Quality Procedure QP81-2

1.0 Purpose

Plan and control of services for certification of Quality Management Systems (QMS).

2.0 Responsibility

SSI Manager and authorized staff is responsible to implementation this procedure.

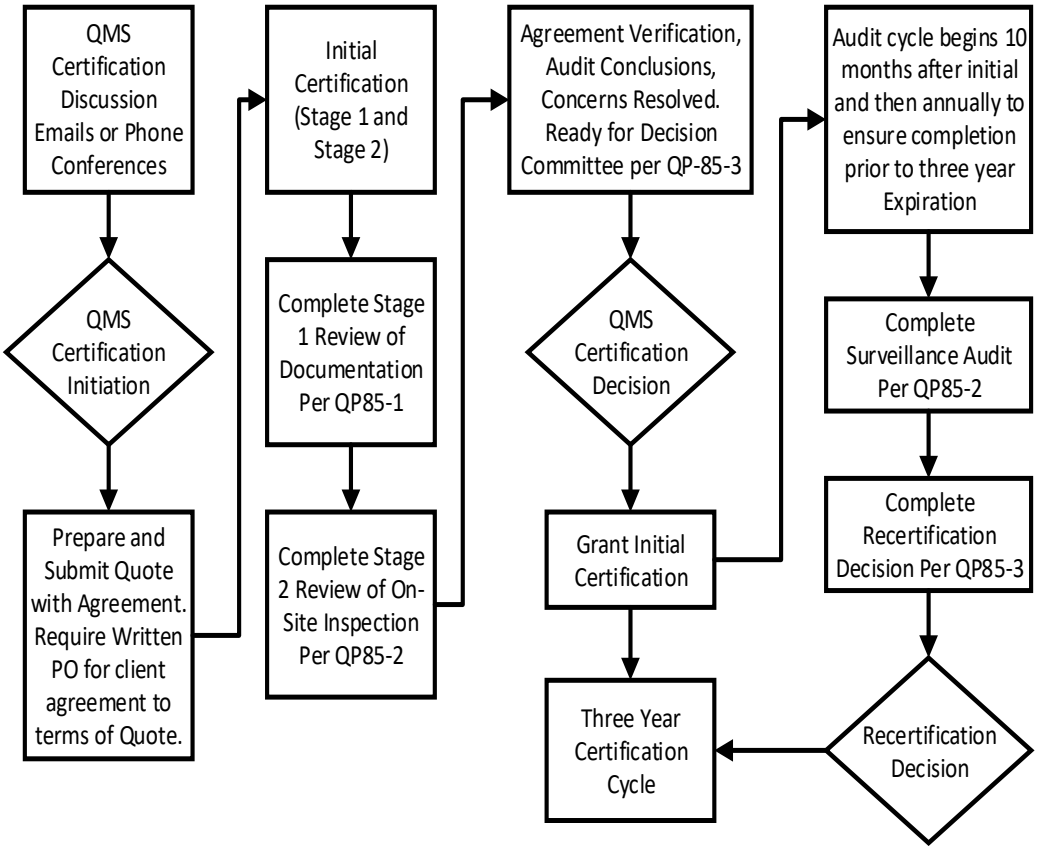
3.0 Risk Management

If any concern arises, then a condensed version of risk shall be applied that includes identifying the problem, failure modes, consequences, and probability of consequence. Review based on risk and use QP61-1 for and in-depth risk analysis.

4.0 Schedule

This procedure describes process for continuous use.

5.0 Process (Certification, Factory Inspection & Ongoing Inspections)



This process applies to all work for QMS Certification per ISO 17021.

Step	
1	Based on communication, a decision is made to initiate QMS certification.
2	Prepare Quote per QP82-1. Initiate contract and any changes to the contract per sales order process QP82-1. A written PO is required to start phase 1.
3	Schedule Activities on SSI Calendar. Work with client for coordination of documentation delivery for review.
4	Review certification documentation per QP85-1. Review QMS: QMS shall conform to appropriate edition of ISO 9001.
5	Identify any concerns with the documentation and resolve with client. The concerns shall be completed prior to continuing to stage 2 (factory audit). There is no limit to completing stage 1.
6	QP85-2 contains a typical audit agenda for performing the on-site factory audits. This agenda shall be sent to the client prior to the audit.
7	Perform factory audit per QP85-2. The inspector shall obtain client concurrence with results (sign signature page of procedure). The inspector(s) shall provide a copy of the results with any Corrective Action Requirements (CARS) to the client. CARs shall be categorized as “Major” or Minor”. **Major** is a nonconformity that significantly affects the likelihood of the management system obtaining intended results. It places substantial doubt that an effective control process is in place, and doubt that the product or service will meet specified requirements. **Minor** does not significantly affect the management system from obtaining specified service or product. It may be a finding that could lead to nonconformity if left unattended indefinitely. Note, an accumulation of many minor CARs related to the same process, may constitute a major CAR. Office staff will type results and file in client electronic folder with scanned/embedded signature page with signatures.
8	Track completion of all CARs. When all CARs are completed with SSI concurrence, document results and supporting documentation in the electronic database. Major CARs must have verified evidence of correction. Minor CARs may be resolved with a response explaining plan to resolve or justification for maintaining the management system. All CARs should be completed within 120 days for the initial QMS certification and 60 days for annual interim audits. If the CARs are not resolved within the designated days, the certification process may be suspended, or new audit (including additional costs) may be imposed. If corrective actions for major CARs are not resolved within 6 months of the inspection, then another onsite inspection shall be performed prior to continuing certification decision process.
9	Prepare for certification decision by completing QP85-3. SSI management to review and

	documentation supporting the certification decision. A third-party employee is added to the decision committee to ensure an impartial review is someone not involved with the audits in phase 1 or phase 2. This includes ensuring that all the documented information is maintained in the SSI database.
10	When the decision is made, a Certificate is issued to the client. Transmit Logo to client for use on equipment labels.
11	SSI management shall verify client electronic database documents are complete, issue final invoice for work completed, and close work order.
12	Determine schedule and update audit calendar file. The first surveillance audit shall be scheduled 10 months after certificate is issued and then annually until recertification.

6.0 Suspend/Revoke/Change Scope of QMS Certification

SSI maintains the option to revoke a certification if the client's QMS has persistently or seriously failed to meet the compliance requirement for the effectiveness of the management system. A certification may be revoked if the client does not allow surveillance or recertification audits. A certification may be revoked if the client requests the certification to be suspended. Under suspension, the certification is invalid.

A change is scope will be reviewed under the contract and amended as required. Changes in scope shall be reviewed for stage 1 if changes involve the clients QMS documentation. An additional surveillance audit shall be determined to be required if the change in scope adds new product lines. A reduction in scope will be accepted without additional reviews and the standard surveillance audits will be maintained.

SSI shall restore the certification if the issue that caused the suspension has bee resolved. The client may appeal any certification decisions per QP82-4.

7.0 Transfer of QMS Certification

The process to transfer an existing QMS certification is simply to provide the certificate with the body providing the certification. If the body is accredited as an QMS certification body then the existing schedule for recertification will be maintained. The schedule for intermittent audits will be scheduled based on the SSI QMS certification process **QP81-2**. The full QMS documentation must be submitted when a decision is made to accept the transfer.

8.0 Evidence of Compliance; Electronic Complaint Log

Production documents shall be controlled in client folders. See QP81-2F, R0 for tracking the completion of all steps for completing audits.