Supplier Quality Manual

Version 2017

Applicable for supplying to

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And all other LINAK sub-contractors worldwide

jointly referred to as "**LINAK**"

Preface

It is LINAK's intention to make long reliable relationships with all suppliers, in order to integrate all areas of business and create a strong trusting line of communication. First step in this process is communicating the requirements of being a LINAK supplier. LINAK have therefore created this uniform guideline for all Suppliers providing LINAK with materials, products, processing and related services, including intra-company Suppliers, and when applicable, to Supplier sub-tier sources.

All suppliers/companies doing or wanting to do business with LINAK must conform to the guidelines stated here in the Supplier Quality Requirement Manual. This manual will act as an instruction for how LINAK do business with their suppliers e.g. assessment, evaluation, qualification, basic demands and how these relationships are managed.

This document describes LINAK's requirements to suppliers' level of quality and service. This will serve as a communication tool of LINAK's quality, supply chain and purchasing philosophy when interacting with suppliers. The document will continuously be revised and controlled to ensure current quality- and business processes are being met and therefore and up-to-date version will always be available.

If you after reviewing the following information and still have questions to LINAK's supplier quality management or have questions regarding this manual, please address them to:

Headquarters:

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Or your local LINAK contact person

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LINAK's suppliers are welcome to use this Quality Manual as a guideline in development of their own quality system. LINAK is willing to integrate supplier into business processes if it is in the interest of LINAK's stakeholders; customers, subsidiaries, shareholders, employees, suppliers and communities.

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Introduction

LINAK

LINAK is a world leader in electric linear actuation, developing electric linear actuators and actuator control systems used in a variety of applications. Our complete range of products includes actuators, lifting columns, control boxes, controls and a wide range of accessories.

LINAK is a globally recognized for high quality, technically advanced, innovative solutions that reach the marketplace as innovative products giving both our customers and us a strategic advantage.

The LINAK mission is to provide innovative actuation solutions that improve people's quality of life and working environment.

Our suppliers

LINAK co-operated with suppliers from all over the world. Our supplier range from local business to global companies exporting high volumes globally. LINAK recognizes the very important role each our Suppliers have in the value we offer our customers. As an extension of our own operations, we rely on our Suppliers to provide material, products, and services, which meet all of the requirements of LINAK contracts, applicable specifications, and the quality management requirements outlined herein.

Supplier Quality Policy

- LINAK is purchasing based on the zero defect principle.
- LINAKs supplier shall maintain a quality system that meets ISO9001, TS16949, ISO13485 or similar.
- LINAKs Suppliers must sign and comply with the Quality Agreement

Supplier Quality Values

Our Supplier Quality Values explains how we implement our Supplier Quality Policy

The Supplier Quality Values assists both LINAK and our Suppliers in aligning our Expectations, attitudes and thereby increases quality and minimises quality costs.

At LINAK, we strive for the following 6 Supplier Quality values:

- At LINAK, we strive for clear and understandable requirements.
- At LINAK, we strive for our Suppliers to have the capability to consistently fulfill LINAKs requirements.
- At LINAK, we expect our suppliers to continuously strive for improvement.
- At LINAK, we strive for having effective communication with our Suppliers.
- At LINAK, we strive for having global partnership with our suppliers.
- LINAK clearly convey our expectation to our suppliers in our Code of Conduct.

Supplier Code of Conduct

The LINAK Supplier Code of Conduct is designed to support LINAK's process for identifying suppliers that demonstrate a firm commitment to safety, ethics, the environment and continuous improvement. We strive to utilize only those suppliers who can adhere to the Supplier Code of Conduct and who can provide us with world-class goods and services with the lowest total cost, best on time delivery, shortest lead-time, exceptional quality, unique capability, and a high level of customer responsiveness.

This Supplier Code of Conduct clearly outlines LINAK's expectations concerning the supplier relationship. We are committed to providing a solid basis for our relationship built on the principles of law, fairness and efficiency. As such, LINAK expects suppliers to follow the code of conduct based on adherence to all applicable laws and regulations with respect to conducting business. These expectations must also be followed by our suppliers' employees and they should be communicate to you sub-tier suppliers.

LINAK adheres to the principles of this Code and expects the same of its suppliers.

LINAK recognizes the Universal Declaration of Human Rights (1948) and the core labor conventions of the International Labor Organization and we expect our suppliers to share our commitment.

This means:

- All suppliers must provide a safe and healthy working environment for all employees.
- Employees must have freedom of association and the right to collective bargaining consistent with applicable local laws.
- Suppliers should refrain from all forms of forced labor.
- Working time shall not exceed the legal limit.
- Suppliers should refrain from using child workers as part of their normal workforce (below 15, or 14 years in countries with ILO exemption).
- Suppliers should refrain from discrimination.
- Suppliers should support a precautionary approach to environmental challenges and work actively to reduce environmental impact.
- LINAK does not accept bribery and corruption and expects its suppliers to refrain from corrupt practices.

If this Code conflicts with national law, the local law will always be followed. In this case, LINAK should be notified.

Compliance:

- LINAK reserves the right to monitor suppliers to ensure compliance with the LINAK Code of Conduct.
- LINAK is willing to engage in dialogue with the supplier to develop a corrective action plan, with appropriate improvements and time for implementation.
- If improvements do not progress LINAK reserves the right to terminate the contract.

Conflict Minerals

The American Congress has adopted a law concerning the use of so-called “conflict minerals”. The “Dodd-Frank Wall Street Reform and Consumer Protection Act” requires U.S. listed companies to disclose whether their products contain “conflict minerals” necessary to the functionality or production of the products and to disclose whether these materials originate from the Democratic Republic of Congo and surrounding countries.

“Conflict minerals” or “3TG” refers to **Tin, Tantalum, Tungsten and Gold (**the derivatives of cassiterite, columbite-tantalite and wolframite).

LINAK is not a U.S. listed company and as such not directly in scope of the Dodd-Frank Act but many of our customers are. They require LINAK as their supplier to provide information regarding these minerals. Therefore, LINAK has decided to impose the reporting requirements on its global supply chain.

LINAK strongly urges all suppliers to undertake the following actions, which are similar to the actions required by other manufacturing companies and aligned with the actions required by our customers.

Step 1 is a general registration – step 2 is reporting of possible supply of conflict minerals to LINAK. We urge you to use the iPoint Conflict Mineral Platform, but as a minimum, you are required to use the EiCC-GeSI Conflict Minerals Reporting template.

If, for some reason, you cannot sign up for iPoint, we require that you use the EICC-GeSI Conflict Minerals Reporting Template to report all data about conflict minerals and smelter to LINAK.

The EICC-GeSI Conflict Minerals Reporting Template is available here:

http://www.conflictfreesmelter.org/documents/EICCGeSIDDtemplate.xlsx

Submit a company-level report including, if known, the smelter data, for all uses of the designated minerals and derivatives in the iPoint tool (or through the EICC-GeSI Conflict Minerals Reporting Template) for any materials, components or products supplied to LINAK. Document all steps taken to collect and report “conflict minerals” information and preserve that documentation.

General requirements

Quality System Requirements

Suppliers shall maintain a Quality Management System (QMS) suitable to the products and services provided to LINAK, that is certified by an accredited third-party certification body to the latest version of the following, as applicable:

- ISO 9001 - Quality Management System Requirements[1]
- ISO/TS 16949 - Quality System Requirements (Automotive, Truck & Heavy Equipment)
- ISO 13485 - Quality Management System Requirements (Medical)

In the absence of third-party certification, depending on the product, its application, value, and criticality, the LINAK Buyer and Quality representative may authorize the acceptance of other evidence of compliance. This may include second-party (LINAK) audit or first-party (self) assessment to the applicable criteria above, or to a set of alternative basic quality requirements.

Calibration Suppliers - shall establish and maintain a measurement management system that is in compliance with either:

ANSI/NCSL Z540 - Calibration Laboratories and Measuring & Test Equipment Requirements, or ISO 10012 - Requirements for Measurement Processes and Measuring Equipment, or
ISO/IEC 17025 - General requirements for the competence of testing and calibration laboratories

Commercial-Off-The-Shelf Suppliers (COTS) - Suppliers that provide commercial products shall establish a QMS in compliance with ISO 9001, or equivalent.

Quality Manual

Upon request, the Supplier shall furnish LINAK with a copy of the Supplier’s Quality Management System Manual, which is to be current and approved by the Supplier's management, including or referring to related documents. The quality management system documentation shall include Supplier’s statements of a quality policy and quality objectives. Top management shall define quality objectives and measurements, which should address customer expectations and be achievable within a defined period of time. The Supplier shall promptly notify LINAK of any substantive changes to the Supplier’s quality management system or personnel.

Change control

The Supplier shall have a process to ensure that relevant versions of applicable documents furnished by LINAK (as well as those specified of external origin) are available at points of use. The Supplier is responsible for the timely review, distribution and implementation of all LINAK engineering standards/specifications and changes in accordance with the schedule required by LINAK. Timely review should be as soon as possible, and shall not exceed two working weeks. The Supplier shall maintain a record of the date on which each change is implemented in production. Implementation shall include updated documents.

Suppliers shall not make changes to their processes, location, facilities, equipment, material, product design (or any change which may affect product design or function) without written approval from the LINAK for:

- Correction of a discrepancy on a previously submitted part;
- Product modified by an engineering change to design records, specifications, or materials; or

- Any planned changes by the Supplier to the design, process, or manufacturing location, such as:
    - Use of other material than was used in previously approved part or product
    - Production from new, additional, replacement or modified tools, dies, molds, patterns, etc.
    - Production following upgrade or rearrangement of existing tooling or equipment
    - Production from tooling and equipment transferred to a different plant site or from an additional plant
    - Change of sub-tier Supplier for parts, nonequivalent materials, or services (e.g. heat treating, plating, etc.)
    - Product produced after tooling has been inactive for production for 12 months or more
    - Change to test/inspection method – new technique (no effect on acceptance criteria)
    - For bulk materials: new source of raw material from new or existing Supplier, or change in product appearance attributes, etc.
    - Use of any non-conventional manufacturing methods such as electro-discharge machining (EDM), electro-chemical machining (ECM), laser or abrasive water jet metal cutting, flame spray coatings, etc.

Control of sub-suppliers

The Supplier, as the recipient of the contract, is responsible for meeting all requirements, including work performed by the Supplier's sub-tier Suppliers (also known as Sub-Suppliers or subcontract Suppliers). When the Supplier uses sub-tier sources to perform work on products and/or services scheduled for delivery to LINAK, the Supplier shall include (flow-down) on contracts, to its sub-tier sources, all of the applicable technical and quality requirements contained in the LINAK contract. This includes quality system requirements, regulatory requirements, the use of LINAK designated sources, and the requirement to document and control 'key characteristics' and/or 'key processes,' and to furnish certifications and test reports as required.

Supplier facility access

LINAK may at any time conduct an audit at the premises of the supplier and/or their sub-contractor, or have the audit conducted by a third party, except from any competitors of the supplier. The supplier must have all relevant information ready for the auditor, both for audit preparation and during execution of the audit. LINAK reserves the right to perform an audit in cases where significant quality problems arise, or at agreed audits.

Statutory and regulatory requirements

LINAK expects all suppliers to comply with all international and national applicable statutory and regulatory requirements.

Legal disputes, if any, must be settled according to Danish law unless otherwise have previously been agreed by both parties.

LINAK is providing products to the medical industry and must therefore be compliant with the European Medical Device Directive and meet national and international regulatory requirements to risk management

for medical devices. That means LINAK follows ISO 14971 for medical Risk Management standards as required by the IEC 60601-1 3rd Edition, harmonized under the Medical Device Directive.

LINAK is certified in ISO 14001 “Environmental Management System”, DS/OHSAS 18001 “Occupational Health and Safety” and ISO 9001 “Quality Management”. This requires that LINAK’s suppliers are trying to meet the requirements from the respective standards. It is not necessary for a supplier to be certified in these areas, however it is important to LINAK that the suppliers tries to meets these standards and that the supplier is ensuring continuous improvement.

At LINAK, there is a requirement to follow these regulations WEEE, REACH and RoHS. WEEE is a European directive on disposal of electric and electronic equipment. REACH is European regulation on chemicals. RoHS is a directive that restricts the use of hazardous substances in electrical and electronic equipment.

Supplier (if applicable) is responsible for ensuring that all UL critical components and materials as specified in LINAK's specifications are proceeding in accordance with UL guidelines and to maintain all necessary records, so they are readily available for review by a UL field representative. UL local representatives will verify that the applicable requirements for traceability programs and requirements are met.

Communication

LINAK encourages open communication between both companies to ensure a successful supplier/costumer relationship. Regular information must be channeled through and supported by LINAK’s Purchasing-, Development, Logistic- and Quality departments and the equivalent department at SUPPLIER. In order to generate, maintain, and expand a good relationship the two parties must strive towards extended cooperation. Particularly in cases with LINAK specified products.

Developing relationships must be done through intensive knowledge about key persons at SUPPLIER, through mutual openness and understanding, and information about LINAK’s needs in the future for long-term relations. Therefore if SUPPLIER makes organizational changes or change the contact person(s) this must be informed to the relevant LINAK contact person and vice versa.

All communication internally and externally at LINAK is preferred to be in English. Therefore SUPPLIER must ensure that they have adequate language and communication skills in order to ensure open and accurate communication without language as a barrier.

LINAK SIS

LINAK SIS (Supplier Information System) is an online SharePoint between supplier and LINAK. LINAK SIS is used to share documents between supplier and LINAK. LINAK communicate through LINAK SIS (Supplier Information System) with the suppliers when an Engineering Change Order (ECO) or an Engineering Change Notices (ECN) occurs. SIS can also be used for RFQ-documents, Supplier evaluation documents and any other shared documents between supplier and LINAK. When the Quality Agreement has been made then the supplier can download LINAK specifications from SIS.

Supplier approval process

LINAK requires all Suppliers to be approved prior to the issuance of contracts. All Suppliers must be approved by LINAK, regardless of approvals by customers or other entities. The following section explains the supplier approval process at LINAK.

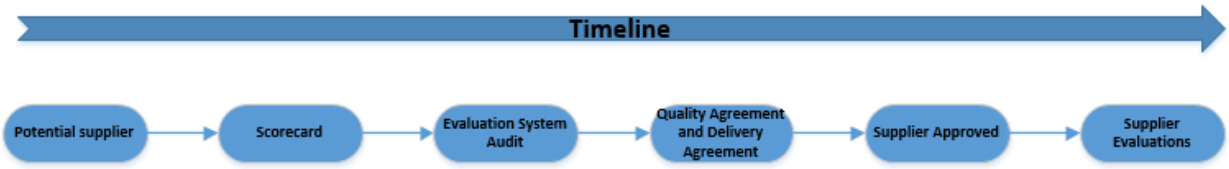

Figure 1: Supplier approval process

Figure 1 is displaying the LINAK process of approving a potential supplier. First, a potential supplier is found and a Request for Quotation is sent out. Then the supplier fills out a supplier scorecard, with the assistance of LINAK. If the scorecard is approved by LINAK, an initial System Audit will take place at the premises of the supplier. LINAK or a third party will carry out the audit. If the supplier is accepted based on the System Audit, a Quality Agreement and a delivery agreement is signed and the supplier is approved, and the production-part-approval-process now starts.

Potential supplier assessment

A supplier is selected based on the total value of:

- Competitive price and other financial conditions.
- Continuous improvement of productivity and price.
- Openness and receptiveness.
- Service.
- Flexibility.
- Quality and quality control system.
- Organization, culture and technology and the will to change this.
- Fulfillment of LINAK's rate of growth.
- Delivery time and ability to supply.
- Expertise and knowledge.

The above is not ranked according to importance. This is in each single case based on an estimation of importance to LINAK.

Furthermore, the supplier is assessed on the ability and will to improve their performance on the quality and productivity side.

Request for Quotation (RFQ)

The RFQ is the basis for all LINAK business negotiation. LINAK operates with a standard template, which consists of three major points: Terms of Delivery, Terms of Payment and Production Part Approval Process (PPAP).

Self-evaluation document (Scorecard)

The scorecard is a self-evaluation excel document that LINAK sends out to all new suppliers in order for them to fill in.
The purpose of this pre-supplier evaluation is to obtain a comprehensive view of a potential LINAK supplier. This evaluation will assist LINAK in evaluating whether a supplier can achieve LINAK's expectations as a preferred supplier. The scorecard considers the key business characteristics of a successful company, as well as their visions for future enhancement. The business elements evaluated are Quality, Logistics, Production & Technology, Finance, Management, Employees, Environment, Feasibility, Market Situation and the suppliers' suppliers (i.e. sub-contractors). The scorecard is a key component in the LINAK supplier selection process.

The scorecard is based on (11) criteria, which included in the evaluation, have different "weighting factors" based on the perceived importance to LINAK. These "weightings" are the current standards, but can be changed based on the particular product and/or business area being serviced.

Some areas in the scorecard represent the minimum requirements a supplier must meet, in order to be a LINAK supplier.

*The scoring procedure: Simply give **1 point** if the evaluation tells you the supplier is at **Level 1**, **2 points** if he is at **Level 2** etc.*

All discussed points must be verifiable via documentation from the supplier for the LINAK assessment.

Audits

LINAK operates with 3 kinds of audits of which 2 are related to quality management, System Audit and PPAP Audit, and the third being a logistic audit.

System Audit:

This audit will be performed after the scorecard has been approved. This audit will cover the quality system and the quality processes of the supplier. The audit question are related to the ISO: 9001 standard and the TS 16949 standard. This audit consists of question from 13 business areas. These areas are as follows:

- Document and Change control
- Control of suppliers and sub-contractors
- Control of incoming materials
- Process planning and follow-up
- Process Control
- Inspection and testing
- Training
- Finished product handling, Storage, and Delivery
- Nonconformities
- Corrective and preventive actions
- Management
- Feasibility
- Code of conduct

Based on the points given to each question, a score will be calculated. This score will be translated in to 3 results: Approved, Conditionally Approved and Not Approved. If the supplier is deemed Not Approved, the approval process is ended. If deemed Approved or conditionally approved, the supplier can continue in the approval process. If deemed conditionally approved the supplier will be given a timeline, to correct the points not approved by the LINAK auditor.

PPAP Audit (optional):

The PPAP audit is supplementary to the System audit. Where the System audit covers the complete quality system of the supplier. The PPAP audit covers a specific product and related processes. The PPAP audit can be performed based on the PPAP of an existing product. The PPAP audit can be used to verify the setup of the quality assurance system documented in the PPAP. The PPAP can also be performed based on non-conformities or deviations in the particular product. The PPAP-audit is optional and will only be conducted if deemed necessary by LINAK.

The areas of covered in the PPAP, are the same areas as filled out in the PPAP. The areas are as follows:

- Design records and Engineering Change Documents
- DFMEA
- Process flow
- PFMEA
- Control plan
- MSA
- Dimensional report

- Records of material performance and test results
- Capability studies
- Qualified laboratory equipment
- Appearance description
- Sample production parts and master sample
- Linak specified requirements

The result of this audit will be areas, where corrective actions are needed.

Logistic Audit:

If viewed necessary there will also be performed a logistic audit on the supplier. This audit may be performed in connection to the quality audit or as an autonomous audit. The supplier will be notified and informed about the process, if an audit will be performed.

Quality Agreement

When the System Audit is approved, a contract stating the exact quality agreements will be signed. The Quality Contact is a more specific contract between LINAK and the supplier than the information stated in this document. Meaning some agreements in the contact may deviate from this document. The contract must be signed by both parties and is therefore a binding agreement.

The contract will normally consist of several points that will be concerned with the quality requirements LINAK has to that specific supplier. The outlining of the contract is based on a streamlined template that then is modified based on negotiations with the individual supplier. Some of the points will also be stated in this manual, but as previously mentioned, there can be deviations from this manual. This document must be seen as a guideline rather than an actual contract.

All LINAK suppliers in group 1 (Linak specified products) and 2 (Process suppliers) must sign a quality contract and conform to this agreement in order to be an approved LINAK supplier. For group 3 component suppliers a quality agreement can also be demanded.

Delivery Agreement

The supplier will also be asked to sign a Delivery Agreement. This agreement contains the LINAK delivery and logistic requirements, and must be signed by both LINAK and supplier.

Production Part Approval Process

When the supplier has been approved, the PPAP process can start. The purpose of the Production Part Approval Process (PPAP) is to secure that all LINAK engineering design records and specification requirements are correctly understood by the supplier. Furthermore, the PPAP is used to determine whether the manufacturing process has the capability to produce products consistently and meeting the stated requirements during an actual production run at the quoted production rate.

Introduction to LINAK PPAP

PPAP is a structured way of assuring that the supplier:

- Has understood the LINAKs design- and specification requirements.
- Can supply a product according to the specification requested by LINAK.
- Has processes that support the specification.

Based on the PPAP standard, LINAK has created PPAP templates, which can be used, when submitting a PPAP to LINAK. The specific requirements of the PPAP depends on, which category the supplier falls in to.

The categories are as follows: Batteries, Box Build, Cables, Coated Parts, Metal, Motors, PCBA, Plastic, Springs, Transformers and Tubes.

Each category is asking for the same type of information regardless of the category in requirement 1 to 16. Requirement 17 will vary from category to category, as it covers the specific requirements for the individual category.

LINAK will decide whether all 17 requirements of the PPAP have to be submitted LINAK. In some cases, LINAK will ask for a requirement to be completed, but not submitted to LINAK. In other cases, some requirements are not applicable, and will therefore not be a requirement for the supplier.

PPAP is only to be used if the part in question fulfils following criteria:

If an order, size is more than 1000 pcs/year. If the order size is below 1000 pcs/year, LINAK will still request a 100% measurement of all checking dimensions on the drawing.

The PPAP workbook

1. Design Records:

The supplier must submit a copy of the drawing with critical to quality measurements (marked with "#"). The PPAP must meet all drawing requirements to be considered for approval.
If the design records are in electronic format, the supplier must produce and submit a hard copy to identify the measurements taken. This could be layout of PCB's or similar.
Furthermore, the supplier must keep a record of all updates to the design.

2. Engineering Change Documents

This is only filled out if the supplier initiates the change. Otherwise, the supplier fills in: "Change requested by LINAK".
If the supplier requests the change:
LINAK must be informed in a timely manner, via written documentation, with detailed information about the change. This is also mentioned in the quality contract. The documentation must contain all relevant information (description of the change, reasons for the change, the requested timing for the change etc.).

3. Customer Engineering Approval

The supplier must obtain written approval for the change from LINAK if the supplier requests the change. Otherwise, the supplier fills in: "Change requested by LINAK".

4. Design FMEA

Applicable only when the supplier has design responsibility.
Otherwise, the supplier fills in: "Design Responsibility: LINAK". The purpose of the DFMEA is to address all potential failure modes, which can be related to the design of the part. Remember to add LINAK critical dimensions.
A copy of the DFMEA should be kept at the supplier's facility for review at any time.

5. Process Flow Chart

A chart explaining the flow of the process from start to finish, this also includes incoming inspection. This document should be so detailed that it can smoothly flow into the control plan and Process FMEA.

6. Process FMEA

An analysis of all potential failure modes, which can happen to/during the processes that the product goes through. Incoming inspection should be included in the analysis.

7. Control Plan

This is a written summary of which controls are carried out and which tools are used. This means: What is checked, how it is checked etc. This should also contain sample rates, frequency etc. The control plan takes into account the output from the PFMEA.

8. Measurement System Analysis (MSA)

The purpose of this record is to verify that the gauge or measurement system is capable of accurately assessing the quality of the parts. This is to be carried out on all initial process studies used for producing LINAK products .Typically 3 repeated measurements by 3 operators on 10 parts are used. Acceptance criteria's are as follows:

Distinct Categories	%Tolerance (SV/Toler)	Acceptance
<5	>30%	Not accepted
	20-30%	Needs improvement
>/= 5	0-20%	Accepted

If the parts supplied are "go/no go" parts, attribute studies must be performed on 20 parts, with 2 operators and 2 trials. To meet acceptance criteria all results from the test must "pass". Meaning that the 2 operators are capable of identifying the bad parts from the good parts.
If the gauge at any time is modified a new study must be submitted to LINAK.

9. Dimensional Results:

LINAK requires 100% dimensional measuring of parts (amount depending on the specific PPAP). The data must be submitted in a convenient and organized format with the actual results recorded.

10. Records of Material / Performance test results

This is to verify that the parts meet all the specifications required by LINAK. This must include a reference to the control plan. If the product is tested additionally, it must be mentioned under this topic.
The data must be submitted in a convenient and organized format with the actual results recorded.

11. Capability Studies

This record is to verify that the parts submitted by the supplier, can meet requirements, measured over a significant production run.
LINAK requires a minimum CpK level of 1,67, measured on 50 pcs. produced in a row, and on all checking dimensions (marked with #). The parts must come from a representative part of the production. If the CpK values are between 1,33 and 1,67 a corrective action needs to be initiated. New studies must be performed after the corrective action is implemented and documented in a new PPAP.
If any dimensions with CpK < 1,67, the supplier must implement a 100% inspection on those dimensions until corrective actions has improved the CpK.

12. Qualified Laboratory Documentation

If the supplier has used an accredited laboratory or testing facility to perform any test, the records must be attached here.
In addition, if calibration is done externally, the certificates for the used measuring equipment should be attached here.

13. Appearance Description

Only applicable for parts with specific requirement regarding appearance. Otherwise, it is filled out with "No specific requirements to appearance".

This can both be physical products, pictures and/or documents. Especially if some criteria's can´t be fulfilled, it must be documented here.
Attach a copy of the work instruction showing, what to check for and which criteria's have to be respected. Check with LINAK if there are any special demands.

14. Sample Production Parts

If requested by LINAK. Otherwise, it is filled out with "No samples required by LINAK".
These parts can be used for appearance and functional evaluation. If parts are submitted, they need to be clearly marked for identification. If more cavities are used, samples from each cavity must be submitted. Also attach LINAK's purchase order number.

15. Master Sample

The supplier shall retain a master sample from the PPAP run. This master must be kept until a new master is requested. The master sample needs to contain an approval date based on LINAK's approval. If more cavities are used, samples from each cavity must be kept.
A picture of the master can be attached.

16. Checking Aids

Add a complete list of checking devices. This could be calipers, visual aids etc. All checking aids used in the everyday processing of a part must be identified.
Please attach pictures of the checking aids.

17. LINAK specific requirements

In this section all LINAK specific requirements will be. These requirements can vary from product to product.

18. PSW

This summarizes the PPAP and concludes if the PPAP is approved or not. You can only have a PPAP approved if all required points are addressed and approved. If points are not approved, the supplier needs to attach an action plan with time lines for when the points can be approved.
The PPAP is not approved before agreed with LINAK.

Running Production

This section will describe LINAK's and the supplier's relationship during running production, meaning this is for approved suppliers delivering approved products. It contains a description of how LINAK does; evaluation, supplier categories, audits, document control and incoming inspection.

Evaluation

This section explains how LINAK evaluates their suppliers, and the process behind the evaluation. Suppliers are evaluated on 2 parameters: Their drop-out in production and their delivery performance. These two generates a result that LINAK uses for internal categorization of suppliers and for how to handle the suppliers. This evaluation process is graphically described underneath.
Evaluation of suppliers will also be conducted by performing supplier audits.

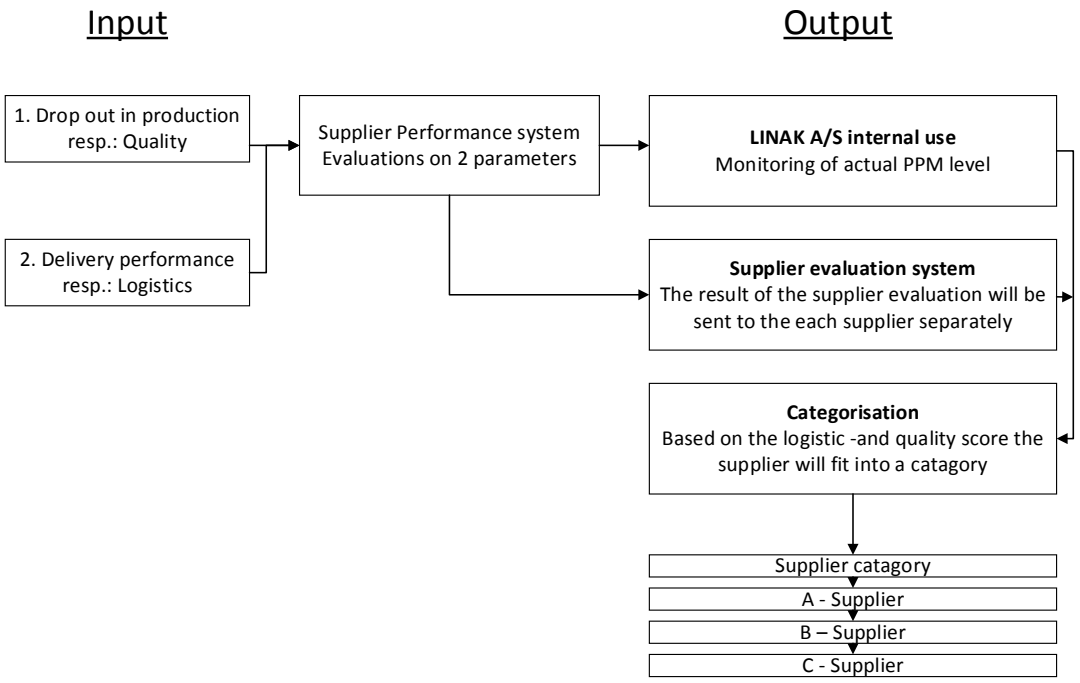

Figure 2: Supplier evaluation process

Supplier performance form

The supplier performance form is based on delivery performance and PPM (Parts Per Million) dropout measures. LINAK's central logistics department is measuring the delivery performance and the Production Quality Specialists are measuring the PPM dropout. Every time there is made an evaluation a report is generated, this will be sent out to the supplier every 3rd month and stored at LINAK for internal use. The evaluation results in a supplier categorization that gives LINAK an overview of which suppliers needs to be motivated to take specific actions and/or helped.

QUALITY

This metric defines the Defective Parts Per Million (DPPM) shipped using the following formula. The definition of "rejected parts" is the total number of parts returned to the Supplier for any valid quality reason

(Including those caused by shipping, packaging and administrative errors):

$$\boldsymbol{DPPM = \frac{Number\ of\ parts\ rejected}{Number\ of\ parts\ received} * 1.000.000}$$

Based on LINAK's current expectations, the following list describes the resulting actions for varying DPPM performance levels:

A+ Excellent – PPM < 50

A Acceptable – PPM 51 – 500

B Improvement Needed – PPM 501 – 3000

C Not Acceptable – PPM 3001 – 10000

C- Critical – PPM > 10000

Unacceptable Systemic corrective action is required and may require Supplier to meet with LINAK management representatives.

DELIVERY

This metric defines the delivery performance rating using the following formula:

"On time" is based on the purchase order date.

$$\boldsymbol{Delivery = \frac{Number\ of\ parts\ received\ on\ time}{Number\ of\ parts\ received} * 100\%}$$

Based on LINAK's current expectations, the following table describes the resulting actions for varying delivery performance levels:

A+ Excellent – Delivery > 98%

A Acceptable – Delivery > 95%

B Improvement Needed – Delivery > 90%

C Not Acceptable – Delivery > 85%

C- Critical – Delivery < 85%

Unacceptable Systemic corrective action is required and may require Supplier to meet with LINAK management representatives.

Document Control

At the first three deliveries of new or changed products, LINAK anticipates that the supplier has enclosed their measuring reports to the delivery. By measuring reports is meant the process control documentation agreed upon. Furthermore, the supplier must keep all measurement reports for 5 years with continuous updates, so LINAK always can require an examination of the last 5 years' measuring reports.

To achieve a safe start-up on new items and to improve the quality level on items in running production, the supplier agrees to prepare a FMEA if LINAK requires it. The FMEA may be prepared in corporation with LINAK.

If LINAK requests:

- The supplier must make a critical check of the drawing and other specifications. Questions and reservations concerning the specifications received shall be resolved before an offer is given. Reservations must be stated and accompany the offer.
- The supplier must specify the expenses to possible product specific measurement/control equipment in the offer.
- The supplier must always be able to send process control documentation for selected batches if LINAK requires it.
- If LINAK requires checking/control instructions on items delivered to LINAK, the supplier must agree to hand over all these documents.

Incoming inspection

LINAK does by default not do quality inspection on incoming goods, because LINAK purchase from a 0-fault principle. The supplier is expected to do outbound inspection at their own facilities. Specifications of the supplier's finished goods inspection and/or process control must be prepared in cooperation between the supplier and LINAK. *The agreed process control shall always be recorded and filed at the supplier, so LINAK can follow up on the supplier if needed*.

LINAK trust that all products delivered meet the specifications and no inspection is necessary, however occasionally LINAK inspects the incoming goods. This inspection can deviate depending on the product, previous experience, requirements and the strategic value of the goods.

If LINAK finds it necessary to supervise the quality of the delivered units, then LINAK will carry out an incoming goods inspection according to DS/ISO 2859-1. LINAK selects the sampling plan.

If LINAK notes one faulty part at this incoming goods inspection LINAK reserves the right to reject and return the whole lot for change or sorting at the supplier. The supplier is obliged to deliver whole or partial replacement delivery according to terms agreed with LINAK. LINAK may start a Supplier Corrective Action Report (SCAR) of faulty units found in the Incoming Goods Inspection Dept.

If LINAK and the supplier come to the agreement that a rejection has been unjustified, LINAK will pay all forwarding costs, which can be traced back to the unjustified rejection.

Managing of deviating and non-conforming products

If the supplier notes deviations in connection with incoming goods, processes or finished goods inspection LINAK must be notified in writing of all deviations before additional processing of non-conforming material. LINAK will then make a decision on the disposition of the non-conforming material and whether to accept the deviations before delivery of the units. If the parts are being exempted, they must be marked with an exemption number given by LINAK.

In case of diverging products found at LINAK the supplier must commit to a quick and effective delivery of new products to LINAK, so lost LINAK production costs are kept to a minimum. If the supplier is unable to deliver new products LINAK will be in their right to sort and do rework on the suppliers costs. This is an undesirable situation unless otherwise agreed with LINAK.

Deviations noted at LINAK

If LINAK notes deviations from the specifications of a product received, in connection with the further manufacturing, and the deviation objectively and unambiguously can be traced back to the product that has been delivered, then the supplier is responsible. In this case LINAK reserves the right, after having informed the supplier, to charge the supplier with the value of the finished product and the value of lost time of production. If LINAK is forwarding costs to the supplier, the costs have to be documented. Examples of costs hours spend, amount of parts where rework/sorting has been done, what type of rework has been done, etc.

In the event that LINAK suffers a production stop due to the supplier's inability to meet the deliveries according to the first confirmed delivery time of acceptable supplier products, the supplier will be held responsible for all expenses LINAK have due to the production stop.

Lost production time is the time that has been used for dismantling the defective units and assembling new non-defective units and/or the additional time the defect may have caused in LINAK's production. Lost time of production is to be settled at a certain agreed amount of money per hour. The finished product is the unit that has been affected by the defect and will have to be replaced.

Deviations noted at the customers of LINAK

If LINAK notes a deviation in connection with a customer complaint, which can be traced back to the supplier, he will be held responsible. LINAK will, after having informed the supplier, charge the supplier with a part of the costs arising from the deviation. Most often, an 8D report will be made, at LINAK, and if the supplier is responsible for the failure, he will be contacted under this process.

In the event that LINAK's customer suffers a production stop due to the suppliers inability to meet the specifications or deliveries, according to the first confirmed delivery time of acceptable supplier products, all applicable LINAK charges be the responsibility of the supplier.

Supplier Corrective Action Report

When critical or extensive non-conformities are detected, LINAK works out a **S**upplier **C**orrective **A**ction **R**eport (SCAR) on the non-conforming parts. The SCAR will clearly express the defect. If the supplier needs additional information LINAK will provide pictures or defective samples and send these to the supplier at the supplier's expense.

The supplier is obliged to react to phase 1 of the SCAR within 1 working day from the issue date, and inform LINAK about the containment actions taken. Within 7 business days of the SCAR issue date phase 2 of the SCAR should be submitted to LINAK. Phase 3 is due 10 business days after the issue date. Phase 4 of the SCAR should be submitted via email within 20 business day. Phase 5, which is the last phase of the SCAR, should be submitted to LINAK within 45 business days.

LINAK have created a SCAR-template as an excel file. The excel file contains all the necessary tools and instruction for completing the SCAR-report. LINAK will sent the SCAR-template to the supplier containing all the necessary information about the non-conformaties, including pictures if deemed necessary. The file will also contain the deadlines for submitting phase 1-5.

All expenses in connection with replacement deliveries for non-conformity deliveries will be at the supplier's account and risk.

Phase	**Title**	**Deadline (Days after issue date**	**Deliverable**
Phase 1	Containment Action	1 business day	The report of the taken immediate actions or containment actions. The supplier must send this by email to the case handler within 1 business day from the SCAR issue date.
Phase 2	Root Cause Analysis	7 business days	The supplier must complete the root cause analysis. They must explain the root cause for occurrence, escape and non-detection in his process. If possible, they can attach their root cause analysis tool.
Phase 3	Corrective Action	10 business days	The supplier must complete the Corrective Action. They must have a corrective action to eliminate the root cause of the issue. In the event that some nonconformities are more complex, the supplier must have a corrective action plan with an outlined action list, target dates and responsible.

Phase 4	Preventive Action	20 business days	The supplier must complete the preventive action. They must have a preventive action to ensure similar products/processes are covered. In this phase, they can describe the system updates or proactive steps, including but not limited to process flow charts, PFMEA, control plan, work instructions, control charts, engineering documentation, MSA, preventive maintenance, training plan, design standard, etc. In the event that some nonconformities are more complex, the supplier must have a preventive action plan with an outlined action list, target dates and responsible.
Phase 5	Follow-Up Plan	45 business days	The supplier must complete a follow up plan. They must describe in detail the objective evidence of compliance and effectiveness of corrective actions. The supplier may contact LINAK personnel for inspection results of product supplier after implementation of corrective and preventive actions.

References

ISO 9001 Quality Management System Requirements (General) www.ansi.org www.iso.org

ISO/TS 16949 Quality Management System Requirements (Automotive) www.ansi.org www.aiag.org

ISO 13485 Quality Management System Requirements (Medical) www.ansi.org www.iso.org

PPAP Production Part Approval Process Manual www.ansi.org www.aiag.org

SPC Statistical Process Control Manual www.ansi.org www.aiag.org

MSA Measurement System Analysis Manual www.ansi.org www.aiag.org

FMEA Potential Failure Mode & Effects Analysis Manual www.ansi.org www.aiag.org

RoHS http://ec.europa.eu/environment/waste/rohs_eee/index_en.htm
REACH https://echa.europa.eu/en/regulations/reach

WEEE http://ec.europa.eu/environment/waste/weee/index_en.htm