

<b>ISPL</b>	<b>Procedure Manual</b>
Section Name	Procedure for Audit of a Multi-site Organization

**1.0. Purpose:**

To document, establish, implement and maintain the system for conducting the audit of a multi -site organization, in accordance with requirements ISO/IEC 17021-1:2015, ISO 17021-2:2016, JAS-ANZ Procedure 2 Part 1, JAS-ANZ Procedure Number 17, Issue No.2, Dated 23<sup>rd</sup>, Aug 2005, ISO 17021-3:2017 & ISO/TS 22003:2013, ISO;27006:2015, ISO:50003:2014 and IAF Mandatory Document for the Certification of Multi-Sites Based on Sampling, IAF MD 1:2018 & IAF MD 5:2015.

**2.0. Scope:**

This procedure is applicable to the audit of a multi-site as defined in section 4.1.1 and does not apply to organizations that have multi-sites where fundamentally different processes or activities are used at different sites or a combination of sites, even though they may be under the same management system. This procedure is applied to all types of audits; initial, surveillance and re-certification, of a multi-site organization.

**3.0. Responsibility:**

Director Operations

**4.0. Procedure:**

**4.1. General requirements -**

**4.1.1.** Multi-site organization is defined as an organization having an identified central function (central office) at which certain activities are planned, controlled or managed and a network of local offices and branches (sites) at which such activities are fully or partially carried out. Examples of possible multi-site organizations are,

- (a) Organizations operating with franchises,
- (b) Manufacturing companies with a network of sales offices (applying to sales network),
- (c) Service organizations with multiple sites offering a similar service
- (d) Companies with multiple branches

**4.1.2.** 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 and be subject to a common management system. The management system is laid down, established and subject to continuous

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surveillance and internal audits by the central office. This means that the central office has rights to ensure that the sites implement corrective actions when needed at any site.

**4.1.3.** 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 provided that the site or sites, which conduct most processes or critical processes, are subject to full audit. All the sites shall be in the same country.

**4.1.4.** Organizations, which conduct their business through linked processes in different locations, are also eligible for sampling under multi-site. Where processes in each location are not similar but are clearly linked, the sampling plan shall include at least one example of each processes conducted by the organization (e.g. fabrication of electronic component in one location, assembly of the same components – by the same company in several other locations)

**4.1.5.** 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 office shall be subject to the organization’s internal audit program and all sites have been audited prior to certification audit. Following certification an internal audit shall be done at each site within the certification period.

**4.1.6.** The central office has established management system in accordance with the relevant ISO and/ or other international management system standards and the whole organization meets the requirements of the standard including relevant legal regulations

**4.1.7** The organization should demonstrate its ability to collect and analyze data (system documentation and changes, management review, complaints, corrective actions, internal audit, legal requirements etc) from all sites including the central office and its authority and also demonstrate its authority and ability to initiate organization changes if required.

**4.1.8.** If all the sites of an 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 ISPL in advance of the sites that it wants to be included in the certification and those which are to be excluded.

## **4.2. Audit process**

**4.2.1.** In case of a multi-site organization the application review & agreement are conducted as per procedure ISPL-QP-09. At this stage the review shall identify the following,

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- (a) The complexity and the scale of the activities covered by the management system and any differences between sites as a basis for determining the level of sampling,
- (b) Identify the central function of the organization with which ISPL has a legally enforceable agreement for the provision of certification,
- (c) To what extent sites of an organization operate substantially the same kind of processes according to the same procedures and methods,
- (d) Are all the sites included in the certification are ready to be submitted for certification at the same time. Sites not ready shall be excluded from the scope of certification
- (e) When certification to multiple management system standards is done by ISPL, the planning for the audit is ensured adequately on-site auditing to provide confidence in the certification

**4.2.2.** The planning & preparation for audit including selection of audit team are done as per documented procedure, ISPL-QP-11.

**4.2.3** The audit of the multi-site including stage-1 and stage-2 audit is performed as per the procedure for initial audit, ISPL-QP-12. If more than one audit team is involved in the audit, ISPL shall designate a unique audit leader whose responsibility is to consolidate the findings from all audit teams and to produce a synthesis report (ISPL-31).

**4.2.4** The central office and the sites selected are audited as per this procedure.

**4.2.5** Whenever any non-conformity is found at an individual site, either through the organizations internal auditing or auditing by ISPL, the auditor shall investigate whether it leads to a system deficiency affecting all other sites or limited to the particular site only. If it is found a system deficiency correction and corrective action should be performed both at central office and at the individual sites. If the corrective action is found limited, to only the site where the nonconformity has been reported, the auditor should seek the justification for limiting its follow up corrective action.

**4.2.6.** The auditor shall verify the evidence of these actions and accordingly increase its sampling frequency and / or the size of the sample until it is satisfied that the control is re-established.

**4.2.7.** At the time of the decision-making process, if any site has nonconformity pending the certification shall be denied to the whole network pending satisfactory corrective action.

**4.2.8.** If any site has nonconformity; the exclusion of that problematic site from the scope is not permitted at this stage. Such exclusion should have been agreed before the certification as stated in 4.2.1 (d).

### **4.3 Certification Document**

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**4.3.1.** The certification documents are issued as per ISPL procedure ISPL-QP-17. The sites included in the certificate are either individually audited or audited as per sampling scheme outlined in section 4.4.

**4.3.2.** These documents shall identify the central office and a list of all sites to which the certification document relate. This document shall indicate clearly the certified activities 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 sites shall be clearly stated.

**4.3.3.** The certificates may be issued to the organization for each site under condition that they contain the same scope or sub-scope of that scope and make a clear reference to the main certification document.

**4.3.4.** ISPL shall withdraw the entire certificate if the central office or any of the sites does not fulfill the necessary provisions for the maintenance of the certification.

**4.3.5.** ISPL shall inform the organization, through document PD-RRCMS-01, about additional requirements for granting multi- site certification and this document shall be sent along with the quotation (Procedure, ISPL-QP-09). This document shall also be made publicly available on ISPL website.

**4.3.6** ISPL shall grant additional sites to the existing certification either through the routine surveillance (ISPL-QP-14), special audit (ISPL-QP-13) or re-certification audit (ISPL-QP-15). Sampling for the additional sites shall be done as specified in section 4.4 & 4.7

## **4.4. Sampling**

### **4.4.1. Methodology**

**4.4.1.1.** Part of the sample shall be selected based on factors stated in Section 4.4.1.3 and partly non-selective and should result in a representative of different sites selected, including the random element of sampling.

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

**4.4.1.3.** The site selection may include among others the following aspects,

- ❖ Results of internal audit sites 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;

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- ❖ Variations in shift patterns and work procedures
- ❖ Complexity of management system and the process conducted at the sites;
- ❖ Modifications since the last certification audit;
- ❖ Maturity of management system and the knowledge of the organization;
- ❖ Differences in culture, language and regulatory requirements; and
- ❖ Geographical dispersion

**4.4.1.4.** It is not necessary to select the sites before starting of the audit process but can also be done after the audit of the central office. The central office needs to be informed of the sites to be included in the certification anyhow. This can be on relatively short notice but should allow adequate time for the preparation of the audit.

#### **4.4.2. Size of the Sample**

**4.4.2.1.** ISPL shall maintain records of multi-site sampling justifying it in accordance with this procedure.

**4.4.2.2. For management systems other than FSMS:** 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 as under

- (a) **Initial audit:** The size of the sample should be square root of the number of remote sites ( $Y = \sqrt{X}$ ), rounded to the upper whole number ( $X$ = number of remote sites;  $Y$ = sample size)
- (b) **Surveillance audit:** The size of the annual sample should be 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
- (c) **Re-certification audit:** The size of the sample should be the same as the 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.  $Y = 0.8 \sqrt{X}$ ), rounded to the upper whole number.

#### **4.4.2.3. For FSMS:**

A multi - site organization is 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 FSMS activities are planned, controlled or managed, and a network of sites at which such activities are fully or partially carried out example of possible multi sites organizations are:

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- organizations operating with franchisees;
- A manufacturing company with one or more production site and a network of sales offices;
- Service organizations with multiple sites offering a similar service;
- Organizations with multiple branches.

ISPL can certify a multi-site organization under one management system, providing that the following conditions apply:

- a) all sites are operating under one centrally controlled and administered FSMS as defined in ISO 22000:2005, clause 4, or equivalent for other FSMS;
- b) an internal audit has been conducted on each site within one year prior to certification
- c) audit findings of the individual sites shall be considered indicative of the entire system.

The use of multi-site sampling is only possible for Categories with more than 20 sites and only for categories A, B, E, F & G (refer Procedure ISPL-QP-10). This applies to initial certification and surveillance audits and re-certification audit. ISPL shall justify its decision on sampling for multi-site certification.

Where multi-site sampling is permitted, following certification, the annual internal audit programme shall include all sites of the organization.

Note: Risk is another consideration when determining sampling and can increase the level of sample indicated in Table on next page.

ISPL offers multi-site sampling and shall utilize a sampling programme to ensure an effective audit of the FSMS where the following apply.

- a. The sampling with 20 sites or Less, all sites shall be audited. The Sampling for More than 20 Sites shall be at the ratio of 1 site per 5 sites. All the sites shall be randomly selected and after the audit, no sampled sites may be non-conforming.
- b. At least annually, an audit of the central office for the FSMS shall be performed by ISPL.
- c. At least annually, surveillance audits shall be performed by ISPL on the required number of sampled site.
- d. Audit findings of the sampled sites shall be considered indicative of the entire system and correction shall be implemented accordingly.

Table-

	Total number of sites								
	x between 1 and 20	21	22	23	24	25	26	27	28
No. of sites above 20	0	1	2	3	4	5	6	7	8
Additional no. of sites to be audited	0	1	1	1	1	1	2	2	2
No of sites to be audited	x	21	21	21	21	21	22	22	22

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**4.4.2.4.** The central office shall be audited during every initial certification and re-certification audit and at least annually as part of surveillance

**4.4.2.5.** ISPL shall increase the size or frequency of sample based on the risk analysis of the activity covered by the organization's management system, under special circumstances in respect of the following factors

- The sizes of the sites and the number of employees (e.g. more than 50 employees on a site);
- The complexity or risk level of the activity and of the management system as defined in WI-CP-01, for the different management systems
- Variations in working practices (e.g. shift working);
- Variations in activities undertaken;
- Records of complaints and other relevant aspects of corrective and preventive action;
- Any multinational aspects;
- Results of internal audit and management review.

**4.4.2.6.** When the organization has a hierarchical system of branches (e.g. Head or central office, National Offices, regional offices, local branches), the sampling model for the initial audit as defined above applies at each level.

For example, (for other management systems except FSMS)

- ✓ 1 Head office: visited at each audit cycle (initial or surveillance or re-certification)
- ✓ 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

#### 4.5. Audit times

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**4.5.1.** ISPL shall justify the time spent on multi-site audits in ISPL-01 and the number of man days per site, including central office shall be calculated as per procedure ISPL-QP-10, procedure for determining auditor time.

**4.5.2.** ISPL may apply reduction in auditor time from that set out in QP-04 taking into account clauses that are not relevant to the central office and /or the local sites and shall record the reasons for the justification of such reductions in ISPL-01. The sites, which carry out most or critical processes, shall not be subject to reductions.

**4.5.3.** For certification of multiple sites where sampling is permitted, the starting point for calculating audit time of the management system is the total involved on each of the sampled sites. The total time spent 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.

Note:

For certification of multiple sites where sampling is not permitted, the starting point for calculating audit time of the management system is the total involved on all of the sites, consistent with Table QMS 1 and Table QMS 2 for quality management systems and Table EMS 1 and Table EMS 2 for environmental management systems.

The proportion of the total time spent on each site shall take into account situations where certain management system processes are not relevant to the site.

#### **4.6. Temporary site**

**4.6.1.** 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 (e.g. construction site)

**4.6.2.** 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

**4.6.3.** If the organization desires to include the temporary sites within the scope of certification ISPL shall do so under an agreement with the client organization. Where included in the scope such sites shall be identified as temporary.

#### **4.7. Additional sites**

**4.7.1.** It is a new site or group of sites that will be added to an existing certified multi-site network

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**4.5.2.** On 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 as per the steps detailed in sections 4.4.1 & 4.4.2.

**4.5.3** 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 the future surveillance or re-certification audits.

## **5. AUDIT AND CERTIFICATION**

ISPL Should 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 single management system governs the processes/activities at all the sites and is actually applied to all the sites. ISPL Should justify and record the rationale for proceeding with any approach to the auditing and certification of a multi-site organization.

### **5.1 Application and Application Review**

5.1.1 ISPL Should obtain necessary information concerning the applicant organization to:

- confirm that a single management system is deployed across the organization;
- determine the scope of the management system being operated and the requested scope of certification and, if applicable, sub-scopes;
- understand the legal and contractual arrangements for each site;
- understand “what happens where” i.e. processes/activities provided at each site and identify the central function;
- determine the degree of centralization of process/activities which are delivered to all sites (e.g. purchasing);
- determine interfaces between the different sites;
- determine which sites may be applicable for sampling (i.e. where very similar processes/activities are provided) and those that are not eligible;
- take into consideration other relevant factors (see also IAF MD 4, IAF MD 5, *IAF MD 11: IAF Mandatory Document for Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS), ISO/IEC TS 17023*);
- determine the audit time for the organization;
- determine the audit team(s)' competence required; and
- identify the complexity and scale of the processes/activities (e.g. one or many) covered by the management system.

### **5.2 Audit Programme**

5.2.1 In addition to the requirement in ISO/IEC 17021-1:2015 clause 9.1.3, the audit programme shall at least include or refer to the following: IAF MD 1:2018

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- processes/activities provided on each site;
- identification of those sites which are liable to be sampled, and which are not; and
- identification of sites which are covered by sampling, and which are not.

5.2.2 When determining the audit programme, ISPL Should allow sufficient additional time for activities which are not part of the calculated audit time, such as travelling, communicating among audit team members, post-audit meetings, etc. due to the specific configuration of the organization to be audited.

*Note: Remote auditing techniques may be used, provided that the processes to be audited are of such a nature that remote auditing is appropriate (see ISO/IEC 17021-1 and IAF MD 4)*

5.2.3 Where audit teams consisting of more than one member are used at any point, it shall be the responsibility of the Certification Body, in conjunction with the team leader, to identify the technical competence required for each part of the audit and for each site and to allocate appropriate team members for each part of the audit.

### **5.3 Calculation of Audit Time**

5.3.1 An organization that satisfies the eligibility criteria may consist of sites that can be sampled, sites that cannot be sampled or a combination of both. The audit time must be sufficient to undertake an effective audit irrespective of the makeup of the organization.

Unless precluded by specific schemes, the reduction of audit time per sampled site shall not be greater than 50%.

For example, 30% is the maximum reduction in audit time allowed by IAF MD 5 while 20% is to be considered the maximum reduction allowed for the single management system processes performed by the central function and any potential centralised processes (e.g. purchasing).

The audit time per selected site (whether it comes from sampling as in 6.1, from non-sampling as in 6.2 or from mixed methodology as in 6.3), including elements of the central function if applicable, shall be calculated for each site using the applicable IAF documents (e.g. IAF MD 5 for quality and environmental management systems, IAF MD 11 for integrated management systems) and, where necessary, any applicable sector scheme requirements for the calculation of man-days. IAF MD 1:2018

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#### 5.4 Audit Plan

5.4.1 In addition to the requirement in ISO/IEC 17021-1:2015 clause 9.2.3, ISPL Should at least consider the following when preparing the audit plan:

- certification scope and sub-scopes for each site;
- management system standard for each site, if multiple management system standards are being considered;
- processes/activities to be audited;
- audit time for each site; and
- allocated audit team.

#### 5.5 Initial Audit: Stage 1

During Stage 1, the audit team shall complete the information to:

- confirm the audit programme;
- plan Stage 2, taking into account the processes/activities to be audited in each site; and
- confirm that the Stage 2 audit team has the required competence.

#### 5.6 Initial Audit: Stage 2

At the outcome of the initial audit, the audit team shall document which processes were audited on each site visited. This information will be used to amend the audit programme and audit plans for subsequent surveillance audits.

#### 5.7 Nonconformities and Certification

5.7.1 When nonconformities, as defined in ISO/IEC 17021-1, are found at any individual site, either through the organization's internal auditing or from auditing by the Certification Body, investigation shall take place to determine whether the other sites may be affected. Therefore, ISPL Should require the organization to review the nonconformities to determine whether or not they indicate an overall system deficiency applicable to other sites. If they are found to do so, corrective action shall be performed and verified both at the central function and at the individual affected sites. If they are found not to do so, the organization shall be able to demonstrate to the Certification Body the justification for limiting its follow-up corrective action.

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5.5.2 ISPL Should 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.

5.5.3 At the time of the decision-making process, if any site has a major nonconformity, certification shall be denied to the whole multi-site organization of listed sites pending satisfactory corrective action.

5.7.4 It shall not be admissible that, 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.

### **5.8 Certification Documents**

5.8.1 The certification document shall reflect the scope of certification and the sites and /legal entities (where applicable) covered by the multi-site certification.

5.8.2 Certification documents shall contain the name and address of all the sites, reflecting the organization to which the certification documents relate. The scope or other reference on these documents shall make it clear that the certified activities are performed by the sites on the list. However, if a site's activities only include a subset of the organization's scope, the certification document shall include the site's sub-scope. When temporary sites are shown on the certification documents, such sites shall be identified as temporary.

5.8.3 Where certification documents for one site are issued, they shall include:

- that it is the management system of the whole organization which is certified;
- the activities performed for that specific site / legal entity which are covered by this certification;
- traceability with the main certificate, e.g. a code; and
- a statement saying "the validity of this certificate depends on the validity of the main certificate".

Under no circumstances, can this certification document be issued to the name of the site/legal entity or suggest that this site/legal entity is certified (the one certified is the client organization), nor shall it include a declaration of conformity of the site processes/activities to the normative document.

5.8.4 The certification documentation will be withdrawn in its entirety if any of the sites does not fulfil the necessary provisions for the maintenance of the certification.

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### **5.9 Surveillance Audits**

5.9.1 Surveillance of multi-site organizations that can be sampled shall be audited in accordance with Section 6.1. The audit time per site shall be calculated in accordance with Clause 5.3 above.

5.9.2 Surveillance of multi-site organizations that cannot be sampled in accordance with Section 6.1 is based on auditing 30% of the sites plus the central function. The sites selected for the second surveillance of a certification cycle shall normally not include any sites sampled as part of the first surveillance audit. The audit time per site shall be calculated in accordance with Clause 5.3 above.

### **5.10 Recertification Audits**

5.10.1 Recertification of multi-site organizations that can be sampled shall be audited in accordance with Section 6.1. The audit time per site shall be calculated in accordance with Clause 5.3 above.

5.10.2 Recertification of multi-site organizations that cannot be sampled shall be audited as per initial audit, i.e. all sites audited plus the central function. The audit time per site and central function shall be calculated in accordance with Clause 5.3 above.

### **5.0 Records**

- (a) ISPL-31– synthesis report
- (b) Other records as per procedures ISPL-QP-09, ISPL-QP-10, ISPL-QP-11, ISPL-QP-12, ISPL-QP-14, ISPL-QP-15

### **6.0 References**

- (a) ISPL-QP-09-Procedure for application review, quotation & agreement
- (b) ISPL-QP-10-Procedure for determining auditor time
- (c) ISPL-QP-11-Procedure for planning & preparation of audit
- (d) ISPL-QP-12- Procedure for initial audit
- (e) ISPL-QP-14-Procedure for surveillance audit
- (f) ISPL-QP-15-Procedure for re-certification audit
- (g) PD-RRCMC-01-Requirements for granting multi-site certification
- (h) ISPL-QP-17-Procedure for Granting, Maintaining, Renewing, Extending, Reducing, Suspending and withdrawing of Certification
- (i) WI-CP-01-work instruction –certification panel

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