IAF Informative Document

Market Surveillance Visits to Certified Organizations

Issue 2, Version 2

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Issue 2, Version 2

The International Accreditation Forum, Inc. (IAF) facilitates trade and supports industry and regulators by operating a worldwide mutual recognition arrangement among Accreditation Bodies (ABs) in order that the results issued by Conformity Assessment Bodies (CABs) accredited by IAF members can be accepted globally.

Accreditation reduces risk for business and its customers by assuring them that accredited CABs are competent to carry out the work they undertake within their scope of accreditation. ABs that 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.

ABs that are signatories to the IAF Multilateral Recognition Arrangement (MLA) are evaluated regularly by an appointed team of peers to provide confidence in the operation of their accreditation programs. The structure of the IAF MLA is detailed in IAF PL 3 - Policies and Procedures on the IAF MLA Structure and for Expansion of the Scope of the IAF MLA. The scope of the IAF MLA is detailed in the IAF MLA Status document.

The IAF MLA is structured in five levels: Level 1 specifies mandatory criteria that apply to all ABs, ISO/IEC 17011. The combination of a Level 2 activity(ies) and the corresponding Level 3 normative document(s) is called the main scope of the MLA, and the combination of Level 4 (if applicable) and Level 5 relevant normative documents is called a sub-scope of the MLA.

- The main scope of the MLA includes activities e.g. product certification and associated mandated standards e.g. ISO/IEC 17065. The attestations made by CABs at the main scope level are considered to be equally reliable.

- The sub scope of the MLA includes conformity assessment requirements e.g. ISO 9001 and scheme specific requirements, where applicable, e.g. ISO 22003-1. The attestations made by CABs at the sub scope level are considered to be equivalent.

The IAF MLA delivers the confidence needed for market acceptance of conformity assessment outcomes. An attestation issued, within the scope of the IAF MLA, by a body that is accredited by an IAF MLA signatory AB can be recognized worldwide, thereby facilitating international trade.

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Introduction to IAF Informative Documents

This IAF Informative Document reflects the consensus of IAF members on this subject and is intended to support the consistent application of requirements. However, being a document for information purposes only, IAF Accreditation Body Members, and the Conformity Assessment Bodies they accredit, are not under any obligation to use or comply with anything in this document.

MARKET SURVEILLANCE VISITS TO CERTIFIED ORGANIZATIONS

0. INTRODUCTION

The traditional methodology used for accreditation of management system certification bodies (CBs), based on ISO/IEC 17011 involves office assessments of the certification body in conjunction with witnessing a sample of the CB's audits.

There have been growing concerns in recent years about the effectiveness of this methodology in ensuring that expected outcomes from management system certification are being achieved consistently around the globe. As a result of work carried out by the ISO 9000 Advisory Group (IAG) and the IAF Technical Committee, the philosophy "Output Matters!" has become widely recognized and forms a core element of the Strategic ISO/IAF "Action Plan to monitor and improve the effectiveness of Accredited Management System Certification".

Consistent with this philosophy, one of the specific actions in the ISO/IAF Action Plan (Item 3.3) is "Development of criteria for the performance of "validation audits" by the ABs at the certified organizations to check the effectiveness of the management system". These have since been re-designated as "Market Surveillance visits", and a methodology for conducting such visits has been developed and validated in the recent UNIDO/ISO/IAF Project TE/RAS/09/003.

This IAF informative document provides suggestions about how short market surveillance visits might be used by accreditation bodies or others in order to complement traditional oversight techniques. In the context of accreditation, this is consistent with Clauses 3.24 and 7.9.5 of ISO/IEC 17011:2017 which states "The accreditation body may conduct extraordinary assessments as a result of complaints or changes, or other matters that may affect the ability of the conformity assessment body to fulfil requirements for accreditation." . It is recognized that some accreditation bodies (and others) already conduct such visits to certified organizations, and whilst the objective of the current document is not to make such visits mandatory, it is hoped that it will provide a common platform and methodology for such visits if and when they are deemed to be appropriate. This informative document uses accredited certification to ISO 9001 as an example, but the methodology could be adapted for application to other management systems.

It is important to emphasize that the adoption of the methodology described in this informative document should not necessarily increase the cost of the accreditation process. On the contrary – the objective is to make the accreditation process more

effective and efficient, by the intelligent use of a “Plan-Do-Check-Act” approach. This means that the output of market surveillance visits could be used to provide input into the planning of subsequent oversight activities by the AB (including the frequency and duration of office assessments and witness audits), (ISO/IEC 17011:2017 Clause 7.9.2). This could mean, for example, that CBs whose certified clients demonstrate a high level of confidence in the effectiveness of their management systems during market surveillance visits might subsequently benefit from a less onerous programme of office assessments and witness audits by the AB. Conversely, CBs whose certified clients do not provide an acceptable level of confidence during market surveillance visits could be subjected to a more intense (and targeted) programme of traditional oversight.

Although the methodology described in this document is for information only, it is hoped that some CB’s and their respective AB’s might see the advantages of adopting such market surveillance visits on a pilot (voluntary) basis, to complement traditional accreditation techniques. In these cases, it is recommended that the experiences obtained from such initiatives (including a cost/benefit analysis) be reported to the IAF Technical Committee for subsequent improvement of this informative document.

1. SCOPE

This informative document is applicable to short market surveillance visits used by accreditation bodies or others in order to complement traditional oversight techniques.

2. DEFINITIONS

2.1 Market Surveillance

Visit is typically a short (one-day) visit to a certified organization, to determine the level of confidence in the conformity of the management system to specified requirements and the effectiveness of the accredited certification process.

NOTE: A market surveillance visit is ***not*** a “repeat audit”, and is not intended to identify or document specific nonconformities; the visit is intended only to provide confidence in the activities of the CB.

3. OBJECTIVES

The objective of a market surveillance visit is to establish the level of confidence in the CB's certification process by direct observations carried out during visits to a sample of its certified organizations, to use the results to define appropriate levels of surveillance of the CB's activities, and to improve the overall credibility of accredited certification.

The methodology for market surveillance visits described in this document could be used not only by ABs, but also by any duly authorized interested party including (but not limited to):

- CB's (e.g. CB head office market surveillance of branch activities, or franchisor market surveillance of franchisee activities),
- Regulators (e.g. to investigate specific concerns that call into question the validity of accredited certification),
- Customers of certified organizations (e.g. when there are indications that their certified supplier is not fulfilling the requirements of the relevant accredited certification),
- Sector schemes / scheme owners (e.g. to provide additional confidence in the scheme).

4. CRITERIA FOR INITIATING A MARKET SURVEILLANCE VISIT

The use of market surveillance visits by ABs and CBs may be on a voluntary basis, by mutual agreement, or may be initiated by the AB (or other interested parties) to investigate specific situations triggered by adverse trends (including the indicators that are required to be identified by the CB and informed on a regular basis to the AB) or market feedback, such as:

- A sudden change in the number of certificates issued by a CB,
- A CB that raises few or no NC's in long period of time,
- Crises that call into question the credibility of accredited certification,
    - Product recalls;
    - Environmental incidents;
- Complaints from customers of certified organizations or other interested parties indicating concerns about the effectiveness of a CB's certification process,

- Negative publicity.
    - Issues raised by media organizations regarding a particular product, organisation or accredited CB, with relation to specific technical areas including, but not limited to EMS, OHS, FSMS;
    - Problems identified through social networking sites;
    - Specific negative feedback from NGOs regarding the performance of accredited certification;
- Unilateral intervention from regulators, or negative feedback from regulators.

` NOTE: ABs may need to establish feedback mechanisms with regulators to ensure that they are made aware of trends in non-compliances with legislation.

Market surveillance visits may be applied on an individual basis, or as part of a program including a larger sample (client-specific, regional, or CB-specific).

5. PLANNING OF MARKET SURVEILLANCE VISITS

Before initiating a programme of market surveillance visits, it is important to define:

- The contractual basis under which the visits will be carried out,
    - AB's are recommended to include legally enforceable requirements in their contracts with accredited CB's (and require accredited CB's to do the same with their clients) to allow the AB to conduct market surveillance visits if and when the need arises;
    - Confidentiality criteria;
- The objective of the visit or programme of visits. These may be:
    - Part of a routine surveillance mechanism agreed with the CB;
    - Triggered as a result of negative market feedback;
- The sampling criteria to be used,
- Who will participate,
    - The AB assessor (in case of foreign accreditation this may be carried out by or in collaboration with the local AB);
    - A CB representative (as an invited observer);
    - Other relevant interested parties, as agreed;

- The competence needed by the assessment team,
    - The assessors should be competent with respect to the management system under consideration, and in the methodology of conducting short market-surveillance visits;

      NOTE: Competence in conducting assessments to ISO/IEC 17021-1 may be advantageous but is not mandatory.
- Who will be covering the costs of the visit(s),
    - This will vary depending on the objective and trigger mechanism for the market surveillance visit, but should be clearly defined before the visit is conducted.

6. METHODOLOGY OF A MARKET SURVEILLANCE VISIT

The UNIDO/ISO/IAF Project TE/RAS/09/003, which was aimed at the specific case of ISO 9001 certification, used a checklist comprising 26 topics to be covered during a one-day visit. These topics are shown in Annex 1, and could be suitably modified for other management systems, or customized depending on the specific objectives of the market surveillance visit. For each item on the checklist, and in particular for overall perceptions about the validity of a specific organization's certification, it has been shown that competent assessors can distinguish between five distinct "confidence levels" during a short, one-day visit, and it is recommended that these be utilized to provide a consistent basis for market surveillance visits, regardless of who carries them out or the reasons for initiating them. These five levels are expressed in simple terms as follows:

- **Grade 1** "Little or no confidence"
    - Little or no evidence to support the implementation of this topic
- **Grade 2** "Some evidence presented, but not at all convincing"
    - Some evidence was presented, but in the professional judgement of the assessor (based on experience), there would probably be evidence to support a nonconformity if a detailed audit trail were to be followed in a full system audit.
- **Grade 3** "OK - No reason to doubt that this is being addressed correctly"
    - The "default" grade, where there is no evidence to suggest reasons for concern, based on the assessor's experience and professional judgement.
- **Grade 4** "Clear evidence that this is being done, and meets the intent of the relevant standard"

- Sufficient objective evidence was available to provide a good level of confidence that the organization is meeting the requirements.

- **Grade 5** “We can be proud to use this organization as a benchmark for this topic”
  - To be reserved for truly excellent performance.

7. ANALYSIS OF RESULTS

Grades 3 to 5 are considered to be acceptable results that confirm the validity of the accredited certification. CBs whose clients are consistently assessed to be Grade 4 or Grade 5 should be considered as having robust certification process and ABs should consider reducing the traditional oversight of surveillance assessment and witnessing.

Grade 2 raises doubts regarding the way in which the accredited certification process has been conducted, but requires a more in-depth analysis before reaching conclusions. Decisions should not be made based on a single “Grade 2” result at a certified organization.

Grade 1 calls into question the validity of the CB’s accreditation, and should lead to further investigation and action.

End of IAF Informative Document for Market Surveillance visits to Certified Organizations.

ANNEX 1 – SUGGESTED METHODOLOGY FOR MARKET SURVEILLANCE VISITS

Visit Plan

Typical Visit plan for One-day visits to ISO 9001-certified organizations

Note: Timings are approximate, and may be adapted to suit local or cultural needs

CB invited to participate as *observer*

Timing	Activity	Comments
09:00 – 09:30h	Opening briefing	• Explain context and objectives of the visit. (This may vary depending on what triggered the visit). • Emphasize that the visit is NOT intended to be an audit, and that the results will be CONFIDENTIAL. It is not intended to determine conformity or non-conformity of the system. The results of the visit will not necessarily affect the organization's certification status. • Objective is to look at effectiveness of the **CB's processes** for ISO 9001 certification on a sample basis. Aim is to ***improve the accredited certification process.*** • Record attendance and sign confidentiality agreements as appropriate. • Agree on schedule for rest of day. • Allow time for short presentation by organization (15 min max).
09:30 – 10:00h	Management representative	• Discuss "self-assessment questionnaire" with MR (Annex 2). Use time to establish empathy with MR.
10:00 – 12:30h	"Site" Tour	Things to look for: • Do employee numbers tie in with those used for audit duration calculations, • General housekeeping and work environment / infrastructure, • Communications Notice boards up-to-date (or electronic communications / intranet etc), • Talk to sample of employees,

Timing	Activity	Comments
		○ Concept of process; ○ Ability to describe responsibilities, activities undertaken etc.; ○ Awareness of Quality Policy, objectives etc.; ○ Link to competence/ effectiveness; • Availability of work instructions as needed, user-friendliness, • Monitoring & Measurement / Inspection & Testing facilities as applicable, ○ Availability of equipment; ○ Sample of calibrations OK.
12:30 – 14:00h	Lunch and discussions with top management (Sequentially or together)	• What are their perceptions? Is certification adding value? • Find out about how they arrived at the quality policy and how does it relate to overall organizational policy and culture. • What about the Quality Objectives; ○ Do these help them to manage the organization, ○ Are they realistic, achievable, measurable, challenging, ○ Relate to company's immediate concerns? • Talk about customers – who are they, what do they want? • Involvement and ability to discuss latest Management Reviews; actions arising etc. • Strengths & weaknesses of their system.
14:00 – 16:30h	Management Representative and others, as needed	• Review certificate: ○ Does scope of certification clearly define what products and services are covered? • Review of Quality Manual, including justification for any exclusions (emphasis on Clause 7.3 & 7.5.2). • Internal audits ○ Are they being done - look at audit plan and recent reports.

Timing	Activity	Comments
		○ Are NC's being identified and closed out? ○ Causes being determined? ○ Corrective actions (not just correction) implemented and effective? ○ Linkage with management review & analysis of data. • Corrective actions – are causes being identified? Is effectiveness verified? • Customer feedback (including customer complaints). • Review recent certification body audit reports.
16:30 – 17:00h	Time to prepare visit summary	• Includes time to tie up any loose ends.
17:00 – 17:30h	Closing briefing	• Summary: Praise if appropriate, if there are problems make it clear that it's between them and their CB* • Avoid negative comments about CB. * Take care not to make conclusions about the conformity (or otherwise) of the management system. Note: It is NOT expected that the visit summary (Annex 3) will be made available to the organization.

ANNEX 2 – "SELF-ASSESSMENT" BY THE CERTIFIED ORGANIZATION

(To be filled out together with the assessor if clarifications are necessary)

The following questionnaire is designed to address several key components regarding your experiences, ***as an ISO 9001- certified organization***, regarding the certification process.

IMPORTANT NOTE:

- *We request that this questionnaire be filled out by MANAGEMENT within your organization, without discussing with any consultant who may have helped in the implementation of your system, or with your certification body. This is not because we don't trust them – it's because we want YOUR opinions!*

1. Name and address of organization:

2. Management:

Name:	
Function:	
E-mail:	
Telephone:	

3. Top Management name(s) (Person or group of people who directs and controls the organization at the highest level")

4. Certification Body (Please attach a copy of the certificate)

5. Scope of certification

6. Number of employees in your organization **(Please mark with an "X" in the appropriate box**)

1 to 5	6 to 10	11 to 15	16 to 25	26 to 45	46 to 65	66 to 85	86 to 125	126 to 175	176 to 275	276 to 425	426 to 625	626 to 875	876 to 1175	1176 to 1550	Over 1550 (please state number)

7. How long have you been certified to ISO 9001? **(Please mark with an "X" in the appropriate box**)

0 – 3 years	4-10 years	Over 10 years

8. How many audit-days did the certification body use during your initial (or most recent full re-certification) audit? (for example, 2 auditors full-time for a total of 3 days = 6 audit-days) : _____(**total number of audit-days**)

9. How often does your certification body visit you to carry out surveillance audits, to ensure your system continues to meet the ISO 9001 requirements?

Every 6 months	Every 9 months	Once a year	Less frequently than once a year

10. How many audit-days does your certification body spend each year on surveillance audits? (for example, 2 auditors full-time for a total of 2 days = 4 audit-days) : _____(**number of audit days per year**)

11. What was the name of the auditor who visited you last time?

    _____

12. Are you happy with the way in which your CB has conducted your audits?

13. What is your own opinion about the status of your management system?

ANNEX 3 – EXAMPLE OF VISIT SUMMARY (QMS EFFECTIVENESS)

NOTE: This is NOT a “Conformity assessment” exercise. Results are to be expressed in terms of confidence levels, based on observations and discussions during the visit.

- **1 = Little or no confidence**
- **2 = Some evidence presented, but not at all convincing**
- **3 = OK - No reason to doubt that this is being addressed correctly**
- **4 = Clear evidence that this is being done, and meets the intent of ISO 9001**
- **5 = We can be proud to use this organization as a benchmark for this topic**

Statement	Confidence level*					Comments and/or justifications (required in case of level 1 or 5)
	1	2	3	4	5	
1) The initial (or most recent full recertification) audit duration was appropriate for the size and complexity of the organization (See IAF MD5)						IAF Table (adjusted for complexity etc): Actual: Comments:
2) The duration and frequency of surveillance audits are appropriate for the size and complexity of the organization (see Clause 5 of IAF MD5)						IAF Table (adjusted for complexity etc): Actual: Comments:
3) The scope mentioned on the organization’s certificate accurately describes its activities, and is not misleading.						
4) Requirements not applicable are appropriate (if all requirements are applicable, give Grade “4” and make a note in comments)						
5) There is evidence of top management’s involvement with and commitment to the implementation of ISO 9001						
6) Internal communication is good, and employees are aware of their roles in the QMS						
7) The “process approach” is clearly understood and implemented throughout the organization						

Statement	Confidence level*					Comments and/or justifications (required in case of level 1 or 5)
	1	2	3	4	5	
8) The organization is managing its QMS processes using a “Plan-Do-Check-Act” –type approach (ISO 9001 Clause 0.3.2)						
9) The quality policy is appropriate for the organization’s situation and culture						
10) The organization has established and deployed meaningful objectives at relevant functions and levels						
11) Documented information is being used and is properly controlled						
12) The organization has adequate resources (competent personnel, equipment etc) to support its system						
13) The work environment is appropriate						
14) Key design and development processes are identified and managed						
15) Processes are being adequately monitored and measured						
16) Product nonconformities are identified and dealt with according to documented procedures						
17) There is a focus on identifying the CAUSE of process, product and system nonconformities, and on implementing effective corrective action						
18) Internal audits are being carried out according to plan, and are effective						
19) Management reviews are being carried out according to plan, and are effective						
20) The organization has a focus on preventing nonconformities						
21) Customer feedback and customer complaints handling mechanisms are appropriate						
22) The QMS is providing confidence in the organization’s ability to “ meet applicable statutory, regulatory and contractual requirements”						
23) The organization has a culture of continual improvement of the effectiveness of its QMS						

Statement	Confidence level*					Comments and/or justifications (required in case of level 1 or 5)
	1	2	3	4	5	
24) The certification process has been conducted effectively by the certification body						
25) OVERALL confidence in this organization's implementation of ISO 9001						

Space for Additional Comments

Assessor: Date:

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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