Procedure for sampling of multi-sites

1.0 Purpose

To describe a procedure for the audit and certification of an organization with a network of sites through sampling method that provides adequate confidence in the conformity of its management system.

2.0 Scope

2.1 This document applies to sampling of sites during Initial, surveillance and Re- audit for an organization having similar multi-sites.

2.2 This document does not apply to the audit of organizations that have multisites where dissimilar manufacturing and/or service processes are used at the different sites, even though under the same quality management system.

3.0 Responsibility & Authority

Quality Manager is responsible for applying the criteria of sampling to audit in accordance with this procedure.

4.0 Policy & Procedure

4.1 Definition

4.1.1 Organization

Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives.

4.1.2 Permanent Site

Site (physical or virtual) where a client organization performs work or from which a service is provided on a continuing basis.

4.1.3 Temporary Site

Site (physical or virtual) where a client organization performs specific work or from which a service is provided for a finite period of time and which is not intended to become a permanent site.

4.2 Multisite Organization: An organization covered by a single management system comprising an identified central function (not necessarily the headquarters of the organization) at which certain processes/activities are planned and controlled, and a number of sites (permanent, temporary or virtual) at which such processes/activities are fully or partially carried out.

4.3 Central Function

The function that is responsible for and centrally controls the management system.

4.4 Virtual Site

Virtual location where a client organization performs work or provides a service using an on-line environment allowing persons from different physical locations to execute processes. A virtual site cannot be considered as such where the processes must be executed in a physical environment e.g. warehousing, physical testing laboratories, installation or repairs to physical products. An example of such a virtual site is a design & development organization with all employees performing work located remotely, working in a cloud environment. A virtual site (e.g. an organization's intranet) is considered a single site for the purpose of calculating of audit time.

4.5 Sub-scope

The scope of a single site. The scope of a single site might be the same as the full scope of the multi-site organization but may also be only a small part of the multi-site organization's scope.

4.6 Top Management

Person or group of people who directs and controls an organization at the highest level.

5 Application

5.1 Site

5.1.1 A site could include all land on which the 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 apply. Other definitions may also be used subject to justification.

5.1.2 Where it is not practicable to define a location (e.g. for services), the coverage of the certification takes into account the organisation's headquarters activities as well as delivery of its services. Where relevant LEX-Q may decide that the certification audit be carried out only where the organization delivers its services. In such cases all the interfaces with its central office are identified and audited.

5.2 Temporary Site

5.2.1 Temporary sites that are covered by the organization's management system subjects 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 and included on the certification document, subject to agreement between LEX-Q and the client organization. When temporary sites are shown on the certification documents, such sites are identified as temporary.

5.3 Multi-site Organization

5.3.1 A multi-site organization need not be a unique legal entity, but all sites should have a legal or contractual link with the central function of the organization and be subject to a single management system, which is laid down, established and subject to continuous surveillance and internal audits by the central function. This means that the central function 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 function and the sites.

5.4 Sampling Approach

- This procedure deals with the auditing of a multi-site organization with a single management system.
- Any one site may perform fully or partially the processes/activities covered by the scope of the management system, and different sites may belong to the same legal entity or not.

- Any legal considerations concerning the organization's management system extending over a single legal entity or multiple legal entities is generally irrelevant to the auditing of the management system, and unless otherwise stated are not covered in this document.
- It is the organization's management system which is to be audited and certified; furthermore, by definition, a management system audit is only based on a limited sample of the information available. However it is to be demonstrated that the management system is capable of achieving its intended results for all sites involved.
- Therefore, it is logical to start by considering the organization and the implementation of its management system, and what type of sampling may be appropriate, if any.
- In the case of a multi-site organization where each site is performing very similar processes/activities, there may be a clear case to be made for appropriate "site sampling" (e.g. a chain of franchise stores or a bank branch network). On the other hand, this procedure also addresses the situation where the application of site sampling is not appropriate. There may be many reasons for this, such as:
  - all the sites perform significantly different processes/activities in connection with the management system scope;
  - the client requests each site to be audited; or
  - there is a sector scheme or regulatory requirement stipulating that each site is to be audited systematically.

Between these two extreme cases, there are many multi-site organizations with part of their sites performing similar processes/activities while other sites are dedicated to very specific processes not performed elsewhere in the organization. As with any sampling process, proper site sampling limits sampling only to those sites which are performing very similar processes/activities, which are part of the organization's scope.

5.5 Eligibility of a Multi-Site organization for Certification

1. The organization should have a single management system.
2. The organization should identify its central function. The central function is part of the organization and not to be subcontracted to an external organization.
3. The central function should have organizational authority to define, establish and maintain the single management system.

4. The organization's single management system should be subjected to a centralized management review.
5. All sites to be subjected to the organization's internal audit programme.
5. The central function is responsible for ensuring that data is collected and analysed from all sites and is able to demonstrate its authority and ability to initiate organizational change as required in regard, but not limited, to:
    1. system documentation and system changes;
    2. management review;
    3. complaints;
    4. evaluation of corrective actions;
    5. internal audit planning and evaluation of the results; and
6. statutory and regulatory requirements pertaining to the applicable standard(s).

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

6. Methodologies

6.1 Methodology for Auditing of a Multi-site Organization Using Site Sampling

6.1.1 Conditions

a) Sampling of a set of sites is permitted where the sites are each performing very similar processes/activities.

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

c) 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 also apply for some schemes, for example those including aerospace (AS 9100 series) or automotive (IATF 16949) and the requirements of such schemes shall take precedence.

d) Lex-Q 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 are defined with respect to:

- scope sectors or processes/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 to address different processes/activities or different contractual or regulatory systems; and
- use of temporary sites that operate under the management system of the organization even if they are not listed in the certification documents.

6.1.2 Sampling

a) The sample is partly selective based on the factors set out below and partly random, and result in a representative range of different sites being selected, ensuring all processes covered by the scope of certification are audited.

b) At least 25% of the sample is selected at random.

c) Taking into account the criteria mentioned hereafter, the remainder is selected so that the differences among the sites selected over the period of validity of the certificate is as large as possible.

d) The site selection criteria includes among others the following aspects:

- Results of internal site audits and management reviews or of previous certification audits,
- Records of complaints and other relevant aspects of corrective and preventive action,
- Significant Variation in the size of the sites,
- Variation 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;
- Environment issues and extent of aspects and associated impacts for environmental management systems,
- Differences in culture, language and regulatory requirements,
- Geographical dispersion,
- Whether the sites are permanent, temporary or virtual.

The additional criteria for ISMS includes:

- Variations of design and operation of controls
- potential interaction with critical information systems or information systems processing sensitive information;
- risk situations of the sites;

- information security incidents at the specified sites

e) This selection is not done necessarily 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 is informed of the sites to be part of the sample. This can be on relatively short notice, but allows adequate time for preparation for the audit.

6.1.3 Size of sample

a) Lex-Q determines the sample size taking into account all the factors described in this procedure.

b) Audit Manager keeps records on each application of sampling for multi-site organization justifying it is operating in accordance with this procedure.

c) The minimum number of sites to be visited per audit is followings

- **Initial audit**: the size of the sample is the square root of the number of sites: ($y = \sqrt{x}$), rounded up to the next whole number, where y is the number of sites to be *sampled and x is the total number of sites.*
- **Surveillance visit**: the size of the annual sample is the square root of the number of sites with 0.6 as a coefficient: ($y = 0.6\sqrt{x}$), rounded up to the next whole number.
- ***Re- certification audit****: the size of the sample is the same as for an initial audit. Nevertheless, where the management system has proved to be effective over the*

certification cycle, the size of the sample could be reduced by a factor 0.8, i.e.: ($y = 0.8\sqrt{x}$), rounded up to the next whole number.

d) The central function is audited during every initial certification and recertification audit and at least once a calendar year as part of surveillance.

e) The size or frequency of the sample is increased where Lex-Q' risk analysis of the process/ activity covered by the management system subject to certification indicates special circumstances in respect of factors like:

- The size of the sites and number of employees,
- Complexity or risk level of the process/ activity and of the management system,
- Variations in working practices (e.g. shift working),
- Variations in process/ activities undertaken,
- Significant and extent of aspects and associated impacts for environmental management system (EMS),

- Records of complaints and other relevant aspects of corrective and preventive action,
- Any multinational aspects;
- Result of internal audits and management reviews.

f) 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.

g) Example:

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

The sample of regional offices include at least one regional office controlled by each national office. The sample of local branches include at least one local branch controlled by each regional office. This may also result in the sample size at each level exceeding the minimum sample size calculated.

h) The sampling process is part of the management of the audit programme. At any time (i.e. before planning the surveillance audit, or when any organization site changes its structure, or in case of acquisition of new site(s) which are to be added into the certification boundary), Lex-Q review the sampling foreseen in the audit programme in order to establish the need to adjust the sample size prior to auditing the sample with a view to maintaining certification.

6.1.4 Additional Sites

On the application of inclusion of new sites or a new group of sites to join an already certified multi-site organization, Lex-Q determines the required activities to be performed before including the new site(s) in the certificate. This includes consideration of whether or not to audit the new site(s). After inclusion of the new site(s) in the certificate, the sample size for future surveillance or recertification audits is determined.

6.2 Methodology for Auditing of Multi-site Organizations Where Site Sampling Using para 6.1 is not Appropriate

6.2.1 The audit programme consists of an initial audit and recertification audit of all sites. In surveillance audits, 30% of sites, rounded up to the whole number, are covered in a calendar year. Each audit include the central function. The sites selected for the second surveillance audit are normally different from the sites selected for the first surveillance audit.

6.2.2 The audit programme has to be designed to ensure that all processes covered by the certification scope are audited over each cycle.

6.2.3 Additional Sites

On the application of a new site to join an already certified multi-site organization, the site has to be audited before being included in the certificate, in addition to the planned surveillance in the audit programme. After inclusion of the new site in the certificate, it is to be cumulated with the previous ones for determining the audit time for future surveillance or recertification audits.

6.3 Methodology for Auditing of Multi-site Organizations that includes a combination of sites that can be sampled and other sites that cannot be sampled

The audit programme is established using para 6.1 for those sites that can be sampled and para 6.2 for the remaining part of the organisation where para 6.1 is not applicable.

7. Audit and Certification

Lex-Q has documented procedures to deal with audits under its multi-site procedure. Such procedures establishes the way the Lex-Q satisfies itself that the single management system governs the processes/activities at all the sites, and is actually applied to all the sites. LEX-Q justifies and record the rationale for proceeding with any approach to the auditing and certification of a multi-site organization.

7.1 Application and Application Review

7.1.1 Lex-Q obtains 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;
- 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.

7.2 Audit Programme

7.2.1 In addition to the requirement in PR05, the audit programme at least include or refer to the following:

- 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.

7.2.2 Lex-Q allows 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

7.2.3 Where audit teams consisting of more than one member are used at any point, Lex-Q takes responsibility, 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.

7.3 Calculation of Audit Time

7.3.1 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 decided is 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 is not 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 and, where necessary, any applicable sector scheme requirements for the calculation of man-days.

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The number of auditor days per site, including the central office, shall be calculated for each site. Reductions may be applied to take into account the parts of the audit that are not relevant to the central office or the local sites. Reasons for the justification of such reductions shall be recorded by the certification body.

7.4 Audit Plan

7.4.1 In addition to the requirement in PR05, Lex-Q 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.

7.5 Initial Audit: Stage 1

During Stage 1, the audit team 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.

7.6 Initial Audit: Stage 2

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

7.7 Nonconformities and Certification

7.7.1 When nonconformities are found at any individual site, either through the organization's internal auditing or from auditing by Lex-Q, investigation takes place to determine whether the other sites may be affected. Lex-Q requires 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 is performed and verified both at the central function and at the individual affected sites. If they are found not to do so, the organization must be able to demonstrate to Lex-Q the justification for limiting its follow-up corrective action.

7.7.2 Lex-Q 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.

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

7.7.4 It is not acceptable 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.

7.8 Certification Documents

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

7.8.2 Certification documents contains 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 should 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 includes the site's sub- scope. When temporary sites are shown on the certification documents, such sites to be identified as temporary.

7.8.3 Where certification documents for one site are issued, they 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 it includes a declaration of conformity of the site processes/activities to the normative document.

7.8.4 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.

7.9 Surveillance Audits

7.9.1 Surveillance of multi-site organizations that can be sampled is audited in accordance with para 6.1. The audit time per site shall be calculated in accordance with para 7.3 above.

7.9.2 Surveillance of multi-site organizations that cannot be sampled in accordance with para 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 normally not include any sites sampled as part of the first surveillance audit. The audit time per site shall be calculated in accordance with Para 7.3 above.

7.10 Recertification Audits

7.10.1 Recertification of multi-site organizations that can be sampled is audited in accordance with para 6.1. The audit time per site is calculated in accordance with para 7.3 above.

7.10.2 Recertification of multi-site organizations that cannot be sampled is 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 para 7.3 above.