 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified).

7.1 Is each product design verified? Yes □ No □

7.2 Do records of these verifications exist? Yes □ No □

7.3 Is each product design reviewed in order to

— evaluate the ability of the results of design to meet requirements, and

— identify any problems and propose necessary actions?

Yes □ No □

7.4 Do records of these reviews exist? Yes □ No □

7.5 Where are the product design, verification design and review design carried out?

7.6 There shall be evidence that prototype products comply with all relevant requirements before they are released for production. There shall be a statement, available to the certification body, on file at the location.

Do the records at the facilities provide this evidence? Yes □ No □

8 Purchasing

Criteria: The quality management system shall comply with the requirements of 7.4 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified).

8.1 A record of all verified components containing the following information shall be maintained:

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

b) the name of the supplier;

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 used to determine conformity;

f) the results of the tests.

Is this record maintained? Yes □ No □

In what form? .....

For how long? .....

Where is it available? .....

9 Production and service provision Criteria: The quality management system shall comply with the requirements of 7.5 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified), if there is no excluded subclause with justification.
9.1 Does the product identification apply? Yes □ No □ If not, please explain.
9.2 How is the monitoring and measurement product status identified?
9.3 Does the product traceability apply? Yes □ No □
9.4 Does the customer provide any property that is to be incorporated in the final product? Yes □ No □ If yes, please list them.
9.5 Is a process validation carried out? Yes □ No □ If yes, please indicate which process and the validation criteria.
10 Control of monitoring and measuring devices Criteria: The quality management system shall comply with the requirements of 7.6 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified).
10.1 What monitoring and measuring equipment is used? List each relevant type by full description, i.e. measured quantity and serial numbers.
10.2 At what intervals is each measuring device calibrated?
10.3 Are written calibration procedures available for each type of measuring device? Yes □ No □
10.4 How is the calibration status of measuring devices identified?
10.5 Are calibration records maintained for each measuring device? Yes □ No □
10.6 Is each measuring device marked to show when it was last calibrated? Yes □ No □
10.7 What standards are used for calibration? Itemize by model and serial number; indicate when last calibrated and when next due for calibration.
10.8 Describe how the standards are traced to international or national standards.
10.9 Describe how required environmental conditions that are specified for monitoring and measurement are controlled.

11 Monitoring and measurement of product

Criteria: The quality management system shall comply with the requirements of 8.2.4 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified).

NOTE The product inspection or test activities are included in ISO 9001 as monitoring and measurement of product.

11.1 A documented monitoring and measurement plan shall be developed which describes all of the production monitoring and measurement necessary to ensure that each product under this product certification scheme complies with the requirements before delivery. This plan shall include details of its implementation as follows:

a) details of verification controls as applied to incoming materials and components, in-production and final product monitoring and measurement;

b) a system for recording the results of production line monitoring and measurement;

c) details of the methods used for control of nonconforming products;

d) details of all required monitoring and measurement of product;

Has such an inspection and test plan been documented? Yes □ No □

Please attach a copy of this plan.

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

Is such information available at these locations? Yes □ No □

11.3 Criteria concerning monitoring and measurement product records

Monitoring and measurement records that demonstrate the conformance of the final product to the requirements shall include as a minimum:

— identification of the product;

— monitoring and measurement performed;

— monitoring and measurement results;

— criteria of acceptance;

— nonconformities;

— date of monitoring and/or measurement;

— person(s) authorizing release of product.

Are such records maintained? Yes □ No □

Do they contain the information described? Yes □ No □

Where are they maintained? .....

11.4 Criteria concerning product records

The following records shall be maintained for each product under this product certification scheme:

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

b) environmental conditions and results of monitoring and measurement performed on the prototype product to verify conformity to the requirements;

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 requirements;

d) schematic drawings of primary and secondary circuits;

e) list of primary circuit components, including a description or drawing of the component and relevant test data to demonstrate conformity to the applicable requirements.

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).

Are such records maintained? Yes □ No □

Do they contain the information described? Yes □ No □

Who has the authority and responsibility to maintain these records?

Name: .....

Where are they located? .....

12 Control of nonconforming product

Criteria: The quality management system shall comply with the requirements of 8.3 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified).

12.1 The organization shall establish a documented procedure for control of nonconforming products.

Has such a procedure been implemented? Yes □ No □

12.2 Components and final products that have been reworked or repaired to comply with the requirements shall be re-verified.

Is this done? Yes □ No □

12.3 Products which bear the certification body's certification mark and which do not comply with the requirements or have not been covered by the product certification scheme shall have the certification mark removed before they are shipped from the facility.

Is this done? Yes □ No □

13 Corrective action Criteria: The quality management system shall comply with the requirements of 8.5.2 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified).
13.1 The organization shall establish a documented procedure for corrective action. Has such a procedure been implemented? Yes □ No □
13.2 The product nonconformities shall be investigated to determine the cause. Is this done? Yes □ No □
13.3 After the cause of nonconformity has been determined, appropriate action shall be taken to avoid repetition. Is this done? Yes □ No □
13.4 Provide an example of a record of corrective action.
14 Preventive action Criteria: The quality management system shall comply with the requirements of 8.5.3 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified).
14.1 The organization shall establish a procedure for preventive action. Has such a procedure been implemented? Yes □ No □
14.2 Any potential nonconformities of the product should be investigated to determine the cause. Has this been carried out? Yes □ No □
14.3 When the cause of a potential nonconformity has been determined, appropriate action should be taken to prevent repetition. Has this been carried out? Yes □ No □
14.4 Provide an example of a record of preventive action.
15 Control of documents Criteria: The quality management system shall comply with the requirements of 4.2.3 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified).
15.1 The organization shall establish a procedure for control of documents. Has such a procedure been implemented? Yes □ No □ Please attach the procedure.
16 Control of records Criteria: The quality management system shall comply with the requirements of 4.2.4 of ISO 9001:2000 or an equivalent quality management system standard (which should be identified).
16.1 The organization shall establish a procedure for record control. Has such a procedure been implemented? Yes □ No □ Please attach the procedure.

17 Summary of general details

Date: .....

Organization's name (in full): .....

Address (in full): .....

17.1 Production (supply) location name (in full):

.....

Address (in full): .....

17.2 Design, test and inspection facility (if applicable):

Name (in full): .....

Address (in full): .....

17.3 Representative responsible for handling matters relating to the certification body:

Representative's name: .....

Position: .....

Location: .....

17.4 Category of product manufactured at manufacturing location:

.....

.....

.....

17.5 Application

Completed by organization's representative:

Name: .....

(Print)

Signature: .....

Date: .....

For certification body's use only

Reviewed by head of certification body's assessment team:

Name: .....

(Print)

Signature: .....

Date: .....

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