International Accreditation Forum, Inc.

IAF Guidance Document

IAF Guidance on the Application of ISO/IEC Guide 62:1996

General Requirements for Bodies Operating Assessment and Certification/registration of Quality Systems

Issue 4

(IAF GD 2:2005)

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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 which 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 the equivalence of their accreditation programs allows companies with an accredited conformity assessment certificate in one part of the world to have that certificate recognised 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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Introduction to IAF Guidance

ISOIEC Guide 62:1996 is an International Guide which sets out criteria for bodies operating assessment and certification/registration of organizations' quality management systems. If such bodies are to be accredited as complying with Guide 62 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/registration bodies. This is an important step towards mutual recognition of accreditation. It is hoped that this Guidance will also be useful to certification/registration bodies themselves and to those whose decisions are guided by their certificates.

For convenience, the headings from ISO/IEC Guide 62 are first printed in **bold**; Guidance where it is offered is, for ease of reference, identified with the letter "G". The requirements against which conformity is determined are found in ISO/IEC Guide 62. This IAF Guidance does not create further requirements.

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 62. Members of the IAF Multilateral Recognition Arrangement (MLA), and applicants for membership in that Arrangement, will assess each others' implementation of ISO/IEC Guide 62, 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 62, are mandatory. The term "should" is used to indicate guidance which, although not mandatory, is provided by IAF as a recognised means of meeting the requirements. Certification/registration 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 62 in an equivalent way.

Behind this Guidance lies the principle, that if organizations' quality management systems are certified/registered to ISO 9001or an equivalent standard or normative document, those systems should give the organization (internally), and its markets, confidence that the organization is capable of systematically meeting agreed requirements for any product or service supplied within the field specified on the certificate. Certification/registration bodies shall demonstrate that the certificates / registrations they issue satisfy this principle.

A certification/registration 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.

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

APPLICATION GUIDANCE TO CLAUSES OF ISO/IEC GUIDE 62:1996

General Requirements for Bodies Operating Assessment and Certification/registration of Quality Systems

Section 1: General

1.1. Scope

1.2. References

1.3. Definitions

IAF Guidance to clause 1.3. (G.1.3.1. – G.1.3.3.)

G.1.3.1. The following definitions apply to the IAF Guidance in this document:

Accredited Certificate: A certificate issued by a certification/registration body in accordance with the conditions of its accreditation and bearing an accreditation mark or statement.

Assessment: All activities related to the certification/registration of an organization to determine whether the organization meets all the requirements of the relevant clauses of the specified standard necessary for granting certification/registration, and whether they are effectively implemented, including documentation review, audit, preparation and consideration of the audit report and other relevant activities necessary to provide sufficient information to allow a decision to be made as to whether certification/registration shall be granted.

Note: In this Guidance the term "organization" is identical to the term "supplier" used in ISO/IEC Guide 62.

Logo: A symbol used by a body as a form of identification, usually stylised. A logo may also be a mark.

Mark: A legally registered trade mark or otherwise protected symbol which is issued under the rules of an accreditation body or of a certification/registration body indicating that adequate confidence in the systems operated by a body has been demonstrated or that relevant products or individuals conform to the requirements of a specified standard.

Nonconformity: The absence of, or the failure to implement and maintain, one or more quality management system requirements, or a situation which would, on the basis of available objective evidence, raise significant doubt as to the quality of what the organization is supplying.

The certification/registration body is free to define different grades of deficiency and areas for improvement (e.g. Major and Minor Nonconformities, Observations, etc.). However all

deficiencies which equate to the above definition of nonconformity should be dealt with as laid down in G.3.5.3 and G.3.6.1.

G.1.3.2. The accredited scope of a certification/registration body is expressed in terms of one or more elements from a list of economic activities. See Annex 1 of this document as a model. Also see IAF guidance G.3.5.5. and G.3.5.6. .

G.1.3.3. Other limitations to the accreditation may apply, for example a restriction to certain offices or locations.

Section 2: Requirements for certification/registration bodies

2.1. Certification/registration body

2.1.1. General provisions

IAF Guidance to clause 2.1.1. (G.2.1.1. – G.2.1.9.)

G.2.1.1. The provision "if an explanation is required" in clause 2.1.1.3. of ISO/IEC Guide 62 should be applied by limiting such documents to those recognised by the accreditation body. The term "and any supplementary documentation required under the system" used in clauses 1.3.2. and 1.3.3. of ISO/IEC Guide 62 should mean documentation recognised by the accreditation body which provides additional or supplementary guidance as to the application of the relevant standard or Guide. See also guidance G.2.1.9. In exceptional cases the certification/registration body itself may issue supplementary documentation, subject to the requirements of clause 2.1.1.3. of ISO/IEC Guide 62.

G.2.1.2. Certification/registration of a quality management system shall give adequate confidence that the system meets specified requirements. A certification/registration of conformity of an organization's quality management system to ISO 9001 shall demonstrate that an organization has implemented and is maintaining an effective quality management system in the area specified on the certificate, and is operating its processes in accordance with that system.

G.2.1.3. In practice "specified requirements" in guidance G.2.1.2. means the requirements agreed between a customer and an organization. If such an organization is the one whose quality management system is subject to accredited certification/registration and sells goods to a claimed specification, a customer may make these "agreed requirements" by the act of purchasing. "Agreed requirements" include "legal requirements" if compliance with them is claimed by, or mandatory upon, the organization. In any case compliance with applicable legal requirements applying to a product or service supplied will normally be a customer requirement if only as an implied term of the contract to be considered under contract review.

G.2.1.4. Certification/registration bodies shall not practice any form of discrimination such as hidden discrimination by speeding up or delaying applications.

G.2.1.5. Clause 2.1.1.2. of ISO/IEC Guide 62 requires certification/registration bodies to make their services available to all applicants. They may, however, provide a certification/registration service which excludes areas of activity where the certification/registration body is not qualified to certify/register, or has elected not to provide service to any organization in a particular category. For example, a certification/registration body may, in so far as the law permits, limit its service to applicants operating in a defined geographic region, or it may limit its service to organizations operating within the technical sector, or a part of a sector, in which the certification/registration body has its accredited scope.

G.2.1.6. A certification/registration body may offer product conformity certification appropriately linked with quality management system certification/registration, or may offer quality management system certification/registration only.

G.2.1.7. Where a certification/registration body certifies / registers an organization against a standard or other normative document other than ISO 9001, the document shall be publicly available.

G.2.1.8. The term "a specific certification/registration program" used in clause 2.1.1.3. of ISO/IEC Guide 62 may include sector-specific schemes.

G.2.1.9. The formulations of explanations as to the application of these documents as referred to in clause 2.1.1.3. of ISO/IEC Guide 62 should be restricted by certification/registration bodies accredited by an accreditation body which is a member of the IAF MLA to guidance published by IAF or affiliated regional groups - see guidance G.2.1.1.

2.1.2. Organization

IAF Guidance to clause 2.1.2. (G.2.1.10. – 2.1.36.)

G.2.1.10. Accreditation shall only be granted to a body which is a legal entity as referenced in clause 2.1.2.d) of ISO/IEC Guide 62 and will be confined to declared scopes, activities and locations. If the certification/registration 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 as defined in guidance G.2.1.23. and G.2.1.24. Relevant information on activities performed by the other parts of the larger organization shall be given by the certification/registration body to the accreditation body.

G.2.1.11. Demonstration that a certification/registration body is a legal entity, as required under clause 2.1.2.d) of ISO/IEC Guide 62, means that if an applicant certification/registration 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/registration body. The part of the legal entity that forms the actual certification/registration body may trade under a distinctive name, which should appear on the accreditation certificate.

For the purposes of clause 2.1.2.d) of ISO/IEC Guide 62, certification/registration 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 body shall comply with all the requirements of ISO/IEC Guide 62.

G.2.1.12. Impartiality and independence of the certification/registration body should be assured at three levels -

1. Strategic and Policy;
2. Decisions on Certification/registration;
3. Auditing.

The guidance to clause 2.1.2. of ISO/IEC Guide 62 is intended to provide for impartiality and independence at all three levels.

G.2.1.13. Impartiality, as required by clause 2.1.2.a) of ISO/IEC Guide 62 can only be safeguarded by a structure, as required by clause 2.1.2.e) of ISO/IEC Guide 62, that enables "the participation of all parties significantly concerned in the development of policies and principles regarding the content and functioning of the certification/registration system".

G.2.1.14. The structure required in clause 2.1.2.e) of ISO/IEC Guide 62 for the safeguarding of impartiality shall be separate from the management established to meet the requirements of clause 2.1.2.c) of ISO/IEC Guide 62, unless the entire management function is performed by a committee or group that is constituted to enable participation of all parties as required in clause 2.1.2.e) of ISO/IEC Guide 62.

G.2.1.15. Conformance with clause 2.1.2.e) of ISO/IEC Guide 62 has the effect of counteracting any tendency on the part of the owners of a certification/registration body to allow commercial or other considerations to prevent the consistent technically objective provision of its service. This is particularly necessary when the finance to set up a certification/registration body has been provided by a particular interest which predominates in the shareholding and/or the board of directors.

G.2.1.16. Clause 2.1.2.e) of ISO/IEC Guide 62, therefore, requires that the documented structure of the certification/registration body has built into it provision for the participation of all the significantly concerned parties. This should normally be through some kind of committee.

This structure shall be formally established at the highest level within the organization either in the documentation that establishes the certification/registration 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 2.1.2.e).

G.2.1.17. It is always a question of judgement 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. Where one sector (eg Government, industry etc) provides more than one individual to represent separate aspects of the sector's interests, the fact that they come from the one sector deems them to constitute a single interest.

G.2.1.18. The management responsible for the various functions described in clause 2.1.2.c) of ISO/IEC Guide 62 should provide all the necessary information, including the reasons for all significant decisions and actions, and the selection of persons responsible for particular activities, in respect of certification/registration, to the committee or equivalent referred to in clause 2.1.2.e) of ISO/IEC Guide 62, to enable it to ensure proper and impartial certification/registration. 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.2.1.19. If the certification/registration body and an applicant or certified/registered body are both part of government, the two bodies should not directly report to a person or group having operational responsibility for both. The certification/registration body shall, in view of the impartiality requirement, be able to demonstrate how it deals with such a case.

G.2.1.20. The requirement for financial stability referred to in Clause 2.1.2.i) requires the certification/registration body to demonstrate that it has a reasonable expectation of being able to continue to provide the service in accordance with its contractual obligations. Certification/registration 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. Accreditation bodies should not attempt any direct audit of the financial accounts of certification/registration bodies.

G.2.1.21. If the decision to issue or withdraw certification/registration in accordance with clause 2.1.2.n) of ISO/IEC Guide 62 is taken by a committee comprising, among others, representatives from one or more certified/registered organizations, the operational procedures of the certification/registration 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.2.1.22. Clause 2.1.2.o) of ISO/IEC Guide 62 addresses two separate requirements. Firstly, the certification/registration body 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/registration body.

G.2.1.23. Consultancy is considered to be participation in an active creative manner in the development of the quality management system to be assessed by, for example:

a) preparing or producing manuals, handbooks or procedures;

b) participating in the decision making process regarding management system matters;

c) giving specific advice towards the development and implementation of management systems for eventual certification.

Note: Management systems as referred to in guidance G.2.1.23. include all aspects of such systems, including financial.

G.2.1.24. Certification/registration bodies can carry out the following duties without them being considered as consultancy or necessarily creating a conflict of interests. However, all potential conflicts of interests should be dealt with in accordance with G.2.1.29:

a) certification/registration including information meetings, planning meetings, examination of documents, auditing (not internal auditing) and follow up of nonconformities;

b) arranging and participating as a lecturer in training courses, provided that where these courses relate to quality assurance, management systems or auditing they should confine themselves to the provision of generic information and advice which is freely available in the public domain, i.e. they should not provide company specific advice which contravenes the requirements of G.2.1.23.c);

c) making available or publishing on request information on the basis for the certification/registration body's interpretation of the requirements of the assessment standards;

d) activities prior to audit aimed solely at determining readiness for assessment; but such activities should not result in the provision of recommendations or advice that would contravene guidance G.2.1.23. and the certification/registration body should be able to confirm that such activities do not contravene these provisions and that they are not used to justify a reduction in the eventual assessment duration;

e) performing second and third party audits according to other standards or regulations than those being part of the scope of accreditation;

f) adding value during assessments and surveillance visits, e.g., by identifying opportunities for improvement, as they become evident, during the audit without recommending specific solutions.

G.2.1.25. Activities under clause 2.1.2.o) of ISO/IEC Guide 62 by a related body and certification/registration 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. It is the duty of the certification/registration body to ensure that none of its clients is given the impression that the use of such activities and certification/registration would bring any business advantage to the client so that the certification/registration remains, and is seen to remain, impartial.

G.2.1.26. Nothing should be said by a certification/registration body that would suggest that certification/registration would be simpler, easier or less expensive if any specified consultancy or training services were used.

G.2.1.27. A related body, as referred to in clause 2.1.2.o) of ISO/IEC Guide 62, is one which is linked to the certification/registration body by common ownership or directors, contractual arrangement, common elements in the name, informal understanding or other means such that the related body has a vested interest in the outcome of an assessment or has a potential ability to influence the outcome of an assessment.

G.2.1.28. The certification/registration body should analyse and document the relationship with such related bodies to determine the possibilities for conflict of interest with provision of certification/registration and identify those bodies and activities that could, if not subject to appropriate controls, affect confidentiality, objectivity or impartiality.

G.2.1.29. Certification/registration bodies shall demonstrate how they manage their certification/registration 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/registration body or from the activities of related bodies. Accreditation bodies will expect certification/registration 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/registration 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/registration 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 the related bodies to provide assurance that control over potential conflicts of interest has been re-established.

G.2.1.30. The requirements of clause 2.1. and clause 2.2.3. of ISO/IEC Guide 62 mean that people who have provided consultancy, including those acting in a managerial capacity, should not be employed to conduct an audit as part of the certification/registration process if they have been involved in any consultancy activities towards the organization in question, (or any company related to that organization), within the last two years. Situations such as an employer's involvement or previous involvement with the organization being assessed may present individuals involved in any part of the certification/registration process with a conflict of interest. The certification/registration 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.2.1.31. The senior executive, staff and/or personnel mentioned in clause 2.1.2. of ISO/IEC Guide 62 need not necessarily be full-time personnel, but their other employment shall not be such as to compromise their impartiality.

G.2.1.32. The certification/registration body should require all assessment sub-contractors or external assessors/auditors to give undertakings regarding the marketing of any consultancy services equivalent to those required by guidance G.2.1.25. and G.2.1.26.

G.2.1.33. The certification/registration 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 such a breach is identified.

G.2.1.34. The certification/registration body should be independent from the body or bodies (including any individuals) which provide the internal audit of the organization's quality management system subject to certification/registration.

G.2.1.35. An auditor shall explain the audit findings and/or clarify the requirements of the assessment standard during the audit and /or at the closing meeting but shall not give prescriptive advice or consultancy as part of an assessment.

G.2.1.36. The policies and procedures referred to in clause 2.1.2 (p) of ISO/IEC Guide 62 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/registration body's procedures shall provide for an appeals process. This appeals procedure should include provision for the following:

a) the opportunity for the appellant to formally present its case;
b) provision of an independent element or other means to ensure the impartiality of the appeals process;
c) provision to the appellant of a written statement of the appeal findings including the reasons for the decisions reached.

The certification/registration 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.

2.1.3. Subcontracting

IAF Guidance to clause 2.1.3. (G.2.1.37. – G.2.1.39.)

G.2.1.37. A certification/registration body may issue certificates on the basis of an assessment carried out by another body provided that the agreement with the subcontracted body requires it to comply with all the relevant requirements of ISO/IEC Guide 62 and, in particular, the requirements of clause 2.2. of ISO/IEC Guide 62. Assessments carried out by subcontracted bodies shall give the same confidence as assessments carried out by the certification/registration body itself. Evaluation of the audit report and the decision on certification/registration shall be made only by the certification/registration body itself, and not by any other certification/registration body. Where joint assessments are undertaken, each certification/registration body shall satisfy itself that the whole of the assessment has been satisfactorily undertaken by competent assessors / auditors.

G.2.1.38. Where a certification/registration body issues certificates in accordance with guidance G.2.1.37. it shall have procedures that ensure conformity with all relevant clauses of this document by subcontracted bodies.

G.2.1.39. The requirement in clause 2.1.3.c) of ISO/IEC Guide 62 does not mean that the consent of the organisation under assessment is required in case of subcontracting of administrative activities such as typing.

2.1.4. Quality System

IAF Guidance to clause 2.1.4. (G.2.1.40 – G.2.1.41.)

G.2.1.40. The requirement in Clause 2.1.4.2 for a certification/registration body to designate a person with direct access to its highest executive level does not preclude the chief executive from assuming this role and responsibility for a) and b).

G.2.1.41. The description required by clause 2.1.4.3.e) of ISO/IEC Guide 62 should include an indication of which party or parties each member of a committee or group (eg a Board) is representing.

2.1.5. Conditions for granting, maintaining, extending, reducing, suspending, and withdrawing certification/registration

IAF Guidance to clause 2.1.5. (G.2.1.42. – G.2.1.45.)

G.2.1.42. Clause 2.1.5 of ISO/IEC Guide 62 does not mention a specific period in which at least one complete internal audit and one management review of the organization's quality management system shall take place. The certification/registration body may specify a period. Irrespective of whether the certification/registration body has chosen to specify a minimum frequency, measures shall be established by the certification/registration body to ensure the effectiveness of the organization's management review and internal audit processes.

G.2.1.43. Certification/registration shall not be granted until there is sufficient evidence to demonstrate that the arrangements for management review and internal audit have been implemented, are effective and will be maintained.

G.2.1.44. Various references in ISO/IEC Guide 62 make it a requirement to work in accordance with ISO 10011 Parts 1 and 2. This series of standards has now been superseded by ISO 19011. However, for the applicable requirements, the term "should" in ISO 19011 shall be interpreted as described in the fourth paragraph of the "Introduction to IAF Guidance".

NOTE: It is important to remember that ISO 19011 sets out guidelines for a wide range of audit situations, so some of the guidelines are inapplicable to third party quality management system certification/registration.

G.2.1.45. The certification/registration body should define the consequences of suspension and of withdrawal. Suspension of certification/registration need not be published by a certification/registration body. However, withdrawal of certification/registration shall result in, as a minimum, an amendment to the directory referenced in Clause 2.1.7.1.g). of ISO/IEC Guide 62. But also note the requirements in Clause 3.1.1.2.e) of ISO/IEC Guide 62.

2.1.6. Internal audits and management reviews

IAF Guidance to clause 2.1.6. (G.2.1.46. – G.2.1.47.)

G.2.1.46. Clause 2.1.6. of ISO/IEC Guide 62 does not mention a specific period in which at least one complete internal audit of the certification/registration body's quality management system and one management review of the certification/registration body's quality management system should take place. Complete internal audits followed by management reviews of the body's quality management system should be carried out at least once each year. The accreditation body may specify a shorter period, depending on the degree of conformity with the requirements of ISO/IEC Guide 62, as found in internal audits and reviews as well as in reports to the accreditation body.

G.2.1.47. The records of internal audits and management reviews should be made available to the accreditation body on request.

2.1.7. Documentation

IAF Guidance to clause 2.1.7. (G.2.1.48.)

G.2.1.48. The description of the means by which the body obtains financial support referred to in clause 2.1.7.1.d) of ISO/IEC Guide 62 should be sufficient to show whether or not the body can retain its impartiality.

2.1.8. Records

2.1.9. Confidentiality

IAF Guidance to clause 2.1.9. (G.2.1.49. – G.2.1.50.)

G.2.1.49. The requirement as to confidentiality includes anyone who might gain access to information which the certification/registration body should keep confidential. Subcontracted personnel shall be required to keep all such information confidential, particularly from fellow employees and from their other employers.

G.2.1.50. The "written consent" mentioned in clause 2.1.9.2 of ISO/IEC Guide 62 only applies to confidential information.

2.2. Certification/registration body personnel

2.2.1. General

IAF Guidance to clause 2.2.1. (G.2.2.1. – G.2.2.8.)

G.2.2.1. Clause 2.2.1.1 requires the personnel of the certification/registration body to have competence with respect to all the functions it performs, be they management, technical, administrative, or other. This guidance focuses on the management and technical competence requirements.

G.2.2.2. The management of the certification/registration body should have enough knowledge of the typical process, product and system requirements relevant to the technical areas in which the certification/registration body is active to enable it to operate an effective system for identifying and defining the specific competence needed to perform certification/registration in each of these areas.

> NOTE: Technical areas referred to above are likely to be more specific than the descriptors of the 39 scope headings listed in Annex 1. While scope 11 "Nuclear Fuel" might constitute a legitimate descriptor for a technical area, few of the other headings would do so.

G.2.2.3. The certification/registration body should be able to demonstrate that it has performed an initial competence analysis (determination of competence requirements in response to evaluated needs) for each technical area in which it operates. In particular, the management should be able to demonstrate that the certification/registration body has the competence to perform the following activities:

a) identify the major processes associated with each technical area in which it operates
b) identify the major product related requirements relevant to each technical area in which it operates
c) define the competence needed in the certification/registration body to certify/register organizations in each technical area in which it operates (this includes the competence of auditors and of those responsible for conducting contract reviews, selecting assessment teams and making certification decisions).

G.2.2.4. In addition to performing competence analyses of technical areas of activity of organizations subject to its certification/registration, the certification/registration body should have the competence to understand the business practices and structures of the organizations subject to certification/registration.

G.2.2.5. The management of certification/registration bodies should have appropriate knowledge to undertake certification/registration in the different countries in which the certification/registration body performs certification/registration. The certification/registration body should be able to demonstrate the effectiveness of how it deals with questions of language, culture and the business environment.

G.2.2.6. In order to undertake a specific contract, based on the above analyses, the management of the certification/registration body should:

a) confirm that personnel with the required competencies, as analysed above, will be available
b) approve procedures for determining the length of time needed to complete the assessment in accordance with Annex 2.

G.2.2.7. Certification/registration bodies shall have personnel competent to:

a) assess applications and conduct contract reviews;
b) select auditors and verify their competence;
c) brief auditors and arrange any necessary training;
d) implement assessment, surveillance and reassessment procedures;
e) decide on the granting, maintaining, withdrawing, suspending, extending, or reducing of certifications/registrations (see Guidance G.3.5.2);
f) set up and operate appeals, complaints and disputes procedures.

G.2.2.8. Clause 2.1.2. (j) of ISO/IEC Guide 62 means that across the whole range of its accredited activities the certification/registration body shall be able to conduct assessments using resources under its own control. The term 'resources under its own control' can include individual auditors who work for the certification/registration body on a contract basis, or other external resources. The management of the certification/registration body shall be in a position to manage, control and be responsible for the performance of all its resources and maintain comprehensive records demonstrating the competence of all the personnel it uses in particular areas, whether they are employees, employed on a contract or provided by external bodies.

2.2.2. Qualification criteria for auditors and technical experts

IAF Guidance to clause 2.2.2. (G.2.2.9.)

G.2.2.9. The management of the certification/registration body shall define the requirements for establishing the competence of the auditors and technical experts that the certification/registration body uses to conduct assessments, whether they are employees, employed on contract or provided by external bodies. These requirements shall incorporate the relevant criteria for assessing and auditor competence in ISO 19011 (which has superseded the ISO 10011 series of standards referred to in ISO/IEC Guide 62).

NOTE: ISO/IEC Guide 62 does not require auditors to be certified/registered by an auditor certification/registration body but such certification/registration may be used as part of the evidence that auditors meet defined levels of competence.

2.2.3. Selection procedure

IAF Guidance to clause 2.2.3. (G.2.2.10. – G.2.2.12.)

G.2.2.10. Clause 2.2.3.1 (b) of ISO/IEC Guide 62 requires the certification/registration body to assess and monitor the conduct and performance of auditors and technical experts. Such assessment and monitoring should include witnessing the activities of the auditors and technical experts on site.

G.2.2.11. The certification/registration body should establish the frequency of witnessing activities to take account of the criticality and volume of the work being undertaken, the experience and performance history of the auditors/technical experts and any data obtained from other types of monitoring activity such as review of audit reports and market feedback.

G.2.2.12. If a certification/registration body uses technical experts, its systems shall include procedures for their selection and how their technical knowledge is assured on a continuing basis. The certification/registration body may rely on help, for example, from industry or professional institutions.

2.2.3.2. Assignment for a specific assessment

IAF Guidance to clause 2.2.3.2. (G.2.2.13. – G.2.2.16.)

G.2.2.13. The certification/registration body's procedures shall ensure that audit teams meet the competence criteria that have been defined by the certification/registration body for the assessments they are assigned. Where an assessment is being performed by a team of two or more it is not necessary for each team member to meet all of the competence criteria for the area of activity involved. The assessment team may consist of one person provided that person conforms with the overall competence requirements for an assessment team.

G.2.2.14. The assessment team shall have the collective competence required to perform an effective assessment of the organization subject to certification/registration and the ability to trace evidence of failures in its products or services back to the relevant requirements of the quality management system (QMS). The certification/registration body shall appropriately assign the team members according to their competence. Competence includes the ability to understand and utilize the technologies that are used by the organization to manage the processes needed for its QMS. Where the audit of a particular activity on site requires specific competence requirements, the team leader shall assign the audit team members accordingly.

NOTE: For example, when assessing a QMS that relies substantially on electronic ("e-based") processes and documentation, the certification/registration body shall take this into account when

determining the necessary team competence for that assessment method, under clause 2.2.3.2 (b) of ISO/IEC Guide 62.

G.2.2.15. In certain instances, particularly where there are critical requirements and special procedures, the background knowledge of the assessment team may be supplemented by briefing, specific training or technical experts in attendance. The certification/registration body may attach non-auditor technical experts to their teams. Technical experts shall not perform an independent auditing function within the team and shall be supervised by an auditor who meets the certification/registration body's generic competence criteria for auditors, and at all times work in close co-operation with such an auditor.

G.2.2.16. The requirements for audit team competence apply not only to initial assessment but also to surveillance and reassessment. In assigning the team for a surveillance activity, the management of the certification/registration body shall ensure that the members of the team have the appropriate competence to assess the activities scheduled for surveillance, and to understand how their findings may relate to the overall operation of the QMS.

2.2.4. Contracting of assessment personnel

2.2.5. Assessment personnel records

2.2.6. Procedures for audit teams

2.3. Changes in the certification/registration requirements

2.4. Appeals, complaints and disputes

IAF Guidance to clause 2.4. (G.2.4.1. – G.2.4.3.)

G.2.4.1. Personnel, including those acting in a managerial capacity, should not be employed to investigate any appeal, complaint or dispute if they have been directly involved in activities as described under clause 2.1.2.o) of ISO/IEC Guide 62 towards the organization, or any other party involved in the appeal, complaint or dispute in question within the last two years.

G.2.4.2. Complaints represent a source of information as to possible nonconformity. On receipt of a complaint the certification/registration body shall establish, and where appropriate take action on, the cause of the nonconformity, including any predetermining (or predisposing) factors within the certification/registration body's management system.

G.2.4.3. The certification/registration body should use such investigation to develop corrective action, which should include measures for:

a) restoring conformity to ISO/IEC Guide 62 as quickly as practicable;
b) preventing recurrence;
c) assessing the effectiveness of the corrective measures adopted.

Section 3: Requirements for certification/registration

3.1. Application for certification/registration

3.1.1. Information on the procedure

IAF Guidance to Clause 3.1.1. (G.3.1.1. to G.3.1.2.)

G.3.1.1. The certification/registration body shall require its certified/registered organizations to have procedures to ensure that the information supplied to the certification/registration body is kept up-to-date.

G.3.1.2 The description of the assessment and certification/registration procedure referred to in clause 3.1.1.1 of ISO/IEC Guide 62 includes the procedures for surveillance and reassessment described in clauses 2.1.4.3 l) 4) and 3.6 of ISO/IEC Guide 62 and G.3.6.1 – G.3.6.15.

3.1.2. The application

3.2. Preparation for assessment

IAF Guidance to Clause 3.2. (G.3.2.1. to G.3.2.4.)

G.3.2.1. The review mentioned in clause 3.2.1. of ISO/IEC Guide 62 is a preliminary review, preceding the review meant in the rest of Section 3.

G.3.2.2. The reference to the language of the applicant in clause 3.2.1.c) of ISO/IEC Guide 62 does not exclude the possibility of using interpreters to assist the assessment team.

G.3.2.3. Under clause 3.2.1.c), special requirements may also include the need to consider auditor competence and information security concerns when auditing an electronic ("e-based") QMS.

G.3.2.4. The assessment plan should identify the computer-assisted auditing techniques that will be utilized during the assessment, as appropriate.

NOTE: Computer assisted auditing techniques may include, for example, teleconferencing, web meetings, interactive web-based communications and remote electronic access to the QMS documentation and/or QMS processes. The focus of such techniques should be to enhance audit effectiveness and efficiency, and should support the integrity of the audit process.

3.3. Assessment

IAF Guidance to clause 3.3. (G.3.3.1. - G.3.3.3.)

G.3.3.1. Certification/registration bodies shall allow auditors sufficient time to undertake all activities relating to an assessment or re-assessment. The time allocated should be based on factors such as the size of the organization, number of locations (including temporary sites – see Annex 2), technology utilized in the implementation of the various components of the QMS (such as documentation and/or process control, control of corrective/preventive action, etc), previously demonstrated performance of the QMS, and the standards which apply to the certification/registration. Annex 2 provides guidance on Auditor Time. The certification/registration body shall be prepared to substantiate or justify the amount of time used in any assessment, surveillance or re-assessment.

G.3.3.2. Annex 3 provides guidance on multi-site certification/registration.

G.3.3.3. Where quality management systems (QMS), environmental management systems (EMS) or other management system audits are conducted simultaneously or consecutively, there may be elements common to all systems. In determining auditor competence for common elements, the main principle is that the integrity of each assessment is maintained. This requires appropriate competence to be deployed for all audit activities. It remains a matter of judgement which aspects of a QMS, EMS or other audit can be performed by an auditor whose training and background are from another discipline, and whether any supplementary knowledge and/or training are required.

3.4. Assessment report

IAF Guidance to clause 3.4. (G.3.4.1. – G.3.4.7.)

G.3.4.1 Clause 3.4.1. b) of ISO/IEC Guide 62 requires more than a generic summary statement. The report of findings provided to the certification/registration body shall be of sufficient detail to facilitate and support a certification decision and should include:

- Areas covered by the assessment (eg. areas of the certification/registration requirements and locations/units/departments/processes/temporary sites of the auditee) including significant audit trails followed and audit techniques utilized (see G 3.2.4);;
- Observations made, both positive (eg. noteworthy features) and negative (eg. potential nonconformities);
- Report (details) of any nonconformities identified supported by objective evidence.

Completed questionnaires/checklists/observation logs/assessor notes might form an integral part of the report that covers the above. If these methods are used, these documents shall be submitted to the certification/registration body as evidence to support the certification/registration decision.

G.3.4.2 The first element of clause 3.4.1.e)5) of ISO/IEC Guide 62 requires the report to contain comments on the conformity of the organization's quality management system with the certification/registration requirements. This can be satisfied by a brief 'written' statement summarising the overall findings (conclusion) of the assessment and a statement of judgement as to the organization's capability of systematically meeting agreed requirements for any product or service supplied within the field specified on the certificate.

G.3.4.3. The second element of Clause 3.4.1.e)5) of ISO/IEC Guide 62 requires these comments to include a clear statement of nonconformity. This can be addressed by the normal methods used by certification/registration bodies for the reporting of nonconformities.

G.3.4.4. The final element of clause 3.4.1.e)5) of ISO/IEC Guide 62 "and, where applicable, any useful comparison with the results of previous assessment of the supplier", does not apply to initial assessments but is relevant only to corrective action follow up visits, partial reassessments and surveillance visits.

G.3.4.5. In addition to the requirements for reporting in clause 3.4.1.e) of ISO/IEC Guide 62, this information should cover:

- The degree of reliance that can be placed on the internal audit;
- A summary of the most important observations, positive as well as negative, regarding the implementation of the quality management system;
- The conclusions reached by the audit team.

G.3.4.6. Clause 3.4.2.b) requires the content of the report to take into consideration the adequacy of the internal organization and procedures adopted by the applicant body to give confidence in the quality management system. Comments on adequacy should be supported by comments on the state of development (maturity) and effectiveness of the quality management system.

G.3.4.7. In an audit which combines audits of more than one management system, the report shall clearly identify all requirements important to each management system standard.

3.5. Decision on certification/registration

IAF Guidance to clause 3.5. (G.3.5.1. – G.3.5.12.)

G.3.5.1. The information gathered during the certification/registration process shall be sufficient:

a) for the certification/registration body to be able to take an informed decision on certification/registration;

b) for traceability to be available in the event, for example, of an appeal;

c) to ensure continuity, for example for planning for the next audit (possibly by a different team).

The information referred to in clause 3.5.1. of ISO/IEC Guide 62 is not necessarily limited to the information contained in the assessment report produced in accordance with clause 3.4.1.b) of ISO/IEC Guide 62, but may also include information gathered from other elements of the certification/registration process (eg application, documentation review etc).

G.3.5.2. The entity, which may be an individual, which takes the decision on granting/withdrawing a certification/registration within the certification/registration body, should include a level of knowledge and experience sufficient to evaluate the audit processes and associated recommendations made by the audit team.

G.3.5.3. Certification/registration shall not be granted until all nonconformities as defined in guidance G.1.3.1. have been corrected and the corrective action verified by the certification/registration body (by site visit or other appropriate forms of verification).

G.3.5.4. Certification/registration documents shall be dated from the date of the formal decision by the certification/registration body. The surveillance cycle should however be programed from the completion of the initial audit

G.3.5.5. Accreditation of a certification/registration body for a scope element means that, in the judgement of the accreditation body, the management of the certification/registration body has the necessary understanding of the sector, and the administrative ability, to manage audits in whatever part of that sector it decides to operate. It does not necessarily mean that the body must offer its services to certify/register quality management systems of all organizations whose activities lie within that scope sector. Applicants and prospective applicants should be made aware of the part(s) of the sector in which the certification/registration body is accredited and/or operates, and therefore a certification/registration body can request a scope to be specified which is only part or a sub-element of a general scope heading.

G.3.5.6. The certification/registration body should inform the accreditation body of the scopes or parts of scope sectors in which it is active. The certification/registration body should maintain procedures to inform the accreditation body if it intends to certify/register in new areas, or in specialised fields (parts of scope sectors) not previously notified to the accreditation body, and it intends to seek accreditation for that part or sector. Procedures should indicate what steps the certification/registration body would take if approached for certification/registration in dormant areas, and should make adequate provision for the acquisition of the necessary knowledge and experience before such applications are accepted

G.3.5.7. An accreditation issued by a laboratory accreditation body that has demonstrated competence through membership of a multilateral agreement group eg: the ILAC Mutual Recognition Arrangement, can be taken as adequate proof that the functions of the organization's quality management system covered by that accreditation are in conformity with those requirements of ISO 9001 which overlap with the requirements of ISO/IEC 17025, or other equivalent accreditation standard. If an organization which has been accredited to ISO/IEC 17025 or other equivalent accreditation standard desires to be certified/registered with respect to ISO 9001, a certification/registration body may assess only those requirements of the quality management system of the organization which are not covered by ISO/IEC 17025 or other equivalent accreditation standard.

G.3.5.8. Certification/registration bodies may be accredited to certify/register the quality management systems of test and calibration laboratories, but it should make it clear to the client that such certification/registration is not equivalent to accreditation of the testing or calibration laboratory. A certification/registration body shall not permit its marks to be applied to laboratory test and calibration reports, as such reports are deemed to be products in this context.

G.3.5.9. The reference in Clause 3.5.3.b)3) to regulations, product standards and other normative documents for products should normally not require that reference to these documents be included in the scope statement on a management system certificate, or elsewhere in relation to management system certification/registration, except when necessary to adequately define the scope of certification/registration. There should be no implication that anything other than the management system has been certified/registered.

G.3.5.10. All certification/registration documents shall identify the period for which the certification/registration is valid. The effective date shall be on or after the date of the formal decision by the certification/registration body. It is recommended that this period be compatible with the arrangements for reassessment, but this linkage is not a requirement. For Guidance on the transfer of accredited certification/registration see Annex 4.

G.3.5.11. For a certification/registration document to be regarded as accredited, it shall be issued by a certification/registration body in accordance with the conditions of its accreditation and unambiguously identify the accreditation body and the issuing certification/registration body.

G.3.5.12. Where a certification/registration body holds more than one accreditation covering the scope of the certification/registration, the accredited certification/registration documents shall identify at least one of the accreditation bodies.

3.6. Surveillance and reassessment procedures

IAF Guidance to clause 3.6.1. (G.3.6.1. – G.3.6.2.)

G.3.6.1. Certification/registration bodies shall have clear procedures laying down the circumstances and conditions in which certifications / registrations will be maintained. If on surveillance or re-assessment, nonconformities, as defined in G.1.3.1., are found to exist, such nonconformities shall be effectively corrected within a time agreed by the certification/registration body. If corrective action is not made within the time agreed certification/registration shall be reduced, suspended or withdrawn. The time allowed to implement corrective action should be consistent with the severity of the nonconformity and the risk to the assurance of the product meeting specified requirements.

G.3.6.2. Surveillance undertaken by the certification/registration body shall give assurance that its certified/registered organizations continue to conform to the requirements of the standard to which they are certified/registered. The certification/registration body should have the facilities and procedures to enable it to achieve this.

IAF Guidance to clause 3.6.2. (G.3.6.3. – G.3.6.15.)

G.3.6.3. Clause 3.6.1. of ISO/IEC Guide 62 requires a certification/registration body to conduct a surveillance and reassessment program at sufficiently close intervals to verify that its certified/registered organizations continue to conform to the certification/registration requirements.

G.3.6.4. The purpose of surveillance is to verify that the approved quality management system continues to be implemented, to consider the implications of changes to that system initiated as a result of changes in the organization's operation and to confirm continued conformity with certification/registration requirements. Surveillance of an organization's quality management system shall take place on a regular basis, normally it should be undertaken at least once a year. The date of the first surveillance audit, following initial certification/registration, should be programed from the completion of the initial certification/registration audit. Surveillance programs should normally include –

a) system maintenance, ie internal audit, management review and preventive and corrective action;
b) a review of action taken on nonconformities identified during the last audit;
c) customer complaints;
d) changes to the documented system;
e) areas subject to change;
f) other selected areas as appropriate.

G.3.6.5. At each surveillance the certification/registration body should check the following and interview the responsible management:

a) the effectiveness of the quality management system with regard to achieving the organization's objectives;
b) the functioning of procedures for notifying management of any breaches;
c) progress of planned activities aimed at continual improvement of system performance;
d) follow up of conclusions resulting from internal audits;
e) use of marks;
f) records of appeals, complaints and disputes brought before the certification/registration body, and where any nonconformity or failure to meet the requirements of certification/registration is revealed, that the organization has investigated its own systems and procedures and taken appropriate corrective action.

G.3.6.6. The certification/registration body should adapt its surveillance program to the issues related to the quality management system of the organization and justify this program to the accreditation body.

G.3.6.7. The surveillance program of the certification/registration body should be determined by the certification/registration body, taking into account the internal audit program and the reliability that can be attributed to it, specific dates for visits may be agreed with the certified/registered organization.

G.3.6.8 For an organization that has consistently demonstrated the effectiveness of its QMS over a period of time, the certification/registration body may, after agreement with the organization, choose to design an individualized program for subsequent surveillance and reassessment, in accordance with Annex 5 (Advanced Surveillance and Reassessment Procedures).

G.3.6.9. Surveillance audits may be combined with audits of other management systems. The reporting should then clearly indicate the aspects relevant for each management system.

G.3.6.10. The surveillance activities shall be subject to special provision if an organization with a certified/registered quality management system makes major modifications to its system or if other changes take place which could affect the basis of its certification/registration.

G.3.6.11. Appropriately competent personnel shall independently review surveillance reports for evidence of adequacy of audit performance and reporting and as a means of review whether the original certification/registration decision needs to be reconsidered. This review need not repeat the original decision process. The review should be conducted at least annually for each certification/registration.

G.3.6.12. In addition to the information specified in guidance G.3.4.1. – G.3.4.7. and G.3.5.1., reports of surveillance and reassessment visits should contain a report on the clearing of each nonconformity revealed previously.

G.3.6.13. Reassessment is a requirement of ISO/IEC Guide 62. The purpose of re-assessment is to verify overall continuing effectiveness of the organization's quality management system in its entirety. In most cases it is unlikely that a period greater than three years for periodic re-assessment of the organization's quality management system would satisfy this requirement. The re-assessment should provide for a review of past performance of the system over the period of certification/registration. The re-assessment program should take into consideration the results of the above review and should at least include a review of the quality management system documents and a site audit (which may replace or extend a regular surveillance audit). It shall at least ensure

a) the effective inter-action between all elements of the system;
b) the overall effectiveness of the system in its entirety in the light of changes in operations;
c) demonstrated commitment to maintain the effectiveness of the system.

G.3.6.14. If, exceptionally, a re-assessment period is extended beyond three years, the certification/registration body should demonstrate that the effectiveness of the complete quality management system has been evaluated on a regular basis, and should have a surveillance frequency that compensates for this in order to maintain the same level of confidence. However, periodic reassessment shall be conducted, regardless of the surveillance regime used.

G.3.6.15. Appropriately competent personnel shall independently review the re-assessment reports, and other information about the client, to make the decision on renewing certification/registration

3.7. Use of certificates and logos

IAF Guidance to clause 3.7. (G.3.7.1. – G.3.7.5.)

G.3.7.1. The certification/registration 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/registration and false use of certification/registration body marks.

G.3.7.2. If a certification/registration body incorrectly claims accredited status for certificates issued before appropriate accreditation has been granted the accreditation body may require it subsequently to withdraw them. Where, for reasons that should be stated to the certification/registration body, the accreditation body restricts the scope of its accreditation to part only of one of the standard scope headings, this fact may be made public by the accreditation body.

G.3.7.3. The provisions in clause 3.7.1. of ISO/IEC Guide 62 referring to "certification/registration mark and logos" and that in clause 3.7.2. referring to a "symbol or logo" are both applicable to marks, logos and symbols.

G.3.7.4. The certification/registration body should allow neither the accreditation mark nor the certification/registration mark to be used on products if only the quality management system of the organization has been certified /registered. Use of the mark on products implies product certification and is not covered by this guidance. Nevertheless the certification/registration body should avoid use of the same mark to indicate different systems of conformity certification/registration (for example product certification and management system certification/registration) and should avoid confusion between the meanings of its own marks if there are more than one.

Note: The table below provides guidance on the use of certification/registration marks for indicating when a product has been made under a certified/registered quality management system.

		On Product *1	On larger boxes, etc. used for transportation of products *2	In pamphlets, etc. for advertisement
Use of marks *3	Without a statement	Not allowed	Not allowed	Allowed *5
	With a statement *4	Not allowed	Allowed *5	Allowed *5

*1. This could be a tangible product itself or product in an individual package, container, etc. In the case of testing / analysing activities, it could be a test / analysis report.

*2. This could be over-packaging made of cardboard etc. that can be reasonably considered as not reaching end users.

*3. This applies to marks that have a specific form including some basic description of its applicability. A statement in words alone does not constitute a mark in this sense. Any such wording should be true and not mislead.

*4. This could be a clear statement that "(This product) was manufactured in a plant whose quality management system is certified/registered as being in conformity with ISO 9001".

*5. When using symbols or logos, adequate attention should be paid to avoid infringement of clauses 3.1.1.2 d) and 3.7 of ISO/IEC Guide 62.

The above Note may be overridden by the conditions for use attaching to particular certification/registration marks.

G.3.7.5. A certification/registration body should have procedures to ensure that certified/registered organizations do not allow its marks to be used in a way which may be likely to confuse purchasers.

3.8. Access to records of complaints to suppliers

IAF Guidance to clause 3.8. (G.3.8.1. – G.3.8.5.)

G.3.8.1. This clause deals only with complaints received by the certificate holder (organization), not by the certification/registration body.

G.3.8.2. Complaints represent a source of information as to possible nonconformity. On receipt of a complaint the certified/registered organization should establish, and where appropriate report on, the cause of the nonconformity, including any predetermining (or predisposing) factors within the organization's quality management system.

G.3.8.3. During surveillance audits certification/registration bodies should check where any such nonconformity or failure to meet the requirements of the standard is revealed, that the organization has investigated its own systems and procedures and taken appropriate corrective action.

G.3.8.4. The certification/registration body should satisfy itself that the organization is using such investigations to develop corrective action, which should include measures for

a) notification to appropriate authorities if required by regulation;
b) restoring conformity as quickly as practicable;
c) preventing recurrence;
d) evaluating and mitigating any adverse quality management system aspects and their associated impacts;
e) ensuring satisfactory interaction with other components of the quality management system;

f) assessing the effectiveness of the corrective measures adopted.

G.3.8.5. The implementation of the corrective action should not be deemed to have been completed until its effectiveness has been demonstrated and the necessary changes made in the procedures, documentation and records.

End of main text

Annex 1 - Scopes of Accreditation

This list of scopes of accreditation is based on the statistical nomenclature for economic activities (NACE Rev. 1.1) 2002 published by the Commission of European Communities (official Journal L6, 10.1 2002).

No	Description	NACE Code
1	Agriculture, fishing	A, B
2	Mining and quarrying	C
3	Food products, beverages and tobacco	DA
4	Textiles and textile products	DB
5	Leather and leather products	DC
6	Wood and wood products	DD
7	Pulp, paper and paper products	DE 21
8	Publishing companies	DE 22.1
9	Printing companies	DE 22.2,3
10	Manufacture of coke and refined petroleum products	DF 23.1,2
11	Nuclear fuel	DF 23.3
12	Chemicals, chemical products and fibres	DG minus 24.4
13	Pharmaceuticals	DG 24.4
14	Rubber and plastic products	DH
15	Non-metallic mineral products	DI minus 26.5,6
16	Concrete, cement, lime, plaster etc	DI 26.5,6
17	Basic metals and fabricated metal products	DJ
18	Machinery and equipment	DK
19	Electrical and optical equipment	DL
20	Shipbuilding	DM 35.1
21	Aerospace	DM 35.3
22	Other transport equipment	DM 34,35.2,4,5
23	Manufacturing not elsewhere classified	DN 36
24	Recycling	DN 37
25	Electricity supply	E 40.1
26	Gas supply	E 40.2
27	Water supply	E 41,40.3
28	Construction	F
29	Wholesale and retail trade; Repair of motor vehicles, motorcycles and personal and household goods	G
30	Hotels and restaurants	H
31	Transport, storage and communication	I
32	Financial intermediation; real estate; renting	J,K 70, K 71
33	Information technology	K 72
34	Engineering services	K 73, 74.2
35	Other services	K 74 minus K 74.2
36	Public administration	L
37	Education	M
38	Health and social work	N
39	Other social services	O

Annex 2 – Auditor Time

This annex provides guidance on clause 3.1.2. of ISO/IEC Guide 62. It should also be read in conjunction with the IAF Guidance on Clauses.3.3 and 3.6 and IAF Guidance G.3.3.1.
This annex provides guidance for a certification/registration body on the development of its own procedures for determining the amount of time required for the assessment of organizations of differing sizes and complexity over a broad spectrum of activities.

Certification/registration bodies need to identify the amount of auditor time to be spent on initial assessment, surveillance and reassessment for each applicant and certified/registered organization.

The Guidance in this annex does not stipulate minimum / maximum times but provides a framework to be used by certification/registration bodies to determine appropriate auditor time, taking into account the specifics of the organization to be audited. Use of procedures in line with this framework at the audit planning phase should lead to a consistent approach to the determination of appropriate auditor time.

The Auditor Time Chart provided below sets out an average number of initial audit days which experience has shown to be appropriate for organizations with a given number of employees. Therefore, the total number of employees for all shifts serves as an appropriate starting point to establish auditor time required.
Experience has also demonstrated that for organizations of a similar size, some will need more time and some less. The variation of time spent on each assessment depends on a number of factors including the size, scope of the audit, logistics, complexity of the organization and its state of preparedness for audit. These and other factors need to be examined during the certification/registration body's contract review process for their potential impact on the amount of auditor time to be allocated. Therefore the Auditor Time Chart cannot be used in isolation.

The Auditor Time Chart below provides the framework for a process that could be used for audit planning by identifying a starting point based on the total number of employees for all shifts, then adjusting for the significant factors applying to the organization to be audited, and attributing to each factor an additive or subtractive weighting to modify the base figure.

Guide for Process to Determine Auditor Time for Initial Audit (Auditor Time Chart)

Number of Employees Note 1	**Auditor Time for Initial Audit (auditor days)** Notes 2+4	**Additive and Subtractive Factors**	**Total Auditor Time**
1-10	2		
11-25	3		
26–45	4		
46-65	5		
66-85	6		
86-125	7		
126-175	8		
176-275	9		
276-425	10		
426-625	11		
626-875	12		
876–1175	13		
1176–1550	14		
1551-2025	15		
2026-2675	16		
2676-3450	17		
3451-4350	18		
4351-5450	19		
5451-6800	20		
6801 –8500	21		
8501-10700	22		
> 10700	Follow progression above		

1. "Employees" as referenced in the table refers to all individuals whose work activities support the scope of the certification/registration as described by the quality management system. The total number of employees for all shifts is the starting point for determination of audit time.

The effective number of employees includes non-permanent (seasonal, temporary, and sub-contracted) staff who will be present at the time of the audit. A certification/registration body should agree with the organization to be audited the timing of the audit which will best demonstrate the full scope of the organization. The consideration could include season, month, day/date and shift as appropriate.

Part-time employees should be treated as full-time-equivalent employees. This determination will depend upon the number of hours worked as compared with a full-time employee.

2. "Auditor time" includes the time spent by an Auditor or Audit Team in planning (including off-site document review, if appropriate); interfacing with organization, personnel, records, documentation and processes; and report writing. It is expected that the "Auditor time" involved in such planning and report writing combined should not typically reduce the total on-site "Auditor time" to less than 90% of the time shown in the Auditor Time Chart. Where additional time is required for planning and/or report writing, this will not be justification for reducing on-site Auditor time. Auditor travel time is not included in this calculation, and is additional to the Auditor time referenced in the chart.

3. If remote auditing techniques such as interactive web-based collaboration, web meetings, teleconferences and/or electronic verification of the organization's processes are utilized to interface with the organization, these activities should be identified in the assessment plan (see G.3.2.4), and may be considered as partially contributing to the total "on-site auditor time".

If the certification/registration body plans an audit plan for which the remote auditing activities represent more than 30% of the planned on-site auditor time, the certification/registration body shall justify the audit plan and obtain specific approval from the accreditation body prior to its implementation.

NOTE: On-site auditor time refers to the on-site auditor time allocated for individual sites. Electronic audits of remote sites are considered to be remote audits, even if the electronic audit is physically carried out on the organization's premises.

Regardless of the remote auditing techniques used, the organization shall be physically visited at least annually.

4. "Auditor time" as referenced in the chart is stated in terms of "Auditor Days" spent on the assessment. An "Auditor Day" is typically a full normal working day of 8 hours. The number of Auditor days employed may not be reduced at the initial planning stages by programming longer hours per work day.

5. For the initial Assessment cycle, Surveillance time for a given organization should be proportional to the time spent at Initial Audit with the total amount of time spent annually on surveillance being about 1/3 of the time spent on the Initial Audit. The planned surveillance time should be reviewed from time-to-time to account for changes in the organization, system maturity, etc., and at least at the time of re-assessment. For the second and subsequent assessment cycles, the certification/registration body may choose to design an individualized surveillance and reassessment program in accordance with Annex 5.

6. The total amount of time spent performing the re-assessment will depend upon the findings of the review as defined in paragraphs G.3.6.12 and G.3. 6.13. The amount of time spent at re-assessment should be proportional to the time that would be spent at initial assessment of the same organization and should be about 2/3 of the time that would be required for initial assessment of the same organization at the time that it is to be re-assessed. Re-assessment is time spent above and beyond the routine Surveillance time, but, when re-assessment is carried out at the same time as a planned routine Surveillance visit, the re-assessment will suffice to meet the requirement for Surveillance as well. Regardless of what conclusion is made, the guidance in G 3.3.1. applies.

Once the general starting point for determining the required Auditor Time has been made for the typical organization with the number of employees indicated, some adjustments need to be considered to account for the differences that could affect the actual Auditor Time required to perform an effective audit for the specific organization to be audited.

Some factors requiring additional auditor time could be, as examples:

- Complicated logistics involving more than one building or location where work is carried out. e.g., a separate Design Centre must be audited
- Staff speaking in more than one language (requiring interpreter(s) or preventing individual auditors from working independently)
- Very large site for number of employees (e.g., a timberland)
- High degree of regulation (food and drugs, aerospace, nuclear power, etc.)
- System covers highly complex processes or relatively high number of unique activities
- Processes involve a combination of hardware, software, process, and service
- Activities that require visiting temporary sites to confirm the activities of the permanent site(s) whose management system is subject to certification/registration. (Note 1 refers)

Some factors permitting less auditor time could be, as examples:

- Organization is not “Design Responsible” and/or other Standard elements not covered in scope
- No/low risk product/processes
- Prior knowledge of organization system (e.g., already registered to another Standard by the same Registrar)
- Very small site for number of employees (e.g., Office complex only)

- Client preparedness for registration (e.g., already registered or recognized by another 3rd party scheme)
- Processes involve a single general activity (e.g., Service only)
- Maturity of management system
- High percentage of employees doing the same, simple tasks
- Identical activities performed on all shifts with appropriate evidence of equivalent performance on all shifts based on prior audits (internal audits and certification/registration body audits)

Note 1.

In situations where the certification applicant or certified organization provides their product(s) or service(s) at temporary sites it is important that evaluations of such sites are incorporated into the assessment and surveillance programs.

A temporary site is a location other than the sites/locations identified in the certification document where activities, within the scope of certification, are implemented for a defined period of time. These sites could range from major project management sites to minor service/installation sites. The need to visit such sites and the extent of sampling should be based on an evaluation of the risks of the failure of a product or service to meet needs/expectations due to system nonconformity. The sample of sites selected should represent the range of the organization's competency needs and service variations having given consideration to sizes and types of activities, and the various stages of projects in progress.

Typically on-site evaluations of temporary sites would be performed. However, the following methods could be considered as alternatives to replace some physical on-site visits.

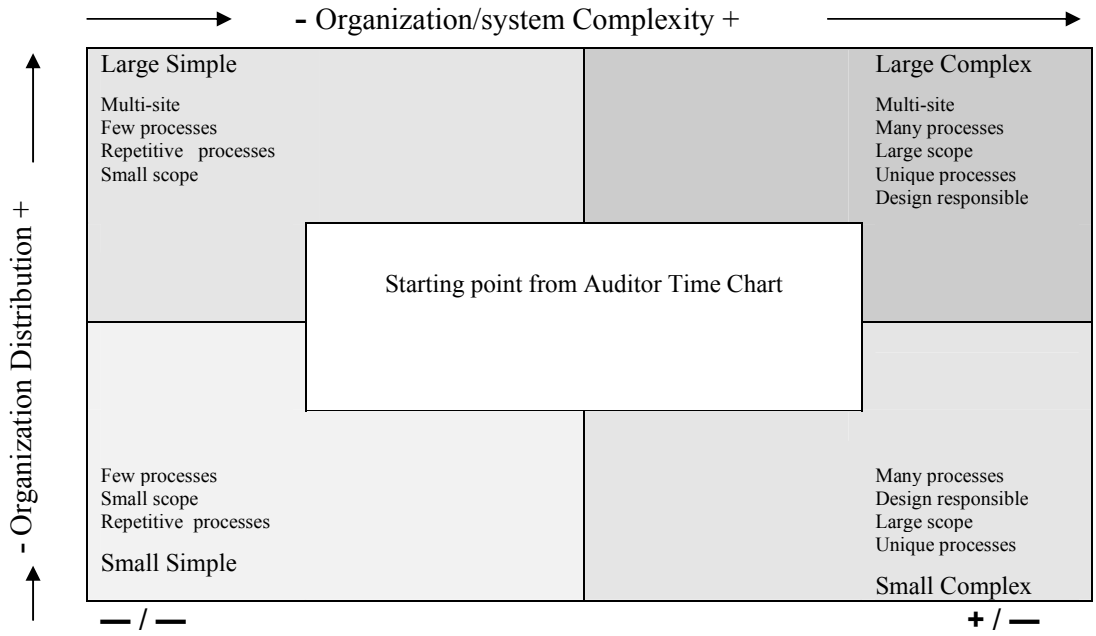
- Interviews or progress meetings with the client organization and/or its customer in person or by teleconference
- Document review of temporary site activities
- Remote access to electronic site(s) that contains records or other information that is relevant to the assessment of the management system and the temporary site(s)
- Use of video and teleconference and other technology that enable effective auditing to be conducted remotely

In each case the method of evaluation should be fully documented and justified in terms of its effectiveness. (See Paragraph3 of this Annex 2, and G.3.2.3., G.3.2.4. and G.3.4.1.)

All attributes of the organization's system, processes, and products/services should be considered and a fair adjustment made for those factors that could justify more or less auditor time for an effective audit. Additive factors may be off-set by subtractive factors. In all cases where adjustments are made to the time provided in the Auditor Time table, sufficient evidence and records shall be maintained to justify the variation.

It would be unlikely that the sum total of all adjustments made for a given organization, considering all factors would reduce the required Auditor Time for the initial audit by more than 30% from the time found in the Auditor Timetable.

The following graphic illustrates the potential interaction of additive and subtractive factors on the Auditor Time found in the chart above.



Annex 3 – Multi-site Certification/registration

This annex provides guidance on Clause 3.3. of ISO/IEC Guide 62. It should be read in conjunction with IAF Guidance G.3.3.2.

0. INTRODUCTION

0.1. The aim of this annex is to establish guidance for the assessment and, if appropriate, the certification/registration of ISO 9001 (including ISO 9002 and 9003 while the 1994 version of the standard is still valid) based quality management systems in organizations with a network of sites, thus ensuring on the one hand, that the assessment provides adequate confidence in the conformity of the quality management system and, on the other, that such assessment is practical and feasible in economic and operative terms.

0.2. Normally assessment for certification/registration and subsequent surveillance should take place at every site of the organization that is to be covered by the certification/registration. However, where an organization's activity subject to certification/registration is carried out in a similar manner at different sites, all under the organization's control, a certification/registration body may put into operation appropriate procedures for sampling the sites both at the assessment and surveillance stages. This annex addresses the conditions under which this is acceptable for accredited certification/registration bodies.

0.3. It does not apply to the assessments of organizations that have multi-sites where dissimilar manufacturing and/or service processes are used at the different sites, even though under the same quality management system. The sampling approach described in this annex is not applicable to the assessments of sites where essentially dissimilar activities take place. The conditions under which certification/registration bodies can make any reduction in the normal full assessment of every site in these circumstances have to be justified on each occasion.

0.4. This annex is applicable to accredited certification/registration bodies that employ sampling in their assessment and certification/registration of multi-site organizations. Nevertheless an accredited certification/registration body may exceptionally deviate from these criteria under condition they are able to produce relevant justifications. These justifications shall, under evaluation by the accreditation body, demonstrate that the same level of confidence can be obtained.

0.5. For reason of simplification, the term "organization" is used to designate any company or other organization owning a quality management system subject to assessment and certification/registration.

1. DEFINITIONS

1.1. Multi-site Organization

1.1.1. A multi-site organization is defined as an organization having an identified central function (normally, and hereafter referred to as a central office) at which certain activities are planned, controlled or managed and a network of local offices or branches (sites) at which such activities are fully or partially carried out.

1.1.2. Such an organization need not be a unique legal entity, but all sites shall have a legal or contractual link with the central office of the organization and be subject to a common quality management system, which is laid down, established and subject to continuous surveillance by the central office. This means that the central office has rights to implement corrective actions when needed in any site. Where applicable this should be laid down in the contract between the central office and the sites.

Examples of possible multi-site organizations are:

1. Organizations operating with franchises,
2. Manufacturing companies with a network of sales offices (this annex would apply to the sales network),
3. Companies with multiple branches.

2. ELIGIBILITY CRITERIA FOR THE ORGANIZATION

2.0.1. The products/services provided by all the sites have to be substantially of the same kind and have to be produced fundamentally according to the same methods and procedures.

2.0.2. The organization's quality management system shall be centrally administered under a centrally controlled plan and be subject to central management review. All the relevant sites (including the central administration function) shall be subject to the organization's internal audit program and have been audited in accordance with that program prior to the certification/registration body starting its assessment.

2.0.3. It shall be demonstrated that the central office of the organization has established a quality management system in accordance with the assessment standard and that the whole organization meets the requirements of the standard. This shall include consideration of relevant regulations.

2.0.4. The organization should demonstrate its ability to collect and analyse data (including but not limited to the items listed below) from all sites including the central office and its authority and ability to initiate organizational change if required:

- System documentation and system changes;
- Management review;
- Complaints;
- Evaluation of corrective actions; and
- Internal audit planning and evaluation of the result.

2.0.5. Not all organizations fulfilling the definition of "multi-site organization" will be eligible for sampling.

2.0.6. Certification/registration bodies should therefore have procedures to restrict site sampling where site sampling is not appropriate to gain sufficient confidence in the effectiveness of the quality management system under assessment. Such restrictions should be defined by the certification/registration body with respect to:

- Scope sectors or activities (i.e. based on the assessment of risks or complexity associated with that sector or activity);

- Size of sites eligible for multi-site assessment;

- Variations in the local implementation of the quality management system such as the need for frequent recourse to the use of quality plans within the quality management system to address different activities or different contractual or regulatory systems;

- Use of temporary sites which operate under the quality management system of the organization.

3. ELIGIBILITY CRITERIA FOR THE CERTIFICATION/REGISTRATION BODY

3.0.1. The certification/registration body shall provide information to the organization about the criteria laid down herein before starting the assessment process, and should not proceed with it if any of the criteria are not met. Before starting the assessment process, it should inform the organization that the certificate/registration will not be issued if during the assessment nonconformities in relation to these criteria are found.

3.1. Contract Review

3.1.1. The certification/registration body's procedures should ensure that the initial contract review identifies the complexity and scale of the activities covered by the quality management system subject to certification/registration and any differences between sites as the basis for determining the level of sampling.

3.1.2.. The certification/registration body shall identify the central function of the organization which is its contractual partner for the performance of the certification/registration.

3.1.3 The certification/registration body should check, in each individual case, to what extent sites of an organization produce or provide substantially the same kind of products or services according to the same procedures and methods. Only after a positive examination by the certification/registration body that all the sites proposed for inclusion in the multi-site exercise meet the criteria may the sampling procedure be applied to the individual sites.

3.1.4. If all the sites of a service organization where the activity subject to certification/registration is performed are not ready to be submitted for certification/registration at the same time, the organization shall be required to inform the certification/registration body in advance of the sites that it wants to include in the certificate.

3.2. Assessment

3.2.1. The certification/registration body shall have documented procedures to deal with assessments under its multi-site procedure. Such procedures shall establish the way the certification/registration body satisfies itself, inter alia, that the same quality management system governs the activities at all the sites, is actually applied to all the sites and that all the criteria in clause 2 above are met. This requirement also applies to a quality management system where electronic document and/or process control, and/or other electronic processes are used.

3.2.2. If more than one audit team is involved in the assessment/surveillance of the network, the certification/registration body should designate a unique audit leader whose responsibility is to consolidate the findings from all the audit teams and to produce a synthesis report.

3.3. Dealing with Nonconformities

3.3.1. When nonconformities are found at any individual site, either through the organization's internal auditing or from auditing by the certification/registration body, investigation should take place to determine whether the other sites may be affected. Therefore, the certification/registration body should require the organization to review the nonconformities to determine whether they indicate an overall system deficiency applicable to all sites or not. If they are found to do so, corrective action should be performed both at the central office and at the individual sites. If they are found not to do so, the organization should be able to demonstrate to the certification/registration body the justification for limiting its follow-up action.

3.3.2. The certification/registration body shall require evidence of these actions and increase its sampling frequency until it is satisfied that control is re-established.

3.3.3. At the time of the decision making process, if any site has a nonconformity, certification/registration shall be denied to the whole network pending satisfactory corrective action.

3.3.4. It shall not be admissible that, in order to overcome the obstacle raised by the existence of a nonconformity at a single site, the organization seeks to exclude from the scope the "problematic" site during the certification/registration process.

3.4. Certificates/Registrations

3.4.1. One single certificate/registration shall be issued with the name and address of the central office of the organization. A list of all the sites to which the certificate/registration relates shall be issued, either on the certificate/registration itself or in an appendix or as otherwise referred to in the certificate/registration. The scope or other reference on the certificate/registration shall make clear that the certified/registered activities are performed by the network of sites in the list. If the certification/registration scope of the sites is only issued as part of the general scope of the organization, its applicability to all the sites shall be clearly stated in the certificate/ registration and any annex.

3.4.2. A sub-certificate/registration may be issued to the organization for each site covered by the certification/registration under condition that it contains the same scope, or a sub-scope of that scope, and includes a clear reference to the main certificate/registration.

3.4.3. The certificate/registration will be withdrawn in its entirety, if the central office or any of the sites does not/do not fulfil the necessary criteria for the maintaining of the certificate/ registration (see 3.2 above).

3.4.4. The list of sites shall be kept updated by the certification/registration body. To this effect, the certification/registration body shall request the organization to inform it about the closure of any of the sites. Failure to provide such information will be considered by the certification/registration body as a misuse of the certificate/registration, and it will act consequently according to its procedures.

3.4.5. Additional sites can be added to an existing certificate as the result of surveillance/ reassessment activities. The certification/registration body shall have a procedure for the addition of new sites.

Note: Temporary sites such as building sites set up by an organization in order to perform specific works are not to be treated as part of a multi-site operation. Any sampling of the activities performed at such sites will be for the purpose of confirming the activities of the permanent office whose quality management system is subject to certification/registration, not for the purpose of granting certificates to the temporary sites themselves.

4. CRITERIA FOR SAMPLING

4.1. Methodology

4.1.1. The sample should be partly selective based on the factors set out below and partly non-selective, and should result in a range of different sites being selected, without excluding the random element of sampling.

4.1.2. At least 25% of the sample should be selected at random.

4.1.3. Taking into account the criteria mentioned hereafter, the remainder should be selected so that the differences among the sites selected over the period of validity of the certificate / registration is as large as possible.

4.1.4. The site selection criteria may include among others the following aspects:

a) Results of internal audits or previous certification/registration assessments,
b) Records of complaints and other relevant aspects of corrective and preventive action,
c) Significant variations in the size of the sites,
d) Variations in the work procedures,
e) Modifications since the last certification/registration assessment,
f) Geographical dispersion.

4.1.5. This selection does not have to be done at the start of the assessment process. It can also be done once the assessment at the central office has been completed. In any case, the central office shall be informed of the sites to be part of the sample. This can be on relatively short notice, but should allow adequate time for preparation for the audit.

4.1.6. The central office shall be examined during every certification/registration audit and at least annually as part of surveillance.

4.2. Size Of Sample

4.2.1. The certification/registration body shall have a procedure for determining the sample to be taken when auditing sites as part of the assessment and certification/registration of a multi-site organization. This should take into account all the factors described in this annex.

4.2.2. In the event that application of the certification/registration body's procedure results in a smaller sample than would result from the application of the guidance set out below, the certification/registration body shall record the reasons justifying this and demonstrate that it is operating in accordance with its approved procedure.

4.2.3. The following guidance is based on the example of a low to medium risk activity with less than 50 employees at each site. The minimum number of sites to be visited per audit is:

Initial audit: the size of the sample should be the square root of the number of remote sites: (y=√x), rounded to the upper whole number.

Surveillance visit: the size of the annual sample should be the square root of the number of remote sites with 0.6 as a coefficient (y=0.6 √x), rounded to the upper whole number.

Reassessment: the size of the sample should be the same as for an initial audit. Nevertheless, where the quality management system has proved to be effective over a period of three years, the size of the sample could be reduced by a factor 0.8, i.e.: (y=0.8 √x), rounded to the upper whole number.

4.2.4. The central office shall be visited in addition.

4.2.5. The size of sample should be increased where the certification/registration body's risk analysis of the activity covered by the quality management system subject to certification/registration indicates special circumstances in respect of factors like:

a) The size of the sites and number of employees,
b) The complexity of the activity and of the quality management system,
c) Variations in working practices,
d) Variations in activities undertaken,
e) Records of complaints and other relevant aspects of corrective and preventive action,
f) Any multinational aspects;
g) Results of internal audits.

4.2.6. When the organization has a hierarchical system of branches (e.g. head (central) office / national offices/regional offices/local branches), the sampling model for initial audit as defined above applies to each level.
Example:

1 head office: visited at each audit cycle (initial/surveillance/reassessment)
4 national offices: sample = 2: minimum 1 at random
27 regional offices: sample = 6: minimum 2 at random
1700 local branches: sample = 42: minimum 11 at random.

4.3. Assessment Times

4.3.1. The audit time to spend for each individual site is another important element to consider, and the certification/registration body shall be prepared to justify the time spent on multi-site assessment in terms of its overall policy for allocation of assessment time.

4.3.2. Normally the number of man-days per site should be consistent with the number shown in the chart in Annex 2 of IAF Guidance on the Application of ISO/IEC Guide 62 - 1996.

4.3.3. Reductions can be applied to take into account the clauses that are not relevant to the local sites and are only examined at the central office.

4.3.4. The complexity of the activity is another factor that may be taken into consideration.

4.3.5. No reduction is permitted for the central office.

4.3.6. The total time expended on initial assessment and surveillance (understood as the total sum of the time spent at each site plus the central office) should never be less than that which would have been calculated for the size and complexity of the operation if all the work had been undertaken at a single site (i.e. with all the employees of the company in the same site). In most cases it will be considerably more.

4.4 Additional Sites

4.4.1. On the application of a new group of sites to join an already certified multi-site network, each new group of sites should be considered as an independent set for the determination of the sample size. After inclusion of the new group in the certificate, the new sites should be cumulated to the previous ones for determining the sample size for future surveillance visits or reassessment audits.

Annex 4 – Transfer of Accredited Certification/registration

This annex provides guidance on clause 3.5 of ISO/IEC Guide 62. See IAF Guidance G.3.5.10. It should also be read in conjunction with ISO/IEC Guide 62, clause 3.8 and IAF Guidance G.2.1.2 to clause 2.1.1.

0. INTRODUCTION

0.1. This annex provides guidance on the transfer of ISO 9001:2000 quality management system certificates between certification/registration bodies.

0.2. The objective of this guidance is to assure the maintenance of the integrity of accredited quality management system certificates issued by one certification/registration body if subsequently transferred to another such body.

0.3. The guidance states minimum requirements for the transfer of certification/registration. Certification/registration bodies may implement procedures or actions which are more stringent than those contained herein provided that an organization's freedom to choose a certification/registration body is not unduly or unfairly constrained.

1. DEFINITION

1.1 Transfer of Certification/registration.

The transfer of certification/registration is defined as the recognition of an existing and valid, [but see clause 2.3.1. of this Annex], quality management system certificate, granted by one accredited certification/registration body, [hereinafter referred to as the "issuing certification/registration body"], by another accredited certification/registration body, [hereinafter referred to as the "accepting certification/registration body"] for the purpose of issuing its own certification/registration.

Note: Multiple certification/registration does not fall under the definition above, and is not encouraged by IAF.

2. MINIMUM REQUIREMENTS

2.1. Accreditation

Only certificates which are covered by an accreditation of an EA, PAC, IAAC or IAF MLA signatory should be eligible for transfer. If the existing certification is accredited by a body that belongs to a regional MLA only, the transfer shall be limited to other accreditations valid within that regional agreement. Organizations holding certificates that are not covered by such accreditations shall be treated as new clients.

2.2. Pre-Transfer Review

A competent person from the accepting certification/registration body shall carry out a review of the certification/registration of the prospective client. This review should be conducted by means of both a paper enquiry and, normally, a visit to the prospective client. The review should cover the following aspects:

2.2.1. Confirmation that the client's certified activities fall within the accredited scope of the accepting certification/registration body.

2.2.2. The reasons for seeking a transfer.

2.2.3. That a valid accredited certificate, in terms of authenticity, duration, scope of activities covered by the quality management system and scope of accreditation, is held in respect of the site or sites wishing to transfer. If practical, the validity of certification/registration and the status of outstanding nonconformities should be verified with the issuing certification/registration body unless it has ceased trading.

2.2.4. A consideration of the last assessment/re-assessment reports, subsequent surveillance reports and any outstanding nonconformities arising therefrom. This consideration should also include any other available, relevant documentation regarding the certification process i.e. handwritten notes, checklists.

2.2.5. Complaints received and action taken.

2.2.6. The stage in the current certification/registration cycle. See paragraph 2.3.4 of this Annex.

2.3. Certification

2.3.1. Transfer should normally only be of a current valid accredited certificate but, in the case of a certificate issued by a certification/registration body that has ceased trading, or that has had its accreditation withdrawn, the accepting certification/registration body may, at its discretion, consider such a certificate for transfer on the basis described in this guidance.

2.3.2. Certificates which are known to have been suspended or to be under threat of suspension should not be accepted for transfer.

2.3.3. Outstanding nonconformities should be closed out, if practical, with the issuing certification/registration body, before transfer. Otherwise they should be closed out by the accepting certification/registration body.

2.3.4. If no further outstanding or potential problems are identified by the pre-transfer review a certificate, dated from the date of completion of the review, may be issued following the normal decision making process. The pattern of the previous certification/registration regime should be

utilised to determine the program of on-going surveillance and re-assessment unless, as a result of the review, the accepting certification/registration body has performed an initial or re-assessment audit.

2.3.5. Where doubt continues to exist, after the pre-transfer review, as to the adequacy of a current or previously held certification/registration, the accepting certification/registration body should, depending upon the extent of doubt, either:

- Treat the applicant as a new client

or

- Conduct an assessment concentrating on identified problem areas

The decision as to the action required will depend upon the nature and extent of any problems found and should be explained to the organization.

Annex 5 - Advanced Surveillance and Reassessment Procedures (ASRP)

This annex provides guidance on clause 3.6 of ISO/IEC Guide 62. See IAF Guidance G3.6.8.

0. INTRODUCTION

0.1 For an organization that has established confidence in its QMS by consistently demonstrating the QMS effectiveness over a period of time, the certification/registration body, in consultation with the organization, may choose to apply the Advanced Surveillance and Reassessment Procedures (ASRP) provided for in this annex. Such an advanced surveillance and reassessment program may place greater (but not total) reliance on the organization's internal audit and management review processes, include targeted surveillance topics, take into account specific design input from the organization and/or use other methods as appropriate, to demonstrate conformity of the QMS.

0.2. The objective of this guidance is to assure the provision of more effective and efficient assessment to organizations that have a proven performance record while at the same time maintaining the integrity of the accredited QMS certificates they hold.

0.3. The guidance states minimum requirements for the application of the ASRP. Certification/registration bodies may implement procedures or actions which are more stringent than those contained herein provided that an organization's justifiable request for the ASRP is not unduly or unfairly constrained.

1. MINIMUM REQUIREMENTS

1.1 Prerequisite

In order to utilize the ASRP, the certification/registration body must first demonstrate to an IAF MLA signatory accreditation body for QMS:

1) That it has been operating an accredited certification/registration scheme for QMS for a minimum of one complete accreditation cycle.

2) That it is competent to design an ASRP program for each individual organization, in accordance with the requirements of ISO 9001:2000 clause 7.3 using the design input criteria mentioned in clause 1.3.2 below.

1.2 Accreditation Scope

The competence of the certification/registration body to meet 1.1 (2) above shall be assessed by the accreditation body after which, if successful, specific reference to the approval for ASRP shall be included in the certification/registration body's accreditation scope.

1.3 Eligibility and Design Input Criteria

The certification/registration body shall inform the accreditation body prior to every new utilization of ASRP for each specific organization, and shall be able to demonstrate that the following criteria in 1.3.1 and 1.3.2 have been satisfied:

1.3.1 Eligibility Criteria

a) The certification/registration body shall confirm that the organization's QMS has been in demonstrated conformity with the requirements of the applicable standard(s) for a period of at least one complete certification cycle including initial, surveillance and reassessment audits.

NOTE: The certification/registration body may base this confirmation of demonstrated conformity on the outcome of the first reassessment (non-ASRP) of the organization conducted at the end of a three-year certification cycle.

b) All nonconformities raised during the certification cycle immediately prior to the utilization of ASRP shall have been successfully resolved.

c) The certification/registration body shall have agreed suitable performance indicators with the organization, on which to judge the ongoing effectiveness of the QMS, and shall ensure that the organization is consistently meeting agreed performance targets. These performance indicators shall address, as a minimum, the organization's demonstrated ability to consistently provide product that meets customer and applicable regulatory requirements (see ISO 9001:2000 clause 1.1), and shall incorporate requirements for the continual improvement of the effectiveness of the QMS.

NOTE In this annex, "indicator" means the characteristic to be measured and "target" means the quantitative/qualitative requirements to be met.

d) The certification/registration body shall have enforceable arrangements with the organization to provide for access to all customer satisfaction data collected or otherwise available. When it becomes necessary for the certification/registration body to communicate directly with the source of such data in order to validate the data, mutually agreed confidentiality policies and procedures shall be applied.

e) The certification/registration body shall verify that the organization's internal audit process is being managed in accordance with the guidance of ISO 19011, with particular reference to auditor competence defined in clause 7. The internal audit process shall be sufficiently coordinated and integrated so as to provide an evaluation of the QMS as a whole, not only the performance of individual components.

f) The certification/registration body shall have contractually enforceable arrangements to enable it to increase the scope, frequency and duration of its audits in the event of a deterioration of the organization's ability to meet agreed performance targets.

1.3.2 Design Input Criteria

In addition to organization-specific input criteria, the design of each individual ASRP shall address the following:

a) The frequency and duration of the certification/registration body audits shall be sufficient to allow the certification/registration body to conform with this Annex 5 including the following b) and c), among others.

For each proposed utilization of ASRP, the certification/registration body shall determine the base level (non-ASRP) auditor time using Annex 2 and, if applicable, Annex 3. If the certification/registration body plans an individual ASRP program that reduces the auditor time to less than 70% of this base-level, the certification/registration body shall justify such reductions and seek specific approval from the accreditation body prior to its implementation.

b) In addition to auditing a statistically significant number of samples of the organization's management system processes to confirm the adequacy and effectiveness of the internal audit process, the certification/registration body itself shall continue to carry out the following activities at each on-site surveillance and reassessment visit, ***as a minimum*** (with other activities defined by the ASRP; see clause 1.4 below):

- interview top management and the management representative;
- evaluate management review inputs and outputs, including a verification of the organization's ability to meet the agreed performance targets;
- review the internal audit process, including the procedures and records of internal audits, and the competence of internal auditors;
- review corrective and preventive actions plans, and verify their effective implementation.

c) The certification/registration body shall ensure that all the requirements for accredited certification (including the requirements of ISO/IEC Guide 62 and any applicable sector scheme) continue to be met.

1.4 Design Output

The design output for each application of the certification/registration body's ASRP program shall include the following (a) – (f):

a) The extent to which the certification/registration body will utilize the organization's internal audit and management review processes to complement the certification/registration body's activities;

b) Criteria for witnessing the organization's internal audits, including sampling of both auditors and processes to be audited;

c) Criteria for accepting and monitoring the competence of the organization's internal auditors and the method of reporting internal audit results;

d) Criteria for ongoing adjustments to the assessment program, taking into account the organization's demonstrated ability over time to meet the agreed performance targets;

e) The components of the QMS that will necessarily be assessed by the certification/registration body at each surveillance and reassessment visit (see 1.3.2 b));

f) Specific certification/registration body auditor competence criteria.

1.5 Certificates

The certification/registration body shall not differentiate between ASRP and non-ASRP methodologies on the certificates it issues.

End of IAF Guidance on the Application of ISO/IEC Guide 62

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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