PROQC
INTERNATIONAL
Global Quality Control and Engineering Solutions

ISO 9001:2015
Quality Systems Audit

** Example Report **

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ISO 9001:2015 Quality System Audit

SUMMARY

Rev.
13

Supplier Name	Audit Date	Report No.
XXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXX	XXXXXXXXXXXX

SUPPLIER'S INFORMATION		CLIENT'S INFORMATION	
NAME :	XXXXXXXXXXXXXXXXXXXX	NAME :	XXXXXXXXXXXXXXXXXXXX
ADRESS :	XXXXXXXXXXXXXXXXXXX	ADRESS :	XXXXXXXXXXXXXXXXXXX
	XXXXXXXXXXXXXXXXXXX		XXXXXXXXXXXXXXXXXXX
CITY :	XXXXXXXXXXXXXXXXXXX	CITY :	XXXXXXXXXXXXXXXXXXX
COUNTRY :	XXXXXXXXXXXXXXXXXXX	COUNTRY :	XXXXXXXXXXXXXXXXXXX
PHONE :	XXXXXXXXXXXXXXXXXXX	PHONE :	XXXXXXXXXXXXXXXXXXX
FAX :	XXXXXXXXXXXXXXXXXXX	FAX :	XXXXXXXXXXXXXXXXXXX

SUPPLIER'S PERSONNEL PARTICIPATING

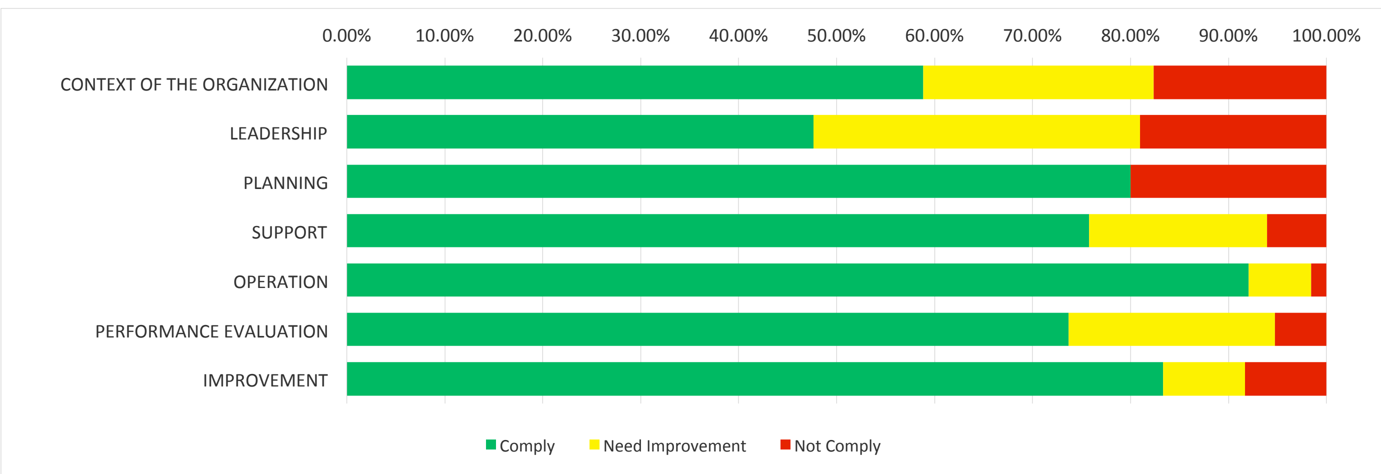
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXXXX	Title:	XXXXXXXXXXXXX	Email:	XXXXXXXXXXXXXX

Pro QC PERSONNEL

Mr./Mrs.	XXXXXXXXXXXXX	Title:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXX	Title:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
Mr./Mrs.	XXXXXXXXXXXXX	Title:	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

Scope : ______________________________

AUDIT RESULTS 82.23%



JUDGEMENT & RECOMMENDATIONS

☐ **Passed**, the QMS is effective, you could consider this supplier a reliable business partner.

☐ **Passed**, the QMS is acceptable with minor NCFs (see **Audit Report**), you consider this supplier a reliable business partner, but push them for improvement to reduce risk.

☒ **On-hold**, the QMS presents few major NCFs (see **Audit Report**), you could request them to provide a CAPA before engaging in any business with them.

☐ **Failed**, the QMS presents serious major NCFs (see **Audit Report**) that could impact upon your business. The better solution would be to source another supplier.

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Scope of Audit:

The intent of conducting a Quality System audit based on ISO 9001 requirements is to provide the client with information useful for making an initial assessment about business viability, and reducing their sourcing risks.

Summary/Recommendation:

The audited factory XXXXXX is located in Longhua New District of Shenzhen. It is a factory that transforms LED components into LED end products, and was founded in the year 2000.

Each production line is managed by total quality control to ensure the quality of LED production in Operating, Safety, Reliability engineering and Maintainability requirements. So far, XXXXXX has over 50 professional quality control staff and various experimental equipment to maintain high product quality.

The factory XXXXX is certified to ISO 9001:2015, with certificate number XXXXXXX. Their products also meet many different International standards such as UL, CE, ETL, RoHS, REACH, FCC and are approved by International accredited labs like Intertek and TUV

The QMS system audited covers the requirements of ISO 9001:2015, except that KPIs are not totally developed to allow proper monitoring and measuring of the effectiveness of the QMS.

Strengths:

1) Certified to ISO 9001: 2015
2) Highly educated technical staff for design and development of new products
3) Large space in the warehouse and workshop to extend production capacity

Opportunities for Improvement:

4.1 a) Responsibility for communication of external / internal issues must be defined.
4.4 b) Each process must have outputs defined.
4.4 d) Each process must have KPIs defined.
4.4 f) Ownership must be defined for each process.
8.4.2 c) Must have a reaction plan when an external service or product provider has poor performance.
9.2 e) Audit findings must be properly documented, with actions taken.
10.2 g) Risks and opportunities must be updated based on non-conformities found.

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	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
4	**CONTEXT OF THE ORGANIZATION (Clause 4.1, 4.2, 4.3 and 4.4)**			
4.1	**Understanding the Organization and its Context**			
a)	Has the organization identified, documented and analyzed **External issues** that can affect customer satisfaction and delivery of quality products and/or services?	*1) Note Doc. # of list of **External issues** identified that may be: **Legal , Technological, Competitive, Market, Cultural, Social, Economic environment**(Local, Regional, National or International). 2) Note of major external issues identified. 3) Photograph the document.*	Yes, the organization has identified and documented external issues in sheet Doc. #. QM-HW-001-02, Rev A/0. The major issues are: 1) An increase by 20% of new local competitors that provide the same service at the lowest rate (SEE PHOTO 4). 2) The change of new ISO 9001 standard to version ISO 9001: 2015.	C
b)	Has the organization identified, documented and analyzed **Internal issues** that can affect customer satisfaction and delivery of quality products and/or services?	*1) Note Doc. # of list of Internal issues identified that may be: Organizational values, culture, knowledge, and performance. 2) Note of major external issues identified. 3) Photograph the document.*	Yes, the organization has identified and documented external issues in sheet Doc. #. QM-HW-001-02, Rev A/0. The major issues are: 1) The level of knowledge of employees that has not been enhanced to meet requirements (SEE PHOTO 4). 2) Stability of employees which is less than 50% compared to what was planned.	C
c	Is there an **authority** for the identification, documentation and communication of external / internal issues ?	*1) Photograph the Organizational chart 2) Note name and title of key person in charge of this process. 3) Photograph any record showing that external / internal issues are reviewed, approved and signed by that authority.*	Yes, there is an organizational chart (SEE PHOTO 5). The audited person explained that the GM, Mr. Wang is in charge of this process, but records show that his signature, as evidence that he monitors this process, was missing.	I
4.2	**Needs & Expectations of Interested Parties**			
a)	Has the organization identified and documented its **interested parties** relevant to the QMS?	*1) Note Doc. # in which Interested parties are identified such as: Customers, Government & non-government organization, Employees, Shareholders. 2) Photograph the document.*	Yes, the organization has identified and documented interested parties in sheet QM-HW-001-03, Rev A/0 (SEE PHOTO 6): 1) 150 full time employees, salary, insurance. 2) 15 material suppliers, 3 subcontractors. 3) 26 Clients, 5 of them constitute 80% of business. 4) 2 shareholders with 90% financial support. 5) Local communities (Env. issues) 6) Local government for tax payment.	C
b)	Are **needs & expectations** from these interested parties identified and documented?	*1) Review Needs & Expectations. 2) Photograph the document*	Yes, the organization has documented needs and expectations of each interested party in sheet QM-HW-003-03, Rev A/0 (SEE PHOTO 6):	C
c)	Is there an **authority** for the identification, and communication of needs & expectations of interested parties?	*1) Photograph the Organizational chart 2) Note name and title of key persons in charge of this process. 3) Photograph any **record** showing that interested parties are **reviewed**, **approved** and **signed** by that **authority**.*	Yes, there is an Organizational chart (SEE PHOTO 7). The audited person explained that the GM, Mr. Wang is in charge of this process, but records show that his signature, as evidence that he monitors this process, was missing.	I
4.3	**Scope of the Quality Management System**			
a)	Has the organization defined the scope of the QMS?	*1) Note the doc number, and Rev in which the scope is defined. 2) Photograph the page.*	Yes, the organization has defined the scope in Doc. # QM-HW-001, Rev. A/0, page 5/ 7 (SEE PHOTO 8)	C
b)	Does the scope address external & internal issues, products & services of the organization, and the commitment to apply all applicable requirements of ISO 9001?	*1) Review scope and check for compliance.*	Yes, the organization has defined the scope in Doc. # QM-HW-001, Rev. A/0 which included all those elements.	C
c)	If applicable, is the exclusion to the scope properly defined, including its justification	*1) Note the doc number, and page of QM in which the exclusion is defined. 2) Note the clause of ISO 9001:2015 that has been excluded from the organization's QMS. 3) Describe the reason of exclusion*	Yes, the organization has a Quality Manual, Doc. # QM-HW-001, Rev. A/0. The organization does not do Design and Development, so they excluded clause 8.3.	C
4.4	**Quality Management System and Process**			

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a)	Are processes needed for the quality management system and their application established and maintained?	*1) Note Doc. # in which processes are mapped / described. 2) Photograph the map that describes their interactions.*	Yes, the organization defines the following 12 processes mapped in sheet QM-HW-001-04 (SEE PHOTO 9): Management Review / Internal Audit / Product Realisation / Purchasing / Incoming Inspection / Maintenance / Employee Training ...etc.	C
b)	Are required **inputs** and expected **outputs** identified and documented?	*1) Verify that each process has **Inputs** and **Outputs** defined. 2) As example select one process, and note his **Inputs** and **Outputs***	10 processes have their inputs and outputs defined, for example of process Internal Audit: 1) Inputs: Audit Plan / certified auditors. 2) Outputs: Audit Result, NC reports …etc. It was noted that 2 processes did not define their outputs such as the process of Purchasing (SEE PHOTO 9)	I
c)	Has the organization determined criteria and methods (WIs, procedures, SOPs) as guidelines tfor implementation of processes?	*1) Verify that each process has defined Procedures / Work Instructions / SOPs 2) As example select one process, and note his **Procedures / WIs defined***	All processes have WIs, Procedures defined, for example of process Internal Audit which use Procedures: QP-12, Rev 2 as guidelines	C
d)	Are criteria and methods monitored, measured, and reviewed through performance indicators? Are there records?	*1) Verify if each process has defined KPIs 2) As an example select one process, and note its KPIs*	No, processes do not have KPIs defined.	NC
e)	Are resources / equipment needed to obtain planned outputs available and documented in the process.	*1) Verify if each process has necessary resources defined. 2) As example select one process, and note resources*	All processes have resources defined, for example of process production which use machine, assembly line, ERP system ..etc.	C
f)	Is there a documented assignation of responsibilities and authorities to ensure compliance of these processes?	*1) Verify if each process has key owner appointed. 2) As example select one process, and note name / title of the process owner.*	No, ownership is not mentioned in processes	NC
g)	Has the organization identified risks and opportunities for each process (use risk-based thinking) in which possible events or activities will impact the achievement of Quality management objectives?	*Ex. Type of Risk: Sub-supplier does not meet delivery deadline. - Probability: Medium - Impact: High - Mitigation: Sub-supplier is delivering weekly - Contingency: Delivery frequency rating will be provided to sub-supplier.*	No, risk and opportunities for each process are not identified	NC
h)	Are there documented results to evaluate the effectiveness of these processes? Are results reviewed in a timely manner by management?	*1) Check management review 2) Review results 3) Review plan for KPIs*	Management review is conducted on a regular basis once per year, record of the last management review conducted last Dec (12th) are available. However, these records do not show the results and improvements of each process since no KPIs were initially planned.	I
5	**LEADERSHIP (Clause 5.1, 5.2 and 5.3)**			
5.1	**Leadership and Commitment**			
5.1.1	**General**			
a)	Can Top Management demonstrate that he is taking accountability for the effectiveness of the quality management system?	*1) Attendee record signed by Top Mgt 2) Management review meeting.*	There are reports of opening / closing meetings with attendance signatures of the Top Management Team. Record of last Management review has the signature of Quality Manager	C
b)	Can Top Management ensure the quality policy and quality objectives are established and compatible with the context and strategic direction of the organization?	*1) Linkage between policy and objectives. 2) Check if this document is reviewed and approved by the Top Mgt*	The document in which policies and related objectives are written and available in sheet QM-WH-010. Evidence such as a signature to demonstrate that it was reviewed and approved by the Top Mgt.	C
c)	Can Top Management demonstrate how they ensure the integration of the quality management system requirements?	*1) Record of Approve of internal audit. 2) Record of opening / closing meeting. 3) Personal resource for QMS*	There are reports of opening / closing meetings with attendance signatures of Top Management Team (See photo 12). The factory has 4 people with Auditor certifications.	C

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d)	Can Top Management demonstrate how they promote the process approach?	*1) Mapping of process and ownership.* *2) Record of Approval of process audit.* *3) Record of opening / closing meeting.*	Processes are mapped and documented, each process has an owner, methods / criteria, inputs / outputs, resources. No KPIs defined for each process. Cannot ensure measurability of the effectiveness of each process.	I
e)	Can Top Management demonstrate how they promote risk-based thinking?	*1) Training on risk-base thinking 2) Encourage proactive action for imp. 3) Record of regular meetings (process base)*	Training about risk-based thinking was scheduled in the annual training program of year 2017, and conducted on 2017-03-17 and 18. All department Managers attended this training. That was recorded on sheet HW-02-12 (See photo 11). However there is no evidence of implementation of risk-based thinking.	I
f)	Can Top Management demonstrate that it has provided resources needed for the QMS?	*1) Manpower, training* *2) Machines, equipment*	Yes, each process identified has an ownership, machines, equipment needed to implement the process and produce expected results.	C
g)	Does Top Management engage, direct, communicate, support, and contribute to achieve the intended quality system results?	*1) Record of Approve of internal audit* *2) Record of opening / closing meeting. 3) Policies review and approve*	There are reports of opening / closing meetings with attendance signatures of the Top Management Team (See photo 12).	C
5.1.2	**Customer Focus**			
a)	Can Top Management demonstrate how they ensure that customer requirements are determined, understood, and consistently met?	*1) Define process and assign its owner/ leader* *2) Write Procedure Doc. #./ Rev.* *3) Record of order review*	Yes, Top Management has appointment a customer representative whose function is to identify customer requirements, and communicate them internally. A procedure QP-HW-05, Rev A/0 has been documented, and it requires conducting order reviews. Results of reviews are documented on sheet QP-HW-05-02, for example of order number 2071-034 for client XXX conducted in 2017-05-23	C
b)	Does Top Management ensure that risks and opportunities that can affect conformity of products & services, and the ability to enhance customer satisfaction are determined and addressed?	*1) Process map* *2) Risk / opportunities in each process?* *3) Note examples of risk / opportunities* *Related actions to address the risk*	Process map exists, no risks and opportunities were identified for each process.	NC
5.2	**Policy**			
5.2.1	**Establishing the Quality Policy**			
a)	Is the quality policy statement appropriate to the purpose and context?	*1) Photograph the place where it was posted.* *2) Evaluate compliance with purpose and context* *(Interview top management)*	The quality policy is posted in the workplace (See photo).	C
b)	Is the quality policy statement defined in a way allowing for setting and reviewing quality objectives?	*1) Linkage between quality policy & objective* ***2) Each policy has Quality Objectives and goals been defined.***	The quality policy is established and documented (See photo). Cannot see respective Quality objectives and KPIs.	I
c)	Does the quality policy include commitment to satisfy requirements?		Yes, the quality policy includes commitment to satisfy requirements related to all interested parties.	C
d)	Does the quality policy include commitment to continual improvement of the quality management system?		Yes, quality policy includes commitment to continual improvement of the quality management system.	C
e)	Is there planning to monitor and review Quality Objectives at reasonable intervals?	***1) Note frequency of review*** ***2) Note current result / trend.*** ***3) Photograph if results are posted.***	Quality objectives and respective KPIs are not defined, so there is no planning of how to monitor and review them.	NC
5.2.2	**Communicating the Quality Policy**			
a)	Is the Quality policy documented or / and posted within the organization?	*1) Photograph if it posted on site*	Quality policy is posted at workplace (See photo).	C
b)	Do staff members understand the Quality Policy?	*2) Interview a few workers.* *3) Any training record*	Record of training of last March 2017. When interviewing senior supervisors, 2 out of 3 do not understand the meaning of the quality policy and how it affect their respective responsibilities.	I

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f)	Are the actions adequate? Can actions appropriately assess the compliance of the risks and opportunities?	*1) Report of last internal / external audit. 2) Feedback from interested parties. 3) Evidence of continual improvement*	Up-to-date, around 45% of issues with RPN > 100 are implemented, with evidence visible. Up until now, the factory has not registered any compliants from interested parties.	C
6.2	**Quality Objectives and Planning to Achieve Them**			
a)	Are the Organization Quality Goals & Objectives documented? Are Quality Objectives measurable and consistent with the quality policy?	*1) If any, **Take photo** of documented Quality Objectives. 2) Check if Quality Objectives is been distributed to relevant departments / responsibilities in terms of metricable values.*	No quality metrics, KPIs are not defined for each process.	NC
b)	Are quality objectives communicated in any sort of media/form?		No quality metrics, KPIs are not defined for each process.	NC
c)	Has the Organization defined a plan or strategy to meet the Quality Goals and Objectives?	*1) Ask Managers / Supervisors to explain their Quality Objectives. 2) Ask them to show the methods / procedure they use to meet these objectives.*	Yes, strategy to meet the Quality Goals and Objectivesare defined in form of procedures and documented information	C
d)	Are Quality Objectives monitored and reviewed at reasonable intervals? (Take photo of the result).	*1) Check if the review interval of Quality Objectives is defined in doc. 2) Check the current result / trend of the last review, and **take photo**. 3) Check if the result of monitoring are posted at a public board for employees to view. **Take photo***	No record of monitoring	NC
6.3	**The Planning of Changes**			
a)	Has the organization identified and documented potential changes?	*Potential changes may be: - In manufacturing process. - Raw material suppliers. - Legal requirements - Manufacturing center ...etc.*	Yes, there is a procedure (QMX-QP-12, Rev. A/O) in which the factory defines potential changes that may occur.	C
b)	Is the purpose of changes defined?	*Provide an example if any, including details of the purpose.*	Yes, for example, the factory implemented a change for purchasing raw materials instead of outsourcing this process this is due to a reduced time for processing.	C
c)	Are potential consequences / risks documented and analyzed prior to applying the changes?	*For example, the consequence could be higher prices of purchased raw material (risk that needs to be addressed)*	Yes, the risk of this change is higher prices of purchased raw material as a consequence, and the risk of using NCF raw material due to lack of incoming inspection.	C
d)	Is there a prevision / plan of how to implement changes to ensure the integrity of the QMS?	*Identify the resources required to put the plan into effect, and assign those resources.*	New supplier of raw material. Implement a strong incoming inspection, ensure back-up material to avoid affecting customer satisfaction in quality and on-time delivery.	C
e)	Are resource available to implement the change?	*Identify the resources required to put the plan into effect, and assign those resources.*	New purchasing Manager, new QC to conduct incoming inspection.	C
f)	Are changes communicated to relevant people? changed responsibilities	*For example, who will be the person in charge of purchasing ?*	Yes, training was conducted, and records are available.	C
7	**SUPPORT (ISO 9001:2015; art. 7.1,7.2,7.3,7.4,7.5)**			
7.1	**Resources**			
a)	Has the organization determined and provided persons / responsible necessary for the establishment, maintenance and continual improvement of the QMS (7.1.1)?	*1) Check if there is a process for that. 2) Check and record who the process owner is. 3) Ask to see his Job description.*	Yes, there is a process for establishment and maintenance of QMS, under the responsibility of the QA department of 4 people lead by the Quality Manager, who also acts as Management Rep.	C
b)	Has the organization determined and provided persons responsible for the effective implementation of its QMS (7.1.2)?	*Check if each process is defined and provide: - Who does what. - Labor contracts. - Training records.*	Yes, each process has a process owner and a team of people to run the process. People working in each process are full-time employees with conform labor contracts.	C

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	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
8.3	**Design and Development of Products and Services**			
8.3.2	**Design and development planning**			
a)	Is there a process for establishment, implementation and maintenance of Design and Development activities?	*1) Product / service requirement (Inputs)* *2) Criteria to controls process* *3) Procedures / WI for inspection, test, verify.* *4) Machines, equip.* *5) Man power*	Yes, there is a process documented in process map as COPs, and it is defined in procedure QP-08, Rev. A/0.	C
c)	Does the organization determined the nature, duration and complexity of design and development?	***1)** Write doc # and current revision level.*	Yes, it is defined for each new project.	C
d)	Are responsibilities and authorities defined for the design and development process?	***1)** Review record of design & development. Note the individual (s) responsible.*	Yes, responsibilities and authorities are defined in sheet QP-08-02 for each new project.	C
e)	Is there a **Plan for Design & Development?** Is there evidence of implementation?	*1) Photograph a gnatt chart .* *2) Check if timeline is clearly defined.*	Yes, there is a gnatt chart for each project, with defined steps. Each step has a deadline and resp.	C
k)	Is the **Design & Development transfer stage** planned?	*1) Write the doc #, and Rev. #*	Yes, the step for transfer is planned at the end.	C
l)	Is the method for the control of **Design & Development change** throughout the product design and life cycle defined in the procedure?	*1) Write the doc #, and Rev#, section.*	Yes, the method to implement changes during design and dev. process is planned in procedure QP-08.	C
8.3.3	**Design and Development inputs**			
a)	Has the organization determined functional and performance requirements for the specific types of products and services to be designed and developed?	*1) Photograph record of inputs*	Yes, functional and performance requirements are identified from client's requirements and recorded on sheet QP-08-03.	C
b)	Are potential consequences of failure due to the nature of the products and services identified and documented?	*1) Review record.*	Yes, failures are identified from previous experience.	C
8.3.4	**Design and development controls**			
a)	Are results to be achieve are clearly defined?	*1) Write doc # and current revision level.*	Yes, planned result to achieve are defined and documented in sheet of Verification and validation	C
b)	Doess the Design & Development include the requirement to conduct **Reviews** at various stages?	*1) Write the doc #, and Rev#, including paragraph*	Yes, review stages are planned in the gnatt chart of audited project # HM-0234	C
c)	Are activities for **verification** defined in the Design & Development Plan?	*1) Write doc #, and Rev#, section where detail of verification method are listed.* ***2)** Photograph record of verification conducted in same product .*	Yes, activities for verification are planned for project HM-0234, to check actual output correspond to requirements in the product drawing. The result of verification is documented in sheet Q-023, and signed by appropriate authority	C
d)	Are activities for **Validation** defined and performed per the plan and documented?	***1) Photograph** of record of validation conducted in same product, and check records are signed by assigned authority.*	Yes, activities for validation are planned for project HM-0234, to check actual performance in field meet requirements. The validation is done at client side, and result documented in sheet Q-0234, and signed by appropriate authority	C
e)	Has the organization taken necessary actions on problems, if any, as determined during the reviews, or verification and validation activities?	*1) record of CA*	Yes, corrective action to solve NCF found during verification or / and validation are planned if necessary.	C
8.3.5	**Design and development outputs**			
a)	Do design and development outputs meet requirements of inputs?	***1) Photograph** record of Design outputs for any product.*	Yes, design and development outputs can meet requirements of inputs, they are recorded on sheet QR-012	C
b)	Do outputs include or reference monitoring and measuring methods, and acceptance criteria, as applicable?	*1) Work Instruction*	Yes, they include methods for monitoring and measuring, and also acceptance criteria.	C

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d)	Does the factory provide warranty provisions for unwanted potential damage goods may suffer post-delivery?	*1) Review warranty policy*	Yes, factory provide warranty provisions for unwanted potential damage goods may suffer post-delivery.	C
e)	Does the organization provide customer feedback for future improvement? If any, is negative feedback reviewed and properly assessed? Are records maintained?	*1)Review feedback records* *2) Take photo if any*	Yes, factory collects feedback as part of customer satisfaction surveys, and they use it as input for further improvement.	C
8.5.6	**Control of Changes**			
a)	Does the organization document, control, and maintain records of changes for production or service provision to ensure continuing conformity with requirements?	*1) Review records of change.* *2) Take photo if any*	Yes, there is a procedure QP-024, Rev A/0 as a guideline to handle changes within the organization, including the production process.	C
b)	Are changes reviewed and authorized by competent personnel?		Yes, records of changes must be reviewed and approved by an authorized person.	C
8.6	**Release of products and services**			
a)	Does the organization identify, monitor and measure product/service characteristics to verify conformity to requirements?	*1) Review records to monitor and measure characteristics.* *2) Product characteristics may be dimensional, functional, performance, reliability, durability, maintainability, life, cost.*	Yes, there are work instructions, for example of WI-QR-34, in which product characteristics are mentioned, including sample plan, and measuring method.	C
c)	Are all personnel, performing monitoring and measurement, trained and competent?	*1) If service is sub-contracted, review competence of sub-contractor.*	Yes, personnel are trained and training records are available.	C
d)	Is there written approval/waiver from a relevant internal authority or the customer prior to releasing the product?	*1) Review approval/waiver from relevant internal authority or customer*	Yes, there is written approval/waiver from the Quality Manager prior to releasing the product.	C
e)	Can authorization records for release of products or service be traced back to a person(s)?	*1) identify traceability of records.*	Yes, signature of the Quality Manager is visible on the record, as evidence.	C
8.7	**Control of nonconforming outputs**			
a)	Is there a procedure that defines the marking and identification of non-conforming material? Is there evidence of compliance?	*1) Write doc # and take photo of Non-conforming product identified if any*	Yes, there is a procedure QP-027, Rev A/0 that defines methods of handling NCF products / materials. Each material is identified, and placed in a red area or red boxes.	C
b)	Is there a procedure that requires evaluation of nonconformities, including documentation of any needed investigation. Is evidence of compliance available?	*1) Write doc # and take photo of Non-conforming product identified if any*	Yes, the procedure QP-027, Rev A/0 requires an evaluation of NCFs to confirm their status, and respective reaction to them.	C
c)	Is there a physical segregation of nonconforming material during subsequent storage & processing? And, is there evidence of compliance?	***1)*** *Check if that area is delimited with a clear red line in the floor, and with a visible label, or protected with a key to avoid unwanted mixing,* ***Take photo*** *of the area.* ***2)*** *Check red boxes are used to separate non-conforming products from good products, and* ***take photo.***	Yes, the factory separates defect by code and boxes. Specific areas painted in red are used to store products away from good one, to avoid mix-ups (SEE PHOTO).	C
d)	Is there a procedure that defines disposition options and conditions of non-conforming material (scrap, rework, return, use as is, deviate)? Is there evidence of compliance?	***1)*** *Write doc # of that procedure*	Yes, reaction plan when found NCF is scrap. Cannot be reworked.	C
e)	Is there a procedure that describes how re-work will be accomplished and documented and is there evidence of compliance?	***1)*** *Write doc # of that procedure.* ***2)*** *Check if there a list describing the content of the area, with part / lot number, date and a decision of what to do with those parts.*	Not applicable	N/A
9	**PERFORMANCE EVALUATION (ISO 9001:2015; art. 9.1, 9.2, 9.3)**			
9.1	**Monitoring, measurement, analysis, and evaluation**			
9.1.1	**General**			
a)	Does the organization determine what needs to be monitored and measured?	*1) It could include:* *- Quality Objectives & Goals* *- Performance indicators* *- Customer satisfaction*	No, each process does not have KPIs as plan for monitoring. No performance indicators, except for customer satisfaction survey.	I

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C = Complies with the requirements, I = Improvement Needed, NC = Not Complies, N/A = Not Applicable

	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
b)	Have methods for monitoring, measuring, analyzing, and evaluating validity of results been defined and identified?	*1) Methods may include statistical performance.* *2) Data analyses processes methods and resources such as time, manpower, computer, software, statistical tools, etc.*	No methods for monitoring, measuring, analyzing, and evaluating results, except for customer satisfactory survey.	I
c)	Are methods describe how (manually, ERP system…etc.), when (Daily, monthly, quarterly…etc.) and who to monitor and measure Quality Goals & Objectives? Are there evidence of implementation?	*1) Take photo if the plan if any* *2) Review record of monitoring and measurement, **take photo***	Not such plan of how, when and who to monitor and measure KPIs.	NC
9.1.2	**Customer Satisfaction**			
a)	Is there a procedure / system as a guideline to conduct customer satisfaction surveys?	*Write doc.# / Rev.#* *- Customer feedback (complaint).* *- Order and delivery performance*	Yes, there is a procedure for customer satisfaction surveys. They are conducted twice per year.	C
b)	Are customer satisfaction surveys conducted in periodical manner as required? How many times a year? Is there evidence of implementation?	*Review the records of customer satisfaction, and **take photo**, if any.*	Yes, twice a year. Each time, the factory will select typical customers for the survey, and collect actual feedback, survey questionnaire and internal performance. Records are available.	C
c)	Are there follow up actions for improvement after the survey?	*1) Check if there is a Corrective Action Plan defining topics to improve, timeline and responsibility, **take photo,** if any.*	Yes, results of follow ups are documented, with an improvement action plan.	C
9.1.3	**Analysis and evaluation**			
b)	Is there a system / procedure for the collection of manufacturing performance (i.e., SPC, Internal PPM, defect rate)? Is there evidence of implementation?	*1) Write doc # and Rev.# (Not mandatory)* *2) Review the summary of trends vs targets, **take photo,** if any.*	No specific plan for collection of results of KPIs since they are not defined, except for customer survey.	I
e)	Is there a system / procedure to evaluate the effectiveness of actions taken to address risks and opportunities?	*1) Write doc # and Rev.# (Not mandatory)* *2) Review the summary of trends vs targets, **take photo,** if any.*	Yes, there is a procedure for identification and evaluation of effectiveness of risk and opportunities.	C
d)	Has the organization identified a need for improvements to the quality management system?	*1) Write doc # and Rev.# (Not mandatory)* *2) Review the summary of trends vs targets, **take photo,** if any.*	Yes, it has identified such a need.	C
9.2	**Internal Audit**			
a)	Does the audit plan / scope address all areas covered by the quality systems & covenant requirements of regulations?	*1) Review the audit checklist used and its record.*	Yes, there is an audit plan documented in sheet QR-010, with a scope covering all areas of applicable ISO 9001 clauses.	C
b)	Is there a documented procedure for internal audits? Does the audit procedure include requirements for re-audits if non-conformities are found?	*1) Review the procedure for internal audit.*	Yes, there is a procedure for internal audit (QP-010, Rev A/0) for conducting internal audit, including the prevision for re-audits in clause 4.5	C
c)	Have Quality system audits been scheduled & completed and are audit documents on file?	*1) Review the last 2 consecutive audits planned, Take a photo of the last audit plan, and write the audit dates.*	Yes, the last 2 internal audits were conducted in 2016-06-12 and 2016-12-23. Result of the audits were published with 11 NCFs found in the 1st audit, and 8 in the 2nd audit.	C
d)	Are Internal auditors trained and are they independent of the areas audited?	*1) Review certificate / training & qualification records of Auditors assigned. **Take photo** of the Auditors certificates, if any.* *2) Review if any and Auditor was scheduled to audit his own department, **take photo** of the Auditors scheduling.*	Yes, the factory has 4 auditors certified by TUV, Certificates are available in HR (See photo). They were scheduled independently.	C
e)	Are any audit findings properly documented and is there evidence of actions taken?	*1) Check if there is a specific form used to record NCFs and corrective action.* *2) Check if all NCFs are closed, and the signature of the Auditor who found the NCF is the same as the one verifying the effectiveness of the correction of that NCF. **Take photo,** of a NCF.*	Yes, audit findings are recorded on sheet QR-010-2 (See photo). As for the last audit of 2016-12-23, it was discovered that 7 NCFs were closed, but only 4 of them had the signature of the auditor as evidence of verification.	I
9.3	**Management Review**			
9.3.1	**General**			
a)	Is there a documented management review procedure / system and is it under revision control.	*1) Write the doc# and Rev.#.*	Yes, there is procedure QP-016, Rev A/0 as a guideline for conducting management reviews. They are conducted once per year.	C
9.3.2	**Management review inputs**			

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	QUESTIONNAIRE	EVIDENCE	FINDINGS	SCORE
f)	Are effectiveness of any corrective actions taken verified?	***Any proof that it is effective.***	Records in the 8D report demonstrate that verification was conducted. However, since they have never produced the products, GH-52 and GH-210, the impact of the CA implemented cannot be seen.	C
g)	Has the document of risks and opportunities been updated based on non-conformities found?		No, it has not been updated.	NC
10.3	**Continual Improvement**			
a)	Is there a procedure as a guideline for continuous improvemement of the QMS?	*1) Write doc # and its revision #. 2) Check what tool is used to identify potential nonconformities (PFMEA).*	Yes, there is a procedure (QP-022, Rev A/0) as s guideline to continuously improve the QMS.	C
b)	Dees the organization consider results of KPIs and evaluate them to determine necessity of improvement?		Yes, KPIs are analysed, but more specifically customer satisfaction. Cannot see further action to improve this satisfaction.	I

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Photos were removed due to confidentiality.

Photo 1

Photo 2

Photo 3

Photo 4

Photo 5

Photo 6