CERTIFICATION OF MANAGEMENT SYSTEM

CERTIFICATION MANUAL Doc No: CM 5_Annex_F

6.2 CONFORMITY ASSESSMENT - CERTIFICATION OF MANAGEMENT SYSTEM PROCESS

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Documents are part of ICS quality system. Copy-holder shall replace new issues and revisions by withdrawing / destroying preceding issues & revisions.	
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6.0 PROCEDURE:

1 SCOPE OF SERVICES:

Certification / Assessment of the Organization's Management System / Product Certification

Under this service, on satisfactory completion of the assessment of a organization management system in accordance with a nominated quality management standard(s) such as ISO 9001, ISO 14000, QS 9000, SA 8000, OHSAS 18001, ISO 45000, TS 16949, ISO 22000, HACCP, based food Safety management system, ISO 27001 Information Security Management System (ISMS), Product Certification and ISO 30000 Ship Recycling Management System (SRMS), Information Technology Service Management (ISO 20000), **ISO 50001 - Energy Mangement System,** ISO 13485, ISO 13488, ICMed 9000, ICMed13485 (Issue 2), GMP depending upon the nature of the organization's business, a Certificate of Compliance is issued to the organization subject to certain conditions for surveillance. These services are rendered to those sectors of industries for which ICS has received the accreditation from its accreditation .

2 ACCREDITATION :

Refer CM 5.

Refer ICS / Accreditation Website - Approvals/Accreditation for scope of accreditation.

Thus any kind of service or manufacturing industry can be certified as per the management systems.

3 REQUEST FOR CONFORMITY ASSESSMENT SERVICES :

3.1 Definitions

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

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

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.

Multi-site 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.

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

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.

Note 1: 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.

Note 2: An example of such a virtual site is a design & development organization with all employees performing work located remotely, working in a cloud environment.

Note 3: A virtual site (e.g. an organization's intranet) is considered a single site for the purpose of calculating of audit time.

Note 4: For further information, see also IAF MD 4: Use of Computer Assisted Auditing Techniques ("CAAT") for Accredited Certification of Management Systems.

Sub-scope - The scope of a single site.

Note: 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.

Note: The above definition of "sub-scope" is to be used for the purposes of implementing the requirements of this document.

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

3.2 Organizations interested to get certified / recertified by ICS for their management system can obtain the quotation request form (QRF_FC/03), by sending a request. On receipt of the request and the required information, ICS will forward the QRF to the applicant. Applications in any other format are not accepted.

The Quotation Request Form contains all necessary information related to the client such as scope, sites - permanent, temporary and virtual, manpower,etc .enabling ICS to furnish the quotation to the customers. The QRF or the request from the client from conformity assessment shall also provide the details of requirement of specific accreditated services, else the services which ICS will be provided as ICS accredited.

In addition to QRF, a Questionnaire _FC/03 to be sent to the potential clients for certification of environmental / occupational health, food safety, information security, ship recycling management system.
The information provided by the authorized representative of the applicant organisation on its processes and activities shall also include the identification of the key hazards and OH&S risks associated with processes, the main hazardous materials used in the processes, and any relevant legal obligations coming from the applicable OH&S legislation.
The application shall contain details of personnel working on, as well as working away from the organisation's premises.

If the client provides services at another organisation's premises, the same shall be verified that the client's OH&SMS covers these offsite activities (notwithstanding the OH&SMS obligations of the other organization). In determining the time to be spent for audit.

A review shall be carried out of the Client Profile and proposed audit / inspection duration and the proposed sampling of multiple sites

3.3 QUOTATION:

ICS prepares and forwards their quotation_FC/24 on the basis of the Information received. ICS fees for the conformity assessment services are based on, standard to be assessed against, the size of the organization, i.e. number of employees, the product (s) and services, number of Units and facilities, risk involved. ICS fees cover the cost of initial and subsequent surveillance

assessment(s) during three years validity of the certification. This excludes the cost of any pre – assessment or follow-up audits that may be required for successful completion & maintenance of the certification process. and travel and subsistence expenses ICS terms & conditions_FA/16 are available as an appendix to the quotation.

Fee Structure :

Registration / Licensing Fee
Stage 1 Audit Fee
Stage 2 Audit Fee
Surveillance (as applicable)

For details on mandays applicable refer to IAF MD 5 & IAF MD9.

3.4 REVIEW OF REQUEST FOR CONFRORMITY ASSESSMENT :

ICS will carry out a review of the request for conformity assessment following the review of the application ensure that all information is available as required about the applicant organization and its management system is sufficient for the conduct of the conformity assessment and to process the certification. ICS shall either accept or decline an application for conformity assessment. On denial of an request for conformity assessment as a result of the review of application, the reasons for declining an application shall be documented and made clear to the client on his request.

3.5 CONTRACT FOR REGISTRATION :

The organization shall complete the relevant CONTRACT form_FC/02, to provide details of the organization and the scope of activities for which conformity assessment is sought. The application form shall be accompanied with applicable fees as per the terms of the quotation. The filled in Contract for Registration is reviewed for conformity assessment by ICS.

Once a client is registered with ICS and Registration No.is issued the client needs to proceed for certification and ensure completion of the certification process within one year of registration. In case the client fails to get the audit carried out and get certified within one year from the date of registration the client's registration number will stand cancelled. The registration fees are non-refundable and will not be considered.

The client will have to seek fresh registration number in such case and pay registration fees for the fresh registration.

The Registration Fees are non-refundable as it involves administration and other costs.
Organization seeking product safety certification shall not have simultaneous contract concluded with other certification and / or notified bodies, covering the same scope of certification.

The organization should provide the Management System Documents covering client's documented informations / QAP and associated documents to ICS for review at the earliest opportunity. At this stage, the organization may indicate preferred dates for the initial assessment.

3.6 MULTISITE CERTIFICATION/REGISTRATION :

Normally assessment for certification/registration for QMS / EMS / OHSAS / ISMS/ FSMS SRMS/HACPP/ ISO 13485 / ICMED 9000 (issue 2) & ICMED 13485 (issue 2) and subsequent surveillance shall take place at every site of the organization that is to be covered by ICS. However, where an organization's activity subject to certification/registration is carried out in similar manner at different sites, all under the organization's control, a certification/registration audit can be carried out on sampling the sites both at the assessment and surveillance stages as per ICS procedures.
However, multisite does not apply to the assessment of the organizations that have multisite where dissimilar manufacturing and/or service processes are used at the different sites, or dissimilar activities take place at sites even though under the same quality management system.

Size sampling shall be restricted with respect to :

Scope sectors or activities (i.e. based on the assessment of risks or complexity associated with that sector or activity);
Size of the sites eligible for multisite assessment;
Variations in the local implementation of the quality management system such as the need for frequent recourse to the use of quality plans within the quality management system such as the need for frequent recourse to the use of quality plans within the quality management system to address different activities or different contractual or regulatory systems;

Use of temporary sites, which operate under the quality management system of the organization.

3.6.1 APPLICATION

Site
- A site could include all land on which processes/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 processes/activities, whether or not fixed. Alternatively, where required by law, definitions laid down in national or local licensing regimes shall apply.

- Where it is not practicable to define a location (e.g. for services), the coverage of the certification shall take into account the organization's headquarters processes/activities as well as delivery of its services. Where relevant, certification audit will be carried out only where the organization delivers its services. In such cases all the interfaces with its central function shall be identified and audited.

Temporary Site
- Temporary sites that are covered by the organization's management system shall be subject to audit on a sample basis to provide evidence of the operation and effectiveness of the management system. They may, however be included within the scope of a multi-site certification and included on the certificate, subject to agreement between ICS and the client organization. When temporary sites are shown on the certification documents, such sites shall be identified as temporary.

Multi-site Organization
- A multi-site organization need not be a unique legal entity, but all sites shall 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.

In addition to the above -
For SRMS :
Examples of possible multiple-site organisations are :
A) Organisations operating with the franchises;
B) Service companies or otherwise organized groups, such as associations offering specific services, including a network of collection/storage, processing, further dismantling and separation or other sites and logistics which carry out similar processes and operate to the same procedures
C) Companies with the multiple branches and/or operational sites all providing the same service.

3.6.2 RATIONALE FOR THE PROPOSED APPROACH

Multi Site Auditing would be applicable to the organisation which operates and will be audited 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 will be audited and certified; furthermore, by definition, a management system audit is only based on a limited sample of the information available.
However it must 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 document 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.

Eligibility Criteria for the organization:
1) The organization shall have a single management system.
3.6.3 2) The organization shall identify its central function.The central function is part of the organization and shall not be subcontracted to an external organization.
3) The central function shall have organizational authority to define, establish and maintain the single management system.
4) The organization's single management system shall be subject to a centralized management

review.
In addition to above point 4, for SRMS,
- Local system documentation and system changes
- Improvement objectives, targets and management programmes.
- Evaluation of complaints, incidents, corrective actions;
5) All sites shall be subject to the organization's internal audit programme.
6) The central function shall be responsible for ensuring that data is collected and analyzed from all sites and shall be able to demonstrate its authority and ability to initiate organizational change as required in regard, but not limited, to:
(i) system documentation and system changes;
(ii) management review;
(iii) complaints;
(iv) Evaluation of complaints, incidents, corrective actions;
(v) internal audit planning and evaluation of the results; and
(vi) statutory and regulatory requirements pertaining to the applicable standard(s).

In case of SRMS - In addition to the above point i, ii, iv & v :
Improvement objectives, targets and management programmes.
The organization shall have carried out a risk-specific process and operation assessment for each site, shall implement the operational controls accordingly and be able to demonstrate through records the effectiveness of those controls for all sites including those not subject to ICS audits.

In case of SRMS -
Ship recycling risks are unique to each operational site; therefore, all operational sites included in an organizations scope of certification/registration shall be subject to audit. The organization shall have carried out a risk, process and operation assessment for each site and shall implement operational controls accordingly. Similarly, ship recycling risks applicable to non-operational sites, such as those providing support administrative services, are also unique, but by the nature of the activities undertaken, may present a lower portion in the whole ship recycling process.(All operational sites shall be subject to ICS audits and the processes and operations presented by other non operational sites shall be evaluated and audited commensurate to those processes and operations.)

There are situations where some relaxation from site-by-site audits may be acceptable. For example, where the services, the sites and all activities provided by waste and other material handling or service companies are substantially the same and are carried out fully in accordance with the same methods and procedures , then there may be sme scope for reducing the audit mandays for some of the sites operated by the same organisation. However for all sites, site-specific processes and operations shall have been identified and subject to a process and operation assessment by the orgabisation and audited by ICS during an on-site audit. In order for reduced auditing to be considered, the following criteria shall be met :
- The organisation's ship recycling management system shall be centrally administred and operated in accordance with a centrally controlled process for acrrying out ship recycling assessments and developing ship recycling facility plans.
- Refer above point 4.

All the relevant changes (including the central administration function) shall be subject to the organisation's internal audit programme and evaluation of audit results and each location shall have been audited in accordance with that programme prior to ICS starting its assessment.

It shall be demonstrated that the central office of the organisation has established a ship recycling management system in accordance with the assessment standard and that the whole oragnisation meets the requirements of the certification standard, This shall include consideration of relevant regulations.

If there is any deviation from the man-day audit durations or “all sites shall be audited by ICS approach for any location that is included in the scope of certification/registration, then ICS shall document and implement procedures which apply a process and operation management approach to justify any deviation from the audit durations and “all sites shall be audited” approach prescribed in standard, such considerations by ICS shall include : Refer below 3.4.6.1.

Records maintained by the central location(s) shall demonstrate the effectiveness of SRMS’s and its implementation for all locations, including those not visited by ICS.

Note: The central function is where operational control and authority from the top management of the organization is exerted over every site. There is no requirement for the central function to be located in a single site.

Eligibility criteria for ICS :

General

ICS shall provide information to the organization about the criteria laid down herein before starting the assessment process, and should not proceed with it if any of the criteria are not met. Before starting the assessment process, it should inform the organization that the certificate/registration will not be issued if during the assessment nonconformities in relation to these criteria are found.

Contract review

ICS procedures should ensure that the initial contract review identifies the complexity and scale of the activities covered by the management system, subject to certification/registration and any differences between sites as the basis for determining the level of sampling.

ICS shall identify the central function of the organization which is its contractual partner for the performance of ICS.

ICS should check, in each individual case, to what extent sites of an organization produce or provide substantially the same kind of processes or services according to the same procedures and methods. Only after a positive examination by ICS that all the sites proposed for inclusion in the multiple-site exercise meet the criteria may the reduced audit procedure be applied to the individual sites.

Assessment

ICS shall have documented procedures to deal with assessments under its multiple-site procedure. Such procedures shall establish the way ICS satisfies itself, inter alia, that the same ship recycling management system governs the activities at all the sites, is actually applied to all the sites and that all the criteria in ‘Eligibility Criteria for the organization - SRMS’:are met.

If more than one audit team is involved in the assessment/surveillance of the network, ICS should designate a unique audit team leader whose responsibility is to consolidate the findings from all the audit teams and to produce a synthesis report.

Dealing with nonconformities

When nonconformities are found at any individual site, either through the organization's internal auditing or from auditing by ICS , an investigation should take place to determine whether the other sites may be affected. Therefore, ICS should require the organization to review the nonconformities to determine whether or not they indicate an overall system deficiency applicable to all sites. If they are found to do so, corrective action should be performed both at the central office and at the individual sites. If they are found not to do so, the organization should be able to demonstrate to ICS the justification for limiting its follow-up action.

At the time of the decision making process, if any site has a nonconformity, certification/registration may be denied to the whole network pending satisfactory corrective action in situations where the activity found to be nonconforming could adversely affect the conformity of operations at other sites.

It shall not be admissible that, in order to overcome the obstacle raised by the existence of a nonconformity at a single site, the organization seeks to exclude from the scope the "problematic" site during ICS process.

The following criteria shall be met by the organizations before starting the assessment process. The assessment process will not proceed if any of the above criteria are not met :

Identify the complexity, risks and scale of the activities / operations covered by the management system subject to certification/registration and any differences between sites as the basis for determining the level of sampling.

Identify the central function of the organization which is its contractual partner for the performance of the certification /registration

Check, in each individual case, to what extent sites of an organization produce or provide substantially the same kind of products or services according to the same procedures or methods.

Where multi-site sampling is used for the audit of a client’s management system covering the same activity in various geographical locations, a sampling programme to ensure proper audit of the management system has to be developed.. The rationale for the sampling plan shall be documented for each client. Sampling is not allowed for some specific certification schemes, and where specific criteria have been established for a specific certification scheme, e.g. ISO/TS 22003, these shall be applied.

NOTE Where there are multiple sites not covering the same activity sampling is not appropriate.

The inclusion of sites in the multisite exercise shall be proposed only if all sites meet the above criteria.

If all the sites of a service organization where the activity subject to certification/registration is performed are not ready to be submitted for certification/registration at the same time, the organization shall be required to inform ICS in advance of the sites that it wants to include in the certificate.

Certificate Of Compliance :

One single certificate/registration shall be issued with the name and address of the central office of the organization. A list of all the sites to which the certificate/registration itself or in an appendix or as otherwise referred to in the certificate / registration.

A sub-certificate / registration may be issued to the organization for each site covered by the certification / registration under condition that it contains the same scope, or a sub-scope of that scope, and includes a clear reference to the main certificate / registration.

The certificate/registration will be withdrawn in its entirety, if the central office or any of the sites does not/do not fulfill the necessary criteria for the maintaining of the certificate / registration.

The organization needs to inform ICS about the closure of any of the sites in order to keep the list of sites updated. Failure to provide such information will be considered as a misuse of the certificate/registration and can result into a withdrawal or suspension of certificate.

Additional site can be added to an existing certificate as the result of surveillance/reassessment activities.
Temporary sites such as building sites those set up / acquired / mobilized by an organization in order to perform specific works are not to be treated as part of a multisite operation. Any sampling of the activities performed at such sites shall be for the purpose of confirming the activities of the permanent office whose management system is subject to certification/registration, not for the purpose of granting certificates to the temporary sites themselves.

METHODOLOGIESFOR SAMPLING
Section 3.6.4.1 - Methodology for Auditing of a Multi-site Organization Using Site Sampling
1) Conditions

- ✓ Sampling of a set of sites is permitted where the sites are each performing very similar processes/activities.
- ✓ Not all organizations fulfilling the definition of “multi-site organization” will be eligible for sampling.
- ✓ 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.
- ✓ ICS shall 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 shall be defined by the ICS with respect to:
- ✧ scope sectors or processes/activities (i.e. based on the assessment of risks or complexity associated with that sector or activity);

3.6.4

- ✧ 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.

The sample should be partly selective based on the factors set out below and partly non-selective, and should result in a range of different sites being selected, without excluding the random element of sapling.

Atleast 25% of the sample should be selected at random.

Taking into account hereinafter, the remainder hereafter, the remainder should be selected so that the differences among the sites selected over the period of validity of the certificate/registration is as large as possible.

The site selection criteria may include among others the following aspects :

a) Results of internal audits or previous certification/registration assessment,
b) Records of complaints and other relevant aspects of corrective and preventive action,
c) Significant variations in the size of the sites,
d) Variations in shift patterns and work procedures
e) Modifications since the last certification/registration
f) Geographical dispersion.
g) complexity of the management system and processes conducted at the sites;
h) maturity of the management system and knowledge of the organization;
i) environmental issues and extent of aspects and associated impacts for environmental management systems.
j) differences in culture, language and regulatory requirements;
k) whether the sites are permanent, temporary or virtual.

This selection need not be done at the start of the assessment process. It can also be done once the assessment at the central office has been completed. In any case, the central office shall be informed of the sites to be part of the sample. This can be done on relatively short notice but should allow adequate time for preparation for the audit.

Size of sample :

The following guidance is 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 :

'y'= size of sample 'x' is number of remote active sites

Complexity Category	No. of employees	Size Of Sample		
		Initial Audit	Surveillance Audit	Reassessment
Low or Medium	>50	$y = \sqrt{x}$	$y = 0.6 \sqrt{x}$	$0.8 \sqrt{x}$

The central function shall be audited during the initial certification and every recertification audit and at least once a calendar year as part of surveillance

The size of the sample should be increased where ICS 's risk registration indicates special circumstances in respect of factors like :

- ✓ The size of the sites and number of employees,
- ✓ The 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,
- ✓ Records of complaints and other relevant aspects of corrective and preventive action,
- ✓ Any multinational aspects, and
- ✓ Results of internal audits and management review..

When the organisation has a hierarchical system of branches (eg. head /central office / national offices / regional offices/local branches), the sampling model for initial audit as defined above applies to each level.

Example :
1 head office : visited at each audit cycle(initial/surveillance/reassessment)
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.

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

The sampling process shall be 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 will be added into the certification boundary), the ICS shall 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.

Additional sites :
On the application of a new group of sites to join an already certified multisite network, each new group of sites should be considered as an independent set for the determination of the sample size. After inclusion of the new group in the certificate, the new site should be cumulated to the previous ones for determining the sample size for future surveillance visits and reassessment audits.

Section 3.6.4.2 - Methodology for Auditing of Multi-site Organizations Where Site Sampling Using Section 3.6.4.1 is not Appropriate

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

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

Additional Sites
On the application of a new site to join an already certified multi-site organization, the site shall 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 shall be cumulated with the previous ones for determining the audit time for future surveillance or recertification audits.

Section 3.6.4.3 - Methodology for Auditing Multi-site Organizations that Include a Combination of Sites that can be Sampled and Other Sites that Cannot be Sampled
The audit programme shall be established using Section 3.6.4.1 for those sites that can be sampled and Section 3.6.4.2 for the remaining part of the organization where Section 3.6.4.2 is not appropriate.

The rationale for the sampling plan for multisite shall be documented for each client.

3.6.5 Calculation of Audit Time for Multi - Site Certification

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 3.6.4.1, from non-sampling as in 3.6.4.2 or from mixed methodology as in 3.6.4.3), 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.

3.6.6 NON CONFORMITIES AND CERTIFICATION - MULTI SITE AUDITS

3.6.6.1 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 ICS, investigation shall take place to determine whether the other sites may be affected. Therefore,ICS shall 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 ICS the justification for limiting its follow-up corrective action

3.6.6.2 ICS shall require evidence of these actions and increase its sampling frequency and/or the size of sample until it is satisfied that control is re-established.

3.6.6.3 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.

3.6.6.4 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.

3.6.7 CERTIFICATION DOCUMENTS :

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

- 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.

- 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.

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.

4 ASSESSMENT OF MANAGEMENT SYSTEM OF ORGANISATION :

4.1 REVIEW OF THE DOCUMENTS:

Upon receipt of the above, ICS appoints an Assessment Team and if considered necessary the Lead Auditor or one of the team member may take a preliminary visit to the organisation's premises. client's documented information along with associated procedures of the organisation is reviewed by the team to verify that it meets with the requirement of the nominated standard. ICS comments and observations on the review of documents prepared in the 'Document Review Report'_FC/10 and submitted to the organisation. Comments given in the document review report are required to be resolved by the organisation prior to the Certification Audit. These amendments will be verified during the Certification Audit by the audit team.

Document Review can also be combined with Stage 1 Audit and carried out onsite.

Before the certification audit, ICS shall ask the client organization to report if any management system records cannot be made available for review by the audit team because they contain confidential or sensitive information. ICS shall determine whether the management system can be adequately audited in the absence of these records. If the auditor in concurrence with Manager (Certification) concludes that it is not possible to adequately audit the management system without reviewing the identified confidential or sensitive records, it shall advise the client organization that the certification audit cannot take place until appropriate access arrangements are granted.

Where it is required by law or by relevant Regulatory Authority, the ICS shall provide the information about certifications granted, suspended or withdrawn to the Regulatory Authority

4.2 DOCUMENTATION ISSUED TO THE ORGANISATION :

At the conclusion of the assessment a summary audit report will be issued by ICS Lead Auditor which gives an indication to the preparedness of the organisations management system for a Certification / Registration Assessment. The report may highlight the deficiencies in the system, if any, with reference to the relevant clauses of the nominated standard.

Refer Activity Flow Chart annexed as Annexure B

5 CERTIFICATION - ASSESSMENT

5.1 Certification-Assessment of Quality / Environment / Occupational Health & Safety / Information Security / Ship Recycling Management System

The Assessment shall be carried out in 2 stages :

5.1.1 Stage 1 Audit :

The stage 1 audit is to assess and report the status of the organisation's management system, concentrating on both correct interpretation of the applicable standard and implementation of the system rather than detailed compliance. Stage 1 audit shall provide an indication to the customer whether all relevant aspects of the standard have been addressed.
The stage 1 audit shall be performed

a) To audits the client's management system documentation;

b) To evaluate the client's location and site-specific conditions and to undertake discussions with the client's personnel to determine the preparedness for the stage 2 audit;

c) To review the client's status and understanding regarding requirements of the standard, in particulars with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;

d) To collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliances (e.g. quality, environmental, legal aspects of the client's operation, associated risks. Etc.)

e) To review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audit;

f) To provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects.

g) To evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audits.

Incase of multi site audits ,
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.

5.1.2 STAGE 2 AUDIT :

The Stage 2 Audit shall be conducted only after closure of the Corrective Action Requests raised in the Stage 1 audit.

The purpose of the stage 2 audit is to evaluate the implementation, including effectiveness, of the client's management system. The stage 2 audit shall take place at the site(s) of the client. It shall include at least the following:

a) Information and evidence about conformity to all requirements of the applicable management system standard or other normative document;

b) Performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document)

c) The client's management system and performance as regards legal compliance;

d) Operational control of the client's processes;

e) Internal auditing and management review;

f) Management responsibility for the client's policies;

g) Links between the normative requirements, policy, performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document, any applicable legal requirements, responsibilities, competence of personnel, operations, procedures, performance data and internal audit finding s and conclusions.

In the case of multiple sites or certification to multiple management system standards being provided by the certification , the planning for the audit shall ensure adequate on site audit coverage to provide confidence in the certification.
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.
- 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.

- 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.

5.4 COMBINING MANAGEMENT AUDITS

The audit can be combined with audits of other management systems. This combination Is possible provided it can be demonstrated that the audit satisfies all requirements for certification of the IMS Integrated Management System. The audit plan will identify the roles of each member of the audit team and the criteria each member is to audit. All the elements of a IMS will appear clearly, and be readily identifiable, in the audit reports.

The quality of the audit should not be adversely affected by the combination of the audits.

When certification to multiple management system standards is being provided by the certification , the planning for the audit shall ensure adequate on-site auditing to provide confidence in the certification.

5.5 Certification – Assessment of Food Safety Management System :

Certification – Assessment of Food Safety Management System is a two stage audit.

ICS Audit Team conducts the preliminary audit and initial audit on the agreed date and for a number of audit days as per Annex 3 to CM 12 B – Guideline for allocation of HAACP Audit.. The process begins with an opening meeting Lead Auditor chairs the opening meeting and explains the scope of certification and audit methodology. The Co-ordination through the Management Representative will be required throughout the audit.

The auditor will ensure with objective evidence –

- The purpose, inputs, outputs, controls and resources applicable to each process are clear and followed.
- Links are established between processes and high level and functional objectives.
- The outputs of the processes are compared with desired outcomes, the purpose of the process and any specific quality objectives.
- The steps in the process and associated responsibilities are determined, where necessary.
- Inter-relating processes are identified.
- Process measures are identified.
- Evidence of continual improvement is sought.
- Needs of internal and external customers are clear.

Lead Auditor shall verify and ascertain the Internal audit and management review by the organization

Internal Audit: At least one complete cycle of internal audits have been performed prior to the certification audit by ICS.

Management Review :At least one management review have been performed prior to the certification audit by ICS.

At the conclusion of the audit, a closing meeting is held where the findings of the audit will be - The possible outcome of the certification assessments are presented by the Lead Auditor.

The Lead Auditor has to ensure that the following prerequisites are taken care before recommending the client for certification.

The client has implemented the Documented system of Management as per relevant ISOstandard. Management System shall be in place for at least minimum 3 months.

Should have carried out minimum one internal audit against the applicable criteria of certification and one management review.

There is no penalty and /or statutory non-compliance against the client
Review of customer dissatisfaction / complaints of any.
All disputes have been resolved.
All Non-conformities are closed effectively with satisfactory objective evidence.
The client has paid all fees.

Recommendation for Certification :

The clean recommendation for certification of there is non non-conformity recorded in the 2nd Stage Audit and non-conformities if any raised in the Stage 1 Audit is effectively closed;

The subjective recommendation to certification when non-conformities are recorded subject to verification of corrective action implementation effectiveness through documented evidence or follow-up audit depending on the nature and complexity of non-conformity;

Non sufficient objective evidence for conformance seen to recommend for certification, re-visit is recommended;

No recommendation for certification, which usually means that a complete re-audit is necessary.

If major Non Conformances were found, the Team Leader shall not recommend certification. It should be explained to the client that a follow up audit will be required within one month to confirm effective corrective action on those elements where Major non-conformities have been identified.

Additional fees and reimbursement of expenses are charged to the organisation as per prevailing man-day rate and reimbursement of expenses at actual in case of reaudit / follow-up audit.

The name of the organisation is registered in the ICS list of certified companies and in the Accreditation Directory

Document Review Report_FC/10 and the Audit Reports_FC/14 will be submitted to the organisations upon completion of each of activities from time to time.

5.6 NON CONFORMITY:

The Lead Auditor / Auditor categorizes the non-conformities into the following two categories major and minor as defined below:

a. MAJOR :

The absence of, or the failure to implement and maintain, one or more management systems requirements, or a situation, which would, on the basis of objective evidence, raise significant doubt as to the capability of Management System to achieve the policy and objectives of the organization.

Incidences leading to the breakdown of the established Management System.

Or

Failure to meet the Legal and Statutory Requirements

Or

Deficiency related to safety of Product or service

b. MINOR :

A minor lapse in either discipline or control of a requirement of Organization Management System which may be an isolated case or may not lead to a total collapse of the system as the basic intent is satisfied.

c. OBSERVATION:

A statement of concern by the Auditor, which is not an identified non-conformity, but which needs to be investigated. It is possible that this may convert into a non-conformity if ignored and not fully investigated.

The non-conformities identified during the audit are documented on Form FC_08 Corrective Action Request.

5.7 CORRECTIVE ACTIONS:
The top management and the organization is expected to follow-up the non-conformities identified during the audit, if any and to submit the proposed corrective actions with target completion dates. Depending upon the nature and degree of the non-conformities, a time scale is to be specified for acceptance of proposed corrective action plan, which shall not be more than 4 weeks (for major NC). In case of minor non-conformities the acceptance of proposed corrective action plan shall be within 3 months.

ICS may verify the implementation of corrective actions by follow up and/or surveillance audit depending on the nature of non-conformities. ICS will conduct follow-up audit for Major Non-conformities and by a surveillance audit for Minor Non-conformities to verify that the outstanding corrective actions are closed in a satisfactory and effective manner.

5.8 CLOSING OF OBSERVATIONS

Recorded observations are not a binding and do not require a formal response as it is not a part of the audit process.

5.9 AUDIT TEAM:

Certification, surveillance and Re-certification management System audits are to be planned and performed by a Lead Auditor, who is competent according to ICS qualification requirements.
The Client would be informed of the names of the audit team members would be carrying out the assessment with sufficient notice to appeal against the appointment of any particular auditors or experts.

LEAD AUDITOR:

Collects and categorizes any corrective action requests raised against the organizations System and review the course of corrective action prepared by the organizations top management.

Prepares an audit summary of the CAR's and copy of which is presented to the organization.

Verifies the scope of certification.

Records attendance of the participants from the organization showing their position during opening and closing meeting

Organization may be requested to enclose Audit Log of the audit for enabling the systems.
The Audit Team is composed in such a way that the necessary expertise is available in the team to cover the specific line of business and / or process of the Organization. In order to accomplish this, technical specialist may supplement the audit team. Such specialist may be an ICS employee or an advisor. It is the responsibility of the external Lead Auditor / Manager

Certification to decide on the use of the specialist in the audit team.
Lead Auditor / Team Leader shall make his recommendation for Certification in the Certification

Recommendation / Review .
Certification Manager in conjunction with CMD & Country Manager, shall be responsible for overall processes (for granting, refusing, maintaining, reviewing, extending / , reducing scope of certification, renewing, suspending and / or withdrawal / or restoring following suspension or withdrawal of the certification). **Either of the 3 shall be in position to make decision in absencia**

Reviewed copy of Audit report shall be sent to client along with "Certificate Of Compliance"

6 ORGANIZATION'S RESPONSIBILITIES:

The Organization must provide the following information to ICS and provide access to ICS Personnel/ Accreditation Personnel to the site to be audited / to visit the client / client's vendor for validation of the certified system.

Provide the conformity assessment team with sufficient information for enabling them to conclude that the Organization Management System has been fully documented in accordance with the nominated standard.

Allow conformity assessment team access to facilities, personnel and records enabling them to verify that the Organizations management system has been established and is being maintained.

Organization shall indicate dates for conformity assessment to ICS at least one week in advance so as to plan the Audit Program to be sent to all concerned well in time.
The above may be relaxed in case the request for conformity assessment has not been provided one week in advance by the client and has requested for the immediate execution of the conformity assessment.

Ensure all requirements as laid down in General Terms & Conditions FA_16 are complied.

7 USE OF CERTIFICATE AND LOGO:

Upon successful completion of the Conformity Assessment, ICS shall issue 'Certificate of Compliance' / 'Certificate Of Fitness' / 'Certificate Of Verification' to the Organization detailing the Standard(s) to which the assessment was made, declaring the scope of supply and location of places audited. The 'Certificate(s) of Compliance' is valid for a period three years from the date of issue.

The client will be issued 'Certificate of Compliance' / 'Certificate Of Fitness' / 'Certificate Of Verification' / with specific accreditation services as agreed by the client at the time of signing the contract for registration, else the 'Certificate of Compliance' / 'Certificate Of Fitness' / 'Certificate Of Verification' / which ICS will be provided as ICS accredited.0

refer CM 5 Section for more details

International Certification Services and Accreditation logo is to be used as per guidelines given in the Trade Mark License Agreement signed between ICS and the certified client.

8 SURVEILLANCE AUDITS:

ICS auditors will perform surveillance audit of the certified management System according to the periodical audit plan in order to ensure that the system and its implementation is being maintained. Periodical audits are to be performed as agreed /scheduled in the contract.

ICS shall notify the Organization prior to such proposed surveillance audit call and agree on the suitable date for periodical audit, in case ICS fails to initiate the call. it shall be the responsibility of the certified organization to ensure that Surveillance audit is planned and conducted as per the schedule mentioned below in the relevant sections.

The 1st Surveillance Audit needs to be carried out within 12 months from the date of certification decision, failing which certificate shall be deemed suspended.

Non conformities , if any during the surveillance audit, will be dealt with as for the initial audit.

The original certificate is affixed with ICS Hologram that is the ICS main Hologram as shown validity mark on the certificate. A another 2 to 5 nos. ICS holograms will be affixed upon successful completion of the Surveillance Audits by the ICS Lead Auditor / Team Leader that will ensure continuity of the certificate.

Surveillance of multi-site organizations that can be sampled shall be audited in accordance with Section 3.6.4.1. The audit time per site shall be calculated in accordance with Section 3.6.5

Surveillance of multi-site organizations that cannot be sampled in accordance with Section 3.6.4.1 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 with Section 3.6.5

9 ADDITIONAL / SPECIAL AUDIT:

Should the circumstances dictate the necessity, Provide ICS to conduct an additional follow-up audit in the course of maintaining the certification. Circumstances may include the organization wishing to extend the scope of certification / upgradation to the new version of the standard, addition of sites, or as required in response to an incident or a significant change and/or system failure in the Organization’s management system.. In such cases the client would have to pay additional fees depending upon the requirement and the mandays required to be spent, logistics,etc.

Special Audits

Extensions / Reduction / Change of Scope

ICS shall in response to an application for extension /reduction / change of the scope of a certification already granted, undertake a review of the application and determine any audit activities necessary to decide whether or not the extension / reduction / change may be granted.

This may be conducted in conjunction with a surveillance audit / special audit/ short notice audit.

This may be carried based on the following factors –

- Application from Client for extension / reduction / change of scope
- Market Feedback
- Based on the Audit carried on the client and analysis of client competence and capability
- Complaints
- Audit by Accreditation
- Client Suspension
- Shut down of manufacturing activity

Short-notice audits

ICS may if deem necessary conduct audits of certified clients at short notice or unannounced audits to investigate complaints, or in response to changes or as follow up on suspended clients. In such cases ICS shall describe and make known in advance to the certified client the conditions under which these short notice visits are to be conducted and

Such Additional, Special, Short-Notice Audits shall be charged additional as they are not a part of the initial contract signed between ICS and the client. The charges would depend upon the purpose of the audit carried out, mandays spent, logistics, etc.

Short notice or unannounced audits may be required when:
i) external factors apply such as:
a. available post-market surveillance data known to ICS on the subject devices indicate a possible significant deficiency in the quality management system

b. significant safety related information becoming known to ICS

ii) significant changes occur which have been submitted as required by the regulations or become known to ICS, and which could affect the decision on the client's state of compliance with the regulatory requirements

The following are examples of such changes which could be significant and relevant to ICS when considering that a special audit is required, although none of these changes should automatically trigger a special audit:

i) QMS – impact and changes:
a. new ownership

b. extension to manufacturing and/or design control

c. new facility, site change
modification of the site operation involved in the manufacturing activity (e.g. relocation of the manufacturing operation to a new site or centralizing the design and/or development functions for several manufacturing sites)

d. new processes, process changes
significant modifications to special processes (e.g. change in production from sterilization through a supplier to an on-site facility or a change in the method of sterilization)
e. QM management, personnel
modifications to the defined authority of the management representative that impact:
o quality management system effectiveness or regulatory compliance

o the capability and authority to assure that only safe and effective medical devices are released

ii) product related changes:

a. new products, categories

b. addition of a new device category to the manufacturing scope within the quality management system (e.g. addition of sterile single use dialysis sets to an existing scope limited to haemodialysis equipment, or the addition of magnetic resonance imaging to an existing scope limited to ultrasound equipment)

iii) QMS & Product related changes:

a. changes in standards, regulations

b. post market surveillance, vigilance

An unannounced or short-notice audit may also be necessary if ICS has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements.

10 RE-CERTIFICATION AUDIT :

At the completion of three year certification period, a re-certification audit shall be performed. The performance of the Organization's management system over the previous three years and guidelines of applicable accreditation use taken into consideration during the re-certification audit.

This activity needs to be initiated 3 months prior to the expiry of the certificate in order to ensure that it is completed as per schedule.

Re-certification audit activities may need to have a stage 1 audit in situations where there have been significant changes to the management system, the client, or the context in which the management system is operating (e.g. changes to legislation).

In the case of multiple sites or certification to multiple management system standards being provided by the certification , the planning for the audit shall ensure adequate on site audit coverage to provide confidence in the certification.

Recertification of multi-site organizations that can be sampled shall be audited in accordance with Section 3.6.4.1. The audit time per site shall be calculated in accordance with Section 3.6.5.

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 Section 3.6.5

ICS shall notify the Organization prior to such proposed recertification audit call and agree on the suitable date for periodical audit, in case ICS fails to initiate the call, it shall be the responsibility of the certified organization to ensure that recertification audit is planned and conducted as per the schedule mentioned in the relevant section

The re-certification audit shall include an on-site audit that addresses the following

a) The effectiveness of the management system in its entirety in the light of internal and external changes and its continued relevance and applicability to the scope of certification;
b) Demonstrated commitment to maintain the effectiveness and improvement of the management system in order to enhance overall performance;
c) Whether the operation of the certified management system contributes to the achievement of the organization's policy and objectives.

Re certification audit activities may need to have a stage 1 audit in situations where there have been significant changes to the management system, the client, or the context in which the management system is operating (e.g. changes to legislation).

When, during a re-certification audit, instances of non-conformity or lack of evidence of conformity are identified, the defined time limits for correction and corrective actions to be implemented shall be prior to the expiration of certification.

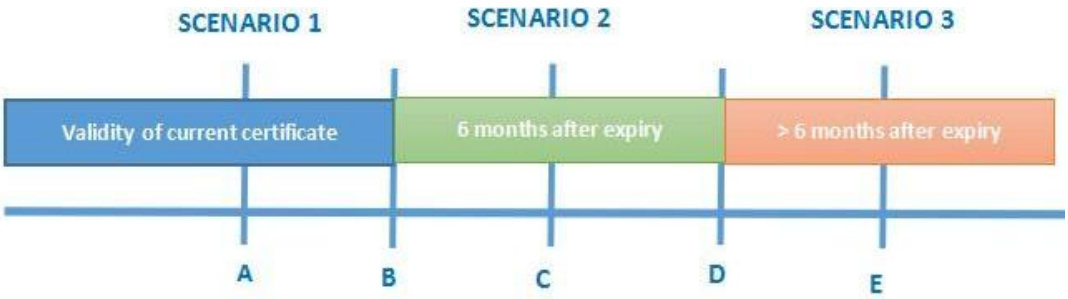
The decision on renewing the certification shall be based on the results of the recertification audit as well as the results of the review of the system over the period of certification and complaints received from users of certification.

The decision on renewing the certification shall be conducted before the expiry of the certificate, failing to which the client shall be considered as a new client and shall not be entitled to any discounts on mandays as applicable.

If the recertification audit has not been completed before the expiry of the certificate or if ICS is unable to verify the implementation of corrections and corrective actions for any major nonconformity) prior to the expiry date of the certification, then during such period the client shall be suspended and the recommendation will be done only after closure of the non-conformities raised / successful completion of the audit process as applicable.

During the such period the client shall be suspended in ICS register of clients online and deleted from the accreditation register. The client cannot claim certification or use the accreditation or ICS logo.

RECERTIFICATION CASES :



SCENARIO 1 -
Re-certification activities (audit, closure & review) is completed before the expiry (B) & if Decision taken (=A)is also before expiry (B), then New certificate starts from (B) and is valid until B+3years - Certificate with history & no gap created.

SCENARIO 2A -
Re-certification activities initiated but not completed before expiry (B) and decision taken (=C) after the expiry but before D, then New certificate starts from (C) & is valid until B+3years - There is a gap in the certification : (B) to
(C) - Certification restored. Certificate with history indicating the gap.

SCENARIO 2B -
Re-certification activities completed before expiry (B) and decision taken(=C) after the expiry but before D, then New certificate starts from (C) & is valid until B+3years - There is a gap in the certification : (B) to (C) - Certification restored. Certificate with history indicating the gap.

SCENARIO 3A -
Re-certification activities not completed before (D), A stage 2 initial audit is necessary. Decision taken (=E) after the expiry and the stage 2 audit, then New certificate starts from (E) & is valid until E+3years
There is a gap in the certification : (B) to (E) - Certificate without history.

SCENARIO 3B -
Decision not taken before (D), A stage 2 initial audit is necessary. Decision taken (=E) after the expiry and the stage 2 audit, then New certificate starts from (E) & is valid until E+3years
There is a gap in the certification : (B) to (E) - Certificate without history.

SCENARIO 4 -
Re-certification activities not initiated before (B), (even if completed before D)A full initial audit is necessary.
New certificate starts from decision taken and is valid (until decision + 3years) + 3 years. There is a gap in the certification : (B) certification decision
- Certificate without history.

11 SYSTEM MAINTENANCE :

The Organization fails to conform with the agreed standard and maintain their management system consistently

The organization undertake action which may bring ICS into dispute.

This information will be given to the Organization in writing by ICS

ICS will co-operate and opportunities to allow the organization to take corrective action but should he fail to take appropriate corrective action within the reasonable time scale, certificate will be withdrawn, cancelled or suspended.

ICS reserves the right to publish in whatsoever and must appropriate way it feels fit the withdrawal, cancellation or suspension of a organization's Certificate(s) of Compliance'

It would be the endeavor of ICS to provide independent, efficient services as detailed in the quotation request.

12 SUSPENSION, WITHDRAWAL OR CANCELLATION / REDUCTION OF SCOPE / EXPANSION OF SCOPE AND RESTORING OF CERTIFICATE:

ICS reserves the right to suspend, withdraw or cancel the Certificate(s) of Compliance / Inspection Report / Inspection Release Note at any time during the three year validity of the certification period.

Suspension:

The certified client's management system has persistently or seriously failed to meet conformity assessment requirements including requirements for the effectiveness of the management system.

Non conduct of 1st Surveillance Audit within 12 months from the last day of certification decision date

The certified client does not allow surveillance or recertification audits to be conducted at the required frequencies, or

The certified client has voluntarily requested a suspension.

Critical Complaints/Penalty received against the client from the Public/Consumer Forum.

Failure to take Corrective action on Major Non-conformity during Surveillance Audit.

Necessary corrective actions against nonconformities are not taken within the agreed timeframe;

Improper use of the 'Certification of Compliance' / Inspection Report / Inspection Release Note and/or accreditation mark & certification mark e.g. misleading literature and business promotional material.

The holder of the Certificate neglects to inform ICS about matters of virtual importance for the certified management system.

Non receipt of ICS fees within stipulated time.

Lock out, long strike of the organisation.

Major organisation changes/merger/takeover by other organisation without prior intimation to Certification .

Non payment of dues in time as per the contract agreement

Notice of Suspension shall be issued to the client and once the client has complied with the necessary action which has been reviewed and accepted by ICS his suspension shall be revoked and his status online shall be updated as active.

In case of the major failure as given under by Auditee to meet the certification requirements, the Auditor / Manager - Certification shall bring it to the notice of the Registrant Management and issue the notice of the system failure. Generally time given to the Organization will be one month to complete the corrective/preventative action. Auditor shall also inform to the ICS Management at the earliest opportunity.

Under suspension, the clients conformity assement is temporarily invalid and the client shall refrain from further promotion of its conformity assessment , the client's marketing material / brochures do not enjoy the benefits of conformity assessment .

The suspended status of the conformity assessment shall be made publicly accessible.

Failure to resolve the issues that have resulted in the suspension in a time established shall result in withdrawal or reduction of the scope of conformity assessment .

System failure notice should be issued immediately on the failure of the one and/or more of any of conditions given above.

System Failure Notice – 1, Form FC_18 will be issued immediately allowing 12 weeks to the Auditee to satisfactory closing of corrective action request by taking appropriate corrective and preventative actions, to improve the situation. Time given to close the CAR's should be generally 12 weeks.
Auditor / Station Manager should keep in touch with organisation to know actual status of the closing of CAR's and other actions.
Where the Auditor / Station Manager cannot resolve the problem and Auditee fails to take an effective corrective/preventative action on the major non confirmity or any other situation that may lead to suspension or withdrawal of certification, the Auditor will give his recommendation to the Manager Certification in his Audit report for the "Notice of Suspension".

In case non compliance with the requirements issue within the stipulated time, ICS will issue System Failure Notice – 2, Form FC_19 with a recommendation to Managing Director/Manager Certification for the suspension of the registration/certificate.

In case where a major non-conformity is observed during the surveillance audit at any of the client's site, the auditor shall immediately recommend to Certification Cell at Corporate Office for issue of Suspension i.e System Failure Notice – 2, Form FC – 19. The Manager Certification shall ensure that System Failure Notice – 2, Form FC – 19 is issued to the client.

Generally time given to the organisation for the corrective and preventive action is 12 weeks only upon the issue of failure notice.

Notice of Suspension shall be issued to the client and once the client has complied with the necessary action which has been reviewed and
accepted by ICS his suspension shall be revoked and his status online
shall be updated as active.

Occurence of a serious incident or breach of regulation necessitating the involvement of the competent regulatory authority, the information will be shared immediately without any delay.

REDUCTION OF SCOPE OF CONFORMITY ASSESSMENT :

The clients scope of conformity assessment shall be reduced to exclude the parts not meeting the requirements, when the client has persistently or seriously failed to meet the conformity assessment requirements for those parts of the conformity assessment. Any such reduction shall be in line with the requirements of the standard used for conformity assessment .

WITHDRAWAL/CANCELLATION FOR THE CERTIFIED MANAGEMENT SYSTEM:

The certificate may be withdrawn in the following cases:

- If no effective corrective action is taken by the suspended
- organization within the stipulated time i.e after issue of Notice of System Failure
- Misuse of Certification / Accreditation Mark
- If a certified organization, being a company enters into liquidation, whether compulsory or voluntary (but not necessarily including liquidation for the purposes of reconstruction),closure of organization or lockout, or
- If a certified organization fails in any respects to comply with the
- law of the land, or
- If a certified organization fails to comply with the conditions specified in the conformity assessment procedure, or
- If the certified organization is unable to close the major non-conformities raised during the audit which may lead to a total breakdown of the organization's management system, or
- The certified organization fails to comply with the timely settlement of his financial obligation.

In case of Multisite operation, if any one of the sites single from the list certified issued for operation is not meeting the requirements of applicable national/international management system at any point of times the certificate shall be withdrawn in whole.

ICS shall cancel the conformity assessment agreement for use of the 'Certificate of Compliance', Certification and Accreditation Mark in the following cases if:

- Certificate holder does not wish to prolong the agreement request in writing.
- Surveillance audit indicates that the non conformance (s) to relevant requirements are of serious nature.
- The conditions of the system conformity assessment are changed and the certified organization either will not or cannot ensure conformity with the new requirement
- Certified Organization ceases to operate the certified system
- The Certified Organization fails to meet any financial obligation to ICS.
- Inadequate measures are taken by the certificated organization in case of suspension.
- On any other ground specifically provided for the general conditions of Conformity assessment System as formally agreed to between ICS and the Certified Organization.

ICS will withdraw / cancel the certificate_Form FC 44 by informing the conformity assessment holder in writing. ICS may publish notification of the cancellation.

The Accreditation will also be informed about withdrawal of the specific certificate.

The certified client upon notice of withdrawal / cancellation of certification discontinues its use of all advertising matter that contains any reference to a certified status.

The cancellation and withdrawn certificate can be revoked by ICS upon verification of the corrective and preventive action through special audits.

ICS shall restore the client's suspended certification after resolving the issues for which the client was suspended.

In the case of minor changes to the Management System, appropriate changes to the Organizations Quality client's documented information or other associated Quality Document then such changes will be reviewed by the Auditor during next surveillance visit. New changes in the Organization's Quality client's documented information provided to ICS will be reviewed by the Auditor for compliance with the requirements.

It is recommended that organization retains one copy of all the superseded documents in their Master file for reference.

13 TRANSFER OF ACCREDITED CERTIFICATION / REGISTERATION

DEFINITION

Transfer of Certification

The transfer of certification is defined as the recognition of an existing and valid management system certification, granted by one accredited certification , (hereinafter referred to as the "issuing certification "), by another accredited certification , (hereinafter referred to as the "accepting certification ") for the purpose of issuing its own certification.

Multiple certification (concurrent certification by more than one certification) does not fall under the definition above, and is not encouraged by IAF.

Minimum Requirements

a) Accreditation :

Only certificates which are covered by an accreditation of an EA, PAC, IAAC or IAF MLA signatory should be eligible for transfer. If the existing certification is accredited by a that belongs to a regional MLA only, the transfer shall be limited to other accreditation valid within that regional agreement. Organizations holding certificates that are not covered by such accreditation shall be treated as new clients. Certificates of Certification to Food Safety Management System are not applicable for Transfer of accredited certification/registration.

Only valid accredited certification shall be transferred. Certification which is known to be suspended shall not be accepted for transfer.

In cases where certification has been granted by a certification which has ceased trading or whose accreditation has expired, been suspended or withdrawn, the transfer shall be completed within 6 months or on expiration of the certification whichever is sooner. In such cases, the accepting certification shall inform the accreditation , under whose accreditation it intends to issue the certification, prior to the transfer.

Certificates of Certification of Occupational Health and Safety Management Systems shall be applicable for transfer in accordance with IAF MD2, but limited to Certification Bodies accredited by JAS-ANZ i.e if the client under transfer is certified by a Certification under JAS-ANZ Accreditation.

b) Pre-Transfer Review :

A competent person from the accepting certification / registration shall carry out a review of the certification / registration of the prospective client. This review should be conducted by means of both a paper enquiry and, normally, a visit to the prospective client. The review should cover the following aspects:

1. Confirmation that the client's certified activities fall within the accredited scope of the accepting certification / registration .
2. confirmation that the issuing certification ’s accredited scope falls within its accreditation ’s MLA scope;

3. The reasons for seeking a transfer.
4. that the site or sites wishing to transfer certification hold a valid accredited certification;

5. That a valid accredited certificate, in terms of authenticity, duration, scope of activities covered by the Quality Management System and scope of accreditation, is held in respect of the site or sites wishing to transfer. If practical, the validity of certification / registration and the status of outstanding nonconformities should be verified with the issuing certification / registration unless it has ceased trading.

6. A consideration of the last assessment / re-assessment reports, subsequent surveillance reports and any outstanding nonconformities arising there from. This consideration should also include any other available, relevant documentation regarding the certification process i.e. handwritten notes,
7. Complaints received and action taken.

8. The stage in the current certification / registration cycle
9. any current engagement by the transferring client with regulatory bodies relevant to the scope of the certification in respect of legal compliance.
10. the initial certification or most recent recertification audit reports, and the latest surveillance report; the status of all outstanding nonconformities that may arise from them and any other available, relevant documentation regarding the certification process. If these audit reports are not made available or if the surveillance audit or recertification audit has not been completed as required by the issuing certification ’s audit programme, then the organisation shall be treated as a new client;
11. considerations relevant to establishing an audit plan and an audit programme. The audit programme established by the ICS should be reviewed if available. See below point C(V) of this document;

ICS shall have a process for obtaining sufficient information in order to take a decision on certification and inform the transferring client of the process. This information shall as a minimum include arrangements regarding the certification cycle.

ICS shall carry out a review of the certification of the transferring client. This review shall be conducted by means of a documentation review and where identified as needed by this review, for example there are outstanding major nonconformities, shall include a pre-transfer visit to the transferring client to confirm the validity of the certification.

Note: The pre-transfer visit is not an audit.

ICS shall determine the competence criteria for personnel involved in pre-transfer review. The review may be conducted by one or more persons. The individual or group conducting the pre-transfer visit shall have the same competence that is required for an audit team appropriate for the scope of certification being reviewed.

C) Certification :
ICS shall not issue certification to the transferring client until:
(i) it has verified the implementation of corrections and corrective actions in respect of all outstanding major nonconformities; and

(ii) it has accepted the transferring client's plans for correction and corrective action for all outstanding minor nonconformities.
(iii) Where the pre-transfer review (document review and/or pre-transfer visit) identifies issues that prevent the completion of transfer,ICS shall treat the transferring client as a new client.
(iv) The justification for this action shall be explained to the transferring client and shall be documented by the accepting certification and the records maintained.
(v)If no problems are identified by the pre-transfer review, the certification cycle shall be based on the previous certification cycle and the accepting certification shall establish the audit programme for the remainder of the certification cycle.
NOTE - ICS can quote the organization's initial certification date on the certification documents with the indication that the organization was certified by a different certification before a certain date.
Where the accepting certification has had to treat the client as a new client as a result of the pre-transfer review, the certification cycle shall begin with the certification decision.
ICS shall take the decision on certification before any surveillance or recertification audits are initiated.

1) Transfer should normally only be of a current valid accredited certificate but, in the case of a certificate issued by a certification / registration may, as its discretion, consider such a certificate for transfer on the basis described in this guidance.

2) Certificates which are known to have been suspended or to be under threat of suspension should not be accepted for transfer.

3) Outstanding nonconformities should be closed out, if practical, with the issuing certification / registration , before transfer. Otherwise they should be closed out by the accepting certification / registration .
4) If no further outstanding or potential problems are identified by the pre-transfer review a certificate, dated from the date of completion of the review, may be issued following the normal decision making process. The pattern of the previous certification / registration regime should be utilized to determine the programme of on-going surveillance and re-assessment unless, as a result of the review, the accepting certification / registration has performed an initial or assessment audit.

5) Where doubt continues to exist, after the pre-transfer review, as to the adequacy of a current or previously held certification, the accepting certification / registration should, depending upon the extent of doubt, either:

-Treat the applicant as a new client
or
- Conduct an assessment concentrating on identified problem areas

The decision as to the action required will depend upon the nature and extent of any problems found and should be explained to the organization.

In conformance with EN 45012, clause 14, ICS will maintain a list of certified organizations and their scope of certification. This list is available to the public and local authorities on request.

13.1 A. If any of the client wants to transfer from ICS to other certification then ICS is responsible to delete the name of that organization from ICS and accreditation website.

B. Case where client is coming to ICS for Transfer of certificate, ICS will ensure that :

- there is transfer of client between two continuing certification bodies.

- ICS will check if the client(who wants to transfer) certification has been withdrawn or cancelled from the accreditation . If so found, then transfer of certificate wont be accepted by ICS.

C) If ICS is accepting the transfer of certificate from client, than below things are taken into consideration :

- ICS shall validate the organization. This is basically done when the marketer receives a client for the transfer of certificate.
The identity of the organization seeking transfer should be validate as follows :
* Confirm the entry on the Accreditation register. If the organization is not registered, then ICS will accept the transfer.
* Verify the business registration details of the clients organization.
* Verify the physical location and management structure of the organization.

- ICS shall advise the accreditation about the clients the business registration, physical location and management structure of the organization.

Once the online registration for the certificate transfer is done, the reviewers of ICS is responsible to review and validate the existence and operation of a certified management systems that has the features and characteristics consistent with the certification validated on the accreditation register.

A management system is validated through, as the minimum, the following :

- Review of documentation
- Review of test reports
- Observation of the application of management system procedure.

ICS will make a declaration to the accreditation that it has undertaken a validation of the management system used by the transferring organization.

ICS must obtain a written acknowledgment as a strict condition of transfer that where accreditation has grounds to doubt the implementation of the management system or the transfer process. The acknowledgments and undertakings will include an indemnification in favor of accreditation by both the accepting and transferring against any claim arising from the failure of the accepting to undertake the transfer effectively.

14 Cooperation Between the Issuing and Accepting Certification Bodies

14.1 The cooperation between the issuing and accepting certification bodies is essential for the effective process for transfer and the integrity of certification. When requested, the issuing certification shall provide to the accepting certification all the documents and information required by this document. Where it has not been possible to communicate with the issuing certification , the accepting certification shall record the reasons and make every effort to obtain necessary information from other sources.

14.2 The transferring client shall authorise that the issuing certification provides the information sought by the accepting certification . The issuing certification shall not suspend or withdraw the organization's certification following the notification that the organization is transferring to the accepting certification if the client continues to satisfy the requirements of certification.

14.3 The accepting certification and/or the transferring client shall contact the accreditation which accredits the issuing certification where the issuing certification
(i) has not provided the requested information to the accepting certification , or

(ii) suspends or withdraws the transferring client's certification without cause

14.4 The accreditation shall have a process for addressing the situation, including the suspension or withdrawal of the accreditation, where the issuing certification does not cooperate with the accepting certification or suspends or withdraws the transferring client's certification without cause.

14.5 Once the accepting CB has issued the certification it shall inform the issuing CB.

15 INVOICING :

On completion of audit / process the invoice is generated and submitted to the client as per the quotation. The client has to make the payment within 15 days of inspection or as agreed in the Contract For Registration & FA_16 General Terms and Conditions / Purchase Order if applicable.

On completion of inspection the invoice is generated and submitted to the client as per the quotation. The client / vendor has to make the payment within 15 days of inspection or as agreed in the Purchase Order.