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## 1 General

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

TRNA assesses and certifies the quality management systems of product manufacturers and service companies. The independence, confidentiality and impartiality of the auditors is guaranteed by TRNA. The TRNA structural and procedural organization ensures that the criteria stated in ISO 17021-1 (current version) and the applicable regulatory programs 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 Quality Management Systems;
- the Order Conditions of TUV Rheinland of North America, Inc.

A condition for certification and certificate issuance is an assessment audit to determine compliance to the specified quality 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);
- Quality Management System Review (Phase 2);
- Certification Audit (Phase 3);
- Certificate Issuance, Surveillance and Recertification (repeat) audits (Phase 4).

Additional information includes:

- duties and responsibilities of TRNA;
- duties and responsibilities of the client;
- Suspension and cancellation of the certification.

## 3 Procedure for the Performance of the Service

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

### 3.1 1st Phase: Certification Preparation

In the first phase, TRNA determines the qualifications needed to provide the requested services. The application scope and applicable standard(s) are determined. This is done through a quotation questionnaire.

Pre-audit is not available for the MDSAP certification.

#### 3.1.1 Information Meeting

TRNA will, if requested, hold an informational meeting with the interested company concerning TRNA'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.

#### 3.1.2 Quotation

TRNA 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.

#### 3.1.3 Contract and Purchase Order

Once the client has accepted the quotation, a contract will be submitted for approval. In order to proceed with the activities in the next sections, a purchase order is required.

#### 3.1.4 Preliminary Assessments (Pre-audits)

Pre-audit is not available for the MDSAP certification.

### 3.2 2nd Phase: Stage 1 Audit

#### 3.2.1 QMS readiness, Management Review and Internal Audits

Prior to applying for certification, the client shall have their QMS (processes, infrastructure, suppliers, etc) operational for at least six (6) months in their final, representative state without significant changes.

Prior to the performance of the Stage 1 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.

### 3.2.2 Audit Plan

The Stage 1 audit is performed in the scope of an on-site visit at the client unless it is deemed not necessary based on the result of an in-office review of the submitted documentation or other circumstances determined by TRNA.

Prior to any the Stage 1 audit, the client receives a Stage 1 record form detailing the activities that will be occurring during the audit. The schedule of activities may be modified with the concurrence of the lead auditor.

### 3.2.3 Audit Conduct

During the audit, the audit team evaluates the readiness of the client's quality management system for a Stage 2 certification audit. It includes

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

### 3.2.4 Audit Conclusion, Stage 1 Audit Record

A Stage 1 audit record that describes the audit results and includes any nonconformities that may have been written will be provided to the client. The audit might result in a recommendation for

- a Stage 2 certification audit (within 3 months);
- a Stage 2 certification audit with potential nonconformities during the stage 2 audit;
- a Stage 2 certification audit with the condition of correcting the actual nonconformities found during the stage 1;
- a repeat of the Stage 1 audit.

## 3.3 3rd Phase: Stage 2, Certification Audit

### 3.3.1 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 are free from conflict of interest, ie were not involved in restricted activities per clause 5.2 of ISO/IEC 17021-1:2015 for the client or their competitors in the three years preceding the planned audit.

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

Under the MDSAP certification scheme for any type of audits (including short-notice and unannounced audits), the client is not allowed to object to the composition of the audit team (as described in ISO/IEC 17021-1:2015, clause 9.2.3.5), but may use the formal complaint process ('Customer Voice') to notify TRNA of their concerns of said audit team composition.

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 quality management system, an appropriate technical expert will be included on the audit team.

### 3.3.2 Audit Plan

Prior to the certification audit the client receives an audit plan detailing the objectives and activities of the upcoming audit. The schedule of activities may be modified with the concurrence of the lead auditor.

### 3.3.3 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 the quality management system's compliance with the implemented standard(s), applicable regulatory requirements **as well as any applicable contractual agreements**.

The audit team may use a question list as a guide in conducting the audit. The use of the question list does not preclude the audit team from going beyond the stated questions in order to better understand the client's procedures and practices or investigate potential or suspected problems with their implementation.

The client's role during the audit is to demonstrate the practical application of the documented procedures.

The auditor's role is to check on the practical application of the documented procedures and to assess the compliance with the requirements of the standard(s) and applicable regulatory requirements.

### 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 nonconformities will be explained and recorded in Nonconformity Report(s). These are signed both by the audit team and by the client's representative indicating that the nonconformities are understood (not necessarily accepted).

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 **grade 5 nonconformities or at least three grade 4 nonconformities**, the audit

team will not recommend the client for certification and a re-audit must be done prior to issuing any certification.

#### 3.3.4.1 Nonconformity Report

If nonconformities are found, the client must propose and implement corrections and corrective actions, where necessary, and submit the completed nonconformity reports with the supporting documents (if requested) prior to the issuing of the certificate. The client typically has **15 calendar days from the last audit date to submit the requested corrective action plan**. Otherwise, TRNA reserves the right to escalate the project and take necessary actions (eg require additional on-site audit time) prior to issuing the certification.

#### 3.3.4.2 Audit Report

A detailed audit report that describes the audit results and includes any nonconformities that may have been written will be provided to the client.

#### 3.3.4.3 Re-audit

If the certification audit resulted in one or more **grade 5 nonconformities or at least three grade 4 nonconformities**, the audit team will not recommend the client for certification and a re-audit must be done prior to issuing any certification.

The client must propose and implement correction(s) as well as propose, implement and verify the effectiveness of corrective action(s) to the nonconformities graded as 4 or 5 before the re-audit can be conducted.

The client has up to six (6) months from the last day of the **Stage 2** certification audit to implement the necessary corrective action(s) and have the re-audit conducted. If a successful re-audit does not occur within the 6 months, a complete (initial) certification audit will be required instead of a re-audit.

#### 3.3.4.4 Addition of Audit Time

Additional audit time may be required, post-audit, to handle the review and closure of nonconformities. This additional audit time may be spent on-site or off-site at the auditor's discretion. The auditor may also elect to add additional time during the **next audit** in order to verify the effectiveness of the client's corrective actions.

### 3.4 4th Phase: Certificate Issuance, Surveillance and Recertification Audits

#### 3.4.1 Certificate Issuance

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

Once issued, the certificate is valid for a default maximum of three years (unless limited by other factors, e.g. **MDSAP** rules). 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 quality management system remains in compliance with the standard(s) and applicable regulatory **and contractual** requirements identified under the certification scope. Surveillance audits are normally done on an annual basis, but may be conducted more frequently at the discretion of TRNA.

The first surveillance audit after an initial certification audit must be conducted within 12 months from the last day of the **Stage 2** certification audit. For scheduling purposes with the client, a flexibility of three months earlier is permissible.

Additional annual surveillance audits should be scheduled based on the anniversary of the original certification / recertification audit. For scheduling purposes with the client, a flexibility of three months earlier is permissible.

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

- management responsibility and quality management system review;
- internal audit conduct and results;
- corrective and preventive action, including customer complaints;
- changes to the quality management system;
- applicable regulatory and accreditation requirements;
- use of certification marks and logos;
- other standard clauses 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 nonconformities from the last audit that have not been previously verified and closed will be reviewed for implementation and effectiveness.

#### 3.4.2.1 Nonconformity Report

See 3.3.4.1.

#### 3.4.2.2 Re-audit

If the surveillance audit resulted in one or **grade 5 nonconformities or at least three grade 4 nonconformities**, then the audit team will not recommend the client for continued certification and a re-audit must be done prior to issuing any certification.

The client must propose and implement correction(s) and corrective action(s) to the major nonconformity(ies) or nonconformities graded as 4 or 5 before the re-audit can be conducted.

The client has up to six (6) months from the surveillance audit date to implement the necessary correction(s) and corrective action(s) and have a successful re-audit conducted. If a successful re-audit does not occur within the 6 months, the client's certification is placed on suspension.

During the suspension, the client's certification is temporarily invalid. The client cannot promote its certification, in any form of media, and TRNA is obligated to make the suspension publicly accessible. The suspension will last until the next regularly scheduled audit, but at a maximum of six (6) months. Failure to resolve the issues that led to the suspension will result in the certification being withdrawn or in a reduction in the scope of the certification.

If a successful re-audit does not occur within the 6 months, at TRNA's discretion, a complete (initial) certification audit will be required instead of a re-audit.

### 3.4.3 Recertification Audits

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

During a recertification audit, all clauses of the entire quality management system as well as any applicable regulatory and contractual requirements are audited.

If applicable, the effective closure of all nonconformities established in the certification cycle are verified.

Due to the fact the company has been certified, the recertification audit may require less time on-site than the certification audit.

The audit process is as described in Section 3.3.

### 3.4.4 Special Audits

A short-notice or unannounced audit may be carried out if any of the following conditions occur:

- the client is certified in a scheme which requires periodic unannounced audits as a mandatory element
- there are complaints filed against or involving the client
- the manufacturer has made significant changes to their QMS or product(s)
- the manufacturer is under suspension
- there are serious doubts about the effectiveness of the quality management system, particularly if it is determined that defective products were put into circulation,
- if counterfeit items were manufactured,
- there is the existence of serious and/or frequent nonconformities (two or more grade 4 and/or one or more grade 5 nonconformities issued cited during the previous audit),
- or there is information that indicates a threat to public health and/or safety.

At any time, TRNA has the right to conduct unannounced audits at the manufacturers' premises as well as at the premises of the manufacturers' critical subcontractors/suppliers. It is the obligation of the holder of the certificate to ensure through contractual agreements, that an audit at the critical subcontractor's/supplier's premises can be conducted. Costs for unannounced audits, including any and all expenses, will be charged to the holder of the certificate.

TRNA has the right to contract with an organization that provides security and protection of its staff during unannounced audits. The costs associated with this contract, as well as any and all expenses of that contracted organization, will be charged to the holder of the certificate.

Clients that reside in areas that require Visa for entrance are required to provide TRNA with an open-dated invitation letter to be used at the discretion of TRNA for the purposes of performing a special/unannounced audit. The format for such a letter is provided upon request.

## 4 General Conditions

### 4.1 Duties and Responsibilities of TRNA

#### 4.1.1 Confidentiality

TRNA will treat all the client's data that is made available as confidential 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 TRNA 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;
- upon request of a regulatory authority
- when the client releases TRNA from its confidentiality agreement for specific reasons;
- during the participation of a regulatory authority in audits.

#### 4.1.2 Liability

The liability of TRNA 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.

#### 4.1.3 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;
- any other circumstance that will hinder the audit team from reaching the audit objective, such as natural disasters or any other force majeure.

#### 4.1.4 Appeals and Complaints

It is the policy of TRNA to handle and resolve all complaints and appeals in a timely and effective manner. Complaints and appeals from any party will be registered and acted upon. TRNA should acknowledge receipt of the appeal or of the complaint, shall provide the appellant or complainant with progress reports and should give a formal notice of the end of the process.

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.

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 applicable regulatory authority for a resolution. The appellant shall have no other remedies and no right to pursue the matter in any way whether outside or within

any judicial procedure including but not limited to a court or arbitration procedure. Customers 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.

Any valid complaint about a certified client shall be referred by TRNA to the certified client in question at an appropriate time.

#### 4.1.5 Quality records

TRNA 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.

#### 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 action necessary on their part. 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 quality 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 either through our official website, [www.tuv.com](http://www.tuv.com), or will be made available upon request.

#### 4.1.8 Openness

In order to increase the confidence from interested parties and specifically regulators that accept or take into consideration [MDSAP certification and audit reports](#) for the purpose of their recognitions, TRNA releases [MDSAP](#) audit report information to [MDSAP Regulatory Authorities via the REPs portal](#).

### 4.2 Client Duties and Responsibilities

Prior to the performance of the certification audit, the client **shall** have their QMS (processes, infrastructure, suppliers, etc) operational for at least six (6) months in their final, representative state without significant changes.

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(s) and any applicable regulatory requirements are to be audited and the results presented to management for discussion during their management review.

The certification audit date may be re-scheduled or canceled by the client up to six weeks before a set audit date. After this date, TRNA reserves the right to charge a percentage of the total quoted fee with respect to the proximity to the audit dates.

All documents relating to the quality management system or regulatory documentation (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 representatives of the Regulatory Authorities under the Medical Device Single Audit Program (MDSAP) 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.

The client agrees to give permission for the recognizing Regulatory Authority(ies) to exchange information with other Regulatory Authorities that maintain Confidentiality Agreements.

The client agrees that, at the request of the Regulatory Authority(ies), the Auditing Organization shall perform a special audit of the manufacturer under the direction of the recognizing Regulatory Authority(ies) requesting the special audit.

The client agrees that, at any time, TRNA as Auditing Organization has the right to conduct unannounced audits at the manufacturers' premises as well as at the premises of the manufacturers' critical subcontractors / suppliers under any scheme for which the client is certified.

It is the obligation of the holder of the certificate to ensure through contractual agreements, that an audit at their critical subcontractor's/supplier's premises can be conducted. Costs for unannounced audits, including any and all expenses, will be charged to the holder of the certificate.

The client agrees that, TRNA has the right to contract with an organization that provides security and protection of its staff during unannounced audits. The costs associated with this contract, as well as any and all expenses of that contracted organization, will be charged to the holder of the certificate.

Clients that reside in areas that require Visa for entrance are required to provide TRNA with an open-dated invitation letter to be used at the discretion of TRNA for the purposes of performing a special/unannounced audit. The format for such a letter is provided as applicable.

The client understands and agrees that the Regulatory Authority(ies) themselves may perform special audits, including unannounced audits, anytime it deems necessary and within the purview of its jurisdiction.

Once certification has been granted, the client shall notify TRNA of:

- all important and/or significant changes in their quality management system or scope of products;

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

When requested for cause, the client will provide TRNA with the current quality documents, such as the quality manual.

If an audit results in a nonconformity, the client will provide a timely and technically acceptable response (as requested by the lead auditor, certification officer or client representative).

The client understands that the information obtained through an audit project may become obsolete and thus the audit in general becomes unsuitable to be used as a basis for making a positive certification decision if the lead auditor cannot make a recommendation for certification (e.g. due to open nonconformity or other pending documents) and does not submit the full required audit documentation to the certification office within 6(six) months after the last day of the audit.

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 trademark and the accreditation marks for advertising and marketing purposes, if allowed. The requirements for use these marks are specified in "Conditions for Promoting Certification and Using Certification Body / Auditing Organization Trade Marks and Accreditation Marks".

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

### 4.3. Reduction of the scope of Certification

TRNA 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.

### 4.3 Suspension, Restoration, and Revocation (Withdrawal) of the Certification

#### 4.3.1 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 on suspension a certificate due to, but not limited to, the following:

- nonconformities graded as 4 or 5 that are not closed with the stated time period;
- the certificate or certification is improperly used or misrepresented;
- the identification of one or more major nonconformities or nonconformities graded as 4 or 5 during a surveillance audit;
- failure to meet financial obligations to TRNA;
- conditions where public safety and/or health is at risk;
- not allowing the audit to be performed;

- not allowing the Regulatory Authority(ies) access to the premises;
- any other reasons which result specifically from these conditions or are agreed formally between TRNA and the client.

#### 4.3.2 Restoration of Certification

Following expiration of certification, TRNA will restore certification within 6 months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 audit shall be conducted.

TRNA will restore 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 by TRNA will result in withdrawal or reduction of the scope of certification.

#### 4.3.3 Revocation (Withdrawal) of Certification

If the certification is revoked (withdrawn), the certificate holder loses the right to use any trademarks, logos and ability to advertise or promote the certification.

TRNA has the right to revoke (withdraw) a certificate for the following:

- the certificate or certification is improperly used;
- the identification of one or more [grade 5 nonconformities](#) or [at least three grade 4 nonconformities](#) during a surveillance audit;
- 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 (determined by TRNA);
- 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 the financial obligations of TRNA;
- the certificate holder requests the cancellation of certification;
- the client does not have the periodic audits carried out according to the General Conditions and Procedural Guidelines for the Certification of Quality Management Systems or the client holds up or restricts the proper performance of the periodic audits.
- if permanent unannounced access to the premises of the manufacturer or his contracted critical suppliers is no longer assured

#### 4.3.4 Revocation of Certification Body's/Auditing Organization's Accreditation, Recognition and/or QMS Qualifications

In the event that the auditing organization's recognition are revoked, TRNA will make every effort to rectify the reasons leading to revocation. If this is not performed within a time frame agreed upon by the accreditation body or regulatory authority, then TRNA will transition all certified companies to another auditing organization that offers the same services and holds the same recognition.

## **5 Voluntary Withdrawal of Accreditation**

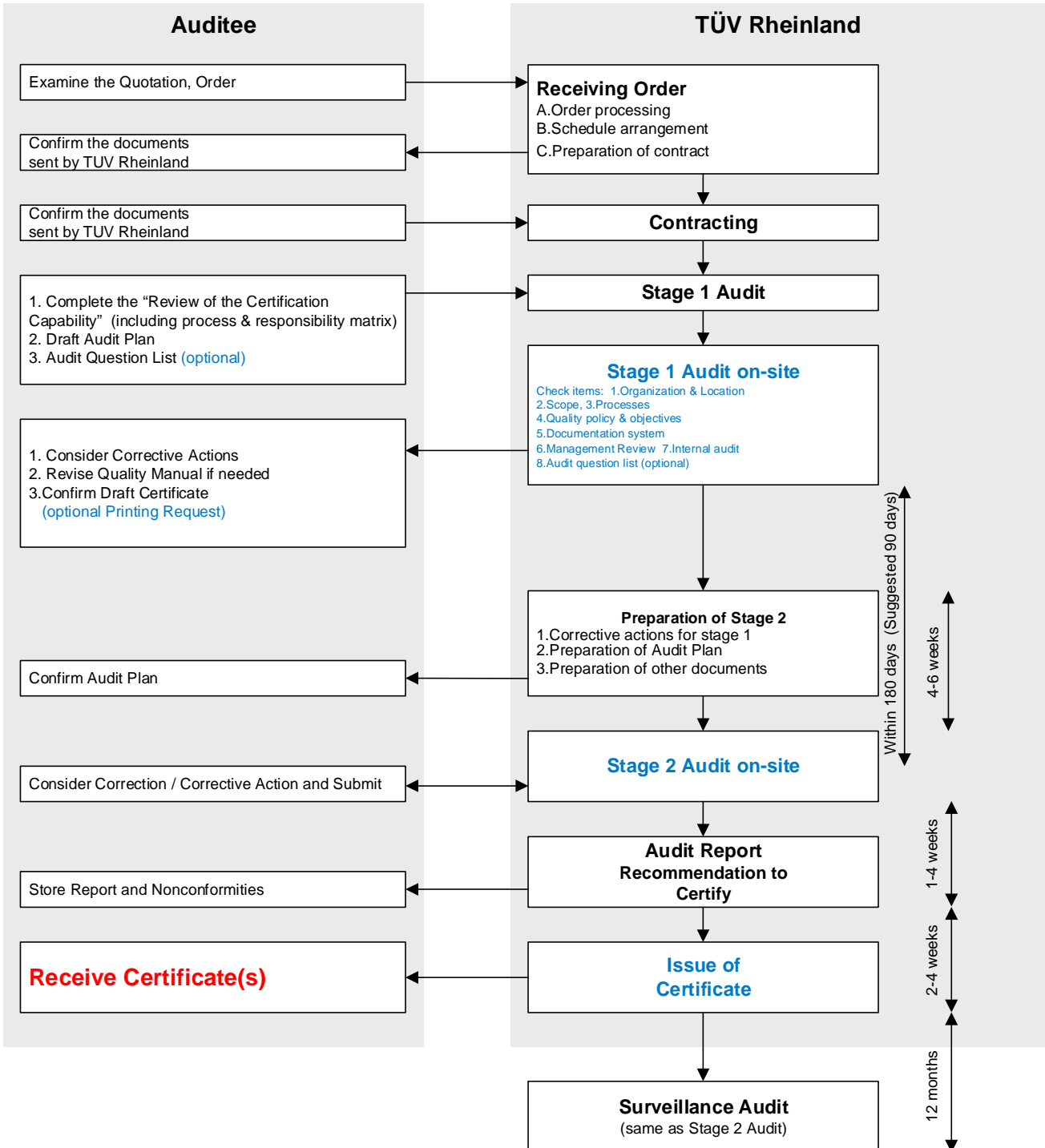
If TRNA chooses to voluntarily terminate its recognition, it will do so by means of a written notification sent to the involved regulatory authority within thirty (30) days. It is the responsibility of TRNA to provide any remedies to any certified companies affected by this withdrawal, appropriate to the nature of the problem that is acceptable to the regulatory authority and in accordance with program requirements. These remedies could include the notification of the withdrawal to the certified companies and any plans to transition the certified companies to another auditing organization that offers the same services and holds the same recognition to minimize any impact

felt by any certified company. Additionally, TRNA will cease to use any advertising materials containing reference to the recognition and will return any recognition documents to the respective regulatory authority. 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 Service Delivery Process



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