



Regulations for Certification of Quality Assurance and Quality Management Systems of SLG Prüf- und Zertifizierungs GmbH

Edition: 01/2011

1. Scope

These Regulations for Certification apply for the assessment and certification of quality assurance and quality management systems (hereinafter referred to as “QA/ QM systems”) conducted by SLG Prüf- und Zertifizierungs GmbH (hereinafter referred to as “SLG”) for their clients on the basis of valid laws and standards. If applicable, accreditation regulations and/or designation regulations are to be kept in addition.

2. Object

2.1 The certification process comprises the following contractual steps based on established procedures:

- Step 1: Performance of a preliminary assessment – project discussion (on request of the client) and/or of a stage 1 audit in case of initial certification in order to determine whether the requirements for certification are met
- Step 2: Assessment of documentation (if applicable during the stage 1 audit)
- Step 3: Conduct of the certification audit (stage 2 audit)
- Step 4: Issuing and registration of certificate, determining of modalities for surveillance and re-audits.

2.2 A contractual agreement shall be reached between the client and SLG prior to performance regarding the actual scope of services required.

3. Commitments of SLG

- 3.1 SLG is an independent provider of services. SLG provides their services to all clients equally without discrimination or delay.
- 3.2 SLG assesses the client’s QA/ QM system in each case depending on the actual order on the basis of the German Appliance and Product Safety Act (GPSG), the German Medical Devices Act (MPG), the standards DIN EN ISO 9001 and DIN EN ISO 13485:2003 and further relevant standards and directives. Assessments and certifications are conducted by qualified auditors in accordance with the procedures established at SLG and verified by independent bodies.
- 3.3 In case the QA/ QM system complies with all relevant regulations – documented in an audit report or final report QA assessment – SLG applies to the certification body for issue of the certificate, which shall be awarded provided that all requirements are met.
- 3.4 During the validity period of the awarded certificate (3 or 5 years) SLG shall conduct annual surveillances. In order to maintain the certification after this period a re-certification including a re-audit conducted within the period of validity of the original certificate is required. For re-certification services the client shall sign a new contract with SLG.
- 3.5 In case of refusing a certification, SLG shall account to the client in writing for their reasons. SLG shall not be liable for any disadvantages accruing to the client as a result of the refusal. Any new application submitted later than 6 months after the refusal of the certification shall require a completely new assessment including a new application.
- 3.6 SLG undertakes to hold in strict confidence all information and business secrets revealed to them by the client and not to use them for any other than the stipulated purpose. The obligation to observe confidentiality shall also extend to the time after termination of the contract.



- 3.7 The client is, however, aware that SLG is obliged to make public towards authorised bodies (e.g. authorities, steering committee, accreditation bodies, surveillance bodies, etc.) any refused, revoked, withdrawn, restricted, suspended and misused certificates and grant third parties access to documents available at SLG and/or provide them with such documents (also in copy). The release of information and provision of documents to such authorised bodies shall not be regarded as a breach of the confidentiality obligation.
- 3.8 Otherwise, SLG keeps all documents submitted by the client in accordance with the legal regulations.

4. Validity of certificates

- 4.1 The certificate granted by SLG contains all essential information concerning validity, certificate holder, location as well as the client's scope of business, of activities and of products.
- 4.2 The certificate becomes void on expiration of the stated validity and shall not be used anymore by the client afterwards. A re-audit may be conducted according to paragraph 3.4 including a new certification.
- 4.3 A certificate may be refused, revoked, restricted or withdrawn if the requirements for issuing or maintaining the certificate are not met or not met anymore or have never been met and if
- the client misuses certificates and approval marks of SLG or the accreditation body/designating body,
 - deviations or deficiencies in the QA/ QM system are found during surveillances and re-audits which no longer guarantee the compliance of the products or of parts of the certification scope with the essential requirements of the relevant directives and standards,
 - the client refuses surveillance actions,
 - the client fails to pay fees by their due date, which were stipulated in the contractual agreement and by the SLG fee scale,
 - authorities or other subordinate bodies legitimately demand the withdrawal of the certificate.
- 4.4 In any case, the approval holder shall be informed and heard prior to any intended change of the certificate status (amongst others according to 4.3). For certifications in the field of medical devices § 18 of the German Medical Devices Act (MPG) shall apply.

5. Commitments of the client

- 5.1 The client undertakes towards SLG to:
- support SLG in any surveillance actions taken to ascertain compliance with the certification rules and requirements,
 - submit all essential documents and procedure documents to the auditors appointed by SLG. All documents submitted remain with SLG. The client is responsible to make copies for his own records,
 - support SLG in conducting regular audits on the basis of stipulated audit plans and to grant access to all locations, equipment, materials and products required by the audit scope,
 - ensure the availability of personnel to be interviewed during the audit as well as one authorized representative of the client as required by the audit plan for determining, coordinating and for information.
- 5.2 The client is obliged to fulfil all legally required assertions concerning the QA system, in particular:
- the obligations arising from the approved QA system,
 - to keep the approved QA system adequate and effective,
 - to introduce and keep up to date a systematic procedure for reviewing experience gained from products in the post production phase and to implement appropriate means for taking corrective



action as well as to inform the relevant authorities and SLG immediately – in accordance with current laws and regulations – on any incidents arising.

- 5.3 The test mark of the QM system certification shall, however, not be used in relation with any product advertising (e.g. statements concerning the product's quality on the type plate or packaging, etc.).
- 5.4 The client shall inform SLG about intended changes of the QA/ QM system and/or the scope of products covered thereby. Any change may require an assessment by SLG. In any case, the client shall ensure that legal regulations and essential requirements on the QA/ QM system are fulfilled.
- 5.5 SLG conducts annual surveillances at the client's premises. The client pays all costs arising thereof to SLG according to the contractual stipulations.
- 5.6 The client shall record any customer complaints and inform SLG thereof.
- 5.7 The client shall inform SLG immediately about any recalls, incidents, near incidents and measures taken.
- 5.8 The client declares that he has not filed any application with any other certification body for assessment/ certification of his QA/ QM system.
- 5.9 The client facilitates Observed/ Witness Audits by the accreditation bodies or the participation of auditors-in-training in the production facilities of the manufacturer and his subcontractors.
- 5.10 Document check and audit reports and protocols shall be forwarded only in their full wording and stating the date of issue. A publication in part shall require SLG's prior written approval. The documents remain the property of SLG.

6. Rights of the client

- 6.1 During the validity of the certificate the client shall be entitled to refer in his legal relations to the awarded certificate and entitlement to use test marks derived thereof, always provided that he observes the legal regulations and other relevant standards and directives (in particular DIN EN ISO 9001, DIN EN ISO 13485). Furthermore, the client shall comply with the requirements of the SLG Mark Statute.
- 6.2 On the basis of an additional agreement, the client shall be entitled to use the SLG company logo in connection with the certification.
- 6.3 The client has the right to lodge complaints with SLG concerning SLG's decisions and determinations. Complaints are processed in accordance with the procedure stipulated in the QM system of SLG.

7. Infringements of these Regulations for Certification of QA/ QM systems

In case of infringements of these Regulations or of the SLG Mark Statute by the certificate holder, SLG shall be entitled to take corresponding measures, in particular in case of illegal use or misuse of SLG certificates and/or marks. Such measures may result in restriction, suspension or withdrawal of the SLG certificate and the entitlement to use test marks derived thereof.

8. Validity

- 8.1 These Regulations shall enter into effect on January 1st, 2011.
- 8.2 The present Regulations for Certification of Quality Assurance and Quality Management Systems are subject to constant changes, e.g. due to changes of legal stipulations, accreditation regulations and/or designation regulations as well as the generally acknowledged rules of technology and relevant standards and directives. Therefore, in each case the current version of these Regulations shall apply.