European co-operation for Accreditation

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EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites

PURPOSE

In order to prevent the possible diminution of the credibility in accredited product certification created by certification schemes applying unacceptable sampling principles this document has been prepared to harmonize generic principles for certification of processes for the production of primary sector products performed by Multi-site organizations and/or producer groups under ISO/IEC Guide 65 accreditation. This guidance addresses certification bodies designing certification systems as well as scheme owners developing and validating schemes being subject to accredited certification.

Authorship
The publication has been written by a task force of the EA Certification Committee.

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

Copyright

Further information
For further information about this publication, you should contact your national member of EA or the Chairman of the Certification Committee.

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CONTENTS

1. FOREWORD

This document has been prepared by a task force under the direction of the European Co-operation for Accreditation (EA) Certification Committee to harmonize generic principles for a specific application of ISO/IEC Guide 65[1] as defined in the purpose.

A growing number of certification schemes enter the market focusing on the specific characteristics of the production process rather than specific characteristics of the products themselves. A product can have non tangible characteristics or can be non tangible (service) which can only be inspected/tested during the production process or can have characteristics which can only be tested on the product by destroying the product. This option is not always economically acceptable. In these cases the certification of a product is performed on the basis of inspecting/testing the essential process characteristics. In these cases it is not only necessary to evaluate the processes of a supplier but it is often necessary to evaluate the processes from the primary level all the way up to the level of the supplier. This means that the work performed by sub-suppliers often has to be evaluated as well. This is a contrast in comparison to "traditional" product certification of quality aspects of tangible products.
Often – e.g. in food or forestry production - there are production processes which are distributed to many locations. Several schemes permit the grouping of producers under one certificate rather than requiring that each location (sub-supplier) must have its own certificate for its process(es).

This guidance paper provides generic rules for sampling of production sites in certification procedures applied to certified process structures, including producer groups, taking into account the principles for multi-site certification as defined in IAF MD1:2007.
The application of IAF MD1:2007 may be appropriate when adapted to the particular application of ISO/IEC Guide 65 (see annex 2 of IAF GD5:2006) as presented in this Guideline. This "extension" of the principles and requirements of the IAF MD1 is supported by the fact that MD1 speaks about the open (that means that it is not restricted to management certification under 17021) use of IAF MD1:2007 as defined in the scope of the IAF MD1:2007. It is used here for the evaluation of the management systems supporting the process certification (see system 6 in ISO/IEC Guide 67:2004) in each respective case.

The focus of this document is restricted to processes of primary production like food or forestry production. Applicability to other certification schemes has to be checked and confirmed later.
Wherever sampling is taken into account the sampling rules shall be

- checked very critically and validated by the scheme-owners,
- confirmed by independent parties and/or public authorities (see also 4.2).

Inspection activities required by a certification scheme are expected to follow the same requirements. This comes as a natural consequence since the audit of the supporting management system will be directly linked to the inspection of the processes at a site.

The level of credibility of certification under ISO/IEC Guide 65 shall be ensured for the certification of processes under consideration.

Sampling of sites in product certification is accepted by accreditation bodies and certification bodies under conditions outlined in this document.

[1] "ISO/IEC Guide 65" is used synonymous also for "EN 45011" throughout this document.

This document SHALL BE read together with IAF MD1:2007 (for convenience the text is included in the annex of this document) **in order to identify all requirements which are to be considered.**

The term "shall" is used throughout this document to indicate those provisions which reflecting the requirements of EA are mandatory. The term "should" is used to indicate guidance which, although not mandatory, is provided as a recognised means of meeting the requirements. Certification bodies and scheme owners whose systems do not follow the guidance in any respect will only be eligible for accreditation if they can demonstrate that they meet it in an equivalent way.

2. NORMATIVE DOCUMENTS

- IAF MD1:2007 "IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling"
- IAF GD 5:2006 "IAF Guidance on the Application of ISO/IEC Guide 65:1996"

3. DEFINITIONS

Apart from the definitions given below and in the normative documents (see chapter 2), the definitions of ISO 17000: 2004 "Conformity assessment – Vocabulary and general principles" apply to this document.

3.1. Supplier

ISO Guide 65 defines the supplier - the party that is responsible for ensuring that products meet and, if applicable, continue to meet the requirements on which the certification is based. For group certification the suppler is the certified legal entity.

3.2. Evaluation

Selection and determination function activities in the certification process as described in ISO/IEC 17000:2004 A.2 and A.3 (ISO/IEC CD 17065)

The selection and determination is in certification of products/processes/services normally mainly consisting of testing and/or inspection.

In process certification the main tool is inspection which, in short terms, is defined as "determination of conformity with specific requirements" (see ISO/IEC 17000:2004 clause 4.3). In some schemes testing is performed by the CB in order to verify the performance of the process. Audits may also be performed to evaluate supporting internal control systems or management systems.

3.3. Certification System

Rules, procedures and management for carrying out third party conformity assessment (on the basis of definition 2.7 of EN ISO/IEC 17000:2005, GD 5:2006 G.3.1)
The certification system of a certification body may constitute the application of a certification programme.

3.4. Certification program (or scheme)

Certification system related to specific products to which the same specified requirements, rules and procedures apply (on the basis of definition 2.8 of EN ISO/IEC 17000:2005, GD 5:2006 G.3.1)

3.5. Site (as defined in IAF MD1:2007 clauses 1.2 and 2.1.1)

A site is a permanent location where an organization carries out production processes.

A site could include all ground or water areas on which activities under the control of an organization at a given location are carried out including any connected or associated storage of raw materials, by-products, intermediate products, end products and waste material, and any equipment or infrastructure involved in the activities, whether or not fixed. Alternatively, where required by law, definitions laid down in national or local licensing regimes shall apply.

3.6. Set of Sites

A number of sites operating to the criteria in IAF MD1:2007 chapter 3.0.1. that are “clustered” with the purpose of enabling sampling among these sites when performing certification activities. (See also IAF MD1:2007 chapter 5.4.1)

Rationale: A certified organisation may include several types of products/processes that are not of substantially the same kind. At the same time there may be several sites operating processes that are of the same kind e.g. 5 sites may be operating process A while 4 sites are operating process B and 8 sites are operating process C. In this example the 5 sites for process A constitutes a set of sites and so do the 4 sites for process B and the 8 sites for process C respectively.

3.7. Multi-site Organization (as defined in IAF MD1:2007)

A multi-site organization is defined as an organization having an identified central function (hereafter referred to as a central office – but not necessarily the headquarters of the organization) 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.

3.8. Multi-site Certification

Certification covering multi-site organisations including several sites (when applying the square root rule of MD1:2007 it means 4 or more sites in practice) and where sampling of these sites may be used by the certification body in its conformity assessment work, under the conditions set up in this document. The scope of certification covers the actual products and processes as defined in the normative documents describing the scheme in question. Every site covered by this certification is mentioned on the main certificate documentation and every site is entitled to get its own sub-certificate (see also MD1 section 4.4).

All sites covered by the multi-site certification have their processes evaluated by the certification body according to the principles of this document and thus they, in general, may trade products with claims of being certified. It shall be addressed in the certification scheme, by the scheme owner, whether sites may trade claimed products.

3.9. Group Certification

In group certification only the certified umbrella organisation is entitled to mark the products.
Group certification is a special case of certification where Scheme owners specify that less extensive sampling can be applied by certification bodies through a focus on the management system of the umbrella organisation in combination with inspection of a sample of the sites. These schemes are often used to support small size producers that according to the scheme owner are at risk of being left out of the market unless these special conditions are applied. In the certification process the audit of the effectiveness of the supporting internal management/control system is essential.
See also figure 2.

3.10. Producer

A legal entity or person performing part of or the entire process or production that is the subject of conformity assessment. In some certification schemes producers are typical sub-suppliers to the supplier (see 2.1). A producer could represent one or several sites.

3.11. Producer Group

Group of legal entities or persons, whose production processes are organised by an umbrella organisation.

3.12. Umbrella organisation

A legal entity or person managing the activities of a producer group. For certification purposes it shall have the authority to enforce the requirements as identified in ISO/IEC Guide 65 (the supplier in ISO/IEC Guide 65) through legally binding agreements with the group members.

3.13. Member

In group certification, producer groups (see 3.11) consist of members. Each member could represent one or several sites.
The purpose of allowing group certification is to enable small producers to take part in the certification system. Therefore the size of the group members is limited (see 4.3.3).
Members are not entitled to have a certificate from a certification body.

3.14. Scheme Owner

The party responsible for designing, validating and maintaining the certification scheme, its normative documents and its related criteria.

3.15. Validation of a certification scheme

Validation of a certification scheme is the confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled. Validation should be consistent with the characteristics of the process to be certified.

4. APPLICATION OF IAF MD1:2007 TO THE CERTIFICATION OF PRODUCTION PROCESSES

According to MD1, normally initial audits for certification and subsequent surveillance and recertification audits should take place at every site of the organization that is to be covered by the certification. However, where an organisation's activity subject to certification is carried out in a similar manner at different sites, all under the organisation's authority and control, a certification body may put into operation appropriate procedures for sampling the sites at the initial audit and subsequent surveillance and recertification audits. This document addresses the conditions under which this is acceptable for accredited certification bodies including the calculation of sample size (IAF MD1:2007 chapter 0.2).

This paper, EA-6/0X, gives guidance to the application of relevant clauses of IAF MD1 to the production processes under consideration.
The application of this paper shall not supersede requirements laid down in requirements of other food safety management systems e.g. ISO 22003, when such requirements are defined for a supporting management system as a part of the certification scheme.

4.1. Types of Multi-Site Organisations

Multi-site organisations may have all various kinds of organisation. Figure 1 shows examples of possible organizations seeking multi-site certification for one or more products.
Detailed requirements for the eligibility of an organisation for sampling are set in clause 4.3.3.

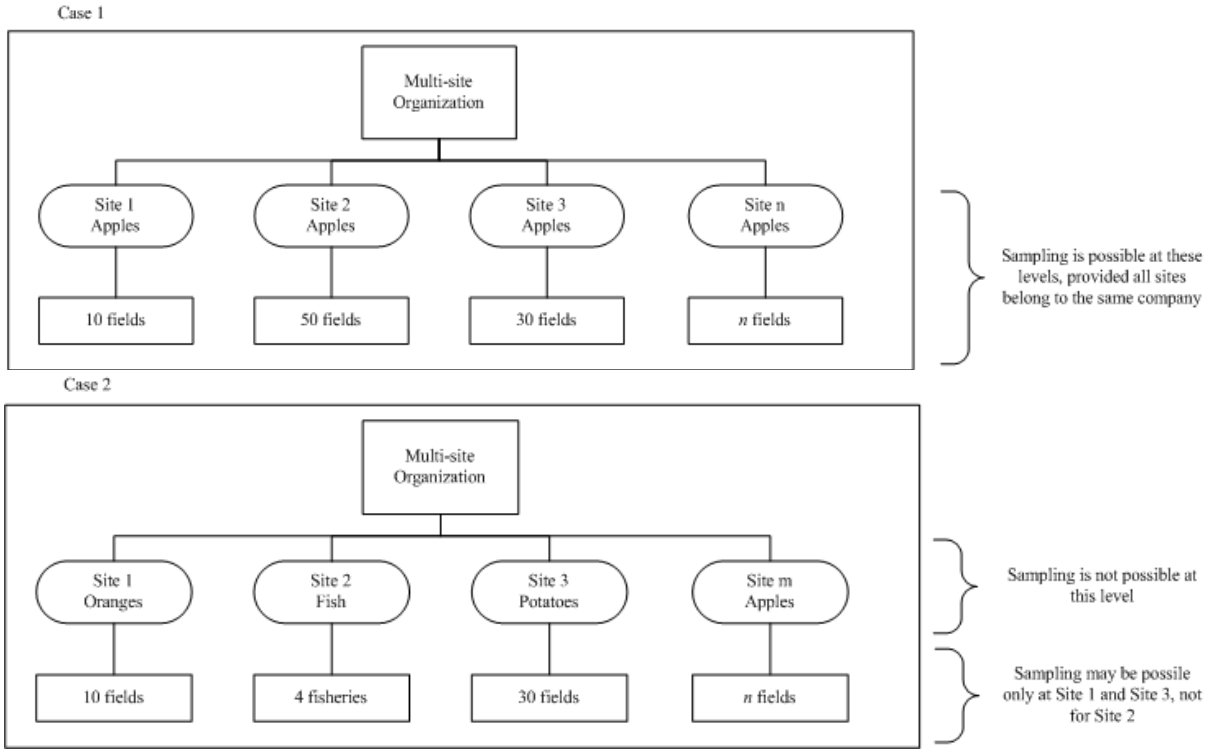

Figure 1 - Example of Multi-site Organisations applying for Certification

The figure gives assistance to CBs for their risk based analysis of the structure of an applicant body. For instance:

- Case 1: The multi-site organisation produces apples at different sites. Sites may consist of a number of fields. Sampling may be possible if the risks are low, e.g. processes are similar, all sites belong to the same company etc.
  In special cases a part of the multi-site organisation can be a producer group (see fig. 2)

- Case 2: Sampling of sites with different kinds of products will normally not be allowed. If you have few companies with risky products like e.g. fish or different processes sampling will not be allowed.

Certification schemes may define specific sampling requirements.

Figure 2 shows an example of a typical organization seeking group certification for one or more products.

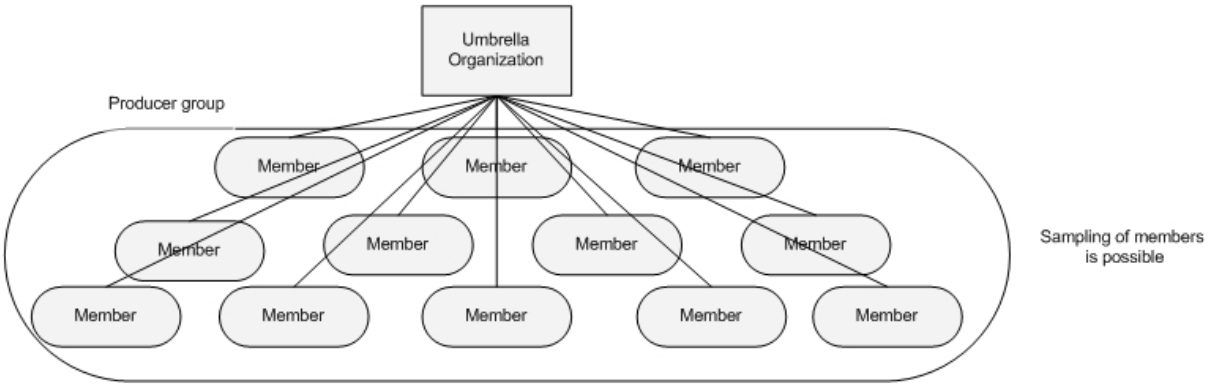

Figure 2 - Example of an umbrella organisation applying for certification

The basic principles for sampling of members of a producer group discussed above apply as well for the evaluation by the certification body as for the umbrella organisation when performing its internal control activities.

Certification bodies have to analyse the structure as stated in IAF MD1 according to written procedures and perform a risk analysis in order to gain sufficient assurance of process conformity as it is required in the certification scheme.

The principle of **multi-site certification** can be accepted as long as it is relying on accredited certification body activities performed according to the criteria of this document.
Group certification can be accepted in order to support small producers. Key aspects of both types of organisations are summarised in table 1.

Table 1 - Key Aspects of Multi-Site Organisations and Producer Groups

Multi-Site	**Group**
A multi-site organization is defined as an organization having an identified central function (hereafter referred to as a central office – but not necessarily the headquarters of the organization) at which certain activities are planned, controlled or managed (see 3.7)	Group of legal entities or persons, whose production processes are organised by an umbrella organisation. The purpose of allowing group certification is to enable small producers to take part in certification. Therefore the size of the group members is limited (see 3.13).
The conformity assessment is based only on third-party certification body activities.	The conformity assessment is based on both third-party certification body activities and the internal function (ref. IAF GD5 Annex2) of the umbrella organisation. Members in group certification may be evaluated by the certification body with lower frequency as opposed to how this is applied in multi-site certification.
Sites are identified in the certificate document, sub-certificates issued to sites are allowed. Sites may trade products with claims of being certified.	Group members are not identified in the certificate. They are not entitled to sell marked products / make claims of being certified on their own. Umbrella organisation must have complete overview/control of the trade of marked products. The member is related to the certified organization in a similar manner to that of a sub-supplier.

4.2. Requirements for normative documents

Product and/or process requirements shall be described in normative documents. Normative documents should be developed, validated and maintained by a process enabling technical input of interested parties such as suppliers, regulators and users of the product (IAF GD 5: G4.1.3).

The certification schemes which are addressed by the paper shall be validated by the scheme owner. Such validation shall include periodical evaluations of sites where the effectiveness of management systems shall be audited and production processes inspected. The results shall be evaluated and relevant improvements shall be introduced into the scheme. If there are schemes where this is not the case the certification body is responsible for the validation of its certification system.

Requirements for normative documents are set up in ISO/IEC 17007. Accreditation bodies shall not be involved in this process. Scheme owners have a task and responsibility for this process (IAF GD5:2006 G 4.1.4).
In case of process certification, the documents cited in clause 4.1.3 of ISO/IEC Guide 65 shall clearly identify the processes to be assessed, the relevant requirements and the methods for assessment of conformity (IAF GD5:2006 G.4.1.5.).

4.3. Requirements to the certification of production processes – Adaptation of IAF MD1:2007

IAF MD1 (for full text see annex) describes generic rules for the certification of management systems. Some of these requirements do not fit directly to certification of processes. Here these clauses are analysed and completed with specific requirements for multi-site and group certification (headlines and clause numbering follows IAF MD1:2007 i.e. 4.3.1 = clause 1, 4.3.2 = clause 2 etc.).

General

- Clause 0 of IAF MD1 does not need to be transferred to the application of this document.
- Throughout the document, read “certification schemes” instead of “management system standards”
- For group certification; read “umbrella organisation” instead of “central office”.

4.3.1. Definitions

- Full application of MD1.

4.3.2. Application

- Full application of MD1.
- Schemes adopting sampling of sites under accreditation to ISO Guide 65 shall include surveillance.

4.3.3. Eligibility of an Organization for Sampling

- full application of MD1:2007
- additional requirements :
  - The organisation’s central office shall be contractually responsible to the certification body for ensuring that the certification standards are fully implemented and enforced at all of the participating sites.
  - The organization shall have implemented an internal control system which has sufficient control of the production processes. The internal audit system shall cover all sites.
  - The organisation’s central office’s procedures for managing the production process shall be clearly documented including those for participating sites.
  - The organisation’s central office shall be responsible for ensuring that any conditions on which certification is dependent and any non-conformities issued by the CB thereafter are fully implemented throughout the organisation, considering the requirement in clause 4.4.5 of IAF MD1:2007.
  - The organisation’s central office shall keep all relevant documents related to participating sites at the organisation’s central office. The organisation’s central office will ensure accurate collecting of inflows and outflows of materials at the site level.
  - The organisation’s central office shall have a system for ensuring that all market claims and trademark use by all participating sites are meeting scheme requirements prior to publication. Any representation of certified status of sites and their products shall be made in reference to the certified organisation.

- The organisation's central office shall provide each site with ready access to updated documentation and information, specifying the relevant terms and conditions of certification under multi-site (or group certification) guidelines paying special attention to clauses 3.0.5, 4.1.4, 4.3.1, 4.3.3, 4.3.4, 4.4.5.
- The organisation's central office shall have sufficient management and technical capacity to implement the responsibilities specified above.

Inspection and Monitoring Responsibilities of the Organisation's central office:

- The organisation's central office shall carry out an initial inspection visit of each site and review the implementation of the documented systems, prior to their application for certification.
- The organisation's central office shall inspect each site covered by the scope of the certificate on-site at least annually. The application of this requirement should take into account the production cycles for the product/process in question.
- The organisation's central office shall have a clear system for reporting on these inspections to the site managers. Records shall be kept centrally and made available to the certification body on request.
- The personnel performing Inspection (including internal audit) shall be competent to perform their designated tasks. They should have relevant experience and training in the field where they are performing their tasks. Internal auditors shall have received special education and training for that work and should meet the guidelines of ISO 19011 when appointed for, and when performing, internal audits. Relevant knowledge of ISO 17020 (inspection principles) and ISO 17025 (laboratory principles) shall be part of the competence held by staff performing any type of inspection and monitoring activities.

Specific requirements for group Certification:

- Producers shall be part of group certification only where the cost of multi-site certification would exceed 2% of the individual producer's turnover. The cost is here to be calculated as the annual cost for direct evaluation work on the member's activities + the members share of the cost for evaluation work on the central office activities. Cost here means the cost for third-party certification body evaluation work.
- Organisations that do not fulfil the maximum size requirements above may become members of the group but the certification body shall treat these as if they were a site in a multi-site certification.
- The umbrella organisation shall have clear, documented procedures for new member sites to be added to the group after a certificate has been awarded. The limits of growth rate in the number of sites that are permitted will be set by the certification body and shall not be exceeded. Likewise, documented procedures for suspension and withdrawal of membership shall be defined. The umbrella organisation shall notify the certification body of the addition or reduction of sites as soon as possible and appropriate.
- Members in group certification may not claim to be individually certified. It is the umbrella organisation that is certified. Members may only claim that they are members in a group certification. The umbrella organisation shall maintain an up-to-date list of members.
- The number of sites to be covered by the umbrella organisation's internal control work e.g. internal audits audit is described in clause 4.3.5

- The umbrella organisation shall have and maintain procedures for resolving complaints relating to products or processes of members covered by certification. The umbrella organisation shall keep records of all complaints and to make these records available to the certification body when requested.
- The umbrella organisation shall keep all relevant documents related to participating sites, including location and surface area, at the organisation's central office. The organisation's central office will ensure accurate collecting of inflows and outflows of materials at the site level.

4.3.4. Eligibility of the Certification Body

- Read ISO/IEC Guide 65 and the relevant clauses of IAF GD5:2006 instead of ISO/IEC 17021.
- Certification documents shall address the guidance in IAF GD5:2005 G.12.8 where the word "should" shall be exchanged for "shall".
- In the case of certification of processes the certification documents shall unambiguously identify both the products and the production processes.
- When group certification is applied the certification documentation shall identify this in a clear manner.
- Members in group certification are not entitled to get sub-certificates to the certificate provided to the umbrella organisation in charge of the group.
- The documented evaluation procedures shall define sampling, inspection, audit and testing methods as appropriate to the scheme and shall also cover surveillance.

4.3.5. Sampling

MD1 text is valid taking into account that the procedures are minimum samples, and there is a duty to increase the number of samples according to the risk level of the organization.

- 5.1.4(MD 1) Add:
  - complaints about products related to certification scope
  - legislation
  - seasonal aspects of agriculture
- 5.1.5(MD 1) Unannounced evaluations should be foreseen by schemes.
- 5.3(MD 1) Inspection and/or testing methods shall be defined and documented. If applicable, time for the evaluation of the supporting management system shall be set by the scheme owner.
- 5.3.2(MD 1) Add normative scheme documents to the IAF documents.

Specific requirements for Multi-site Certification

- 5.1(MD 1) Using the square root principle in Multi-site certification of product/processes is acceptable, however, the principle is not useful for big numbers of sites; the relative number of evaluated sites becomes very small. Thus, when defining sets of sites, the maximum number of sites in a set shall be 50.

  Note: A certificate may cover several sets.

- 5.2(MD 1) The Certification body may **not** apply sampling of sites during evaluation for **initial** certification.

Note: Certification of products often includes a message to end users by means of on-product marking/labelling. the message conveyed by this mark or label suggests a level of credibility which is generally considered to be expected and perceived as higher as compared to what is perceived from certification of management systems.
In order to make a clear distinction between certification of products/processes and certification of management systems the requirement above should be applied in certification of products/processes.

Specific requirements for Group Certification

5.2(MD 1) Before the evaluation work for initial certification can be finalised by the certification body, the umbrella organisation shall have evaluated **all** sites of the group using an evaluation method that has been monitored and approved by the certification body.

When the certification body performs sampling in a set of sites, they shall as a minimum apply the square root with a minimum of 5%. This applies for initial audit, surveillance and re-assessment.

The number of sites evaluated by the umbrella organisation in the work with internal control work should be minimum 4 times as many as those evaluated by the certification body.

5. REQUIREMENTS FOR SCHEME OWNERS

This document specifies minimum requirements to be met by certification bodies and certified organizations when they wish to apply sampling of sites in accredited product certification under ISO Guide 65 under accreditation by an EA member.

Scheme owners shall make sure that the requirements stated in this document are addressed in normative documents of the certification scheme in question and are in line with EA-2/11(EA Policy for Conformity Assessment Schemes). The minimum criteria shall be met. Failing to do so will lead to the scheme not being accepted for accredited certification by members of EA.

For certification of processes, clause G4.1.5 in IAF GD5:2006 shall be taken into account.

6. ANNEX 1: IAF MD1:2007

Here the unchanged text of MD 1:2007 is included for 2 reasons:
- for convenience for the reader (MD1:2007 is basic part of the document)
- in case of changes of MD1 the 2007 version is available.

IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling

This document is mandatory for the consistent application of Clause 9.1.5. of ISO/IEC 17021:2006 and is based upon guidance previously provided in IAF GD2: 2005 Annex 3 and IAF GD6:2003, clause G.5.3.5 – G.5.3.13. All clauses of ISO/IEC 17021:2006 continue to apply and this document does not supersede any of the requirements in that standard. This mandatory document is not exclusively for Quality Management Systems (QMS) and Environmental Management Systems (EMS) and may be used for other management systems. However, relevant standards may provide specific requirements for multiple sites or preclude the use of sampling (eg. ISO/IEC 27006, ISO/TS 22003).

0. INTRODUCTION

0.1. This document is for the audit and, if appropriate, the certification of management systems in organizations with a network of sites to ensure that the audit provides adequate confidence in the conformity of the management system to the relevant standard across all sites listed and that the audit is both practical and feasible in economic and operative terms.

0.2. Normally initial audits for certification and subsequent surveillance and recertification audits should take place at every site of the organization that is to be covered by the certification. However, where an organization's activity subject to certification is carried out in a similar manner at different sites, all under the organization's authority and control, a certification body may put into operation appropriate procedures for sampling the sites at the initial audit and subsequent surveillance and recertification audits. This document addresses the conditions under which this is acceptable for accredited certification bodies including the calculation of sample size and audit duration.

0.3. This document does not apply to the audits of organizations that have multi-sites where fundamentally dissimilar processes or activities are used at the different sites, or a combination of sites, even though they may be under the same management system. The conditions under which certification bodies can make any reduction in the normal full audit of every site in these circumstances have to be justified at each site where a reduction is proposed.

0.4. This document is applicable to accredited certification bodies that employ sampling in their audit and certification of multi-site organizations. Nevertheless an accredited certification body may exceptionally deviate from this document under condition it is able to produce relevant justifications. These justifications shall, under evaluation by the accreditation body, demonstrate that the same level of confidence in the conformity of the management system across all the sites listed can be obtained.

0.5. When an organization is considered a candidate for certification based on sampling, the certification body shall have arrangements to explain the application of this document to the organization prior to the commencement of the audit.

1. DEFINITIONS

1.1. Organization

The term organization is used to designate any company or other organization owning a management system subject to audit and certification.

1.2. Site

A site is a permanent location where an organization carries out work or a service.

1.3. Temporary Site

A temporary site is one set up by an organization in order to perform specific work or a service for a finite period of time and which will not become a permanent site. (eg. construction site).

1.4. Additional Sites

A new site or group of sites that will be added to an existing certified multi-site network.

1.5. Multi-site Organization

A multi-site organization is defined as an organization having an identified central function (hereafter referred to as a central office – but not necessarily the headquarters of the organization) 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.

2. APPLICATION

2.1. Site

2.1.1. A site could include all land on which activities under the control of an organization at a given location are carried out including any connected or associated storage of raw materials, by-products, intermediate products, end products and waste material, and any equipment or infrastructure involved in the activities, whether or not fixed. Alternatively, where required by law, definitions laid down in national or local licensing regimes shall apply.

2.1.2. Where it is not practicable to define a location (e.g. for services), the coverage of the certification should take into account the organization’s headquarters activities as well as delivery of its services. Where relevant, the certification body may decide that the certification audit will be carried out only where the organization delivers its services. In such cases all the interfaces with its central office shall be identified and audited.

2.2. Temporary Site

2.2.1. Temporary sites that are covered by the organization's management system may be subject to audit on a sample basis to provide evidence of the operation and effectiveness of the management system. They may, however be included within the scope of a multi-site certification subject to agreement between the certification body and the client organization. Where included in the scope, such sites shall be identified as temporary.

2.3. Multi-site Organization

2.3.1. A multi-site 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 management system, which is laid down, established and subject to continuous surveillance and internal audits by the central office. This means that the central office has rights to require that the sites implement corrective actions when needed in any site. Where applicable this should be set out in the formal agreement between the central office and the sites.

Examples of possible multi-site organizations are:

- Organizations operating with franchises
- Manufacturing companies with a network of sales offices (this document would apply to the sales network)
- Service companies with multiple sites offering a similar service
- Companies with multiple branches

3. ELIGIBILITY OF AN ORGANIZATION FOR SAMPLING

3.0.1 The processes at all the sites have to be substantially of the same kind and have to be operated to similar methods and procedures. Where some of the sites under consideration conduct similar, but fewer processes than others, they may be eligible for inclusion under multi-site certification providing that the sites(s) which conduct the most processes, or critical processes are subject to full audit.

3.0.2 Organizations which conduct their business through linked processes in different locations are also eligible for sampling providing all other provisions of this document are met. Where processes in each location are not similar but are clearly linked, the sampling plan shall include at least one example of each process conducted by the organization (eg. fabrication of electronic components in one location, assembly of the same components – by the same company in several other locations).

3.0.3 The organization's management system shall be under a centrally controlled and administered 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 all shall have been audited in accordance with that program prior to the certification body starting its audit.

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

3.0.5 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 also demonstrate its authority and ability to initiate organizational change if required:

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

- Changes to aspects and associated impacts for environmental management systems (EMS) and
- Different legal requirements.

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

3.0.7 Not all management systems standards are suitable for consideration for multi-site certification. For example, multi-site sampling would be unsuitable where the audit of variable local factors is a requirement of the standard. Specific rules apply also for some schemes, for example those including automotive (TS 16949) and aerospace (AS 9100 series) and the requirements of such schemes shall take precedence.

3.0.8 Certification bodies should have documented procedures to restrict such sampling where site sampling is inappropriate to gain sufficient confidence in the effectiveness of the management system under audit. Such restrictions should be defined by the certification 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 audit;
- Variations in the local implementation of the management system such as the need for frequent recourse to the use of plans within the management system to address different activities or different contractual or regulatory systems;
- Use of temporary sites that operate under the management system of the organization and which are not to be included within the scope of certification.

4. ELIGIBILITY OF THE CERTIFICATION BODY

4.0.1. The certification body shall provide information to the organization about the application of this document and the relevant management system standards before starting the audit process, and should not proceed if any of the provisions are not met. Before starting the audit process, the certification body should inform the organization that the certificate will not be issued if during an initial audit nonconformities are found.

4.1. Contract Review

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

4.1.2. The certification body shall identify the central function of the organization with which it has a legally enforceable agreement for the provision of certification activities.

4.1.3. The certification body shall check, in each individual case, to what extent sites of an organization operate substantially the same kind of processes according to the same procedures and methods. See clause 3.1.1 for sites which conduct fewer, but similar processes than other sites and clause 3.1.2 for sites involving linked processes. Only after a positive examination by the certification body that all the sites proposed for inclusion in the multi-site exercise meet the eligibility provisions may the sampling procedure be applied to the individual sites.

4.1.4. If all the sites of a service organization where the activity subject to certification is performed are not ready to be submitted for certification at the same time, the organization shall be required to inform the certification body in advance of the sites that it wants to be included in the certification and those which are to be excluded.

4.2. Audit

4.2.1. The certification body shall have documented procedures to deal with audits under its multi-site procedure. Such procedures shall establish the way the certification body satisfies itself that the same management system governs the activities at all the sites, is actually applied to all the sites and that all the eligibility criteria for the organization in clause 3 above are met. This requirement also applies to a management system where electronic documents, process control or other electronic processes are used. The certification body shall justify and record the rationale for proceeding with a multi-site approach.

4.2.2. If more than one audit team is involved in the audit or surveillance of the network, the certification 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.

4.3. Nonconformities

4.3.1. When nonconformities, as defined in ISO/IEC 17021 clause 9.1.15 (b), are found at any individual site, either through the organization's internal auditing or from auditing by the certification body, investigation should take place to determine whether the other sites may be affected. Therefore, the certification body should require the organization to review the nonconformities to determine whether they indicate an overall system deficiency applicable to other sites or not. If they are found to do so, corrective action should be performed and verified both at the central office and at the individual affected sites. If they are found not to do so, the organization should be able to demonstrate to the certification body the justification for limiting its follow-up corrective action.

4.3.2. The certification body shall require evidence of these actions and increase its sampling frequency and/or the size of sample until it is satisfied that control is re-established.

4.3.3. At the time of the decision making process, if any site has a nonconformity, as defined in ISO/IEC 17021 clause 9.1.15 (b), certification shall be denied to the whole network of listed sites pending satisfactory corrective action.

4.3.4. 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 process. Such exclusion can only be agreed in advance (See clause 4.1.4).

4.4. Certification Documents

4.4.1. Certification documents can be issued covering multiple sites provided that each site included in the scope of certification has either been individually audited by the certification body or audited using the sample approach outlined in this document.

4.4.2. The certification body shall provide certification documents to the certified client by any means it chooses. Such certification documents shall comply in all respects with ISO/IEC 17021.

4.4.3. These documents shall contain the name and address of the central office of the organization and a list of all the sites to which the certification documents relate. The scope or other reference on these documents shall make clear that the certified activities are performed by the network of sites on the list. If the certification 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. . Where temporary sites are included in the scope, such sites shall be identified as temporary in the certification documents.

4.4.4. Certification documents may be issued to the organization for each site covered by the certification under condition that they contain the same scope, or a sub-scope of that scope, and include a clear reference to the main certification documents.

4.4.5. The certification documentation will be withdrawn in its entirety, if the central office or any of the sites does not fulfil the necessary provisions for the maintenance of the certification.

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

4.4.7. Additional sites can be added to an existing certification as the result of surveillance or recertification activities or enhancement of scope. The certification body shall have documented procedures for the addition of new sites.

5. SAMPLING

5.1. Methodology

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

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

5.1.3. Taking into account the provisions mentioned below, the remainder should be selected so that the differences among the sites selected over the period of validity of the certificate is as large as possible.

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

- Results of internal site audits and management reviews or previous certification audits;
- Records of complaints and other relevant aspects of corrective and preventive action;
- Significant variations in the size of the sites;
- Variations in shift patterns and work procedures;
- Complexity of the management system and processes conducted at the sites;
- Modifications since the last certification audit;
- Maturity of the management system and knowledge of the organization;
- Environmental issues and extent of aspects and associated impacts for environmental (EMS) management systems;
- Differences in culture, language and regulatory requirements; and
- Geographical dispersion.

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

5.2. Size Of Sample

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

5.2.2. The certification body shall have records on each application of multi-site sampling justifying it is operating in accordance with this document.

5.2.3. The following calculation is an example 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: ($y=\sqrt{x}$), rounded to the upper whole number.
- **Surveillance audit:** the size of the annual sample should be the square root of the number of remote sites with 0.6 as a coefficient ($y=0.6\ \sqrt{x}$), rounded to the upper whole number.
- **Re-certification audit:** the size of the sample should be the same as for an initial audit. Nevertheless, where the 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.: ($y=0.8\ \sqrt{x}$), rounded to the upper whole number.

5.2.4. The certification body should define within its management system the risk levels of activities as applied above

5.2.5. The central office shall be audited during every initial certification and recertification audit and at least annually as part of surveillance.

5.2.6. The size or frequency of the sample should be increased where the certification body's risk analysis of the activity covered by the management system subject to certification indicates special circumstances in respect of factors such as:

- The size of the sites and number of employees (eg. more than 50 employees on a site);
- The complexity or risk level of the activity and of the management system;
- Variations in working practices(eg. shift working);
- Variations in activities undertaken;
- Significance and extent of aspects and associated impacts for environmental management systems (EMS);
- Records of complaints and other relevant aspects of corrective and preventive action;
- Any multinational aspects; and
- Results of internal audits and management review.

5.2.7. 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 or surveillance or recertification)

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.

5.3. Audit Times

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

5.3.2. The number of man-days per site, including the central office, should be calculated for each site using the most recently published IAF document for the calculation of man-days for the relevant standard.

5.3.3. Reductions can be applied to take into account the clauses that are not relevant to the central office and/or the local sites. Reasons for the justification of such reductions shall be recorded by the certification body.

Note: Sites which carry out the most or critical processes are not subject to reductions (clause 3.1.1).

5.3.4. The total time expended on initial assessment and surveillance is the total sum of the time spent at each site plus the central office and 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).

5.4. Additional Sites

5.4.1. 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 or recertification audits.

End of IAF Mandatory Document for the Certification of Multiple Sites Based on Sampling.