PT. TÜV NORD Indonesia

MANAGEMENT SYSTEM CERTIFICATION PROCEDURE

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Checked by	Approved by
	
Dept Manager	**VP**

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Revision Sheet

Number	Revision Number	Revision Date	Section Number	Revision Notes
1.	13	05-01-2016		Adjusting standard ISO/IEC 17021 Part 1 – 2015
2	14	28-10-2016	4.2	Adding point: • Approving the "A Team & Effort Approval" form or delegates the approval process to the competent auditors.
			4.3	Adding point: • Reviewing the application from the client and approve the "A Team & Effort Approval" form, if delegated by the Head of CB/QM. • Auditor shall use the most current version of the related forms.
			4.5	Revised wording of point: • After receive the filled questionnaire, the sales person need to prepare an "A Team & Effort Approval (preliminary)" form before they make a quotation and request for an approval from the competence personnel (Head of CB/QM/auditor). For ISO 13485/MDD, the sales person need to prepare as well a "Calculation of Audit Process" Form (P11F004e Rev. 06/2013-10), this is a 4-years audit program calculation where sales person need to update yearly whether the calculation for the related years is still valid or need to be revised. Adding point: • For existing client which due for surveillance audit, the sales person has to contact the client to ensure that the client's data is up to date. The information is recorded in an "Informasi Data Klien Terkini" Form. • For DAkkS scheme After receive a filled in questionnaire from the client and get an approval from the relevant auditor, sales person will immediately draft an ATEA and admin will upload it to the Work Flow. When upload the documents, admin shall make a note "For Offer Only", so the ATEA team will immediately notice to approve the ATEA so the client can get a ZA number and the sales person can continue with making an offer. • Sales person must use the current template form.
			4.6	Adding point:

Number	Revision Number	Revision Date	Section Number	Revision Notes
				• Update the master list of internal and external relevant document. • Ensure that the document use by all certification personnel is the most current version.
			6.1	Additional wording: Based on the information from the questionnaire, the costs and efforts are calculated using the respective sections (calculation sheet for certification procedure audits stage 1 and stage 2 and surveillance audits), and save it as a-tea (preliminary) in the server. In calculating the audit efforts, any addition or reduction factors in summary shall not exceed 30%.
			6.7.1	For integrated systems audit, the veto person/s shall represent each audited standard.
3	15	02.05.2017	6.15	Integrated Management System
			6.8	Add suspension rules
4	16	08.08.2018	3	Add definition of joint audit, combine audit,audit of integrated management system
			5	Add IAF MD-17:2015, IAF MD-1:2018, IAF MD-9:2017, IAF MD-5:2015, DPLS 12, ISO/IEC 27006:2015, ISO 50003:2014, DPLS 28, DPLS 08
			6.1	Add "The questionnaire as application from client is reviewed by Head of CB or competence auditor *who have technical competence of the scope of the audit or at least within the same group of technical cluster (applicable for QMS/EMS, see FMLF-TNI-096)"*
			6.15.7	Replace 30% to 20%
5	17	10.01.2019	6.4	Add IAF MD 4
			6.11	Add the action to be taken .....
6	18	14.03.2019	6.7.1	*If both of Head of Certification Body are carried out the audit, certification decision will be done by President Director / Operational Director / QHSE Manager.*
7	19	20.09.2019	6.1	*Adding SCS Operational Manager as application reviewer*
			6.3	*Adding paragraph: "Any changes identify by the auditor during the audit shall be notified to SCS Operational department including the sales using form FMLF-TNI-094-Evaluation of notified changes."*
				The stage 1 audit has to conducted by competent personnel to met the objective of stage 1 audit.
			6.5	Adding 2 points (blue font):

Number	Revision Number	Revision Date	Section Number	Revision Notes
				The following shall be agreed by both parties: • Any nonconformities shall be presented in such manner that the client understood, and the timeframe for responding it • *On-site audit report* • *Draft of certificate (both English and Bahasa version)*
			6.6	Specifying the timeline for managing the NC
			6.7.1	Certification Release timeline
			6.9	Adopting A00VA02 for Recertification Audit part
			6.12	*Menyesuaikan isi prosedur dengan IAF MD 2:2017*
			6.15	*Refer the calculation method and its example to IAF MD 11:2019 for each extended and standard audit approach.*
			7.1	*Adding personnel VP Operational I & II:* "The certificate will be issued with the sign of President Director/Operational Director/*VP Operational I/VP Operational II*"
8	20	20.11.2019	6.7.1	Deleted → If only a competent certification decision cannot be made with listed veto persons, the veto person could be made by 3 (three) auditors EMS or QMS that none of them carried out the audit. **(not applicable for FSMS and ISO 13485)**.
9	21	17.12.2019	6.1	*Sales shall confirm to the client for implementation of management system minimum 3 months*
10	22	01.07.2020	5.0	add and update KAN-K.7 & IAF-MD
11	23	2408.2020	1.0	add scope of ISO 17065
			3.0	Add definition of evaluation, product, process and services
			5.0	Add ISO 17065 Standard
			6.1	Add word "evaluation" and rules of the audit time
			6.3, 6.4, 6.5, 6.6, 6.7	Add requirements of ISO 17065
			6.16	Add changes affecting certification
			7	Update additions for specific standards

Number	Revision Number	Revision Date	Section Number	Revision Notes
12	24	01.11.2021	6.3 , 6.7.3	- The time interval between the two audit stages until certificate release should generally not be longer than 6 months. - NC: The verification must be completed within 6 months (for CA, RC) and 3 months (for SA) after the last day - The audit file is then reviewed by Veto Person and approved by Head of Certification Body or Appointed Lead Auditor

1. Purpose

Procedure PMLF-TNI-02 describes the roles, responsibilities and processes in a certification body **by ISO 17021-1** involved in the certification of management systems (MS) and ISO 17065 involved in the certifying products, processes or services .

The certification process consists of the phases:

- contract review and offer preparation,
- audit preparation,
- performance of audit stage 1,
- performance of audit stage 2 / Evaluation
- issue of the certificate, and
- surveillance

The sequence is repeated at the end of the term of validity of the audit, except for audit stage 1. Recertification audit activities may need to have an audit stage 1 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 in legislation).

In addition to this procedure the requirements of the specific standards are laid down.

2. Scope

This procedure applies to PT. TÜV NORD Indonesia and its auditors.

3. Definitions

Audit Stage 1:

On-site or off-site assessment of the readiness for certification of a company's management system and planning of audit stage 2. This includes the review of management system documentation.

The stage 1 audit is basically performed on site. Under certain conditions (small companies) [< 50 employees] or if reasons for reductions are present, the stage 1 audit can be performed during the same period as the stage 2 audit.

If the stage 1 audit is not carried out in particularly justified cases - e.g. the management system of the organization is already known through audits according to other standards - the justification must be fixed in writing and recorded in the audit documentation.

Audit Stage 2:

On-site assessment of establishment, implementation and effectiveness of a management system with respect to the issue of a certificate.

Evaluation :

Combination of the selection and determination functions of conformity assessment activities

Product :

Result of process

Process:

Set of interralated or interacting activities which transforms inputs into outputs

Services:

Result of at least one activity necessarily performed at the interface between the supplier and the customer, which is generally intangible

Completion of audit:

Last day of audit stage 2, typically the day of the final closing meeting.

Planning-relevant date (PRD) for surveillance audits:

Surveillance Audits:

PRD = last day of stage 2 audit + 12 / 24 months

Re-Certification Audits:

PRD = last day of stage 2 audit + 36 months

Surveillance Audit:

Periodical (yearly, optionally half-yearly), post-certification on-site audit of management system implementation and effectiveness in representative areas and functions covered by the scope of the management system of the organization at defined intervals with respect to the maintenance of a certificate.

Re-Certification Audit:

Review of overall management system implementation and effectiveness in the organization with respect to new issue of the certificate.

Extension Audit:

Evaluation of management system implementation and effectiveness in additional or changed areas or sites of the scope, or after removal of parts of the scope with respect to changes of the scope of a certificate.

Short-notice Audit:

Audits of certified clients at short notice to investigate complaints, or in response to changes, or as follow up on suspended clients.

Nonconformity:

A nonconformity is the non-fulfilment of **one** requirement of the standard.

There are two types of nonconformities:

a) Major nonconformity (NCA)

A nonconformity that limits the ability of the management system to achieve its intended results.

Nonconformities can be categorized as major

- If there is considerable doubt that efficient process control is in place or that products or services fulfill the specified requirements;
- If several minor nonconformities which relate to the same requirement or the same problem could represent a system-related failure and therefore result in a major nonconformity

b) Minor nonconformity (NCB)

Nonconformity that does not limit the capability of the management system to achieve the intended results.

Follow-up Audit:

On-site assessment of the implementation and effectiveness of corrections and corrective actions for nonconformities issued during the audit.

Evaluation of documentary evidence:

Off-site assessment of the implementation and effectiveness of corrections and corrective actions for nonconformities issued during the audit. The assessment is carried out by means of documents that are submitted (documents or records).

Correction:

Action to eliminate a detected nonconformity.

Corrective Action:

Action to eliminate the cause of a detected nonconformity.

Audit day:

An audit day basically comprises 8 hours (net). Where it seems useful, a 10 hours audit day might be accepted by the appointed person.

Appointed Person:

Competence Personnel who are appointed to perform certain, defined tasks on behalf of Head of Certification Body , i.e. QM Managers or veto persons.

Observers:

The presence and justification of observers during an audit activity shall be agreed to by the certification body and client prior to the conduct of the audit. The audit team shall ensure that observers do not influence or interfere in the audit process or outcome of the audit.

Note: Observers can be members of the client's organization, consultants, witnessing accreditation body personnel, regulators or other justified persons.

Combined, joint or integrated audits:

A combined audit is when a client is being audited against the requirements of two or more management systems standards together.

A joint audit is when two or more auditing organizations cooperate to audit a single client.

An integrated audit is when a client has integrated the application of requirements of two or more management systems standards into a single management system and is being audited against more than one standard.

Technical area:

Area characterized by commonalities of processes relevant to a specific type of management system. A technical area is equal to an EA scope (EA scope 1 – 39 including the sub-scopes).

Business sector:

Summary of technical areas due to characteristics in common.

Audit programme:

An audit programme shall be planned for the full certification cycle, taking into consideration the importance of the processes and areas to be audited, as well as the results of previous audits (FMLF-TNI-085)

The audit programme shall include a two-stage initial audit, surveillance audits in the first and second years, and a recertification audit in the third year prior to expiration of certification. The three-year certification cycle begins with the certification or recertification decision. The determination of the audit programme and any subsequent adjustments shall consider the size of the client organization, the scope and complexity of its management system, products and processes as well as demonstrated level of management system effectiveness and the results of any previous audits.

Total Audit Time:

In accordance to MD 5 the duration of the “total audit time” of the audit stage 2, the surveillance and recertification audit may not last less than one day. The time for preparation/follow up should not be less than 4 hours.

In exceptional cases, the total audit time may be less than one day (e.g.: surveillance audits in accordance to ISO 9001 for small organizations with low risk). A deviation from the minimum audit time is to be justified in the "ATEA". A special release by Head of CB is required.

4. Responsibilities

4.1 Head of Certification Body

With respect to the scope of this procedure, the Head of Certification Body is ultimately responsible for :

- Select and appoint auditors, senior auditors and appointed persons,
- Review and approval of certification files and by involving competent auditors if necessary. These auditors shall not have been part of the certification pro-

cess activities,

- Approving the “A Team & Effort Approval” form or delegates the approval process to the competent auditors.
- Awarding the certificate.

The Head of Certification Body is authorized to delegate responsibilities to personnel for areas covered by a particular management system standard whenever applicable.

Certain tasks from the certification process can be performed in the offices**.**

4.2 QM Manager / Management Representative

The QM manager is the Management Representative of PT. TÜV NORD Indonesia

4.3 Auditors

Auditors are responsible for the proper conduct of the certification process in line with this procedure and other relevant KAN regulations.

within the audit team, the lead auditor has the following additional responsibilities :

- Reviewing the application from the client and approve the “A Team & Effort Approval” form, if delegated by the Head of CB/QM.
- Determination of scope of the management system in agreement with customer,
- Drafting of an audit plan and report for the Audit Stage 1 including assessment of the MS documentation in the case of first certification.
- Drafting of the audit plan and the report for the Audit Stage 2 in cooperation with the audit team,
- The audit team leader, in consultation with the audit team, shall assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities. Such assignments shall take into account the need for competence, and the effective and efficient use of the audit team, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts.
- Evaluation of the previous period (last 3 years) before the recertification audit
- Evaluation of the MS documentation in the case of (re-)certification and documentation in the form “Review Documentation” or in the audit report.
- Documentation of audit findings and any nonconformities in consultation with the audit team,
- Recommendation for issue / maintenance of the certificate or required corrective action and its scope, or decision to terminate an audit,

- Submission of the complete certification documents to the certification body in good time for release.
- Auditor shall use the most current version of the related forms.

Within the context of the competent certification decision lead auditors permanently employed at PT. TÜV NORD Indonesia who are not involved in the audit procedure can be included in the review and release process

4.4 Technical experts, translators, interpreters, observers and auditors-in-training

Technical experts, translators, interpreters, observers and auditors-in-training can be employed to complete competence requirements for an audit team. The technical or linguistic competence is ensured before the engagement. Documents required for proof of competence (CV, certificates, training certificates, etc.) shall be forwarded to Head of CB/Operational Manager SCS. After a positive evaluation, the technical experts, translators and interpreters are registered in the SAP database and can be engaged. All team members always act under the direction of the audit team leader.

The presence of technical experts and observers during an audit shall be agreed by the certification and the client prior to the conduct of the audit. The technical experts shall be accompanied by an auditor. The audit team shall ensure that observers do not unduly influence or interfere the audit process or outcome of the audit. All team members must sign the declaration regarding independence/confidentiality.

The time spent by any team member that is not assigned as an auditor (i.e. technical experts, translators, interpreters, observers and auditors-in-training) shall not count in the above established audit time.

4.5 Sales

- After receive an inquiry from the applicant, sales team is requesting the applicant to fill in Questionnaire/Application form. Sales team shall guide the client thus all the crucial information which are used to determine the audit days, audit scope, *etc.* are completed.
- After receive the filled questionnaire, the sales person need to prepare an “A Team & Effort Approval (preliminary)” form before they make a quotation and request for an approval from the competence personnel (Head of CB/QM/auditor). For ISO 13485/MDD, the sales person need to prepare as well a “Calculation of Audit Process” Form (P11F004e Rev. 06/2013-10), this is a 4-years audit program calculation where sales person need to update yearly whether the calculation for the related years is still valid or need to be revised.
- For DAkkS scheme After receive a filled in questionnaire from the client and get an approval from the relevant auditor, sales person will immediately draft an ATEA and admin will upload it to the Work Flow. When upload the documents, admin shall make a note “For Offer Only”, so the ATEA team will immediately notice to approve the ATEA so the client can get a ZA number and the sales person can continue with making an offer.

- The sales person handles the cost calculation of orders, the formulation of the offer and conclusion of contract as well as the implementation of the certification procedure in terms of the PT. TÜV NORD Indonesia system.
- They responsible to follow up and monitor the Questionnaire, A-team preliminary, Quotation (offer) and Contract for Certification to Client.
- The sales person is responsible to maintain the Original Record of Contract for Certification, A-team preliminary, Quotation and Questionnaire in the server and notify administration support team once updated.
- After scheduled, the sales team shall ensure that all preliminary documents needed prior to audit must be submitted by the client to administration support team.
- For existing client which due for **surveillance audit**, the sales person has to contact the client to ensure that the client's data is up to date. The information is recorded in an "Informasi Data Klien Terkini" Form.
- Sales person shall use the current version form.

4.6 Administration

- The employees of the administration maintain and update the auditors and experts record.
- They prepare the issue of the certificates and send them to the customers. They file the certification records**.**
- They monitor and organise the performance of the Certification, Surveillance and Re-certification audits on behalf of the certification body management
- Update the master list of internal and external relevant document.
- Ensure that the document use by all certification personnel is the most current version.

5. Reference

- MI-TNI-01 , Manual Integrasi
- ISO/IEC 17021 Part 1 : 2015, Conformity assessment – Requirements for bodies providing audit and certification of management system
- ISO 9000 : 2015; Quality Management Systems – Fundamentals and Vocabulary
- SNI ISO/TS 22003:2013, Sistem Manajemen Keamanan Pangan – Persyaratan Lembaga Penyelenggara Audit dan Sertifikasi Sistem Manajemen Keamanan Pangan

- SNI ISO 17065 : 2012, Penilaian Kesesuaian – Persyaratan untuk Lembaga Sertifikasi Produk, Proses dan Jasa
- *KAN K-07.01 Persyaratan Tambahan Akreditasi Lembaga Sertifikasi Sistem Manajemen Mutu*
- *KAN K-07.02 Persyaratan Tambahan Akreditasi Lembaga Sertifikasi Sistem Manajemen Lingkungan*
- *KAN K-07.03 Persyaratan Tambahan Akeditasi LSSHACCP & LSMKP & FSSC*
- *KAN K-07.04 Persyaratan Tambahan Akreditasi Lembaga Sertifikasi SMKI*
- *KAN K-07.05 Persyaratan Tambahan Akreditasi Lembaga Sertifikasi Sistem Manajemen Energi*
- *KAN K-07.06 Persyaratan Tambahan Akreditasi LSSMMAK*
- *KAN K-07.07 Persyaratan Tambahan Akreditasi LSSMAP*
- *KAN K-07.10 Persyaratan Tambahan Akreditasi LSSMK3*
- *KAN K-07.11 Persyaratan Tambahan Akreditasi LSUP*
- *KAN K-07.12 Persyaratan Tambahan Akreditasi LSSMOP*
- *IAF MD-1:2018 (issue 22) : IAF Mandatory Documents for the Audit and Certification of a Management System Operated by a Multi-Site Organization*
- *IAF MD 2:2017: Transfer of Accredited Certification of Management System*
- *IAF MD 5:2019 Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems*
- *IAF MD-9:2017 : Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)*
- *IAF MD 11:2013 IAF Mandatory Document for Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS)*
- *IAF MD 17:2019 Witnessing Activities for the Accreditation of Management Systems Certification Bodies*
- *IAF MD 22:2019 Application of ISO/IEC 17021-1 for the Certification of Occupational Health and Safety Management Systems (OH&SMS)*
- ISO/IEC 27006:2015, Information Technology – Security Techniques – Requirements for Bodies Providing Audit and Certification of Information Security Management Systems

- ISO 50003:2014, Energy Management Systems – Requirement for Bodies Providing Audit and Certification of Energy Management System

6. Procedure

The process is initiated when an applicant makes an inquiry or an order received through sales activities. The applicant is informed of the basic certification process

6.1 Customer Inquiry / Drafting of Offer

The questionnaire is sent to the applicant so that an offer can be prepared and is completed either by the applicant or with the sales of PT. TÜV NORD Indonesia. Sales shall confirm to the client for implementation of management system minimum 3 months. Based on the information from the questionnaire, the costs and efforts are calculated using the respective sections (calculation sheet for certification procedure audits stage 1 and stage 2 or evaluation / surveillance / recertification), and save it as a-tea (preliminary) in the server. In calculating the audit efforts of MS Certification, any addition or reduction factors in summary shall not exceed 30% (Further reduction for integrated MS shall not exceed 20%). The questionnaire as application from client is reviewed by Head of CB or SCS Operational Manager or competence auditor.

The determination of audit time is based on the calculation standards of each certification schemes. The audit time for all types of audits includes the total time on-site at a client's location (physical or virtual) and time spent off-site carrying out planning, document review, interacting with client personnel and report writing. The duration of MS Certification audit should typically not be less than 80% of the audit time calculated following the methodology of certification schemes. This applies to initial, surveillance and recertification audits.

The offer is completed and after acceptance, a contract is concluded with the applicant. When the result of application review is declined, the reason for declining of an application shall be documented and made clear to the client by Sales.

For MS Certification, with the criteria given it is decided whether the audit stage 1 is performed off-site or on-site. If an audit stage 1 is required an audit plan shall be established.

Based on the customer requirements the audit stage 2 may be performed as a direct follow-up of the audit stage 1. However, it is required to inform the customer that weak points which might erase in the audit stage 1 may lead to nonconformities in the audit stage 2. As a consequence the interruption of the audit is also possible.

It is good practice that the time gap between the two audit stages is not longer than three months.

In case of combined audits the audit effort shall be calculated according to the guidance given in the respective section

Records of applicants shall be maintained for one year.

The audit process begins following the conclusion of the certification agreement and is divided into:

- Audit preparation and planning,
- Audit performance,
- Documentation of the audit results.

After a positive certification decision, the certificate is granted and the process of monitoring the application of the certification and management systems begins.

6.2 Audit Preparation

A Team and Approval has to be approved by Head of Certification Body or QM Manager or QHSE Manager or President Director prior to the audit.

An audit team is appointed and the customer is informed of the team members once the contract is signed. Clients must be informed in advance that they can object to any member of the audit team with proper justification. Technical expert will be involved audit to covering audit scope. Sub order form will be sent to expert as an audit team member confirmation, if cancelled the audit will be re-scheduled (if possible, a justification shall always be made). If the technical expert comes from client, PT TUV NORD Indonesia will send the information letter for client approval regarding technical expert participation. (applicable for ISO 13485)

The members of the audit team must fulfil the requirements described in Requirements for and appointment of PT. TÜV NORD Indonesia auditors

In the case of dependent and auditing offices, the audit team and the audit time has to be approved by Head of Certification Body or QM Manager or President Director prior to the audit.

Head of certification body shall ensure that the persons that approved Audit Team are different from those who carried out the audits.

If Head of Certification Body as Lead Auditor or Auditor, Head of Certification Body must appointed competence personnel to approved A Team. The criteria for composing the audit team are:

a) the audit must be performed with the participation of a PT. TÜV NORD Indonesia nominated lead auditor,

b) for audits of less than four days on-site, the use of an audit team of at least two auditors is **optional**,

c) for audits of four days or more on-site, the use of an audit team of at least two auditors is **mandatory** (in respect to single site),

d) at least one member of the audit team must have the technical competence of the scope of the audit or one the members of audit team have a group within the EA Code allocation as in PM-TNI-005 Annex 3 (QMS) and PL-TNI-014 Annex 2 (EMS). In audits of more than one management system by the same team, the competence requirements must be fulfilled for each standard.

The lead auditor is responsible that during the audit technical competence is always ensured.

The audit team leader, in consultation with the audit team, shall assign to each team member responsibility for auditing specific processes, functions, sites, areas or activities. Such assignments shall take into account the need for competence, and the effective and efficient use of the audit team, as well as different roles and responsibilities of auditors, auditors-in-training and technical experts. Changes to the work assignments may be made as the audit progresses to ensure achievement of the audit objectives.

6.3 Audit Stage (St.) 1

The audit stage 1 is only applicable for the MS Certification (in basis ISO 17021)

The purpose of the audit St-1 is:

a) to audit the management system documentation of the customer,

b) to assess the location and the location-specific conditions of the customer and to discuss various aspects with staff at the customer's organisation in order to determine readiness for the Audit St-2,

c) to assess the status of the customer and also to assess the customer's understanding of the standard, particularly with regard to identification of key items which must be fulfilled and also other important aspects, processes, objectives and operation of the management system,

d) to obtain necessary information with regard to the scope of the management system, the client's site (s), the processes and equipment used, level of control established (particularly in case of multisite clients) as well as associated legal regulations and regulations related to official authorities, and to establish if the customer is fulfilling these regulations;(e.g. relating to quality, environmental and legal aspects of the customer's activities, associated risks etc.),

e) to evaluate the resources which have to be allocated to the Audit St-2 and to discuss and agree on the details of the Audit St-2 with the customer,

f) to create a main focus for planning the audit St-2 by gathering sufficient understanding of the customer's management system and of the activities carried out on site and any significant aspects relating to these,

g) to judge if internal audits and management reviews are planned and carried out and to ensure that the level of implementation of the management system

proves that the customer is ready for the audit St-2.

h) Addition requirements for ISO 13485
Where higher risk medical devices are concerned, the St-1 audit should be performed on-site.
When a certification body has audited a client against a regulatory scheme that includes or goes beyond the requirements of ISO 13485, it does not need to repeat the audit for conformity with the elements of ISO 13485 previously covered, providing the certification body can demonstrate that all of the requirements of this document have been complied with.
Note: Typical regulatory schemes that include or go beyond the requirements of ISO13485 are AMDD: Asean medical devices directive, MDD: Medical Device Directive

An Audit Plan is drawn up for the stage 1 audit. The stage 1 audit has to conducted by competent personnel to met the objective of stage 1 audit.

In exceptional cases, The stage 1 audit can take place within the same period as the stage 2 audit (see Clause 3, definitions of stage 1 audit). The following prerequisites must be fulfilled before performance:

- The customer must be made aware of the risk that the audit may be broken off.
- A review of the management documentation must be performed before the stage 1 audit in order to ensure than any nonconformities that are identified are rectified before the audit.
- The certification body must approve the way of proceeding.

The weaknesses that are identified that could lead to a nonconformity in the stage 2 audit are documented in the report of the stage 1 audit.

The Audit Team Leader decides on the basis of the weaknesses that have been identified whether

- the stage 2 audit can be performed as planned without limitations,
- the stage 2 audit can be performed as planned following implementation of suitable actions to address the identified weaknesses,
- the effective correction of the identified weaknesses has to be verified before the stage 2 audit (repeat of stage 1 audit).

The decision is documented in the report of the stage 1 audit.

The submission of an action plan and the assessment by the audit team leader are not required.

When determining the time interval between the stage 1 and stage 2 audits, the requirements of the customer should be taken into consideration, in order to find solutions to weaknesses that were identified during the stage 1 audit. It may also be necessary for the certification body to modify the items to be audited in the stage 2 audit. The time interval between the two audit stages until certificate release should generally not be longer than 6 months.

At the end of the stage 1 audit, the exact formulation of the scope of the certificate must be established **(DRAFT CERTIFICATE)** in agreement with the customer not later than four weeks before the stage 2 audit. If any significant changes which would impact the management system occur, it will be considered the need to repeat all or part of st-1. The customer shall be informed that the results of st-1 may lead to postponement or cancellation of st-2. Any changes identify by the auditor during the audit shall be notified to SCS Operational department including the sales using form FMLF-TNI-094-Evaluation of notified changes.

6.4 Audit planning (Stage 2 / Evaluation)

The Lead Auditor is responsible for preparing an audit plan which includes all requirements to be audited, the names of the relevant units within the customer's organisation and a timescale for the audit. The Lead Auditor will coordinate the audit plan with the audit team and the customer`s representative. The audit plan shall be sent to the client at least 7 days before the audiFt.

An audit programme for the full certification cycle shall be developed to clearly identify the audit activities required to demonstrate that the client's management system fulfills the requirements for certification to the selected standard(s) or other normative document(s).

The audit objectives shall be determined by the certification body. The scope and criteria shall be established after discussion with the client. The audit scope shall describe the physical locations, organizational units, activities and processes to be audited. If in initial audit or re-certification process covering different locations (more than one), the scope of an individual audit may not cover the full certification scope, but the totally shall be consistent with the scope in the certification document.

The audit criteria shall be used as a reference against which conformity is determFined, and shall include the requirementsand documentation of the management system developed by the client.

The auditors may work as a team or independently, however there must be a splitting of the auditors for approx. **50%** of the audit time, taking always into consideration the auditors' competence. The proof of splitting has to be provided in the audit plan (*e.g.* if 2 auditors per department/process are planned in, at least 2 contacts from the company side must appear in the audit plan).

The MS requirements for the respective standards are defined which must be audited together by the auditors.

Remote auditing techniques may be used occasionally for auditing low risk processes. The time for remote auditing may not exceed 30% of the entire on-site time.

The use of electronically based audit techniques *in IAF MD 4* (e.g. document inspection, inspection of corrective and preventive actions, video conferences) shall be taken into consideration in the audit plan (e.g. video conferences) if applicable.

In situations where a customer provides a product or service at temporary sites (e.g. installation sites, project locations etc.) it is important that evaluations of such sites are incorporated into the certification and surveillance program. The need for visits will depend on the relevance of these sites. The reasons for the selection of the specific sites must be documented in the audit report (reasons: special product-specific/service-relevant features, size, complexity, only site, results from previous audits). Suitable values are determined by the lead auditor and must be noted in the audit report.

Additional requirements ISO 13485:

Short notice audits may be required when:

a. external factors apply such as:
   i. available post-market surveillance data known to the CB on the subject devices indicate a possible significant deficiency in the quality management system
   ii. significant safety related information becoming known to the CB

b. significant changes occur which have been submitted as required by the regulations or become known to the CB, 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 the CB when considering that a special audit is required, although none of these changes should automatically trigger a special audit:

   i. QMS – impact and changes:
      - New ownership
      - Extension to manufacturing and/or design control
      - 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)
      - 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)
      - QM management, personnel
        - Modifications to the defined authority of the management representative that impact
          - quality management system effectiveness or regulatory compliance
          - the capability and authority to assure that only safe and effective medical devices are released

   ii. Product related changes:
      - New products, categories
      - 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:

- Changes in standards, regulations
- Post market surveillance, vigilance

An unannounced or short-notice audit may also be necessary if the CB has justifiable concerns about implementation of corrective actions or compliance with standard and regulatory requirements (see FMLF-TNI-074-1A & 1B - Contract For The Certification of MS point 2.4.c)

Additional Requirements for Certification based on ISO 17065 :

If the certification has already granted to the client or has already granted to the other clients, to omit any activities, then the Certification Body shall reference the existing certification in its records. If requested by the client, the justification for omission of activities shall be provided.

The audit plan is depend on the characteristics of the certification scheme and the product requirements, the plan can be either a generic plan applicable to all activites including evaluation of quality management system, when applicable or a specific one for a particular activity or a combination of both.

All necessary information and/or documentation is made available for performing the evaluation tasks.

6.5 Audit Stage 2 / Evaluation

The audit commences with an opening meeting which shall usually conducted by the audit team leader, where attendance shall be recorded and be held with the client's management, is to provide a short explanation of how the audit activities will be undertaken and details.

The task of the audit team is to review the practical application of the management system and to asses it for fulfilment of the requirements of the standard. This is carried out by means of questions put to the staff, viewing of other documents, records, orders and guidelines as well as by an on-site visit to the relevant areas. The audit questionnaire can serve as a guide during this process. Each auditor shall be accompanied by a guide, unless otherwise agrred to by the audit team leader and the client. The audit team shall ensure that guides do not influence or interefere in the audit process or outcome of the audit

The presence and justification of observers, if needed, during an audit activity shall be agreed to by the certification body and client prior to conduct of the audit. The observers shall not influence or interefere in the audit process or outcome of the audit.

During the audit, the audit team shall periodically assess audit progress and exchange information. The audit team leader shall reassign work as needed between the audit team members and periodically communicate the progress of the audit and any concerns to the client (e.g.: daily closing meetings).

The client shall be given opportunity for questions. Any diverging opinions regarding the audit findings or conclusions between the audit team and the client shall be discussed and resolved where possible. Any diverging opinions that are not resolved shall be recorded and referred to the certification body. At the end of the on-site audit, a final closing meeting takes place which shall normally conducted by the audit team leader where attendance shall be recorded and be held with the client's management, is to present the audit conclusios, including the recommendation regarding certification. The following shall be agreed by both parties:

- Any nonconformities shall be presented in such manner that the client understood, and the timeframe for responding it
- On-site audit report

Additional Requirements for Certification based on ISO 17065 :

The evaluation tasks can inlcude activities such as design and documentation review, sampling, testing, inspection and audit. The evaluation activities undertake with its internal resources and manage outsourced resources in accordance with the audit plan. The product shall be evaluated against the requirements covered by the scope of certification and other requirements specified in the certification scheme.

The evaluation results shall be related to certification completed prior to the application for certification, where it takes responsibility for the results and satisfies itself that the performed the evaluation fulfils requirements of resource and those specified by the certification scheme.

6.6 Audit Findings

The auditors record their findings during the audit either by hand or electronically. The findings are assigned to requirements of the standard and evaluated:

- **conformity**,
- **potential for improvement (PI)**, and
- **non conformities (NC),** *that represent 1) Failure to fulfill one or more requirements of the management system standard, or 2) A situation that raises significant doubt about the ability of the client's management system to achieve its intended outputs; can be classified as* ***major NC (hereafter is indicated as Nonconformity A/NC A)****.* Other nonconformities can be classified as **minor NC** ***(hereafter is indicated as Nonconformity B/NC B)****.*

Examples of nonconformities are as follows:

a. Failure to address applicable requirements for quality management systems (e.g. Failure to have a complaint handling or training system)
b. Failure to implement applicable requirements for quality management systems
c. Failure to implement appropriate corrective and preventative action when an investigation of post market data indicates a pattern of product defects
d. Products which are put onto the market and cause undue risk to patient and/or users when the device is used according to the product labelling (iso 13485 only)
e. The existence of products/services which clearly do not comply with the client's specifications and/or the regulatory/standard requirements
f. Repeated nonconformities from previous audits
g. An excessive number of any other nonconformities than ones shown in b) of 9.1.15 of iso/iec 17021 against a particular requirement for quality management systems

The audit report is prepared based otn the audit findings.

In the Audit Report, in addition to the standardised information contained in the automated audit documentation (name of the certification body, name and address of the client and the client's representative for the audit, audit type, audit criteria, audit objectives, audit scope, dates and places for the audit, Audit Team Leader and Audit Team Members, nonconformities, potentials for improvement, audit findings/conclusions, unresolved aspects, combined/multisite/integrated audit (in so far as appropriate), note on the random sample nature of the audit, recommendation of the audit team, use of the test mark, result of the verification of the actions from the previous audit, implementation of the internal audits and the management review, statement on the suitability of the scope, fulfilment of the audit objectives and capability of the management system to fulfil the relevant requirements).

The Audit Team Leader documents:

- each deviation from the Audit Plan and the reasons,
- each significant aspect that has an impact on the audit programme,
- significant changes which have taken place since the previous audit and which have an impact on the management system.

Nonconformities and potentials for improvement are documented in the audit report. Action plans for nonconformities are prepared by the customer in consultation with the audit team leader.

A finding of nonconformity shall be recorded against a specific requirement of the audit criteria, contain a clear statement of the nonconformity and identify in detail the objective evidence on which the nonconformity is based. Nonconformities shall be discussed with the client to ensure that the evidence is accurate and that the nonconformities are understood. The auditor, however, shall refrain from suggesting the cause of nonconformities or solutions to them.

The action plan with root cause analysis, specific corrections and corrective actions regarding the NC A and NC B nonconformities must be submitted by the client within six weeks following the last day of the audit

NC A Nonconformities: verification of the effectiveness of the corrections and corrective actions can be performed on the basis of a review of the documented information submitted by the client or by means of a re-audit, if appropriate. The verification must be completed within 6 months (for CA, RC) and 3 months (for SA) after the last day of the audit. An evaluation of the actions taken with regard to the nonconformities is performed in the following audit.

If the nonconformities are not closed within the specified time, the certificate is suspended or the decertification process is initiated in cooperation with the QM Manager.

If the verification of the implementation of corrections and corrective actions of any major nonconformity could not be performed within 6 months (for CA, RC) after the last day of stage 2, another stage 2 should be conducted prior to recommending certification.

NC B nonconformities: verification of the effectiveness of corrections and corrective actions can be performed on the basis of an action plan and if appropriate on the basis of documented information submitted by the client. The verification must be completed within 6 months (for CA, RC) and 3 months (for SA) after the last day of the audit an evaluation of the actions taken with regard to the nonconformities is performed in the following audit.

Where the available audit evidence indicates that the audit objectives are unattainable or suggests the presence of an immediate and significant risk (e.g. safety), the audit team leader shall report this to the client and, if possible, to the certification body to determine appropriate action. Such action may include reconfirmation or modification of the audit plan, changes to the audit objectives or audit scope, or termination of the audit. The audit team leader shall report the outcome of the action taken to the certification body.

If a minor nonconformity (NCB) cannot be verified positive in the follow-up audit, the auditor shall escalate this nonconformity in the follow-up audit-and record a major nonconformity (NCA). New corrections and corrective actions shall be submitted by the customer. The new major nonconformity (NCA) shallt be closed

and verified within the specified deadline.

The lead auditor decides which of these measures are appropriate and *fill out* ***form Management of Nonconformities*** *then the client shall be informed of the result of the review and verification.*

Additional Requirements for Certification based on ISO 17065 :

The classification of non conformities and the deadline of corrective action for certification based on ISO 17065 is depend on requirement of each certification schemes which is described on each specific procedure.

6.7 Certificate Issue and Surveillance

6.7.1 Certificate Issue

The information provided for the certification decision:

Sales provides the following records for the purpose of the review :

- Contract Agreement with Client
- Questionnaire
- A Team and Approval

The lead auditor provides the following records for the purpose of the review :

- Review environmental policy aspect (for EMS)
- Report on Document Review
- Audit Plan and Audit Program
- Audit Report stage 1
- Audit Report stage 2 / evaluation
- Non Conformity Report (For major nonconformities, it has reviewed, accepted and verified the corretion and corrective action ; for minor nonconformities, it

has reviewed and accepted the client's plan for correction and corrective action)

- Recommendation of Opportunity for improvement
- Hand Written Note Auditor for audit stage 1 and 2 or evaluation, which allow identification of the requirements of the MS standard and their evaluation, or audit protocol/checklist.
- Draft Certificate (signed by client)
- Release Audit Documentation
- Review of Recertification Period (only for RC)

The result of audit/evaluation activities shall be documented prior to review.

Head of certification body shall ensure that the persons that make the decision for granting or refusing certification, expanding or reducing the scope of certification, suspending or restoring certification, withdrawing certification or renewing certification are different from those who carried out the audits.

A review of the certification file could be by veto person to assist Head of Certification Body make a certification decision. Veto person is auditor/technical expert or competence personnel but different personnels from those who carried out the audits.

Head of Certification Body shall ensure at least one person that review of the certification file and make the certification decision have the technical competence of the scope of the audit. If Head of Certification Body as Lead Auditor or Auditor, Head of Certification Body must appointed competence personnel to make certification decision

If veto person does not have the technical competence of the scope of the audit (EA code), the review of Certification File shall be reviewed together with Veto Person who have technical competence of the scope of the audit or at least within the same group of the scope (see The List of EA Code of Auditor and Veto Person). For integrated systems audit, the veto person/s shall represent each audited standard. **(not applicable for FSMS, ISO 13485 and certification based on ISO 17065)**.

If the review is positive, the Head of Certification Body Release the Certification File. *Note*: *If both of Head of Certification Body are carried out the audit, certification decision will be done by President Director / Operational Director / QHSE Manager.*

If the result of certification decision is not to grant certification the reasons for the decision shall be identified and the client shall be notified. If the client expresses interest in continuing the certification process, the process evaluation can resume from point 6.5

The certificate will be issued with the sign of President Director/Operational Director/Senior VP

Deadlines for the release of the certificate:

- Procedures without NC A/B: 3 months.
- NC A: 4 months (3 months + 1 month for the veto (release))
- NC B: 4 months (3 months + 1 month for the veto (release))

The deadline is always calculated from the last day of the stage 2 audit.

6.7.2 Certificates

In general, the validity of the MS certificate does not exceed three years from the issue date.

The validity of certificate for certification based on ISO 17065 depends on requirements of each certification schemes (e.g ISPO Certification, the validity certificate does not exceed five years from the issue date). For the specific information is described on each specific procedure.

Expiry of validity depends on the date of certificate decision.

6.7.3 Surveillance Audit

Within the validity of the certificate (3 years) surveillance audits shall be conducted at least once a calender year, except in recertification years.

The criteria for composing the audit team are:

- At least one member of the audit team must have the technical competence of the scope of the audit. In audits of more than one management system by the same team, the competence requirements must be fulfilled for each standard.

  Or
- One member of Audit Team as Auditor or Lead Auditor Certification Audit (in the same client)

  Or
- At least one of Surveillance within the validity of the certificate (3 years) one member of the audit team must have the technical competence of the scope of the audit

The planning of all surveillance audits is carried out on the basis of PRD.

First surveillance audit following the initial certification audit

- The date of the **first surveillance audit** following the initial certification audit is based on the PRD and may not be later than 12 months after the certification decision date. In case of exceeding the deadline the **suspension is carried out**.

Following surveillance audits

- **All the following surveillance audits** are planned on the basis of PRD and have to be conducted **at least once a year**. The planning based on the PRD ensures that the surveillance audits will be performed in time and once a year. Capacity problems (at the end of the year) will be avoided. **A suspension of the certificate in case of exceeding the PRD is not necessary**.

Deadlines for the release of the surveillance procedure:

- Procedures without NC A/B: 3 months.
- NC A: 4 months (3 months + 1 month for the veto (release) procedure,
- NC B: 4 months (3 months + 1 month for the veto (release) procedure.

The deadline is calculated from the last day of the stage 2 audit in each case. A Lead Auditor must participate in surveillance audits. The sector competence must be present in the audit team.

During preparation of the audit, the audit team leader initiates an inquiry to the customer regarding changes in the structural and procedural organization, the size of the company and the company activities. This includes in particular a review of the current system documentation. In addition, materials used for public relations (e.g. Internet, advertising material) can be used for preparation purposes. This inquiry is documented in the audit programme.

At least the following points must be taken into consideration during a surveillance audit:

- internal audits and management review,
- a review of the corrective actions undertaken in response to the nonconformities found in the previous audit,
- handling of complaints against the management system,
- effectiveness of the management system in relation to achievement of objectives and goals,
- progress with regard to planned continual improvement activities,
- process control,

- review of changes,
- use of logos and (trade) marks.

Addition requirements ISO 13485:

The surveillance programme shall include a review of actions taken for notification of adverse events, advisory notices, and recalls.

case of nonconformities, the Lead Auditor should proceed as in the certification audit. Suspension of the certificate may also be taken into account.

The audit file is then reviewed by Veto Person and approved by Head of Certification Body or Appointed Lead Auditor. Veto person/s is/are auditor/s or/and technical expert/s or/and competence personnesl but different personnels from those who carried out the audits and have the technical competence of the scope and standard of the audit. If Head of Certification Body as Lead Auditor or Auditor, Head of Certification Body must appointed competence personnel to review the audit file.

The Lead Auditor makes the following documents available for the review:

- Approval Team
- Audit Plan
- Audit Report
- Non Conformity Report (if available)
- Recommendation of Opportunity for improvement (if available)
- Hand Written Note
- Release of Audit Documentation

If the review is positive, the veto persons release the audit file.

Additional Requirements for Certification based on ISO 17065 :

The criteria ad process for surveillance activities are defined by each certification scheme which is described on each specific procedure.

When continuing use of a certification mark is authorized for placement on a product (or its packaging, or information accompanying it (for process or service) of

a type which has been certified, surveillance shall be established and shall include periodic surveillance of marked products to ensure ongoing validity of the demonstration of fulfilment of product requirements.

When continuing use of a certification mark is authorized for a process or service , surveillance shall be established and shall include periodic surveillance of marked products to ensure ongoing validity of the demonstration of fulfilment of product requirements.

6.8 Suspend and withdrawn of Certificate

- For DAkkS accreditation certificate, suspension, withdrawal, restoring, renewing, refusing, cancellation and limitation of the certification is laid down in the higher-level work instruction CERT-310-AA-015 “Suspension, Withdrawal, Restoring, Renewing, Refusing and Cancellation of Certificates “)
- In addition to the reasons for suspension of certification given in Clause 5.1 of CERT-310-AA-015, certificates are suspended if
  a) The deadline for nonconformity management 6 months (CA,RC) and 3 months (SA) is exceeded,
  b) The deadline for release according to Clause 6.7.1 is exceeded,
  c) The deadline of 12 months following the date of the certification decision for the first surveillance audit which follows the initial certification is exceeded,
  d) A surveillance audit has not been performed each calendar year.

If some aspects within the scope of the certification do not fulfil the requirements of the standard to be certified on a permanent basis, the scope must be limited by removing these aspects.
A certificate may be suspended for a maximum of 6 months. If the problems that led to the suspension have not been solved within the given 6 months, the certificate will be withdrawn. After the withdrawal, the certificate can only be restored by new certification.
Exceptions, which may also exist due to specific standard requirements, may override this general rule. A case-by-case decision by the certification body remains possible.

Example for point (c) and (d) above:

stage	PRD	Certification Decision	Next Audit Schedule (A)	Suspension due to miss “A”.	Withdrawn
CA	27/05/2019	27/07/2019	-	No suspense	-
SA-1	27/05/2020	-	Not later than 27/07/2020	28/07/2020 – 28/01/2021	28/01/2021
SA-2	27/05/2021	-	Not later than 31/12/2021	01/01/2022 – 01/07/2021	01/07/2021
RC	27/05/2022	TBD	Not later than 27/07/2022	No suspense	N/A - Expired on 26/07/2022

6.9 Re-Certification audit

Within the context of the audit preparation, a new calculation for the procedure must be carried out by the auditor, to ensure that the conditions of the contract still apply. The auditor asks the company about any changes in the structural and procedural organization of the company, the size of the company, the company activities and the scope. In determining the calculation of the audit effort / audit program he shall take into account the results of previous audits and decides to waive the audit stage 1. It may be necessary to perform a stage 1 audit in the context of a recertification audit if there have been significant changes to the management system or in relation to the activities of the company (e.g. changes in the law). The documentation shall be in the calculation/ audit program.

Recertification audits include a review of management system documentation with confirmation of the review in the audit report. If there have been significant changes, the result of the review must be documented separately and an on-site audit carried out. The results of the previous surveillance programme(s) over the course of the certificate validity shall be taken into account. All requirements of the standard must be audited.

The audit methodology is equivalent to the methodology of a stage 2 audit.

At least the following points should be reviewed in the recertification audit:

- effectiveness of the interaction between all quality management elements in the management system with regard to internal or external changes, and the continuing significance and applicability of the management system within the scope of the certification,
- verification that the obligation to maintain the effectiveness of the system and to improve it has been fulfilled in order to increase overall performance capacity within the organization,
- verification that the certified management system contributes to achievement of the policies and objectives of the organization.

Audit performance, documentation and also issue of certificates shall be performed in accordance with the rules applying to certification audits.

Competence requirements for the auditors in a recertification audit will remain the same as for the initial audit.

Onsite recertification audits, the verification of the corrective actions and the independent certification decision should be completed prior to the expiry date of the certificate.

If the recertification is not completed before the expiration of the certificate, the audits, the verification of the corrective actions and the independent certification decision can be done within 6 months after the expiration date under the following conditions:

a. The offer-, order- and contract process as well as coordination of audit planning have to be completed demonstrable before the expiration of the old certificate.
b. The new certificate starts with the date of veto decision for recertification and the expiration date of the previous certification cycle (expiration date old certificate + 3 years)

c. The period between expiration of the old certificate and beginning of the new certificate, in which there is no valid certification, must be shown on the new certificate
d. The certification body must point out timely the organization to the consequences of the status non-certified.
e. The compliance with the abovementioned conditions must be proved by the certification body according ISO/IEC 17021-1:2015 par. 9.9.

Example:

The old certificates were valid until 13.05.2017.
Veto decision: 13.07.2017

Information on the certificate:
Validity old certificate: 13.05.2017
Valid from: 13.07.2017
Valid until: 13.05.2020

Initial certification taken from the old certificate.
Jakarta, 13.07.2017
ARD (audit relevant date) in the monitoring of audit remains.

Gap-free recertification is also possible if the certification decision has been made 3 months at the most before the expiration date.

If the recertification cannot be completed within 6 months after the expiration of the certificate, the recertification process must be stopped and a new certification can be done only under the terms of an initial certification.

The recertification period is reviewed just before the recertification is due by auditor with form FMLF-TNI-065.

6.10 Extension/Reduction Audit

An extension/reduction audit can be performed to extent or reduce the scope of an existing certificate. The extension/reduction audit may be carried out within the scope of a surveillance audit, re-certification audit or on an independently selected date.

The validity period of the certificate remains unaffected. Exceptions have to be justified in writing.

The audit team leader/audit team will review the MS documents concerning the extended areas / new locations and audit all requirements which are affected by the extension.

The further procedure with regard to the documentation and release of the audit procedure corresponds to a certification audit.

6.11 Short – Notice Audits

Short notice audits may be necessary to conduct audit of certified client to investigate complaints, or in response to changes, or as follow up suspended clients. In such cases:

a. Describe and make known in advance to certified clients the conditions under which such audits will be conducted

b. Exercise additional care in the assignment of the audit team because of the lack of opportunity for the client to object to audit team members.

The audit team member shall provide grounds to decide on the actions to be taken, including a suspension or withdrawal of the certification. In cases where it can be demonstrated that the system seriously failed to meet the certification requirements. Such requirements shall be part of the contractual agreements.

Further detail is stated on the Contract For The Certification of MS point 2.4.c (FMLF-TNI-074-1A & 1B)

6.12 Transfer of certificates from other Certification Bodies

The following minimum requirements shall apply:

a. Prerequisites

- Only certification which is covered by an accreditation of an IAF or Regional MLA signatory at level 3 and where applicable level 4 and 5 shall be eligible for transfer (as per IAF PR 4:2015). Organizations holding certification that is not covered by such accreditations shall be treated as new clients.
- 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 body which has ceased trading or whose accreditation has expired, been suspended or withdrawn, the transfer shall be completed within 6 months. In such cases, the accepting certification body shall inform the accreditation body, under whose accreditation it intends to issue the certification, prior to the transfer.

b. Pre-transfer review

- A "pre-transfer review" shall always be carried out by a competent auditor. 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. Additional audit time might be necessary. The audit time depends on the size and complexity of the organization. If necessary the additional audit time has to be documented in the ATEA Form (FMLF-TNI-008)

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

- The pre-transfer review is documented in the Checklist / Documentation on Certificate Transfer (FMLF-TNI-082 Annex 6).
- The Pre-Transfer Review must cover the following aspects:
  - confirmation that the client's certification falls within the accredited scope of the issuing and accepting certification body;
  - confirmation that the issuing certification body's accredited scope falls within its accreditation body's MLA scope;
  - the reasons for seeking transfer;
  - that the site or sites wishing to transfer certification hold a valid accredited certification;
  - the initial certification or most recent recertification audit reports, and the latest surveillance report; the status of all outstanding nonconformities 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 body's audit programme, then the organisation shall be treated as a new client;
  - complaints received and the action taken;
  - considerations relevant to establishing an audit plan and an audit programme. The audit programme established by the issuing certification body should be reviewed if available;
  - any current engagement by the transferring client with regulatory bodies relevant to the scope of the certification in respect of legal compliance.

c. <u>Transfer of Certification</u>

The accepting certification body 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.

Where the pre-transfer review (document review and/or pre-transfer visit) identifies issues that prevent the completion of transfer, the accepting certification body shall treat the transferring client as a new client.

The justification for this action shall be explained to the transferring client and shall be documented by the accepting certification body and the records maintained.

The normal certification decision making process shall be followed including that the personnel making the certification decision be different from those carrying out the pre-transfer review.

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 body shall establish the audit programme for the remainder of the certification cycle.

NOTE: The accepting certification body can quote the organization's initial certification date on the certification documents with the indication that the organization was certified by a different certification body before a certain date.

Where the accepting certification body 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.

The accepting certification body shall take the decision on certification before any surveillance or recertification audits are initiated.

Cooperation between the issuing and accepting certification bodies

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 body shall provide to the accepting certification body all the documents and information required by this document. Where it has not been possible to communicate with the issuing certification body, the accepting certification body shall record the reasons and make every effort to obtain necessary information from other sources.

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

The accepting certification body and/or the transferring client shall contact the accreditation body which accredits the issuing certification body where the issuing certification body

- has not provided the requested information to the accepting certification body, or
- suspends or withdraws the transferring client's certification without cause.

Once the accepting certification body has issued the certification it shall inform the issuing certification body.

For IATF 16949 Transfer Audit, please refer to IATF Rules 5th Edition clause 7.1

6.13 Multisite certification (Group/Matrix Certification)

Described in procedure PM-TNI-004 and IAF MD 1:2018	For ISO 27001, please refer to PS-TNI-001

For ISO 37001, Pariwisata, and PPIU, multisite certification does not apply. For ISO 22000 and HACCP, please refer to PF-TNI-002 point 6.4.1	For ISO 50001, please refer to PEn-TNI-003

6.14 Operational Control

Certification activities for branch offices are limited only as sales department (see point 4.5).

6.15 Integrated Management System

a. All the elements important of each management system shall appear clearly, and be readily identifiable, in the audit reports.

b. Audit plans cover all areas and activities applicable to each management system standard/specification covered by the scope of the audit and are addressed by competent auditor(s).

c. The audit team as a whole shall satisfy the competence requirements, for each technical area, as relevant for each management system standard/specification covered by the scope of the audit of an IMS (Integrated Management System).

d. The audit shall be managed by a team leader, competent in at least one of the audited standards/specifications.

e. **Using standard audit approach:** To determine the audit time for an audit of an IMS (Figure 6.15) covering two or more management system standards e.g. standard A + B + C, then sales shall:

   i. Calculate the required audit time for each management system standard separately (applying all relevant factors provided for by the relevant application documents and/or scheme rules for each standard, e.g., IAF MD 5, IAF MD 9, ISO/TS 22003, ISO/IEC 27006);

   ii. Calculate the starting point t for the duration of the audit of the IMS by adding the sum of the individual parts (e.g. T = a + b + c);

   iii. Audit of an IMS could result in increased time, but where it results in reduction, **it shall not exceed 20%** from the starting point t, depending on the integration level and qualification of the audit team. Reduction max 20% basically due to saving of time because of the integration audit of elements like company's policy, objectives and programmes, documentation, internal audits, corrective actions, management review as well as performing the opening meeting, in-between summary and closing meeting,

   The calculation of reduction of audit time is done as follows:

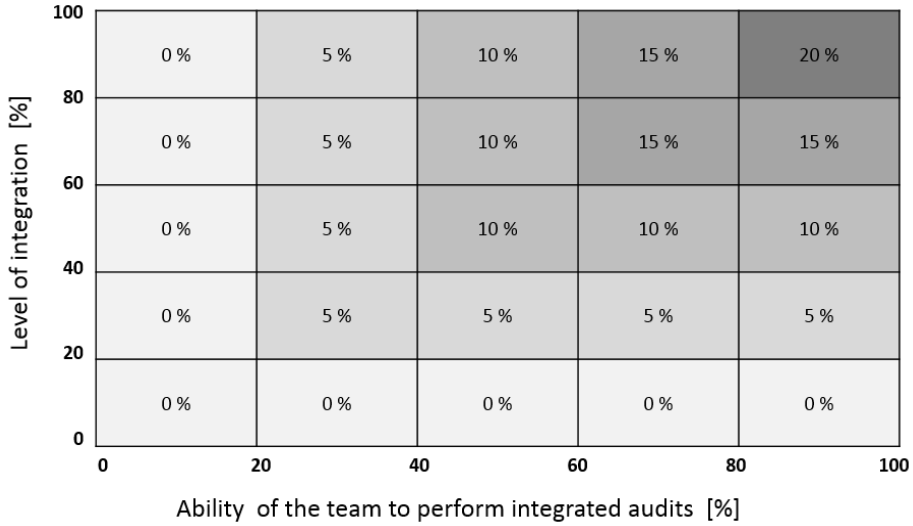

Figure 6.15.2 Reduction of Audit Time (%)

Vertical axis: level of integration of an organization's management system (see below), which should include a consideration of the auditee's ability to respond to multi-aspect questions. An Integrated Management System results when an organization uses one single management system to manage multiple aspects of organizational performance. It is characterized by (but not limited to):

1. an integrated documentation set, including work instructions to a good level of development, as appropriate;
2. Management reviews that consider the overall business strategy and plan;
3. an integrated approach to internal audits;
4. an integrated approach to policy and objectives;
5. an integrated approach to system processes;
6. an integrated approach to improvement mechanism, (corrective and preventive action, measurement and continual improvement) and
7. integrated management support and responsibilities.

Horizontal axis: The extent given as a ratio to be multiplies by a factor of 100 in order to achieve the extent given as percentage, to which individual

audit team members are qualified:

$$\frac{100((X1-1)+(X2-1)+(X3-1)+(Xn-1))}{Z(Y-1)}$$

Where X1,2,3..n is the number of standards for which an auditor is qualified relevant for the scope of the integrated audit, Y is the number of management system standard to be covered by integrated audit, Z is the number of auditors.

Example:
An audit team of three auditors is planned to cover three different management system standards. One auditor is qualified for all three standards, one for two of the standards and the other auditor is qualified for one standard.
The percentage figure to be used for the horizontal axis is:

$$\frac{100((3-1)+(2-1)+(1-1))}{3(3-1)} = 50\%$$

The method for the calculation of the total expenditure for a combined audit ISO 14001/ISO 9001/OHSAS 18001/SCC is shown in the following chart.
In case the audit team is not yet determined at the time of the calculation, a maximum of 15 % may be reduced.
As soon as the audit team is fixed, the calculation should be adapted.

iv. For further detail explanation of the calculation and their examples please refer to **IAF MD 11:2019 point 2.2 ANNEX II.**

f. **Using extended audit approach:** Please refer to **IAF MD 11:2019 point 2.3 and ANNEX I**

g. The factors for reduction shall include but are not limited to:
- The extent to which the organization's management system is integrated;
- The ability of the organization's personnel to respond to questions concerning more than one management systems standard; and
- The availability of auditor(s) competent to audit more than one management system standard/specification.

h. The factors for increases shall include but are not limited to:
- The complexity of the audit of an IMS compared with single management system audits.
-

i. The starting point figure and justification for increase or reduction shall be documented.

j. All applicable requirements of each management system standard/specification relevant to the scope of the IMS shall be audited.

k. Audit reports can be integrated or separate, with respect to the management systems audited. Each finding raised in an integrated report shall be traceable to the applicable management system standards/specifications

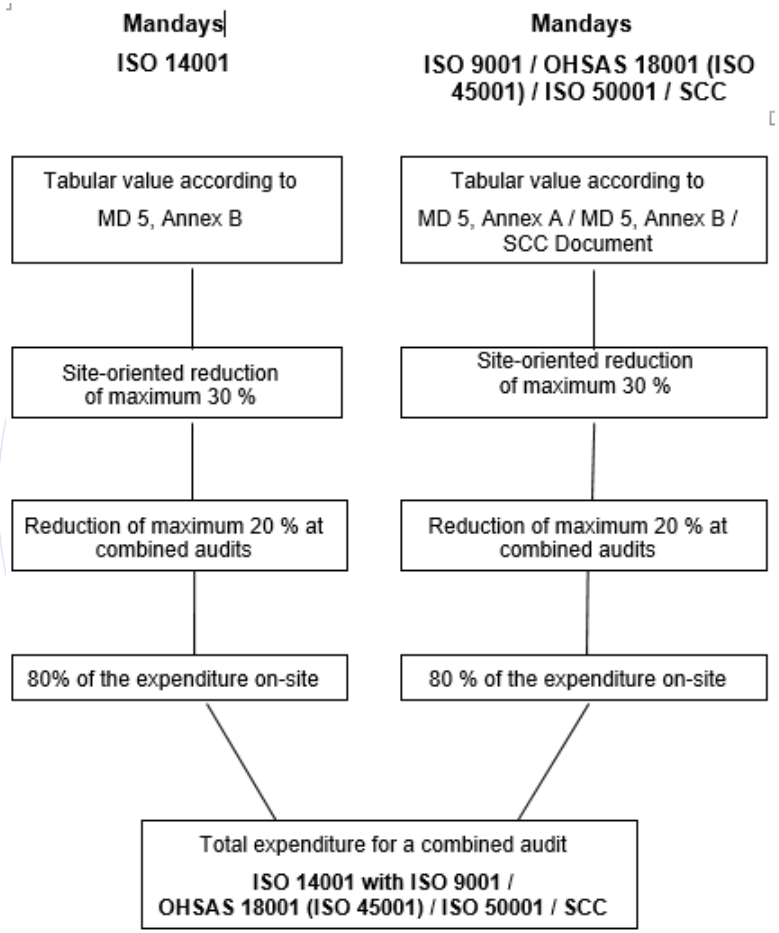

Figure 6.15.2 Reference Diagram of Total Expenditure for a Combined Audit

6.16 Changes Affecting Certification

When the certification scheme introduces new or revised requirements that affect the client, these changes are communicated to all clients and shall verify the implementation of the changes by its clients also shall take actions required by the scheme.

The certification body will consider other changes affecting certification, including changes initiated by the client, and shall decide upon the appropriate action.

The actions to implement changes affecting certification shall include, if required, the following:

- Audit / evaluation (see 6.5)
- review and certification decision
- issuance of revised formal certification documentation to extend or reduce the scope of certification;
- issuance of certification documentation of revised surveillance activities (if surveillance is part of the certification scheme)

7. Additions for specific standards

Requirements in accordance to specific standards PM-TNI- 003 (For QMS)

Requirements in accordance to specific standards PL-TNI- 001 (For EMS)

Requirements in accordance to specific standards PF-TNI- 001 (For FSMS & HACCP)

Requirements in accordance to specific standards PS-TNI- 001 (For ISMS)

Requirements in accordance to specific standards PEn-TNI- 001 (For EnMS)

Requirements in accordance to specific standards PAB-TNI- 001 (For ABMS)

Requirements in accordance to specific standards PO-TNI- 001 (For OH&SMS)

Requirements in accordance to specific standards PT-TNI- 004 (For Tourism Certification)

Requirements in accordance to specific standards PU-TNI- 001 (For PPIU)

Requirements in accordance to specific standards PISPO-TNI- 01 (For ISPO)

8. Applicable Documents

MI-TNI-01	Manual Integrasi
PM-TNI-004	Multisite Certification Procedure
PMLF-TNI-028 and its annex	Certification and Accreditation Marks Procedure
FMLF-TNI-082	Questionnaire in preparation for certification and its annexes
FMLF-TNI-007A	Audit plan stage 1
FMLF-TNI-007B	Audit plan stage 2
FMLF-TNI-008	A Team approval
FMLF-TNI-006	Review system documentation
FMLF-TNI-074	Quotation form
FMLF-TNI-074 Annex 1	Contract for The Certification Management System
FMLF-TNI-007C	List of Participant
FMLF-TNI-007D	Declaration of Independences
FMLF-TNI-002	nonconformity report
FMLF-TNI-005	Hand Written Note
FMLF-TNI-002A	Management of nonconformities
FMLF-TNI-009	Audit Report stage 1
FMLF-TNI-010	Audit Report stage2
FMLF-TNI-011	Doc audit release
FMLF-TNI-023	Customer Survey
FMLF-TNI-061	Veto and Reviewer Feedback
FMLF-TNI-064	Informasi Data Klien Terkini

FMLF-TNI-065	review certification period
FMLF-TNI-085	Audit Program
	Certificate Draft
FMLF-TNI-094	Evaluation of Notified Changes