GUIDE 53

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

First edition 1988

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.

Printed in Switzerland

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.

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

This page intentionally left blank

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.*