International Accreditation Forum, Inc.

IAF Mandatory Document

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

Issue 1, Version 3

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The International Accreditation Forum, Inc. (IAF) operates programs for the accreditation of bodies that provide conformity assessment services. Such accreditation facilitates trade and reduces demand for multiple certification.

Accreditation reduces risk for business and its customers by assuring them that accredited Conformity Assessment Bodies (CABs) are competent to carry out the work they undertake within their scope of accreditation. Accreditation Bodies (ABs) which are members of IAF and their accredited CABs are required to comply with appropriate international standards and IAF mandatory documents for the consistent application of those standards.

AB members of the IAF Multilateral Recognition Arrangement (MLA) conduct regular evaluations of each other to assure the equivalence of their accreditation programs. The IAF MLAs operate at two levels:

- A MLA for the accreditation of CABs to standards including ISO/IEC 17020 for inspection bodies, ISO/IEC 17021 for management systems certification bodies, ISO/IEC 17024 for personnel certification bodies and ISO/IEC Guide 65 for product certification bodies, is considered a framework MLA. A framework MLA provides confidence that accredited CABs are equally reliable in the performance of conformity assessment activities.

- A MLA for the accreditation of CABs that also includes the specific conformity assessment standard or scheme as a scope of accreditation provides confidence in the equivalence of certification.

An IAF MLA delivers the confidence needed for market acceptance of certification. An organization or person with certification to a specific standard or scheme that is accredited by an IAF MLA signatory AB can be recognized worldwide thereby facilitating international trade.

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Introduction to IAF Mandatory Documents

The term “should” is used in this document to indicate recognised means of meeting the requirements of the standard. A Conformity Assessment Body (CAB) can meet these in an equivalent way provided this can be demonstrated to an Accreditation Body (AB). The term “shall” is used in this document to indicate those provisions which, reflecting the requirements of the relevant standard, are mandatory.

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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

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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.

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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

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- 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.

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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. RESPONSIBILITY 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.

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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 3.0.1 for sites which conduct fewer, but similar processes than other sites and clause 3.0.2 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.

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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.

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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.

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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.

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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 3.0.1).

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.

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Further Information

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

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