Internal Audit Questions - Supplier

<Short Name> ISO 9001:2015

Quality Management

- Is the quality system documented, controlled and maintained to clearly describe current practice?
- Do quality reports, trend charts and data analysis identify areas of opportunity and used by management on a routine basis?
- Are quality-performance targets clearly defined, included in the business plan and monitored for improvements?
- Does top management participate in periodic quality system reviews that address quality related feedback from customers and internal quality metrics?
- Is the quality system properly documented, controlled and maintained to clearly describe current practice?
- Do quality reports, trend charts and data analysis identify areas of opportunity and are they used by management on a routine basis?

Quality Planning

- Are production samples inspected and provided to customers upon request?
- Are customer production requirements and quality specifications reviewed to ensure they can be met on a consistent basis?
- Is testing used to verify the design specifications, drive design improvements and provide an on-going check of materials and workmanship?

Design & Development

- Are customer needs and requirements incorporated into product designs and/or production processes?
- Are characteristics which are critical to quality identified, understood and records retained?
- Are product specifications and drawings generated, controlled and maintained for new or changed product designs?
- Is design validation is an integral part of the design process and occurs prior to production release?

Customer Documentation

- Are new and revised customer specifications reviewed and implemented in a timely manner?
- Are current process control documents in place and used for production start-up and continuing production?
- Does customer notification/approval occur for changes to control plans, production site, product transfers and raw material?

- Is there a record control system is in place for the identification, storage, protection, retrieval, retention time, and disposition of quality records?
- Are quality records maintained?

Procurement & Supply

- Is there a formal process used for the selection, qualification and re-qualification of suppliers?
- Are purchases from unapproved suppliers prevented by a properly controlled and available approved supplier list?
- Are preventive actions taken to continuously improve performance of the supplier base?
- Does the supplier assurance system ensure that all purchased product or material conforms to defined specifications and applicable regulatory or customer requirements?
- Does a system exist for the identification, verification and protection of customer supplied product that includes notifying the customer if product is damaged or lost?
- Is receiving inspection performed in accordance with documented procedures?
- Is inspected material adequately identified as to acceptance or rejection and traceable to receiving inspection report?
- Do supplier corrective action requests requiring root cause investigation show that responses are analyzed?

Production Quality & Process Control

- Is there is a formal method used to qualify new or rebuilt production equipment prior to production use?
- Are control plans used to plan and deploy inspection and test functions throughout the production process?
- Are appropriate work instructions available where needed that accurately describe all work methods including inspections and tests to be done during production?
- Are appropriate inspections, tests and process adjustments made in accordance with applicable work instructions to verify conformance at key points throughout the process and prior to shipment?
- Is the inspection and process status of the product identified and maintained throughout the production process?
- Are customers notified of issues that potentially affect product reliability?
- Are control plans used to plan and deploy inspection and test functions throughout the production process?
- Are appropriate work instructions available where needed that accurately describe all work methods including inspections and tests to be done during production?

- Are key part characteristics and process parameters reviewed and statistically based controls and/or problem solving tools used to control variation?
- Are written improvement plans implemented to reduce sources of variation?
- Are out of control conditions noted on charts and is documented corrective action taken to bring the process back into control?

Non-conforming Parts, Products & Material

- Are non-conforming materials, parts and assemblies segregated (where practical) and identified to prevent unapproved use?
- Are reworked material, parts and assemblies re-inspected or re-tested to confirm compliance to requirements?
- Is the use of non-conforming material documented under a formal waiver or concession system?
- Is product traceability maintained to facilitate problem evaluation and corrective action?

Monitoring & Measurement

- Are repeatability and reproducibility analyses conducted to verify suitability of measuring devices for their use in checking product quality or control of processes?
- Are measuring devices and gauges and test equipment routinely calibrated and controlled as in accordance with documented procedures?
- Are gauges and test equipment calibrated against standards traceable to a recognized regulatory body or agency?
- Are assessments made to check the validity of previous measurements done on products where out-of-calibration measuring devices were used?

Maintenance

- Are tools stored in an appropriate, clearly defined area, with systematic tracking that provides traceability, particularly of customer-owned tools and equipment?
- Does a formal preventive maintenance system (PM) exist for production equipment, tools and fixtures?
- Is the preventive maintenance schedule followed so that product cannot be made with tools that are outside of their maintenance period?

Storage & Packing

- Are areas around the facility clean and orderly and are tools and equipment properly stored and readily available for use?
- Is lighting and air quality adequate?
- Are proper equipment and methods used to prevent product damage or loss in all phases of the material handling process?

- Are documented procedures followed to ensure the proper control and preservation of handling, storage (FIFO), packaging, and delivery of product?
- Is the suitability of product packaging reviewed and any concerns communicated to the customer prior to initial production shipment?
- Is stored product/material periodically inspected, and where applicable, actions taken to prevent deterioration in accordance with documented procedures?
- Have contingency plans been developed that describe actions to be taken in the event of a major interruption of the manufacturing process?

Education & Training

- Is the skill and education level required for quality critical jobs documented and appropriate training provided?
- Is employee qualification/certification maintained where the quality outcome of the process cannot be verified and is strongly dependent upon operator skill?
- Are suitable methods used to verify training effectiveness?
- Are suitable records maintained?

Continuous Improvement

- Are preventive actions taken based on the analysis of significant business trends, design reviews, customer satisfaction surveys or other meaningful inputs?
- Is there a formal approach used to actively pursue continual improvement activities throughout the organisation?
- Is a corrective action system in place that provides root cause analysis and takes timely and effective action to prevent recurrence?
- Does the corrective action system cover customer, internal and supplier issues?
- Are preventive actions taken based on the analysis of significant business trends, design reviews, customer satisfaction surveys or other meaningful inputs?