1 GENERAL

TÜV Rheinland of North America, Inc. (hereinafter referred to as TRNA) offers interested companies its services for management system certification.

TRNA assesses and certifies the management systems of product manufacturers and service companies. The independence, confidentiality and impartiality of the auditors is required by TRNA. The TRNA structural and procedural organization ensures that the criteria stated in ISO 17021:2015 are fulfilled. The certification organization and process are documented.

For the certification process to occur, a signed contract and/or purchase order is required. The following documents are considered as part of the contract and are binding on both parties:

- Service Agreement, Quotation and Executed Purchase Order Form;
- TÜV Rheinland of North America, Inc., General Terms and Conditions, (MS-0002298);
- General Conditions and Procedural Guidelines for TRNA Audits, (MS-0043256);
- General Conditions and Procedural Guidelines for AS91xx Certifications, (MS-0005710);
- General Terms and Conditions of Certification of TÜV Rheinland Cert GmbH / LGA InterCert GmbH, (MS-0043514);
- Promoting Certification and Using the TRNA and ANAB Marks, (MS-0005743).


2 SCOPE

These “General Conditions and Procedural Guidelines…” apply to the total certification process, specified in section 3.

3 CERTIFICATION PROCESS

This section describes the general process for a company seeking management system certification.

3.1 Phase 1: Certification preparation

In the first phase, TRNA determines the qualifications needed to provide the requested services. The scope and applicable standard are determined via an application questionnaire.

If requested, TRNA will provide preliminary assessments to assist the client in determining their level of preparation for the certification audit.

3.1.1 Information meeting

TRNA will, if requested, hold an informational meeting with the interested company concerning TRNA’s certification services prior to the signing of a contract. This meeting may cover, the following points:

- the aim and benefits of certification;
- the basic requirements for certification;
- performance of the certification procedure;
- standard or standards applied;
- verification level, scope of application;
- estimated costs;
- proposed schedules.

3.1.2 Quotation

TRNA provides each prospective client a quotation detailing the services that will be provided and the associated costs. Audit duration is determined by TRNA procedure MS-0005685 and IAF MD5. Quoted audit time may vary at auditors discretion based on organizational size, changes, complexity, risk, etc.

The associated costs are also summarized over the validity of the certification. TRNA reserves the right to apply annual increases in alignment with the Consumer Price Index. If travel is required, travel expenses are charged to the client at the actual cost plus a 10% service fee. Travel time will be invoiced at a minimum of a half man day rate but could be charged up to one man day rate, based on distance/time the auditor must travel.

Audits occurring outside of the United States may incur an annual processing fee.

3.1.3 Preliminary assessments

Agreement can also be made concerning more comprehensive preliminary assessments to be carried out by TRNA. These can cover, for example:

- assessment of the management system by means of a document review, either on or off-site;
- performance of an on-site pre-audit.

The goal of the preliminary assessments is to identify weak points in the management system and to decide upon the next steps in the certification process. The client receives a written report on the results of the preliminary assessments. These services can be ordered at any time before the certification audit, but are not a prerequisite or requirement for certification.

3.1.4 Audit team selection

At a time prior to the audit the client will be informed about the audit team members.

It will be ensured that the auditors were not involved in consulting activities with regard to setting up a management system for the client in the two years preceding the planned audit and are not in the year following certificate issue.

All auditors for TRNA have signed an agreement not to disclose to third parties any information obtained during the audit process and related activities.

The client has the right, with reason, to request any change in audit team members. If requested, a determination will be made as to whether alternate auditors are available. The client will be informed, on request, about the certifications in which the audit team members have previously participated.

If specific technical issues must be addressed in order to assess the management system, an appropriate technical expert will be included on the audit team.

3.2 Phase 2: Stage 1/Readiness Review Audit

3.2.1 Audit plan

The stage 1 audit is performed to evaluate the client’s readiness for the stage 2, certification audit. The stage 1 audit is typically conducted on site except in cases whereby justification is provided to allow offsite/remote review.

The client receives an audit plan detailing the activities that will be occurring during the audit. The schedule of activities may be modified with the concurrence of the Lead Auditor.

3.2.2 Audit conduct

During the audit, the audit team evaluates how much the management system of the client is ready for a stage 2 certification audit. It includes:

a) review the client’s management system documented information;
b) evaluate the client’s site-specific conditions and to undertake discussions with the client’s personnel to determine the preparedness for stage 2;
c) review the client’s status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system;
d) obtain necessary information regarding the scope of the management system, including:
   - the client’s site(s);
   - physical and organizational boundaries;
   - processes and equipment used;
   - levels of controls established (particularly in case of multisite clients); applicable statutory and regulatory requirements;
e) review the allocation of resources for stage 2 and agree the details of stage 2 with the client;
f) provide a focus for planning stage 2 by gaining a sufficient understanding of the client’s management system and site operations in the context of the management system standard or other normative document;
g) evaluate if the internal audits and management reviews are being planned and performed, and that the
   level of implementation of the management system substantiates that the client is ready for stage 2.

3.2.3 Audit conclusion, Stage 1 audit report
A detailed audit report that describes the audit results and includes any concerns will be sent promptly to the client. The audit might result in a recommendation for:

   - stage 2 certification audit within 6 months;
   - stage 2 certification audit under the condition of implementation of corrective actions;
   - repeating the stage 1 audit or continuing the audit on-site in the event that an off-site audit was conducted.

3.3 Phase 3: Stage 2/Certification Audit

3.3.1 Management review and internal audits
Prior to conduct of the stage 2 certification audit, the client shall conduct one complete internal audit and management review cycle. All clauses of the applicable standard are to be audited and the results presented to management for discussion during their management review.

If it is determined during the certification audit that this requirement has not been fulfilled, then a successful re-audit of the deficient area may be required prior to issuing the certification.

3.3.2 Audit plan
Prior to the certification audit the client receives an audit plan detailing the activities that will be occurring during the audit. The schedule of activities may be modified with the concurrence of the Lead Auditor.

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

   a) information and evidence about conformity to all requirements of the applicable management system standard or other normative documents;
   b) performance monitoring, measuring, reporting and reviewing against key performance objectives and targets (consistent with the expectations in the applicable management system standard or other normative document);
   c) the client’s management system ability and its performance regarding meeting of applicable statutory, regulatory and contractual requirements;
   d) operational control of the client’s processes;
   e) internal auditing and management review;
   f) management responsibility for the client’s policies.

The audit team will conduct an opening meeting to discuss how the audit will be conducted and provide any requirements to the client.

Through interviews, observation and review of documents and records the audit team assesses the level of conformance the client has achieved with respect to the requirements of the management system standard.

The company’s role during the audit is to demonstrate the practical application of the establish processes/practices.

3.3.4 Audit conclusion
Upon completion of the audit, the client will be notified of the outcome of the audit in a closing meeting.

Any nonconformity will be documented and explained by means of the Nonconformity Report. They are submitted to the client and countersigned by the client’s audit representative.

A certification audit ending in no nonconformities will receive a recommendation for certification by the audit team.

A certification audit ending with only minor nonconformities will receive a recommendation for certification by the audit team up on acceptable review of proposed corrections and corrective action plans, except where the specific standard requires closure of all nonconformities before a recommendation can be granted.

If the certification audit resulted in one or more major nonconformities, then the audit team may recommend that a re-audit be done prior to issuing the certification.

3.3.5 Nonconformity Report
A general definition for a minor nonconformity is an individual occurrence that does not affect the capability of the management system to achieve the intended results.

A general definition for a major nonconformity is the absence of, or failure to that affects the capability of the management system to achieve the intended results.

Nonconformities could be classified as major in the following circumstances:

   - if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements
   - a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.
   - if the application of the established process/practices.

Minor nonconformities can be resolved with completed containment and corrective action plan only and corrective actions can be implemented after that timeframe.

Nonconformities may be written associated not only with deviations from the Client system, the respective standard but also with the contractual documents as they are considered binding for both parties. For instance, improper use of the Promoting Certification and Using the Registrar Trademark and the Accreditation Marks will result in a nonconformity.

The requirements for nonconformities stated here and elsewhere in this document are general in nature. Specific requirements for each standard are provided with the nonconformity reports at the time of the audit.
3.3.6 Audit Report
A detailed audit report that describes the audit results and includes any nonconformity that may have been written will be provided promptly to the client.

3.3.7 Re-audit
When the audit results in one or more major nonconformities, a re-audit may be required. The client must propose and implement corrective action to the major nonconformities before the re-audit can be conducted.

The client has up to 90 days from the date of the closing meeting or less as specified in the Nonconformity Report to implement the necessary correction and corrective action and have the re-audit conducted. If the re-audit does not occur within specified timeframe, at TRNA’s option a new complete certification audit may be required instead of the re-audit.

3.4 Phase 4: Certificate Issuance, Surveillance and Recertification Audits

3.4.1 Certificate issuance
The TRNA Certification Office is the final step in the certification process. Based on the recommendation of the audit team, the Certification Office decides whether the certification will be granted and the certificate issued or whether a re-audit is required.

Once issued, the certification and certificate are valid for three years. The certification’s continued validity is dependent on the surveillance audits having a positive outcome.

3.4.2 Surveillance Audits
The certification requires periodic surveillance audits to determine whether the implemented management system remains in compliance with the standard identified in the certification. Surveillance audits can be semi-annual or annual, based on client preference, but there must be an audit in each calendar year.

The first surveillance audit after a certification audit shall be conducted within 9 months after the initial certification date.

Annual surveillance audits shall be conducted at least three months prior to the anniversary date of the certificate expiry date. If semi-annual is preferred, the second surveillance audit in the year shall be conducted at least three months prior to the anniversary date of the certificate expiry date.

During the surveillance audits, an evaluation is made of:

- internal audits and management review;
- a review of actions taken on nonconformities identified during the previous audit;
- complaints handling;
- effectiveness of the management system with regard to achieving the certified client’s objectives and the intended results of the respective management system(s);
- progress of planned activities aimed at continual improvement;
- continuing operational control;
- review of any changes;
- use of marks and/or any other reference to certification.

The basic process of conducting the surveillance audit is similar to the certification audit including audit team selection, audit plan, opening and closing meeting, nonconformity reports, if needed, and a written report with the audit results.

During the surveillance audit, any nonconformity from the last audit that has not been previously verified and closed will be reviewed for implementation.

3.4.3 Re-audit
If the surveillance audit resulted in one or more major nonconformities, then the audit team may recommend that a re-audit be done prior to continuing the certification.

The client must propose and implement corrective action to the major nonconformities before the re-audit can be conducted.

The client has up to 90 days from the date of the closing meeting to implement the necessary correction and corrective action and have the re-audit conducted. If the re-audit does not occur within the 3 months the client’s certification is put on suspension.

The client then has an additional 90 days to implement the necessary correction and corrective action and have the re-audit conducted.

During the suspension the client’s certification is temporarily invalid. The client cannot promote its certification, and TRNA is obligated to make the suspension publicly accessible.

If a successful re-audit does not occur within this second 90-day period the certification will be withdrawn.

3.4.4 Recertification audits
The purpose of the recertification audit is to confirm the continued conformity and effectiveness of the management system as a whole, and its continued relevance and applicability for the scope of certification. A successful recertification audit shall extend the certification validity for another three years.

The recertification audit shall be conducted at least three months in advance of the certificate expiry date. During a recertification audit, all elements of the entire management system are audited.

The audit process is as described in Sections 3.3 and 3.4.

3.4.5 Short Notice Audits
It may be necessary for TRNA to conduct audits at short notice to investigate complaints, or in response to changes, or as follow-up on suspended clients.

3.4.6 Remote Audits
In some cases, an audit may be conducted using various methods of Information and Communication Technology (ICT). The percentage of these remote audits may be anywhere between 1% and 100%.

The determination of remote auditing time is based on a review of risk including the following:

- Complexity of client/management system risk
- Results of last audit
- Documentation (hard copy vs. electronic)
- Compliance performance
- Organizational/management system changes
- Changes to locations/sites and/or key processes
- Prior knowledge of client system
- Network connection
- Security/confidentiality

This review will occur between the client and Project Manager.

A remote audit will incur additional preparation and audit time. The addition of time is based on the total audit duration and will cover:

- ICT Setup and testing
- ICT logistics and documentation review
- Recovering for remote audit delays

If the audit was not quoted as a remote audit, a revised PO is required prior to scheduling.
4 GENERAL CONDITIONS

4.1 Duties and responsibilities of TRNA

4.1.1 Confidentiality
TRNA will treat in confidence the entire client’s data that is made available and will use it only for the agreed purpose and per the terms of the General Terms referenced above. Documents made available will not be provided to third parties. Exceptions to this are:

- Access to client’s file by the Accreditation Bodies shown on the certificate(s) issued to the client;
- When the client releases TRNA from its confidentiality agreement for specific reasons.

4.1.2 Audit Termination
TRNA reserves the right to terminate an audit in cases of:

- obvious and demonstrated lack of interest or opposition by the senior management regarding the audit;
- members of the audit team are threatened, blackmailed or bribed.

4.1.3 Complaints
If a Customer or certificate holder is not satisfied with the service or other deliverables provided, other than an appeal, the Customer has the option of filing a complaint with TRNA. TRNA shall work with the Customer to resolve the complaint, keep the Customer apprised of the complaint’s progress, and provide the Customer with detailed reasons for its final decision. All complaints should be sent to wecare@us.tuv.com.

4.1.4 Appeals
If a Customer or certificate holder is not satisfied with decisions made, the Customer has the option of filing an appeal with TRNA. TRNA shall work with the Appellant to resolve the appeal; keep the Appellant apprised of the appeal’s progress, and provide the Appellant with detailed reasons for its final decision. Appeals should be submitted to wecare@us.tuv.com.

At any time the Appellant may formally present its case.

Where allowed, the Appellant may approach the Accrediting Body of the Certification Body for final resolution. Appellant shall have no other remedies and no right to pursue the matter in any way whether outside nor within any judicial procedure including but not limited to a court or arbitration procedure. Customer herewith already irrevocably waives any right to any judicial procedure regarding any decision by TRNA, the Certification Body or its Affiliates.

4.1.5 Quality records
TRNA maintains records of its activities with its clients. This is done so that performance of these activities can be demonstrated. The records maintained include but are not limited to:

- Quotations;
- Contracts;
- Correspondence;
- Audit documentation.

These documents will be kept for at least one three-year cycle of audits plus one year.

4.1.6 Notification of changes in the certification process
TRNA will inform its clients of changes to the certification process stating at what date the modified requirements will become effective and advising the client of any need to take action. The transition periods for the implementation of changes in the certification process is between three months and three years and will be identified to the client.

Clients should comment on these changes within a specified period of time – normally 30 days - after receiving the notification.

If the client gives confirmation within the specified period of acceptance of the modification, its participation in TRNA’s management system certification program will be continued.

If the client does not give confirmation within the specified period of acceptance of the modification the certification shall be terminated on the date on which the modified requirements became effective unless otherwise decided by TRNA.

4.1.7 List of Certified Companies
TRNA will maintain a list of certified companies, stating the respective scope of application. The list will be available to the public upon request.

4.2 Client Duties and Responsibilities

Prior to conduct of the Stage 2 audit, the client shall conduct one complete internal audit and management review cycle. All elements of the applicable standard are to be audited and the results presented to management for discussion during management review.

All documents relating to the management system (including records) shall be made available to TRNA.

The client will identify to TRNA an audit representative who will act as the main point of contact for all audit-related activities.

The client will permit the auditors access to the relevant departments in the company.

The client agrees to permit accreditation body and where required by specific standards, OEM representatives to participate in any audit to monitor TRNA’s personnel during on-site audits. TRNA will inform the client prior to the audit upon receiving such a request from any third party.

Once certification has been granted, the client shall notify TRNA of all changes related to:

a) the legal, commercial, organizational status or ownership;
b) organization and management (e.g. key managerial, decision-making or technical staff);
c) contact address and sites (e.g. additional buildings added);
d) scope of operations under the certified management system;
e) major changes to the management system and processes; including headcount, shift schedules, ITAR status, etc.
f) occurrence of an environmental, health or safety incident/ breach/violation of regulation.

When requested for cause, the client will provide TRNA with the current management system documents.

The client agrees to allow short notice audits when provided with advance notice by TRNA.

The client agrees to regularly scheduled surveillance and recertification audits as required to maintain their certification. Such audits may be re-scheduled or canceled by the client up to six weeks before a set audit date. The cancellation and modification policy is as follows:

4.2.1 Cancellation & Modification Policy

Between 4-6 weeks prior to the scheduled audit dates (25%) charge applies.

Between 2-4 weeks prior to the scheduled audit dates (50%) charge applies.

Less than 2 weeks prior to the scheduled audit dates (100%) charge applies.

The certificate holder can use the TRNA Certificate for commercial purposes (e.g. as evidence submitted to customers and authorities),
for advertising purposes, or for demonstrating the duty of care in product liability cases.

The client may use the TRNA trade mark and the accreditation marks for advertising and marketing purposes. The requirements for use of these marks are specified in “Conditions for using the Registrar Mark and the Accreditation Marks” MS-0005743.

The certificate holder shall keep record of complaints and remedial actions relative to the management system. These records shall be made available to TRNA upon request and during audits.

4.3 Amendments to scope

4.3.1 Reduction to scope

TRNA reserves the right to reduce the scope of certification:
- upon request from the client,
- as the result of an audit outcome, or
- as a result of other activities.

4.3.2 Extension to scope

TRNA will review applications for extensions to the scope of certification already granted and determine any audit activities that are necessary to decide whether or not to grant such an extension. An extension to scope audit may be done at any time.

4.4 Suspension and revocation of the certification

4.4.1 Suspension of certification

If the certification is placed on suspension, the certificate holder cannot actively promote the certification until such time as the certification is re-instated.

TRNA has the right to place a certification on immediate suspension due to the following:
- major nonconformity(s) not closed with the stated time period;
- the certificate or certification is improperly used;
- the identification of one or more major nonconformities during a surveillance audit;
- the client’s certified management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the management system;
- the certified client does not allow surveillance or recertification audits to be conducted at the required frequencies;
- the certified client has voluntarily requested a suspension.
- failure to meet financial obligations to TRNA;
- conditions where environmental, safety and/or health is at risk;
- any other reasons which result specifically from these conditions or that are agreed formally between TRNA and the client.

4.4.2 Revocation of certification

If the certification is revoked, the certificate holder loses the right to use the trademark. In such a case the certificate holder may continue to use existing documents, media etc., which are printed with the trademark, for no more than one month from definitive cancellation of the certification.

TRNA has the right to revoke a certificate for the following:
- the certificate or certification is improperly used;
- the identification of one or more major nonconformities during a surveillance audit;
- failure to allow for the conduct of an audit within the required timeframe defined by TRNA;
- failure to allow for the conduct of a scheduled audit;
- conditions where environmental, safety and/or health is at risk, including violations to such;
- there are any other reasons which result specifically from these conditions or are agreed formally between TRNA and the client;
- the certificate holder ceases to supply a product, process or service for an extended period of time;
- the system rules are changed and the certificate holder will not or cannot ensure conformance to the new requirements;
- the certificate holder fails to meet financial obligations to TRNA;
- the certificate holder requests the cancellation;
- the client does not have the periodic audits carried out according to the General Conditions and Procedural Guidelines for the Certification of Management Systems.

4.4.3 Revocation of Registrar’s accreditation and/or management system qualifications

In the event that the registrar’s accreditation and/or QMS/EMS/OHSMO qualifications are revoked TRNA will make every effort to rectify the reasons leading to the revocation. If this is not performed within a time frame agreed upon by the accreditation body, then TRNA will transition all certified companies to another registrar that offers the same services and holds the same accreditation.

5 VOLUNTARY WITHDRAWAL OF ACCREDITATION

If TRNA chooses to voluntarily terminate its accreditation, it will do so by means of a written notification sent to the Accreditation Body within thirty (30) days.

It is the responsibility of TRNA to provide any remedies to any certified client affected by this withdrawal, appropriate to the nature of the problem that is acceptable to the Accreditation Body and in accordance with program requirements.

These remedies could include the notification of the withdrawal to the certified client and any plans to transition the certified clients to another accredited registrar that offers the same services and holds the same accreditation.

Additionally, TRNA will cease to use any advertising materials containing reference to the accreditation and will return any accreditation documents to the Accreditation Body. All unpaid fees will be paid upon the withdrawal.

6 CNCA SPECIFIC REQUIREMENTS

Certified Companies with sites in China must follow the guidelines set forth by the CNCA.

The client commits to:
- Run their management system continually and effectively.
- Comply with the certification and accreditation laws and regulations, assist supervision and inspection by certification supervision unit, and provide truthful relevant materials and information for any relevant inquiry or investigation.
- Use certificate, certification logo and relevant information correctly after certified; do not unauthorized use QMS certificate and relevant words, symbol to mislead the public to think of their products or service are certified.

Notify CB promptly when the following situations occurred:
- major complaints from the customers and interest party.
- products or services are identified by law enforcement supervision unit do not comply with the statutory requirements.
- product or service quality or safety incidents occurred.
- relevant situation changes include: legal status, production operation, organization status or ownership; administration permit, mandatory certification or other qualification certificate; legal representative, top management, main contact person; production operation and service sites; activities scope covered by QMS; QMS and important processes, etc.

Other important situation influence QMS running.