PT. TÜV NORD Indonesia

MANAGEMENT SYSTEM CERTIFICATION PROCEDURE

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MANAGEMENT SYSTEM CERTIFICATION PROCEDURE

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Table of Content

Table of Content 1

Revision Sheet 3

1. Purpose 5
2. Scope 5
3. Definitions 5
4. Responsibilities 7
   - 4.1 Head of Certification Body 7
   - 4.2 QM Manager / Management Representative 7
   - 4.3 Auditors 7
   - 4.4 Technical Experts 8
   - 4.5 Sales 8
   - 4.6 Administration 9
5. Reference 9
6. Procedure 9
   - 6.1 Customer Inquiry / Drafting of Offer 10
   - 6.2 Audit Preparation 10

6.3 Audit Stage 1 11
6.4 Audit planning 12
6.5 Audit Stage 2 14
6.6 Audit Findings 14
6.7 Certificate Issue and Surveillance 15
6.7.1 Certificate Issue 15
6.7.2 Certificates 17
6.7.3 Surveillance Audit 17
6.8 Suspend and withdrawn of Certificate 19
6.9 Re-Certification audit 19
6.10 *Expanding*/ Reduction Audit 20
6.11 *Short* – Notice Audits 21
6.12 Transfer of certificates from other Certification Bodies 21
6.13 Multisite certification (Group/Matrix Certification) 22
6.14 Operational Control 22
7. Additions for specific standards 24
8. Applicable Documents 24

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: • Update the master list of internal and external relevant document. • Ensure that the document use by all certification personnel is the most current version.

Number	Revision Number	Revision Date	Section Number	Revision Notes
			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 stand-ard.
3	15	02.05.2017	6.15	Integrated Management System
			6.8	Add suspension rules

1. Purpose

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

The certification process consists of the phases:

- contract review and offer preparation,
- audit preparation,
- performance of audit stage 1,
- performance of audit stage 2,
- issue of the certificate, and
- surveillance of the certified management system.

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 in the annexes.

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.

An on-site assessment may not be needed as an exception **.**

Audit Stage 2:

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

Completion of audit:

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

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:

Non-fulfilment with respect to the certification requirements.

a) The effectiveness of correction and corrective actions, for all nonconformities that represent
   - a failure to fulfil one or more requirements of the management system standard, or
   - a situation that raises significant doubt about the ability of the management system to achieve its intended outputs.

   have to be reviewed, accepted and verified prior to the release of the audit file.

b) For any other nonconformities the auditor reviews and accepts the client`s planned corrections and corrective actions prior to the release of the audit procedure; the verification is performed in the following scheduled audit (e.g. surveillance).

The verification may be satisfied by presenting personalized evidence or on a follow-up visit.

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.

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

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 process 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.

- drafting of an audit plan and report for the Audit Stage 1 including assessment of the MS documentation,
- drafting of the audit plan and the report for the Audit Stage 2 in consultation with the audit team,
- assigning audit responsibilities during the audit,
- 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,
- determination of scope of the management system in agreement with customer,
- 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

Technical experts can be employed to complete competence requirements for an audit team. They always act under the direction of an auditor and do not contribute to 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

- MM-TNI-001 , Manual Mutu
- 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
- DPLS 05 Rev 04 Tahun 2015, Persyaratan Tambahan Bagi Lembaga Sertifikasi Sistem HACCP dan Lembaga Sertifikasi Sistem Manajemen Kemanan Pangan
- DPLS 11 Rev 0 Tahun 2013, Persyaratan Tambahan untuk Lembaga Sertifikasi Sistem Manajemen Mutu Alat Kesehatan (LS SMMAK)

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. 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 additionucor reduction factors in summary shall not exceed 30%. *The questionnaire as application from client is reviewed by Head of CB or competence auditor.* The offer is completed and after acceptance, a contract is concluded with the applicant.

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 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 1

The purpose of the audit stage 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 stage 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 stage 2 and to discuss and agree on the details of the Audit stage 2 with the customer,

f) to create a main focus for planning the audit stage 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 stage 2.

h) Addition requirements for ISO 13485

Where higher risk medical devices are concerned, the stage 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

In the report regarding the audit stage 1, the decision as to whether it is possible to perform the certification audit in the company without the need for further steps is described. The lead auditor is primarily responsible for the report. If the requirements of the standard are not fulfilled, corrective measures are required from the customer. If all the requirements of the standard are fulfilled, detailed planning for the audit stage 2 follows. The exact formulation of the scope of the certificate must be established in agreement with the customer not later than four weeks before audit stage 2.

If any significant changes which would impact the management system occur, it will be considered the need to repeat all or part of stage 1. The customer shall be informed that the results of stage 1 may lead to postponement or cancellation of stage 2.

6.4 Audit planning

The Lead Auditor or Auditor is responsible for preparing an audit plan which includes all MS 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.

An audit programme for the full crtification 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 determined, 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.

The use of electronically based audit techniques (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 (f.e installation sites, project locations etc.) it is important that evaluations of such sites are incorporated into the certification and surveillance program. Sample size and audit time will depend on the number, size and complexity of the activities of sites, extent of records available there and the amount of variations between individual sites. 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.

6.5 Audit Stage 2

The audit commences with an opening meeting which shall usually conducted by the audit tean 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.

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.Any nonconformities shall be presented in such manner that the client understood, and the timeframe for responding shall be agreed.

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**,
- **opportunity for improvement**, and
- **non conformities,** *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 non conformities (hereafter is indicated as Nonconformity A/NC A)***. Other nonconformities can be classified as **minor nonconformities** ***(hereafter is indicated as Nonconformity B/NC B)***.

Addition requirements for ISO 13485

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
e. the existence of products which clearly do not comply with the client's specifications and/or the regulatory 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 on the audit findings. Nonconformities and opportunities for improvement are documented in the audit report. *Nonconformities are written in Nonconformities Report.* Action plans for nonconformities are prepared up by the customer.

The corrections and corrective actions which are proposed by the client are verified by means of follow-up-audit or submission of documentation within a maximum of 90 days, or by verification of a proposed action plan during the next audit. 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 verifiication.*
If the audit team are not able to verify the implementation of corrections and corrective actions of any major nonconformity within 6 months after the last day of stage 2, the client shall be conducted another stage 2 prior to recommending certification.

6.7 Certificate Issue and Surveillance

6.7.1 Certificate Issue

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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
- Audit Report stage 1
- Audit Report stage
- 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
- Draft Certificate
- Release Audit Documentation

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). 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)**. For integrated systems audit, the veto person/s shall represent each audited standard. **(not applicable for FSMS and ISO 13485)**.

If the review is positive, the Head of Certification Body Release the Certification File.

The certificate will be issued with sign President Director. Note: if President Director is not available The President Director is authorized to delegate responsibilities to Director Operational or General Manager or QMM.

6.7.2 Certificates

In general, the validity of the certificate does not exceed three years from the issue date. *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 date of the first surveillance audit following initial certification shall not be more than 12 months from the certification decision date.*

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

New customers:

- The date of the first surveillance audit following the initial certification shall not be more 12 months from the last day of the certification decision date.

Already registered Customers

- The planning of the annual surveillance audit is the date of the last day of certification or Re Certification Audit (day and month) minus 1 month.

New and registered customers:

- The audit reference date is decisive for all following audits (surveillance and re-certification audits).
- All surveillance audits – including the review of corrective actions relating to identified nonconformities, audit reporting and the release process – shall be completed at the latest 3 months after the audit reference date ("due date").

During preparation of the audit, the Lead Auditor or a person nominated for this activity initiates an inquiry to the customer regarding changes in the structural and procedural organisation, the size of the company and the company activities. This includes in particular a review of the valid management manual. In addition, materials used for publicity (e.g. Internet, advertising material) can be used for preparation purposes.

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 non conformities found in the previous audit,
- Complaints handling,
- Effectiveness of the management system in relation to achievement of objectives and goals,
- Progress with regard to planned continuous improvement activities,
- Continuing operational control,
- Review of any changes,
- use of logos and marks.

Addition requirements ISO 13485:

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

In 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. Veto person is auditor/technical expert or competence personnel but different personnels from those who carried out the audits and *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 review 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

6.8 Suspend and withdrawn of Certificate

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

Any further delays require approval by the accreditation body or result in suspension of the certificate. If the surveillance audit will not be performed until the expiry of the due date, the certificate will be suspended. *An audit can be performed and restored the suspended certification if the issue that has resulted in the suspension has been resolved. Failure to resolve the issues that have resulted in the suspension in a time established, Head of the Certification Body shall result in withdrawal or reduction of the scope of certification. The suspension would not exceed six months.*

6.9 Re-Certification audit

Re-Certification audits – including the review of corrective actions of identified nonconformities audit, auditors recommendation either to issue, *refuse*, maintain, or to suspend or *restore certification* – have to be completed prior to the expiry of the certificate. Any exceptions must be agreed in advance with the certification body.

The audit release process shall be completed three months after the audit as the latest.

A re-certification audit shall not be performed three months prior to the expired date of the certificate.

In case that a previous certification was performed by another MLA accredited Certification Body, the previous certificate and audit reports have to be reviewed.

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

Within the context of the audit preparation, "Sales Service" in requests a new calculation of the procedure from the lead auditor to ensure that the conditions of the contract still apply. The lead auditor asks the company about any changes in the structural and procedural organisation of the company, the size of the company, the company activities and the scope.

This includes among other things inspection of the current management manual. In addition, materials used to present the company to the public can be used for the preparation (e.g. Internet, advertising material).

Re-certification audits include a review of management system standard and an on-site audit. The results of the previous surveillance audit reports and performance of the management system over the most recent certification cycle shall be taken into account. All requirements of the standard will be audited.

It may be necessary to perform an audit stage 1 in the context of a re-certification 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 recorded decision regarding the necessary action is made by Head of Certification Body. The audit methodology is equivalent to the methodology of an audit stage 2.

Points of emphasis are at least:

- effectiveness of the interaction between all quality management elements in the management system with regard to internal or external change, 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 organisation,
- verification that the certified management system contributes to achievement of the policies and objectives of the organisation.

Audit conduct, documentation and also issue of certificates will be performed accordance with the provisions of a certification audit. *For any major nonconformity shall be implemented and verified prior to the expiration of certification.*

When recertification activities are successfully completed prior to the expiry date of the existing certification, the expiry date of new certification can be based on the expiry date of the existing certification. The issue date on a new certificate shall be on or after the recertification decision.

If the recertification audit has not completed or unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then recertification shall not be recommended and the validity of the certification shall not be extended. The client will be informed and the consequences will be explained. Following expiration of certification, restore certification can be provided within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 shall be conducted. The effective date on the certificate shall be on or after the recertification decision anf the expiry date shall be based on prior certification cycle.

6.10 *Expanding*/ Reduction Audit

An *expanding* / reduction audit can be performed to expand or reduce the scope of an existing certificate. The *expanding* / 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 lead auditor / audit team will review the management system standard concerning the expanded / reduced scope and audit all requirements which are affected by the *expanding* / reduction. The further progress 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.

6.12 Transfer of certificates from other Certification Bodies

The following minimum requirements shall apply:

Prerequisites

As a general rule, only certificates issued by accredited certification bodies can be transferred; the accrediting body must have signed the IAF Multilateral Agreements (MLA). Companies with certificates from non-accredited certification bodies are to be treated as new customers.

Pre-Transfer Review

A Pre-Transfer Review must be conducted by a competent auditor: this generally comprises review of important documents and a visit to the customer. The required number of audit days has to agree with the specialist manager.

The Pre-Transfer Review must cover the following aspects:

Confirmation that the certified activities of the customer are covered by the scope of our own accreditation.

The reasons for transfer of the certificate:

- confirmation that a valid management system certificate with regard to term of validity and performance profile of the customer, issued by an accredited certification body, is to be transferred; if possible, the validity of the certificate and the status of any existing nonconformities should be reviewed together with the former certifier
- discussion of the two previous reports on the Certification or Recertification Audit and the subsequent Surveillance Audits and of all nonconformities dealt with in these reports: this discussion should also include all other available relevant documents and records on the certification process, such as handwritten

notes and checklists
- any complaints received and the action taken
- the current status of the surveillance cycle

Certificates

As a general rule, only a valid certificate issued by an accredited certification body can be transferred. If that prerequisite is not satisfied, the individual case must be judged on its merits.

It is not possible to transfer suspended certificates or certificates which are under the threat of suspension.

Any unresolved nonconformities have to be clarified with the previous certification body prior to transfer wherever practicable. Such nonconformities must otherwise be reviewed in the course of the audit.

A certificate can be issued with the date of completion of the Pre-Transfer Review as date of issue (subject to the usual release process) if there are no longer any unresolved or potential problems.

Future Surveillance and Recertification Audits are based on the previous Surveillance and Recertification programme.

Additional information transfer of Certification Body (CB) for RSPO:

- The new CB shall officially communicate to the old CB and RSPO.
- The old CB shall provide all reports, including non-conformance forms, to the new CB.
- Transfer of CB shall not be permitted until all major non-conformances are closed or all financial obligations have been met.
- The new CB shall conduct a new audit assessment using the previous report as guidance.
- After conclusion of the audit, a new certificate shall be issued to the company by the new CB maintaining the previous expiry date. Upon issuance of the new certificate RSPO shall be informed.

Transfer of certification body is allowed at any stage of the certification cycle.

6.13	**Multisite certification (Group/Matrix Certification)**
	Described in procedure PM-TNI-004
6.14	**Operational Control**
	Certification activities for branch offices are limited only as sales department (see point 4.5).
6.15	**Integrated Management System**

6.15.1 Audit of Integrated Management System is an audit of an organization's management system against two or more sets of audit criteria/standards conducted at the same time. The management system audit can be combined with other management systems.. All the elements important of each management system shall appear clearly, and be readily identifiable, in the audit reports.

6.15.2 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).

6.15.3 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).

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

6.15.5 To determine the audit time for an audit of an IMS covering two or more management system standards e.g. A + B + C, 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 MD5, IAF MD 9, ISO/TS 22003, ISO/IEC 27006);

6.15.6 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)

6.15.7 Audit of an IMS could result in increased time, but where it results in reduction, it shall not exceed 30% from the starting point T. Reduction max 30% basically due to saving of time because of the jointly auditing of elements like company's policy, objectives and programmes, documentation, internal audits, corrective actions, managementreview as well as jointly performing the opening meeting, in-between summary and closing meeting,

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

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

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

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

6.15.12 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

6.15.13 the applicable management system

7.	**Additions for specific standards**
	Requirements in accordance to specific standards PM-TNI- 003 (For QMS)
	Requirements in accordance to specific standards PM-FS-TNI- 001 (For FSMS)
	Requirements in accordance to specific standards PS-TNI- 001 (For ISMS)
	Requirements in accordance to specific standards PEn-TNI- 001 (For EnMS)

8.	**Applicable Documents**
MM-TNI-001	Lembaga Sertifikasi Manual
	Requirements for and appointment of PT. TÜV NORD Indonesia auditors for MS_ISO 9001)
	Multi-site Certification (Group/Matrix Certification)
	Questionnaire / application in Preparation for the Certification
	Offer (Quotation)
	A Team and Effort Approval
	Attendant List
	Audit Schedule
	Report on Review of ISO 9001 and ISO 14001 Documentation
	Certification Audit Report stage – 1
	Audit Report
	Release of Audit Documentation
	Hand Written Note
	Recommendation of Opportunities for Improvement
	Non Conformity Report

	Certificate Draft
	Sub Order (If External audit and/or Expert are involved)
	Management of Non conformities
FMLF-TNI-064 Rev 00	"Informasi Data Klien Terkini" Form.