Sterility Assurance Limited

Audit and Certification Process Policy

Contents

Document Approval			
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1. Locations Covered

Sterility Assurance Limited (SAL) resides and operates only within the United Kingdom.

2. Application

It is the responsibility of the Applicant to provide the most accurate information to the best of their knowledge during the application process. SAL will review all applications to determine the applicants' organisations activity, sites and locations, factors affecting certification activity and the Impartiality and availability of competence of the resources of SAL. SAL shall retain the right to accept or decline any application (with an informed justification). Once the application process be complete, a proposal shall be finalised by Sterility Assurance Limited (SAL) (including an audit programme), along with a certification agreement from the application stage, and in line with mandatory standards. SAL retains the right to amend any proposal, agreement and audit programme should the information provided at the application stage be intentional or unintentionally inaccurate.

The application process shall require the following information as a minimum from the client seeking certification:

a) The desired certification standard
b) Relevant details of the applicant organisation as required by the specific certification scheme, including its name and the addresses of its site(s), its processes, and operations, human and technical resources, functions, relationships and any relevant legal obligations.
c) Identification of outsourced processes used by the organisation that will affect conformity to the requirements.
d) Whether consultancy relating to the management system to be certified has been provided and if so, by whom.

3. Audit Programme

As the responsibility of the certification body, SAL will construct and provide the client with an audit programme in the proposal covering a 3-year period of certification. The audit programme shall be used to monitor and plan audits throughout the certification process at defined intervals. The audit programme shall include the following audits in the following order during a certification cycle (also see appendix 1):

Year 1	Initial Certification*/Recertification audit	Full system audit
Year 2	Surveillance audit	Partial system audit
Year 3	Surveillance audit	Partial system audit

*Applicable to the first audit cycle only

SAL shall perform audits annually as a defined interval. It will be the responsibility of SAL to notify clients of upcoming audits due to be performed with a reasonable amount of notice, and no less than 30 days before the planned audit date. In order to allow efficient planning, SAL and in turn clients shall be amenable within reason to planning audit dates.
Should SAL and the client not be able to agree on audit dates within the due date, plus the allowance (see table below) SAL shall reserve the right to suspend the certification status of the client as a last resort should the validity of the certification be compromised.

Audit Type	Due Date (i.e., latest date allowable)	Target Date
Initial – Stage 1	N/A	Client to be notified of expected lead time during application process
Initial – Stage 2	6 months after Stage 1 Audit (further extension possible if there is suitable justification)	3 months after Stage 2 audit (can be sooner or later, justification to be provided in the stage 1 report)
Recertification	3 years after initial certification decision date and then each 3-year anniversary thereafter, minus 30 days.	60 days before the due date
1st Surveillance after initial certification.	1 year after initial certification decision.	30 days before the due date
All other surveillance audits	1 year after the anniversary of the initial certification decision date (or recertification decision date if there is a gap in certification), plus 30 days	30 days before the due date

SAL aims to perform recertification audits at least 30 days before certification expire to allow sufficient time for post audit activities and certification decisions to be completed before the expiry of the current certificate. If the audit is performed after the due date because of restrictions in client availability, SAL shall not be held responsible for any lapse of certification.
Suspension shall be lifted with immediate effect once the due audit has been completed, by written confirmation that an audit with an outcome of "recommend continuation of certification" has been completed.

4. Audit Planning

Prior to conducting the audit, a detailed audit plan shall be developed, considering the scope, objectives and criteria of the audit, and in line with SAL procedures. The audit plan shall be sent to the client as soon as possible, but no less than 2 weeks prior to the audit, allowing adequate time for communication and amendment of the plan between auditor and client. The auditor shall reserve the right to change the audit plan at any time, and during audit activities should the auditor see reason too, e.g.: increased efficiency, status of importance, unforeseeable circumstances. Communication of such changes shall be immediate with the client.
Where the client has failed to communicate any changes or expected delays that may compromise audit time, the client will remain liable for SAL's time expenditure at the agreed rate documented within the proposal.

5. Conducting audits

The conduct, impartiality, competence, openness, and professionalism shall be expected of both auditor and auditee as detailed in SAL's POL-1 General Certification Policy.
Auditors shall conduct audits to the defined audit plan with exception to any changes as covered in section 3 of this policy. Auditors shall be required to document all evidence of compliance/non-compliance during the audit. The client shall be kept up to date of all findings as soon as the auditor is aware.

Any delays to the audit as results of the clients' conduct shall be recorded in the audit report, if deemed to compromise the outcome of the audit. Should the audit time be extended as a result, the client shall remain liable at the agreed rate documented within the proposal.
Clients will be required to be fully open and facilitate the audit with out undue delay.

6. Non-conformity Management

Non-conformities identified during the audit shall be communicated to the client, who will be given an opportunity to address and correct them within a specified timeframe (see table below).

SAL shall grade CARs as either a minor or major according to the following rationale and managed accordingly.

Category	Rationale	Time frame of CA
Minor CAR	- Non-conformance with a non-regulatory standard clause where the clause is only partially met. - Non-conformance with a regulatory standard, where safety and performance of the device and risk to patient is justified as low.	Auditee shall perform the corrective action for SAL to Follow-up at the next audit.
Major CAR	- Complete absence of conformity to a standard clause, or where systemic failure is seen such as multiple minor CARs associated with the same requirement or issue. - Where significant doubt that effective process control is in place, or that product or services will meet specified requirements. - Non-conformance with a regulatory standard, where safety and performance of the device and risk to patient has been demonstrated or is reasonably foreseeable.	Immediate taking into consideration of risk versus required action. Maximum time allowed = 6 months.

The rationales for potential CARs shall be presented in the opening meeting by auditor in order to establish complete openness of the process for a non-conformity.

Management of Majors CARs

Where Corrective action has been performed by the client but not completed in entirety to remove root cause the corrective action shall be assessed for removal of risk to patient. Where risk to patient is deemed no longer present by the auditor, shall be reduced a minor and closed at the next onsite audit.

Where the action has not been sufficient to remove risk to the patient, SAL shall evaluate the status of certification and consider suspension of the certificate until such time the risk to patient has been removed. If action remains at this point but with no risk to patient, SAL shall re-instate the clients certificate but follow up at the next audit for complete closure of remaining actions.

Where the client has no demonstrated any effort to complete corrective actions of a Major CAR, the client certification status shall be considered immediately for suspension.

Management of Minor CARs

Where the client has demonstrated sufficient effort to complete corrective action but the verification has been ineffective, the minor CAR shall remain open and closed at the next onsite audit.

Where the client has demonstrated no effort to complete corrective action the CAR shall be upgraded to a MAJOR CAR in order to force urgency in corrective action from the client.

The assessment of upgrading and down grading CARs shall be assessed by the responsible lead auditor documented in the CAR form.

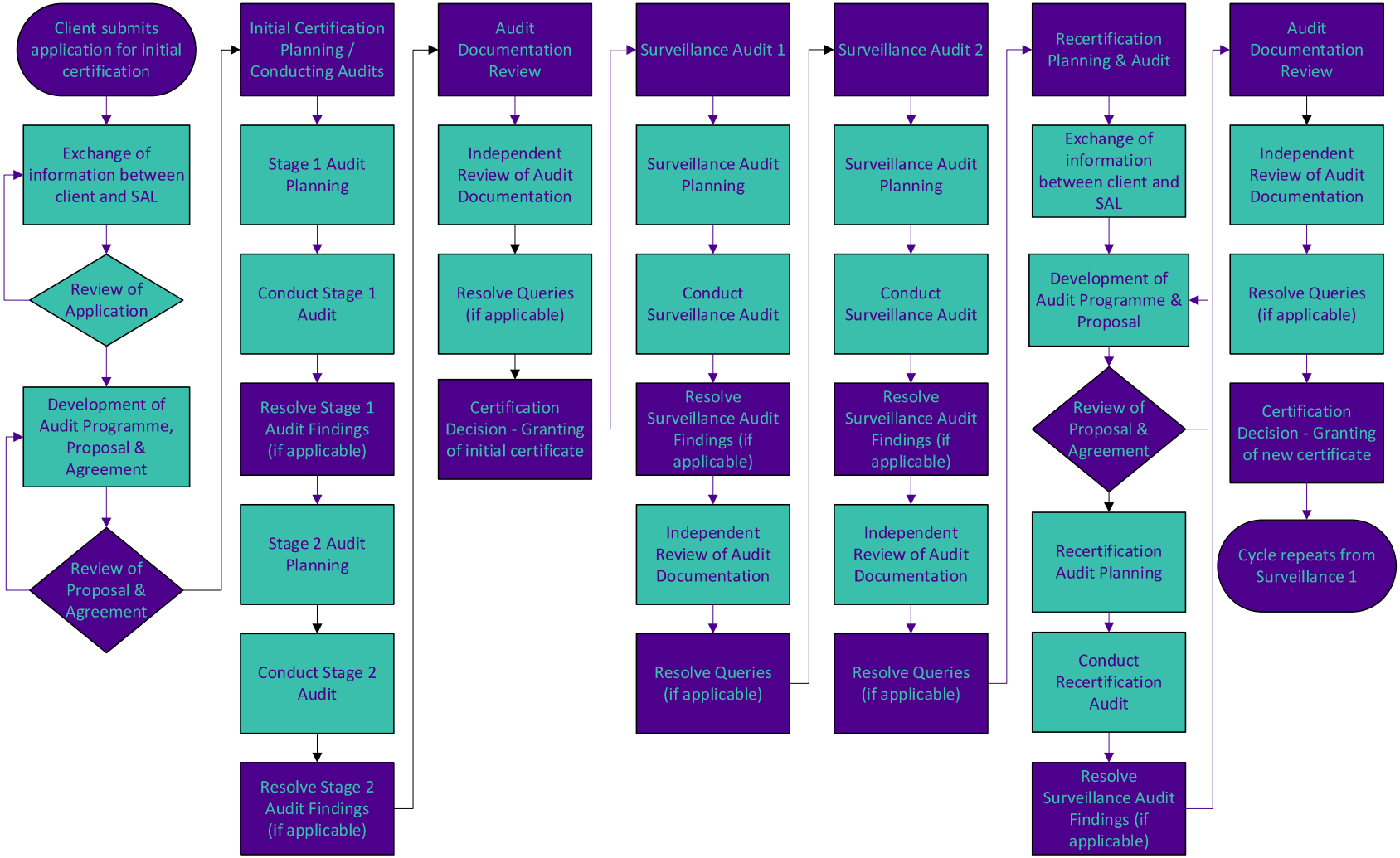
The client shall be held liable for any extra time required to manage and close CARS, taking into account the complexity and number of corrective actions to assess and close either remote, at the next audit or if a special audit is required onsite to close open CARs. Extra time shall be recommended by the auditor and charged to the client at the rate agreed at the proposal stage. Where a special audit is required, travel expenditures will be included at the cost to the client.

Where CARs are drawn against individual activities within the certification scope, SAL may look to reduce the certification scope instead of suspension of the full certification scope, where feasible.

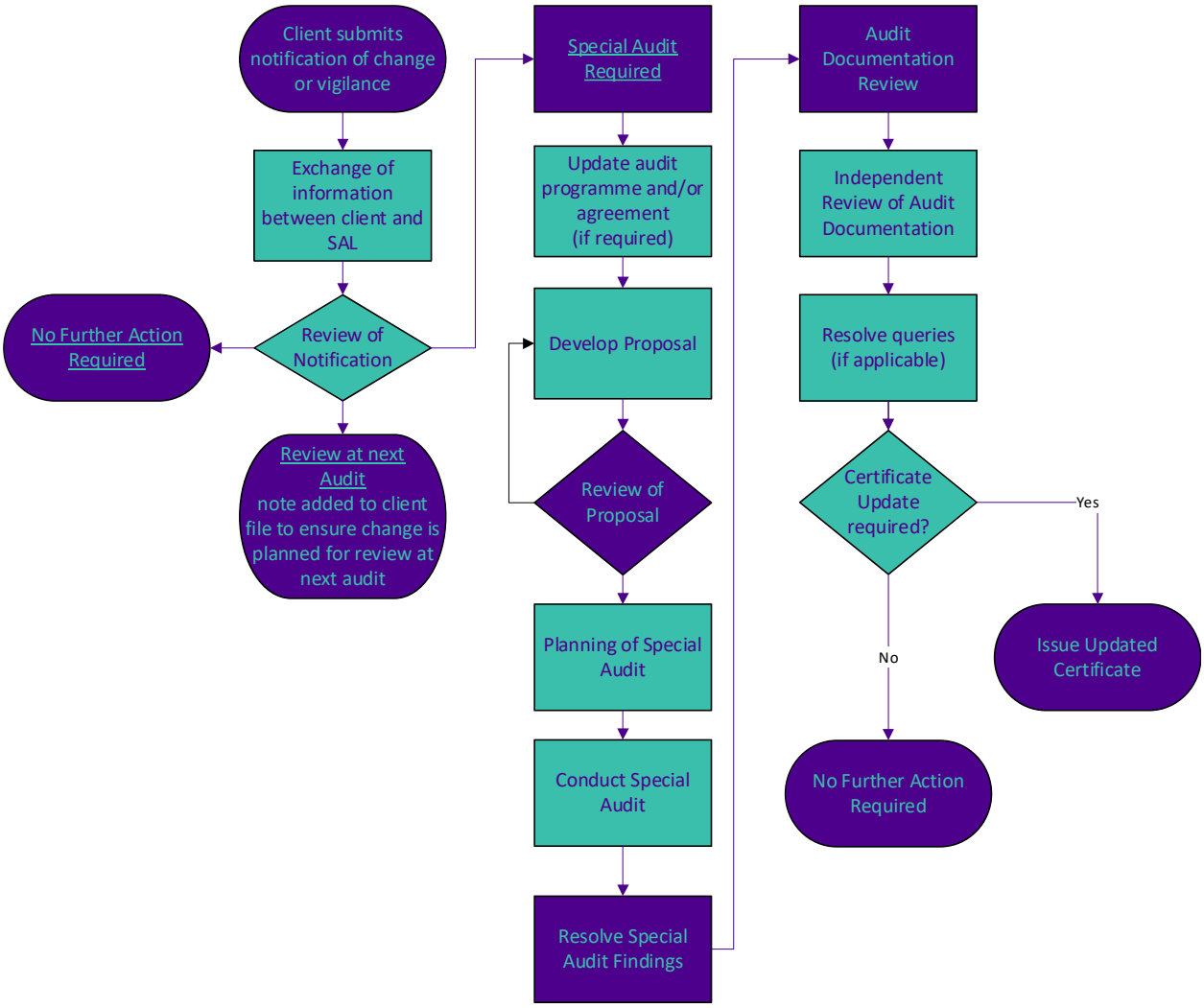
7. Granting Certification

Once the certification decision has been made, SAL shall provide certificates via the contact details provided at application within 30 days of the certification decision been made.

Appendix 1 – Routine Audit Process Flowchart



Appendix 2 – Special Audit Process Flowchart



Appendix 3 – Transfer Audit Process Flowchart