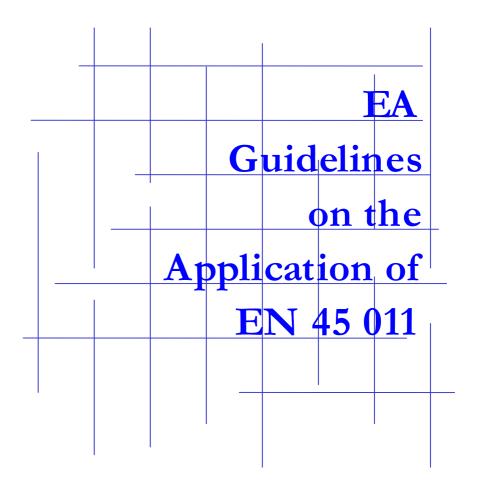


Publication Reference

**EA-6**/01



## **PURPOSE**

The text of this document has been produced by a working group in the International Accreditation Forum (IAF). The purpose of the document is to provide explanations with a view to harmonise the application of ISO/IEC Guide 65/EN 45 011 in the field of accreditation of certification/registration bodies. ISO/IEC Guide 65/EN 45 011 remains the authoritative document and in case of dispute concerning the application of this document, the individual accreditation bodies will adjudicate on unresolved matters.

June 1999 Page 1 of 19

# IAF Copyright

EA acknowledges International Accreditation Forum Inc's copyright of the text of this document.

# Official language

The text may be translated into other languages as required. The English language version remains the definitive version.

# Further information

For further information about this publication, contact your national member of EA.

Country	Member Organisation	Phone No.*	Fax No.*	E-mail *	
EA Members					
Austria	BMWA	+43 1 711 02 248	+43 1 714 3582	guenter.friers@bmwa.gv.at	
Belgium	BELCERT (certification)	+32 2 206 47 21	+32 2 206 57 44	BELCERT@pophost.eunet.be	
	BELTEST (testing/insp)	+32 2 206 46 80	+32 2 206 57 42	BELTEST@pophost.eunet.be	
	BKO/OBE (calibration)	+32 2 206 46 85	+32 2 206 57 45	BKO.OBE@pophost.eunet.be	
Czech Republic	CAI	+420 2 232 4572	+420 2 232 6052	ruzicka@cai.cz	
Denmark	DANAK	+45 35 86 84 20	+45 35 86 85 78	vagn-andersen@efs.dk	
Finland	FINAS	+358 9 61 67 61	+358 9 61 67 341	finas@mikes.fi	
France	COFRAC	+33 1 44 68 82 25	+33 1 44 68 82 21	cofrac@club-internet.fr	
Germany	DAR	+49 30 8104 1940	+49 30 8104 1947	monika.wloka@bam.de	
Greece	ESYD	+30 1 7204 600	+30 1 7204 500	icm@elot.gr	
Hungary	MAB	+36 1 217 3646	+36 1 216 5057	nat@mail.datanet.hu	
Iceland	ISAC	+354 5681122	+354 5685998	arsaell@ls.is	
Ireland	NAB	+353 1 607 3003	+353 1 607 3109	nab@nab.ie	
Italy	SINCERT (cert/insp)	+39 02 5681 4816	+39 02 5681 4880	sincert@sincert.it	
	SINAL (testing)	+39 06 8841 169	+39 06 8841 199	sinal@flashnet.it	
	SIT (calibration)	+39 011 391 92 19	+39 011 346 384	segreterio.sit@imgc.to.cnr.it	
Latvia	LATAK	+371 7 37 3051	+371 7 36 2990	mikelsons@latak.apollo.lv	
Lithuania	LA	+370 2 70 9356	+370 2 70 9358	laccr.bureau@ip.lt	
Netherlands	RvA	+31 30 239 45 00	+31 30 239 45 39	postmaster@rva.nl	
Norway	NA	+47 64 84 84 84	+47 64 84 84 85	norsk.akkreditering@ justervesenet.dep.telemax	
Portugal	IPQ	+351 1 2948201	+351 1 2948202	acredita@mail.ipq.pt	
Slovakia	SNAS	+421 7 396 411	+421 7 396 059	snas@normoff.gov.sk	
Spain	ENAC	+34 91 457 32 89	+34 91 458 62 80	enac@enac.es	
Sweden	SWEDAC	+46 33 17 77 00	+46 33 10 13 92	registrator@swedac.se	
Switzerland	SAS	+41 31 323 35 11	+41 31 323 35 10	sasmaster@eam.admin.ch	
United Kingdom	UKAS	+44 181 917 8494	+44 181 917 8500	rb@ukas.com	
Associate Members					
Estonia	EVS	+372 2 49 3561	+372 6 54 1330	evs@evs.ee	
Slovenia	SMIS	+386 61 178 3000	+386 61 178 3196	samo@usm.mzt.si	

<sup>\*</sup>If you have problems with the phone and fax numbers, please check our website for up-to-date information http://www.european-accreditation.org

June 1999 Page 2 of 19

# EA introduction

The revised European standard EN 45 011 (February 1998) is identical to the international ISO/IEC Guide 65 (1996). The European co-operation for Accreditation (EA) has, within the framework of the International Accreditation Forum (IAF), participated in the drafting of the IAF Guidance on the Application of ISO/IEC Guide 65:1996, General Requirements for Assessment and Accreditation of Certification/Registration bodies. This guidance document was approved by the IAF in March 1999. In June 1999 the EA General Assembly approved the IAF Guidance document as EA Guidelines to the revised EN 45011. The present document therefore contains the original version of the IAF Guidance on the Application of ISO/IEC Guide 65, General requirements for bodies operating product certification systems, in an EA cover.

EA-6/01, First Edition, June 1999, supersedes EAC G2, Rev 00, 06-1996.



June 1999 Page 3 of 19

# International Accreditation Forum, Inc.

# IAF GUIDANCE ON THE APPLICATION OF ISO/IEC GUIDE 65:1996,

# GENERAL REQUIREMENTS FOR BODIES OPERATING PRODUCT CERTIFICATION SYSTEMS

**March 1999** 

June 1999 Page 4 of 19

The International Accreditation Forum, Inc. (IAF) brings together a number of bodies from around the world with the aim of providing for global accreditation coverage for certification/ registration of Management Systems and Product Certification. For further information and copies of this document, please contact any member body of IAF, they are listed together with contact names at the back of this Guidance. This Guidance to ISO/IEC Guide 65 was approved for use by the IAF Board on 27 March 1999 following agreement on the text by vote of the full membership of IAF.

June 1999 Page 5 of 19

# IAF GUIDANCE ON THE APPLICATION OF ISO/IEC GUIDE 65:1996

# GENERAL REQUIREMENTS FOR ASSESSMENT AND ACCREDITATION OF BODIES OPERATING PRODUCT CERTIFICATION SYSTEMS

# **CONTENTS**

Introduction to IAF Guidance to Guide 65	8
1. Scope  IAF Guidance to clause 1.1 (G.1.1.)  IAF Guidance to clause 1.2. (G.1.2.)	<b>9</b> 9 9
2. References	9
3. Definitions  IAF Guidance to clause 3 (G.3.1.)	<b>9</b>
4 Certification body	10
<ul> <li>4.1. General provisions <u>IAF Guidance to clause 4.1.</u> (G.4.1. to G.4.7.)</li> <li>4.2. Organization</li> </ul>	10 10 10
IAF Guidance to clause 4.2. (G.4.8. to G.4.32.) 4.3. Operations  IAF Guidance to clause 4.3. (G.4.33.)	10 13 13
<ul> <li>4.4. Subcontracting <u>IAF Guidance to clause 4.4.</u> (G.4.34. to G.4.36.)</li> <li>4.5. Quality system</li> </ul>	14 14 14
<u>IAF Guidance to clause 4.5.</u> (G.4.37. to G.4.38.)	14
<ul><li>4.6. Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification</li><li>4.7. Internal audits and management reviews</li><li>IAF Guidance to clause 4.7. (G.4.39. to G.4.40.)</li></ul>	15 15
4.8. Documentation <u>IAF Guidance to clause 4.8.</u> (G.4.41. to G.4.42.)	15 15
<ul><li>4.9. Records</li><li>4.10. Confidentiality</li></ul>	15 15
5. Certification body personnel	16
5.1. General	16
5.2. Qualification criteria  IAF Guidance to clause 5. (G.5.1. to G.5.2.)	16 16
6. Changes in the certification requirements	16
7. Appeals, complaints and disputes  LAF Guidance to clause 7 (G.7.1, to G.7.4.)	<b>16</b>

June 1999 Page 6 of 19

# EA-6/01 • EA Guidelines on the Application of EN 45 011

8. Application for certification	17
8.1. Information on the procedure	17
8.2. The application	17
9. Preparation for evaluation	17
10. Evaluation	17
11. Evaluation report	17
12. Decision on certification	17
IAF Guidance to clause 12 (G.12.1. to G.12.7.)	17
13. Surveillance	18
IAF Guidance to clause 13 (G.13.1. to G.13.2.)	18
14. Use of licences, certificates and marks of conformity	19
IAF Guidance to clause 14 (G.14.1. to G.14.4.)	19
15. Complaints to suppliers	19

June 1999 Page 7 of 19

# IAF GUIDANCE ON THE APPLICATION OF ISO/IEC GUIDE 65:1996

# GENERAL REQUIREMENTS FOR BODIES OPERATING PRODUCT CERTIFICATION SYSTEMS

#### Introduction to IAF Guidance to Guide 65

ISO/IEC Guide 65:1996 is an International Guide which sets out criteria for bodies operating certification of products. If such bodies are to be accredited in a worldwide harmonised manner as complying with Guide 65 some Guidance to the Guide is necessary. These guidance notes provide it. One aim is to enable accreditation bodies to harmonise their application of the standards against which they are bound to assess certification bodies. This is an important step towards mutual recognition of accreditation. It is hoped that this Guidance will also be useful to certification bodies themselves and to those whose decisions are guided by their certificates.

For convenience, the headings from ISO/IEC Guide 65 are first printed in **bold**; Guidance where it is offered is, for ease of reference, identified with the letter "G".

This Guidance will form the basis of mutual recognition agreements between accreditation bodies, and is considered necessary for the consistent application of ISO/IEC Guide 65. Members of the IAF Multilateral Agreement (MLA), and applicants for membership in that Agreement, will assess each others' implementation of ISO/IEC Guide 65, and all of this Guidance is expected to be adopted by accreditation bodies as part of their general rules of operation.

The term "shall" is used throughout this document to indicate those provisions which, reflecting the requirements of ISO/IEC Guide 65, are mandatory. The term "should" is used to indicate those provisions which, although they constitute guidance for the application of the requirements, are expected to be adopted by a certification body. Any variation from the guidance by a certification body shall be an exception. Such variations will only be permitted on a case by case basis after the certification body has demonstrated to the accreditation body that the exception meets the requirements of the relevant clause of ISO/IEC Guide 65 and the intent of this Guidance in some equivalent way.

An accreditation body shall at all times maintain its impartiality as required by clause 2.1 of ISO/IEC Guide 61. Nevertheless, it shall be prepared to discuss this guidance and its interpretation with an applicant body, and, where appropriate, to respond to enquiries.

IAF has prepared this document as guidance on the application of ISO/IEC Guide 65. IAF has also published guidance documents for ISO/IEC Guides 61, 62 and 66.

June 1999 Page 8 of 19

# IAF GUIDANCE ON THE APPLICATION OF ISO/IEC GUIDE 65:1996 GENERAL REQUIREMENTS FOR BODIES OPERATING PRODUCT CERTIFICATION SYSTEMS

# 1. Scope

#### IAF Guidance to clause 1.1

G.1.1 The guidance material contained below is mainly directed at the conventional certification of tangible products. Much of it can also be applied to the situation where the product that is certified is the end product of a process where only the process can be subject to evaluation.

# **IAF Guidance to clause 1.2.**

G.1.2 The product certification system should include the necessary working documents for the purpose of assessment by the certification body e.g. design appraisals, evaluation reports, inspection plans, check lists, test reports.

#### 2. References

#### 3. Definitions

#### IAF Guidance to clause 3

G 3.1 The following definitions apply to the IAF Guidance in this document:

Normative document: Document that provides rules, guidelines or characteristics for activities

or their results.(ISO/IEC Guide 2)

<u>Standard</u>: Document, established by consensus and approved by a recognized

body, that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context. (ISO/IEC Guide 2)

<u>Certification System</u>: System that has its own rules of procedure and management for carrying

out certification. (ISO/IEC Guide 2)

<u>Certification Scheme</u>: Certification system as related to specified products to which the same

particular standards and rules, and the same procedure, apply. (ISO/IEC

Guide 2)

Nonconformity: Deviation of product from specified requirements, or (if the product

certification system includes assessment of the supplier's management system) the absence of, or failure to implement and maintain, one or more required management system elements, or a situation which would, on the basis of available objective evidence raise significant doubt as to the conformity of what the supplier is supplying. (Developed by IAF

from ISO/IEC Guide 2 and ISO 8402)

Production Surveillance: An evaluation to determine the continued conformity of the certified

product with specified requirements. (ISO/IEC Guide 2)

June 1999 Page 9 of 19

# 4 Certification body

# 4.1. General provisions

#### IAF Guidance to clause 4.1.

- G.4.1 Certification bodies shall not practice any form of discrimination such as hidden discrimination by speeding up or delaying the processing of applications.
- G.4.2 To qualify for product certification, applicants shall demonstrate that they have responsibility for ensuring that products comply with the certification requirements. (See definition of supplier in clause 3.1)
- G.4.3 Documents cited in clause 4.1.3 that specify requirements for the product, and, where applicable, the management system to assure quality, shall be available to the applicant and to the public. These may include National/Regional/International standards or parts thereof; other normative documents defining activities such as sampling, testing, inspection, and assessment of an associated quality management system as appropriate; and documents which explain the implementation of the product requirements. Documents developed by the certification body should use a process that takes into account the views of the significant interested parties. The documents should assure a common understanding by the supplier and the certification body and other significant interested parties of the requirements for the product and, where applicable, the quality management system to assure quality.
- G.4.4 When a subjective judgement is required to determine compliance, the certification body should document explanatory information in accordance with G.4.3. The detail of the explanation should assure consistent and uniform application of the requirements and related certification decisions.

# 4.2. Organization

#### IAF Guidance to clause 4.2.

- G.4.5 Accreditation shall only be granted to a body which is a legal entity as referenced in clause 4.2.d) of ISO/IEC Guide 65, and will be confined to declared scopes, activities and locations. If the certification activities are carried out by a legal entity which is part of a larger organization, the links with other parts of the larger organization shall be clearly defined and should demonstrate that no conflict of interest exists, see guidance G.4.21 to G.4.23 inclusive. Relevant information on activities performed by the other parts of the larger organization shall be documented.
- G.4.6 Demonstration that a certification body is a legal entity, as required under clause 4.2.d) of ISO/IEC Guide 65, means that if an applicant certification body is part of a larger legal entity, accreditation shall only be granted to the entire legal entity. In such a situation, the structure of the entire legal entity may be subject to audit by the accreditation body in order to pursue specific audit trails and/or review records relating to the certification body. The part of the legal entity that forms the actual certification body may trade under a distinctive name, which should appear on the accreditation certificate.
- G.4.7 For the purposes of clause 4.2.d) of ISO/IEC Guide 65, certification bodies which are part of government, or are government departments, will be deemed to be legal entities on the basis of their governmental status. Such bodies' status and structure shall be formally documented and the bodies shall comply with all the requirements of ISO/IEC Guide 65.

June 1999 Page 10 of 19

- G.4.8 If the certification body and its client are both part of government, the two bodies shall not directly report to a person or group having operational responsibility for both. The certification body shall, in view of the impartiality requirement, be able to demonstrate how it deals with a case where both itself and its client are part of government. The certification body shall demonstrate that the applicant receives no advantage and that impartiality is assured.
- G.4.9 Impartiality and independence of the certification body should be assured at three levels:
  - Strategy and Policy;
  - Decisions on Certification;
  - Evaluation.
- G.4.10 Impartiality, as required by clause 4.2.a) of ISO/IEC Guide 65 can only be safeguarded by a structure, as required by clause 4.2.e) of ISO/IEC Guide 65, that enables "the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the certification system".
- G.4.11 The structure required by ISO/IEC Guide 65, clause 4.2.e) for the safeguarding of impartiality shall be separate from the management established to meet the requirements of ISO/IEC Guide 65, clause 4.2.c), unless the entire management function is performed by a committee or group that is constituted to enable participation of all parties as required by ISO/IEC Guide 65, clause 4.2.e).
- G.4.12 Clause 4.2.e) of ISO/IEC Guide 65 is intended to counteract any tendency on the part of the owners of a certification body to allow commercial or other considerations to prevent the consistent technically objective provision of its service. Conformity with this clause is particularly relevant when the finance to set up a certification body has been provided by a particular interest which predominates in the shareholding and/or the board of directors.
- G.4.13 Clause 4.2.e) of ISO/IEC Guide 65, requires that the documented structure of the certification body has built into it provision for the participation of all the significantly concerned parties. This should normally be through some kind of committee. The structure established should be prescribed in the certification body's written constitution and should not be subject to change without notification to the accreditation body.
- G.4.14 Application of clause 4.2.e) of ISO/IEC Guide 65 requires judgment on whether all parties significantly concerned in the system are able to participate. What is essential is that all identifiable major interests should be given the opportunity to participate, and that a balance of interests, where no single interest predominates, is achieved. The members should normally be chosen at least from among representatives of the following groups: manufacturers or suppliers, users, conformity assessment experts. For practical reasons there may be a need to restrict the number of persons.
- G.4.15 On request of the committee or equivalent referred to in clause 4.2.e) of ISO/IEC Guide 65, the management responsible for the various functions described in clause 4.2.c) of ISO/IEC Guide 65 should provide to that committee or equivalent all the necessary information, including the reasons for all significant decisions, actions, and the selection of persons responsible for particular activities, in respect of certification, to enable the certification body to ensure proper and impartial certification. If the advice of this committee or equivalent is not respected in any matter by the management, the committee or equivalent shall take appropriate measures, which may include informing the accreditation body.
- G 4.16 The certification body should be able to demonstrate that supervision of the finances of the body by the responsible management (4.2.c) 5.) has included actions to confirm conformity with 4.2.i)

June 1999 Page 11 of 19

- G.4.17 If the decision to issue or withdraw certification in accordance with clause 4.2.n) of ISO/IEC Guide 65 is taken by a committee comprising, among others, representatives from one or more clients, the operational procedures of the certification body should ensure that these representatives do not have a significant influence on decision making. This can e.g. be assured by the distribution of voting rights or some other equivalent means.
- G.4.18 Clause 4.2.0) of ISO/IEC Guide 65 addresses two separate requirements. First, the certification body shall not under any circumstances provide the services identified in subparagraphs 1), 2) and 3) of that clause. Secondly, although there is no specific restriction on the services or activities a related body may provide, these shall not affect the confidentiality, objectivity or impartiality of the certification body.
- G.4.19 Activities under clause 4.2.0) of ISO/IEC Guide 65 by a related body and certification should never be marketed together and nothing should be stated in marketing material or presentation, written or oral, to give the impression that the two activities are linked.
- G.4.20 Nothing should be said by a certification body that would suggest that certification would be simpler, easier or less expensive if any specified activities under clause 4.2.0) of ISO/IEC Guide 65 were used.
- G.4.21 A related body, as referred to in clause 4.2.0) of ISO/IEC Guide 65, is one which is linked to the certification body by common ownership, in whole or part, directors, contractual arrangement, a common name, informal understanding or other means such that the related body has a vested interest in any certification decision or has a potential ability to influence the process.
- G.4.22 The certification body should analyse and document the relationship with related bodies to determine the possibilities for conflict of interest with provision of certification and identify those bodies and activities that could, if not subject to appropriate controls, affect confidentiality, objectivity or impartiality.
- G.4.23 Certification bodies shall demonstrate how they manage their certification business and any other activities so as to eliminate actual conflict of interest and minimise any identified risk to impartiality. The demonstration shall cover all potential sources of conflict of interest, whether they arise from within the certification body or from the activities of related bodies. Accreditation bodies will expect certification bodies to open up these processes for audit. This may include, to the extent practicable and justified, pursuit of audit trails to review records of both the certification body and its related body for the activity under consideration. In considering the extent of such audit trails account should be taken of the certification body's history of impartial certification. If evidence of failure to maintain impartiality is found there may be a need to extend the audit trail back into related bodies to provide assurance that control over potential conflicts of interest has been re-established.
- G.4.24 The requirements of clause 4 and clause 5.2.2 of ISO/IEC Guide 65 mean that personnel, including those acting in a managerial capacity, shall not be employed to conduct an evaluation as part of the certification process if they have been involved in activities as described under clause 4.2.0) of ISO/IEC Guide 65 towards the applicant or supplier in question, or any body related to the supplier, (see G.4.21), within the last two years. Situations such as an employer's involvement or previous involvement with the supplier being evaluated may present individuals involved in any part of the certification process with a conflict of interest. The certification body has a responsibility to identify and evaluate such situations and to assign responsibilities and tasks so as to ensure that impartiality is not compromised.

June 1999 Page 12 of 19

- G.4.25 Clause 4.2.c).1) of ISO/IEC Guide 65 differentiates between testing, inspection, evaluation and certification. Clause 4.2.f) of ISO/IEC Guide 65 requires that each decision on certification is taken by a person(s) different from those who carried out the evaluation. Inspection, among others, is an evaluation task. Therefore the certification decision shall not be undertaken by a person who has undertaken an inspection activity being considered as part of that certification.
- G.4.26 The senior executive, staff and/or personnel mentioned in clause 4.2. of ISO/IEC Guide 65 need not necessarily be full-time personnel, but their other employment shall not be such as to compromise their impartiality.
- G.4.27 The certification body should require all evaluation sub-contractors or external assessors/auditors to give undertakings regarding the marketing of any activities under clause 4.2.0) equivalent to those required by guidance G.4.19 and G.4.20.
- G.4.28 The certification body should be responsible for ensuring that neither related bodies, nor sub-contractors, nor external assessors/auditors operate in breach of the undertakings that they have given. It should also be responsible for implementing appropriate corrective action in the event that such a breach is identified.
- G.4.29 The certification body is allowed to explain its findings and/or clarify the requirements of the standards but shall not give prescriptive advice or consultancy as part of an evaluation. This does not preclude normal exchange of information with the clients and other interested parties.
- G.4.30 The policies and procedures referred to in 4.2.p) should ensure that all disputes and complaints are dealt with in a constructive and timely manner. Where operation of such procedures has not resulted in the acceptable resolution of the matter, or where the proposed procedure is unacceptable to the complainant or other parties involved, the certification body's procedures shall provide for an appeals process. The appeals procedure should include provision for the following
  - the opportunity for the appellant to formally present its case;
  - provision of an independent element or other means to ensure the impartiality of the appeals process;
  - provision to the appellant of a written statement of the appeal findings including the reasons for the decisions reached.

The certification body shall ensure that all interested parties are made aware, as and when appropriate, of the existence of the appeals process and the procedures to be followed.

# 4.3. Operations

# **IAF Guidance to clause 4.3.**

G. 4.31 Certification of products based on testing/inspection of batches of the product should be in accordance with a defined sampling schedule utilising statistically proven techniques with stated confidence levels.

In specifying any requirements for sampling, the certification body shall establish documented procedures for the selection and control of samples to ensure traceability, and that they are representative of production.

June 1999 Page 13 of 19

# 4.4. Subcontracting

#### IAF Guidance to clause 4.4.

- G.4.32 A certification body may issue certificates on the basis of subcontracted work (e.g. testing or inspection) carried out by another body, provided that the arrangement with the subcontracted body requires it to comply with all the relevant requirements of ISO/IEC Guide 65 and where applicable, ISO/IEC Guides 25, 39 and 62 in accordance with clause 4.3.
- G 4.33 The certification body shall have contractual agreements in place for any sub-contracted testing/inspection of the product. The certification body shall specify the tests/inspections required, and be able to justify selection of the testing/inspection facilities. Where a certification body certifies in accordance with guidance G.4.32, it shall have procedures that ensure conformity with all relevant clauses of ISO/IEC Guide 65 by subcontracted bodies. If this assurance is based partly or in full on the accreditation of the subcontractor, the scope of accreditation should cover the activities to be carried out under the certification scheme and the certification body shall have records available to show that it has checked the status of the accreditation of the subcontractor.
- G 4.34 Activities carried out by subcontracted bodies shall give the same confidence as those carried out by the certification body itself. Evaluation of the report and the decision on certification shall be made only by the certification body itself, and not by any other body. Where joint evaluations are undertaken, each certification body shall satisfy itself that the whole of the evaluation has been satisfactorily undertaken by competent personnel.
- G 4.35 Where independent testing facilities are not available, the certification body should ensure that specified controls are in place at the supplier's testing facilities, that they are managed in a manner which provides confidence in the results obtained from the tests, and that records are available to justify the confidence.
- G.4.36 Note 2 describes a situation where the certification body will be reliant on the work of another body. Such reliance needs to be supported by a technical evaluation of the work undertaken. Such an evaluation shall be documented by the certification body.
  - Note 3 also describes a situation where the certification body will be reliant on the work of another body. It should therefore ensure that information on any evaluation work on which it relies is updated as appropriate.

## 4.5. Quality system

## **IAF Guidance to clause 4.5.**

- G.4.37 Clause 4.5.3.i) of ISO/IEC Guide 65 requires the certification body to monitor the performance of its own personnel. In addition to other methods of monitoring performance, provision should be made, where applicable, for the periodic witnessing of those activities normally undertaken by its personnel at supplier and subcontractor sites.
- G.4.38 The description required by clause 4.5.3.e) of ISO/IEC Guide 65 should include an indication of which party or parties each member of a board or a committee is representing.

June 1999 Page 14 of 19

# 4.6. Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification

## **IAF Guidance to Clause 4.6.**

G 4.39 Where certification is suspended rather than withdrawn, the certification body shall require that, during the period of suspension, the supplier makes no misleading claims as to the status of certification, and ceases to use the certification mark on the products manufactured since the date of notification of suspension.

If relevant, the certification body may require in addition:

- that no certified product is placed upon the market;
- that potentially defective certified product is subject to corrective action, including product recall where appropriate.

## 4.7. Internal audits and management reviews

#### IAF Guidance to clause 4.7.

- G.4.40 Clause 4.7 of ISO/IEC Guide 65 does not mention a specific period in which internal audits of the certification body's quality system and management reviews of the certification body's quality system should take place. Internal audits followed by management reviews of the body's quality system should be carried out at least once each year.
- G.4.41 The records of internal audits and management reviews should be made available to the accreditation body on request.

#### 4.8. Documentation

#### IAF Guidance to clause 4.8.

- G 4.42 The information required by clause 4.8.1.c) of ISO/IEC Guide 65 should clearly detail the precise basis of certification based on the elements included or referred to in clause 1.2 of ISO/IEC Guide 65.
- G.4.43 The description of the means by which the body obtains financial support referred to in clause 4.8.1.d) of ISO/IEC Guide 65 should be sufficient to show whether or not the body can retain its impartiality. The description (e.g. financial report) should also demonstrate that the body will have sufficient resources to continue its operations.
- G.4.44 The document referred to in clause 4.8.1.g) of ISO/IEC Guide 65 should include, in addition to listings of products and suppliers, the standards to which products are certified, see clause 12.3.b)2) of ISO/IEC Guide 65.

#### 4.9. Records

#### 4.10. Confidentiality

June 1999 Page 15 of 19

# 5. Certification body personnel

#### 5.1. General

#### 5.2. Qualification criteria

## **IAF Guidance to clause 5.**

G.5.1 The certification body shall have sufficient personnel for the operation of the product certification system and schemes, see clause 4.2.j) of ISO/IEC Guide 65. This includes technical personnel competent for the development of the product specific criteria (explanatory documents, sampling, testing and inspection requirements, management systems elements/quality systems evaluation and certification).

The certification body shall have personnel technically competent to assess the products and the processes and decide whether or not to certify a product on the basis of information from the evaluation process, including inspection and test results.

Records should show which personnel are designated as competent and the date of validation.

# 6. Changes in the certification requirements

# 7. Appeals, complaints and disputes

#### IAF Guidance to clause 7

- G.7.1 Personnel, including those acting in a managerial capacity, should not be employed to investigate any appeal, complaint or dispute if they have been involved in activities as described under clause 4.2.0) of ISO/IEC Guide 65 towards the applicant or supplier in question, or any body related to the supplier, (see G.4.21), within the last two years.
- G.7.2 Appeals, complaints and disputes represent a source of information as to possible nonconformity. On receipt of a complaint the certification body shall establish, and, where appropriate, take action on, the cause of any nonconformity found, including any predetermining (or predisposing) factors within the certification body's management system.
- G.7.4 The certification body should use such investigation to develop remedial/corrective action, which should include measures for:
  - minimizing the consequences of any nonconformity;
  - restoring conformity with certification requirements as quickly as practicable;
  - preventing recurrence of the nonconformity;
  - assessing the effectiveness of the remedial/corrective measures adopted.

June 1999 Page 16 of 19

- 8. Application for certification
- 8.1. Information on the procedure
- 8.2. The application
- 9. Preparation for evaluation
- 10. Evaluation
- 11. Evaluation report

## 12. Decision on certification

### **IAF Guidance to clause 12**

- G.12.1 The information gathered during the certification process should be sufficient:
  - for the certification body to be able to take an informed decision on certification;
  - for traceability to be available in the event, for example, of an appeal or for planning for the next activity (possibly by a different person or body);
  - to ensure continued conformity with certification requirements.
- G.12.2 Any information on which a decision is based which comes from any source other than the evaluation process should be made known to the applicant or supplier along with information on the evaluation process. The applicant or supplier should be given the opportunity to comment on it.
- G.12.3 Records should provide objective evidence to support the evaluation and decision, and the documentation made available to the supplier should indicate the applicable certification system as detailed in clause 1.2 of ISO/IEC Guide 65.
- G.12.4 Where the certification body takes account of work related to certification performed by another body, the certification body should have arrangements in place for confirming the scope and currency of the certification it is relying upon and any other data pertaining to the competency of the body it is relying upon, before the issue of its own certification.
- G.12.5 Certification shall not be granted until all nonconformities as defined in Guidance G.3.1 have been corrected and the correction verified by the certification body (by site visit or other appropriate forms of verification). The nonconformities and their resolution should be documented by the certification body.
- G.12.6 An accredited certificate should state the standard(s) or other normative document(s) against which certification is granted, the name of the certification body that issued it and the name of the relevant accreditation body or bodies. It should be made clear that the certificate is issued within the accredited scope of the certification body.

June 1999 Page 17 of 19

- G.12.7 All certificates issued by an accredited certification body which are within its scope of accreditation should bear the relevant accreditation body's mark. In the case of a supplier requesting a certificate to be issued without an accreditation mark, for the certificate to be regarded as an accredited certificate it shall include the name of the accreditation body and the registration number.
- G.12.8 In those cases where a certification body has been accredited by more than one accreditation body, the certificate should bear at least one accreditation mark, as appropriate to suit market needs

#### 13. Surveillance

## IAF Guidance to clause 13

- G 13.1 Surveillance undertaken by the certification body should give assurance that certified products continue to comply with the criteria of the standard to which they are certified. The surveillance procedures required under clause 13.1 of ISO/IEC Guide 65 in a certification system should include, as appropriate, surveillance testing, surveillance inspection and/or surveillance of the applicant's quality system (see also clause 1.2 of ISO/IEC Guide 65). Samples for surveillance testing should be typical of production. Preferably they should be selected by the certification body from the factory (e.g. production, stock) or the open market (e.g. distributors' or retailers' stock). Further information on surveillance procedures can be found in ISO/IEC Guides 28, clause 8, and 53, clause 7.
- G 13.2 Surveillance activities conducted for a specific supplier may vary as the supplier's demonstrated ability to meet certification requirements on an ongoing basis changes. In such situations, certification bodies should have documented procedures for altering surveillance activities.
- G 13.3 Many activities are available to certification bodies to conduct surveillance. These techniques can often be conducted at various points and at varying frequencies during the design/production/distribution/sale/use chain. At the same time, characteristics of production processes can aid or hinder ongoing conformity with certification requirements. As a part of meeting the requirements of clause 4.2.j) of ISO/IEC Guide 65, certification bodies should therefore have personnel qualified to make appropriate choices in the design and operation of surveillance programs.

#### G 13.4 Since

- surveillance plays a direct role in achieving the intended benefits from a certification system,
- a wide variety of activities are available from which to operate a surveillance program,
- the elements of a surveillance program can change on an ongoing basis,

the committee or equivalent by which the certification body complies with clause 4.2.e) of ISO/IEC Guide 65 should address surveillance. Specifically, a mechanism should be in place by which the input of parties significantly concerned with the surveillance activities of the certification body can be received.

- G 13.5 Some typical activities used in surveillance are:
  - inspection or testing of certified products selected at the location of manufacture, assembly, distribution, or from the market;
  - audit of inspection or testing of products conducted by the manufacturer;

June 1999 Page 18 of 19

• audit of a quality system which includes elements designed to assure ongoing conformity of products with certification requirements.

# 14. Use of licences, certificates and marks of conformity

## **IAF Guidance to clause 14**

- G.14.1 The certification body should avoid using the same mark to indicate different systems of conformity certification, and should avoid confusion between the meaning of its marks if there is more than one. This does not exclude the use of the same corporate logo in different marks for different systems of conformity.
- G.14.2 The certification body should have documented procedures for the use of its mark, and for the procedures it is to follow in case of misuse, including false claims as to certification and false use of certification body marks.
- G.14.3 If a certification body incorrectly claims accredited status for certificates issued before appropriate accreditation has been granted, the accreditation body may require it subsequently to withdraw them.
- G.14.4 A certification body should have procedures to ensure that its clients do not allow its marks to be used in a way which may be likely to confuse purchasers.
- G. 14.5 Where the certification body makes use of a mark which it has been assigned from another body, e.g. the owner of the mark, its agreement with that body shall ensure conformity with the intent of all sections of this clause.

# 15. Complaints to suppliers

End of IAF Guidance on ISO/IEC Guide 65

June 1999 Page 19 of 19