

1 GENERAL

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

TUV Rheinland assesses and registers the management systems of product manufacturers and service companies. The independence, confidentiality and impartiality of the auditors is guaranteed by TUV Rheinland. The TUV Rheinland structural and procedural organization ensures that the criteria stated in ISO 17021:2006 are fulfilled. The certification organization and process are documented.

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

the written quotation;

the General Conditions and Procedural Guidelines for the Certification of Management Systems to QMS and EMS International Standards (MS-0005708 Appendix 2);

TUV Rheinland of North America, Inc. General Terms and Conditions (MS-0002298)

Conditions for Using the Registrar Trademark and the Accreditation Marks (MS-0005743)

A condition for certification and certificate issuance is a certification audit to determine compliance to the specified management system standard. The audit must conclude with a positive result.

2 SCOPE

These "General Conditions and Procedural Guidelines..." apply to the total certification process which includes:

Certification Preparation (Phase 1);

Management System Review (Phase 2);

Certification Audit (Phase 3);

Certificate Issuance, Surveillance and Recertification Audits (Phase 4).

Additional information includes:

duties and responsibilities of TUV Rheinland;

duties and responsibilities of the client;

suspension and cancellation of the certification.

3 CERTIFICATION PROCESS

This section describes the general process for a company seeking management system certification. [Also see Annex 1.](#)

3.1 Phase 1: Certification preparation

In the first phase TUV Rheinland determines the qualifications needed to provide the requested services. The application scope and applicable standard are determined. This is done through a quotation questionnaire.

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

Information meeting

TUV Rheinland will, if requested, hold an informational meeting with the interested company concerning TUV Rheinland's certification service prior to the signing of a contract. This meeting can cover, inter alia, 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.

Quotation

TUV Rheinland provides each prospective client a quotation detailing the services that will be provided and the associated costs. The costs are also summarized over the validity of the certification.

Contract and purchase order

Once the client has accepted the quotation, two sets of contracts will be submitted for signature. In order to proceed with the activities in the next sections, a purchase order is required.

Preliminary assessments

Agreement can also be made concerning more comprehensive preliminary assessments to be carried out by TUV Rheinland. 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.

3.2 Phase 2: Stage 1 audit

Audit plan

The stage 1 audit is performed to evaluate the client's readiness for the stage 2, certification audit. The stage 2 audit is conducted on site except in very limited situations, where the small number of employees, limited processes and simple scope may allow the audit to be conducted off-site through the client completing a very detailed questionnaire.

Prior to any on-site stage 1 audit the client receives a Stage 1 Questionnaire. The questionnaire aids in the development of the audit plan and must be completed prior to the stage 1 audit. If the questionnaire is not returned, additional on-site time will be added to the on-site time, to be completed prior to commencing the stage 1 audit.

Once the Stage 1 Questionnaire is returned, 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.

Reaudit 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:

- Review of the client's management system documentation (The client shall submit the documents at least 2 weeks before the stage 1 audit.);
- evaluation of the location and site-specific conditions;
- review of general understanding of the requirements of the standard, identification of processes and key performance parameters;
- review of the identification of statutory and regulatory aspects;
- review of the necessary resource and time allocation for the stage 2 certification audit;
- confirmation of performance of internal audits and management review

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 a recommendation for:

- stage 2 certification audit within 3 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.

Management review and internal audits

Prior to conduct of the 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 will be required prior to issuing the certification.

3.3 Phase 3: Stage 2 audit

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 TÜV Rheinland have signed an agreement not to disclose to third parties information obtained during the audit process and related activities.

The client has the right to reject, **with reason**, any audit team members. If rejected, alternate auditors will be offered. The client will be informed, on request, about the certifications in which the audit team members have previously participated.

The certification audit will generally be carried out by at least two auditors (lead auditor, auditor). 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.

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.

Audit conduct

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

During the audit the audit team evaluates how well the management system complies with the implemented standard.

Through interviews, observation and review of documents and records the audit team assess the level of compliance 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 documented procedures.

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 upon acceptable review of proposed corrections and corrective actions, except were 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 will recommend that a re-audit be done prior to issuing the certification.

3.3.1.1 Nonconformity Report

A general definition for a minor nonconformity is an individual occurrence that is not likely to result in a management system failure or materially reduce the system's ability to assure controlled processes and products.

A general definition for a major nonconformity is the absence of, or the failure to implement and maintain, one or more required management system elements, or a situation which would, on the basis of available objective evidence raise significant doubt as to the quality of what the supplier is supplying.

In general all nonconformities must be closed within 90 days of the date of the final report. Minor nonconformities not closed in that timeframe are escalated to major nonconformities. See 3.3.4.3.

The requirements for nonconformities stated here, in 3.3.4.3 and elsewhere in this document are general in nature. Specific requirements for each standard are provided with the nonconformities reports at the time of the audit.

3.3.1.2 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.

3.3.1.3 Re-audit

When the audit results in one or more major nonconformities, a re-audit is 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 three months from the date of the final audit report 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, at TUV Rheinland'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

Certificate issuance

The TUV Rheinland 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.

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 are normally done on an annual basis.

The first surveillance audit after a certification audit shall be scheduled within 12 months after the last day of the certification audit.

Additional annual surveillance audits are typically scheduled to occur in a two month timeframe before the anniversary date of the original certification audit.

At least once a year during the surveillance audits, an evaluation is made of:

- management responsibility and management system review;
- internal audit conduct and results;
- corrective and preventive action, including customer complaints
- changes to the management system;
- other Standard elements determined on a random and/or need basis.

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.

3.4.1.1 Nonconformity report

See 3.3.4.1.

3.4.1.2 Re-audit

If the surveillance audit resulted in one or more major nonconformities, then the audit team will 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 three months from the date of the final audit report 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 three months 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 the TUV Rheinland is obligated to make the suspension publicly accessible.

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

Recertification audits

Before the expiration of the certification and certificate, a recertification audit of the company is performed to extend the certification validity for another three years.

The recertification audit must be scheduled sufficiently in advance so that any issues resulting from the audit or the certification office review can be resolved prior to the certification expiration.

During a recertification audit, all elements of the entire management system are audited. Due to the fact the client has been previously certified, the recertification audit may require less time on-site than the certification audit.

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

Short notice audits

It may be necessary for TUV Rheinland to conduct audits at short notice to investigate complaints, or in response to changes, or as follow-up on suspended clients.

4 GENERAL CONDITIONS

4.1 Duties and responsibilities of TUV Rheinland

Confidentiality

TUV Rheinland will treat in confidence the entire client's data that is made available and will use it only for the agreed purpose. Documents made available will not be provided to third parties. Exceptions to this are:

For the submission of detailed reports to the TUV Rheinland Advisory Board in the case of appeals;

Access to client's file by the Accreditation Bodies shown on the certificate(s) issued to the client;

When the client releases TUV Rheinland from its confidentiality agreement for specific reasons.

Liability

The liability of TÜV Rheinland towards the client or third parties exists only insofar as is prescribed by law in the event of gross negligence. More extensive claims are excluded.

Audit termination

TÜV Rheinland 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.

Complaints

If a Customer or certificate holder is not satisfied with the service or other deliverables provided during the test and certification procedure, 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.

Appeals

If a Customer or certificate holder is not satisfied with decisions made during the test and certification procedure, 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.

At any time the Appellant may formally present its case.

Where allowed, the Appellant may approach the Accrediting Body of the TCB 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 TCB or its Affiliates in a testing and certification procedure.

Quality records

TÜV Rheinland maintains records on 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 seven years from the expiration of the validity of the certificate.

Notification of changes in the certification process

TÜV Rheinland 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 TÜV Rheinland.

List of certified companies

TÜV Rheinland 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 1 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 their management review.

The Stage 2 audit date may be re-scheduled or canceled by the client up to six weeks before a set audit date. After this date, TÜV Rheinland reserves the right to charge up to 100% of the quoted audit fee based on time of notification.

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

The client will identify to TÜV Rheinland 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 TÜV Rheinland's personnel during on-site audits. TÜV Rheinland 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 TÜV Rheinland of:

all important and or significant changes in their management system or scope of registration;

changes in the company's organizational structure which have an influence on the management system.

When requested for cause, the client will provide TÜV Rheinland with the current management system documents such as the management manual.

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

The client agrees to regularly scheduled surveillance and recertification audits as in order to maintain their certification. Such audits may be re-scheduled or canceled by the client up to six weeks before a set audit date. After this date, TÜV Rheinland reserves the right to charge up to 100% of the quoted audit fee based on time of notification.

The certificate holder can use the TÜV Rheinland 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 TUV Rheinland 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".

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

4.3 Amendments to scope

Reduction to scope

TUV Rheinland reserves the right to reduce the scope of certification:

upon request from the client,

as the result of an audit outcome, or

or as a result of other activities.

Extension to scope

TUV Rheinland 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

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.

TUV Rheinland 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;

failure to allow for the conduct of a scheduled audit;

failure to meet financial obligations to TUV Rheinland;

conditions where public safety and/or health is at risk;

any other reasons which result specifically from these conditions or that are agreed formally between TUV Rheinland and the client.

Revocation of certification

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

TUV Rheinland 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 a scheduled audit;

conditions where public safety and/or health is at risk;

there are any other reasons which result specifically from these conditions or are agreed formally between TUV Rheinland 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 can not ensure conformance to the new requirements;

the certificate holder fails to meet financial obligations to TUV Rheinland;

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*.

Revocation of Registrar's accreditation and/or management system qualifications

In the event that the registrar's accreditation and/or QMS/EMS qualifications are revoked TUV Rheinland 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 TUV Rheinland will transition all certified companies to another registrar that offers the same services and holds the same accreditation.

5 VOLUNTARY WITHDRAWAL OF ACCREDITATION

If TUV Rheinland 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 TUV Rheinland N. A., Inc. 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, TUV Rheinland N. A., Inc. 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 TERMINATION OF CONTRACT

This contract may be terminated by either party after giving 30 days' prior written notice to the other party.

7 CNCA SPECIFIC REQUIREMENTS

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

The client commits to:

run QMS 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.

Acceptance of the quote requires completing Annex ISO 9001(2L-F-CERT-APPL-UV-R-QM-rev1

ANNEX 1

