PROCEDURA PG. - 07.2

Performance of the certification service of the Quality Management System in multisite organizations.

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CONTENT

NORMATIVE REQUIREMENTS

- ✓ UNI-EN-ISO-17021-1
- ✓ IAF MD1
- ✓ IAF MD5
- ✓ IAF MD19
- ✓ RT –

në rishikimet më të fundit.

1. Introduction

This document defines the main objectives and phases of the multisite Quality Management System Audit and Certification Service that CCI provides to its clients.

This procedure complements and does not exclude PG-07.1.1 - Performance of the Management Systems Certification Service - as the specific audit methods are determined by the multisite organization.

2. Conditions

It is defined as a multi-site organization, an organization covered by a single management system, including a central function identified (not necessarily the organization's headquarters) where certain processes / activities are planned and controlled, and a number of sites (permanent, temporary or virtual) in which these processes / activities are carried out in whole or in part.

This type of organization is not necessarily a single legal entity, but each site must have a legal or contractual relationship with the headquarters of the organization and must be submitted to a common

quality system, which has been designed, implemented and submitted to continuous surveillance and internal audits by the central office responsible for it. The central office has the power to activate corrective and / or preventive actions, when necessary, at any site.

The following examples are cited as indicative and not exhaustive:

- ✓ *organizations operating in franchising;*
- ✓ *a network of bank branches;*
- ✓ *service or production companies with several operating units and / or temporary sites offering similar services;*
- ✓ *production companies with a network of sales offices located throughout the territory;*
- ✓ *organizations grouped in structures with a lead organization (eg consortia, associations) that coordinate the activities of the participants.*

The Multisite system only exists if all the following requirements and prerequisites are met, failure to comply with even one of the following requirements prevents the management of the practice as "Multisite":

- ✓ **the organization must have a single management system;**
- ✓ **the organization must identify its central function. Central fiction is part of the organization and can not be subcontracted to an external organization;**
- ✓ **the central function must have the organizational authority to define, establish and maintain the only management system;**
- ✓ **The organization's single management system must be subject to a centralized review and all sites must be subject to the organization's internal audit program;**
- ✓ **the central function must demonstrate its authority and ability to initiate organizational changes and the ability to collect, analyze and manage all the sites (operating units and / or temporary sites) for the following data:**
  - * **documentation of the management system and its modifications;**
  - * **management reviews;**
  - * **complaints;**
  - * **evaluation of corrective actions;**
  - * **planning of internal audits and analysis of results;**
  - * **statutory and regulatory requirements regarding applicable standards.**

Note: the central function is that whose operational control and the authority of the organization's top management are exercised in each site. It is not necessary for the central function to be located in a single site.

Continued deviations in the application of the Multisite QMS procedures by some subjects (such as the need for frequent recourse to different quality plans, different contractual or regulatory, etc.) does not allow the management and maintenance of the multisite certification.

Operational unit is defined: Any office other than the registered office where the organization lends its business or part of it and in any case must be present on the Chamber of Commerce as a "Local Unit", or in the presence of a regular lease .

A temporary site is defined: Any office other than the registered office and different from the operational unit (therefore not present on the organization's chambers of commerce) in which the organization carries out significant processes of the fixed-term contract (days, months or years); own activity or part of it (the customer premises where the terminal phases of the main process already carried out at the registered office, the operating unit or the temporary site are not considered as temporary sites).

3. Certification request.

Any organization interested in CCI certification services must manage the certification request as defined in the PG.-07.1.1.
Attached to the offer request RO.PG.03.1 the customer must complete the Attachment RO.PG.03.1 Multisite - specific for multisite organizations.
The contract will be stipulated directly between CCI and the central office requesting the Multisite certification.

Audit Plan

In addition to the provisions of ISO 17021-1, the audit plan must contain:
- certification scope and sub-areas for each site;
- SG standard for each site;
- processes / activities to be verified;
- audit time for each site;
- assigned audit group.

4. Initial Audit
CCI plans the Initial Audit as defined in P.G.- 07.1.1

Stage I Audit
The initial Phase I Audit is conducted at the legal or operational headquarters of the applicant for certification that assumes a central function within the Multisite system (leader). Phase I must participate all the representatives of the organizations belonging to the Multisite that require certification.
In this phase all the requirements of the Multisite defined in the previous point are checked (eligibility criteria - same QMS - etc.), the audit program confirmed, phase 2 planned taking into account the processes / activities to be tested at each site and confirmed that the audit group for phase 2 has the required skills. If, in phase I, the non-applicability of the multisite system is found, it will proceed as defined in P.G.- 07.1.1 - par 6. At the end of Phase I, a single audit report will be issued to the lead partner.

Stage II audit
The initial Phase II Audit is conducted at the organizations belonging to the multisite. At the phase 2 outcome, the audit team must document which processes have been audited for each

site visited. The information will be used to modify the audit program and plans for subsequent audits.
There are 2 cases of multisite: with or without sampling.

Multisite without sampling
A multisite is without sampling in the following cases:
- the participating organizations carry out activities that are significantly different from one another, even if they are similar;
- the customer requests that each site be checked;
- there is a sectoral scheme or a regulatory requirement according to which each site must be systematically verified.

In the case of multisite without sampling, for the calculation of audit times all company employees must be considered and the proportion of total time spent for each site will be determined, taking into account the importance of certain processes for the site.

Multisite with sampling
A multisite is sampled when the participating organizations perform activities that are very similar or equal to each other.
There may also be cases where some sites have similar processes / activities, while other sites are dedicated to very specific processes not performed elsewhere. In this case the sampling is limited only to those sites that perform very similar processes / activities. The other sites will always be audited.
In other cases, multisite sampling would not be appropriate where the audit of variable local factors is a requirement of the standard.

In any case, ICDQ, before proceeding with the calculation of the audit times, will carefully evaluate the applicability or not of the sampling or its possible limitation. To this end it will consider:
- sector or process / activity of the required certification scope with risk assessment or complexity associated with this sector of activity;
- size of the sites to be considered for sampling;
- any changes in the local implementation of the management system to deal with different processes / activities or different contractual or regulatory systems;
- any temporary sites that operate under the management system of the organization, even if not listed in the certification documents (think for example temporary cooking centers for a company that performs collective catering).

If the sampling can be performed, the provisions of the Internal Instruction I.I.-2.6.13 will be applied. Definition of the sample size to be verified and of the audit time applicable to organizations with multiple sites for QMS.

When sampling, it is necessary to calculate the audit times based on the specifications defined by the IAF-MD5 and IAF-MD1 document for each site subject to verification, as if they were independent companies, but possibly applying a reduction factor even higher than the 30%.

For each audited organization, the Audit team issues a specific report containing the number and description of the relevance, as well as the certification purpose proposed according to the evidence gathered during the audit..

The final meeting is held at the lead organization of the entire Multisite system. The audit team will communicate and document, through a final report to the lead organization, all the classifications classified by category that affect the entire multisite system.
The leader shall manage any eventualities for the whole Multisite system.

The calculated audit times do not include:
- movements;
- communications between the members of the audit team;
- meetings subsequent to the audit.

The CAAT (remote audit) techniques can be used provided that the processes to be controlled, are of a nature that allows the remote audit and according to the limits defined by the specific instruction.

Non-conformity management
If at the end of the audit, non-conformities are issued on individual sites, they are extended to the single management system.
The organization must perform an extension analysis to check if the other sites may be affected. If the extension to other sites and / or to the whole multisite is highlighted, the corrective actions must be carried out and verified both at the central office and at the individual sites concerned (follw-up).
If CCI deems that corrective actions have not been adequately managed, it may increase the sampling frequency and / or sample size until the control is reestablished. If a single site has a greater non-compliance, the certification is denied to the entire organization, pending satisfactory corrective actions (and related evidences). It is not permissible for the organization to decide, during the certification process, to exclude the problematic site from the management system in order to obtain certification.

5. Certification and use of the logo

Successful completion of the Initial Audit ICDQ issues a single certificate with the company name and the address of the headquarters of the lead organization, with a list of the organizations belonging to the multisite attached.
A "sub - certificate" is issued to each organization forming part of the multi - site system, reporting the specific data of the individual organization (company name, addresses of the operating units, specific purpose and related EA code), also references to the Multisite System (with the phrase "the validity of this certificate depends on the validity of the main certificate"). All certificates belonging to the multisite have a unique issue and expiry date. The leader organization has the obligation to promptly communicate to CCI any changes related to the multisite system and to the organizations belonging to the operating units and temporary sites.
Failure to communicate the above is considered as improper use of the certification, leading to the application of the appropriate measures as per procedure P.G.-07.1.1.

Upon request by the lead organization, during the surveillance audit and / or extension it is possible to proceed with both the expansion of the Multisite and the scope of the certification.
In the case in which there are temporary sites, these will not be included on the certificate, but will have the sole purpose of being used to confirm the activities carried out by the organization..

For the use of the CCI logo, see the documents P.G.-07.1.1. and II 2.6.8.

6. Surveillance audit.

In the case of multisite with sampling, the size of the sample to be audited is previously determined, the CCI informs the leading organization of the Organizations belonging to the Multisites to be audited with the data of the relevant operational units and the temporary sites in which the audit will be carried out periodic. confirming that the leading organization will always be audited.
In cases where there are findings that prejudge the maintenance of the certificate of one of the certified operating units, the entire multisite system may be suspended / revoked according to the provisions of procedure P.G.-07.1.1.

In the case of multisite without sampling, proceed with sampling at least 30% of the sites (the value obtained will be rounded up to the whole number) and determine the percentage of the total time spent for each site, taking into account the importance of finding some processes for the site.

7. Expansion of the organizations belonging to the multisite

In case the entry of new organizations or operating units in the multisite system is requested, the head of the line must send an explicit request to the CCI indicating all the data foreseen in the doc. RO.PG.03.1 - Multisite.
CCI analyzes the data provided to verify compliance with the multisite requirements as defined in this procedure.
The inclusion of each new group of operating units in the Multisite is considered as an independent set for the determination of the sample to be submitted to initial certification audit (phase I + phase II).
The inclusion of each new group of operating units in the Multisite is added to the pre-existing group for the recalculation of the sample for the surveillance and renewal audit times.

In case of multisite without sampling, each site to be added will be checked.

Each addition to the multisite involves updating the three-year planning by the CB with the possibility of increasing both the audit times and the number of sites to be audited, as required by the specific Operating Instruction.

8. Renewal audit

Without prejudice to the calculation of audit times, as per specific operational instruction, the renewal audit, for multisite with sampling, necessarily requires the auditing of organizations that up to that point have never been subjected to on-site audits.

In case of renewal of multisite with CCI sampling will re-examine the information received for:

- Confirm that a single SG is applied throughout the organization;
- Determine the scope of the SG used and the scope of certification required and, if applicable, the sub-areas;
- Understand the legal and contractual provisions for each site;
- Understand "what happens where" the processes / activities present in each site and identify the central function;
- Determine the degree of centralization of the processes / activities that are performed at all sites (eg purchases);
- Determine the interfaces between the different sites;
- Determine which sites can be applicable to sampling and those that are not eligible;
- Consider other factors relevant to integrated management systems;
- Determine the audit time for the organization;
- Determine the skills required by the audit team;
- Identify the complexity of the processes / activities covered by the SG.

In the case of multisite without sampling, an audit will be carried out on each site and the proportion of the total time spent for each site is determined, taking into account the importance of certain processes for the site.

9. Audit program

CCI will prepare and maintain an audit program for multisite organizations, regardless of whether sampling is applied or not.
The audit program, in addition to the provisions of ISO 17021-1, must contain:
- Processes / activities for each site;
- Identification of sites that can be sampled and those that can not be sampled;
- Identification of sites covered by sampling and which are discovered.

At any time (ie before planning the surveillance audit or when any organization's site changes its structure, or in case of acquisition of new joins that will be added), ICDQ, re-examines the planned sampling (if any) and updates the audit program.