# Sterility Assurance Limited

# General Certification Policy

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| Document Approval | | | |
|---|---|---|---|
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## 1. General

Sterility Assurance Limited (SAL) is a registered company limited by shares, as provided for by the Companies Act 2006 of The United Kingdom of Great Britain and Northern Ireland. The principles outlined in this policy will be upheld by all shareholders, directors/officers, employees and contractors of the company.

SAL shall ensure that sufficient Professional Indemnity Insurance, Public Liability Insurance and/or Employers Liability (as appropriate) is in place, taking into account the nature of the certification services offered, the geographic location of those services, the financial turnover of the company and the number of employees and subcontractors.

SAL is financed independently from any other legal entity, with funding (if needed) sourced from Director Loans or other suitable creditors that do not compromise the impartiality of SAL.

SAL shall obtain its income solely from the certification services offered and profitability shall be maintained solely by ensuring audit and certification fees are set appropriately. No other financial incentives are permitted as these may compromise the impartiality of SAL. The following examples are presented as a non-exhaustive list of such forbidden incentives:

- Referral fees or commission paid from any related service providers, e.g., test laboratories, calibration or maintenance providers, training providers, consultancy providers…etc.
- Additional fees obtained for any preferential service, e.g., “fast track” service.
- Grants or other funding (besides audit and certification fees) from the NHS, Department of Health and Social Care, healthcare providers, manufacturers or any other providers to the sector serviced by SAL or any associated trade associations.

SAL shall ensure the principles outlined in ISO/IEC 17021-1:2015 and detailed in the subsequent sections of this document shall be used as the basis for the conduct of the company’s certification activities.

## 2. Impartiality

SAL’s certification decisions shall be based on objective evidence of conformity (or non-conformity) obtained through the auditing process described in this policy (and elaborated on further in Audit and Certification Policy, POL-02) and shall not be influenced by other interests of other parties.

SAL’s certification processes and activities shall be designed and implemented in such a way to minimise the risk of any associated person or body acting in their own interest, including but not limited to financial self-interest, such that the impartiality of the certification activities and processes are compromised.

It is SAL’s policy that no associated person or body shall review work completed by themselves, including but not limited to auditing the management system of a client to whom that person or body has provided management system consultancy (i.e., the participation in establishing, implementing or maintaining a management system), for a minimum of 2 years after such consultancy activities have been delivered. It is also SAL’s policy that no associated person or body shall audit the management system of a client if they have provided training to that client, for a minimum of 1 year after such training has been delivered.

SAL maintains a policy of not providing management system consultancy or internal audits on behalf of any clients. This applies equally to any other companies that are part of the same legal entity as SAL or under the organizational control of SAL. Additionally, SAL shall not outsource audits to any company or organisation that perform management system consultancy. However, SAL may use an individual auditor, individually contracted from such a company, provided all other aspects of this policy are applied in the process.

SAL's process for the selection of auditors and other personnel shall ensure that familiarity shall not compromise the process of obtaining objective evidence. This includes such measures as prohibiting audits or certification decisions being conducted by close family members of key personnel at our clients and through the use of regular rotation of auditors.

SAL shall not tolerate any coercion or intimidation in the delivery of certification activities, whether open or secretive. This includes a zero-tolerance policy towards coercion or intimidation from any person or body associated with our clients towards any persons or bodies associated with SAL. This also includes a zero-tolerance policy towards any coercion or intimidation from company shareholders, directors/officers, employees, contractors or any person or body associated with SAL towards auditors and/or certification decision makers. It is SALs policy not to join any industry alliance or association unless it has robust impartiality policies that prohibit discussion or any activity where there is a collective interest in certain certification outcomes.

If SAL or any associated persons or bodies has any links to any organization that provides management system consultancy, then it is SAL policy that they are prohibited from suggesting to any party whatsoever that SAL's certification activities are in any way linked to those of the management system consultancy organization, lest such a link be construed as an endorsement of either organisation on that basis.

SAL has implemented a robust process to identify, analyse, evaluate, treat, monitor, and document the risks related to conflict of interests arising from provision of certification to our clients, including conflicts arising from our relationships and from the activities of other persons, bodies or organizations associated with SAL. This includes, but is not solely limited to:

- Ensuring no relevant SAL personnel were involved in the design, manufacture, construction, marketing, installation, servicing or supply of the medical devices being certified, or any associated parts and services.
- Ensuring no relevant SAL personnel were involved in the design, construction, implementation, or maintenance of the quality management system being audited (as outlined above).
- Ensuring no relevant SAL personnel act as an authorized representative of the client organization, nor represent the parties engaged in these activities.
- Ensuring no relevant SAL personnel have a financial interest in the client organization being audited (e.g., holding stock in the organization).
- Ensuring no relevant SAL personnel are employed by a manufacturer producing similar/competitive medical devices.
- Ensuring no relevant SAL personnel are employed by a research or medical institute or as a consultant having a commercial contract or equivalent interest with the manufacturer or manufacturers of similar medical devices.

To this end SAL has appointed a committee of representatives from client organisations (or trade association(s) representing those organisations) and customers of those organizations (or trade association(s) representing those organisations) to consult on matters of impartiality, openness and public perception. SAL is committed to acting on the recommendations of this committee when implementing this risk management process.

## 3. Competence

Competence of SAL's personnel is critical to ensure the certification it provides is received with confidence by any and all interested parties. It is SAL's policy that any auditor, independent reviewer or certification decision maker (those roles crucial to ensuring compliance with the certified standards) meet the following criteria:

- They shall have either:
  - 4 years minimum work experience in the field of medical devices or related sectors, or
  - 2 years minimum work experience as above as well as successful completion of a bachelor's degree or higher in life sciences or related discipline.
- They shall have demonstrable knowledge of:
  - The applicable regulations and quality management system elements to the devices being certified.
  - The applicable technologies, risks and standards associated with the devices being certified.
- They have gained experience in the entire process of auditing medical device quality management systems, including review of documentation and risk management of applicable medical devices, parts or services, implementation audit and audit reporting.
- They have gained experience by participating as a trainee either in SAL or in another accredited certification body in a minimum of four audits for a total of at least 20 days, 50% of which shall be against ISO 13485, and the rest in any other accredited QMS program.
- Audit team leaders shall additionally have experienced as an audit team leader role under the supervision of a qualified team leader for at least three ISO 13485 audits.

## 4. Responsibility

It is the certified client, not SAL, that has the responsibility for consistently achieving the intended results of implementation of the management system standard and conformity with the requirements for certification.

It is SAL's responsibility to assess sufficient objective evidence upon which to base their certification decision. Based on audit conclusion, SAL will make a decision to grant certification if there is sufficient evidence of conformity, or not to grant certification if there is not sufficient evidence of conformity. Any audit is based on sampling and therefore cannot be construed as a 100% guarantee of conformity with requirements.

## 5. Openness

SAL is committed to the principle of access to, or disclosure of, appropriate information. More details about the information provided by SAL can be found in specific company policies as outlined below:

- POL-02: Audit and Certification Process Policy
- POL-03: Complaints, Appeals and Information Policy
- POL-04: Policy on Use of Certification Marks

These policies will be communicated with certified clients during the application process and will also be maintained on our website, www.sterilityassurance.co.uk, along with this policy, for all interested parties to see at any time.

## 6. Confidentiality

Confidential information refers to any data or information relating to the business of any certified client which would reasonably be considered to be proprietary to the client including, but not limited to, accounting records, business processes, and client records and that is not generally known in the industry of the client and where the release of that confidential information could reasonably be expected to cause harm to the client.

SAL will not disclose, divulge, reveal, report or use, for any purpose, any confidential information which has obtained during the course of auditing and certification activities, except as authorised by the client or as required by law.

## 7. Responsiveness to Complaints

SAL will investigate and respond to all complaints made by certified or prospective clients as well as any complaints received by SAL about certified clients. More details can be found in POL-03 (as detailed above).

## 8. Risk-Based Approach

SAL shall take into account any and all risks associated with providing consistent and impartial certification. This can include, but is not limited to:

- Risks associated with the audit objectivity.
- Risks associated with the conduct of audits.
- Risks associated with the impact of the audit on the client.
- Risks associated with legal, regulatory and liability issues.
- Risks associated with organizational reputation, both of SAL and its certified clients.