



Document Name	Complaints, Appeals & Information Policy	Doc. Ref.	POL-03
Issue Date	14 th November 2023	Issue No	1
Changes since last issue	N/A – First issue		

Sterility Assurance Limited

Complaints, Appeals & Information Policy

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Document Approval			
Name	Job Title	Signature	Date
Jack Walters	Commercial Director	 <small>Jack Walters (Nov 14, 2023 20:25 GMT)</small>	Nov 14, 2023
Brad Bold	Operations Director		Nov 15, 2023
Annette Callaghan	Technical Director		Nov 20, 2023

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1. Complaints

It is SAL's policy that any complaints received from clients, applicants or other interested parties must be made in writing (email is acceptable) and must clearly state the reason for the complaint. The Commercial Director is responsible for overseeing the complaints procedure, as they are independent of the audit and certification processes. Submission, investigation and decision on complaints shall not result in any discriminatory actions against the complainant.

An acknowledgement shall be sent to the complainant by email, within 5 working days of receipt, summarising the steps that shall be taken to investigate and act upon the complaint, as appropriate. If the complaint is from a third party in relation to a certified client, and is deemed valid by SAL, the client shall be informed of the complaint at an appropriate time. No details related to the certified client shall be shared with the third party unless previously agreed with the client in writing (see information policy, below).

2. Appeals

2.1. Appeals Against Audit Findings

All appeals against audit findings shall be made in writing to the Technical Director within 7 calendar days of the findings being communicated to the client. The client must clearly state the grounds for the appeal. The Technical Director shall acknowledge the appeal in writing within 5 working days of receipt summarising the steps that shall be taken to investigate and act upon the appeal, as appropriate.

Investigation of appeals will be assigned to an appropriately qualified independent party to ensure impartiality from any financial consequences of the outcome of the investigation. The outcome of the appeal investigation shall be communicated to the appellant in writing, by the Technical Director, within 30 calendar days of receipt. If it is determined that the appeal is valid and shall be upheld, either as a whole, or in part, the Technical Director shall act upon this decision accordingly. If the appeal is determined to be invalid, the client shall be informed, and their file shall be updated with details of the decision.

2.2. Appeals Against Certification Decisions

All appeals against certification decisions shall be made in writing to the Commercial Director within 30 calendar days of the decision being communicated to the client. The client must clearly state the grounds for the appeal. The Commercial Director shall acknowledge the appeal in writing within 5 working days of receipt. summarising the steps that shall be taken to investigate and act upon the appeal, as appropriate.

Investigation of appeals will be assigned to an appropriately qualified independent party to ensure impartiality from any financial consequences of the outcome of the investigation. The outcome of the appeal investigation shall be communicated to the appellant in writing, by the Commercial Director, within 30 calendar days of receipt. If it is determined that the appeal is valid and shall be upheld, the Technical Director shall act upon this decision and revise the certification decision as appropriate. If the appeal is determined to be invalid, the client file shall be updated with details of the decision.

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3. Information

3.1. Public Information

Upon request, SAL will provide the following information:

- Geographical areas in which SAL operates and any other information about certification schemes offered.
- The status of a given certificate.
- The name, related normative document, scope and geographical location (city and country) for a specified certified client.

Any other information about a certified client shall be treated as confidential, as outlined below.

3.2. Confidential Information

Information gathered during the performance of certification activities may be divulged by SAL to the United Kingdom Accreditation Service (UKAS) as part of the monitoring of SAL's management system, however confidentiality agreements shall be maintained preventing UKAS from divulging this information to any other parties, unless expressly required by law.

Confidential information may also need to be divulged by SAL to regulatory authorities such as the Medicines and Healthcare products Regulatory Agency (MHRA) as required by law following SALs certification activities.

With the exception of the previous 2 scenarios and the public domain information stipulated above, it is SALs policy not to divulge any confidential information to any third parties without the express written consent of the certified client.

To this end, SAL will maintain appropriate legal agreements with all employees and contractors preventing them from releasing such information.

3.3. Notice of Changes

SAL policies are communicated with clients as part of the proposal process and are displayed on our website. When a change is made to any of our policies, our certified clients will be contacted via email with an overview of the change and a direction to review them on our website. Confirmation of receipt of change notices will also form part of the opening meeting of each routine audit.

Certified clients are required to notify SAL of any of the following changes, as soon as possible after knowledge of such an impending change is confirmed and before such a change is implemented, as far as is reasonably practicable:

- Legal, commercial, or organizational status or ownership
- Management structure or key staff changes (e.g., management rep)
- Changes to contact details (e.g., names, email or phone details)
- Certified address(es) and/or certified departments
- Scope of certified operations and/or applicable standards
- Major changes in the quality system structure or processes
- Change to critical suppliers or subcontractors.
- Changes in staff numbers (full time equivalents) that move the client into a new category as follows:

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|----------|-------------|--------------|
| ○ 1-5 | ○ 126-175 | ○ 2026-2675 |
| ○ 6-10 | ○ 176-275 | ○ 2676-3450 |
| ○ 11-15 | ○ 276-425 | ○ 3451-4350 |
| ○ 16-25 | ○ 426-625 | ○ 4351-5450 |
| ○ 26-45 | ○ 625-875 | ○ 5451-6800 |
| ○ 46-65 | ○ 876-1175 | ○ 6801-8500 |
| ○ 66-85 | ○ 1176-1550 | ○ 8501-10700 |
| ○ 86-125 | ○ 1551-2025 | ○ >10700 |

Certified clients are also required to notify SAL of any serious incidents, i.e., any incident where a deficiency in the certified clients quality management system and/or products released by the certified client’s quality management system, have resulted in any of the following:

- A serious public health threat.
- Led, or might have led, to the death of a patient, user, or other person.
- Led, or might have led, to the temporary or permanent serious injury of a patient, user, or other person.

SAL-15 is the appropriate form for clients to report changes or serious incidents. A copy of this form can be requested at any time from info@sterilityassurance.co.uk.