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หลักเกณฑ์ / เงื่อนไข

เอกสารอ้างอิงประกอบการตรวจประเมินหน่วยรับรอง

GAP และ Organic



สำนักรับรองมาตรฐานสินค้าและระบบคุณภาพ
สำนักงานมาตรฐานสินค้าเกษตรและอาหารแห่งชาติ
กระทรวงเกษตรและสหกรณ์

คำนำ

เอกสาร IAF Guidance on the Application of ISO/IEC Guide 65:1996 General Requirements for Bodies operation Product Certification Systems Issue 2 (IAF GD 5:2006) เป็นเอกสารที่สำนักงานมาตรฐานสินค้าเกษตรและอาหารแห่งชาติ (มกอช.) ใช้เป็นข้อกำหนดในการรับรองระบบงานแทน IAF Guidance ฉบับเดิม(Issue 1 : 1996) โดยใช้ร่วมกับมาตรฐาน ISO/IEC Guide 65:1996 ในการรับรองระบบงานสาขา GAP (Good Agricultural Practices) และ Organics โดยได้จัดทำเป็นเอกสารหลักเกณฑ์/เงื่อนไข เอกสารอ้างอิงประกอบการตรวจประเมินหน่วยรับรองระบบงาน GAP และ Organic เพื่อแจกจ่ายให้กับผู้ยื่นคำขอ ที่ต้องการยื่นขอการรับรองระบบงาน (Accreditation) และหน่วยรับรอง (Certification Body) ที่ได้รับการรับรองระบบงาน จาก มกอช.

โดย มกอช.นำเอกสารดังกล่าวมาใช้เป็นแนวทางในการตรวจรับรองระบบงาน ดังนั้น เพื่อให้เกิดความเข้าใจตรงกันระหว่าง มกอช.กับผู้ยื่นคำขอและหน่วยรับรอง มกอช.จึงได้จัดทำสำเนาเอกสารนี้ขึ้นเพื่ออำนวยความสะดวกให้กับผู้ยื่นคำขอ/หน่วยรับรอง และผู้สนใจในการขอการรับรองระบบงานตามมาตรฐานดังกล่าว และประกาศใช้เอกสารฉบับนี้เป็นแนวทางในการให้การรับรองระบบงาน

International Accreditation Forum, Inc.

IAF Guidance Document

IAF Guidance on the Application of ISO/IEC Guide 65:1996

General Requirements for Bodies operating Product Certification Systems

Issue 2

(IAF GD 5:2006)

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Accreditation reduces risk for business and its customers by assuring them that accredited bodies are competent to carry out the work they undertake. Accreditation bodies that are members of the International Accreditation Forum, Inc. (IAF) are required to operate at the highest standard and to require the bodies they accredit to comply with appropriate international standards and IAF Guidance to the application of those standards.

Accreditations granted by accreditation body members of the IAF Multilateral Recognition Arrangement (MLA), based on regular surveillance to assure the equivalence of their accreditation programs, allows companies with an accredited conformity assessment certificate in one part of the world to have that certificate recognized everywhere else in the world.

Therefore certificates in the fields of management systems, products, services, personnel and other similar programs of conformity assessment issued by bodies accredited by members of the IAF MLA are relied upon in international trade.

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0.1. Introduction to IAF Guidance

0.1.1. ISO/IEC Guide 65:1996 is an International Standard which sets out criteria for bodies operating certification of products, services and processes. If such bodies are to be accredited worldwide in a harmonized 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 harmonize 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 intended that this Guidance should also be useful to certification bodies themselves and to those whose decisions are guided by their certificates.

0.1.2. This guidance document does not include the text of ISO/IEC Guide 65. Users must purchase that document from the appropriate Standards organization. Guidance, where it is offered, is identified with the letter "G". The requirements against which conformity is determined are found in ISO/IEC Guide 65. This IAF Guidance does not create further requirements.

0.1.3. This Guidance will form the basis of mutual recognition arrangements between accreditation bodies, and is considered necessary for the consistent application of ISO/IEC Guide 65. Members of the IAF Multilateral Recognition Arrangement (MLA), and applicants for membership in that Arrangement, 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.

0.1.4. 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 guidance, which, although not mandatory, is provided by IAF as a recognized means of meeting the requirements. Certification bodies whose systems do not follow the IAF Guidance in any respect will only be eligible for accreditation if they can demonstrate to the accreditation body that their solutions meet the relevant clause of ISO/IEC Guide 65 in an equivalent way.

0.1.5. A certification body may seek advice from the accreditation body on any matter which may affect its accreditation. The accreditation body should respond with advice or a decision.

0.1.6. IAF has prepared this document as guidance on the application of ISO/IEC Guide 65. IAF has also prepared guidance documents for ISO/IEC Guide 61, 62, 66 and ISO/IEC 17024.

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APPLICATION GUIDANCE TO CLAUSES OF ISO/IEC GUIDE 65: 1996

General Requirements for Bodies operating Product Certification Systems

1. Scope

IAF Guidance to clause 1.1

G.1.1.1 The guidance material contained below is mainly directed at certification of tangible products. It can also be applied to certification of non-tangible products (e.g. software, service) and to process certification. The distinctive features of service certification and of process certification are addressed in Annex 1 and Annex 2, respectively. Unless otherwise noted, the word "product" is intended to include services and processes.

IAF Guidance to clause 1.2 (G.1.2.1 to G 1.2.3)

G.1.2.1 In establishing a product certification system the purpose is to demonstrate to the marketplace and/or regulators that a supplier can and does produce products in conformity with a normative document.

G.1.2.2 Within a product certification system the roles of a supplier and of the certification body are complementary, the former being responsible for conformity of the product (see clause 3.1 of ISO/IEC Guide 65) and the latter being responsible for the operation of a certification scheme providing confidence on the conformity of the product to the marketplace and/or regulators.

G.1.2.3 In some cases inspection is a part of product certification. The purpose of inspection is to provide information on the compliance of a specific product to the party on whose behalf the inspection is performed. If inspection is part of a product certification scheme then that party is the certification body ł

G.1.2.4 Guidance on different types of product certification systems including various types of assessment may be obtained from ISO/IEC Guide 67 or other relevant ISO/IEC documents.

2. References

ISO/IEC Guide 67 Conformity assessment – Fundamentals of product certification;

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ISO/IEC 17000 Conformity assessment – Vocabulary and general principles;

ISO/IEC 17011 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies;

ISO/IEC 17020 General criteria for the operation of various types of bodies performing inspection;

ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories;

ISO/IEC 17030 Conformity assessment – General requirements for third-party marks of conformity;

ISO/IEC 19011 Guidelines for quality and/or environmental management systems auditing.

3. Definitions

IAF Guidance to clause 3 (G.3.1)

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. The term "normative document" is a generic term that covers such documents as standards, technical specifications, codes of practice and regulations. A "document" is to be understood as any medium with information recorded on or in it. The terms for different kinds of normative documents are defined considering the document and its content as a single entity (ISO/IEC 17000).

Certification System: Conformity assessment system that includes selection, determination, review, and finally certification as the attestation activity.

Certification Scheme: Certification system related to specified products to which the same specified requirements, specific rules and procedures apply (ISO/IEC 17000). A scheme may be developed among others by a certification body or by a "scheme owner" representing a specific group of interests. The scheme may contain requirements on conformity assessment procedures and functions of the certification bodies complementary to those established by ISO/IEC Guide 65.

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Nonconformity: Deviation from specified requirements related to the product or to certification requirements defined by the certification body. The certification body is free to define different grades of deviations and areas for improvement (e.g. major or minor nonconformities, observations, etc). However all deviations which lead to any doubts about the conformity of the product to specified requirements should be dealt with as set out in G.12.6.

Surveillance: Systematic iteration of conformity assessment activities as a basis for maintaining the validity of the statement of conformity (ISO/IEC 17000).

Formal Certification Documents: Documents issued under the procedures of a certification system and attesting that a demonstration has been made that a product fulfils specific requirements.

4. Certification body

4.1. General provisions

IAF Guidance to clause 4.1. (G.4.1.1 to G 4.1.5)

G.4.1.1 Certification bodies shall not practice any form of discrimination such as hidden discrimination by speeding up or delaying the processing of applications.

G.4.1.2 To qualify for product certification, applicants shall demonstrate that they have responsibility for ensuring that products conform with the certification requirements.

G.4.1.3 Documents cited in clause 4.1.3 of ISO/IEC Guide 65 that specify the requirements for the product, and other applicable requirements shall be available to the applicant and to the public on request. Normative documents should be developed, validated and maintained by a process enabling technical input of the interested parties such as suppliers, regulators and users of the product. Validation should be consistent with the characteristics of the product to be certified.

G.4.1.4 Documents cited in clause 4.1.3 of ISO/IEC Guide 65 include those developed by scheme owners (See definition of certification scheme). The scheme owners should adhere to the same principles for the development and maintenance of the documents.

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G.4.1.5 In case of process certification, the documents cited in clause 4.1.3 of ISO/IEC Guide 65 shall clearly identify the processes to be assessed, the relevant requirements and the methods for assessment of conformity.

4.2. Organization

IAF Guidance to clause 4.2. (G.4.2.1 to G 4.2.32.)

G.4.2.1 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 and locations. The accreditation scope for a product certification body should identify the certification schemes, products and normative documents used for the certification.

G.4.2.2 The accreditation scope for certification bodies may be defined in terms of categories of products or families of normative documents provided the product certification body has a proven capability as a product certifier and demonstrate it has:

- access to competent personnel for the complete category of products;
- the technical ability to develop, extend or modify certification schemes;
- procedures for the validation of these extended or modified schemes.

G.4.2.3 If the certification activities are carried out by a legal entity which is part of a larger organisation, the links with other parts of the larger organization shall be clearly defined and should demonstrate that no conflict of interest exists as defined in guidance G 4.2.20 to G 4.2.22. Relevant information on activities performed by the other parts of the larger organization shall be given by the certification body to the accreditation body.

G.4.2.4 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 can only demonstrate it's legal entity status within part of a larger legal entity, accreditation shall only be granted to the larger legal entity. In the situation where the certification body is part of a large legal entity, in order to pursue specific audit trails and/or review records relating to the certification body, other functions of the large legal entity might be assessed. This shall be limited to those functions whose activities are intended to fulfil the requirements of ISO/IEC Guide 65 .

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G.4.2.5 The part of the legal entity that forms the actual certification body may trade (be identified) under a distinctive name, which should appear on the accreditation certificate and certificates issued to certified organizations.

G.4.2.6 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. The status and structure of such bodies shall be formally documented and the bodies shall comply with all the requirements of ISO/IEC Guide 65.

G.4.2.7 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.4.2.8 Impartiality and independence of the certification body should be assured at three levels:

- Strategy and Policy;
- Decisions on Certification;
- Evaluation.

G.4.2.9 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.4.2.10 The structure required by ISO/IEC Guide 65, clause 4.2.e) for the safeguarding of impartiality should 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.4.2.11 The structure required by ISO/IEC Guide 65, clause 4.2.e) should also be such that commercial or other financial considerations do not prevent the consistent, objective provision of the certification body´s service.

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G.4.2.12 Clause 4.2.e) of ISO/IEC Guide 65, requires that the documented structure of the certification body contains provision for the participation of all the significantly concerned parties. This should normally be through some kind of committee, or similar input mechanisms

G 4.2.13 This structure shall be formally established at the highest level within the organization either in the documentation that establishes the certification body's legal status or by some other means that prevents it being changed in a manner that compromises the safeguarding of impartiality. Any change in this structure should take into account advice from the committee, or equivalent, referred to in clause 4.2.e).

This committee, or equivalent, shall

a) assist in developing the policies relating to impartiality of its certification activities

b) counteract any tendency on the part of the owners of a certification body to allow commercial or other considerations to prevent the consistent objective provision of certification activities.

c) advise on matters affecting confidence in certification, including openness and public perception

G.4.2.14 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 are 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, consumers, conformity assessment experts. For practical reasons there may be a need to restrict the number of persons.

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G.4.2.15 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.4.2.16 The requirement for financial stability (referred to in clause 4.2.i) requires the certification body to demonstrate that it has a reasonable expectation of being able to provide and to continue to provide the service in accordance with its contractual obligations. Certification bodies are responsible for providing the accreditation body with sufficient evidence to demonstrate viability, e.g. management reports or minutes, annual reports, financial audit reports, financial plans.

G.4.2.17 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 , for example, be assured by the distribution of voting rights or some other equivalent means.

G.4.2.18 Clause 4.2.o) of ISO/IEC Guide 65 addresses two separate requirements. First, the certification body together with the senior executive and the staff shall not under any circumstances provide the services identified in sub-paragraphs 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.4.2.19 Consultancy services on matters that are barriers to certification would be participation in an active creative manner in the development and ongoing monitoring/improvement of the product, process, or service. by, for example;

a) providing specific support/advise on elements of the design.

b) preparing or producing manual, handbooks or procedures.

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c) involvement in the supplier's monitoring , review and decision making process applicable to the product..

G.4.2.20 Activities listed under clause 4.2.o) of ISO/IEC Guide 65 performed by a related body and certification should never be marketed in such a manner as to give the impression that the two activities are related in a way that might compromise the impartiality of the certification body.

G.4.2.21 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.o) of ISO/IEC Guide 65 were used.

G.4.2.22 A related body, as referred to in clause 4.2.o) of ISO/IEC Guide 65, is one which is linked to the certification body by common ownership in whole or part, common 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.4.2.23 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.4.2.24 Certification bodies shall demonstrate how they manage their certification business and any other activities so as to eliminate actual conflict of interest and minimize 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.

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G.4.2.25 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, should 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.o) of ISO/IEC Guide 65 involving the applicant or supplier in question, or any body related to the supplier, (see G.4.2.20, within the last two years. Situations such as an employee's current or previous involvement at any time with the supplier being evaluated may present 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.

G.4.2.26 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. Testing and inspection, among others, are evaluation tasks. Evaluation tasks include the verification of any corrective actions taken to address any nonconformities identified.

G.4.2.27 The senior executive, staff and/or personnel need not necessarily be full-time personnel, but their other professional activities shall not be such as to compromise their impartiality.

G.4.2.28 The certification body should require all sub-contractors involved in evaluation or external assessors/auditors to give undertakings regarding the marketing of any activities under clause 4.2.o) equivalent to those required by guidance G.4.2.20 and 21.

G.4.2.29 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.4.2.30 The certification body is allowed to explain its findings and/or clarify the requirements of the normative documents 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.4.2.31 The rights mentioned in clause 4.2.g) may include a contract with the scheme owner or any other recognition established under the scheme rules.

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G.4.2.32 The means by which the certification body obtains financial support should be such to allow the certification body to retain its impartiality.

4.3. Operations

IAF Guidance to clause 4.3. (G.4.3.1 to G 4.3.3)

G.4.3.1 The certification body must be able to demonstrate to the accreditation body that all conformity assessment activities it conducts (testing, inspection, quality management system evaluation, surveillance etc.) are carried out in a competent and reliable manner consistent with the applicable requirements of the normative documents for these activities. Demonstration of the competence of the testing activity may be based on a documented evaluation performed by internal or external competent personnel according to appropriate procedures. If the evidence supplied by the certification body does not provide confidence in the testing activity, additional assessment at the testing location should be considered by the accreditation body. The same is applicable to other conformity assessment activities. (For subcontracted activities see G.4.4.2).

G.4.3.2 Requirements of specific certification schemes shall be available to the applicant and on request to the public. These may include documents defining activities such as sampling, testing, inspection, surveillance and assessment of an associated management system as appropriate. Scheme documents should be developed and maintained by a process that takes into account the views of the interested parties.

G.4.3.3 Documents cited in clause 4.3 include those developed by scheme owners (See definition of certification scheme in G.3.1).

Examples of typical complementary requirements from schemes owners are:

- requirements on auditor qualification, experience, training and registration;
- requirements on audit reports;
- requirements on duration and frequency of the audits;
- other guidance to certification bodies for conformity assessment procedures.

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4.4. Subcontracting

IAF Guidance to clause 4.4. (G.4.4.1 to G.4.4.6)

G.4.4.1 A certification body may subcontract work to another body (e.g. testing or inspection or quality management system evaluation), provided that the arrangement with the subcontracted body require it to comply with all the relevant requirements of ISO/IEC Guide 65 and where applicable, ISO/IEC 17025 and 17020 and ISO/IEC Guide 62.

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.4.4.2 If the subcontracted bodies employed are not accredited according to the relevant standard for the specific activities required by the certification schemes, the certification body shall demonstrate the competence of the subcontracted body by other means, such as documented evaluation performed by qualified personnel according to appropriate procedures that includes an initial evaluation of competence and ongoing monitoring of performance of the sub contracted bodies.

G.4.4.3 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.

Individuals working under formal agreement for the certification body, within the accredited systems, and under the authority and control of the CB management are not deemed to be sub contractors.

G.4.4.4 Where independent testing facilities are not utilized, the certification body shall 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. In this case the provisions of G.4.4.1 and /or G 4.4.2 also apply and depending on the extent of controls imposed by the certification body some requirements of ISO/IEC 17025 may not be required or applicable. The same is applicable to other conformity assessment activities.

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G.4.4.5 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 describes a situation where the certification body will be reliant on the work or on a certification of another certification body. It should therefore ensure that information on any evaluation work on which it relies is updated as appropriate. In cases where the certification body takes into account work previously performed by another certification body it shall have all relevant reports and records to demonstrate the competence and the conformity with the requirements (established by the certification body) of the other certification body for the period of time when the work was carried out.

G.4.4.6 The certification body should confirm the scope, currency and applicability of any certification or accreditation it is relying upon (as required by the relevant certification scheme of the certification body).

4.5. Quality system

IAF Guidance to clause 4.5.

G.4.5.1 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 it's personnel at supplier and subcontractor sites.

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

IAF Guidance to Clause 4.6.

G.4.6.1 Where certification is suspended, the certification body shall require that, during the period of suspension, the supplier makes no misleading claims and should advise relevant existing and potential purchasers regarding the status of certification, and ceases to use the certification mark on the products manufactured since the date of notification of suspension.

A certification body shall have procedures in place to ensure that a defective certified product that gave rise to suspension of certification is:

- Subject to corrective action including, where appropriate, product recall

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- Prevented, by all practical means, from being placed on the market after the suspension is invoked.

Note 5 of clause 14 of ISO/IEC Guide 65 also applies.

4.7. Internal audits and management reviews

IAF Guidance to clause 4.7. (G.4.7.1 to G 4.7.2)

G.4.7.1 Internal audits and management reviews of the certification body's quality management system as required by ISO/IEC Guide 65 should be carried out at least once each year.

The frequency of internal audits may be reduced if the certification body can demonstrate that its management system has been effectively implemented and has proven stability. A risk based audit programme should be planned, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits.

G.4.7.2 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.4.8.1 The information required by clause 4.8.1.c) of ISO/IEC Guide 65 should clearly detail the elements included or referred to in clause 1.2 of ISO/IEC Guide 65 and the information or the source of the information on normative documents to which products are certified.

4.9. Records

4.10. Confidentiality

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5. Certification body personnel

5.1 General

5.2. Qualification criteria

IAF Guidance to clause 5. (G.5.2.1 to G5.2.2)

G.5.2.1 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).

G.5.2.2 The term "personnel" can include individual persons who work for the certification body on a contract basis, and other external resources. The certification body shall be in a position to manage, control and be responsible for the performance of all its resources and maintain comprehensive records controlling the suitability of all the staff it uses in particular areas, whether they are employees, employed on contract or provided by external bodies.

The certification body shall have personnel technically competent to assess the products and decide in accordance with 4.2 f) of ISO/IEC Guide 65 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 to G.7.3)

G.7.1 Personnel, including those acting in a managerial capacity, should not be employed to investigate any appeal, complaint or dispute if there are any relationships that may compromise the impartiality of the investigation.

G.7.2 Appeals, complaints and disputes represent a source of information as to possible nonconformity with ISO/IEC Guide 65. When nonconformities are identified, the certification body should take appropriate action.

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G.7.3 The policies and procedures referred to in clause 4.2.p) should ensure that all appeals, complaints and disputes are dealt with in a constructive and timely manner. The certification body shall have an appeals procedure that includes provision for the following:

- an opportunity for the appellant to formally present its case;
- ensuring the impartiality of the appeals process;
- a written statement to the appellant, 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 procedures to be followed.

8. Application for certification

9. Preparation for evaluation

IAF Guidance to clause 9. (G.9.1.)

G.9.1 Depending on the characteristics of the certification scheme and the product requirements, the plan referenced in clause 9.2 can be either a generic plan applicable to all activities, including evaluation of the suppliers quality system when applicable or a specific one for a particular activity or a combination of both.

10. Evaluation

11. Evaluation report

12. Decision on certification

IAF Guidance to clause 12 (G.12.1 to G.12.9)

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);
- for the basis for ongoing surveillance activities to ensure continued conformity with certification requirements.

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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.

G.12.4 The person(s), who take(s) the decision on granting/withdrawing certification within the certification body shall have a level of knowledge and experience sufficient to evaluate the information obtained from the evaluation process.

G.12.5 Where the certification body takes account of work related to certification performed by another body, the certification body shall have arrangements in place for confirming the scope, currency and applicability of the certification (as required by the relevant certification scheme of the certification body) 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 (see also clause 4.4, Note 2 of ISO/IEC Guide 65).

G.12.6 Certification shall not be granted until all criteria are met. Nonconformities, which raise any doubt as to the conformity of the product must be corrected and the correction verified by the certification body (by site visit or other appropriate forms of verification) before certification is granted The nonconformities and their resolution should be documented by the certification body.

G.12.7 For a certification document to represent accredited certification it should be issued by a certification body in accordance with the conditions of its accreditation and should unambiguously identify the accreditation body and the issuing certification body. Where a certification body holds more than one accreditation covering the scope of the certification, the accredited certification documents should identify at least one of the accreditation bodies.

G.12.8 The certification document (ISO/IEC Guide 65, clause 12.3 b)1) should clarify whether a product, service or process is certified.

The certification document should include or refer to an appropriate description of the certification scheme (see clause 1.2 of ISO/IEC Guide 65 and/or ISO/IEC Guide 67).

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G.12.9 If there is no reference to an expiry date on the certification document, there shall be enough information on the document to readily confirm the validity of the certification within the relevant certification system (see clause 12.3 of ISO/IEC Guide 65).

13. Surveillance

IAF Guidance to clause 13 (G.13.1 to G.13.5)

G.13.1 In cases where surveillance is part of the certification system it should be such to give confidence that certified products continue to comply with the normative documents to which they are certified. The surveillance procedures required under clause 13.1 of ISO/IEC Guide 65 should include, as appropriate, testing, inspection and/or assessment of the production and/or of the quality system etc. (see also ISO/IEC Guide 67). Samples for surveillance testing should be typical of production. They should be selected by, or under the control of, the certification body from the factory (e.g. production, stock) or the market (e.g. distributors' or retailers' stock) in a manner that ensures that the impartiality of selection and the integrity of the sample cannot be compromised.

G.13.2 Surveillance requirements 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 adapting surveillance activities e.g. taking into account the complexity of the product, maturity of the normative documents, experience of the supplier, life cycle of the product, changing of technology.

G.13.3 Many techniques are available to certification bodies to conduct surveillance. These techniques may be conducted at various points and at varying frequencies during the design-production-distribution-sales 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 competent 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;

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- the elements of a surveillance program can change on an ongoing basis;

surveillance requirements shall be considered by the parties (e.g. authorities) involved in the development of the scheme.

G.13.5 If the certification body licenses or grants a supplier the authorisation to affix a mark on conforming products, an appropriate surveillance regime shall be established.

14. Use of licenses, certificates and marks of conformity

IAF Guidance to clause 14 (G.14.1 to G.14.6)

G.14.1 The certification body should avoid using the same mark to indicate different certification systems (Products, QMS etc.), and should avoid confusion between the meaning of its marks. The certification body can use the same corporate logo in different systems or schemes provided the marks are clearly distinguishable.

G.14.2 The certification body shall have documented procedures for the use of its mark (see also ISO/IEC 17030), and for the measures to be adopted 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 marks are not used in a way that may be likely to confuse or mislead the market.

G.14.5 Where the certification body makes use of a mark that it has been assigned by 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.

G.14.6 The certification body should have documented procedures to ensure a traceable link from its mark to the relevant certification requirements.

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15. Complaints to suppliers

End of main text IAF Guidance on ISO/IEC Guide 65

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Annex 1 – Service Certification

1.1 Introduction

The term "Product" as defined in ISO/IEC Guide 65 includes service, so the general Guidance provided in this document applies to the certification body providing certification of services. Nevertheless for the special characteristics of services, further guidance is needed.

This Annex provides guidance to the certification body performing certification of services.

In this document "service" is any activity offered by an organization (supplier) to its customer different from tangible products and processes. Such activity includes, for example, legal and advisory services, transport services (passenger and freight), hotel services. Service certification is the assessment of the conformity of specific features of a service to applicable requirements.

From the above it is deduced that internal activities of organizations such as management systems of any type cannot be considered as service. To be certified, a service has therefore to be provided by a supplier to its clients.

1.2. Normative Document and Scheme

A service certification scheme should include:

Requirements of the service: The requirements describing the service to be certified shall be established in the normative document and should objectively and measurably specify the characteristics of the service to be certified. The established requirements shall be described in such a way that their fulfilment could be evaluated both by the supplier that offers the service and by the certification body.

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Requirements for the Service Supplier: For the correct operation of a certification scheme, it is essential for the supplier to be able to demonstrate to the certification body that the service fulfils established specified requirements. For this reason the scheme documentation should include the requirements that assure that the supplier has proper control at all times that the service provided fulfils the requirements and that it keeps appropriate records of such control. This could include a requirement for a quality management system that covers the characteristics of the service, indicators, quality metrics, or others.

1.3. Operation

The certification body shall document the way in which it assesses the fulfilment of the requirements established in the normative document.

For this it should operate two types of assessment methods that in general will require different evaluation techniques:

Evaluation of the conformity with the service requirements: The certification body should directly observe how the supplier delivers the service to assure that all the established requirements are properly accomplished. In the case that this observation could not be performed without influencing the persons providing the service, the certification body should use appropriate techniques as "mystery shopper" (a qualified person, acting as a customer on behalf of the certification body in order to assess the service) that allow the evaluation of the service in real conditions.

Evaluation of the internal control performed by the supplier: The certification body should assure that the processes followed by the supplier to guarantee the continued fulfilment of the certification requirements are properly implemented and are effective. The certification body shall review supplier's documentation to determine the conformity of the system, as documented, with the certification criteria, this may include relevant management system documents and records. The certification body should prepare an evaluation plan to provide the basis for the agreement between the supplier and the certification body regarding the conduct of the evaluation..

Both types of assessment should be used in both the initial and the surveillance process.

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Annex 2 - Process Certification

2.1 Introduction

The term "Product" as defined in ISO/IEC Guide 65 includes process, so the general Guidance provided in this document applies to the certification body providing certification of processes. Nevertheless for the special characteristics of processes, further guidance is needed.

This Annex provides guidance to the certification body performing certification of processes.

In this document "process" is a set of interrelated or interacting activities that transforms inputs into outputs. Process certification is the assessment of the conformity of specific features of a process to applicable requirements.

Certification of processes only applies to processes delivering an output intended for direct use by suppliers external stakeholders .ISO/IEC Guide 65 should not be used for certification of a supplier's internal management systems/processes (or part of) such as those referred to in management systems standards unless the specified requirements of the scheme can be shown to meet the requirements of this standard.(see below). Examples of processes are, welding engineering processes (ISO 3834), heat treatment processes, manufacturing processes requiring confirmation of process capability (e.g. operating or producing product within specified tolerances).

2.2 Normative Document and Scheme

A process certification scheme should include:

Requirements of the process (Process Specifications): The requirements describing the process to be certified shall be established on the basis of the relevant normative document and should objectively and measurably specify the characteristics of the process to be certified. The process certification may require conformity to the criteria of the product that is the result of the process. The established requirements shall be described in such a way that their fulfilment could be evaluated both by the supplier that carries out the process and by the certification body.

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Requirements for the supplier: For the correct operation of a certification scheme, it is essential for the supplier to be able to demonstrate to the certification body that the process fulfils established specified requirements. For this reason the scheme documentation should include the requirements that assure that the supplier has proper control at all times that the process carried out fulfils the requirements and that it keeps appropriate records of such control. This could include a requirement for a quality management system that covers the characteristics of the process, indicators, quality metrics, or others.

3.3 Operation

The certification body shall document the way in which it assesses the fulfilment of the requirements established in the normative document. For this it should operate two types of assessment methods that in general will require different evaluation techniques:

Evaluation of the conformity with the process requirements: The certification body should directly evaluate the processes carried out by the supplier to assure that all the established requirements are properly accomplished with regard to the following items.

(1) Adequacy of the process specifications

(2) Proper resources (Personnel, equipment, environmental conditions, etc.)

(3) Conformity of the implementation of the process with the process specifications

(4) Product conformity with the product criteria, ----where applicable.

Evaluation of the internal function performed by the supplier: The certification body should assure that the internal function followed by the supplier to guarantee the continued fulfilment of the certification requirements are properly implemented and are effective. To achieve this, the certification body should perform some type of audit similar to the management system audit described in ISO/IEC 19011 including the preparation of a specific evaluation plan.

Both types of assessment should be used in both the initial and the surveillance audit.

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End of IAF Guidance on the Application of ISO/IEC Guide 65

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Further Information

For further Information on this document or other IAF documents, contact any member of IAF or the IAF Secretariat.

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